

NATIONAL QUALITY FORUM

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ENDOCRINE MEASURE ENDORSEMENT PROJECT  
STANDING COMMITTEE

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WEDNESDAY  
FEBRUARY 26, 2014

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The Standing Committee met at the National Quality Forum, 9th Floor Conference Room, 1030 15th Street, N.W., Washington, D.C., at 8:30 a.m., William Golden and James Rosenzweig, Co-Chairs, presiding.

PRESENT:

WILLIAM GOLDEN, MD, Co-Chair

JAMES ROSENZWEIG, MD, Co-Chair

ROBERT BAILEY, MD, Janssen Scientific  
Affairs

TRACY BREEN, MD, North Shore-LIJ Health  
System

WILLIAM CURRY, MD, Penn State College of  
Medicine, American Academy of Family  
Physicians

VICKY DUCWORTH, The Boeing Company

JAMES DUDL, MD, Kaiser Permanente

INGRID DUVA, PhD, RN Veterans Health  
Administration

STARLIN HAYDON-GREATTING, Pharmacy Quality  
Alliance

ANN KEARNS, MD, PhD, Mayo Clinic

SUE KIRKMAN, University of North Carolina  
Diabetes Care Center

ANNE LEDDY, MD, American Association of  
Clinical Endocrinologists

GRACE LEE, MD, Virginia Mason Medical  
Center

LAURA MAKAROFF, DO, Health Resources  
Services Administration (HRSA)  
ANNA McCOLLISTER-SLIPP, Galileo Analytics  
PATRICIA McDERMOTT, RN, Aetna  
JANICE MILLER, CRNP, Thomas Jefferson  
University School of Nursing  
CLAUDIA SHWIDE-SLAVIN, American  
Association of Diabetes Educators  
JANET SULLIVAN, MD, Hudson Health Plan  
WILLIAM TAYLOR, MD, Beth Israel Deaconess  
Medical Center, Harvard Medical  
School

NQF STAFF:

POONAM BAL, Project Analyst  
HELEN BURSTIN, MD, Senior Vice President,  
Performance Measurement  
ANN HAMMERSMITH, JD, General Counsel  
KAREN JOHNSON, Senior Director,  
Performance Measurement  
KAREN PACE, PhD, Senior Director,  
Performance Measurement  
LINDSEY TIGHE, Senior Project Manager,  
Performance Measurement

ALSO PRESENT:

MARY BARTON, MD, National Committee for  
Quality Assurance (NCQA)  
KATHY DOMZALSKI, The Joint Commission  
DAVID LEE, National Bone Health Alliance  
BOB REHM, National Committee for Quality  
Assurance (NCQA)  
ROBERT SAUNDERS, National Committee for  
Quality Assurance (NCQA)  
ETHEL SIRIS, MD, The Joint Commission  
ANN WATT, The Joint Commission

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

8:33 a.m.

CO-CHAIR GOLDEN: Good morning, everyone. Welcome to the Endocrine Steering Committee Meeting.

I'll make a couple of opening comments. I'm Bill Golden. I'm Co-Chair with Jamie Rosenzweig and I am Medical Director at Arkansas Medicaid. I'm also Professor of Medicine and Public Health, University of Arkansas.

Just a couple of my perspectives. This is a big job and I don't know how many of you -- just to help us, how many of you have never been on an NQF Committee before? Okay. Hum. Okay. So, there we are.

This is a big job and it can easily get -- you can easily get lost in some of the rules and nuances, but what we're doing here really determines impact on what people collect. Which is work. Whether or not quality actually improves. Because if you

1 have a funny measure and people do or do not  
2 -- either don't use the measure or don't  
3 collect it correctly, they end up not having  
4 the impact of making a difference in how care  
5 is delivered.

6 So, there's a lot here. You know,  
7 sometimes measures have a vision, but don't  
8 have the infrastructure to actually make it  
9 happen. So, all of that is really on the  
10 table.

11 And the good news is that because  
12 this is a new format, in the old days, if a  
13 measure failed because of a technical issue or  
14 a specification or something, it was a one-  
15 time window and then they were out of luck and  
16 apparently with the notion now that we're a  
17 standing committee, if we like or the  
18 Committee likes the ideas, but the  
19 specifications or technical aspect limits the  
20 effectiveness of the measure, the developers  
21 can come back in six months or a year with a  
22 revision. Which is a whole new framework than

1 used to be.

2 So, that's an opportunity for us  
3 and makes our lives a little easier because we  
4 can only approve or disapprove what's written  
5 and then what's specified. So, keep that in  
6 mind as we move forward.

7 So, Jamie, do you have some  
8 comments?

9 CO-CHAIR ROSENZWEIG: Sure. I'm  
10 Jamie Rosenzweig. I'm an endocrinologist,  
11 Director of Diabetes Services at Boston  
12 University School of Medicine and also,  
13 Associate Professor of Medicine there.

14 And I've participated on a few NQF  
15 committees in the past. The most recent one  
16 was on diabetes and cardiovascular disease.

17 I think we have an awful lot of  
18 measures to go through and in two days, I hope  
19 we can get through everything in time. So,  
20 we're going to be trying to keep things moving  
21 as best as we can while giving people enough  
22 time to be able to discuss the various issues

1 related to each of the measures.

2 But, the whole process is a fairly  
3 complex one, but very comprehensive. So, I  
4 hope -- I'm looking forward to spending the  
5 next couple of days with all of you.

6 CO-CHAIR GOLDEN: Before we go  
7 around the room and have everyone introduce  
8 themselves, does NQF staff want to do any  
9 ground rules or any information or how do you  
10 want to proceed here?

11 MS. HAMMERSMITH: Hi, everyone.  
12 I'm Ann Hammersmith. I'm NQF General Counsel.

13 What we're going to do is we'll  
14 combine the introductions with the disclosures  
15 of interest.

16 It seems that most of you have not  
17 served on NQF committees. So, welcome. We're  
18 glad to have you here.

19 I will go through some of the  
20 background around disclosures. What we're  
21 looking for you to disclose this morning and  
22 then we can go around the table.



1           If you recall, several months ago  
2 when you were nominated to the Committee, you  
3 should have received an email message to fill  
4 out a detailed form regarding your  
5 professional activities. We go through those  
6 as we are seating the Committee.

7           Now that you're on the Committee,  
8 in the spirit of transparency and openness, we  
9 would like you to disclose things that you put  
10 on the form or anything that's happened since  
11 that's relevant to the work before the  
12 Committee. The idea is not to summarize your  
13 resume. The idea is to tell your fellow  
14 Committee Members and anyone who's listening  
15 to the meeting what your interests are that  
16 may be relevant to the work before the  
17 Committee.

18           So, we are particularly interested  
19 in any consulting activity, research activity,  
20 grants that you may have received or speaking  
21 engagements, but only if they are relevant to  
22 the Committee's work.

1                   Just a few reminders. You sit as  
2                   an individual. You are here because you are  
3                   subject matter experts. You don't represent  
4                   your employer. You don't represent anyone who  
5                   may have nominated you to the Committee.

6                   The other thing I'd like to remind  
7                   you of is that our conflict of interest  
8                   disclosure process is a bit different because  
9                   we don't ask only about financial interests.  
10                  Because of the nature of the work that NQF  
11                  does, we also ask people to disclose if they  
12                  have done any, for example, work on a  
13                  committee that has something to do with the  
14                  subject matter of this Committee even if you  
15                  weren't paid.

16                  Sometimes that's confusing to  
17                  people. People will say I have no financial  
18                  conflicts of interest which is great, but  
19                  we're also interested in any volunteer  
20                  activities you have done that may be relevant  
21                  to the work today.

22                  So, with that, any questions?

1 I know most of you are new. So,  
2 ask if there are any questions before we  
3 start. Okay.

4 We'll go around the table. Tell  
5 us who you are, who you're with and if you  
6 have anything to disclose and I want to stress  
7 just because you disclose something does not  
8 mean it is a conflict. The point here is to  
9 be open.

10 So, let's start with the chairs.

11 CO-CHAIR GOLDEN: All right. So,  
12 as I said, I'm a Professor of Medicine and  
13 Public Health. I have no financial conflicts.  
14 I am on the Executive Committee of the PCPI  
15 and I've chaired some of their committees on  
16 development of measures. None of them in  
17 endocrinology and I do some consulting or  
18 potential consulting with General Dynamics in  
19 their Performance Measurement Group, but at  
20 this point, it's not active in this area  
21 either. So, I'd be more or a less a measure  
22 consultant.

1 CO-CHAIR ROSENZWEIG: Yes, I'm on  
2 the faculty at Boston University and at Boston  
3 Medical Center and I've been chair of several  
4 committees at The Endocrine Society that  
5 involve performance measures. I was Chair of  
6 the Performance Measures Subcommittee for the  
7 Endocrine Society as well as I'm now Chair of  
8 the Quality Improvement Subcommittee of the  
9 Endocrine Society.

10 I've done some consulting work for  
11 some disease management organizations. I'm  
12 currently on the Scientific Advisory Board of  
13 the Alere Corporation, but I don't have any  
14 direct work with them.

15 MEMBER BREEN: Good morning. I'm  
16 Tracy Breen. I'm an Associate Professor of  
17 Medicine at the Hofstra North Shore-LIJ School  
18 of Medicine. I'm Division Chief of Endocrine  
19 there.

20 I have no financial conflicts of  
21 interest to disclose. I serve as a subject  
22 matter expert on the Dartmouth High Value

1 Health Care Collaborative around diabetes and  
2 I've also done some collaborations with YMCA  
3 organizations in our region around their  
4 diabetes prevention program; I think that's  
5 the most pertinent.

6 MEMBER KEARNS: I'm Ann Kearns.  
7 I'm from the Mayo Clinic in Rochester. There  
8 I serve as the Chair of Quality for  
9 Endocrinology.

10 I don't have any financial  
11 conflicts or interests. I've not served on  
12 other committees regarding quality measures.

13 I am in the process of setting up  
14 a fracture liaison service at our institution  
15 which brings me very close to some of the  
16 osteoporosis measures and I'm happy to be  
17 here.

18 MEMBER CURRY: Hi. My name is  
19 Bill Curry. I'm a Professor of Family and  
20 Community Medicine and also in the Department  
21 of Public Health Sciences at Penn State  
22 University in Hershey. I'm here at the

1 invitation of the American Academy of Family  
2 Physicians.

3 In my work at Penn State, I do a  
4 lot of quality work, quality measures and a  
5 lot of that's around diabetes care. I've done  
6 some research with retinopathy and screening  
7 for retinopathy and also involved in a project  
8 right now looking at the effects of the  
9 patient-centered medical home on that outcomes  
10 of diabetes care.

11 MEMBER SHWIDE-SLAVIN: Hi. I'm  
12 Claudia Shwide-Slavin. I'm an Advance  
13 Practice Registered Dietitian, diabetes  
14 educator and I'm representing the American  
15 Association of Diabetes Educators. I've done  
16 a lot of work with both my organization, the  
17 Academy of Nutrition and Dietetics. They've  
18 changed their name. Formerly the American  
19 Dietetic Association and also with the NCBDE,  
20 the licensing board for diabetes educators in  
21 development of standards of practice,  
22 professional development competencies and I

1 also do work that I am paid for as a subject  
2 expert with the development of education  
3 materials with Eli Lilly.

4 MS. HAMMERSMITH: I'm just going  
5 to jump in for a moment and gently remind all  
6 of you that you sit as individuals. You're  
7 not representing an organization. Thank you.

8 MEMBER SULLIVAN: Hi. Despite my  
9 name tag people call me Jessie. So, my name  
10 is Jessie Sullivan and I am the Chief Medical  
11 Officer of Hudson Health Plan which is a  
12 Medicaid health plan in New York. So, all  
13 health plans are measured by HEDIS measures  
14 and some of the measures we look at are HEDIS  
15 measures. So, in that sense, there is some  
16 impact on my life in what happens here, but  
17 none of my salary is dependent on that and I  
18 have participated on committees for the NQF,  
19 for PCPI, for the American Academy of  
20 Dermatology and none of the committees that  
21 I've participated on were looking at the  
22 measures that we're reviewing.

1                   MEMBER KIRKMAN:  Hi.  I'm Sue  
2 Kirkman.  I'm an endocrinologist on the  
3 faculty at the University of North Carolina.

4                   I have one financial conflict of  
5 interest which is that I'm doing a clinical  
6 trial for Novo Nordisk where the money goes to  
7 my university.

8                   Prior to 15 months ago, I was on  
9 staff at the American Diabetes Association and  
10 was very involved in their guideline  
11 development process.  So, may have a little  
12 bit of an intellectual, I don't know if it's  
13 conflict, but something there.

14                  And while I was at the ADA, I was  
15 on several committees with NCQA including  
16 their diabetes expert panel and the Clinical  
17 Programs Committee that oversaw recognition  
18 programs like the Diabetes Recognition  
19 Program, the PCMH Programs and so forth.  But,  
20 it's been more than a year.

21                  MEMBER TAYLOR:  Hi.  I'm Bill  
22 Taylor.  I have no relevant conflicts of



1 interest. I don't think I have an irrelevant  
2 conflicts of interest either.

3 I'm a primary care physician at  
4 Beth Israel Deaconess in Boston and I'm on the  
5 faculty at Harvard Medical School where I'm an  
6 Associate Professor of Population Medicine and  
7 an Associate Professor of Medicine and I  
8 direct that Primary Care Residency Program at  
9 Brigham and Women's Hospital and Harvard  
10 Vanguard Medical Associates where I'm also  
11 Director of Medical Education.

12 MEMBER LEE: Hi. I'm Grace Lee.  
13 I'm from Virginia Mason Medical Center. I  
14 have no financial disclosures.

15 My research interest previously  
16 was grounded in insulin-resistant HIV. When  
17 I went to Kaiser Permanente in Northern  
18 California, I then became involved with their  
19 population-based metrics and published on  
20 their hypertension program and currently, I'm  
21 at Virginia Mason and have research interest  
22 in hospital glycemic control and outpatient

1       glycemic control.

2                   MEMBER DUCWORTH:  Hi.  I'm Vicky  
3       Ducworth with the Boeing Company and I manage  
4       our clinical programs and delivery systems  
5       innovation and in a nutshell, that's health  
6       systems engineering.  I've previously served  
7       on CMS' innovations grants as their overview  
8       panelist.  I've done some consulting primarily  
9       in health information technologies.

10                   I am not as accomplished as you  
11       all, but if there's a problem, I can find it  
12       and I'm pretty good at fixing it.  Everything  
13       I do is dependent on a measurement.  So, happy  
14       to be here.

15                   MEMBER MCDERMOTT:  Thank you.  I'm  
16       Patricia McDermott from Aetna.  I don't have  
17       any conflict of interest that I'm aware of.

18                   I do measures for Aetna for their  
19       performance tools.  Pay for performance and  
20       the like.  So, I'm a user of the metrics.  So,  
21       I'm aware of how -- and I'm very aware of how  
22       metrics are constructed and the issues around

1 the use of metrics with providers. So, that's  
2 the expertise I bring to this.

3 But, as far as conflicts of  
4 interests, I don't believe I have any.

5 MEMBER HAYDON-GREATTING: Hi. I'm  
6 Starlin Haydon-Greatting. I'm not on that  
7 standing committee roster because I was late  
8 to the game. I'm a clinical pharmacist with  
9 an emphasis in epidemiology. I means I didn't  
10 get a PharmD. I got a Master's in  
11 Epidemiology instead. I worked 20 years for  
12 Medicaid and did performance measures in the  
13 Medicaid populations.

14 When the State of Illinois drove  
15 me crazy, I broke out in shingles and left and  
16 went into the private world and I work with  
17 self-insured employers in setting up work site  
18 diabetes and cardiovascular education  
19 programs.

20 I am part of the American  
21 Pharmacist Association, the American Society  
22 of Health System Pharmacists and I serve on

1 the Pharmacy Quality Assurance where we  
2 develop measures for adherence and  
3 medications.

4 And I teach at seven -- we have  
5 seven pharmacy schools now in the State of  
6 Illinois. So, my goal is to educate and  
7 create advanced practice pharmacists so that  
8 they come out into the world and become part  
9 of the team right from the get go and I'm  
10 proud to be here. Thank you.

11 MEMBER MAKAROFF: Hi. I'm Laura  
12 Makaroff. I'm a family physician and I work  
13 at the Health Resources Services  
14 Administration now. I have no relevant  
15 financial disclosures that I'm aware of.

16 My work at HRSA is with the Health  
17 Center Program and I work in the office that  
18 supports and manages the Quality Measures and  
19 Performance Improvement Program for all the  
20 health centers that we fund.

21 So, we are users of NQF measures,  
22 but I have nothing to do with measure

1 development and no financial interests in  
2 them. Thank you.

3 MEMBER MILLER: Good morning. I'm  
4 Janice Miller. I'm a nurse practitioner at  
5 Thomas Jefferson University in Philadelphia.  
6 I'm also a certified diabetes educator. I'm  
7 a primary care nurse practitioner for 17  
8 years. In addition to that, I am now an  
9 Assistant Professor with the School of  
10 Nursing.

11 I have received and do receive  
12 consulting fees from an organization called  
13 MyNetDiary as a content expert.

14 Additionally, I had done some work  
15 several years ago on the measure development  
16 for some of the cardiovascular measures for a  
17 contract organization.

18 I am just very happy to be part of  
19 the Committee and looking forward to working  
20 with you all and learning from you all.

21 MEMBER DUVA: Good morning. I'm  
22 Ingrid Duva and I am a quality scholar at the

1 Atlanta VA with the Veterans Health  
2 Administration. I have no conflicts of  
3 interest. I have previously served on the ANA  
4 Measures Committee for Care Coordination  
5 Framework Development and I currently perform  
6 some research, I guess you'd call it, with the  
7 nurses in our Patient Center Medical Care  
8 Homes who are trained to meet the measures  
9 that have been developed by implementing  
10 different programs to improve diabetes  
11 management.

12 MEMBER LEDDY: I am Anne Leddy. I  
13 have done clinical endocrinology in my own  
14 office for a very, very, very long time. I am  
15 quite interested in all the performance  
16 measures because I feel in my heart they're  
17 needed and very important.

18 I have no relevant financial or  
19 other conflicts to report.

20 MEMBER BAILEY: Good morning. My  
21 name is Bob Bailey. I work on the Health  
22 Economics and Outcomes Research Team at

1 Janssen Scientific Affairs. I lead diabetes  
2 focused projects in the area of health care  
3 quality, quality improvement and disparities  
4 of care and I'm a nephrologist by training.  
5 Was in private practice in nephrology for ten  
6 years prior to coming over to Janssen about 11  
7 years ago and I'm an employee of Johnson &  
8 Johnson which markets devices and  
9 pharmaceuticals in the diabetes base and I'm  
10 also a stockholder of Johnson & Johnson.

11 MEMBER DUDL: Hi. I'm Jim Dudl  
12 from Kaiser Permanente. I've worked in -- I  
13 am an endocrinologist. I have no financial  
14 disclosures. We've worked with performance  
15 measures specifically on cardiovascular  
16 disease and adherence for many years.

17 MS. HAMMERSMITH: All right.  
18 Thank you very much, everyone.

19 There are no Committee Members on  
20 the phone? No. Okay.

21 I'm going to give you my final  
22 reminder now. With regard to conflict of

1 interest or bias, if during the Committee  
2 meeting you think you may have a conflict of  
3 interest or if you think someone else has a  
4 conflict of interest, we want you to raise  
5 that right away.

6 You are welcome to do it openly in  
7 the meeting. If you don't want to do it that  
8 way, you can go to your co-chairs who we'll  
9 work with NQF staff or you can go directly to  
10 NQF staff. Helen Burstin, our Senior VP for  
11 Performance Measurement is sitting right there  
12 and you can raise it.

13 We do not want you sitting there  
14 if you're unsure or if you're uncomfortable  
15 and not speaking up. It's part of your work  
16 as a Committee Member to be mindful of  
17 conflicts of interest and bias.

18 So, if you have any concerns about  
19 it, please do speak up.

20 In that spirit given the  
21 disclosures that we've just done, does anyone  
22 have any questions of me or anything that you



1 would like to raise with your fellow Committee  
2 Members?

3 Okay. Thank you.

4 CO-CHAIR GOLDEN: I guess we will  
5 be moving forward. In a little bit, we're  
6 going to be doing electronic voting. Correct?  
7 Do you want to go over how that works?

8 MS. BAL: Hello, everybody. So,  
9 we will be doing electronic voting and I  
10 handed out these little fun notepads to  
11 everybody. So, if someone doesn't have one,  
12 let me know. Jim may not.

13 So, basically, each Committee  
14 Member will be assigned a keyboard for use  
15 during the meeting and you should use the same  
16 one everyday. I'll keep track of the numbers  
17 and make sure you have the same one.

18 There is no on and off. It's  
19 automatically on once you press this little  
20 button right here. I guess it's a little red  
21 square and it will turn off automatically once  
22 the response is collected.

1                   When you push the button, it will  
2                   turn green and then no light will show on. If  
3                   you push the button and then it goes green and  
4                   then a flashing red, that indicates your  
5                   battery is low. If it goes just to red, a  
6                   solid red, that means it's dead and your  
7                   response did not go through.

8                   You can click the button as many  
9                   times you want. If you change your mind, go  
10                  ahead and click it or if you're just not sure  
11                  if it went through, you can click it again.  
12                  It won't mess up the system or the count or  
13                  anything. Every clicker only gets one vote.  
14                  So, you can click it as much as you want and  
15                  not have to fear about that.

16                  Basically, the voting cannot start  
17                  until the timer starts. So, I'm going to do  
18                  a sample run for everybody. So, you need to  
19                  -- it's the two screens down at the end. I  
20                  don't know -- if the voting is not open, it'll  
21                  always turn red. Yes. So --

22                  CO-CHAIR ROSENZWEIG: Are we

1       suppose to press send after we hit the button  
2       or --

3                   MS. BAL: No. No sending. Just  
4       pushing the button.

5                   CO-CHAIR ROSENZWEIG: Okay.

6                   MS. BAL: So, we're going to do a  
7       test run. So everybody make sure they  
8       understand.

9                   Right now, the screens are in the  
10      back. Yes, we'll move them so they're a  
11      little more convenient. But, for the sample  
12      run, the screens will be in the back and there  
13      will be two scales generally. One that's a  
14      yes and no which this question is and then the  
15      other one will be more of this sort where it's  
16      a high, moderate, low and then so on.

17                   So, they'll be rating -- you all  
18      received instructions. The rating scale will  
19      be on that and then it'll also be on the  
20      screens so you can understand it better.

21                   So, let's go ahead and just do one  
22      sample run. Once I push the button and you

1 can see the timer, that's when you can start  
2 putting in your answer.

3 So, right now, you can see the  
4 screen's up, the timer's up. So, go ahead and  
5 push the button.

6 Oh, make sure you point at me and  
7 not the screen. Sorry.

8 DR. BURSTIN: The screens are  
9 being moved. Sorry.

10 MS. BAL: Okay. Yes, so, point at  
11 me. Yes, if it's goes red, it's bad. Let me  
12 know and I can get you a different one.

13 DR. PACE: Let me explain. It's  
14 only if it flashes red. If it -- if you get  
15 a red light, it means it's not communicated  
16 with the base and just try it again. But, if  
17 it's flashing red, then let us know.

18 MS. BAL: So, you will get 60  
19 seconds for each one and if I get enough  
20 responses beforehand, then I'll just stop  
21 early. So, we do have 18 responses.

22 And yes, Jim doesn't have one yet.

1 I need to give him one. Oh, okay. Then never  
2 mind. I'm -- unfortunately, it's been off  
3 now, but were you answering? Okay. So, yes,  
4 your -- I'll get you a different one.

5 Great. So, does everybody  
6 understand the concept? Is anyone having  
7 difficulty with it? Okay.

8 DR. PACE: You can't tell right  
9 now because it's not registering voting. So,  
10 the question is whether when you vote it goes  
11 green and after that, if you get a flashing  
12 red light, then let us know. So.

13 MS. BAL: Yes, right now, if you  
14 push the button, it'll turn red.

15 I'm sorry. Could you repeat that?

16 MEMBER HAYDON-GREATTING: So, if  
17 you voted and you don't think you voted,  
18 you'll get a green flashing --

19 MS. BAL: No.

20 DR. PACE: No, that's not what  
21 flashing red means.

22 MEMBER HAYDON-GREATTING: So,

1 anytime you get a flashing --

2 DR. PACE: After you get a green.

3 So, let's --

4 MS. BAL: We'll do one more round.

5 DR. PACE: Let's do one more.

6 DR. BURSTIN: This is the hardest  
7 part of the meeting.

8 MS. BAL: So --

9 CO-CHAIR ROSENZWEIG: Those  
10 screens could be moved a little more towards  
11 the middle. It would be helpful. I can't  
12 really read them.

13 MS. BAL: Yes.

14 DR. PACE: What Devon's doing.  
15 Yes.

16 CO-CHAIR ROSENZWEIG: Yes.

17 DR. PACE: Yes, that's what he's  
18 doing. Right. Yes.

19 MS. BAL: We're shifting them  
20 right now. So, basically, if the timer is not  
21 on, it will show up red. Because right now,  
22 it's not communicating with the system. So,

1       until the timer's on, anytime you push any  
2       button, it's going to show up as red.

3                 So, right now, I'm going to re-  
4       push the button and you can see that the  
5       timer's on. So, now, you can send in  
6       responses. So, we request that everybody send  
7       in any response. Doesn't matter what it is as  
8       long as it's one through five.

9                 DR. PACE: Right. It has to be  
10       one of the numbers that are on this slide. In  
11       this case, one through five.

12                MS. BAL: That means you're not --  
13       you need to point it more towards me. Yes.

14                MEMBER KIRKMAN: So, if it just  
15       blinks green once and then that's it?

16                MS. BAL: You're good. That  
17       means, yes.

18                MEMBER KIRKMAN: It's in?

19                MS. BAL: Everything's fine.

20                MEMBER KIRKMAN: Okay. I guess I  
21       have to stare at it while it's --

22                DR. PACE: You don't have to face

1 -- do essentially that. Just --

2 MS. BAL: We'll know.

3 DR. PACE: -- we'll notice it.

4 MS. BAL: Yes.

5 DR. PACE: We'll know if votes  
6 aren't registering.

7 DR. BURSTIN: We'll see the  
8 totals. Yes.

9 MS. BAL: I think we just need to  
10 give you a new one. Yours is just busted I  
11 think.

12 DR. BURSTIN: And it doesn't  
13 matter how many times you press it, you still  
14 just get one vote. So, don't feel concerned  
15 if you're hitting it again and again. It's  
16 not Chicago.

17 MS. BAL: So, just one more  
18 confirmation. Everybody understands how it  
19 works and okay. So, that's pretty much it.

20 If anybody has questions, you're  
21 free to ask during the meeting. Thank you.

22 DR. BURSTIN: One small. We're



1       only allowed to have three mikes on at a time.  
2       So, just remember to turn off your mike when  
3       you're done talking as well or else we'll stop  
4       communication.

5                   I just want to add my welcome.  
6       I'm Helen Burstin. As Ann mentioned, I head  
7       over our Performance Measurement Group here.

8                   So, again, if at any time, any  
9       questions, any concerns during the process,  
10      please come see me.

11                   And again, really thank you. We  
12      recognize this is a lot of work for your  
13      volunteer time that very few of us have to  
14      give towards these kinds of activities. So,  
15      we really do appreciate it.

16                   And just lastly just, you know,  
17      you will be hearing from our measure developer  
18      colleagues who are lined up on the side here  
19      who will be joining us at the table. At the  
20      time, we are talking about their measures  
21      just, you know, keep in mind there's a lot of  
22      work that goes into that process. Before they

1 get to our door, you know, they've had  
2 committees as well who have had these  
3 discussions.

4 It's not really an opportunity to  
5 kind of wordsmith or change their measures on  
6 the fly. You really kind of give your best  
7 thinking about the measure, how useful it  
8 could be and again, you know, obviously, be  
9 respectful of their intellectual work to date.  
10 This really is intended to be a collaborative  
11 process with our developers, with all of you,  
12 with experts and the multi-stakeholders at the  
13 table.

14 So, thank you.

15 CO-CHAIR GOLDEN: Developers love  
16 their children. Right? So, is that what it  
17 is?

18 The other thing that's useful as a  
19 convention is that since it's hard to get  
20 people to raise their hands, you get tired,  
21 use your card and put it upright if you want  
22 to talk. That way we can see that someone is

1 waiting to be recognized. Otherwise, there  
2 would be mild to moderate chaos. So, that  
3 would be helpful as well.

4 And every now and then, you'll get  
5 your cards up and we'll say do you want to  
6 talk and that kind of thing. It'll help.

7 Why don't we go over the Karen and  
8 Katie to talk about the overview and the  
9 project introduction, et cetera.

10 MS. STREETER: Thank you and good  
11 morning. My name's Katie. I'm a project  
12 manager here at NQF. Thank you all for coming  
13 today. It's nice to finally meet you all  
14 after working with your for the past couple of  
15 months.

16 I just wanted to review some of  
17 the roles and expectations of the Committee  
18 and how we will run the meeting today.

19 We kind of have a standard script  
20 of the expectations that I'm going to read to  
21 you. So, as you know, NQF is working to  
22 improve committee meetings based on input from

1 a variety of stakeholders and we've made a few  
2 changes to our meeting process.

3 We recognize that we are fortunate  
4 to have the measure developers present and we  
5 will be asking them to briefly introduce their  
6 measures as they come up for discussion.

7 Selected work group  
8 representatives will then begin to discussion  
9 of the measures in relation to the measure  
10 evaluation criteria.

11 We also provided a designated  
12 place for developers at the main table during  
13 the introduction and discussion of their  
14 measures. Here they may more easily respond  
15 to questions from the Committee and correct  
16 any misunderstandings about their measures  
17 during our discussion.

18 As is the case with the committee  
19 members, developers may put up their cards to  
20 indicate when they wish to respond to  
21 questions raised or correct any statements  
22 about their measures.

1                   During measure evaluation,  
2                   Committee Members often offer suggestions for  
3                   improvement to the measures. These  
4                   suggestions can be considered by the developer  
5                   for future improvements. However, the  
6                   Committee is expected to evaluate and make  
7                   recommendations on the measures per the  
8                   submitted specifications and testing.

9                   Committee Members act as a proxy  
10                  for NQF's membership. As such, this multi-  
11                  stakeholder group brings varied perspectives,  
12                  values and priorities to the discussion.

13                  Respect for differences of opinion  
14                  and collegial interactions among Committee  
15                  Members and measure developers are expected.

16                  The full Committee meeting agendas  
17                  are typically quite full. All Committee  
18                  Members, co-chairs, developers and staff are  
19                  responsible for insuring that the work of the  
20                  meeting is completed during the time allotted.

21                  So, ground rules for today's  
22                  meeting. We ask that all Committee Members

1 are prepared having reviewed the measures  
2 beforehand. We will base -- you will base the  
3 evaluation and recommendations on the measure  
4 evaluation criteria and guidance. We ask that  
5 you all remain engaged in the discussions,  
6 attend the meeting at all times except at  
7 breaks.

8 We will be taking a break at 10:15  
9 and I believe it's 2:15 with lunch at 12:30.

10 We ask that you keep comments  
11 concise and focused, avoid dominating a  
12 discussion and allow others to contribute and  
13 indicate agreement without repeating what has  
14 already been said.

15 And now, Karen Johnson's going to  
16 talk about our portfolio.

17 MS. JOHNSON: Thank you, Katie and  
18 good morning, everybody. I'm Karen Johnson.  
19 I'm the Senior Director, Office Projects. So,  
20 it's nice to see you guys and thank you so  
21 much for coming. I haven't got a chance to  
22 say hello personally yet, but I will

1 throughout today and tomorrow.

2 So, we're doing something a little  
3 bit different this time in terms of standing  
4 committee. So, Bill has already alluded to  
5 this being a pilot and we have transitioned  
6 from just calling condition specific  
7 committees every three years or so and asking  
8 you guys to serve on a standing committee and  
9 part of what that will entail is overseeing  
10 our portfolio.

11 So, we have our endocrine  
12 portfolio that you guys are now the overseers  
13 of, for lack of a better word. It is a new  
14 function for us. So, we will all be learning  
15 as we go, but we try to put down on this slide  
16 some of the responsibilities.

17 So, what are we thinking when we  
18 say you are an overseer of the portfolio?

19 So, the first is we would like you  
20 to provide input as you care to on the  
21 relevant measurement frameworks. So, we will  
22 be showing you a couple of frameworks. One

1 for diabetes and one for osteoporosis and  
2 these frameworks are designed to help folks  
3 think through measure development. So, we'll  
4 talk about those in a few minutes, but we will  
5 be asking specifically on feedback on the  
6 osteoporosis framework because right now,  
7 that's a draft.

8 We would also like for you to know  
9 which measures are included in your portfolio  
10 and we will be helping you with that and also,  
11 ask you to understand the importance to the  
12 portfolio and again, as we go through, I think  
13 you will understand what we mean by that.  
14 But, if you have any questions, you can  
15 certainly let us know.

16 We want you to think about as you  
17 consider the portfolio, and again, all of this  
18 is stuff that you will have in the back of  
19 your mind really, but think about measure  
20 standardization and parsimony. So, what we  
21 mean by that is it's not helpful a lot of  
22 times to have lots of different measures



1 measuring almost but not quite the same thing.  
2 It gets really confusing out there. So,  
3 that's what we mean by standardization and  
4 also by parsimony.

5           If there's two measures that are  
6 pretty much doing exactly the same thing, why  
7 are there two and sometimes there's good  
8 reasons to have two, but again, that's  
9 something you'll keep in mind not only as you  
10 think about the portfolio, but also as you go  
11 through the actual evaluation of the measures  
12 themselves.

13           We will use this time and  
14 throughout the meeting really to think about  
15 gaps in the portfolio. So, as we walk through  
16 our portfolios, it'll probably become apparent  
17 that there are measures that we don't yet  
18 have. So, we will ask you to give us some  
19 input on what you think those gaps are and  
20 that can go out to the field and have  
21 developers think about and take advantage of  
22 the good thinking that you guys are doing in

1 terms of gaps.

2 We would like you to be aware of  
3 other NQF measurement activities for the topic  
4 area. So, there's a lot going on at NQF not  
5 just in the measured endorsement part of our  
6 organization. So, we will give you some  
7 information about that so that you also learn  
8 what other groups similar to yourselves are  
9 thinking about these measures.

10 We would ask you to be open to  
11 external input on the portfolio and you've  
12 already had a chance I think to see some of  
13 that external input. If you've noticed that  
14 in the front matter of the measure  
15 submissions, when we had them, we put in some  
16 pre-meeting comments that came from outside.  
17 So, pretty much the public was invited to make  
18 comments on these measures and if we've got  
19 any of the comments, we made those available  
20 to you.

21 So, again, that's just so that you  
22 are aware of what others out in the world are

1 thinking about these measures.

2 We would like you to provide  
3 feedback about how the portfolio should  
4 evolve. So, that is similar to the gaps  
5 discussion, but maybe a little bit different.  
6 So, if you have feeling about different ways  
7 of measuring or different areas of  
8 measurement, that sort of thing, we will give  
9 you an opportunity to tell us about that.

10 And then finally, we would ask you  
11 to consider the portfolio when you're  
12 evaluating individual measures. So, we will  
13 go through the evaluations and we have  
14 criteria for you guys to use, but you also  
15 will keep in the back of your mind the  
16 portfolio and what is really needed to really  
17 try to drive quality improvement for interim  
18 conditions.

19 So, let me stop there and see if  
20 there's any questions before we go on and look  
21 at our portfolio.

22 Oh, okay and Lindsey just told me

1 that we have another Committee Member at the  
2 table. I'm sorry. I didn't see you come in.

3 Would you like to introduce  
4 yourself?

5 MEMBER MCCOLLISTER-SLIPP: Okay.  
6 Now, here we go. All right. I'm going to  
7 break out in song.

8 My name's Anna McCollister-Slipp.  
9 My company is Galileo Analytics, but I'm also  
10 here as a Type 1 diabetes patient with  
11 complications. So, that's how I got  
12 interested in these issues.

13 MS. JOHNSON: Thank you very much.

14 Okay. So, to start us off  
15 thinking about our endocrine portfolio, right  
16 now, the two conditions that we have measures  
17 for are diabetes and osteoporosis and you guys  
18 are not surprised about that because you've  
19 looked at measures for both of those  
20 conditions.

21 Theoretically, we could have  
22 measures in this portfolio on thyroid disease,

1 on metabolic syndrome or on other endocrine  
2 conditions. They are in a different color  
3 there to show you that right now we do not  
4 have measures in those areas.

5 Okay. Next slide please.

6 So, this slide and the next really  
7 are what Reba calls bringing coals to  
8 Newcastle, but just to get us on the same page  
9 about diabetes, we know that it is a high  
10 mortality condition. It's the seventh leading  
11 cause of death in the U.S. right now.

12 Prevalence is more than 25 million and many of  
13 those are not diagnosed. Incidents, almost  
14 two million new cases per year and it's also  
15 a very expensive condition. More than \$174  
16 billion per year.

17 Next slide please.

18 And this slide is just to remind  
19 us all that there are many complications of  
20 diabetes including heart disease and heart  
21 attack, stroke, high blood pressure, vision  
22 impairments, retinopathy and blindness,

1 chronic kidney disease, potentially ESRD,  
2 peripheral neuropathy, peripheral artery  
3 disease, poor wound healing and chronic  
4 ulceration and then potentially another  
5 complication is lower limb amputations.

6 So, again, those are potential  
7 complications and we might be thinking it  
8 would be nice to have measures that might look  
9 at some of those areas.

10 So, this slide just gives a quick  
11 snapshot. It's not the most up-to-date  
12 snapshot, but it's just a quick look at some  
13 of the preventive care that is being done in  
14 the U.S. and we can see that maybe that  
15 preventive care is not as high as we would  
16 like those bars to be.

17 And these kind of reflect some of  
18 the measures that we'll be looking at today  
19 and tomorrow.

20 Okay. So, this is our first  
21 measurement framework. This is for diabetes  
22 and this framework is based on what we at NQF

1 call our episode of care framework. So, that  
2 is a framework that was developed at NQF back  
3 in 2008 and really, it is meant to be broadly  
4 applicable to different types of conditions  
5 and it has a patient-centered focus.

6 So, you can see how the -- we also  
7 call it informally the bubble diagram. But,  
8 you start at population at risk and then you  
9 go through really the trajectory of disease.  
10 So, in this case, phase one is the risk  
11 population.

12 Just a second. She's going to  
13 help you out. Yes, we might -- we would get  
14 our technical guys to move it. That might  
15 work.

16 Okay. So, the second phase is the  
17 evaluation and ongoing management of diabetes  
18 and then finally, that third phase that's on  
19 the diagram is exacerbation of diabetes and  
20 complications treatment.

21 So, and also what you see on this  
22 framework is the idea -- really a couple of

1 things. Some of the measures, it's kind of  
2 hard to say if some of these measures belong  
3 in the middle bubble or the third bubble and  
4 in a way, that's kind of an academic exercise.  
5 It really doesn't matter, but that little set  
6 of arrows going around and around in there  
7 just indicates that some things just are  
8 iterative. You get your care on a regular  
9 basis.

10 What is also shown on this  
11 framework is four trajectories indicating  
12 different types of diabetes scenarios if you  
13 will. So, the first is folks who are in  
14 remission or have very tight control. Others  
15 who just have the ongoing management. You  
16 have a third trajectory that has patients who  
17 may go on to have these cardiovascular  
18 complications or the fourth trajectory, the  
19 kidney disease complications.

20 So, and then also what's pictured  
21 here in the framework is things to remind us  
22 to think about as we think about measurements.



1 One is that there is room in the development  
2 of measures for patient reported outcomes that  
3 reflect diabetes in people with diabetes and  
4 there are lots of other issues to think about  
5 throughout the episode and I won't read those,  
6 but I'm sure you're all very familiar with  
7 things like care coordination and access to  
8 care and those kinds of issues.

9 So, let's go to the next slide.

10 I wanted to walk you through our  
11 portfolio. So, I'm walking through again  
12 those bubbles. So, the first bubble is  
13 population at risk and what this shows you is  
14 that we have four measures right now that we  
15 have considered as being part of our portfolio  
16 under population at risk and what you see from  
17 this slide each of the measure numbers has an  
18 asterisk by it and that is indicating that we  
19 will not -- as an endocrine standing  
20 committee, those will not be measures that you  
21 will be evaluating. They are evaluated in  
22 other projects.

1                   So, one thing that you see there  
2                   is how we put measures into certain projects  
3                   or other projects is to some extent arbitrary  
4                   and we do the best we can.

5                   Obviously, some things could be in  
6                   two or three different committees. So, the  
7                   first two, for example, we are looking at in  
8                   population health. So, they're a more  
9                   population-based set of measures. So, we'll  
10                  be looking at those measures in a different  
11                  project, but they still are under your purview  
12                  because they are in the endocrine portfolio.

13                  The third and fourth ones there,  
14                  those are measures relating to diabetes, but  
15                  they are very narrowly applied to folks in the  
16                  first one with bipolar disorder and then in  
17                  the second there, it's schizophrenia or  
18                  bipolar. So, what that's showing you is that  
19                  there is some screening and assessment  
20                  measures that we have, but they are very  
21                  narrowly focused to this one population of the  
22                  mentally ill.

1                   Okay. Next slide please.

2                   Most of the measures that we have  
3 right now we have placed into phase two, the  
4 evaluation and ongoing management and I've  
5 split them out into groupings. So, the first  
6 one is eye care and you'll recognize the first  
7 one, the comprehensive diabetes eye care eye  
8 exam measure and that is one that we will be  
9 considering later on today.

10                  The next two have to do with  
11 diabetic retinopathy and some work around  
12 that. Some care processes around that and  
13 those again have asterisks. So, those are  
14 going to be considered in our HEENT. That's  
15 the Head, Eye, Ears, Nose and Throat Project.  
16 So, again, a little bit of arbitrariness here,  
17 but those are what we have right now on eye  
18 care measures for diabetes.

19                  For foot care, we have four  
20 measures and all of these are in our work  
21 today. We'll be talking about all four of  
22 these measures today.

1                   In terms of glucose testing, we  
2 will be looking at 0056 today, the HbA1c  
3 testing measure and there is another measure  
4 that looks at HbA1c as well as LDL  
5 cholesterol, but that one is also in a very  
6 narrow population. The schizophrenic  
7 population. So, that is in our behavioral  
8 health project. That's where that one's being  
9 looked at.

10                   The next slide.

11                   We have some measures that are  
12 directly related to cardiovascular processes.  
13 One is LDL screening and appropriate treatment  
14 of hypertension. Those you guys will  
15 eventually be evaluating. Not in this cycle  
16 of the project, but later on and I'm sure you  
17 guys are well aware that there have been new  
18 guidelines from JNC 8 and AAC/AHA and so, we  
19 have purposely pushed those out probably at  
20 least until next year so that people can work  
21 out any kinks of those guidelines. So, we'll  
22 be looking at those a little bit later.

1           The next two are actually going to  
2 be looked at in our cardiovascular project.  
3 One measure on kidney disease. You should be  
4 familiar with that one because we will be  
5 looking at that one today as well and then we  
6 have medication measures.

7           The first one on that list 0541 is  
8 a measure that is in a way similar to the  
9 three below it, but right now, it is being  
10 considered in the safety project. I think  
11 because it's a little bit of medication  
12 management kind of measure. That one may end  
13 up or at least a piece of it may end coming  
14 back to you.

15           So, we're still kind of trying to  
16 figure that measure out, but in the meantime,  
17 you do have the adherence measures that we'll  
18 be talking about tomorrow for statins,  
19 ACE/ARBs and oral diabetes agents.

20           Okay. Next slide.

21           And then this is what we have for  
22 phase three and again, some of those that we

1 just talked about could have been considered  
2 in phase three, but this is what we've said is  
3 the phase three. So, we have the poor control  
4 and the good control measures and then there's  
5 also blood pressure and LDL control measures  
6 that just like the other ones that we talked  
7 about we'll be pushing those out until at  
8 least next year so that we can think about the  
9 guidelines that have come out.

10 We have also a composite measure,  
11 optimal diabetes care. That one we have  
12 pushed out as well because one of the  
13 components of that measure, it's an all or  
14 none measure, but one of the components has to  
15 do or actually maybe a couple of the  
16 components have to do with the LDL and the  
17 blood pressure levels. So, again, that one  
18 has to be pushed out.

19 The next two on that list are in  
20 orange and that's to signify that you are  
21 considering them, but they are new measures  
22 that are coming to us this time around. So,

1 they have not been NQF endorsed yet and that  
2 will be what you will decide tomorrow or at  
3 least make a recommendation for us. So, they  
4 may or may not become part of our portfolio,  
5 but they're up for membership in our  
6 portfolio.

7           We have a few outcomes measures.  
8 They are complications due to diabetes and  
9 those are hospital measures and then some  
10 amputation, one amputation measure and an  
11 uncontrolled diabetes readmission rate. Those  
12 are all a level of analysis as a population.  
13 So, again, those are in our -- well, we used  
14 to call it population health. I think we're  
15 calling it the health and well-being now, but  
16 those are being looked at in a different  
17 project. But, we do have a few outcomes  
18 measures.

19           And then finally, right now, we do  
20 have one resource use measure, relative  
21 resource use for people with diabetes and the  
22 star there again indicates that that's not

1 something you guys will have to look at. We  
2 have another project that looks specifically  
3 at cost and resource use measures. So, they  
4 will be evaluating those measures.

5 Okay. There are several other NQF  
6 measurement activities going on that relate to  
7 our endocrine measures and the first is the  
8 Measure Applications Partnership Diabetes  
9 Family of Measures.

10 So, in case you're not familiar  
11 with the Measure Application Partnership or  
12 MAP as we call it, it is a public/private  
13 partnership that is convened by NQF and it was  
14 created for a couple of reasons, but mainly to  
15 provide input to the Department of Health and  
16 Human Services on the selection of performance  
17 measures that will be used in their programs.

18 So, that one is a statutory  
19 requirement that that be done and that group  
20 is also, like you, a multi-stakeholder group  
21 that considers measures. They do not get into  
22 the weeds. So, our group, the endorsement



1 projects get into the weeds of the measures.  
2 The MAP thinks of things a little bit more  
3 high level.

4 So, what they did with their  
5 family of measures -- well, let me back up a  
6 minute. Not only does the MAP recommend  
7 measures for use in Federal programs, but they  
8 also try to encourage alignment of measures in  
9 the public and private sectors.

10 So, part of that work, that  
11 alignment, they have created different  
12 families of measures. So, they actually have  
13 a diabetes family of measures and what a  
14 family of measures means to the MAP folks is  
15 they are sets of related measures and measured  
16 gaps that span programs, settings, levels of  
17 analysis and populations for specific target  
18 areas. In this case, diabetes and they try to  
19 indicate the highest priorities per  
20 measurements.

21 That's the gaps and the best  
22 available measures in their opinion within

1 each topic area. So, again, there is a  
2 diabetes family of measures that have been  
3 decided upon by the MAP people.

4 And if you're curious, they had  
5 some rationale when they were picking measures  
6 because there are a few to pick from and  
7 generally, they were looking for outcome  
8 measures as opposed to if they had the choice,  
9 they would prefer outcome over process  
10 measures. They noted gaps that -- they didn't  
11 really have patient and family engagement  
12 measures. But, they did prefer more broadly  
13 applicable measures and then that's enough  
14 there.

15 Let's go to the next slide.

16 Probably the most famous thing  
17 that the MAP does is recommend measures for  
18 Federal programs and they just went through a  
19 set of recommendations. Their report just  
20 came out I think a month ago or something like  
21 that and basically, what MAP does is for the  
22 various Federal programs they either support,

1 do not support and then they have a  
2 conditional support category.

3 So, I'm not going to read all of  
4 these for you. Again, this is just a way of  
5 taking input from other folks that have opined  
6 about these measures.

7 There are several of the measures  
8 that are in front of you today or that will be  
9 in front of you a little bit later that the  
10 MAP has not supported for use in their  
11 programs. So, the programs specifically  
12 listed here are the Physician Compare. That's  
13 a public reporting program and then the Value-  
14 Based Payment Modifier Program.

15  
16 And in general, on this slide, I  
17 gave you a little bit of their rationale about  
18 why they maybe didn't support a particular  
19 measure. So, just the first one, they had a  
20 preference for outcome measures and also, I  
21 just want to make sure that everybody  
22 understands that these are the MAP

1 recommendations and obviously, not everybody  
2 agrees that they should or shouldn't have been  
3 used in programs. So, you know, there is  
4 controversy about the MAP recommendations.

5 CO-CHAIR GOLDEN: Maybe you can  
6 just spend two seconds because that's one of  
7 the things that's confusing even to someone  
8 like myself bouncing around for awhile. The  
9 MAP is not the NQF. The NQF is not the MAP.  
10 The MAP -- the NQF has a portfolio of endorsed  
11 measures and this indicates a user group and  
12 their opinion about using an NQF measure.

13 So, if the MAP says no, does that  
14 continue the endorsement of the NQF measure?

15 DR. BURSTIN: Yes, it's a good  
16 question and it's a little complex and we are  
17 increasingly trying to think about how to  
18 better integrate those functions because they  
19 do feel somewhat detached at the moment.

20 I think the key issue here is that  
21 this was -- and what's not on here is the  
22 recommendations for the PQRS Program. Which

1 is sort of more to the starter set program for  
2 a lot of physicians and other clinicians to  
3 begin doing quality measurement and which many  
4 of these measures are on the list.

5 I think this was specifically  
6 getting to more of the programs that either  
7 have a significant financial stake associated  
8 with them or the newly emerging Physician  
9 Compare. That some of those measures  
10 indicating a preference for where they want  
11 the portfolio to go.

12 So, I think Karen's really making  
13 this point to give you a sense of since you're  
14 talking about the portfolio many of these are  
15 where we are right now. This was a sense of  
16 a multi-stakeholder group coming forward and  
17 saying this is kind of where we want to go to  
18 give you a sense of it.

19 It doesn't mean necessarily that  
20 some of these individual measures won't work  
21 for a variety of different uses currently and  
22 NQF does endorse measures for a variety of

1 purposes including quality improvement and  
2 various accountability programs.

3 So, I think it was more so in that  
4 sense that we're giving you this input as part  
5 of the discussion of the portfolio review.  
6 What we really want from you as part of this  
7 discussion is really quite simple. You've  
8 looked at some measures. You have a sense  
9 from Karen of what we have in our portfolio.

10 What's missing? What should we  
11 really be trying to incentivize the field to  
12 move towards developing as a result of this?

13 So, this gives you a flavor, for  
14 example, of, you know, a clear indication for  
15 wanting more outcomes, more composites. The  
16 kinds of things we hear a fair amount. Just  
17 to kind of put that in context.

18 Does that help, Bill? Sir.

19 CO-CHAIR GOLDEN: I think so. It  
20 just adds to our complexity, but that gives  
21 you a sense.

22 I guess down the road as we move

1 along, we may want to keep this piece of paper  
2 in front of us because it really has impact on  
3 some of the measures and how we move about  
4 things I would think. But, I'm just, you  
5 know --

6 DR. BURSTIN: Yes, although one  
7 important distinction and some of this -- you  
8 know, there's a lot of things in flux at NQF  
9 at the moment including this question of  
10 whether NQF should ultimately move towards an  
11 endorsement decision that's not binary yes/no,  
12 but is more nuanced around the particular  
13 intended use of the measure. You're going to  
14 come against this issue repeatedly today.

15 At our current point, and you need  
16 to act within our current structure and our  
17 current rules of the road, we do have binary  
18 endorsement. It is yes/no.

19 This is a much more nuanced  
20 interpretation of saying for some of those  
21 programs and some people, you know, that the  
22 highest impact programs in terms of payment or

1 public reporting, for example, some the MAP  
2 didn't think these measures necessarily rose  
3 to that level. They weren't universally  
4 considering the boarder -- all broad intended  
5 uses of measures.

6           Ultimately, one question would be  
7 -- and we're actually going to do some  
8 additional lean work this year to think about  
9 how to really better integrate the work of  
10 endorsement of MAP. Should the endorsement  
11 side put forward clearer recommendations  
12 around the science which support this measure  
13 for this purpose and the question is how much  
14 can the science actually -- what's the  
15 underpinning there to say this measure's  
16 better for payment, this measure's better for  
17 QI and that's where it gets difficult. But,  
18 from where we sit right now, we don't yet have  
19 that.

20           So, you need to think about the  
21 broadest possible uses of measures which could  
22 include quality improvement and some of the



1 sort of starter programs and again, I think  
2 ultimately this process will likely give  
3 clearer recommendations. So that when the MAP  
4 has to sit down and make these recommendations  
5 to the Federal Government about particular  
6 programs, hopefully, they'll have additional  
7 guidance from these kinds of groups who  
8 evaluated really the scientific properties of  
9 the measure. We want you to really -- you  
10 know, we've grounded the criteria quite  
11 clearly into all your materials.

12 Karen Pace is joining us today as  
13 our lead methodologist. Has, you know, worked  
14 with our committees and CSAC to try to give  
15 you a flow chart to really try to give you a  
16 grounding and staying in the science, the  
17 criteria, the scientific properties.

18 The intended uses of the measures  
19 will certainly come up as part of the  
20 discussion, but again, try to keep in  
21 particular this discussion grounded here.

22 We'll capture some of those other

1        comments. We'll feed them back to the MAP.  
2        We'll feed them back to the developers who are  
3        fortunately all here with us today. So,  
4        you'll have, you know, real time feedback into  
5        those processes.

6                    But, this was really intended to  
7        help us think about this is where we are right  
8        now. Where do we need to go? How do we try  
9        to incentivize the measure development dollars  
10       out there to help some of the developers find  
11       dollars to actually develop some of these  
12       measures that many of you will say you will  
13       likely want.

14                   CO-CHAIR GOLDEN: I see we have a  
15       couple of questions. Sue.

16                   MEMBER KIRKMAN: So, I don't want  
17       to belabor this too much, but can you explain  
18       the overlap or are they synonymous of the MAP  
19       with PQRS or is the MAP just sort of a group  
20       that kind of advises any Federal program  
21       whether it's the VA or Medicare?

22                   DR. BURSTIN: Right. At this

1 point, yes. Sorry to interrupt. At this  
2 point --

3 MEMBER KIRKMAN: And is physician  
4 compare? I guess that's my other question.

5 DR. BURSTIN: Okay. So, at this  
6 point, the Measures Application Partnership  
7 was specifically asked by the Federal  
8 Government to provide input to CMS. So, at  
9 this point, it is primarily the CMS programs.

10 I think there's 30-some odd  
11 programs, believe it or not, within CMS, some  
12 of us are not surprised by that, where they  
13 have to give guidance. Including, for  
14 example, the SRD Program, PQRS, across the  
15 board. So, it is not unique to PQRS at all.

16 And what they are asked to do is  
17 say here is the set of measures that CMS puts  
18 forward on this list affectionately referred  
19 to as the MUC list, the Measures Under  
20 Consideration, and then the multi-stakeholder  
21 groups -- yes, we've loved that nuance there  
22 and then the group then tries to think about

1 does this measure potentially work for this  
2 particular program.

3 So, it's not unique. It's not  
4 directly tied to PQRS. That is one of the  
5 programs that the Clinician Work Group in  
6 particular spent a lot of time talking about  
7 just because the volume of measures is so  
8 large for that to cover all the various  
9 disciplines and specialties.

10 Is there another question?  
11 Jessie.

12 MEMBER SULLIVAN: It's not a  
13 question. It's just a comment.

14 Since our work group call, I've  
15 been thinking so much about something Bill  
16 said on the work group call and it just speaks  
17 to this contradiction.

18 In looking at what the MAP says  
19 and it looks to me like the MAP is coming from  
20 the point of view of what we want for a  
21 population or a person with diabetes. That we  
22 really want, you know, composite measures. We

1 want to make sure that everything's done. We  
2 want to see the outcomes and I think that  
3 makes so much sense from the point of view of  
4 an individual.

5           And I think the contradiction that  
6 I have trouble with and I think we're all  
7 going to be grappling with is that the  
8 measures are not mostly measuring outcomes for  
9 an individual or for a population. They're  
10 measuring the performance of a physician and  
11 so, those are two different things.

12           So, I think that's where the  
13 contradiction is a lot and we're going to be  
14 struggling with this and I'm really glad to  
15 hear you say that the NQF is looking at maybe  
16 not having a binary thing.

17           But, at this point, we're sort of  
18 in the position of wanting to set standards  
19 for the care that a person or population will  
20 receive based on measures where the physician  
21 is the accountable entity. When in order to  
22 get to the outcome we need, there's more

1 involved than the physician.

2 DR. BURSTIN: Just to build on  
3 that, I think that's a good comment, Jessie.

4 The other really important piece  
5 of this in terms of where I think we're all  
6 going as well is trying to get to alignment.

7 So, the last thing you want is the  
8 population measure that Bill's using for  
9 Medicaid to look different in terms of the  
10 science phase compared to the measure that  
11 you're using at the physician level.

12 So, some of this is -- begin  
13 saying even if you have a measure in front of  
14 you that might be at a physician level or a  
15 health plan level, again, because this is the  
16 group that's suppose to be the science base  
17 for what we do, really look critically at the  
18 measurement properties, the evidence. If that  
19 works, I think the issue is ultimately  
20 thinking about how those measures can move  
21 towards aggregation up, for example, to a  
22 population level. Even if it's just the

1 numerator and the denominator kind of gets  
2 changed over time, is the science there at  
3 least in the way it's being put forward and  
4 Bill looks --

5 CO-CHAIR GOLDEN: So, not to get  
6 ourselves into a philosophy class, but that  
7 gets back to my original comments about some  
8 of our charge. We have measures. We have  
9 silos and the ultimate question is does it  
10 make a difference and so, that's sort of where  
11 we're heading with the MAP and with the NQF.

12 You know, there's no point in  
13 having -- in measuring something if it's just  
14 to measure something as opposed to making a  
15 difference in care and I think that's  
16 ultimately what we're charged with doing is to  
17 try to figure out is it just an exercise or  
18 does it actually have value in the long run to  
19 how people get care and how we exhort people  
20 to do things better.

21 DR. BURSTIN: And just to remind  
22 you as you'll go through it again, the four

1 criteria are, you know, there's a -- they are  
2 hierarchical. So, first, you'll deal with  
3 importance including evidence. Then  
4 scientific acceptability. Then we flipped it.  
5 So, then feasibility and ultimately use and  
6 usability. So use and usability is one of the  
7 four cornerstones here.

8 But, I think because we're  
9 starting from the lens here of the scientific  
10 acceptability of those measures, it's  
11 hierarchical beginning with evidence and  
12 science and testing. So, the use and  
13 usability is really important, but it's only  
14 really important if you've actually made it  
15 through those first few and that's why I think  
16 so much of your work today will be around  
17 evidence and scientific acceptability of the  
18 measures themselves and then assuming that's  
19 good, you can move on to feasibility and  
20 usability.

21 But, that hierarchy was  
22 intentional to kind of get at that.



1                   MEMBER DUDL: This concept of  
2                   importance of measuring, the one thing that  
3                   has escaped me is why we don't have a health  
4                   plan or whatever level of reporting heart  
5                   attacks and strokes.

6                   And the reason I mention that is  
7                   when I give -- have given some lectures on  
8                   improving diabetes, heart attacks and strokes  
9                   to a very high level of people in hypertension  
10                  and they totally miss the need for adding a  
11                  statin when they're high risk hypertensive and  
12                  they don't do it and they don't advise it.

13                  I think that it's -- we're missing  
14                  an element.

15                  Also, there's simplicity. If you  
16                  say okay, let's just go ahead and let's go  
17                  right after heart attacks and strokes. We  
18                  want to drop them 5/10 percent. Which is what  
19                  we're really after. We're really not after  
20                  hypertension, blood pressure and lipids.  
21                  There's real distortion when you go after  
22                  those subsets and you don't go after -- so, it

1 just seems like it's funny we don't measure  
2 the one thing that we're really trying to go  
3 at.

4 It's that kind of thing I think  
5 that if you -- is that what you're talking  
6 about that we need to consider?

7 DR. BURSTIN: Those are really the  
8 gaps and there's lots of reasons how difficult  
9 that is and people go on and off health plans  
10 as our friends from NCQA could certainly tell  
11 you. Getting the longitudinality we all know  
12 we desperately want from the HRs and other  
13 HIEs and other electronic systems would be  
14 great.

15 I mean I think that's why I think  
16 some of this discussion is what do we need and  
17 then beginning to think about the  
18 infrastructure you would then need to get to  
19 those measures.

20 We do have a health care system  
21 currently that is using these measures and I  
22 think we are responsible as part of the

1 maintenance process to say do these measures  
2 still meet the bar as you're going through  
3 your process today.

4 CO-CHAIR GOLDEN: Did Anna? Okay.

5 MEMBER MCCOLLISTER-SLIPP: Yes,  
6 and as admittedly probably the least  
7 scientifically trained person on this panel  
8 here as sort of a patient who's nerdy enough  
9 to be involved in something like this and  
10 occasionally read scientific journals for fun,  
11 one question that I have as somebody who's had  
12 Type 1 for 28 years. I have all the  
13 microvascular complications. There's been  
14 lots of effort taking care of myself, doing  
15 all the right stuff.

16 I used to get into very  
17 philosophical discussions with my former  
18 physician all the time about these issues. He  
19 was absolutely excellent and very well known  
20 in the field and he always used to say that  
21 if, you know, faced with these kinds of  
22 measures that he would have fired me as a

1 client a long time ago because I have very  
2 difficult to control diabetes.

3 So, for me, it's kind of difficult  
4 to think about quality measures in a vacuum  
5 when you think -- without thinking about what  
6 the implications of these quality measures may  
7 be both intended and unintended and that's why  
8 I already expressed some degree of discomfort  
9 with the whole binary thing and I know that's  
10 what we're doing here and that's fine. You  
11 know, I'm more than happy to do that.

12 But, it's difficult to divorce  
13 those two within this discussion because these  
14 are very kind of blunt quality standards that  
15 are going out to many, many physicians. Will  
16 have real life implications and I think we  
17 need to consider that within the context of  
18 our discussion when we're deciding even based  
19 on lots of data that, you know, 8 is the  
20 number.

21 What happens if you're 8.2 I mean  
22 or 8.1 or I mean if you're 7.9, that's fine.

1 If you're, you know, 8 then that's not I mean.  
2 So, I guess that's my primary comment.

3 DR. BURSTIN: You know, and again,  
4 I just want to emphasize how much we really  
5 value the patient voice. It's often times --  
6 I've watched enough of these committees over  
7 the years to see that it is often the patient  
8 who stops a very nerdy conversation in mid-  
9 flow about, you know, decimal points on things  
10 and just puts it in reality. So, thank you  
11 for that.

12 Again, just to recall, you will  
13 get to talk about usability and use and  
14 included in there is explicitly a discussion  
15 about the positive impact of those measures as  
16 well as potential unintended consequences and  
17 that was added just in the last couple of  
18 years or so explicitly for the fact that  
19 people are really increasingly having concerns  
20 about unintended consequences of measurement  
21 and that needs to be on the table as well.

22 CO-CHAIR GOLDEN: Well, we're

1 beginning to develop topics for the 9:00  
2 brandy conversation in the lobby. But, Sue.

3 MEMBER KIRKMAN: So, I just had a  
4 more general question. Although this group  
5 kind of looking at existing measures, you  
6 know, brought this to mind again and that is  
7 if we're reviewing existing measures and we're  
8 sort of going through the same process that we  
9 would for new measures, how do we deal with  
10 issues such as -- I mean there were a couple  
11 of measures where I was actually surprised  
12 that they were endorsed to begin with because  
13 they didn't seem to meet the standards that  
14 we're going through now and so, you know, kind  
15 of what are the implications of kind of un-  
16 endorsing a measure or does that happen or is  
17 there sort of a higher bar because it's  
18 already out there? I just struggle with that  
19 in our work group.

20 CO-CHAIR GOLDEN: Can I make a  
21 comment on that and maybe Jamie can make a  
22 comment, too.

1                   Jamie and I have been involved  
2                   with this.  Something like the primordial ooze  
3                   and there was a time when there was a  
4                   desperate need for measures and pre-PQRS,  
5                   there was a demand that, you know, specialists  
6                   have to have measures and there was a, you  
7                   know, build as you're flying kind of approach.  
8                   So, there was some things that were approved  
9                   because there wasn't anything.

10                   So, just because it exists now  
11                   doesn't mean it should exist in the future.  
12                   Because it was, you know, sort of like you go  
13                   back home.  You're not using an Apple 2 Plus  
14                   any more on your desk.  So, you know, it was  
15                   the best at the time, but may not be the best  
16                   now.

17                   DR. BURSTIN:  In fact -- sorry.

18                   CO-CHAIR ROSENZWEIG:  Yes, I would  
19                   just comment as well that the standard of  
20                   evidence that's been required for measures has  
21                   really increased substantially from five/ten  
22                   years ago.

1                   It used to be that measures  
2                   basically were derived from guidelines and the  
3                   guidelines themselves had varying basically  
4                   evidence standards and that's changed a lot  
5                   now and because we're actually looking -- in  
6                   approving these measures here, we have to look  
7                   at the evidence ourselves to a certain extent.

8                   DR. BURSTIN: Just to build on  
9                   that comment, again, the criteria have changed  
10                  significantly over the years. It is a higher  
11                  bar certainly I think. Certainly around  
12                  evidence and testing to a certain degree than  
13                  it was in the past.

14                  As an example, in 2012, we had a  
15                  hundred measures added to the portfolio and a  
16                  hundred measures removed from the portfolio.

17                  So, again, I think there is a  
18                  recognition that, you know, we need new, but  
19                  also, I think that a countervailing balance to  
20                  that is there are programs that need measures.

21                  So, I think we also don't want to  
22                  throw the baby out with the bath water of



1 something. You know, the common -- I'm sure  
2 somebody will say it today. So, I'll be  
3 first. Don't let the perfect be the enemy of  
4 the good. It's something that will come up a  
5 lot as well.

6 You know, are these helping? To a  
7 certain degree, they may not be where we  
8 necessarily want to go, but I think not  
9 letting perfect be the enemy of the good is an  
10 important countervailing balance I think to  
11 the raising of the bar.

12 CO-CHAIR ROSENZWEIG: The other  
13 issue, of course, is unintended negative  
14 consequences of measures which we have to at  
15 least think about. Because I mean sometimes  
16 measures will be used for the purpose of paper  
17 performance that might be inappropriately used  
18 as a base to these measures or physician  
19 tiering. Things of that sort which can get  
20 very complicated.

21 MS. JOHNSON: Thank you. What a  
22 great discussion right in the middle of these

1 lists of measures.

2 Can you go to the next slide  
3 please?

4 Oh, yes, go ahead.

5 MEMBER BAILEY: Just wanted to  
6 make one other comment. In terms of the  
7 outcome, any accountability, you have an  
8 intermediate outcome. You can hold the  
9 current providers whether it's the payer or a  
10 physician accountable. It's a longer term  
11 outcome. Unfortunately, the retinopathy,  
12 cardiovascular disease, those types of  
13 complications may have been impacted by care  
14 prior to the current entities that are  
15 accountable.

16 MS. JOHNSON: Katie, can you go to  
17 our next slide please?

18 Just so you don't think that the  
19 MAP didn't support anything in our portfolio,  
20 that's actually not true. They did support  
21 several of the measures that you'll be looking  
22 at and I'm certainly not going to go through

1 these lists, but we did want to tell you that  
2 there was support and sometimes conditional  
3 support for measures and interestingly and I  
4 think it was in the staff reviews for the  
5 hyper- and hypoglycemia measures that are new.

6           Again, those have not yet been  
7 endorsed. There was conditional support by  
8 the MAP for those measures and conditional  
9 because it hadn't gone through the in-depth  
10 analysis that you're going to look at and  
11 also, there was a little bit of concern that  
12 those are e-measures. So, something that  
13 we'll delve into tomorrow.

14           And when the MAP does their work,  
15 they also identify gaps. So, the gaps that  
16 the MAP folks have identified and I think  
17 we've already talked about those, they noticed  
18 that there's not a lot of measures addressing  
19 glycemic control for the complex patients and  
20 they didn't see pediatric measures and also  
21 not measures looking at the sequelae of  
22 diabetes.

1                   Next slide please.

2                   There is additional work that NQF  
3 has done. We did a couple of years ago a huge  
4 gaps report. So, looking at a lot of  
5 different groups of measures and thinking  
6 about what might be the gaps in those and  
7 again, we're kind of back to the same things  
8 that we've already mentioned already. Access  
9 to care, patient-centered measures, quality of  
10 life, care coordination, communication  
11 transitions. So, again, a lot of these things  
12 are gaps and these are the ones that were  
13 mentioned specifically about diabetes.

14                   And then finally, let me at least  
15 tell you that we have a measures pipeline. It  
16 was unveiled I think maybe a month ago or a  
17 little bit more and the idea of this is to try  
18 to start things, some intelligence if you  
19 will, about things that developers are working  
20 on, things that will be coming down the pipe  
21 and we're hoping that they will submit their  
22 measures or concepts.

1                   They might not even be fully-  
2                   developed measures at this point, but we're  
3                   hoping that they will tell us about them and  
4                   just so you know, it is new. So, far, we do  
5                   not have any measures in our pipeline that we  
6                   know about of diabetes measures. So, nothing  
7                   to date yet from that source.

8                   Going very quickly into  
9                   osteoporosis. Again, it is a large problem.  
10                  High prevalence in the U.S. The main  
11                  complications are hip fractures and spine  
12                  fractures, but there are other fragility  
13                  fractures as well.

14                  And we'll go through the  
15                  statistics. I'm sure you guys all know that  
16                  hip fracture and the spine fractures, you  
17                  know, it is a problem more among women than  
18                  men, but it is a problem of men and the  
19                  functional impairment and pain I guess really  
20                  comes -- and I'm not a clinician. I'm  
21                  assuming that it comes more from the  
22                  fractures, but those kind of things do belong

1 in a portfolio thinking about osteoporosis.

2 Next slide please.

3 This graphic is just to show you.

4 What you see there is osteoporosis versus low-

5 bone mass. Just the prevalence by age group.

6 On the right-hand side is women. Left-hand

7 side men. So, it's not something that isn't

8 a problem among men.

9 Next slide please.

10 This -- and we don't really have

11 time to go into this, but it is something that

12 we'd like your input on as we go through and

13 you guys are our standing committee. So, we

14 certainly have time to go further in further

15 months. This is our draft episode of care

16 model for osteoporosis.

17 I neglected to tell you that the

18 model that you saw earlier for diabetes was

19 actually agreed upon by another set of folks

20 who look specifically at diabetes. So, that

21 one was -- we did have a lot of expert input

22 into that model.

1                   This one we pretty much made up  
2 ourselves and I think Lindsey did a great job  
3 on this one.

4                   So, again, we think that this is a  
5 pretty good model, but we will ask you to just  
6 at some point -- we may not have time today to  
7 go into the weeds of this, but, you know, big  
8 picture things. Are these the right things to  
9 be thinking about? We have kind of three  
10 trajectories there. Are those the right  
11 trajectories? Are there other things that  
12 should be on our conceptual model as we go  
13 through?

14                   Next slide.

15                   This is the one slide that we have  
16 for osteoporosis measures. So, the portfolio  
17 is very small for osteoporosis. A couple for  
18 population at risk. A couple for ongoing  
19 management and then a few for post-fracture  
20 care.

21                   And what I'm showing you here  
22 again as before, the measures with the

1 asterisk to the side are ones that you will  
2 not be evaluating as part of the endocrine  
3 group. They belong to other groups.

4 That first one there is a concept  
5 only, but that is -- it actually will live in  
6 the GI/GU project and this was -- we tried  
7 just looking at concepts. So, this isn't a  
8 fully-baked measure yet. It might be at some  
9 point. It may come back as a fully-developed  
10 measure.

11 The last three there are new  
12 measures that came in in this cycle. So, you  
13 guys will be discussing those a little bit  
14 later today.

15 The other osteoporosis measures,  
16 we have pushed off until our next cycle. So,  
17 we will be looking at those and asking you to  
18 evaluate those in the fall.

19 Okay. Next slide.

20 In terms of other measurement  
21 activities around osteoporosis, same sort of  
22 thing. I have what I could find in the MAP



1 report about the MAP recommendations. I think  
2 -- I'm trying to see this. Pretty much the  
3 MAP didn't say as much about osteoporosis as  
4 diabetes, but there was support for some of  
5 the measures, not all of them, and in terms of  
6 the gaps report, that one did not look  
7 specifically at osteoporosis. So, there was  
8 no information on gaps and in our pipeline, we  
9 do not have any measures or concepts right now  
10 that we know of that are coming along on  
11 osteoporosis.

12 I put this slide in just to make  
13 sure that everybody remembers that we do have  
14 something called a National Quality Strategy.  
15 It is what we think of as our north star  
16 really of what things we need to think about  
17 in terms of developing and measuring  
18 performance. So, we have better care, healthy  
19 people, healthy communities and affordable  
20 care. That's the triple aim that you hear  
21 about and then in the center box are the six  
22 priorities.

1           So, again, as you think about, you  
2 know, potential gaps, this is a way to  
3 organize different types of measures, you  
4 know, affordability measures, patient safety  
5 measures, et cetera. Okay.

6           And so, we've already started this  
7 conversation to some point, but we have about  
8 15 minutes I think. Yes, so, here's some  
9 questions to consider about the frameworks.

10           Do they facilitate understanding  
11 of improvement opportunities? Because that's  
12 what these are suppose to help us do. Think  
13 about how we can improve.

14           And then specifically, any  
15 comments about the osteoporosis framework.  
16 Again, we might not quite have the time to go  
17 into that in depth, but maybe a discussion  
18 about why the measures are important. Do they  
19 address the -- do the measures that are in our  
20 portfolio actually the quality problems or are  
21 other types of measures needed?

22           And then finally as I mentioned

1 right now, we only have diabetes and  
2 osteoporosis. Are there other important  
3 conditions and measures for those that we  
4 should have in our portfolio and don't?

5 CO-CHAIR GOLDEN: I think some of  
6 that last one could be done at the end of the  
7 day or, you know, tomorrow probably for the  
8 expansion perhaps.

9 MS. JOHNSON: Yes, we certainly  
10 could.

11 CO-CHAIR GOLDEN: Yes.

12 MS. JOHNSON: I think we will have  
13 time, but we have about 15 minutes now.

14 CO-CHAIR GOLDEN: A quick  
15 question, then I'll get to the group. I was  
16 shocked when I looked at the list a couple of  
17 slides back that screening for osteoporosis  
18 was not recommended. Can you explain that  
19 one? It was very strange looking. I  
20 didn't --

21 MS. JOHNSON: Can you go back,  
22 Katie?

1 CO-CHAIR GOLDEN: Go back two  
2 slides I think. Right there. So, MAP, most  
3 recent recommendations 0046 do not support for  
4 the Medicaid Shared Savings Program. Do not  
5 support for Physician Compare. Both of them  
6 did not support 0046.

7 I was just curious. That's a  
8 little surprising to me.

9 MS. JOHNSON: On the first one  
10 there for the Medicare Shared Savings Program  
11 which that's a program that I'm not really  
12 familiar at all with.

13 DR. BURSTIN: It's the ACO  
14 Program.

15 MS. JOHNSON: Okay. It's the ACO  
16 Program. My understanding if I understood  
17 right, they only were looking to expand their  
18 recommendations for cross-cutting measures.  
19 So, I guess those went out and I don't know.  
20 That's about the best I can do without really  
21 going back and looking, but I can do that for  
22 you tonight.

1                   For Physician Compare and the  
2 Value-Based Payer Modifier Programs, it's  
3 probably -- if I don't have a reason like I  
4 had on the other slide, they didn't say  
5 specifically other than what they had in  
6 quotes does not adequately address current  
7 needs of the program and so, I don't know.

8                   Helen, do you recall any more than  
9 that?

10                  DR. BURSTIN: Don't have the  
11 specifics in front of me and again, there was  
12 not significant conversation measure by  
13 measure. It was more conceptually just to be  
14 clear. So, that I think it wasn't -- they  
15 didn't have a specific conversation about that  
16 measure and say do not support.

17                  I think it was more so again the  
18 idea of wanting more cross-cutting measures  
19 particularly for the ACO Program and I think,  
20 again, there was a desire, in particular as I  
21 recall at the Clinician Work Group, if there  
22 were measures of screening that they should

1        somehow be attached to a follow-up action.

2                        So, I think things that were pure  
3        screening without a follow-up action were ones  
4        that were not in general preferred. So, I  
5        think that was sort of caught in this net as  
6        opposed to being anything about particular  
7        scientific issues around the measure itself.

8                        CO-CHAIR GOLDEN: Sue.

9                        MEMBER KIRKMAN: Yes, I just had a  
10       comment about the osteoporosis episode of care  
11       and that is that the focus on prevention of  
12       fractures is only in the box for the  
13       relatively healthy adult and then once  
14       someone's had a fracture, it falls out and  
15       since, you know, having had a fracture is the  
16       biggest risk factor for a subsequent fracture,  
17       I just think that that needs to not fall out.  
18       You know, once you've had a fracture,  
19       prevention of fractures should be really  
20       important and is probably where the best  
21       evidence is and the best bang for the buck.  
22       So, that was just my comment.

1 CO-CHAIR GOLDEN: Other comments  
2 or questions. Let's go to the last slide  
3 again. I guess you can remind folks. Well,  
4 good.

5 MEMBER KIRKMAN: I mean I guess  
6 this is going to wait until tomorrow, the  
7 discussion about other measures, but I would  
8 hope that we could also maybe discuss some  
9 measures of overuse because I do think in  
10 endocrinology there are, you know, sort of  
11 overuse. I'm thinking thyroid nodules and  
12 ultrasounds and, you know, there's even  
13 emerging evidence that perhaps thyroid cancers  
14 are being over diagnosed and treated. So,  
15 just something to think about.

16 CO-CHAIR GOLDEN: As an aside, I'm  
17 working with a committee now on radiology  
18 measures looking exactly at that. So, there  
19 are a couple in the pipeline.

20 CO-CHAIR ROSENZWEIG: I think  
21 that's a very good point. A lot of the data  
22 related to the thyroid nodules especially.

1                   MEMBER SHWIDE-SLAVIN: One of the  
2 other endocrine conditions, I was wondering  
3 why it wasn't included, is pre-diabetes.  
4 That's huge and it's not anywhere.

5                   DR. BURSTIN: It' probably in more  
6 of our population health focused where more of  
7 sort of pre-condition measures are focused,  
8 but I'm not even sure there actually is a  
9 measure yet on -- I think there's one newly  
10 proposed on diabetes screening at a population  
11 level. Good point though.

12                   MEMBER MCDERMOTT: I mean there's  
13 huge efforts for metabolic syndrome even from  
14 health plans. If you are in any of the big  
15 ones, you get credit on your premium now for  
16 doing that kind of screening no matter what  
17 age you are and so forth and so on.

18                   So, I think that that's a very  
19 good topic and even the definition of  
20 qualifying for a metabolic syndrome and how  
21 that's working I think is a very interesting  
22 topic to explore at some point.



1 CO-CHAIR ROSENZWEIG: Is metabolic  
2 syndrome within the purview of this committee  
3 or is it more in the cardiological sphere?

4 DR. BURSTIN: It crosses it. It  
5 doesn't matter. That's the whole point of  
6 having standing committees. You guys can work  
7 collaboratively over time and figure out just  
8 what needs to get done and where it could live  
9 is less of an issue.

10 MEMBER MCCOLLISTER-SLIPP: And  
11 maybe I'm missing something, but why is  
12 thyroid not addressed? Was it? Did I miss  
13 something?

14 DR. BURSTIN: Thyroid's in this  
15 portfolio. We just have very few measures and  
16 they're not yet up for maintenance.

17 MS. JOHNSON: Right. We don't  
18 have any.

19 DR. BURSTIN: We had a few. But,  
20 okay. I thought in the past.

21 MS. JOHNSON: Yes.

22 DR. BURSTIN: Yes, very few

1       measures.

2                   MEMBER DUCWORTH:  It would be a  
3       better -- so, I think a better understanding  
4       of how certain thresholds are established on  
5       clinical outcomes measures.

6                   My understanding, and it could be  
7       naive is, I guess, the body of evidence.  They  
8       just perform a series of retrospective  
9       analyses and they determine a population mean  
10      and what's the most desirable, I guess,  
11      target.  For instance, like an 8.0 under for  
12      A1c.

13                  But, are they looking at the  
14      overall population mean?  Are they then taking  
15      a subpopulation and then targeting that?  The  
16      ideal for that ideal population.  How are they  
17      determining that threshold?  Because that  
18      tells us a lot about, you know, what is  
19      desirable in establishing these metrics.

20                  It goes back to what Anna was  
21      suggesting.  Do we target an 8.0 and under or  
22      an 8.1 or 8.2?

1                   The scientific community, how are  
2 they identifying that threshold?

3                   DR. BURSTIN: We'll shortly get to  
4 that conversation where those measures come  
5 up.

6                   MEMBER DUCWORTH: Okay. Yes.  
7 Thanks.

8                   DR. BURSTIN: We've got lots of  
9 folks at the table to help. But, that's --  
10 those are, you know, important evidence  
11 questions.

12                   CO-CHAIR GOLDEN: What you're  
13 saying is the diabetic is not a diabetic is  
14 not a diabetic?

15                   MEMBER DUCWORTH: Well, I just  
16 don't -- okay. So, for instance, I'm from the  
17 private sector. Right. Am I going to save my  
18 organization \$200 million by getting everyone  
19 at 7.8 and below or 7.5 and below? You know,  
20 the cost savings would be workplace  
21 improvements, improved quality of life for our  
22 members.

1                   But, I want to know the science.  
2                   Like how are they approaching that? Because  
3                   if I don't like the science, I'll just have a  
4                   more aggressive target.

5                   CO-CHAIR GOLDEN: Thank you and as  
6                   we move along, if you can move your mike a  
7                   little closer. You're a little more difficult  
8                   to hear than some. That's great. Super.

9                   MEMBER DUCWORTH: Oh, sorry.  
10                  Thanks. That's it. I'll wait for the future  
11                  conversations.

12                 MEMBER BAILEY: I also just wanted  
13                 to raise the topic of BMI because currently it  
14                 appears to be identifying the population at  
15                 risk, but then when you look at the population  
16                 that has diagnosed diabetes specifically Type  
17                 2 and the evidence-based guidelines recommend  
18                 weight loss or increased exercise in that  
19                 population. I'd advocate for also having a  
20                 measure in that population that's also  
21                 diagnosed as well or at least, development of  
22                 a plan or evidence of a plan that has been

1 discussed.

2 MEMBER DUVA: So, I feel like  
3 we're jumping back and forth on topics related  
4 to this slide, but if we can go back to your  
5 framework if you're looking for feedback on  
6 the osteoporosis and we've not talking about  
7 it again later, I think it was Sue that had a  
8 great comment about the middle box losing the  
9 prevention of fractions.

10 And I also wanted to throw in  
11 there you're looking at this sort of model,  
12 but the screening is so important in so many  
13 of our populations depending on where you're  
14 at. The majority of people could be screened  
15 at risk.

16 So, I think going on with Sue's  
17 comment in the next box what you're really  
18 interested in maybe is injury prevention.  
19 Because once you get to a certain population  
20 perhaps the elderly or whomever it may be, the  
21 screening, you know, it's kind of like an  
22 80/20. You might have 80 percent of your

1 people screening positive. So, then what  
2 you're really interested in is the injury  
3 prevention and it affects a lot of the  
4 processes.

5 CO-CHAIR GOLDEN: You know, this  
6 kind of a conversation's one of those things  
7 where you'll be walking your dog or carrying  
8 out the garbage, you know, you'll have a great  
9 thought come to you. You might want to have  
10 this sort of as an ongoing share point where  
11 people can submit these ideas over time as  
12 part of our activities since there's, you  
13 know, no point in having it in a five-minute  
14 window. We might as well keep our creative  
15 ideas available for future use.

16 Yes, sir.

17 MEMBER TAYLOR: I'm not sure if  
18 this is the moment. This will come up  
19 repeatedly as we speak, but we're stuck in a  
20 sort of difficult paradigm that the diabetes  
21 and osteoporosis measures both exemplify  
22 really well.

1                   Which is we have people at risk  
2 based on some continuous variable that's a  
3 poor predictor of what's going to happen, but  
4 the best we have. Like bone mineral density  
5 or hemoglobin A1c and when we take the  
6 population and that distribution and  
7 arbitrarily cast a line somewhere. We're  
8 going to have that problem that Anna said so  
9 eloquently about people who are close to that  
10 line.

11                   What we want clinicians to do,  
12 since these end up being measures to help  
13 encourage physicians to do what's right, is to  
14 do things when there's more benefit than harm  
15 from the patient's perspective and if you look  
16 at the distribution, wherever you draw the  
17 line, the most people in the distribution that  
18 we care about will be clustered right around  
19 the place you draw the line wherever you draw  
20 it. Right.

21                   And then you'll have the problem  
22 with, you know, it's the person with the A1c

1 of 8.1 somehow needs an intervention. Well,  
2 you know, if the intervention has some risk  
3 going from 8.1 to 8, might do more harm than  
4 good. Right.

5 Then you get into the issue of  
6 patient centeredness and values and how you  
7 make that distinction and those sort of  
8 problems pervade this whole approach where we  
9 define a disease by taking a distribution,  
10 drawing a line and saying on this side of it,  
11 you have the disease and on that side of it,  
12 you're okay.

13 CO-CHAIR GOLDEN: So, welcome to  
14 the second half hour of our brandy  
15 conversation.

16 You know, you get into the issue  
17 of if everybody has a similar population, you  
18 know, it's a normative process and you can  
19 compare rates as opposed to the individual  
20 position everyone's going to have a variant.

21 But, your point is well taken and  
22 it gets to her point about is everybody the



1 same. So, but that's a good point for coffee  
2 maybe.

3 Maybe we can say that for the last  
4 time during the next two days we're on time as  
5 far as schedule if -- I'm sorry, Tracy.

6 Didn't see you.

7 MEMBER BREEN: Okay. Just one  
8 comment and again this is kind of for very  
9 heavy brandy later, but looking at these  
10 measures as we slice it across, what we're  
11 really, I think, looking for as clinicians is  
12 the delta. Right? The delta of taking  
13 someone with an A1c of 10 and moving them to  
14 8.5 and the risk reduction that happens there  
15 or the delta of taking someone with a LDL of  
16 130 and getting them to 105 and the risk  
17 reduction.

18 And I know that's beyond the scope  
19 of what we're talking about, but that's really  
20 what we're looking at and that's what the  
21 doctors are looking at in their practices when  
22 they're managing complicated high-risk

1 patients. They want credit for the delta.

2 So, I just want to throw that out  
3 there as a goal much later.

4 MEMBER MILLER: Along that same  
5 line and in the vein, pardon the pun, of  
6 having a delta, we have measures that we're  
7 going to be discussing about diabetes  
8 education regarding foot exams. I'm very  
9 interested in what measures we have. I  
10 haven't seen any measures about diabetes  
11 education itself.

12 And we know that the majority of  
13 care happens outside of the office. We know  
14 that patients are not always aggressive in  
15 seeking out care and they -- or I'm sorry. Of  
16 seeking out education and the information they  
17 get is from mostly, you know, precariously  
18 reliable sources.

19 So, I'm very interested in what  
20 measures we have or are being considered for  
21 diabetes education locations.

22 CO-CHAIR ROSENZWEIG: That's an

1 interesting point because it's been very  
2 difficult for measures developers to come up  
3 with the specific criteria for judging whether  
4 or not a person's received diabetes education  
5 or not.

6 Interestingly enough, the recent  
7 NCQA AMA PCPI group that's been developing  
8 measures has come out now with an education  
9 measure, but for years, we were working on  
10 developing diabetes related education measures  
11 and when we came up to the evidence-based  
12 issues and how to actually define education,  
13 they got shot down. So, it's been a very  
14 difficult issue.

15 But, we're sort of in the  
16 situation really of considering measures that  
17 have been developed by others. I mean I don't  
18 think our mandate is to develop measures. We  
19 can suggest to other organizations issues  
20 related to that, but we have to consider  
21 what's coming up to us. I don't think that  
22 we're going to get involved in actually

1 creating the measures that we necessarily  
2 think are helpful.

3 DR. BURSTIN: And just to build on  
4 that just briefly, so, the issue that has come  
5 up repeatedly when education measures come  
6 forward is it's often difficult I think  
7 particularly for patients and purchasers to be  
8 comfortable with the idea that it is a  
9 clinician checking a box that I educated a  
10 patient.

11 So, I think there has been very  
12 much a sense at NQF in our Content Standards  
13 Approval Committee that you're nothing about  
14 the patient without the patient and those  
15 measures have been traditionally so much more  
16 difficult to built, but that is absolutely  
17 where I think we need to go. So, just wanted  
18 to add that.

19 MEMBER MILLER: And there's such a  
20 variety in what constitutes patient education  
21 in diabetes. There are a hundred different  
22 components.

1                   MEMBER BREEN:   And I was just  
2                   going to comment on that.   One of the  
3                   challenges or limitations of I think groups  
4                   like this is that the measures come from the  
5                   data.   Right?   And if there's not data out  
6                   there, it doesn't mean that there's not a  
7                   problem or an issue.   Right?

8                   And one of the challenges that  
9                   we've had even looking at diabetes education  
10                  is that some of the data is pretty lousy in  
11                  terms of how the study was done, how the  
12                  education was done.   No standardization of the  
13                  education.

14                  So, it's not that we don't know  
15                  that education is important, but if we're  
16                  relying on the data to drive the measures,  
17                  it's not going to happen because the data  
18                  hasn't been there.

19                  I think the data's out there, but  
20                  someone has to collect that.   Right?

21                  And so, encouraging our thinking  
22                  how you develop a measure without data or what

1 box that needs to sit in is I think really  
2 challenging.

3 MEMBER MCCOLLISTER-SLIPP: One  
4 question I have and the previous discussion  
5 was a great segue into it, is there was a  
6 reference to some sort of pipeline  
7 recommendation process that you just opened  
8 which I think sounds really encouraging. I  
9 have never heard of it.

10 But, I think I mean if there's  
11 nothing on there, I know some people who'd  
12 like to make some recommendations for things  
13 especially within the Type 1 community, those  
14 of us who wear CGMs. I mean there's a lot of  
15 interesting stuff being done about time and  
16 range or ambulatory glucose profile or  
17 whatever.

18 So, if there's anything that you  
19 have in terms of an announcement, I think it  
20 would be great to send it out to some of the  
21 people who are working on these measures to  
22 say hey, here's this process. Sure you've

1 still got some work to do in terms of the  
2 research to support it and building the  
3 evidence profile and all of that, but I think  
4 that would be something I know that the  
5 patient community would be particularly  
6 excited about.

7 DR. BURSTIN: Just one last point.  
8 We are actually in the process of trying to  
9 get funding to do a design session we're  
10 calling a measure incubator to allow those  
11 sort of innovative ideas to come forward.  
12 Hopefully marry them with data, funders, and  
13 experts and create those measures more  
14 rapidly, but it's sort of coming.

15 But, again, anything you can share  
16 on those gaps or those emerging concepts, we'd  
17 be delighted to bring it forward.

18 CO-CHAIR GOLDEN: And just as an  
19 aside, one of the things I noticed that it  
20 really isn't any measures separating Type 1  
21 and Type 2 diabetes. It's all one. That's  
22 interesting. Yes.

1                   MEMBER SHWIDE-SLAVIN:  There's  
2                   also the issue with education.  When somebody  
3                   is documented as having education, at what  
4                   point did they have education?

5                   The most recent -- American  
6                   Diabetes Association just came out with new  
7                   nutrition recommendations and within there is  
8                   the recommendation for everyone to be sent for  
9                   education when they're diagnosed.  Most people  
10                  are not sent for education until there's a  
11                  complication and I think if there was a  
12                  measure, it would help physicians to refer  
13                  people to people and programs that could  
14                  provide education.  Not just the physician  
15                  doing the education.

16                  CO-CHAIR ROSENZWEIG:  Yes, I think  
17                  you're absolutely right with respect to that,  
18                  but then you have to consider whether or not  
19                  these particular programs are available  
20                  geographically in lots of different areas and  
21                  so, the different geographic areas may not be  
22                  able to be judge similarly if they don't have



1 ADA recognized programs within the vicinity of  
2 their area and things like that.

3 MEMBER SHWIDE-SLAVIN: But, there  
4 are also -- there may be a registered  
5 dietitian in the area and the registered  
6 dietitian could do medical intrusion therapy  
7 which would cover education at least for the  
8 nutrition aspects of what a person needs when  
9 they have diabetes.

10 So, there may be something or  
11 someone, or pharmacies. There's a lot of  
12 pharmacies that are beginning to do education  
13 and so, there may be a pharmacy that's in the  
14 area and that be a recognized program.

15 I think that there's a lot of need  
16 to look into this.

17 CO-CHAIR ROSENZWEIG: Yes, but the  
18 issue has come up as to whether or not it's a  
19 -- that the individuals are certified diabetes  
20 educators or not. Is that required?

21 MEMBER SHWIDE-SLAVIN: These are  
22 big --

1 CO-CHAIR ROSENZWEIG: What's the  
2 content of the actual education? I mean these  
3 are things that have become very complicated.

4 MEMBER SHWIDE-SLAVIN: Yes, I  
5 know.

6 CO-CHAIR GOLDEN: Let's have two  
7 last comments. So, Jessie and then --

8 MEMBER SULLIVAN: Well, I just  
9 wanted to underscore that that last  
10 conversation takes us back to the thing of are  
11 we setting standards for what patients should  
12 receive or are we setting standards for what  
13 a physician should deliver? Because if a  
14 patient should receive it, the fact that it's  
15 not available in the area is a flaw in the  
16 health care delivery system that needs to be  
17 addressed.

18 But, if the standard is that a  
19 doctor should deliver it, the doctor really  
20 can't deliver it if it's not available and if  
21 the measure's holding the doctor accountable,  
22 that's -- so, I just think that's one of the

1 contradictions we're really dealing with.

2 MEMBER MCDERMOTT: I just wanted  
3 to go back to the concept of measurement  
4 developers and the pipeline. Going back to  
5 the surge of measures that we had five or six  
6 years ago, one of those measures falling off  
7 the radar out of NQF endorsement because the  
8 measure developer, what I'm hearing is,  
9 doesn't want to maintain them.

10 And that's a crime because if we  
11 have a good measure that's developed based on  
12 good standards, that measure should be  
13 maintained and there should be some  
14 accountability or some pick up by somebody  
15 else.

16 So, I'm hoping that as we accept  
17 measures and approve measures in the future  
18 that there will be a certain amount of  
19 accountability associated with those measures  
20 to maintain them. Because if they're based on  
21 drugs, LOINC codes, lab tests, whatever and  
22 even diagnosis codes for ICD-10, the fact that

1 they're now being dropped is really a  
2 disappointment to those of us in the industry  
3 that are trying to follow those standards and  
4 knowing that they have to be updated in order  
5 for them to be credible and then it begins to  
6 look like a variance.

7 So, it's just another piece of  
8 measurement development that needs to stay.

9 CO-CHAIR GOLDEN: And that is the  
10 challenge.

11 MEMBER MCDERMOTT: Yes.

12 CO-CHAIR GOLDEN: The process of  
13 specification is expensive and nobody is  
14 paying for it and that's a real challenge for  
15 everybody going down the road.

16 MEMBER MCDERMOTT: Yes.

17 CO-CHAIR GOLDEN: So, it's a  
18 problem.

19 It is a little after 10:15. We  
20 have about a ten-minute break. So, then we'll  
21 get back to do the real work I guess.

22 (Whereupon, the above-entitled

1 matter went off the record at 10:19 a.m. and  
2 resumed at 10:38 a.m.)

3 CO-CHAIR GOLDEN: Okay. It's  
4 about that time, and we are going to, I guess,  
5 start with doing the measures themselves and  
6 the voting and the talking. And we are going  
7 to start with Measure 59. Some of them are  
8 interrelated.

9 We get assigned a certain amount  
10 of time, probably because it is the first  
11 measure, this one will take a longer period of  
12 time. And we will then learn from ourselves  
13 in the process so that the other measures will  
14 go quicker. So we won't necessarily panic too  
15 quickly about time spent on the first measure.

16 Know all good things or all  
17 confused things come to an end at some point,  
18 and we will try to keep ourselves on task. So  
19 please don't be offended if Jamie or I say  
20 that we have to move on, or we have to focus  
21 our comments. You know, we do need to try to  
22 keep, as best we can, on some sort of a

1 framework and some sort of pathway to getting  
2 all the work done.

3 So we will do a little creative  
4 nagging here and there to keep people moving  
5 forward.

6 CO-CHAIR ROSENZWEIG: Yes. I  
7 think this is especially -- you know,  
8 obviously, the people who are the measures  
9 developers who are here want to be heard as  
10 part of this. But we certainly need to keep  
11 things focused. There are a tremendous number  
12 of different measures that we have to go  
13 through.

14 CO-CHAIR GOLDEN: So I think that  
15 what we will do -- okay. You want to start  
16 with the measure developer doing it? Okay.  
17 So I was going to say, what is the format?  
18 The format would be having someone introduce  
19 the measure in about three minutes. You're  
20 going to do all of them at the same time.  
21 Okay. All of them at the same time, since  
22 they're all yours, so that will give you a

1 little extra time.

2 And then we'd have the primary  
3 discussants give an overview for -- a very  
4 brief overview of your general impressions,  
5 and the secondary person then get into the  
6 components we have to vote on and talk about  
7 them specifically. Does that sound  
8 reasonable?

9 CO-CHAIR ROSENZWEIG: So you're  
10 saying NCQA is going to present all of the  
11 different measures together or --

12 DR. BURSTIN: The first four.

13 CO-CHAIR ROSENZWEIG: The first  
14 four. Okay. So that's 0059, 575, 57, and  
15 what's the fourth? 55. Okay. All right.

16 MEMBER KIRKMAN: So, I mean, just  
17 to comment, I realize that might be more  
18 convenient for NCQA, but I'm going to find  
19 that very confusing, if we are trying to talk  
20 about multiple measures or talk about the  
21 fourth measure two hours after hearing about  
22 it.

1 DR. BURSTIN: And maybe just sort  
2 of an overview of the suite of measures,  
3 because they are kind of all related, and then  
4 perhaps they could jump in before each of the  
5 individual measures if there is something you  
6 guys want to have specific. Is that okay?  
7 Okay.

8 CO-CHAIR GOLDEN: You know,  
9 actually, I would think -- I think 59 and 75  
10 are related; 57 and 55 are kind of separate.  
11 Maybe just do the first two. Oh, is that to  
12 start?

13 DR. BARTON: Why don't I just try  
14 doing hemoglobin Alc together. And if you  
15 want me to come back, I'll be happy to speak  
16 out before you consider the next thing.

17 First of all, I just wanted to  
18 thank you all very much for inviting NCQA to  
19 participate, not only in today's meeting, but  
20 in the thoughtful conversations that the  
21 working groups held, which really, you know,  
22 involved a lot of very insightful



1 conversations and enabled us to hone our  
2 thinking and our preparation for this meeting  
3 and for thinking about the measures going  
4 forward.

5 In terms of the, you know, NCQA's  
6 role, I think it probably is something most of  
7 you are familiar with. NCQA is not only a  
8 measure developer, but an implementer of  
9 measures, a user of measures, and we take very  
10 seriously the maintenance of the measures that  
11 we develop, which is not to say that we don't  
12 sometimes decide to not maintain something,  
13 but it's usually for very good reason and  
14 something that we think about hard before we  
15 drop it.

16 The other thing that I wanted to  
17 just mention is that the -- you know, because  
18 you did see the recommendations of the MAP to  
19 the value-based measures set to CMS. There's  
20 an appeal to saying, "We don't need any of  
21 these individual components. We can just use  
22 an all or none composite measure." And I

1 think that there is a good reason to think  
2 that high-performing systems and highly  
3 coordinated teams can do well with all-or-  
4 nothing composite measures.

5 I worry that the state of U.S.  
6 health care is not consistently 100 percent in  
7 such high-performing teams, and so I think  
8 that the fact that there are also the  
9 potential for unintended consequences with  
10 all-or-nothing composite measures is also  
11 true.

12 NCQA has a comprehensive set of  
13 diabetes measures. You are going to be  
14 hearing about them one by one, but we view  
15 them as a set that works together and that is  
16 -- you know, that have driven -- it has driven  
17 a lot of quality improvement.

18 CO-CHAIR GOLDEN: And just, again,  
19 for -- never mind.

20 DR. BARTON: So hemoglobin Alc, we  
21 have three measures. One, 0059, is poor  
22 control, the percent of patients who have a

1 hemoglobin A1c greater than nine percent.  
2 0575 is good control, the portion who have a  
3 hemoglobin A1c of less than eight percent.  
4 And then 0057, testing, measures aim to  
5 bracket good enough care.

6 I think, you know, the Goldilocks  
7 principle is not too high, not too low, and  
8 with -- I think it goes without saying that  
9 the testing measure is there because you need  
10 to -- if you're going to manage against  
11 something, you need to have that information.  
12 You can't manage against an A1c without having  
13 that information. So that's the reason for  
14 having the testing measure.

15 There is one thing I wanted to say  
16 about the physician level measures, because  
17 several of these have physician level  
18 counterparts. The reliability information  
19 that we have on the physician specification is  
20 from our recognition program, which is made up  
21 of practices that have volunteered, stepped  
22 forward, paid money to be recognized

1 practices.

2 As part of their scoring of this  
3 program, they have to achieve approximately 60  
4 to 70 percent performance on most of the  
5 measures. And as a result of that, the  
6 beta-binomial approach that we use for  
7 determining reliability in health plans which  
8 says this measure spreads people out well, it  
9 helps me to determine good from bad, does not  
10 provide us with the same kind of information  
11 from our physician practices.

12 That is not to say that if it was  
13 a -- if we had data from another source, if we  
14 had, you know, excellent data from PQRS maybe,  
15 or if there were other more diverse samples of  
16 clinicians, that the measure would perform  
17 that way, but it is just -- it's the only data  
18 that we have available to us.

19 And so I think that the -- in the  
20 future, I'm not even sure that we would  
21 present reliability data in the same way, and  
22 I think that's something that, you know, we're

1 really interested in working with NQF to think  
2 about going forward. But that's just one  
3 point that I wanted to make, and I thank you  
4 for letting me have the floor.

5 CO-CHAIR GOLDEN: So the first  
6 measure, 59, poor control. Ingrid was the  
7 reviewer. So do you want to make some  
8 comments, some initial comments about it?

9 MS. TIGHE: Yes. Ingrid, I'll  
10 just jump in. We'll ask you just to give your  
11 kind of overview of the measure, and then  
12 we'll ask you to discuss the 1A evidence piece  
13 of the committee discussion that you had in  
14 your workgroup, and then we'll stop there and  
15 open it up for discussion at that point.

16 MEMBER DUVA: Okay. So what do  
17 you want me to start with?

18 CO-CHAIR GOLDEN: I think we're  
19 going to start with just a general overview,  
20 what you thought about the measure, and then  
21 we go into the components, and we'll go into  
22 the evidence, and so forth.

1                   MEMBER DUVA: Okay. So the  
2                   measure -- I think you can see it here -- has  
3                   the title Comprehensive Diabetes Care:  
4                   Hemoglobin Alc Poor Control, so greater than  
5                   nine percent. Basically, the population is  
6                   for the 18- to 75-year-old patients with  
7                   diabetes, and that is Type 1 and Type 2.

8                   The measure is to screen the  
9                   patient for their Alc, and then the cut point  
10                  is nine percent as a definition of poor  
11                  control. So we reviewed the measure in our  
12                  committee workgroup, and you can scroll down  
13                  to our comments if you want to, in terms of  
14                  going through the areas, the importance that  
15                  I think -- this is just a quick summary, but  
16                  the workgroup felt like that the -- it rated  
17                  high in importance, that there was evidence to  
18                  support that the --

19                  I'm sorry, that the evidence did  
20                  not necessarily support the cut point of nine  
21                  percent, although evidence did support that  
22                  the higher glucose that the Alc represents was

1 associated with poor health outcome, so that  
2 it was important from that aspect.

3           There was a performance gap that  
4 was noted, and that was particularly related  
5 to the physician practices and the reliability  
6 issues that the developer just mentioned. But  
7 in terms of the health plans, the reliability  
8 was strong for the measure, not for the  
9 physician practices. There was a performance  
10 gap. I just mentioned that. And, let's see,  
11 what am I missing? I have missed one of the  
12 -- was it the usability --

13           CO-CHAIR GOLDEN: Just to clarify,  
14 when you say "performance gap," do you mean  
15 practice variation? Or do you mean missing  
16 the standards? There's a difference.

17           MEMBER DUVA: Oh, I'm sorry. I'm  
18 sorry. So there was two things going on, so  
19 we looked at the validity of the measure, and  
20 then we looked at the reliability of the  
21 measure. And with the reliability of the  
22 measure there was poor -- there was good

1 reliability within the health plans but not  
2 with the physician practices. And we can  
3 scroll down to look at the developers --

4 CO-CHAIR GOLDEN: We'll get to  
5 that later.

6 MEMBER DUVA: Okay.

7 MS. JOHNSON: Maybe let's stop  
8 there and do evidence first, and then we'll  
9 have you come back and go through, because  
10 we're going to vote on each of those  
11 separately.

12 MEMBER DUVA: Oh, okay.

13 CO-CHAIR GOLDEN: But, again, a  
14 quick summary, was the general feel of it  
15 positive? Mixed? I mean, just in terms of  
16 your overall approach to the measure.

17 MEMBER DUVA: Oh. The overall  
18 approach to the measure, I think there was --  
19 it was positive from the perspective that we  
20 know that patients whose diabetes is out of  
21 control will know. The evidence supports that  
22 patients whose diabetes is out of control have



1 poor long-term outcomes.

2 The concern was the cut point of  
3 the nine percent. We have had that discussion  
4 already this morning that that is not  
5 necessarily supported as strongly by the  
6 evidence. And that's it.

7 CO-CHAIR GOLDEN: So why don't we,  
8 then, go into the evidence discussion.

9 MEMBER DUVA: Yes.

10 MS. JOHNSON: And if I might just  
11 cut in here just for a second and draw your  
12 attention -- if you haven't already noticed,  
13 we have the evidence algorithms in front of  
14 you. So handy-dandy cheat sheets here for  
15 your algorithms.

16 And this is what we call an  
17 intermediate outcome measure, so we are  
18 expecting to see some kind of quantity,  
19 quality, and consistency in the body of  
20 evidence, either through guideline grading, or  
21 through summaries of those -- of the QQC. So  
22 we will help you go through the algorithm

1 today if you need to. That's how you will  
2 rate.

3 And I think we've done this  
4 exercise in the workgroup, so hopefully you're  
5 starting to get comfortable with that. But if  
6 you have questions about that, please let us  
7 know as we walk through this one especially.

8 MEMBER DUVA: So our overall  
9 rating of the evidence was moderate, and that  
10 was based on the fact that the evidence are  
11 supported primarily by guidelines. There were  
12 some systematic reviews that were presented by  
13 the developer, but they weren't exactly on  
14 point with this measure. So we didn't have  
15 the quantity and the quality and the  
16 consistency of evidence to consider.

17 However, the evidence that we did  
18 consider was supportive of the outcomes that  
19 I discussed previously, and we can go to that  
20 page where the developer presents the evidence  
21 and the gradings. You have that in your  
22 SharePoint if you want that up.

1 CO-CHAIR GOLDEN: And your concern  
2 about the evidence, I mean, when you say it's  
3 poor, I mean, the purpose of the measure --

4 MEMBER DUVA: I didn't say it was  
5 poor.

6 CO-CHAIR GOLDEN: Oh, I'm sorry.

7 MEMBER DUVA: No.

8 CO-CHAIR GOLDEN: Moderate.

9 MEMBER DUVA: Sorry. We rated it  
10 moderate, and that's based on our algorithm  
11 and the level of the evidence that was  
12 presented to support the measure. And the  
13 developer presents it in this paperwork, but  
14 it primarily comes from the guidelines, which  
15 is positive.

16 However, the systematic reviews  
17 were not exactly on point with the cut point  
18 of the nine percent, and the quality,  
19 quantity, and consistency of evidence was not  
20 presented. So, therefore, moderate was the  
21 highest rating --

22 CO-CHAIR GOLDEN: Okay.

1                   MEMBER DUVA:  -- that it can  
2 receive.

3                   CO-CHAIR GOLDEN:  Comments from  
4 the other committee members about that?

5                   (No response.)

6                   So let's -- I'm going to rely on  
7 --

8                   CO-CHAIR ROSENZWEIG:  I could make  
9 one comment, if I'm -- if Chair, I don't know  
10 if I -- but the original -- you know,  
11 originally when this particular measure set  
12 was created the cut point was 9.5 percent, but  
13 that turned out to represent too small a  
14 population within the overall population of  
15 patients as time went on to be able to effect  
16 an improvement with.  So it eventually was  
17 changed to nine percent.  And certainly there  
18 is a continuum of increased risk as you get to  
19 higher and higher Alc's.

20                   So with respect to -- is your  
21 concern with respect to the specific amount,  
22 the specific cut point of nine percent as

1       opposed to nine and a half or eight and a half  
2       percent? Obviously, the higher the A1c, the  
3       greater the risks to the patient. So the  
4       evidence certainly confirms that. Is it the  
5       issue that nine percent being defined as poor  
6       control is the problem?

7                   MEMBER DUVA: Well, we were  
8       talking specifically about the evidence, and  
9       so the evidence didn't directly address nine  
10      percent as the cut point.

11                   CO-CHAIR ROSENZWEIG: Okay. So  
12      the evidence demonstrates the poor outcomes  
13      for the patients, and that we felt was strong,  
14      but it wasn't specific to the nine percent.  
15      That was a little bit more arbitrary. Does  
16      that answer your questions?

17                   CO-CHAIR ROSENZWEIG: Yes.

18                   MEMBER DUVA: Okay.

19                   CO-CHAIR GOLDEN: So -- okay. So  
20      -- I'm sorry.

21                   MEMBER KIRKMAN: Just, you know,  
22      my comment about the evidence is that some of

1 this evidence that, you know, really high  
2 Alc's are associated with really poor outcomes  
3 is very old. I mean, it's sort of -- I guess  
4 this is a philosophical comment in some ways,  
5 but it is kind of like the evidence that, you  
6 know, the higher the people's blood pressure  
7 is the more likely they are to have a stroke.

8           And so there is not necessarily  
9 going to be, you know, an updated, systematic  
10 review of something that has kind of been  
11 known for a long time. It is a little bit  
12 different from the evidence for, you know, a  
13 specific intervention. But a lot of the sort  
14 of observational epidemiological evidence  
15 linking poor control to poor outcomes is from,  
16 you know, the DCCT, or the Wisconsin  
17 retinopathy studies. I mean, it is very old  
18 evidence. That doesn't mean it's bad  
19 evidence, but it's not necessarily going to  
20 show up in a systematic review that has been  
21 done, you know, more recently, or at all.

22           CO-CHAIR GOLDEN: But, conversely,

1 no one would say anything over nine is good  
2 control.

3 MEMBER KIRKMAN: Right. But, I  
4 mean, I think -- I mean, I think it ends up  
5 being okay, because it is still going to be  
6 moderate level. But I just think that, you  
7 know, for some of these things you are -- the  
8 evidence is so embedded into the distant past  
9 and into our knowledge of everything that has  
10 come since that it is not necessarily going to  
11 come out as high level on the algorithm. If  
12 that makes sense.

13 MS. TIGHE: Just a process point,  
14 we can only have three microphones on at one  
15 time. So if you're not speaking, please turn  
16 your microphone off.

17 MEMBER TAYLOR: Is this the point  
18 where we're going to talk about the evidence?  
19 So I think the blood pressure analogy is a  
20 really important one for us to consider,  
21 because in -- we're not going to spend much  
22 time on blood pressure, but there is that

1 continuous graded risk relationship.

2 And there is also very strong  
3 trial evidence that when you move down the  
4 blood pressure curve your risk goes down. It  
5 is much more difficult, although there is  
6 UKPDS 33, and there is DCCT, and there are a  
7 couple of other things that we can use to make  
8 that argument, it is harder to tease out that  
9 kind of risk relationship that when you lower  
10 the blood sugar you, you know, universally  
11 improve outcomes.

12 You know, with blood pressure you  
13 reduce stroke, you reduce MI, you reduce total  
14 mortality. It is much harder to show that  
15 with the -- you know, lowering blood sugar,  
16 lowering A1c improving outcomes, especially  
17 the cardiovascular outcomes and total  
18 mortality.

19 And we also have those scary  
20 findings from things like ACCORD where tighter  
21 control means mortality goes up. So we  
22 probably ought to acknowledge something, I



1 would think, about the evidence as we go  
2 through it and say that there is a lot of  
3 reason to believe that lower glucose is better  
4 than higher glucose. But it's not powerful  
5 slam-dunk that you might have, for instance,  
6 that -- in the blood pressure.

7           The other point, while I have the  
8 microphone, is I'm a little concerned about  
9 the two little letters N/A for non-applicable  
10 about the unintended consequences of doing  
11 this. You know, I don't know how we fold that  
12 into our purview. Sue was kind enough to send  
13 me a reference at the beginning, because I  
14 know evidence base is everything.

15           But, anecdotally, there is a lot  
16 of people who are, for instance, getting their  
17 Alc's aggressively managed who don't fall  
18 within the guideline, people over 75, people  
19 with multiple risks, and so on, who suffer  
20 consequences of hypoglycemia and get hurt by  
21 this. The big unintended consequence of any  
22 guideline is the time that is taken to address

1 this is not taken to address other things --  
2 the opportunity cost. And I'm not sure they  
3 are big or small, or how they fit in, but I  
4 would think it would at least take a moment of  
5 our time --

6 CO-CHAIR GOLDEN: Well, we'll get  
7 to that and usability and all sorts of other  
8 issues. So -- but, yes, we'll get there.

9 Jessie?

10 MEMBER SULLIVAN: I guess, Bill, I  
11 have just a question for you, because I think  
12 we are discussing the greater than nine, and  
13 it seems to me that the thing you said about  
14 the risks of hypoglycemia in some populations  
15 is an argument in favor of keeping this  
16 measure, which is looking at poor control  
17 greater than nine. You know, that the good  
18 control measures run more risk of unintended  
19 consequences, unless I'm misunderstanding what  
20 you're saying.

21 CO-CHAIR GOLDEN: Tracy?

22 MEMBER BREEN: Thank you. Just to

1 clarify some of the data pieces. In the DCCT  
2 trials, there was clear cardiovascular benefit  
3 on that slope of lowering blood sugar. So to  
4 be clear, on Type 1's, there is associated  
5 cardiovascular risk reduction with blood sugar  
6 lowering. And we do talk about risk  
7 reduction, and like the UKPDS trial on that  
8 slope there is strong microvascular data to  
9 support.

10 So I just -- for those of us who  
11 don't think about this all the time, I think  
12 it's just important to say that there has been  
13 clear data to say that on that slope there is  
14 risk reduction. I think that the issue has  
15 become how low do you go. But for this  
16 measure, we are talking way in the high end;  
17 we're talking an A1c of nine.

18 We can argue all day whether  
19 that's 8.5 or nine or 9.5. I think the  
20 challenge is when you look at the data, there  
21 is no data to support that particular  
22 arbitrary cutoff. But if we accept that is an

1 arbitrary cutoff, and how does the data around  
2 that arbitrary cutoff support it, it seems  
3 clear that there is clear risk that has been  
4 documented at greater than that number.

5 So it seems to me that that's a --  
6 you know, for lack of a better number, that's  
7 a reasonable arbitrary cutoff to hang.

8 CO-CHAIR ROSENZWEIG: Yes. I  
9 would just echo that and say that the evidence  
10 related to poor control and the microvascular  
11 complications is indisputable, I mean, through  
12 many, many different studies. And it is only  
13 more recently that the connection between  
14 cardiovascular disease has been shown in  
15 long-standing patients.

16 But the issue of nine as opposed  
17 to, let's say, eight or various others, it's  
18 my understanding -- and people from NCQA could  
19 address this -- but the HEDIS, you know, you  
20 list HEDIS measures on a yearly basis, and  
21 they have steadily come down somewhat. But  
22 nine sort of tracks eight, and, I mean, the

1 same groups that have improvement in nine also  
2 have the same improvements in eight. I mean,  
3 there is not really a distinguishing factor  
4 between -- in any of these cutoffs, is there?  
5 Or could you just address that?

6 DR. BARTON: It's true that the --  
7 there is a high correlation that -- between  
8 the less than eight and the greater than nine  
9 measure. And so what that leads us to think  
10 about is, you know, practices that are doing  
11 -- you know, paying close attention to  
12 hemoglobin A1c are hitting the mark of, you  
13 know, that sort of not too hot/not too cold,  
14 sort of Goldilocks picture that I was  
15 referring to before.

16 In terms of the -- I don't know  
17 that I could say -- they don't correlate  
18 perfectly, and I can't imagine that I know  
19 enough about the way that they are used in  
20 different places to say, for example, one  
21 might argue, if these were highly correlated  
22 you only need one of them. You don't need

1 both.

2 And I think that actually  
3 depending on the practice and the issues  
4 related to that patient population, and the  
5 issues related to that team, and the resources  
6 available to them, there may be some practices  
7 that are driven by one and others that are  
8 driven by the other. It's an open question,  
9 and I can't pretend to be an expert on that.

10 CO-CHAIR GOLDEN: Thank you. For  
11 those of you who haven't looked at the DCCT  
12 trial in the last 15 years, you remember the  
13 complication rate was not linear. It was  
14 hyperbolic. So as you get down below nine and  
15 eight, it begins to level out. So, but that  
16 would be -- so that's a part of the issue  
17 also.

18 Maybe we are ready to -- oh, I see  
19 one more down there.

20 MEMBER DUDL: Just as I would echo  
21 the need to keep both, I am the diabetes lead  
22 for Kaiser National, and I can tell you when

1 we try to deal with the over nines, we are  
2 dealing with much more of a behavioral issue.  
3 It is no longer, you know, technical getting  
4 information back and forth. Over eight is  
5 much different. So I do think they are  
6 different populations. I do think both  
7 measures are valid and valuable.

8 MEMBER MILLER: Also, remember in  
9 this denominator is included people who have  
10 not had an Alc measured at all. So that is  
11 really a big component of this, too. It is  
12 not just people who are poorly controlled. It  
13 is people whose control we are not even  
14 measuring. So just to keep that in mind as we  
15 discuss.

16 CO-CHAIR GOLDEN: We might be  
17 ready to vote on evidence. So is it a scale?  
18 Is it a yes/no? Tell me what --

19 MS. TIGHE: It's a high, moderate,  
20 low.

21 CO-CHAIR GOLDEN: High, moderate,  
22 and low.

1 MS. TIGHE: And insufficient.

2 MS. JOHNSON: And insufficient.

3 So in this particular one, there is an option  
4 number 4, insufficient evidence with  
5 exception. That is not -- that would not be  
6 an option for you today, because we are not  
7 talking about exceptions. So your choices are  
8 1, high; 2, moderate; 3, low; or 5,  
9 insufficient.

10 CO-CHAIR GOLDEN: So what are the  
11 implications of voting for 1, 2, or 3?

12 MS. JOHNSON: If you vote for 1 or  
13 2, we will continue discussing the measure.  
14 If the -- and it used to be straight majority.  
15 It is not quite straight majority, but  
16 basically threes and fives mean we stop  
17 discussion of the measure. We don't go  
18 forward; it just dies.

19 CO-CHAIR GOLDEN: So a 1 or a 2 is  
20 acceptable, and anything else is not. Okay.

21 DR. PACE: Right. And in this  
22 case, the question 1 is -- I think someone



1 mentioned that there wasn't the quantity,  
2 quality, and consistency of the systematic  
3 review presented, and so according to the  
4 algorithm then that is eligible for a moderate  
5 rating.

6 CO-CHAIR ROSENZWEIG: I assume we  
7 are voting separately on each measure. In  
8 other words -- okay.

9 CO-CHAIR GOLDEN: Okay. Are we  
10 ready to vote on the Alc greater than nine,  
11 poor control, for evidence?

12 MS. BAL: Yes. Just give me one  
13 second. I just want to -- okay. So please  
14 don't put your number in until I have clicked  
15 the timer. And don't -- feel free to click as  
16 many times as you feel you --

17 CO-CHAIR GOLDEN: Well, I just  
18 want to make sure that people are ready to  
19 vote. So you get yourself ready. Anybody  
20 else? Any final comments?

21 (No audible response.)

22 Okay. All right.

1                   MEMBER TAYLOR:  And you'll review  
2 exactly what the question is that we are  
3 rating this way.

4                   CO-CHAIR GOLDEN:  It's the  
5 evidence of the measure.  Is it high,  
6 moderate, low, or insufficient, to justify  
7 this measure to being -- for continued  
8 discussion and for inclusion.  Correct?

9                   MS. JOHNSON:  And can everybody  
10 see the voting slides?  What you're voting on  
11 is available there, and I'm a little bit  
12 nervous that the folks on this side of the  
13 room may not be able to see the screen over  
14 here.  Can you guys see that well enough to --

15                   CO-CHAIR ROSENZWEIG:  We're also  
16 voting for evidence for use of the measure.  
17 It's not specifically, necessarily evidence  
18 for saying whether nine percent is poor  
19 control.  Isn't that the case?  Can we clarify  
20 that?

21                   CO-CHAIR GOLDEN:  I think  
22 usability is later.  So I think this is just

1 -- is evidence over nine, poor control.  
2 Period.

3 DR. PACE: Yes. This is evidence  
4 about what is being measured in the measure.  
5 So it's about the numerator, evidence of poor  
6 -- the greater than nine percent.

7 MS. BAL: All right. You can go  
8 ahead and put your vote in now. Make sure you  
9 aim at me, not the screen.

10 CO-CHAIR GOLDEN: So look for a  
11 green light?

12 MS. BAL: Yes. And we have 20, I  
13 think.

14 CO-CHAIR GOLDEN: Okay. So that's  
15 20 people. Okay. So 80 percent said 2, so we  
16 continue. What's next? What section is next?

17 MS. BAL: Performance gap.

18 CO-CHAIR GOLDEN: Performance gap.

19 So this is a section to say, is  
20 there either practice variation or deviation,  
21 or is everybody -- I guess the question here  
22 is, does everybody -- does every diabetic meet

1 this goal, so therefore, this is irrelevant?  
2 Or are there people that still need to be  
3 looked after?

4 So any comments from the reviewer?

5 MEMBER DUVA: Sorry. I was trying  
6 to pull up the exact graphs that the developer  
7 included. But in our workgroup committee, we  
8 found that there was a performance gap between  
9 plans that was high. So we still feel it was  
10 relevant.

11 CO-CHAIR GOLDEN: Well, the  
12 committee believes there's lot of people who  
13 have hemoglobin Alc's over nine and need  
14 attention. Any discussion? Pat? Patricia?

15 MEMBER McDERMOTT: Has there been  
16 testing or anyone ever looking at -- I'm  
17 thinking from the health plan perspective, and  
18 I can also say looking at it when we go to  
19 measure providers. This is requiring not only  
20 that a test was done, but that you have the  
21 result and you can review the result, and in  
22 health plans -- a health plan does not have,

1 we all work to try to get all the results for  
2 our members. But we don't get them all,  
3 because we haven't been able to harvest them  
4 all from all of the people that do lab  
5 testing. So we are --

6 CO-CHAIR GOLDEN: I think your  
7 comments are for usability. So let's hold on  
8 that, perhaps.

9 MEMBER McDERMOTT: Well, it's a  
10 bias that might be contributing to this  
11 variability, because you're getting more  
12 people where you just don't have the test.  
13 And, therefore, it looks like they are bad  
14 performers when, in fact, it has nothing to do  
15 with --

16 CO-CHAIR GOLDEN: Again, this  
17 measure may not be just for health plans; it  
18 could be for practices and for physicians and  
19 --

20 MEMBER McDERMOTT: Right. I'm  
21 speaking for --

22 CO-CHAIR GOLDEN: -- for

1 populations.

2 MEMBER McDERMOTT: I'm rooting for  
3 the provider as well. When you are trying to  
4 use administrative data to figure out whether  
5 -- how well a provider is performing, managing  
6 his diabetic patients. Without the benefit of  
7 electronic medical record or doing chart  
8 review, we have to use administrative data to  
9 know that a provider has done the right thing  
10 for his member. And there is a huge challenge  
11 in sometimes gathering all that information.

12 CO-CHAIR GOLDEN: I believe that  
13 will be under feasibility.

14 MEMBER McDERMOTT: Okay. That's  
15 great.

16 CO-CHAIR GOLDEN: So that will be  
17 under feasibility. So right now, the question  
18 is -- on the table is, are there -- I think  
19 the question on the table is, if every  
20 diabetic or most diabetics are under nine,  
21 then the measure is irrelevant because there  
22 is no performance gap.

1 DR. PACE: And, actually, it's  
2 related also to this actual performance  
3 measure. So part of the performance gap is  
4 how this performance measure identifying -- so  
5 the question is, are all health plans doing  
6 well on this performance measure?

7 CO-CHAIR GOLDEN: It's not just  
8 health plans. It's all providers.

9 DR. PACE: Right.

10 MEMBER KIRKMAN: So most of the  
11 data are for health plans, because most of it  
12 is HEDIS data, other than the DPRP data, or  
13 whatever. But, I mean, to me -- I mean,  
14 again, I'm thinking simplistically, but there  
15 is a gap identified because, for example, in  
16 the Medicaid health plans, you know, the  
17 proportion meeting this measure is much lower.

18 And so, you know, again, I don't  
19 -- I don't think of this so much as a  
20 physician measure, but it's more of a  
21 population measure or health system measure.  
22 I think somebody said, you know, these are

1 sort of unique patients that are -- you know,  
2 that are difficult and have lots of struggles,  
3 and so forth.

4 So, you know, I think there is a  
5 gap, but I don't know that it's just people  
6 delivering bad care as opposed to the system  
7 is not --

8 CO-CHAIR GOLDEN: But just to be  
9 clear, okay --

10 MEMBER KIRKMAN: -- doing well.

11 CO-CHAIR GOLDEN: -- this is not  
12 specified just for health plans. So, for  
13 example --

14 MEMBER KIRKMAN: I thought it said  
15 at the top that it was for health plans.

16 CO-CHAIR GOLDEN: Well, I mean,  
17 right now this measure is being used by FQHCs  
18 to assess the performance in managing a  
19 population. So I -- it can be used broadly.

20 MEMBER KIRKMAN: It says level of  
21 analysis, health plan, integrated delivery  
22 system --



1                   MS. TIGHE: Yes, I'll jump in. I  
2 apologize. We were supposed to update this,  
3 but I guess we forgot to. If you look at the  
4 next -- the measure information form, which is  
5 actually what the developer submitted, it  
6 contains the correct information, that this is  
7 a clinician-level measure and also a health  
8 plan-level measure.

9                   MEMBER KIRKMAN: Okay. But  
10 anyway, there are big differences between  
11 different systems of care. So to me, that is  
12 a gap.

13                   MEMBER BAILEY: I'd just like to  
14 raise an important issue to address a point  
15 made by Patricia earlier. So if there's a  
16 claim available for hemoglobin A1c testing,  
17 and the value's not available, that doesn't  
18 necessarily appear in the denominator,  
19 correct? So it's only if a hemoglobin A1c  
20 level has been checked and the value is not  
21 within the target range or there's no claim,  
22 that's when it's included in the

1 specifications. So there wouldn't necessarily  
2 be a penalty there.

3 CO-CHAIR GOLDEN: I believe the  
4 denominator is anybody with a value, and the  
5 numerator would be those that had --

6 MEMBER BAILEY: Or no evidence of  
7 a hemoglobin A1c.

8 MEMBER SULLIVAN: Not for this  
9 measure. This measure is anyone with  
10 diabetes. And if they don't have a value, they  
11 fail. And if the value is greater than nine,  
12 they fail.

13 CO-CHAIR GOLDEN: That gets into  
14 specification issues. So --

15 MEMBER SULLIVAN: It does mean  
16 something for understanding what's being  
17 measured.

18 CO-CHAIR GOLDEN: Right.

19 MEMBER McDERMOTT: It can directly  
20 relate to the rate. That's what I'm getting  
21 at. So if you say you have variability in the  
22 rate, the question is, is it the member's care

1 and the member's stability? Or is it that you  
2 just don't have the data because you can't see  
3 it?

4 MEMBER BREEN: I have a question.  
5 If we're trying to define what the gap is,  
6 right, is it a gap amongst patients with  
7 diabetes, or is the gap amongst members, or is  
8 the gap amongst health systems? I think  
9 either way we define it, we're going to find  
10 that there is a gap, right? So I think if we  
11 take -- is there a gap between zip code A and  
12 B? Yes, there's a gap. Is there a gap  
13 between plan A and B? Yes, there's a gap.

14 So I think just to simply it, it  
15 seems that there is clearly a gap no matter  
16 which way we define it. I don't know if  
17 anyone wants to comment on that.

18 CO-CHAIR ROSENZWEIG: Yes. You've  
19 got the HEDIS data right there in front of  
20 you, and there certainly is a gap if you can  
21 see the numbers.

22 MEMBER MILLER: I was going to

1 comment that the gap is very wide going from  
2 the diabetes recognition programs of about 12  
3 percent to some of the others that are about  
4 76 percent when we are talking about, say, the  
5 50th percentile. So we've got a tremendous  
6 gap, you know, and obviously the diabetes  
7 recognition programs are going to skew our  
8 numbers completely.

9 But I think if we are talking  
10 about a performance gap, I think there is a  
11 tremendous gap that exists. I also think that  
12 regarding administrative data, throughout  
13 every measure there is going to be a bit of a  
14 problem with administrative data because  
15 administrative data is never current. It  
16 always lags behind the performance of  
17 something, so that the administrative data  
18 we're given may not represent all of the  
19 things that were performed because not all of  
20 the bills have been submitted and paid yet, if  
21 that makes any sense.

22 CO-CHAIR GOLDEN: So, again, to --

1 I'm going to say that you're going to have to  
2 help me. I'm going to just keep trying to  
3 refocus us. So the discussion on the table is  
4 -- we have a measure with some evidence. Is  
5 there a performance gap, just in general with  
6 patients or with performance of the system?

7 After we do this vote and this  
8 discussion, we go into Criteria 2, which gets  
9 into scientific acceptability of the measure  
10 and its properties. So the discussion that  
11 came up about the numerator and the  
12 denominator is appropriate there. So there  
13 may be issues on how it is measured, but right  
14 now the issue on the table is, is there, in  
15 general, a performance gap in diabetes care  
16 with poor control or good control?

17 So the issues that were brought up  
18 by Patricia about -- you know, about -- the  
19 issues of how the measure is constructed will  
20 come up shortly, but not right now. Does that  
21 make sense? Maybe?

22 Okay. Are we ready to take a vote

1 about performance gap?

2 (No audible response.)

3 Seeing no cards, seeing no  
4 coughing --

5 DR. PACE: And I just want to make  
6 one other comment, that this is also where if  
7 there is evidence about disparities by  
8 population subgroups that that would be also  
9 considered as part of performance gap. So  
10 just for future reference.

11 MS. JOHNSON: And another  
12 reminder, you will be using the generic scale.  
13 So you have -- at the back of algorithm 3,  
14 this is your generic scale, which reminds you  
15 of how to think about this rating scale.

16 CO-CHAIR GOLDEN: So, once again,  
17 a vote for 1 or 2 continues the -- is  
18 acceptable; 3 or 4 is unacceptable. So give  
19 us a shout when you're ready for us to vote.

20 MS. BAL: All right. Please go  
21 ahead and vote.

22 CO-CHAIR GOLDEN: Okay. So, if

1 people are happy --

2 MS. TIGHE: Sorry. I'm just going  
3 to jump in so we have it in our transcript.  
4 So we have 17 votes for high and three votes  
5 for moderate.

6 CO-CHAIR GOLDEN: So the next item  
7 is going to be priority. Is that correct?  
8 Okay. So the next issue is 1(c), high  
9 priority or high impact, does this address a  
10 significant health problem? Prevalence, cost  
11 issues, et cetera, et cetera.

12 MEMBER DUVA: When we discussed  
13 this, we -- the workgroup decided that, yes,  
14 this was a high impact problem with a high  
15 cost associated for the microvascular and  
16 macrovascular outcomes that have been shown to  
17 be associated with the poor glucose control  
18 that leads to the HbA1c greater than nine.  
19 Does anybody else --

20 CO-CHAIR GOLDEN: Does anybody  
21 want to --

22 MEMBER DUVA: -- on the committee

1 need to comment on that?

2 CO-CHAIR GOLDEN: Does anybody  
3 want to question or disagree with the  
4 committee discussion?

5 (No response.)

6 Perhaps we're ready to vote on  
7 this item. So why don't you get that set up.

8 MS. BAL: All right. Go ahead and vote,  
9 please. And make sure you point at me.

10 We're still missing two people, so  
11 if everybody could just try to vote one more  
12 time to make sure we got everybody that would  
13 be great. Thank you.

14 So we had 100 percent, all high,  
15 20 people.

16 CO-CHAIR GOLDEN: So now we're  
17 moving on. And just since -- I know I've got  
18 my cheat sheet. So just so you know what's  
19 coming up next, give you some sense for this  
20 focused discussion, the next item will be  
21 about reliability of the specifications. The  
22 next one will be validity of the



1 specifications. Then we'll discuss  
2 feasibility, then use and usability, and then  
3 overall recommendations. So that's the  
4 sequence we are going to be following going  
5 forward. Okay?

6 So now we get to reliability of  
7 the specifications and reliability testing,  
8 which means when we say about reliability, is  
9 it consistently collected, correct?

10 MEMBER DUVA: Okay. So here's  
11 where we run into some interpretation and  
12 probably opportunity for discussion. But in  
13 terms of the reliability -- and we commented  
14 on this -- the developer mentioned that they  
15 may not report it the same way. But in terms  
16 of the data that we got, the reliability was  
17 strong amongst the health plans, and it was  
18 not strong amongst the providers, but that  
19 data came from a -- can you say the name of  
20 that program again? Diabetes Recognition  
21 Program.

22 So I don't know if you want to

1 discuss at this time the numerator and  
2 denominator and spell out exactly --

3 CO-CHAIR GOLDEN: Why don't you at  
4 least describe the numerator and the  
5 denominator, so everyone knows what fails and  
6 what passes, and so forth.

7 MEMBER DUVA: Okay. So the  
8 numerator statement are patients whose most  
9 recent Alc level is greater than nine percent  
10 or is missing a result or for whom the Alc  
11 test was not done during the measurement year.

12 The outcome is the result of the  
13 Alc test indicating the poor control of  
14 diabetes, so the denominator statement would  
15 be those patients 18 to 75 years of age by the  
16 end of the measurement year who had a  
17 diagnosis of diabetes, Type 1 or Type 2,  
18 during that measurement year or the year prior  
19 to the measurement year.

20 So we had some discussion about  
21 that on the workgroup call, but I don't know  
22 if the developer wants to comment on the

1 numerator and the denominator in terms of the  
2 time period. That was one of the questions  
3 that we had on our call.

4 So they're 18 to 75 years by the  
5 end of the measurement year or prior to the  
6 year. Does that leave an opportunity to miss  
7 patients who are turning 18 legitimately? No?  
8 Okay.

9 DR. BARTON: They just have to  
10 have reached their 18th birthday by the end of  
11 the period being measured. So I think that  
12 that would not lead anybody to be missed on  
13 that end, but --

14 MEMBER DUVA: I mean, for the  
15 reporting of it, would you potentially miss  
16 those patients if they weren't 18 yet when you  
17 saw them, but by the end of the reporting year  
18 they were 18? Because they may have had the  
19 diabetes diagnosis that year or the year  
20 prior, is that --

21 DR. BARTON: It would not -- the  
22 date of the visit would not be the determining

1 factor. So it's your -- you've reached 18 by  
2 the end of the measurement period, and then  
3 they look back to see whether you had any  
4 qualifying diagnoses or medications in the  
5 relevant years.

6 CO-CHAIR GOLDEN: So it would  
7 strike me that if you have a panel of patients  
8 or an enrollment, you can identify diabetics.  
9 If you are in a fee-for-service environment,  
10 you don't know for sure the patient is still  
11 in your practice or not, I would assume, so  
12 the denominator would be difficult. Is that  
13 a fair statement? Is that discussed by your  
14 committee?

15 MEMBER DUVA: I mean, I feel like  
16 we didn't come to a conclusion about that in  
17 our committee. I mean, in general, it seems  
18 like a fair assessment. Maybe somebody else  
19 on the committee wants to discuss, but I can't  
20 speak for the committee to say that we felt  
21 like that was exactly spot-on.

22 CO-CHAIR GOLDEN: So a question

1 for the NQF staff in some ways. I mean, the  
2 denominator statement -- I guess it gets into  
3 feasibility and everything else, but the  
4 universality of its utility diminishes by how  
5 the denominator is defined. Is that -- how do  
6 we deal with that issue in terms of the  
7 endorsement process? And I'll get --

8 MEMBER LEDDY: I want to make a  
9 comment about that age range.

10 CO-CHAIR GOLDEN: We'll get to  
11 that in a second. Okay. Let me hold that for  
12 a second. I want to get through --

13 DR. PACE: So could you say a  
14 little bit more about the question about the  
15 denominator that you have? Because it's too  
16 broad, is that what you're saying?

17 CO-CHAIR GOLDEN: No, it's  
18 actually too narrow.

19 DR. PACE: Okay.

20 CO-CHAIR GOLDEN: What it's  
21 basically saying is you know who the diabetics  
22 are in your practice. And if they don't show

1 up, that counts against you in the numerator.  
2 And if you're in a fee-for-service  
3 environment, you don't know if someone has  
4 moved away, you don't know if they are part of  
5 your practice. You know, if you have a panel  
6 and you are assigned a panel, okay, you have  
7 a universe.

8 DR. PACE: So a couple of things  
9 to distinguish here. Under reliability, we  
10 are talking about, are the specifications such  
11 that people could implement them consistently?  
12 And then we're also looking at reliability  
13 testing results. The question you're asking,  
14 about is that going to be a valid indicator of  
15 quality that we want to get at under validity?

16 CO-CHAIR GOLDEN: Well, the other  
17 issue is, I could say that in terms of  
18 reliable -- or using -- being able to apply  
19 it, some people could and some people  
20 couldn't. That's the problem.

21 MEMBER DUVA: That's why -- I'm  
22 sorry; I didn't mean to talk so loud. That's

1       why I brought it up right now is I just -- I  
2       needed -- I didn't feel like I could represent  
3       our workgroup to say that we had definitely  
4       said that, yes, this was something you could  
5       reliably institute because of the denominator.  
6       And so I just needed that spoken to or the  
7       rest of the group to address it.

8                       CO-CHAIR GOLDEN:   And the  
9       technical -- so if the question is, if some  
10      people could and some people couldn't, what  
11      does that mean?

12                      DR. PACE:   So that may be more a  
13      feasibility issue in general or the usability  
14      issue.   So, again, if you have these  
15      specifications, could you implement it  
16      consistently?   But I think your question is,  
17      is it that every health plan couldn't do it?  
18      Or is it if it's used outside of a health plan  
19      situation?   That's your main concern.   And I  
20      don't know if the developer wants to respond  
21      to that question.

22                      DR. BARTON:   I think that the

1 development of performance measures for known  
2 denominators is years ahead of the development  
3 of performance measures for fee-for-service  
4 where you don't have a known denominator. And  
5 I would, from a parochial point of view, say  
6 that the measures that have been developed and  
7 used now over a decade in health plans are  
8 much higher bar measures and more consistent  
9 with what NQF has been espousing and  
10 encouraging us to do than really most of what  
11 you'll find in the PQRS system, because of the  
12 fact that that's -- whoever comes in your door  
13 that day, it's really not designed to enable  
14 clinicians to do planned care or managing the  
15 care.

16 But I don't think that that is  
17 actually a fault of the measure that we use in  
18 health plans necessarily.

19 CO-CHAIR GOLDEN: I don't want to  
20 -- my debate would be if you're in a practice  
21 and you have a universe of tests that you've  
22 done, you can determine of the people you've



1 tested how they've done, and you can't avoid  
2 that you've done the test, because you have  
3 already been judged on whether or not you did  
4 the test.

5 So this measures misses a universe  
6 of practice opportunities to do measurement.  
7 That's my concern.

8 MR. REHM: If I can just add  
9 something. Measures don't live in a vacuum.  
10 These measures are used in a variety of  
11 programs. You know, the ACL program, they're  
12 used in PQRS. Each program -- AF4Q --  
13 everyone has their own rules of the road,  
14 their own guidelines driving this. They have  
15 their attribution requirements.

16 And I think if a clinician was  
17 just individually interested in their  
18 population, they would probably look for  
19 people with diabetes, either using the  
20 specification here or some hybrid, and go and  
21 see if those things were done. I don't think  
22 it's -- I think attribution is a fascinating

1 world, and there is a lot of competition about  
2 whose attribution rules are better and what is  
3 getting at the true thing. But I think from  
4 a spiritual level if you will, these things  
5 are doable, but there are different rules of  
6 the road. Unfortunately, you do have to --

7 CO-CHAIR GOLDEN: I would  
8 disagree. If you're saying attribution can  
9 shift around your denominator, that's a real  
10 problem. That is a significant problem that  
11 you just can't -- I mean, if the measure is  
12 insufficiently specified, that attribution  
13 could be all over the place and it's  
14 independent. That's a problem.

15 DR. BARTON: I do not think that  
16 we were saying that the specification is all  
17 over the place. When -- and guidelines may be  
18 too inside baseball a term for us to be able  
19 to explain, but I would say that the  
20 implementation of HEDIS measures in health  
21 plans relies on a set of guidelines that are  
22 things that don't even show up in these

1 specifications. You know, how much of the  
2 year does a patient have to have been enrolled  
3 in your health plan for you to consider them  
4 your patient? Those are the kind of things  
5 that are considered guidelines.

6 To me, that does not connote an  
7 "all over the place." I think that a program  
8 that uses measures has to have guidelines, and  
9 it's the responsibility of the program to  
10 create guidelines that work for that program.  
11 I would suggest that in your practice you  
12 would not just look for the universe of people  
13 who had tests.

14 If you wanted to hold yourself to  
15 a high bar, you would look for the universe of  
16 people who had filled hypoglycemic scripts  
17 that you wrote and look at all of those people  
18 for who had achieved the outcomes or the  
19 process measures that you set out for  
20 yourself. You would want to take the best  
21 indication that you could of, who are all of  
22 your diabetics? You probably would have set

1 up a registry a few years ago.

2 MEMBER SULLIVAN: I just wanted to  
3 speak to an experience with that. So the  
4 Westchester New York Diabetes Coalition did a  
5 project about six years ago where we took the  
6 HEDIS measure and applied it to practices, and  
7 these were not practices that tried to achieve  
8 recognition for best practices. These were  
9 community health centers, rural practices,  
10 Medicaid practices for the most part.

11 And the biggest change that we saw  
12 was in people who had not been tested and then  
13 became tested. That was the greatest  
14 improvement that we saw was people who had  
15 been lost to care got found.

16 CO-CHAIR ROSENZWEIG: In line with  
17 this question, I just wanted to ask the  
18 measure developers, I mean, the diagnosis of  
19 diabetes, which is usually listed as a  
20 secondary diagnosis, it's usually not the  
21 first one on the list, it tends to stick to  
22 someone. Once you're diagnosed with diabetes,

1       you know, you don't lose your diabetes.

2                       So do you have evidence that going  
3       back two years, which is the way you specify  
4       at least with respect to the identification of  
5       diabetes, that going back two years captures  
6       the full amount of patients with diabetes, do  
7       you have any evidence related to that?

8                       MR. REHM: Yes. You know, in the  
9       -- on our submission it's Section SA -- these  
10       are esoteric little headings, but it talks  
11       about it's the patient with at least two  
12       outpatient visits, observation visits, or  
13       non-acute inpatient encounters on different  
14       dates of service with a diagnosis and/or  
15       patients with at least one acute inpatient  
16       encounter with a diagnosis or patients with  
17       one ED visit with a patient diagnosis; or, on  
18       the pharmacy side, patients who are dispensed  
19       insulin or hypoglycemic agents during the  
20       measurement year or the year prior.

21                       So we feel that that adequately  
22       captures, you know, the population of

1 interest. It's multiple things.

2 MEMBER DUVA: So I raised that  
3 during the reliability discussion because I  
4 just wanted the group to discuss that that can  
5 affect the ability to implement this  
6 consistently, which is what reliability is.  
7 But I also know that in the one place it says  
8 that the level of analysis is for health plan  
9 and provider, and then when it also includes  
10 private practice. But I think we are taking  
11 the private practice group out of this. It is  
12 intended for the health plan and the provider.  
13 Or is that just how you tested it for your  
14 reliability? Which came up very strong for  
15 health plan and we have already discussed  
16 that.

17 Not as strong for the physicians,  
18 but that had some reporting -- a lot of noise  
19 I guess is how it was defined.

20 MR. REHM: If I can respond. If  
21 you believe that the health plan -- and I  
22 welcome Aetna's -- or Hudson Health Plan's

1 perspective -- if you think of the health plan  
2 as really a distillation of provider practice  
3 out in the community, then you would say that  
4 there is a direct connection between those.

5           The fact that either the PQRS  
6 program, the way it's designed, is capturing  
7 its own kind of self-selected group, and that  
8 the Diabetes Recognition Program that we  
9 happen to implement captures its own  
10 self-selected group notwithstanding, that is  
11 the data we have available. Unfortunately,  
12 it's not one that shows a large range of where  
13 we can compare and contrast and we can say  
14 that's better and that's best. So it's all we  
15 have.

16           I think if we had nothing on the  
17 physician level, I think there are certain --  
18 pardon the use of terms around reliability,  
19 but there's a certain face validity about that  
20 the data would extend, that measuring those  
21 patients at the provider level would be  
22 essentially a smaller version of what you are

1 reporting at the health plan level.

2 So in some ways maybe we do  
3 ourselves a disservice by having a program  
4 that reaches 3,600 physicians around the  
5 country who like to hang their hat and say,  
6 "We do a good job around diabetes care." In  
7 the same way, PQRS may be doing a disservice  
8 because there is about 30,000 or 40,000 people  
9 reporting on the diabetes measures in that  
10 program, and, again, self-selected because  
11 they have to pick some measures to report, and  
12 they picked those.

13 So, in many ways, I'd like to  
14 think of them as people trying to do a really  
15 good job and doing it well. The fact that  
16 there is not a lot of variability in their  
17 performance notwithstanding I don't think  
18 should spiritually undermine the measure, but  
19 I can appreciate from a raw testing  
20 perspective you'd like to see something  
21 better. But maybe wider use of these measures  
22 at the physician level where we see that data



1 could be instructive.

2 CO-CHAIR GOLDEN: Other comments  
3 on this issue?

4 MEMBER MAKAROFF: Just going back  
5 to this idea of how you define the  
6 denominator, so I'll just -- in the Health  
7 Center Program, our experience is that we ask  
8 health centers to be responsible for their  
9 patients, and a patient is defined as a  
10 patient who has one visit. So a patient may  
11 come to the health center for an acute visit  
12 and never come back, and that becomes part of  
13 the population.

14 And so I think that's an issue not  
15 just for this measure but probably a lot of  
16 measures of how we define our population, and  
17 we -- you know, is that fair? You know, as a  
18 physician, no, I don't think so actually.  
19 But, you know, it's sort of like what we have  
20 and how we look at the population and how  
21 we're managing the population and really  
22 encouraging registries and population health

1 management. So just a comment to add to the  
2 discussion.

3 CO-CHAIR GOLDEN: Other comments  
4 on this issue? Denominator? Yes. Okay.

5 MEMBER McDERMOTT: From a health  
6 plan perspective, the continuous enrollment is  
7 helping to control what a health plan is  
8 responsible for measuring when you look at  
9 your diabetic population. So that is kind of  
10 creating a bar for the HEDIS measures.

11 The issue of having to have a test  
12 is still an issue for health plans, because  
13 when we don't have a test we have to go do  
14 chart abstraction to find it in the records.  
15 So then we are dealing with samples, whereas  
16 if we had -- we were able to limit the  
17 denominator to those people where we have  
18 testing, and then say, "What's the effect?" we  
19 would not have to do administrative data  
20 polls.

21 From the provider perspective,  
22 when you look at the guidance from NCQA, with

1 the original guidance when they first  
2 published their physician-specific measures,  
3 they talk about the concept of attribution  
4 there and fairness and how to do attribution.  
5 And there are certain measures that have been  
6 developed, for example, by the AMA that say  
7 you can look at this member to see if they  
8 have CHF, and if they have this drug, based on  
9 two visits within the year. And they specify  
10 physician attribution.

11 The HEDIS measures do not, but we  
12 take -- we have done research on the concept  
13 of one visit. And if a member has something  
14 based on that one visit, we give the doctor  
15 credit, else we look for a second visit, and  
16 often within a longer period of time, to make  
17 sure that they have seen the patient more than  
18 once and it's not just a single visit for a  
19 sore throat before we assign attribution.

20 That happens to be how we do it  
21 within Aetna. I believe that Cigna, Unita,  
22 all the others, have come up with ways to --

1 and have looked at their data and have talked  
2 to their physician population.

3 ACOs are -- we know who that  
4 population is, and we are doing a metric  
5 supporting them, just to give a flavor of  
6 what's going on in the industry based on  
7 getting these kinds of specifications and  
8 figuring how to use them to get valid  
9 information.

10 MEMBER DUCWORTH: Okay. The  
11 denominator inclusion criteria, they become  
12 essentially constraints for people like me.  
13 I can only use certain metrics and certain  
14 programs as indicators or assays.

15 Now, when we are looking at this  
16 particular metric, I think if we are -- the  
17 testing, that population that doesn't have  
18 that Alc, that can be good for P for P  
19 programs as a carrot or an extra stick for  
20 providers who aren't, one, performing that  
21 Alc.

22 But, James, I agree with you, it

1 doesn't necessarily give us an accurate  
2 representation of the population that we are  
3 evaluating. So I think if we are going to go  
4 forward with this type of -- or with this  
5 criteria in the denominator, then I think it  
6 is kind of our responsibility to really be  
7 specific to organizations on how we use this  
8 particular metric.

9           It should not be assumed that this  
10 represents the health of a population or a  
11 panel or necessarily the -- maybe more so the  
12 performance of the physician. It leans more  
13 towards the outcome or, I'm sorry, of process,  
14 because you're combining two approaches.

15           CO-CHAIR GOLDEN: Other comments  
16 on this issue?

17           (No response.)

18           Somebody -- you wanted to talk  
19 about the age range. The age range might  
20 belong in usability or feasibility. I don't  
21 know. Does it belong here? Validity. Age  
22 range belongs in validity. So it's not in

1 reliability, but it will be in validity. I  
2 continue to have you in the parking lot. I'm  
3 sorry.

4 MEMBER DUVA: So the next thing  
5 we're discussing is validity.

6 CO-CHAIR GOLDEN: They have to  
7 vote so --

8 MEMBER DUVA: Oh, we have a vote?

9 CO-CHAIR GOLDEN: Karen?

10 DR. PACE: I just want to make a  
11 comment about the -- and this is probably more  
12 the validity issue, but it has come up several  
13 times about the measure construction, and that  
14 if you don't have a test result it goes  
15 against you in the numerator.

16 This is one suggested way from our  
17 Consensus Standards Approval Committee of  
18 constructing a measure so that, you know, the  
19 issue is if -- if the patient has -- you know,  
20 if you can't find the lab results, maybe  
21 that's a problem as well. So it may lead you  
22 to a different kind of improvement efforts if

1 you discover that the reason for your bad  
2 score is because you don't have lab results.  
3 That may have a different solution than if  
4 you're really having patients with greater  
5 than nine percent.

6 But it does combine things in a  
7 way that drives to overall improvement, and it  
8 is one suggested way of constructing measures.

9 CO-CHAIR GOLDEN: Has the NQF done  
10 anything about standards about attribution or  
11 any kind of consistency?

12 DR. PACE: No. And that is an  
13 ongoing issue, right.

14 DR. BURSTIN: Get through SES and  
15 risk adjustment, which is the big one at the  
16 moment, and then we'll work on that one. We'd  
17 like to.

18 MEMBER McDERMOTT: Just one other  
19 point, if I could make it, is that there is a  
20 diabetic screening hemoglobin A1c measure  
21 separate from this measure that is  
22 consistently done by the HEDIS and in provider

1 performance. So you already know the  
2 diabetics that are never getting screened.  
3 Just a thought.

4 So this is adding on that  
5 population that never gets screened, plus  
6 those that have a level greater than nine.  
7 Yes, they have to be a diabetic. Right. But  
8 then there is another measure that is simply  
9 saying how many diabetics have not had annual  
10 screening.

11 MEMBER KIRKMAN: Annual testing, I  
12 guess is -- I thought you meant screening  
13 people for diabetes.

14 MEMBER McDERMOTT: Hemoglobin Alc.  
15 Hemoglobin Alc testing.

16 CO-CHAIR GOLDEN: I don't see  
17 anybody looking for attention here. Are we  
18 ready to vote? Yes. So let's vote, and it's  
19 reliability.

20 MS. TIGHE: Okay. Go ahead and  
21 vote. Everyone keep pushing until we get to  
22 20. Sorry. If everyone could try again.



1       Okay.  There we go.

2                   All right.  We have five for high,  
3       13 for moderate, and two for low.  So we'll  
4       move forward.

5                   CO-CHAIR GOLDEN:  Okay.  So now we  
6       move up to -- excuse me, I've got my cheat  
7       sheet missing.  Validity.  There it is --  
8       validity.  Thank you.  And the concept here  
9       is, does it actually test what you want it to  
10      test?

11                  DR. PACE:  Right.  And this  
12      actually includes quite a lot.  It is -- you  
13      know, are the specifications consistent with  
14      the evidence that was presented?  And then  
15      formal validity testing, or I think in the  
16      case of this measure face validity was what  
17      was done.  But also, what we can term "threats  
18      to validity," which has to do with, you know,  
19      who is excluded; for outcome measures risk  
20      adjustment, are there actually meaningful  
21      differences in performance; if there are  
22      multiple specifications, do you get comparable

1 results; and that -- so it's a combination of  
2 all of those things.

3 MEMBER DUVA: Right. So in our  
4 workgroup we discussed that this measure did  
5 have strong face validity in terms of expert  
6 consensus in the ability of the measure. This  
7 measure also lined up well with other measures  
8 of quality for diabetes, which supported the  
9 validity.

10 So from that perspective, the  
11 measure had high validity in that also we  
12 spent a lot of time discussing the threats I  
13 guess to validity, which would be patient  
14 factors that cannot be controlled for,  
15 concerns about -- there was a small discussion  
16 about stratification because of different  
17 population groups that -- where the gap was  
18 higher in the different health plans versus  
19 Medicaid/Medicare I believe it was.

20 So there was some concern about  
21 that, and then of course there is the  
22 discussion we just had about whether or not

1 it's specified correctly.

2 CO-CHAIR GOLDEN: Okay. Comments  
3 on this one?

4 (No response.)

5 Are we ready to move on to a vote?

6 MS. BAL: Go ahead and vote,  
7 please.

8 MEMBER KIRKMAN: We've voting very  
9 specifically on different categories, but we  
10 are just being -- it flashes up there and we  
11 are supposed to vote, and we have to turn this  
12 way to vote. So I don't know if anybody else  
13 is having a problem with this, but I just wish  
14 somebody could read what we are voting on. I  
15 mean, I know we're voting on --

16 DR. PACE: Right. So --

17 MEMBER KIRKMAN: -- validity, but,  
18 I mean, the specific --

19 DR. PACE: Right. And just a  
20 couple of things that, first of all, under  
21 validity a measure can only get a high rating  
22 if there was empirical validity testing of the

1 performance score. So this measure is relying  
2 on face validity, so you would be talking  
3 about a moderate reading at the highest level,  
4 and then you would go from there.

5           So, but -- so, you know, this is  
6 where you're considering, you know, will this  
7 be a valid reflection of quality of care? And  
8 some of the things that you look at here is,  
9 you know, how it is specified, who is  
10 excluded, are they the right exclusions, you  
11 know, does it actually distinguish -- you  
12 know, indicate meaningful differences in  
13 performance across those being measured.

14           And so, you know, if it's an  
15 outcome -- I know this is an intermediate  
16 outcome that is not risk adjusted. I don't  
17 know if you had discussions about that or  
18 discussions with the developer about that.  
19 But for outcome measures that might be a  
20 consideration under validity as well.

21           So it is, you know, taking all of  
22 that into account, you know, in general to

1 give it a rating, and it needs to get a high  
2 or a moderate to continue.

3 MS. JOHNSON: And let me just put  
4 in here they actually did do some empirical  
5 validity testing. They did some correlation  
6 analysis. So --

7 DR. PACE: Okay. So -- sorry, I  
8 missed that. And so that it's eligible for a  
9 high rating.

10 CO-CHAIR GOLDEN: I have a  
11 question before we vote. I guess it was a  
12 question for our colleague from the -- from  
13 HRSA, for Laura. Periodically, I have people  
14 from FQHCs say that you need to risk adjust  
15 for socioeconomic status. Has that been -- I  
16 was just curious, in general, how HRSA views  
17 that kind of commentary? I don't know where  
18 that sits and whether it's valid or not. I  
19 just --

20 MEMBER MAKAROFF: Yes. It's --  
21 the question of whether it's valid or not, I  
22 don't know that I know the answer to that, but

1 that's something we hear a lot, too,  
2 especially for health centers that service  
3 special populations, which we define that as  
4 serve a high percentage of homeless  
5 populations, migrant seasonal farm workers,  
6 things like that, as well as, you know,  
7 generally speaking I would probably say the  
8 health center population all has socioeconomic  
9 factors, you know, that influence their care  
10 and their outcomes.

11           So as far as we're -- what we do  
12 about that, so we ask health centers to report  
13 their actual performance on our measure set.  
14 We have like 12 or 14 measures that we collect  
15 annually, and then we have an adjusted  
16 quartile ranking methodology that we go  
17 through that adjusts for some of those things.  
18 So we kind of compare health centers to other  
19 like health centers.

20           So it adjusts for things like  
21 percentage of homeless, percentage of  
22 uninsured patients that a health center may

1 care for, things like that, to be able to see  
2 kind of relative performance that way. But  
3 I'm happy to talk with you more about it. I'd  
4 love your insight, too, or anyone else's. I  
5 think it's something that we spend a lot of  
6 time sort of thinking about and how do we --  
7 is it worth adjusting for?

8 I mean, this conversation actually  
9 happened yesterday in my office, too. It was  
10 like, you know, HEDIS doesn't, to my  
11 knowledge, adjust for, you know, other  
12 socioeconomic factors. So I don't know that  
13 any other programs are doing that, but that is  
14 something that we kind of do to look at  
15 relative performance.

16 CO-CHAIR GOLDEN: Has NCQA ever  
17 discussed this or looked into this issue?

18 DR. BARTON: NCQA has. NCQA is  
19 against adjusting away socioeconomic  
20 differences from a belief that there is no  
21 reason why we should expect -- seeing evidence  
22 that excellent care can be provided to

1 challenging populations, to then excuse away  
2 that responsibility is not consistent with the  
3 overall mission of improving health care  
4 quality.

5                   And I think actually what our --  
6 the HRSA representative just described is  
7 actually stratification, comparing peers to  
8 like peers, which is different than  
9 adjustment, which tries to make everybody  
10 comparable to each other, you know, using  
11 statistical techniques. And so I think that  
12 I just wanted to make that distinction between  
13 stratification and adjustment.

14                   MR. REHM: And if I can just tag  
15 on to Mary's comment, we do have two measures  
16 in the HEDIS set that are risk adjusted.  
17 Those are our plan all-calls readmission  
18 measure, because we perceive that as an  
19 outcome measure and necessarily needs that  
20 adjustment at the health plan level of  
21 specification, and then also our relative  
22 resource use measures. Those are five



1 measures that are looking at resource use cost  
2 and quality. So we felt that that's  
3 appropriate as well.

4 DR. BARTON: But they were  
5 adjusted by health conditions, not --

6 MR. REHM: Correct.

7 DR. BARTON: -- socioeconomic.

8 MR. REHM: Not SES. Right.

9 CO-CHAIR ROSENZWEIG: I should  
10 mention, though, I mean, in the data that you  
11 have all showed us with respect to each of the  
12 plans, I mean, in almost all of the categories  
13 the Medicaid patients did worse than the --  
14 than the HMO plans.

15 Now, does that mean that they're  
16 -- the Medicaid patients got worse care, or  
17 does it mean that there was an adverse  
18 selection? You don't know.

19 DR. BURSTIN: And I'll just  
20 mention that NQF is in the middle of doing a  
21 pretty significant body of work on this very  
22 question of SES and risk adjustment with a

1 draft report out next month. This month.  
2 Sometime in March. So we really welcome your  
3 input on this. This has become, obviously, an  
4 increasingly high profile issue as more and  
5 more measures are being used for higher stakes  
6 uses, including patients selecting providers  
7 as well as payments. So more on that to  
8 follow, but it's obviously an important issue.

9 MEMBER KIRKMAN: I think one thing  
10 is that I don't think you can just narrowly  
11 look at a measure like this as a measure of  
12 the quality of care, like, you know, one  
13 physician with one patient, because these are  
14 generally patients that just -- there is just  
15 lots of issues going on.

16 I mean, I think more broadly you  
17 can think of it as a measure of how our entire  
18 system doesn't do well with particular kinds  
19 of patients or patients with particular, you  
20 know, socioeconomic or comorbidity,  
21 psychiatric comorbidity, things like that, but  
22 I would hesitate to say that this is by itself

1 just a measure of quality of care, at least on  
2 the kind of micro level, because I think it's  
3 -- I think you're going to end up sort of  
4 beating up a physician or a health care system  
5 for things that they probably can't really  
6 control. But if you look at it as sort of our  
7 whole system, or lack of system of care, then  
8 maybe it is.

9 MEMBER SULLIVAN: Yes. At Helen's  
10 invitation, I did want to comment on what Mary  
11 said. I think, to me, one of the really  
12 important things here is the difference  
13 between stratification and risk adjustment.  
14 If you risk adjust, you don't know what's  
15 going on.

16 So we know that black women have  
17 poor birth outcomes every time it's tested.  
18 So if you risk adjust, that goes away. You  
19 don't know that. But if you don't stratify,  
20 you can't figure out who is doing better  
21 within that population because the only -- the  
22 biggest correlation is between race and

1 outcome, and that is all you see, if that's  
2 what you -- so I think the way HRSA does it is  
3 the right way. You don't risk adjust, but  
4 then you stratify.

5 CO-CHAIR GOLDEN: All right. Are  
6 we ready to vote?

7 MS. BAL: Go ahead and vote,  
8 please. So we are still just missing a few  
9 more. If people could just try to make sure  
10 that we're getting everybody's results. Thank  
11 you. Perfect. Thank you. The final results  
12 are high, seven; moderate, 13.

13 CO-CHAIR GOLDEN: Okay.  
14 Feasibility. So feasibility is -- again, make  
15 sure we have our concepts down -- extent to  
16 which the specifications, measure logs require  
17 data that are readily available but could be  
18 captured without undue burden and to be  
19 implemented for performance measurement.

20 MEMBER DUVA: Despite -- I know  
21 the challenges of the administrative data,  
22 perhaps we didn't consider that enough in the

1 workgroup, but we rated feasibility high, and  
2 this is a measure that has been in place and  
3 it is being currently reported.

4 CO-CHAIR GOLDEN: Comments?

5 Jessie, are you up, or are you -- okay. We  
6 have kind of been discussing this for the last  
7 little bit anyway. Any other comments?

8 (No response.)

9 Ready to vote? All right. The --

10 MS. BAL: Please begin.

11 CO-CHAIR GOLDEN: -- polls are  
12 open.

13 (Laughter.)

14 Okay.

15 DR. BURSTIN: Data collection can  
16 be implemented.

17 MS. BAL: So we have high, 14;  
18 moderate, five; and low, one.

19 CO-CHAIR GOLDEN: All right. Use  
20 and usability. Correct? So this is the  
21 extent to which potential audiences --  
22 consumers, purchasers, providers, policymakers

1 -- are using or could use the results for both  
2 accountability and improvement to achieve the  
3 goal of high quality, efficient health care  
4 for individuals or populations.

5 So a quick question on that one  
6 for definitions. You know, I haven't been  
7 around too long. The use of the word "and"  
8 versus "or" -- accountability or performance  
9 improvement, accountability and performance  
10 improvement, there's a big difference. So can  
11 you elaborate on that for me?

12 DR. BURSTIN: As I mentioned  
13 earlier, at this point it is an "and." But I  
14 think one of the questions is, is there  
15 recognition that, you know, going forward  
16 there may be some measures that are  
17 potentially suitable for one versus the other?  
18 And do the criteria need to change with that?  
19 So broadly we are asking you about the measure  
20 for a wide range of potential uses.

21 CO-CHAIR GOLDEN: Comments on this  
22 issue? Usability. Okay. Bill?

1                   MEMBER TAYLOR: Is this the point  
2                   at which we bring in the issue of unintended  
3                   consequences? So building on what Anna said  
4                   before, you know, if I have a hemoglobin Alc  
5                   above nine, is this -- you know, do I have --  
6                   does the physician then have higher  
7                   performance standards if he makes the -- her  
8                   or his practice inhospitable to that patient?  
9                   If the patient has mental illness or English  
10                  is not their first language? Are there things  
11                  that would happen as a consequence of this  
12                  standard where care might be -- instead of  
13                  improved, it might be degraded  
14                  unintentionally. Is this an unintended  
15                  consequence of making a standard like this?  
16                  Is this the place where that --

17                  CO-CHAIR GOLDEN: I have seen  
18                  practices who were not -- have non-adherent  
19                  diabetes tell the patients to leave the  
20                  practice, so it becomes --

21                  MEMBER TAYLOR: Yes. That's a  
22                  good example. So but this is -- we're voting

1 here -- is on this topic. It includes this  
2 notion of unintended consequences. Is that  
3 correct?

4 DR. PACE: Right. But also, you  
5 know, it helps if there is some evidence about  
6 that versus the theoretical or anecdotal  
7 stories. And to look at that in weighing in  
8 relationship to the benefits, so you want to  
9 weigh both the benefits and the potential  
10 unintended consequence.

11 CO-CHAIR ROSENZWEIG: Yes. It's  
12 my perception -- and maybe -- I'd be  
13 interested in hearing from other people --  
14 that the issue of cherry-picking has always  
15 been raised with respect to this kind of  
16 situation. But, in fact, there is not a lot  
17 of evidence that -- certainly in large groups  
18 that such actually occurs.

19 So it's -- but it is more  
20 anecdotal than anything else. But if people  
21 have other evidence to present, that would be  
22 of interest.



1           The other issue, of course, that  
2           is always raised by endocrinologists is that  
3           endocrinologists would be caring for mainly  
4           patients who have high Alc's that are referred  
5           to them. So if they're compared with the  
6           primary care doctors, there may be problems in  
7           terms of evaluating those kinds of things.

8           MEMBER BREEN: And this comes back  
9           to stratification again. You know, do you  
10          compare hospital-based clinics to  
11          hospital-based clinics that have a very  
12          different patient population than their  
13          faculty private practice two blocks down the  
14          road? I think it's the same issue we have  
15          already discussed.

16          But, again, I don't think there is  
17          any expectation that any measure should have  
18          zero harm, right? We're talking about a  
19          balance in benefits versus harm. And even  
20          though that they're -- I agree, I don't think  
21          there is any data out there to suggest that  
22          this cherry-picking process is going on. I

1 don't know that anyone has looked to see if  
2 this cherry-picking process is going on. So  
3 lack of data doesn't mean that the concept is  
4 nothing.

5 MEMBER KIRKMAN: So two things.  
6 One is there is evidence from the UK where  
7 they put in a very aggressive pay for  
8 performance system that there actually was  
9 very little cherry-picking. Of course, that's  
10 a very different system from ours. But I  
11 don't know whether this is the time to bring  
12 up whether the -- whether performance is  
13 improving over time, because my understanding  
14 with this measure it has remained pretty  
15 steady.

16 And I think -- I suspect that's  
17 partly because I'm not sure that this really  
18 measures quality of care so much as kind of  
19 bigger issues that, you know, are -- as a  
20 society we are not able to fix very well. But  
21 I just wanted to throw that out there, that  
22 this -- I mean, I actually really like this

1       measure, and I think it's really important.  
2       But I don't think we are seeing changes in the  
3       proportions, unless I'm reading the data  
4       wrong. It has remained pretty fixed, the  
5       proportion of patients that are above nine  
6       percent. Is that right? Or am I wrong?

7                   DR. BARTON: I'm not sure if I  
8       understood exactly your point. But I would  
9       just say that, you know, the median is one  
10      thing, and then another question is how the  
11      10th and 90th percentiles are going. And I  
12      think there is no question that there are  
13      places that are improving through the -- you  
14      know, the issues that you were discussing  
15      earlier, that this is a particular set of  
16      patients who you have to go after with  
17      different tools to actually get them into  
18      care. And so there are places that have been  
19      very successful at doing that.

20                   So I think, has the whole nation  
21      moved? I'm not sure that it has. But have  
22      there been pockets of improvement driven by

1 attention to this? I would say yes.

2 MEMBER DUDL: Yes. Let me just  
3 respond to that. We just got through  
4 interviewing the top 10 performers in Alc's  
5 over eight and nine, and what was very  
6 interesting is all of them actually do more of  
7 a population base where they go after looking  
8 at all of the people. We all know that there  
9 is a top 10 percent, that you are not going to  
10 move 65 visits and nothing happens.

11 But it turned out there were quite  
12 a few that were in the panel but just not  
13 coming in. So I don't think this is  
14 exhaustive.

15 MEMBER MILLER: I think when I  
16 wrote some comments to myself about this  
17 measure and use and usability, regarding the  
18 question of if performance is improving for  
19 glucose control, I made a note that it appears  
20 that each type of health plan had results that  
21 have varied within a small range up and down  
22 over the course of years.

1                   And so, you know, I really thought  
2                   that a lot of that had to do with, you know,  
3                   practice level management skills. But it also  
4                   may be reflective of what you were discussing  
5                   earlier with a roaming denominator. That may  
6                   also account for some of the small variations  
7                   that we are seeing up and down year to year.

8                   CO-CHAIR GOLDEN: It was my  
9                   impression that the FQHCs had seen some  
10                  improvement. Is that -- are other folks  
11                  looking at their data?

12                 MEMBER MAKAROFF: With this  
13                 measure in particular there has been like --  
14                 from what I know, which is annual  
15                 measurements, we have one data point once a  
16                 year for all 1,200 health centers. That  
17                 number hasn't really changed in the past three  
18                 years since we've been measuring.

19                 MEMBER BAILEY: Just to address  
20                 the question of changes over time based on  
21                 anything that was published in The New England  
22                 Journal of Medicine last year, '99 to 2002, 18

1 percent had hemoglobin Alc's greater than  
2 nine; 2003 through 2006, 13 percent; and 2007  
3 through 2010, 12.6. So there is positive  
4 movement towards lowering Alc. So it is a  
5 select population, but, still, evidence on a  
6 nationwide sample, that there is positive  
7 movement there.

8 MEMBER KIRKMAN: Although for some  
9 reason the NHANES data are always different  
10 than the HEDIS data, right? I don't know why.  
11 Because in NHANES they are actually measuring  
12 Alc's on a selected, you know, representative  
13 sample.

14 CO-CHAIR ROSENZWEIG: I do think  
15 -- my recollection is that, yes, 10 years ago  
16 there was steady improvement in the HEDIS data  
17 as well, but it seems to have flattened out in  
18 the last -- at least certainly in the last  
19 three years.

20 CO-CHAIR GOLDEN: So, again, what  
21 are we voting on? So make Sue happy here.  
22 Accountability, transparency, everyone can

1 read it perhaps.

2 DR. PACE: Right. Usability and  
3 use includes, you know, is it being used and  
4 can be used in accountability and transparency  
5 programs. So public reporting, pay for  
6 performance, accreditation, et cetera. And  
7 the expectation is that they -- you know,  
8 especially on endorsement maintenance, that  
9 the measure is being used.

10 4(b) is about improvement, because  
11 the whole point of endorsing these is to make  
12 improvement. And then the third element is  
13 about the unintended consequences. That has  
14 been raised. So taken together overall.

15 MS. BAL: Okay. Please vote now.  
16 So the final results are high, nine; moderate,  
17 11.

18 CO-CHAIR GOLDEN: So we're in the  
19 home stretch. Overall recommendations for  
20 endorsement. So it's a yes or no. Probably  
21 don't need a lot of discussion on this one,  
22 given how we have been going. Does anybody

1 want to have further discussion on this  
2 measure for overall endorsement?

3 MEMBER KIRKMAN: Can I just ask a  
4 question? Because, I mean, I just want to get  
5 back to this question of physician level  
6 reporting on this measure versus health plan  
7 reporting, because to date it has primarily  
8 been health plan reporting, other than -- and  
9 even in the physician recognition program, it  
10 is just that you pass this Chinese menu of  
11 options, so we don't really know that Dr. X,  
12 you know, is here, and Dr. Y is that.

13 So, I mean, so -- but is there a  
14 plan? I mean, can you see in the future where  
15 -- because I would look really bad. You know,  
16 I have a lot of people referred to me with  
17 really high Alc's that I don't necessarily get  
18 down. I mean, and I don't know whether that's  
19 really a question at this point, because I  
20 think on all of the measures we sort of  
21 decided this measure is okay, but --

22 CO-CHAIR GOLDEN: That's going to



1 be the second hour, the Brandy conversation I  
2 think.

3 MEMBER KIRKMAN: Okay. And maybe  
4 it should have --

5 CO-CHAIR GOLDEN: No, you have a  
6 good point, and that's --

7 MEMBER KIRKMAN: Maybe it should  
8 have come up in the usability.

9 CO-CHAIR GOLDEN: Yes.

10 MEMBER KIRKMAN: It does concern  
11 me if this, in this future, is going to be  
12 publicly reported on the physician level,  
13 because I think it could have a lot of sort of  
14 unintended -- it is kind of an unintended  
15 consequence. You're sort of punishing people  
16 for something that is really not a quality of  
17 their care.

18 CO-CHAIR GOLDEN: Jamie and I had  
19 a side bar, and that, you know, one of the  
20 problems -- we talked about attribution,  
21 coming back to your attribution missing link,  
22 is that if you're in practice and you get

1 attribution done by the payer, you often get  
2 the patients attributed to you at the time of  
3 measurement so you don't know you're being  
4 measured on the patient, which gives you  
5 little time to react.

6 So, yes, there are some issues.

7 So --

8 CO-CHAIR ROSENZWEIG: There are  
9 other issues that have come up, especially the  
10 idea -- actually, this occurred even more when  
11 there was a less than seven measure. But  
12 plans may be accountable, but what they then  
13 do will then institute a variety of procedures  
14 to make their individual providers  
15 accountable, such as pay for performance, or  
16 tiering, or a variety of other things.

17 So even though HEDIS might just  
18 hold the plans accountable, it does filter  
19 down to the physicians as an unintended  
20 consequence in many cases.

21 CO-CHAIR GOLDEN: Do you have a  
22 comment?

1                   MEMBER DUVA: Well, just I know we  
2                   vote now whether or not we recommend the  
3                   measure. When is it that we talk about  
4                   parsimony and -- that Karen mentioned earlier,  
5                   you know, in terms of all the measures when  
6                   you're looking across the board at all the  
7                   measures and if there is redundancy or some  
8                   that are better than others. Do we do that at  
9                   the very end?

10                  CO-CHAIR ROSENZWEIG: Ready to  
11                  vote? Not yet?

12                  MS. BAL: Go ahead and vote. So  
13                  the final results are yes, 20.

14                  DR. BURSTIN: So it always takes  
15                  an hour and a half for the first measure. I  
16                  just thought I'd put that out there. Never  
17                  seen it happen in any less time. You'll speed  
18                  up. Don't worry.

19                  CO-CHAIR ROSENZWEIG: Of course I  
20                  thought the conversation was good, and I think  
21                  it sets up some of the other discussions for  
22                  later. So that's a big help.

1                   So next, 575. So Alc's under  
2 eight. Okay. They're calling in?

3                   MS. TIGHE: Yes. We have some  
4 folks -- I'm sorry. So we do have some folks  
5 who just call in right at the appointed public  
6 comment times, and so we are trying to hold  
7 true to them. It's awkward timing, since we  
8 only got through one measure.

9                   But since we're pretty close to  
10 12:15, I do just want to pause and see if we  
11 have any NQF member and public comment either  
12 on the phone or in the room. Yes. It's a  
13 commenting free-for-all for those who are  
14 looking to comment. You can provide comment  
15 on whatever you would like.

16                  MR. LEE: Thanks so much. I am  
17 David Lee, the Executive Director of the  
18 National Bone Health Alliance, which is a  
19 public-private partnership on bone health that  
20 includes 51 organizations from public  
21 specialty society and nonprofit sectors as  
22 well as industry as well as four government

1 liaisons. And we are here to -- I guess I'm  
2 here to talk about the three osteoporosis  
3 measures that will be looked at this  
4 afternoon, which are very important to our  
5 constituency because they really support  
6 fracture prevention programs which have not  
7 been widely utilized here in the United  
8 States, other than closed systems like Kaiser  
9 and Geisinger.

10           And I think especially the  
11 exciting part, one, because they will help  
12 address the narrow 80 percent post-fracture  
13 care gap. It is also because I know that our  
14 hope is that if they were to be endorsed by  
15 NQF today, and through the process, that they  
16 would become a potential new core measure set  
17 that the Joint Commission would use in terms  
18 of reaccreditation, which I think is a very  
19 important stick for folks, because if you see  
20 the kind of flat-lined, you know, care gap  
21 that really has not changed much in a long  
22 time, and certainly lack of awareness, both by

1 health care professionals and consumers about  
2 post-fracture care and osteoporosis, I just  
3 want to make sure that we emphasize as -- our  
4 full partnership are fully behind this and  
5 fully prepared to engage with our health care  
6 professionals and consumers that we can reach  
7 to help make this a reality and to really  
8 change the face of osteoporosis care here in  
9 the United States.

10 Thanks so much.

11 MS. TIGHE: Operator, if you could  
12 see if anyone on the phone would like to  
13 provide a comment at this time?

14 OPERATOR: If you would like to  
15 make a comment, please press star and then the  
16 number one on your telephone keypad.

17 Okay. At this time, there are no  
18 comments.

19 MS. TIGHE: Thanks. Apologies for  
20 that untimely interruption. Turn it back to  
21 you.

22 CO-CHAIR GOLDEN: So we --

1 technically, we're going to have lunch  
2 sometime soon. On the other hand, we could  
3 continue moving, so -- I'm sorry? 12:30 is  
4 the lunch? Okay. So let's get moving along,  
5 then. That's fine.

6 So who was assigned this one?  
7 Sorry. Vicky, okay.

8 MEMBER SHWIDE-SLAVIN: So I agree.  
9 My fingers are crossed that we can move  
10 through this one quickly. It's just like 59,  
11 except it's at the other end. We're looking  
12 at A1c control less than 8.0 percent. This is  
13 for patients 18 to 75 years of age with  
14 Diabetes Type 1 and 2, whose most recent level  
15 was below -- oh, you still can't hear me?  
16 Sorry. Was below 8.0. And develop a  
17 rationale -- is that the measure is critically  
18 important from both a clinical and financial  
19 perspective because the largest improvement in  
20 outcomes occurs by a reduction of blood sugar  
21 levels in those patients with the highest  
22 glycohemoglobin level.

1           One second, my -- okay. So shall  
2 we just jump right into evidence? Okay. So  
3 our group felt like that there was sufficient  
4 evidence to support this measure, and I think  
5 we only had one real comment where someone did  
6 express concern on whether or not this measure  
7 was good in general to evaluate a population,  
8 but we didn't go into intense discussion  
9 around that. Do you recall that, Ingrid?

10           MEMBER DUVA: The discussions  
11 about the evidence, it demonstrated increase  
12 mortality, and I think it was -- Bill, do you  
13 want to comment on this? The patient's -- the  
14 increased mortality of patients when their A1c  
15 gets too -- gets in the tighter control group?

16           The ACCORD study, there is a lot  
17 of references to the ACCORD study because that  
18 was --

19           MEMBER TAYLOR: Yes. I mean, I  
20 think ACCORD is the one where with tighter  
21 control total mortality went up, which was a  
22 big red flag to people. And it -- you know,



1 for old people, you know, the first time there  
2 was a big diabetes control study and outcomes  
3 were measured goes back to UGDP. I'm looking  
4 down at the end of the table for people who  
5 know about that, you know, but that's back in  
6 the 1960s where the first question about  
7 increased mortality came up with tighter  
8 control. That was sort of, you know, pushed  
9 aside.

10 But, similarly, in the UKPDS 33,  
11 there was a subgroup of the overweight people  
12 where there was a question of increased  
13 cardiovascular mortality, so the question  
14 keeps sort of percolating through the studies  
15 that -- are we doing some harm at the same  
16 time that we're accomplishing -- there's no  
17 question that the microvascular qualifications  
18 go down, retinopathy goes down, nephropathy  
19 goes down. I mean, that happens over and over  
20 again. But interspersed in the studies are  
21 these worries about either total mortality or  
22 cardiovascular events that pop up here and

1 there, not with great consistency, but enough  
2 to, for some people, raise concerns. And  
3 certainly with the tightest control in ACCORD,  
4 when the total mortality went up in the more  
5 aggressively treated group, it got at least a  
6 few people's attention.

7 MEMBER DUVA: So I think the  
8 summary of the discussion in our workgroup was  
9 the concern about the tighter control leading  
10 to the adverse outcomes, and so then the  
11 definition of the eight percent and whether or  
12 not that was loose enough to account for  
13 variability in the glucose readings reflected  
14 by an A1c of 8.0.

15 MEMBER KIRKMAN: So just to -- I  
16 know we don't want to get into a huge, long  
17 discussion about ACCORD, but just remember  
18 that the control group in ACCORD had an A1c  
19 target of 7.0 to 7.9, and they had lower  
20 mortality. So it would be a little bit hard  
21 to say that a target of less than eight  
22 percent is going to increase mortality. I

1 mean, we could get into the issue of the lower  
2 limit, but -- you know, and the other thing is  
3 that -- and everybody knows this, but the  
4 people that did poorly in ACCORD were people  
5 actually in the intensive arm who had the  
6 highest Alc's, not the lowest. So it's a very  
7 complicated issue, but I think this measure to  
8 me is sort of like the control group in ACCORD  
9 in terms of the goal.

10 CO-CHAIR ROSENZWEIG: Something's  
11 blinking. Okay. I was going to make the  
12 exact same points about ACCORD. And you can  
13 -- and ADVANCE and VADT similarly. The big  
14 issue also is that these patients were of an  
15 older age and also had coexistent  
16 cardiovascular disease.

17 Now, that raises the issue as to  
18 whether or not within the spectrum of patients  
19 -- I mean, the American Diabetes Association  
20 has raised its range of goals to go from --  
21 anywhere from 6.5 or seven percent up to  
22 eight, eight and a half percent with respect

1 to different individuals. So elderly patients  
2 with a short potential life span and patients  
3 with multiple complications might very well  
4 manage okay with Alc's between eight and eight  
5 and a half or something like that.

6 The question is, what percentage  
7 of the total population is going to be  
8 affected when you're looking at broad numbers  
9 of people? I think the big issue is whether  
10 or not the supplies to the Medicare  
11 population, over 65, whether or not those  
12 patients actually form a significant part of  
13 the population.

14 Anyone else want to address that?

15 MEMBER TAYLOR: So I want to make  
16 clear what -- my position is not any kind of  
17 disagreement with people getting their Alc's  
18 below eight and restricting it to people 18 to  
19 75. My concern is the unintended consequence  
20 that people don't always read the fine print  
21 of what the American Diabetes Association says  
22 or what these guidelines are.

1                   And as we push clinicians by how  
2 we pay them and what the standards are to  
3 believe that tighter control is better and  
4 they should be worrying about it, the  
5 unintended consequence that I worry about --  
6 and I don't have data to support it -- are  
7 people being treated inappropriately, more  
8 aggressively?

9                   CO-CHAIR GOLDEN: I think it has  
10 to be for a different segment of the  
11 discussion if that's okay.

12                  MEMBER TAYLOR: Yes. That's all.

13                  CO-CHAIR GOLDEN: All right.

14                  MEMBER McCOLLISTER-SLIPP: And,  
15 again, I want to raise the possibility of the  
16 unintended consequences, too, because I don't  
17 think we can discuss these kinds of things  
18 without really thinking through that. I mean,  
19 again, I've had Type 1 for 28 years. My blood  
20 sugar is very stress responsive, even when I  
21 don't feel stressed.

22                   You know, my former endo is now

1 Chief Science and Medicine Officer at ADA, and  
2 there were lots of times while I was under his  
3 care that my A1c was above eight. It doesn't  
4 mean that he wasn't providing excellent care.  
5 I couldn't get any better. It doesn't mean I  
6 wasn't doing everything that I should be  
7 doing. I was. It's just difficult.

8 And it's hard enough to find an  
9 endocrinologist to start with, especially if  
10 you've got complex disease and you're, you  
11 know, difficult to control. I mean, I really  
12 haven't found one since Bob left clinical  
13 practice. So I think we really need to think  
14 about that because these things have a way of  
15 getting calcified.

16 And even though -- I mean, the ADA  
17 -- and Sue can certainly speak to this better  
18 than me, but the ADA has gone out of their way  
19 to make sure that their guidelines reflect the  
20 individuality of each patient. And the  
21 ability of each patient, given their own set  
22 of circumstances, disease progression, et

1 cetera, to be able to meet certain criteria  
2 that, you know, they've gone out of their way  
3 to say these are our targets, but you've got  
4 to take it on a case-by-case basis.

5 When we're studying these kinds of  
6 standards, I completely understand the need  
7 for them, I completely understand why we're  
8 doing this. That's why I volunteered. You've  
9 got to start somewhere.

10 But it's difficult to make a  
11 binary decision one way or the other when  
12 there will be real consequences of this. I  
13 mean, if the measure is widely -- widely  
14 adopted and it's used, you know, maybe some  
15 physicians will get paid more, some will get  
16 paid less. And over time you create a  
17 disincentive -- an additional disincentive  
18 because there are already lots of  
19 disincentives for people to go into  
20 endocrinology and for people to specialize in  
21 those of us who are difficult to treat.

22 MEMBER BREEN: So I think it just

1 -- oh, I'm sorry.

2 MEMBER McCOLLISTER-SLIPP: I was  
3 going to say the challenge becomes you are  
4 creating a tool, but we don't necessarily have  
5 oversight over how that tool is going to be  
6 employed. Right? The measure, I think we  
7 would agree, is valid, that for the majority  
8 of people with diabetes, an A1c less than  
9 eight represents reasonable or a goal of  
10 control. The question is how that measure  
11 will be utilized by either plans, is it going  
12 to be utilized as -- at an age level.

13 Do you carve out -- I mean, we're  
14 talking in our health system right now, who do  
15 you carve out of that, right? Who do you  
16 identify as your high-risk subpops that you  
17 don't put into that? And I think -- I don't  
18 know how much pre-thinking or advanced  
19 downstream thinking we can do on this other  
20 than to note that it's a concern, and keep  
21 bringing it up as a concern.

22 CO-CHAIR GOLDEN: And, again, it's



1 for other elements of the discussion. So I  
2 guess you could argue -- I mean, I'm just  
3 trying to make sure we're not glossing over  
4 it, but less than eight is better potentially  
5 than not less than eight. But then you have  
6 some populations issues, and so forth. So I  
7 guess the scientific validity would be, are  
8 there populations where it's not appropriate?  
9 And that would be a fair game for this  
10 discussion. So that would be like exclusions,  
11 and so forth, down the road.

12 DR. PACE: And the other thing is  
13 I think this is one reading, the most recent  
14 reading, I mean, the other discussion along  
15 that line is, you know, I think it was brought  
16 up before, time in range or an average, you  
17 know, so that can be brought up in the other  
18 discussion as well.

19 MEMBER KIRKMAN: So I think it  
20 sort of gets into a bigger philosophical --  
21 more philosophical question, but I don't think  
22 it just applies to this performance measure,

1 and that is that the -- you know, more and  
2 more we realize that care has to be  
3 individualized and we have to take into  
4 account patient preferences and all of these  
5 different factors.

6 And so at the bedside your  
7 definition of quality of care is really going  
8 to depend on that patient. But for  
9 performance measures it has to be something  
10 that can sort of be collected simply, and it  
11 does end up sort of being kind of like a one  
12 size fits all.

13 So I think it's just that tension  
14 between performance measures, which can't --  
15 you can't go into every single chart and say,  
16 "Well, this seemed reasonably good quality."  
17 You have to sort of set some limits. And I  
18 think that tension is just going to keep  
19 growing as care becomes more individualized,  
20 so --

21 CO-CHAIR GOLDEN: As an aside,  
22 down the road, I mean, you know, we have drawn

1 episodes of care and total cost management.  
2 We did it for perinatal. And we decided you  
3 couldn't risk adjust a pregnancy on a sickle  
4 cell patient, or you couldn't risk adjust a  
5 pregnant -- so we just excluded things.

6 So, you know, it got to the point  
7 where we say, "Look, if we covered 85, 90  
8 percent of the pregnancies, that's not a bad  
9 deal." So, you know, it gets into the same  
10 issue. There are just some risk categories  
11 that aren't worth, you know, covering because  
12 it's just -- you can slice and dice it that  
13 well.

14 MEMBER McCOLLISTER-SLIPP: But  
15 since we're not in control of how these  
16 measures are used, I think it's our  
17 responsibility to think this through. And  
18 I'll just throw this out as a quick example,  
19 just because it literally happened last night  
20 after I got in from a long day and a very late  
21 flight.

22 I recently switched insurance

1 companies. I take Aranesp and Erythropoietin  
2 because I have CKD-related anemia, and you  
3 have to get recertified every three months or  
4 whatever. So I received a letter last night  
5 from my insurance company saying that the  
6 anemia drug was not medically necessary  
7 because my hemoglobin was 11.1. If it were 11  
8 or 10.9, I would have been fine. So basically  
9 they are denying care based on this guideline  
10 which is based on studies that were looking  
11 for something very different.

12 So by drawing this arbitrary line,  
13 you know, it gives people the ability to deny  
14 care in a way that is completely inappropriate  
15 because it is taken completely out of context.

16 CO-CHAIR GOLDEN: Jessie?

17 MEMBER SULLIVAN: Yes. I was just  
18 going to speak to the point that had been  
19 raised earlier that the measures that we have  
20 -- when the measures are a threshold measure,  
21 we're left with this. But it's not impossible  
22 to measure improvement at the patient level,

1 you know, hemoglobin A1c change, delta. We  
2 just don't have measures that do that.

3 CO-CHAIR GOLDEN: So I'm going to  
4 push us along here and say that I think that  
5 we have some issues here we can discuss on  
6 other parts of this discussion. But I think  
7 that we -- I think we have enough discussion  
8 here to discuss the evidence for less than  
9 eight. Unless people want to violently  
10 disagree, I'll -- I will move us along. So we  
11 can I think take a vote on the evidence  
12 question -- low, high, medium, and something  
13 else.

14 MS. BAL: Okay. So everyone can  
15 start voting now. Let's just try one more  
16 time to get those last two in there.

17 Okay. So the final results are  
18 high, nine; moderate, eight; low, three.

19 CO-CHAIR GOLDEN: Okay.  
20 Performance gap. So are there disparities in  
21 care? Are there practice variations? Is  
22 there variation in care?

1                   MEMBER DUCWORTH: Yes. The  
2                   workgroup found that -- or we believe that  
3                   there were care disparities across plans, and  
4                   that there is a substantial gap, even for DRPs  
5                   that have demonstrated better outcomes than  
6                   health plan data, and that this measure should  
7                   be possibly indicated as disparity-sensitive.

8                   Yes, that's it. There's a  
9                   disparity or a gap.

10                  CO-CHAIR GOLDEN: Do we have  
11                  people who want to address this? Sue, you're  
12                  up, but I don't know if you mean to be up.  
13                  There's one other there. Patricia? No.  
14                  Okay. Going once. People are getting hungry.  
15                  Good. So we vote.

16                  MS. BAL: Go ahead and vote.  
17                  Okay. We have high, 16; moderate, four.

18                  CO-CHAIR GOLDEN: Okay. Now we go  
19                  to impact.

20                  MEMBER DUCWORTH: Okay. The group  
21                  also feels that we do think that this is a  
22                  high priority or demonstrates an opportunity

1 -- high impact opportunity. And rationale --  
2 there are significant implications for both  
3 morbidity and mortality cost of care across a  
4 very large patient population.

5 CO-CHAIR GOLDEN: Comments?

6 Questions?

7 (No response.)

8 Are we ready to vote? Going once,  
9 twice. Time to vote.

10 MS. BAL: Okay. And then just to  
11 repeat the question, the question is, does  
12 this measure address a significant health  
13 problem? And so you can begin voting now.

14 Okay. The results are high, 16;  
15 moderate, three; low, one.

16 CO-CHAIR GOLDEN: Okay.

17 Reliability of the specifications. And just  
18 for the record, why don't you tell us or  
19 remind everybody what the specifications are.  
20 Did I confuse you? I'm sorry. I've got them  
21 here.

22 MEMBER DUCWORTH: For the

1 numerator and denominator?

2 CO-CHAIR GOLDEN: Yes, please.

3 MEMBER DUCWORTH: Okay. Patients  
4 whose most recent Alc is less than 8.0 during  
5 the measurement year, the outcome is the  
6 result of an Alc test. Denominator is  
7 patients 18 to 75 years of age by the end of  
8 the measurement year who had a diagnosis of  
9 diabetes, Type 1 or Type 2, during the  
10 measurement year or the year prior to that  
11 measurement year.

12 CO-CHAIR GOLDEN: What is similar  
13 to the high measure but similar to --

14 MEMBER DUCWORTH: Yes. And there  
15 are exclusions in this population as well.  
16 However, not that one exclusion that we were  
17 kind of upset with in 59. Exclusions include  
18 patients who did not have a diagnosis of  
19 diabetes in any setting in the measurement  
20 year or year prior. Also, patients who meet  
21 the following criteria -- a diagnosis of  
22 polycystic ovaries in any setting or a



1 diagnosis of gestational or steroid-induced  
2 diabetes in any setting.

3 CO-CHAIR GOLDEN: Now, in this  
4 case, just to be clear on the numerator, if no  
5 test was done, it would still count against  
6 you, correct?

7 MEMBER DUCWORTH: Yes.

8 CO-CHAIR GOLDEN: Okay.

9 MEMBER DUCWORTH: Okay. So the  
10 group -- scrolling down, excuse me. We do --  
11 or the group did feel that the health plan  
12 data has sufficient reliability. Now, there  
13 was concern that the physician level data had  
14 weak reliability. The differences in  
15 performance by individual -- or individual  
16 providers would be less reliability  
17 distinguished, and overall moderate, high with  
18 health plans, low with providers.

19 CO-CHAIR GOLDEN: A similar  
20 conversation.

21 MEMBER DUCWORTH: Yes.

22 CO-CHAIR GOLDEN: Comments or

1 questions on this item?

2 MEMBER KIRKMAN: Can I just ask  
3 NCQA to explain again why the reliability is  
4 low for physicians? I know it's from the DPRD  
5 data. Is it just because of the way the data  
6 are submitted? Because this is one where I do  
7 think it's going to be provider level. You  
8 know, I think there's a lot of provider level  
9 reporting of this.

10 DR. BARTON: Right. So there is a  
11 menu from which practices can choose.

12 However, what we look -- what we noticed when  
13 we looked at the physician level data, it  
14 looks like the huge majority of practices  
15 select the hemoglobin A1c less than -- not  
16 greater than nine and less than eight as  
17 measures that they want to report on.

18 So the mean is high and the  
19 distribution is real close, because they are  
20 all doing pretty darn well on this, and that  
21 is kind of why they want to be in the program  
22 and think themselves worthy of being in the

1 program. So that kind of data distribution is  
2 mathematically designed to do poorly on a  
3 beta-binomial assessment, because the  
4 beta-binomial is asking, do you have enough  
5 spread on this to be able to distinguish good  
6 performers from bad performers?

7 And, unfortunately, this data  
8 source doesn't allow us to access information  
9 about that at all. It is really --

10 MEMBER KIRKMAN: Okay. So by  
11 definition they are sort of all pretty good  
12 performers, and there is not much --

13 DR. BARTON: Variation.

14 MEMBER KIRKMAN: There's not a way  
15 you can tell --

16 DR. BARTON: There's not good  
17 spread.

18 MEMBER KIRKMAN: Okay.

19 DR. BARTON: Yes.

20 DR. PACE: Did you provide any  
21 information about sample size? Because that  
22 is also a factor when you get to the sample

1 size. So I was just curious with your  
2 provider level data if that was a factor.

3 MR. REHM: I think the sample size  
4 is 30 patients. Again, this is physician.  
5 They do this in their own offices, and it's a  
6 sequence of physicians. They start the date  
7 and then whoever comes in with that diagnosis  
8 is the person tested, so that it prevents  
9 gaming.

10 CO-CHAIR GOLDEN: So the numerator  
11 -- the denominator creation is much different  
12 than for the plan.

13 MR. REHM: Correct. Again, and  
14 then it would be different for PQRS, or it  
15 would be different for an -- I mean, it's --

16 CO-CHAIR GOLDEN: Yes. But that  
17 -- I mean, that gets back to holding. If the  
18 denominator can vary, then your specifications  
19 are all over the place.

20 MR. REHM: You know, I think the  
21 feeling is is that there are programs out  
22 there that design their programs. And CMS

1 designs program X way, and we are not  
2 measuring the program, we are just -- we can  
3 articulate the program that we update it from,  
4 which is our own.

5 CO-CHAIR GOLDEN: But, you know,  
6 I've heard Peggy O'Cain comment about HEDIS  
7 light and not happy. Then again, from the NQF  
8 standpoint, the specification of the  
9 specifications, and if you do it differently  
10 it's not -- I had a conversation with a plan  
11 person. He wanted to collect the -- we were  
12 going to use the NYU algorithm for emergency  
13 room care.

14 And she goes, "Oh, we'll report  
15 the emergency room use. We just will report  
16 it differently." And I said, "Well, you're  
17 not, then, reporting the measure. And so you  
18 either report the measure as specified or you  
19 don't." So that -- you know, that's a  
20 problematic issue that you bring up that you  
21 can make up your own denominator and say  
22 you're still reporting the measure. And

1 that's something we have to face as a group;  
2 the denominator is the denominator.

3 DR. PACE: So you're saying that  
4 how this is applied to physicians is it's a --  
5 they do a 30-patient sample, so that's the  
6 difference?

7 DR. BARTON: That's what they're  
8 required to do for program --

9 CO-CHAIR GOLDEN: It is a  
10 different -- fundamentally, then, a different  
11 measure.

12 MEMBER KIRKMAN: Yes. But they're  
13 not using this measure per se, right? I mean,  
14 it's really --

15 CO-CHAIR GOLDEN: They have  
16 reported the reliability on that --

17 MEMBER KIRKMAN: -- because the  
18 denominator --

19 CO-CHAIR GOLDEN: -- on a  
20 different measure.

21 MEMBER KIRKMAN: Well, yes.  
22 Right. But that is why the reliability is

1 probably not good. And, again, it's a  
2 voluntary program, and so people with poor  
3 quality are probably not going to --

4 CO-CHAIR GOLDEN: No. But I would  
5 say if they've submitted reliability data on  
6 this measure using their physician reporting,  
7 they are reporting reliability on a different  
8 measure.

9 MEMBER KIRKMAN: But they also  
10 report it on the HEDIS data. So that's not  
11 the only reliability data that --

12 CO-CHAIR GOLDEN: No, I agree.

13 CO-CHAIR ROSENZWEIG: I'm unclear.  
14 Is the physician reporting -- that's an  
15 entirely different process. Is that still  
16 considered within the purview of this measure?

17 DR. BARTON: The measure -- NQF  
18 asked us to say how we were looking for this  
19 measure to be endorsed. We have this measure  
20 specified for health plan reporting, and it is  
21 used by many health plans and has been for a  
22 long time, and using these specifications. We

1 also have a physician level specification. It  
2 has been picked up by a variety of programs,  
3 and, like it or not, they each have their own  
4 -- they are only going to apply it to the  
5 people who are in their program.

6 So the -- I'm afraid I'm not  
7 understanding --

8 CO-CHAIR GOLDEN: That was not --

9 DR. BARTON: I'm not understanding  
10 your concern.

11 CO-CHAIR GOLDEN: If you have  
12 changed the construction of the denominator,  
13 which is what you've said you've done, it is  
14 a different measure.

15 CO-CHAIR GOLDEN: If you have a  
16 set of specifications, and you apply it to  
17 these people and it gives you this group, and  
18 I apply those same specifications to this  
19 other group, it gives me a different group.  
20 So the denominators are different. That's not  
21 to say that they are -- the specifications are  
22 different. So I don't --



1 CO-CHAIR GOLDEN: That's the whole  
2 point of specifications. Yes, Patricia?

3 MEMBER McDERMOTT: There's many  
4 ways that you can collect a measure. You can  
5 do it using administrative data, claims,  
6 encounters, and that's the only way you get  
7 the measure. Or you can do it through  
8 e-measures where they use their electronic  
9 medical record in order to say, "These are the  
10 diabetics." And you go into the record and  
11 you say, "Do they have this lab test?"

12 That's -- it's using the same  
13 specifications, and you'll find when you look  
14 at the different ways -- when you go through  
15 the documents that have been released by NCQA,  
16 whether you use the physician specifications  
17 or the health plan specifications, you can use  
18 it all through administrative data, or you can  
19 do what's called a hybrid measure for health  
20 plans, where abstractors go out to doctors'  
21 offices and they find all of these things  
22 using a random sample method.

1                   There's a random sample method  
2 where you go in and go to the doctor's office.  
3 You're going to get higher, more credible  
4 rates than you get using the same  
5 specification, because there is more  
6 information there that is not available  
7 administratively. But it's the same  
8 specification.

9                   DR. PACE: But this measure  
10 requires looking at the -- getting the actual  
11 value. That's not going to be in  
12 administrative claims.

13                   MEMBER McDERMOTT: If we have --  
14 with LOINC codes, yes, we have the  
15 administrative data. Yes.

16                   CO-CHAIR ROSENZWEIG: You're  
17 talking about the physician recognition  
18 program for diabetes? Is that what you're  
19 referring to with this particular  
20 physician-based measure?

21                   MR. REHM: I know this is kind of  
22 hard to grapple with. We have a program that

1 uses the -- what we would reference as the  
2 parent measure, which is -- has a longer  
3 history, which is the HEDIS health plan  
4 measure. And the physician groups got  
5 together and said what would be appropriate  
6 physician measurement for people who want to  
7 be recognized, and they developed that  
8 program.

9 We are not asking NQF to endorse  
10 that program. We happen to have data on the  
11 use of a physician level measure, and we are  
12 sharing that with you. That is --

13 CO-CHAIR GOLDEN: But let me just  
14 make sure I understand. So in the denominator  
15 for that program, it is 30 consecutive  
16 diabetics in your practice?

17 MR. REHM: Yes. That is a  
18 fundamentally different denominator. I think  
19 the intention -- you know, measure  
20 implementation, whether it's at a health plan  
21 level or a provider level or a group level, or  
22 you can cut it in a variety of different ways,

1 is probably going to have implementation  
2 requirements that are unique to themselves.

3 I think if you look at the  
4 portfolio of NQF measures, all 8- or 900 of  
5 them, I would imagine that you would not have  
6 each measure -- 600, sorry, Helen. You  
7 wouldn't have a measure that was specified  
8 perfectly for each type of use that would be  
9 out there. It would be almost impossible to  
10 --

11 CO-CHAIR GOLDEN: And that is part  
12 of the NQF's problem.

13 MR. REHM: Well, you know, I think  
14 we can -- we would love to address the  
15 totality issue. And we feel your pain because  
16 we also try to get the balance right. And I  
17 guess what I'm just trying to share with you,  
18 had we not had a physician recognition  
19 program, then we would have had the PQRS  
20 program that is using the measure.

21 And it's out there and it has its  
22 own rules of the road. And is it finding the

1 same variation in practice? Yes, about the  
2 same. I mean, it's -- I just think we can,  
3 you know, chew on the bone of how it's used in  
4 this program or that program or another  
5 program. It might end up being less filling,  
6 and I can understand why it's unsatisfying to  
7 have a specification that does not fit  
8 perfectly into every single implementation or  
9 use.

10 And I'm just trying to educate  
11 folks about --

12 CO-CHAIR GOLDEN: I don't want to  
13 pound this on the ground, but that's why we  
14 have -- there has been a cycle. We have rooms  
15 like this, we have rooms at NCQA, and then we  
16 have other rooms with the same people talking  
17 about harmonization of measures. And what  
18 you've just described is why nothing is  
19 harmonized, because everyone is making up  
20 their own variations to fit their programs.

21 MR. SAUNDERS: Can I clarify? I  
22 think the difference here, though, is that the

1 -- how you get into the denominator is  
2 consistent across every implementation here.  
3 These are the things that you have to trigger  
4 to be a diabetic. What is different in the  
5 implementation here, and what we're describing  
6 about the testing results, is about the  
7 sampling strategy and how you -- the validity  
8 of the performance rate. It's a different  
9 question than the denominator. The  
10 specification of how we sample cases and the  
11 data that you are reviewing is not part of the  
12 specification, and that is I think where the  
13 distinction is.

14 DR. BURSTIN: This is a really  
15 complex issue and we recognize this, and this  
16 is certainly bigger than NCQA, and I think it  
17 affects all of us. But, again, this measure  
18 is not about its use in the physician  
19 recognition program. It is the physician  
20 level measure below -- clinician level measure  
21 I hope below the overall health plan level  
22 measure, which at least gives us some

1 alignment.

2 So I think the alignment issue  
3 here is actually important. But, again, it is  
4 not -- you are not approving the measure that  
5 is in use in the sampling strategy for the  
6 physician recognition program. That is NCQA's  
7 program. This is the measure specifications  
8 at this other level of performance.

9 So, I mean, I know there are  
10 questions being raised because these -- the  
11 testing you have been presented is on the  
12 physician recognition program, but I think  
13 they are slightly different questions.

14 MEMBER DUVA: I just wanted to  
15 suggest that we stick to what the issue is,  
16 and this data was presented for reliability of  
17 the measure. Reliability is different than --  
18 well, like any measure, you have to test for  
19 reliability in whatever population you put it  
20 in. So this measure may not be reliable in  
21 that population. We don't know because of the  
22 noise, so we don't know either way.

1           I think what the developer did was  
2 present to us what data they had in terms of  
3 reliability, and we cannot say that it is  
4 reliable in that specific population. But it  
5 does not mean that the measure is not reliable  
6 in other populations, and it doesn't mean that  
7 the specifications are inappropriate or have  
8 changed. It is whether or not it is reliable  
9 in that specific population that they happen  
10 to produce at the provider level, and that's  
11 it. That's all we have, and we can't read any  
12 more into it because then we're going way  
13 beyond what we have been presented.

14           MEMBER KIRKMAN: What she said.  
15 And I think this is a -- this is a meta issue  
16 and not specific to this measure or to NCQA or  
17 to diabetes measures. And I suggest we move  
18 on.

19           CO-CHAIR GOLDEN: That's fine. We  
20 should vote, unless people want to have final  
21 comments.

22           MS. BAL: So to repeat the



1 question, do the results demonstrate  
2 significant reliability to the -- sorry, I  
3 can't read from there. So the differences in  
4 performance can be identified both -- for both  
5 plans and individual physicians. And the  
6 voting is open.

7 We are just waiting on one more,  
8 so if everybody could just retry just in case.  
9 Okay. Perfect. Thank you. So we have high,  
10 three; moderate, 14; low, three.

11 CO-CHAIR GOLDEN: We go now to  
12 validity.

13 MEMBER DUCWORTH: Okay. The group  
14 -- here again, we rated this moderate to high.  
15 There were parallel concerns that we saw on  
16 the reliability testing that one of the  
17 comments was, yes, correlation coefficients  
18 were generally strong to very strong, that we  
19 are seeing higher validity and correlation for  
20 health plan data than physician level data.  
21 So, here again, moderate to high.

22 CO-CHAIR GOLDEN: Comments?

1 Questions?

2 (No response.)

3 Ready to vote?

4 MS. BAL: All right. To repeat  
5 the questions at hand, do the results  
6 demonstrate significant validity so that  
7 conclusions about quality can be made? Do you  
8 agree that a score from the measure, as  
9 specified, is an indicator of quality? Is  
10 testing adequate for both plan/system level  
11 and physician/group level? And it is now  
12 open.

13 So the final results are high,  
14 four; moderate, 12; low, four.

15 CO-CHAIR GOLDEN: Okay.

16 Feasibility.

17 MEMBER DUCWORTH: The workgroup --  
18 we agreed that the data for the measures or  
19 the data is routinely generated and used  
20 through care delivery, and that moves the EHRs  
21 and claims data, make collection analysis of  
22 this metric relatively easy, straightforward.

1 CO-CHAIR GOLDEN: Comments or  
2 questions on this one?

3 (No response.)

4 All right. Ready to vote?

5 MS. BAL: Okay. So feasibility,  
6 we're looking for data that is generated  
7 during care, electronic sources, and data  
8 collection can be implemented. And so the  
9 voting is now open.

10 Let's try one more time. We are  
11 missing one person. There we go. So it's  
12 high, 17; moderate, three.

13 CO-CHAIR GOLDEN: Use and  
14 usability.

15 MEMBER DUCWORTH: The group noted  
16 that the developer listed five current uses of  
17 the measure, including public reporting.  
18 There was some concern about patient factors  
19 regarding glucose control that are beyond the  
20 control of the provider. However, overall the  
21 workgroup did agree that the measure is a  
22 useful measure that is easy to use.

1 CO-CHAIR GOLDEN: Any other  
2 comments? This is your adverse consequences,  
3 and so forth. Didn't know if anybody wanted  
4 to say anything. I'm just giving -- opening  
5 the door for them. I cut them off before.

6 MEMBER KIRKMAN: So, I mean,  
7 again, I don't know whether this is the place  
8 to bring this up, but there is this issue of  
9 the last hemoglobin A1c, so, I mean, I guess  
10 it could work out either way. But, you know,  
11 you could have somebody that, you know, had  
12 been 12 and a half and is now eight and a  
13 half, and, you know, you made a huge benefit.  
14 But it just so happens that their last one is  
15 above this cut point. I think that's the  
16 whole issue with these threshold-based  
17 measures, though.

18 MEMBER LEE: So I just wanted to  
19 bring back up the issue of the patient voice.  
20 Of all the measures today, I feel like this  
21 one is most out of control of the physician  
22 and most in the control of the diabetic.

1 Diabetes care has changed drastically since  
2 I've been practicing the last 10 or 15 years,  
3 in that we have moved from much more -- less  
4 of a prescriptive way of dealing with diabetes  
5 to much more shared decision-making and having  
6 the patient have a voice in what they do.

7 And so I would definitely be in  
8 favor of seeing this measure perhaps  
9 reexamined or modified to include more of what  
10 the ADA has recommended, because one size is  
11 very difficult to fit all.

12 CO-CHAIR GOLDEN: What does the  
13 ADA recommend? I'm sorry.

14 MEMBER LEE: Well, the ADA  
15 recommendations that we brought before for  
16 different populations. But I think of all of  
17 the measures this is the one where the patient  
18 really comes into play, where, you know, we'll  
19 say, you know, get your -- you know, take more  
20 insulin or check more often, but it's really  
21 in the hands of the patient.

22 And I think shared decision-making

1 and patient voice should be something in  
2 consideration to a measure. That has been  
3 very valid, has been around for a long time,  
4 but I think diabetes care is changing over  
5 time.

6 MEMBER McCOLLISTER-SLIPP: Just to  
7 defend the patients, I mean, oftentimes  
8 statements like that -- and I don't think you  
9 meant this -- are construed as patients are  
10 completely unadherent and noncompliant. I  
11 mean, it's just -- we really don't have very  
12 good treatments at this point. So part of it  
13 is biology. Part of it is choice and  
14 lifestyle. And part of it is limitations  
15 like, you know, working three jobs and can't  
16 make it to the gym.

17 So just to state that for the  
18 record. It's not always an issue of choice;  
19 it's an issue of biology or circumstances.

20 MEMBER LEE: I apologize for that.

21 So --

22 CO-CHAIR GOLDEN: Ingrid?

1                   MEMBER DUVA: I have a question.  
2           This might -- this is clarification that might  
3           -- for later as we go through these meetings.  
4           But, Sue, what you said about the patient that  
5           goes from 12.5 to 8.5, so if you are reporting  
6           on both of these measures at once, are you  
7           still then penalized? Because either they  
8           have dropped out of your greater than 9.0 poor  
9           control group, but you still -- is it still  
10          kind of a -- I mean, help me understand, is  
11          that still kind of a penalty, then? Because  
12          now they're not within your under eight group?  
13          I just think it might come up later when we're  
14          talking about parsimony and what measures are  
15          -- you know, what is more useful to measure.

16                   MEMBER KIRKMAN: Yes. I mean, I  
17          think in some ways it is going to balance out.  
18          But, you know, it -- I do think it's -- you  
19          know it's a little bit -- it's sort of like  
20          saying it's not good quality of care because  
21          this percentage of your people were above  
22          eight percent, or they didn't fall in the less

1 than eight percent, when, you know, some of  
2 them could have been moving there. But, you  
3 know, I think it's going to probably balance  
4 out in the end.

5 I just wanted to say, I mean, I  
6 agree completely with what you're saying about  
7 individualization and the patient voice. But  
8 there actually are -- you know, there are very  
9 few sort of groups of patients that the ADA  
10 recommends a goal that is higher than less  
11 than eight. So it's -- you know, it's the  
12 very frail elderly, with limited life  
13 expectancy, but otherwise the sort of general  
14 ADA recommendations, it is kind of six and a  
15 half to eight.

16 So, you know, it's -- there are  
17 not going to be huge populations of people,  
18 but I totally agree. I mean, I think it,  
19 again, gets to this -- it's difficult to do  
20 patient-centered care and speak to  
21 individualized care when we sort of by  
22 definition in a performance measure have to



1 say we're going to slice the pie here. I  
2 think it's difficult.

3 MEMBER McCOLLISTER-SLIPP: Yes.  
4 And I'm not suggesting that we should all  
5 shoot for, you know, whatever makes sense and  
6 whatever feels good and whatever is  
7 convenient. I mean, I obviously shoot to get  
8 my Alc under eight, and I think anybody would.

9 But I don't want to penalize my  
10 physician, and that's kind of what we're  
11 looking at. I mean, conceivably this could be  
12 used as a mechanism for limiting access to  
13 drugs. I don't think it's analogous at this  
14 point in time, but maybe it could be something  
15 like what I experienced with my anemia drug.

16 But I think the biggest issue is,  
17 are we disincentivizing physicians for taking  
18 care of the most complex, difficult-to-treat  
19 patients? And, you know, there is a lot of  
20 stuff that we've learned about diabetes, and  
21 we have gotten much better treatments, but we  
22 still don't have very good treatments and it's

1 very imprecise and it takes a lot of work.  
2 And, you know, it's easier for some people  
3 than others, and we don't really know why.

4           And I just don't want to  
5 discourage more people from taking on patients  
6 like me and the many others like me by, you  
7 know -- and, I mean, that's why I like -- what  
8 I like about what you guys did at ADA and what  
9 they are continuing to do, is it is kind of a  
10 target. But use your sense, use your judgment  
11 with the discretion. If we're studying a line  
12 in the sand, there will be implications for  
13 that, and I don't want -- we have already got  
14 a shortage of endocrinologists. I don't want  
15 that to be one of the implications, because  
16 that ultimately will hurt patients and it  
17 won't help the system.

18           CO-CHAIR GOLDEN: As an aside, I  
19 think in England in their quality programs  
20 you're allowed to exclude some people. And,  
21 you know, there are some people -- I have a  
22 couple of patients that, regardless of what I

1 do, they're going to not be in the ballpark on  
2 a parameter. But I don't want them to become  
3 orphans either, so -- so maybe that's down the  
4 road something to consider as well. You know,  
5 people are very brittle, and that kind of  
6 thing.

7 MEMBER LEDDY: I just need to  
8 speak for the practicing endocrinologists. I  
9 mean, we all know that diabetes is a hugely  
10 labor-intensive endeavor, diabetes management.  
11 And it would be good if we could put some  
12 advisory node, that there are these tough  
13 patients that are very, very hard to manage,  
14 and it would be good not to penalize  
15 physicians who care for them.

16 I practiced in a multi-specialty  
17 group for a number of years, and there is no  
18 question as these guidelines became more  
19 specific and limits were placed that I  
20 accumulated the toughest patients, the ones  
21 that were the hardest to manage. And, you  
22 know, happily or not, a lot of them didn't

1       come back because I was too tough on them.  
2       But it is a huge burden, and we mustn't forget  
3       about it.

4                   MEMBER HAYDON-GREATTING:   So this  
5       is the epidemiology view.  We need a severity  
6       of illness to add to the perspective, so that  
7       we can stratify those patients.  And I don't  
8       know -- we can't do it now because we don't  
9       have all of the -- we can't get it there.  We  
10      have to have a massive database.

11                   But if you can stratify patients  
12      by the severity of illness, then you can have  
13      -- you don't orphan, I mean, those patients  
14      that are out there.  I just worked three years  
15      to get someone from a 12 down to a nine, and  
16      we are celebrating that.  And so with this,  
17      that would leave -- my physician would be  
18      lifted out on that, but I want to honor her  
19      for busting her butt with us together to get  
20      that patient down there.  And I think we all  
21      have one of those patients or 10 of those  
22      patients, or, in some cases, in Mississippi,

1 150 of those patients.

2 CO-CHAIR GOLDEN: Yes. Oh, go  
3 ahead, please.

4 DR. PACE: I just want to, you  
5 know, ask -- you know, I know you're having to  
6 deal with the measure as it's specified, but  
7 that's exactly the question I was going to ask  
8 is about the possibility of adjusting for  
9 severity. You know, what would be the factor  
10 that would be used? Or if there were specific  
11 patients to exclude versus just  
12 self-identifying, I want to exclude these  
13 patients. Are there specific parameters that,  
14 you know, would be supported in the evidence  
15 that should be excluded?

16 So just maybe for future  
17 discussion when you get to the future.

18 CO-CHAIR ROSENZWEIG: My question  
19 about this measure is, to what -- what does it  
20 add to the previous measure that we have just  
21 considered, which we approved unanimously?  
22 The big issue I suppose is that people would

1 feel that just by adopting the other measure  
2 it would encourage physicians to basically  
3 have mediocre control of their patients, that  
4 once they got them under nine percent they  
5 would just not bother to get better control.

6 I'm not sure that's really the  
7 case, but I think that's probably the --  
8 that's the only, really, issue that -- to me  
9 that is -- that comes up here that we have to  
10 think about.

11 CO-CHAIR GOLDEN: Are we ready? I  
12 think, Anne, you've got to put yourself down  
13 there.

14 Any final comments?

15 (No response.)

16 Ready to vote? And we are voting  
17 on -- somebody read what we're voting on.  
18 Hopefully, we won't be that close.

19 MS. BAL: Okay.

20 CO-CHAIR GOLDEN: About usability  
21 -- it's used for transparency, used for  
22 improvement, benefits outweigh evidence of

1 unintended negative consequences.

2 MS. BAL: You can begin voting  
3 now.

4 Okay. The final result is high,  
5 seven; moderate, eight; low, four.

6 CO-CHAIR GOLDEN: And now we get  
7 to the big picture. Endorse, yes or no?  
8 Final comments?

9 (No response.)

10 Ready to vote.

11 MS. BAL: You may vote now.

12 We're waiting for two more. Let's  
13 try one more time. Okay. We have yes, 17;  
14 no, two.

15 CO-CHAIR GOLDEN: So they are --  
16 we're done. It's time for lunch I think. It's  
17 time for lunch. Let's get lunch. When do we  
18 reconvene? Thirty minutes? 1:30? All right.

19 (Whereupon, the above-entitled  
20 matter went off the record at 1:04 p.m. and  
21 resumed at 1:42 p.m.)

22

1 A-F-T-E-R-N-O-O-N S-E-S-S-I-O-N

2 (1:42 p.m.)

3 CO-CHAIR ROSENZWEIG: Okay. I  
4 think we'll get started again. We have a big  
5 agenda ahead of us.

6 I'd like to thank Bill for doing  
7 all of the heavy lifting. I think hopefully  
8 things will go smoother from here on in, and  
9 we'll be able to move a little bit more  
10 quickly.

11 And so, I think the next one on  
12 our agenda is going to be Number 57. And I'm  
13 looking for the list of people. Do you have  
14 the list of people who are reviewers?

15 MS. TIGHE: Yes. Anna  
16 McCollister-Slipp is the primary, and Bill  
17 Taylor is secondary, for 57.

18 CO-CHAIR ROSENZWEIG: Are we  
19 supposed to hear from the measure developers  
20 first, or have you pretty much given us --  
21 okay.

22 MEMBER MCCOLLISTER-SLIPP: Hello



1           there. I'll try to do this without getting  
2           curry on me, but we'll see.

3                        So, I mean, I can walk through  
4           this in great detail if we'd like. I would  
5           think that this might be one that would be --  
6           since it's a process measure especially, that  
7           it might be one that would be relatively  
8           straightforward.

9                        I mean, we didn't have a lot of  
10          discussion around it in terms of a measure for  
11          process during our call. And, colleagues,  
12          please tell me if I'm misremembering something  
13          other than the philosophical discussions that  
14          we have already had previously about Alc as a  
15          measure in and of itself. But, I mean,  
16          certainly my conclusion of the necessity for  
17          it was that it is certainly necessary. There  
18          is strong evidence correlating Alc -- showing  
19          Alc as an important measure of control.

20                        You know, maybe it's -- I mean, I  
21          think in my comments I described it as a  
22          necessary perhaps, but not for sufficient

1           measure of quality. So, you know, is it a  
2           high priority? Yes. There seems to be  
3           evidence to suggest a significant health  
4           problem, that we need, you know, to get better  
5           control of in a population. This is a great  
6           way of assessing general control and quality.

7                         And there wasn't much discussion  
8           around that. Bill, do you remember it any  
9           differently?

10                        CO-CHAIR ROSENZWEIG: Any other  
11           comments?

12                        MS. JOHNSON: So maybe we can just  
13           open it up to talk about the evidence a little  
14           bit. The measure is about doing the test for  
15           Alc, so is there --

16                        CO-CHAIR ROSENZWEIG: I think,  
17           obviously, there probably isn't much  
18           disagreement about the need for doing the  
19           test. The question of course comes up always,  
20           the frequency of the test. Why once a year,  
21           let's say, as opposed to once every six months  
22           or once every two years, or so forth. Any

1           comments about that?

2                           (No response.)

3           Okay. I mean, obviously -- sorry?

4                           (Off-mic comment.)

5                           CO-CHAIR ROSENZWEIG: All right.

6           Well, in this case the -- but the numerator  
7           statement is -- for this case is once a year.  
8           You've got to realize a lot of people aren't  
9           seen more than once a year in certain  
10          situations. And the other issue of course is  
11          that in order to be able to get the outcomes  
12          measures for the previous two performance  
13          measures that we just evaluated, you need at  
14          least once-a-year measurement on a yearly  
15          basis for that purpose.

16                          I mean, there are -- certainly  
17          people wouldn't disagree with the fact that  
18          patients on insulin and with Type 2 diabetes  
19          -- Type 1 diabetes might need a more frequency  
20          A1c measurement. But at least once a year  
21          certainly is a reasonable number.

22                          Okay. So any other comments?

1 Yes.

2 MEMBER DUDL: I'm wondering if --  
3 and this is something for the NCQA, et cetera.  
4 I'm wondering if we get above 95th percentile,  
5 instead of saying, you know, one plan got to  
6 98 and the other one got 97, you know, there  
7 is a small part of the population who, you  
8 know, you may not want to test, if they have  
9 Alzheimer's, et cetera.

10 I'm wondering if we couldn't say  
11 that above a certain threshold, that you've  
12 attained success and we are no longer going to  
13 rate you, because I see some people -- what  
14 happens is some people drive to get the last  
15 few percent that really aren't super important  
16 to get, instead of working on control of  
17 getting the over nines or over eights on down.  
18 It's just a thought.

19 CO-CHAIR ROSENZWEIG: Well,  
20 actually, it's a reasonable thought, because  
21 we are going to be getting to the performance  
22 gap issue in a minute. I think that's

1           actually going to be part of the discussion  
2           there.

3                           Any other -- yes.

4                           MEMBER SULLIVAN: I don't know if  
5           this is the right place to raise it, but I'd  
6           be interested in knowing what the developers  
7           thought about making this into a composite  
8           measure of the other processes of diabetes  
9           care. I know in our health plan, that's how  
10          we use it. That's how the state of New York  
11          is using it.

12                           I think it has become kind of  
13          common and you get away from the high  
14          performance, then, because, you know, having  
15          done all of the measures. So I just wondered  
16          what the developers want to say about that.

17                           MR. REHM: The humor here is that  
18          we did have an NQF-endorsed composite. It is  
19          simply not used in the market. And when you  
20          don't have a use -- thinking about use and  
21          usability -- so we withdrew it because the  
22          market said thank you, but not all that

1 interested.

2 There are clearly competing  
3 measures. Later on, in Phase 2, you'll look  
4 into the all-or-nothing measure, which is in  
5 many ways a hybrid of many of the measures  
6 you're looking at here and then some other  
7 preventive health measures.

8 So, you know, I think Mary spoke  
9 to why we see some advantage of having these  
10 individual measures in play. And when we talk  
11 about performance, you know, I can just point  
12 out that there is a gap, you know, a gap that  
13 we feel about 10 to 15 percent, between the  
14 10th percentile and the 90th percentile of  
15 performers.

16 So when we see that, that's  
17 cautionary. When we see gaps between  
18 commercial and Medicaid, that's cautionary.  
19 And then we don't share it with you, but we  
20 have regional data that shows, as you can  
21 imagine, although it's different for each  
22 measure, different gaps in care there.

1 CO-CHAIR ROSENZWEIG: Any other  
2 comments related to evidence? Yes, Bill.

3 MEMBER TAYLOR: So we did discuss  
4 briefly, in our subcommittee conversation,  
5 that there is no evidence for the periodicity  
6 with which the testing gets done, and there  
7 never will be. Nobody has ever done a trial  
8 comparing every six months and every 12 or 15  
9 or nine or something. So it's sort of what is  
10 reasonable and what is the sense, you know, if  
11 you do it too much, and what are the  
12 consequences, or not enough, and it's going to  
13 be a sort of face validity judgment call  
14 around the table, I think, about the  
15 periodicity question, as it is elsewhere when  
16 it is, you know, why do we do these things  
17 once a year?

18 The other one -- I think the --  
19 this was one of the ones that measure  
20 applications partnership did not endorse. Is  
21 that correct? Is there something we should  
22 learn from that?

1 DR. PACE: Well, one of the  
2 things, I mean, it's probably related to the  
3 fact that this is what we often refer to as a  
4 distal process. And as someone pointed out,  
5 it is necessary but not sufficient. And when  
6 you look at the evidence that is presented, it  
7 is based on expert opinion. So that's  
8 something that you all will have to think  
9 about, whether you want to make an exception  
10 to our evidence criterion for this measure,  
11 meaning that, you know, most of the evidence  
12 is about the control or the treatment versus,  
13 you know, taking the assessment once a year or  
14 several times a year.

15 So, you know, and this was  
16 actually embedded in those control measures.  
17 So patients -- if the assessment wasn't done,  
18 it didn't -- you know, it marked against the  
19 performance. So I think that's the main  
20 motivation from the map standpoint is that  
21 it's one of these process measures. It's very  
22 distal. It's necessary, but it's not



1 sufficient. And they're trying to drive  
2 towards, you know, more intermediate outcomes,  
3 outcomes, and the actual treatment kinds of  
4 process measures.

5 Helen, anything else?

6 CO-CHAIR ROSENZWEIG: Sue?

7 MEMBER KIRKMAN: So, I don't know  
8 if we're still on evidence because it seems  
9 like we've -- we're having some non-evidence.  
10 But it was kind of my point, too. I mean,  
11 it's almost like this is already embedded in  
12 several other measures that are going to  
13 continue. And so, what's the point? I mean,  
14 maybe that's just a bigger question.

15 And, you know, it's a little bit  
16 like, you know, there's a lot of outcome  
17 evidence for high blood pressure or lowering  
18 blood pressure, and so, you know, if 99  
19 percent of people are getting their blood  
20 pressure measured, do you really need a  
21 performance measure on it? I mean, it's not  
22 quite as high here, but performance is pretty

1 high.

2 CO-CHAIR ROSENZWEIG: Yes. I  
3 think that is going to be -- we're going to  
4 deal with that in the second issue related to  
5 the performance gap, I think, which is going  
6 to obviously come up.

7 MEMBER KIRKMAN: So I guess we  
8 should, you know, finish up the discussion of  
9 evidence and vote on that.

10 CO-CHAIR ROSENZWEIG: Yes. So any  
11 other additional comments about the issue of  
12 evidence?

13 DR. PACE: So if you -- just to  
14 remind you about the algorithm for evidence,  
15 Algorithm 1, when we have a measure that's  
16 based primarily on expert opinion, you know,  
17 Box 10, the first question is, are there or  
18 could there be performance measures of a  
19 related health outcome or evidence-based  
20 intermediate clinical outcome or process?

21 And if the answer is yes, then the  
22 algorithm says no exception. And then if the

1           answer to that is no, is there evidence of a  
2           systematic assessment of expert opinion? And  
3           you answered that. And then the last question  
4           is, does the Steering Committee agree that it  
5           is okay or beneficial to hold providers  
6           accountable for performance in the absence of  
7           empirical evidence?

8                         So I guess the question here is,  
9           you know, first of all, kind of working  
10          through this, whether you -- you know, what  
11          we'll be asking you is to -- you would need to  
12          vote whether it meets our exception criteria  
13          to move this measure forward.

14                        So maybe we should have a  
15          discussion about that first, the algorithm.  
16          Mary, do you want to --

17                        CO-CHAIR ROSENZWEIG: Yes. Tracy?

18                        MEMBER BREEN: Sorry. All of a  
19          sudden I had brain fog. We are just talking  
20          about A1c testing as a value of measuring for  
21          diabetes control, right? Is that what we're  
22          saying?

1 CO-CHAIR ROSENZWEIG: Yes.

2 MEMBER BREEN: So it's almost like  
3 we should have done this one first, right?  
4 Because this is the basic measure, like, we  
5 need to do this test in order to measure  
6 diabetes control. And then whether it's  
7 greater than nine or less than eight is really  
8 kind of drilled down on that, so I think  
9 that's maybe where my brain fog is coming in.  
10 So if we just separate that out and say, are  
11 we saying that there's data to support Alc  
12 testing and outcomes? I think there is very  
13 clear data on that.

14 DR. PACE: So this is, you know,  
15 where it gets a little fuzzy is that there is  
16 -- the evidence is about the control, right?  
17 And obviously, in order to manage it, you have  
18 to do the test.

19 And the question is, do you have  
20 to have a -- I don't think there is anyone at  
21 all that questions that it's important and  
22 necessary to do the test. The question here

1 is, do you need a performance measure on doing  
2 the test? Or can you construct performance  
3 measures that are based on the outcome and the  
4 treatment? That's the major question that you  
5 are addressing.

6 So, you know, we have a process  
7 for you to accept -- you know, to pass this on  
8 an exception to the evidence if you think  
9 it's, you know, important to continue this as  
10 a performance measure on evidence. And then  
11 you will get to the performance gap, as you  
12 have been talking about, so that may be  
13 another issue where you have some concerns.  
14 But the first question is about the evidence.

15 CO-CHAIR ROSENZWEIG: Any other  
16 comments? Yes. Bob?

17 MEMBER BAILEY: Well, I guess the  
18 major question would be here because you're  
19 not dependent on having a laboratory value,  
20 that your measurement population is larger  
21 both in terms of the numerator and the  
22 denominator. And does that provide any

1 different insights as opposed to having --  
2 limiting it to the population where you have  
3 the specific laboratory values?

4 CO-CHAIR ROSENZWEIG: Were you  
5 going to comment?

6 DR. BARTON: If I might.

7 CO-CHAIR ROSENZWEIG: Sure.

8 DR. BARTON: So I would say to the  
9 initial formulation, I agree that it's a  
10 judgment call, whether you say that the  
11 evidence is only for the management and  
12 doesn't include the step of the testing, but  
13 -- so be that as it may, I think the point  
14 that you just made is absolutely true.

15 If the hemoglobin A1c testing can  
16 be reported on an entire population by use of  
17 administrative claims, it potentially is being  
18 reported on a much larger population of  
19 diabetics than the ones whose -- you know,  
20 there was some discussion before about the  
21 hybrid reporting. And, you know, in our --  
22 both in our Medicaid and our commercial groups

1 of health plans, 95 percent of the plans do go  
2 look at charts to get the hemoglobin results  
3 for the less than eight and greater than nine  
4 measures.

5 So those samples are 411. That's  
6 what NCQA has determined is statistically  
7 reliable for our health plan reporting. And  
8 so, there would be a difference in the use of  
9 the hemoglobin A1c testing. I would also say  
10 that, again, you know, would that we all were  
11 at Kaiser and had, you know, 98 percent on so  
12 many things. But health care in this country  
13 is not uniformly at that level, and so I think  
14 that finding that measures look too low bar in  
15 some tables, and that if you were to go  
16 somewhere else you would find that that's what  
17 they're just struggling with, the first steps.

18 CO-CHAIR ROSENZWEIG: I think the  
19 big issue here is, 10 years ago, this  
20 obviously was an important measure. Is it  
21 still an important measure now?

22 Should we vote on the evidence

1 issue? Oh, comment. Sorry. Bill?

2 MEMBER CURRY: So from a  
3 practicing clinician's point, this process  
4 measure is embedded in the two previous  
5 measures that we looked at. But when I get  
6 the data from my payers, or I as the quality  
7 person in our medical group provide this  
8 information to my partners, we need to have a  
9 list of the individuals whom we're serving who  
10 have a gap. And if we get that information,  
11 if we get -- if we try to get that information  
12 from the previous two measures from our  
13 insurers, we'll just know if they're in range  
14 or they're over nine. But I won't know who  
15 has not had the Alc. It's there. It's part  
16 of the --

17 CO-CHAIR ROSENZWEIG: It's part of  
18 the numerator. Yes.

19 MEMBER CURRY: But we'll have  
20 difficulty culling that out. So for the  
21 provider at the field, this I think is an  
22 important piece to help them identify those



1 patients in their population who have the gap.  
2 I think it will be much easier for this to be  
3 information used at the provider level.

4 CO-CHAIR ROSENZWEIG: Okay. Any  
5 other comments?

6 (No audible response.)

7 All right. Why don't we vote on  
8 the evidence.

9 MS. BAL: Go ahead and vote.

10 CO-CHAIR ROSENZWEIG: Not enough  
11 yet?

12 MS. BAL: Still missing two more,  
13 if we could just try to click one more time.

14 Okay. We have high, 10; moderate,  
15 six; low, one; and insufficient evidence for  
16 three.

17 CO-CHAIR ROSENZWEIG: Okay. So  
18 the next issue is related to the performance  
19 gap that is addressed by this measure. And  
20 here, I think there is no question that over  
21 a period of time, the performance gap has  
22 narrowed. Would the reviewers like to comment

1 on this?

2 MEMBER McCOLLISTER-SLIPP: Yes. I  
3 mean, obviously, the performance gap has  
4 narrowed. There is, you know, in some health  
5 plans, like commercial health plans, there is  
6 significant compliance in meeting this  
7 quality.

8 But having said that, I would say  
9 that there is enough variation, especially if  
10 you look at Medicaid, that this still needs to  
11 be -- and even Medicare, the HMO rate for  
12 Medicare, I mean, it kind of blows my mind  
13 that somebody wouldn't be testing somebody who  
14 has diabetes for Alc. I mean, as, you know,  
15 just sort of a -- I'm not a huge fan of it as  
16 a measure, but it's -- if somebody is not  
17 doing that, there is a pretty good chance that  
18 it's not a particularly high-quality  
19 physician.

20 CO-CHAIR ROSENZWEIG: You know,  
21 I'm not actually as concerned about the  
22 Medicare rates. They are pretty high, and

1           there are a lot of very elderly people in that  
2           population that probably don't necessarily  
3           need yearly Alc rates. But the Medicaid  
4           certainly is, you know, 20 percent of the  
5           patient population is not getting Alc's on a  
6           regular basis. So I think that probably is  
7           more significant than I thought it would be.

8                         Someone else had a comment over  
9           here? Bill.

10                        CO-CHAIR GOLDEN: Yes. You know,  
11           in our state, it's worse. And some of it is  
12           -- and there may not be the position or the  
13           clinic. It could be the access issues and the  
14           outreach needs, especially with ACA and  
15           expansion of potential new patients under the  
16           systems with coverage. Unfortunately, it  
17           still has some validity and use. So it's --  
18           we're using it now in dashboards for big  
19           systems, and it's -- there is still quite a  
20           bit of a performance gap.

21                        CO-CHAIR ROSENZWEIG: Sue?

22                        MEMBER KIRKMAN: So is the

1 performance gap narrowing or improving? I  
2 mean, it looks to me like since it was last  
3 endorsed the numbers have stayed about the  
4 same. I mean, Medicaid is lower. Everybody  
5 else is at about 90 percent over the three  
6 years. So is it really driving improvement in  
7 care at this point? Or is it kind of where  
8 it's going to be and it's not driving  
9 improvements?

10 MR. REHM: In that section that  
11 has our performance data, which is I think  
12 1(b)(2), if you'll look at the 10th percentile  
13 unit, which is really the lowest bracket,  
14 you'll see that that is moving up, and it's  
15 moving up, it looks like about a point or a  
16 point and a half.

17 Generally, over all of our  
18 measures a point a year is not -- that's  
19 pretty good. It's actually moving a lot of  
20 populations into improved care. I think the  
21 other thing that we really don't understand  
22 here, and Robert, who is head of our Research

1 Unit, may throw a brick at me for asking to  
2 think about other things, but we will probably  
3 increase -- and I don't know the epidemiology,  
4 but my sense is that we are adding more people  
5 with diabetes into the denominator than we  
6 are, if you will, treating correctly.

7 And so you are chasing something  
8 that's ballooning. And to maintain a rate  
9 like that -- so I'm speculating because I  
10 don't have the data and I'm sorry. That could  
11 be a significant accomplishment. So sometimes  
12 there is more underneath the radar here than  
13 we may see from just the performance rates.

14 MEMBER KIRKMAN: But it seems like  
15 the 10th percentile in some groups it has gone  
16 down, in other groups it has gone up. Am I  
17 reading this data wrong?

18 MR. REHM: I was focused on the  
19 Medicaid, because that had been brought up as  
20 an important area. I think that has gone up.

21 MEMBER KIRKMAN: Okay. But like  
22 commercial HMO, it's actually gone down.

1 Commercial PPO, it's gone up. There is one  
2 where it went from 63 to 34 to 62 over three  
3 years.

4 DR. BARTON: I think the 34 is an  
5 error in that table.

6 MEMBER KIRKMAN: Okay. But,  
7 again, if the -- it went from 63 to 62. So I  
8 guess I don't really see this trend towards  
9 even the 10th percentile going up.

10 MR. SAUNDERS: I think one thing  
11 we might sort of emphasize is that -- so  
12 HEDIS, as it's implemented across these health  
13 plans -- Medicaid, Medicare, commercial -- is  
14 a pretty mature program, and many of the plans  
15 that are participating in this have been doing  
16 this for a while.

17 But the measure has uses outside  
18 of HEDIS, and that -- say, use in the  
19 exchanges or use in other contexts where you  
20 sought health plans that may be measuring  
21 populations for the first time, you may --  
22 while it may be a low bar in some

1           circumstances, it will not be a low bar for  
2           those populations.

3                         And so we might see greater  
4           performance gaps in other measured  
5           populations. It's just that we don't see that  
6           in our data because many of these plans have  
7           been working on this for so long.

8                         MEMBER KIRKMAN: But I guess,  
9           again, and maybe I'm getting too meta here,  
10          but, you know, if you're spending time  
11          collecting this performance measure, you're  
12          not spending time on something else. So, you  
13          know, I mean, I just -- I don't see a clear  
14          pattern that it's improving care. Rates are  
15          pretty high, and it's embedded in another --  
16          two other measures.

17                        So, I mean, I think it is -- you  
18          know, you can't just say oh, it's okay, we can  
19          keep collecting it, because again, if you're  
20          collecting this, you're not doing something  
21          else. So, and there can be too many measures.

22                        MEMBER McCOLLISTER-SLIPP: Is that

1 true, though? I mean, and I honestly don't  
2 know how this is done. I would think that  
3 that would be a relatively easy thing to  
4 extract from EHR data or other things that you  
5 are going to already be collecting.

6 MEMBER KIRKMAN: Well, even so, I  
7 mean, if -- it does take some time, even if  
8 it's pretty easy. And so if it's not worth  
9 doing, or if you're -- if you're not able to  
10 do something else that might be more  
11 worthwhile because you're doing this, then  
12 that seems like a reason not to do it. But --

13 CO-CHAIR ROSENZWEIG: There are  
14 two issues. There is whether or not there is  
15 enough of a gap, and then there is the issue  
16 of whether or not this gap is amenable to  
17 being improved. So the question I have -- I  
18 would have related to this is, what percentage  
19 of the patients who don't get Alc's measured  
20 are not seen in the previous year? Do you  
21 have any data on that?

22 DR. BARTON: We don't have data on



1           that.  But I would say that, you know, the  
2           question is, is there -- is there a gap in  
3           care?  Not is there a gap in care everywhere?  
4           And what -- you know, the data that we have  
5           provided to you shows that, you know, just,  
6           for example, the Medicaid HMO rate is very  
7           stable I the median, 77, 78, 79, but the 10th  
8           percentile has gone up from 41 to 59 percent.

9                        So these are places that are, you  
10           know, organizing their care differently to get  
11           more -- I mean, at least you have to get the  
12           patient in if they are going to get their A1c  
13           tested.  But we don't have data to answer your  
14           exact question.

15                       CO-CHAIR GOLDEN:  Okay.  Can I  
16           make a comment about burden?  I would say that  
17           this -- the burden of this measure is trivial  
18           for a couple of reasons.  One, it's an  
19           administrative measure; people are familiar  
20           with it.  Two, they have already developed the  
21           algorithms.  So it is already -- it is just  
22           off-the-shelf software for most programs now,

1 so they just have to rerun the algorithm.

2 So I don't think it would be --  
3 the amount of work involved now to replicate  
4 the measure year in and year out is pretty  
5 small.

6 MEMBER KIRKMAN: Well, again, I  
7 mean, I -- so I'm new to this process, but you  
8 do retire measures, right? You do sometimes  
9 drop them. I mean, even though you say -- I  
10 mean, I agree, it's easy, but it's kind of  
11 like we tell our primary care doctors, well,  
12 it's easy to just do one more thing or to do  
13 -- you know, follow one more guideline. Or,  
14 you know, this is not going to take that long,  
15 but again, it's the totality and I just think  
16 we should think carefully about whether this  
17 is providing enough benefit and enough  
18 additional information to continue it.

19 CO-CHAIR ROSENZWEIG: Any other --  
20 yes, Ingrid.

21 MEMBER DUVA: I have a question  
22 for Bill Curry. Can you explain again -- you

1           said that the eight percent and the nine  
2           percent, the good care and the bad care, they  
3           are not going to provide the provider the  
4           information they need. I didn't understand  
5           that, because I thought you would need the  
6           measure just to calculate those measures.  
7           They are not available?

8                         MEMBER CURRY: So if we look at  
9           the list of patients who have an Alc over nine  
10          percent, embedded in that population is a  
11          group of people that did not have an Alc in  
12          the past year. So it's going to be more  
13          difficult perhaps to be able to give that list  
14          to the provider to say, you know, here's a  
15          list of patients that have an Alc over nine.  
16          Or are they on that list because they weren't  
17          tested in that year?

18                         So the process measure is embedded  
19          in both of those. But to provide a list of  
20          patients who did not get checked in the last  
21          year, as this one is doing, as an easy way for  
22          them to look at the gap and then have their

1 care team engage that patient in care, it  
2 makes it easier for those people that are  
3 using this kind of -- either claims data from  
4 our carriers or that we generate internally.

5 MEMBER DUVA: Okay. I just --  
6 thanks. That clarified it. I just wanted to  
7 know that works on the assumption that you are  
8 not trying to, you know, take apart your  
9 process and figure out what is wrong with your  
10 process because you've got all these people  
11 with -- in the over nine percent category that  
12 may not be over.

13 Now, I know at the VA, we make a  
14 directed effort to get everybody tested, so we  
15 get them out of that. If they are erroneously  
16 in that, you know, denominator, then they are  
17 -- or in the numerator, then they're out. So  
18 I see what you're saying. Thank you.

19 CO-CHAIR ROSENZWEIG: Jessie.

20 MEMBER SULLIVAN: Yes. I guess I  
21 just wanted to offer Ingrid another  
22 explanation. So we're a health plan, and many

1 of -- about 60 percent of the providers in our  
2 network are small doctors in private practices  
3 in rural areas, and they don't -- many of them  
4 don't have EHRs and they are not doing  
5 measurements themselves.

6 So we give them lists of their  
7 failing members, and that allows them to do  
8 this quality. But they -- as Mary pointed  
9 out, the sample for the value of A1c is for 11  
10 across the membership of our entire plan. So  
11 it might be one of the diabetics in your  
12 practice, but the denominator for this measure  
13 is everyone. So we are giving them a list of  
14 everyone who hasn't been in, whereas on that  
15 measure we'd just be giving them the one  
16 person who fell in the sample.

17 MEMBER DUVA: Okay. So how does  
18 that not cover just the standard A1c testing,  
19 then? I mean, you're still going to be  
20 attacking the same problem when you try to  
21 improve. You've got to get the test done,  
22 right? No?

1                   MEMBER SULLIVAN:  So I guess I'm  
2                   saying that because this is a measure, we give  
3                   doctors in our practice a list of their  
4                   hundred patients with diabetes and which ones  
5                   haven't been tested.  If we were only doing  
6                   the Alc level test, we would give them the  
7                   name of the one person who fell in the measure  
8                   in the same and had failed.  So we are giving  
9                   them a much smaller sample because this  
10                  measures everybody.

11                  DR. PACE:  So did the other  
12                  measures.  The denominator was everybody,  
13                  right?

14                  MEMBER SULLIVAN:  Not as it's  
15                  implemented by NCQA.

16                  MS. BAL:  So we'll be voting on  
17                  performance gap, which is -- hold on one  
18                  second -- which will be data demonstrating  
19                  considerable variation, overall less than  
20                  optimal performance across providers and/or  
21                  population groups.  And you can vote now.

22                  Okay.  We have high, three;

1 moderate, 13; low, four.

2 CO-CHAIR ROSENZWEIG: Okay. Let's  
3 move on now to discuss the impact. Any  
4 comments?

5 MEMBER KIRKMAN: Can I ask a more  
6 general question about this priority category?  
7 It's not necessarily that the disease is a  
8 high priority. It's that the measure itself  
9 is a high priority, right? So, I mean, for --  
10 if it's just the disease, we could say all of  
11 the diabetes ones are a high priority, right?  
12 So it's really the measure. Is that correct?

13 CO-CHAIR ROSENZWEIG: It's my  
14 understanding, yes, that it's the measure  
15 itself, not the -- obviously, not the disease.  
16 So it's the priority of this particular -- the  
17 impact of this measure on overall health. I  
18 mean, obviously, diabetes has a high priority.  
19 But whether or not this particular measure is  
20 going to influence or be associated with  
21 improved care -- yes.

22 MEMBER TAYLOR: And to put a

1           little finer point on that one, it's -- if I  
2           understand it right, it is in the context of  
3           having the other measures that are already out  
4           there right -- our less than nine and our less  
5           than eight. Incrementally, how much does this  
6           add, as a priority? Is that the correct way  
7           to see this question?

8                           CO-CHAIR ROSENZWEIG: I believe  
9           so. Is that the general view?

10                          DR. PACE: You know, we ask you to  
11           look at the measures independently, but, you  
12           know, certainly it is looking at the condition  
13           as well as the impact of poor quality on this  
14           particular measure, so -- or, on what is in  
15           the numerator. So it's a combination of those  
16           things, but I think you're right in -- you  
17           know, so I think in terms of your evaluation,  
18           we look at each measure independently.

19                          So, you know, it really is to  
20           think about the target population as well as  
21           the numerator event or process that's being  
22           measured and what impact that has.



1 CO-CHAIR ROSENZWEIG: Okay. Any  
2 other comments?

3 (No audible response.)

4 Okay. Why don't we vote on  
5 priority, then.

6 MS. BAL: Okay. So high priority  
7 addresses a specific national health goal or  
8 priority, or data demonstrated a high-impact  
9 aspect of health care. And you can begin  
10 voting.

11 Okay. So we have high, eight;  
12 moderate, seven; low, five.

13 CO-CHAIR ROSENZWEIG: Quite a  
14 spread. Okay. So the next issue is the  
15 reliability of the specifications. Comments  
16 by the reviewers?

17 MEMBER McCOLLISTER-SLIPP: In  
18 terms of the specification or specificity, I  
19 mean, the workgroup certainly concluded that  
20 it was highly specific. Are we looking at  
21 that specifically or -- no pun intended.  
22 Reliability, I mean, there seems to be a

1           pretty high suggestion of reliability in terms  
2           of the ability to collect the data. And, I  
3           mean, I don't think there was much discussion  
4           around that. Do you remember, Bill? It has  
5           been a few weeks, but based on the comments  
6           here it seems to be relatively -- relative  
7           degree of certainty about the reliability.

8                           CO-CHAIR ROSENZWEIG: Okay. Any  
9           comments by anyone else?

10                           (No audible response.)

11                           Let's vote on this one.

12                           MS. BAL: Okay. So reliability  
13           would be the specifications and testing for  
14           this, and the voting is now open.

15                           Can we try again? We're missing  
16           one person. This one has high, 16; moderate,  
17           four.

18                           CO-CHAIR ROSENZWEIG: Okay. So  
19           let's go on to validity here.

20                           MEMBER McCOLLISTER-SLIPP: Again,  
21           trying to remember back to where we were, I  
22           mean, some of the validity questions that were

1 raised by the workgroup were -- you know,  
2 would it -- does it make sense to include  
3 people under 18 or over 75? And I would say  
4 that there is -- I'm not completely sure why  
5 that determination was made.

6 And, I mean, the test, in and of  
7 itself, seems to be relatively valid. I think  
8 this gets back to some of the necessary but  
9 sufficient -- that the way the test is  
10 conducted seems to be valid.

11 Bill, any further comments? I  
12 just don't know how much detail you want me to  
13 get into.

14 CO-CHAIR ROSENZWEIG: No, I think  
15 that's okay.

16 MEMBER McCOLLISTER-SLIPP: Okay.

17 CO-CHAIR ROSENZWEIG: I think the  
18 issue about over 75 is -- I mean, obviously,  
19 a lot of people over 75 would benefit from A1c  
20 testing, but at a certain point you do get  
21 into a situation where, especially in patients  
22 who have relatively mild diabetes, whether or

1 not getting Alc's would necessarily be of that  
2 much benefit.

3 With respect to less than 18, I  
4 think we are just restricting ourselves to the  
5 adult population as far as this measure is  
6 concerned. And probably, you know, the  
7 pediatric population, you know, will have to  
8 have additional measures for them separately.

9 MEMBER HAYDON-GREATTING: I don't  
10 know that there's a reliability of the Alc  
11 past that age range because of the variability  
12 in the hemoglobin when you get into those  
13 complicated elderly patients. I mean, as an  
14 example, my mother-in-law runs 200s, 300s on  
15 her finger checks and her Alc came back last  
16 week at 6.5. So it should be showing higher  
17 for her if she's running these daily glucoses  
18 at 300s and 200s and -- but she's 86 years  
19 old. She gets a little -- she says she gets  
20 goofy, she sits down, she -- you know, I mean,  
21 so she's managing it, and I see a lot of  
22 elderly patients, especially little, mini,

1 frail people who the hemoglobin A1c may not be  
2 the -- and there's some study out there.  
3 There's somebody that just recently hit  
4 Newsweek about challenging -- you know, should  
5 we put all of our credit into the HbA1c as we  
6 are.

7 CO-CHAIR ROSENZWEIG: Well, this  
8 issue has come up, obviously -- oh, I'm sorry.

9 MEMBER KIRKMAN: It actually, on  
10 average, it tends to run a little higher in  
11 older people. But I don't -- but I think, you  
12 know, the other issue might be that, you know,  
13 at a certain point also, it might not be that  
14 they have such mild disease, but maybe  
15 somebody's got so much comorbidity. You know,  
16 an Alzheimer's patient in a nursing home, do  
17 they need an A1c? Probably not.

18 CO-CHAIR ROSENZWEIG: Yes, that  
19 was --

20 MEMBER KIRKMAN: That's not saying  
21 everybody over 75 falls into that, but --

22 CO-CHAIR ROSENZWEIG: Yes. As I

1           get older, I -- I mean, there are a lot of  
2           people -- yes, at a certain age, even if the  
3           A1c is accurate, is it really necessary? Of  
4           course, as I get closer to age 75, I think,  
5           oh, it must be much more important.

6                               (Laughter.)

7                       But the other issue that has come  
8           up that's really a separate issue from this,  
9           but it more relates to the issue of using A1c  
10          to diagnose diabetes, is that there has been  
11          a lot of controversy about that because of  
12          their different relationships between A1c and  
13          average blood glucose control in different  
14          ethnic populations, which has come up. East  
15          Asians, Indian populations, as well as  
16          Hispanic populations, as far as I can recall.

17                           But I don't think that that  
18          necessarily applies here where you are looking  
19          for overall glycemic control in patients with  
20          diabetes.

21                           Any other comments?

22                           (No audible response.)

1                   Okay.  So let's vote on this.

2                   MS. BAL:  Okay.  We're voting on  
3                   if the specifications are consistent with  
4                   evidence, and that testing and threats are  
5                   addressed.  There is -- the exclusions, risk  
6                   adjustment, meaningful differences, multiple  
7                   specifications, and missing data are all  
8                   looked at.  And then you can go ahead and vote  
9                   now.

10                   So we're just looking for two  
11                   more.  If we could just try and -- I guess try  
12                   one more time.  There we go.  Thank you, guys.  
13                   And so we have high, 11; moderate, nine.

14                   CO-CHAIR ROSENZWEIG:  Okay.  
15                   Feasibility.

16                   MEMBER McCOLLISTER-SLIPP:  Oh,  I  
17                   found my place this time, so slightly less  
18                   flipping around.

19                   In terms of feasibility, there was  
20                   general agreement this is a pretty feasible,  
21                   pretty easy to access statistic, or pretty  
22                   easy measure to extract from existing claims

1 data or EHR data, things that people are  
2 already collecting. So it didn't seem -- the  
3 workgroup did not seem to think it would be  
4 additional burden.

5 If there are processes -- I mean,  
6 I do EHR data stuff, so my sense is that it  
7 would be relatively easy to extract. But if  
8 there are processes that would affect smaller  
9 practices or other people, I'd love to know  
10 what those are. I don't know, but it seems  
11 like of the measures this would be pretty easy  
12 to come by.

13 CO-CHAIR ROSENZWEIG: Any  
14 comments?

15 (No response.)

16 Let's vote.

17 MS. BAL: So we're voting on  
18 feasibility, and that is for -- that the data  
19 generated during care, there is electronic  
20 sources, and data collection can be  
21 implemented. And the voting has started.

22 And the results are 18, high;



1 moderate, two.

2 CO-CHAIR ROSENZWEIG: Okay. So  
3 use and usability. This may have slightly  
4 more discussion. Yes.

5 MEMBER SHWIDE-SLAVIN: Well, I  
6 think there would be a possible unintended  
7 consequence if this was not done, because it  
8 has taken a long time to educate the public  
9 that they need to have an Alc test done to  
10 understand how their diabetes is doing and for  
11 the physicians to take the test. And if they  
12 weren't being measured, I wonder if that  
13 message would continue to be heard out there.

14 CO-CHAIR ROSENZWEIG: So, a good  
15 point. I mean, that has been applied in other  
16 situations. Yes. A lot of times the presence  
17 or absence of measures is used as a basis for  
18 denying care or essentially letting a plan say  
19 that we won't pay for this or that measure,  
20 this or that test. Obviously, Alc is not a  
21 very expensive test, but we will be getting  
22 into issues related to bone densitometry

1 later.

2 Any other comments?

3 MEMBER McCOLLISTER-SLIPP: No. I  
4 mean, that workgroup seemed to be -- I mean,  
5 putting the philosophical issues aside about  
6 whether or not Alc is a good test of quality  
7 or whatever, the existence of using this as a  
8 process measure was pretty unanimously  
9 accepted. I mean, it seems useful.

10 Again, if somebody is not doing an  
11 Alc test on one of their diabetic patients, I  
12 would question what -- you know, whether or  
13 not they were a competent physician. So, and  
14 I think the workgroup was in agreement with  
15 that, unless anybody remembers something I'm  
16 forgetting.

17 CO-CHAIR ROSENZWEIG: Okay. Let's  
18 vote on use and usability.

19 MS. BAL: All right. So for use  
20 and usability, we are looking at  
21 accountability, transparency, demonstrated  
22 improvement, and the benefits outweigh

1 evidence of unintended negativity, negative  
2 consequences. And it's open now.

3 And the results are high, 14;  
4 moderate, four; low, two.

5 CO-CHAIR ROSENZWEIG: Okay. So  
6 now we are going to vote on the overall  
7 recommendation for endorsement. Any comments  
8 first? I don't see why there should be, but  
9 --

10 (No response.)

11 Okay.

12 MS. BAL: Okay. Voting is now  
13 open for overall suitability.

14 Final results are yes, 18; no,  
15 two.

16 CO-CHAIR ROSENZWEIG: Okay.  
17 Thanks. Let's move on to the next one. Which  
18 one was that? It's going to be 0055,  
19 comprehensive diabetes care, eye exam, retinal  
20 eye exam performed. Who were the reviewers?  
21 Oh, sure. Absolutely.

22 DR. BARTON: Okay. Thanks very

1           much. The comprehensive diabetes set that  
2           NCQA uses to evaluate health plans includes  
3           this measure, 0055, which looks to see if  
4           those people who have diabetes, which is  
5           defined exactly the same as for the other  
6           indicators that you've seen, with the  
7           implication being, and in fact the practice  
8           being, that they collect all this information  
9           on one defined group of people.

10                           The high risk for  
11           vision-threatening microvascular complications  
12           of diabetes is very well-known, and the  
13           opportunity for early intervention by an  
14           ophthalmologist to treat the kinds of  
15           microvascular events and hemorrhages in order  
16           to preserve vision is really the focus of this  
17           measure.

18                           And the numerator of the measure  
19           can be complied with by seeing any eye care  
20           professional, so that includes optometrists as  
21           well as ophthalmologists and -- within the  
22           measurement year, or having had a normal or

1 negative exam the year before. And that's  
2 0055.

3 CO-CHAIR ROSENZWEIG: In their  
4 definition, do they include retinal photos  
5 that are done remotely that might be read by  
6 a qualified eye person? Because that was --  
7 that has always been an issue.

8 DR. BARTON: I'm sure if the  
9 reader bills the visit, it would meet the  
10 criteria for the code. Because this is  
11 something that uses claims to determine  
12 whether they had a visit with an optometrist  
13 or an ophthalmologist. So I don't know the  
14 particulars of that kind of distance care  
15 arrangement, but something tells me that the  
16 person reading would charge for that. And so  
17 it would get counted.

18 MEMBER McCOLLISTER-SLIPP: It was  
19 a formal interpretation that they would bill  
20 for.

21 CO-CHAIR ROSENZWEIG: Correct. I  
22 mean, a lot of -- there are a lot of

1           photographic telemedicine systems now that --  
2           in which you can get the picture taken in the  
3           primary care office, and then it's sent to be  
4           read officially. So that would count, then,  
5           as part of this.

6                       MS. TIGHE: Anna, do you want to  
7           start with evidence for this measure?

8                       MEMBER MCCOLLISTER-SLIPP: Sure.  
9           Sorry. I'm just having a hard time following  
10          where -- the printed worksheet. So I think  
11          this is maybe one big massive blond moment.  
12          I'm sorry.

13                      Okay. Here we go. Thank you very  
14          much. So the evidence for this seems to be  
15          pretty strong. I mean, one question I had  
16          about -- in sort of the philosophical  
17          discussion we had during the workgroup, the  
18          call was who was actually being measured for  
19          this. Is it health plans? Is it physicians?  
20          Is it my endocrinologist? Is it the  
21          ophthalmologist? Because I think that will  
22          matter substantially.

1                   And I know the  
2           numerator/denominator statement, you know,  
3           talks about the patient specifically, but, you  
4           know, I don't necessarily think it's  
5           appropriate to hold my endocrinologist  
6           accountable for whether or not I make it to  
7           the ophthalmologist or not for a dilated eye  
8           exam. And given the fact that there are much  
9           improved point of care retinal exams that  
10          could be given in the primary care setting, I  
11          don't think that's particularly ubiquitous.  
12          So expecting primary care physicians or  
13          endocrinologists to be able to do that would  
14          probably be inappropriate, at this point in  
15          time at least.

16                   So I guess the question -- we  
17          discussed this a bit in the workgroup -- that  
18          I would have in terms of the measure is, what  
19          was the rationale for that? And is there some  
20          degree of specificity on this that at least I  
21          haven't seen, in terms of who is being  
22          measured.

1                   CO-CHAIR ROSENZWEIG: Well,  
2                   obviously, you couldn't hold the  
3                   ophthalmologist or the person reading these  
4                   responsible for the percentage of patients who  
5                   are actually read, because obviously the  
6                   denominator includes all people with diabetes  
7                   within that certain age group.

8                   So it would either have -- if  
9                   you're talking about it, it would either have  
10                  to -- the responsibility would either have to  
11                  be on the plan level or on the primary care  
12                  level to a certain extent. And I guess  
13                  primary care doctors are being held  
14                  responsible for sending their patients to the  
15                  ophthalmologist. If they don't get to the  
16                  ophthalmologist, that is a valid issue. But  
17                  the issue is also that -- whether or not --  
18                  how vigorous the individual person is or the  
19                  system is in getting the person to be tested.  
20                  Yes?

21                  MEMBER BREEN: Just it's an  
22                  interesting discussion, because when we get



1           into medication adherence, right, and how  
2           practices are being measured on that, at first  
3           blush clinicians may say, "Well, you can't  
4           measure me on medication adherence. It's not  
5           my problem if my patient doesn't take their  
6           meds."

7                         However, when you really begin to  
8           look at that data, you see major practice  
9           variability amongst the similar demographic of  
10          people that says there are ways that you can  
11          structure your practice, right, to deliver  
12          better care. And I think closing this loop on  
13          the eye exam is one of the things that primary  
14          care should be challenged to do, and  
15          endocrinologists as well, because there is a  
16          range of activity that I can do when I have a  
17          patient. I never tell you to go see the eye  
18          doctor. I tell you to go see the doctor. I  
19          tell you to go see the eye doctor and I write  
20          you a referral slip. I tell you to go see the  
21          eye doctor, I write a referral slip, and my  
22          secretary calls the ophthalmologist and books

1           you while you're right there versus -- you  
2           know, I mean, you see where the spectrum is.

3                       So I do think it's a valid measure  
4           from a clinical standpoint. The burden is on  
5           us to just do this.

6                       CO-CHAIR ROSENZWEIG: Okay. Let's  
7           try to focus on evidence specifically. Yes.

8                       MEMBER CURRY: I just wanted to  
9           comment about that there is no specificity in  
10          the measure that says that a mydriatic or  
11          non-mydriatic digital photo of the retina  
12          meets the definition in here. You know, our  
13          region -- our insurers will not cover that.  
14          They have to have a visit in the optometrist's  
15          or ophthalmologist's office. We have tried to  
16          do this in our rural practices and in our  
17          academic practices, and they will not accept  
18          that.

19                       So it -- the specific language of  
20          digital retinal photograph is not in there, so  
21          they will not cover it.

22                       CO-CHAIR ROSENZWEIG: That doesn't

1 mean that they're right.

2 MEMBER CURRY: I'm just saying --

3 CO-CHAIR ROSENZWEIG: Okay. Okay.

4 Someone else? Oh, yes. Oh, but one other  
5 issue that does pertain to evidence is that  
6 there are a number of studies that show  
7 in-patients with diabetes who are very well  
8 controlled, that they don't necessarily need  
9 yearly retinal exams, that they could go every  
10 two years. There are papers by Joe Selby, I  
11 think Carol Mangione, and several other papers  
12 that -- but the issue -- yes?

13 MEMBER KIRKMAN: There's evidence  
14 that people can go for three years if they had  
15 a negative exam.

16 CO-CHAIR ROSENZWEIG: Correct.

17 MEMBER KIRKMAN: Including in the  
18 Medicare age population.

19 CO-CHAIR GOLDEN: So to follow up  
20 on that, that is a concern I was going to  
21 raise is, you know, obviously, a yearly  
22 standard drives costs and inconvenience and

1 measurement. And if the evidence now shows  
2 you can do it less often, then is this measure  
3 appropriate? And so the question is, what is  
4 the evidence for frequency? Do we have that?

5 CO-CHAIR ROSENZWEIG: Well, the  
6 evidence certainly is there for patients who  
7 are not well controlled, but the -- but for  
8 patients who are extremely well controlled --

9 MEMBER KIRKMAN: Well, I think it  
10 has to do with your -- the findings on your  
11 initial retinal exam. So there is -- I mean,  
12 there is even fundus photography evidence that  
13 if you had a normal fundus photograph you can  
14 go three -- people can go three years before  
15 their next one with no difference in outcome.

16 So I'm concerned that this is a  
17 little bit more aggressive than the evidence  
18 would suggest.

19 MEMBER MILLER: Concerning the  
20 photographic exams, the ADA guidelines say  
21 that the photo is okay periodically, but the  
22 American Association of Ophthalmology says

1           that it's of limited value for very early  
2           detection and diagnosis.

3                       CO-CHAIR ROSENZWEIG:   Yes.   For  
4           Type 1 diabetes, it is usually not recommended  
5           for the first four years.  It used to be five  
6           years, but it's more like --

7                       MEMBER MILLER:   Yes.  Three to  
8           five for people who are initially diagnosed.  
9           But, I mean, for initial diagnosis of  
10          retinopathy they're saying that it's not  
11          always the best, the camera.

12                      CO-CHAIR ROSENZWEIG:  Oh.  You're  
13          talking about the camera specifically.

14                      MEMBER MILLER:   Yes.

15                      CO-CHAIR ROSENZWEIG:  Oh.

16                      CO-CHAIR GOLDEN:  So to follow up  
17          on Sue's comment before the NCQA comments, you  
18          know, the question is, is this a measure for  
19          screening?  Which would indicate a certain  
20          frequency.  And if you already have an  
21          existent disease, it is no longer screening.

22                      So that would require a more

1 intensive followup. And are we mixing apples  
2 and oranges in how we construct a measure and  
3 the frequency?

4 MR. REHM: Just to read from the  
5 denominator, the patient is  
6 numerator-compliant if the eye exam was  
7 performed or a negative eye exam was  
8 documented in the year prior to the  
9 measurement year. So it's more than just the  
10 measurement year. If you have a negative  
11 finding, then -- so --

12 MEMBER KIRKMAN: But I can tell  
13 you that every letter I get from Aetna or, you  
14 know, other people it's basically your patient  
15 hasn't had an exam this year. So I'm not sure  
16 it's really being -- that is really being  
17 adhered to. But even the two years is  
18 probably stricter than the data.

19 CO-CHAIR ROSENZWEIG: Also, the  
20 measure specifies screening in the numerator.  
21 But it doesn't specify patients who have  
22 existing retinopathy as an exclusion in the

1 denominator. That's a point that should be  
2 looked into, since by -- you know, after 10 or  
3 15 years, the majority of patients with  
4 diabetes have some retinopathy.

5 So you're talking about actually a  
6 fairly significant number of patients in the  
7 population that may not necessarily need to be  
8 dealt with in this particular measure.

9 DR. BARTON: The workgroup brought  
10 up that point, and I think it's an excellent  
11 one. That this -- and as we further look at  
12 these measures, we will be looking at those  
13 things, both the interval and the question of  
14 existing disease.

15 I guess the issue about existing  
16 disease -- and it reminds me that this is a  
17 measure that is, you know, best used in a  
18 population of people. And when you are  
19 comparing one entity, like one health plan to  
20 another health plan, the likelihood is that  
21 they each have similar proportions of patients  
22 in those various -- either the people who only

1           need every three years versus every two, and  
2           the people who need more often because they've  
3           got eye disease. And so the -- drawing a line  
4           somewhere, you know, is the way the measure  
5           works.

6                           CO-CHAIR ROSENZWEIG: But let's  
7           just talk about -- we want to focus on the --  
8           I mean, this measure may be a useful measure  
9           for people to do to encourage eye screening.  
10          But right now we are talking about the  
11          evidence base for it. So --

12                          CO-CHAIR GOLDEN: So let me just  
13          make sure I understand what you just said.  
14          You seem to indicate you are going to revise  
15          this or it should be revised. Should we pull  
16          this now and have you come back in six months?

17                          DR. BARTON: The cycle on which we  
18          work is not that rapid.

19                          (Laughter.)

20                          So --

21                          CO-CHAIR GOLDEN: What if we  
22          encourage you?



1 DR. BARTON: So we -- as you can  
2 imagine, our diabetes set, which also includes  
3 indicators that you are not seeing today that  
4 have to do with LDL screening and control, are  
5 going to keep us pretty busy over the next six  
6 months?

7 So we are -- I was indicating  
8 points that we wanted to keep in the queue for  
9 when we reevaluate this measure the next time.

10 CO-CHAIR GOLDEN: So you're saying  
11 we should endorse a measure that you think  
12 needs to be revised.

13 MR. REHM: Having been through  
14 this in other groups, other measurement  
15 domains, multiple times, we annually update  
16 our measures, and we get feedback from the  
17 marketplace thousands and thousands of either  
18 happy physicians or happy health plans or  
19 unhappy health plans and unhappy physicians,  
20 depending on the measure.

21 And we are constantly revising  
22 these measures, and we -- NQF has a terrific

1 process of -- because we have over 100  
2 measures in play of doing quarterly updates.  
3 We update these with new code sets. We update  
4 these based on new technology. We update  
5 them.

6 So to think that a measure is  
7 static from the moment you endorse it is not  
8 fair. It is a very dynamic -- whether NQF was  
9 here or not, it's very dynamic in our world.  
10 It's so dynamic we put out technical updates  
11 in October, even though we reduced the measure  
12 specs in July, to capture the latest and  
13 greatest.

14 We don't release the NDC codes for  
15 any measures with drugs until late November,  
16 to capture the very, very last update of that  
17 -- you know, that compendium. So many times  
18 we bring measures where, because of timing  
19 issues, we are actually in the middle of  
20 evaluating the measure.

21 When we brought breast cancer in  
22 three years ago, we were right in the middle

1 of the evaluation. We couldn't say where we  
2 were going to land. And, you know -- and so  
3 sometimes it is just a timing issue.

4 I think the openness to change on  
5 any measure is a great thing, and, you know,  
6 we are not trying to dig out feet in the sand.  
7 It's just for something like intervals, we get  
8 feedback from you which is quite helpful.  
9 It's one of the benefits of participating in  
10 the process is that -- I hate to say this, but  
11 this is a free measurement advisory panel to  
12 help us develop our measures as well.

13 So you add that up with our own  
14 panels, and we bring back the feedback, that's  
15 part of the cycle of measure development and  
16 refinement. So I wouldn't say that the best  
17 solution to this, because we may be unsure  
18 about intervals, is to say that not endorsing  
19 the measure is the best thing to go -- but,  
20 you know, that's your decision obviously.

21 CO-CHAIR ROSENZWEIG: Just to get  
22 back, we are not discussing as to whether or

1 not this measure should be endorsed. We are  
2 -- let's focus, at least for the present, on  
3 evidence related to the measure. Anyone?  
4 Janice, do you have a comment? Sue?

5 MEMBER KIRKMAN: Yes. And, again,  
6 maybe I'm getting ahead of the evidence a  
7 little bit, too. But, I mean, I do think this  
8 is an example where we probably shouldn't let  
9 the perfect get in the way of the good. I  
10 mean, I think this is a measure that has been  
11 around a long time. I think it has done a lot  
12 of good. You can see there are still a lot of  
13 gaps in care. You know, I don't think it's  
14 all just because there are a lot of people  
15 with normal exams that aren't being referred  
16 back every year or two.

17 So, you know, I think, you know,  
18 in the future it would be good to tweak it a  
19 little bit maybe, but -- and the other thing  
20 is I think it becomes really difficult when  
21 you get different intervals for different  
22 people, and it is hard to tell from a -- you

1 know, an administrative level or SARP review  
2 level who is supposed to be at what interval.  
3 So, I mean, it --

4 CO-CHAIR GOLDEN: But wearing my  
5 Medicaid Medical Director hat, and speaking  
6 for other Medicaid Medical Directors, that is  
7 a cost item. And so it actually -- this has  
8 a big impact. So it does make a difference.

9 MEMBER McCOLLISTER-SLIPP: What's  
10 the potential cost of missing a vitreous  
11 hemorrhage? I mean, you know, every other  
12 year it really isn't that extreme, if that's  
13 -- if you're looking at cost issues. I mean,  
14 and I went in for a retinal exam and happened  
15 to be having a hemorrhage, and because I was  
16 going in for my regular exam while this  
17 happened I still have 20/20 vision.

18 So I think it's incredibly  
19 important, and I purposely go to a physician  
20 who is in like Southeast D.C., so I can see  
21 what it's like for other people for whom this  
22 is a huge burden to get there and to get back.

1           And it's sometimes a family project.

2                       But, I mean, if we're looking at  
3           this from a cost perspective, the relative  
4           cost of requiring, you know -- using it as a  
5           quality measure coming in at least once every  
6           other year versus the cost of potential  
7           blindness or other complications -- or other  
8           types of surgery as a result of not doing it,  
9           I think the cost-benefit would probably weigh  
10          in favor of doing it.

11                      CO-CHAIR ROSENZWEIG: I would  
12          mention, yes, I work in a safety net hospital  
13          with lots of people with disparities. And  
14          basically we have terrible eye screening  
15          rates. I mean, we have done all sorts of  
16          things to try to encourage the patients to get  
17          screened. We send them to the  
18          ophthalmologist; they don't show. A variety  
19          of other things.

20                      But we also -- also identify a lot  
21          of patients with very severe eye disease at  
22          the very first -- at the very first interval,

1           so -- where we have missed the boat.  So I  
2           think this is an issue that is -- it has  
3           certainly been raised by my colleagues at the  
4           Beetham Institute at Joslin that there are --  
5           you know, that if you cut back on emphasis on  
6           screening that you could end up with a lot  
7           worse disease.

8                         CO-CHAIR GOLDEN:  Let me just  
9           clarify my comment, just so I could make it --  
10          that doesn't bring it up on cost.  But as a  
11          Medical Director looking at expenses for a  
12          program, if the evidence doesn't justify the  
13          frequency, then it's not a necessary expense.  
14          There are other things to spend the money on.

15                        So I'm not saying just cut it back  
16          because of cost, but the question is, what  
17          does the evidence justify?  That was my  
18          question and my point.  So if there's  
19          questions about the evidence justifying mass  
20          screening on a yearly basis, then it has cost  
21          implications.

22                        CO-CHAIR ROSENZWEIG:  Yes.  Bill?

1                   MEMBER TAYLOR:   Procedurally, what  
2                   is the option for us if we believe in  
3                   retinopathy screening and we think that this  
4                   can be tweaked and improved?  What is the most  
5                   expeditious way for us to help get there if  
6                   that's what we, as a group, conclude?

7                   CO-CHAIR ROSENZWEIG:  That's a  
8                   good question.

9                   MS. TIGHE:  So we are asking you  
10                  to vote on the measure as it is presented  
11                  today.  The tweaks that you all are suggesting  
12                  are major changes to the specifications of the  
13                  measure.  It is not something that we could do  
14                  through our annual update process.  So the  
15                  developers certainly can take that feedback as  
16                  they are revising the measure, but you do need  
17                  to look at it as specified today.

18                  CO-CHAIR ROSENZWEIG:  Okay.  Let's  
19                  have a vote on the evidence.

20                  MS. BAL:  Okay.  So we are voting  
21                  on evidence which should be -- the following  
22                  should be considered -- quality, quantity, and



1 consistency, graded guidelines, empirical  
2 evidence, and expert opinion. Voting is now  
3 open.

4 Let's just all try one more time,  
5 get that last person in. Okay. The final  
6 results are high, four; moderate, 12; low,  
7 four.

8 CO-CHAIR ROSENZWEIG: Okay.  
9 Performance gap. Anna?

10 MEMBER McCOLLISTER-SLIPP: Based  
11 on the data presented, there seems to be a  
12 somewhat frightening level of performance gap  
13 from my perspective. So there certainly seems  
14 to be a need to emphasize this as something  
15 that should be done, you know, given the  
16 potential morbidity associated with not doing  
17 it I think.

18 And, again, other workgroup  
19 members, if there is anything I'm missing from  
20 our discussion, please let me know.

21 MEMBER MILLER: There was also  
22 somewhere in the developer's evidence,

1 discussion about disparities, that lower  
2 income patients were also less likely to  
3 receive eye exams. Just putting that out  
4 there, as far as the performance gap.

5 CO-CHAIR ROSENZWEIG: Yes.  
6 There's a lot of evidence. Okay. So let's  
7 vote.

8 MS. BAL: Okay. So we're voting  
9 on performance gap, which is data demonstrate  
10 a considerable variation or overall less than  
11 optimal performance across providers and/or  
12 population groups. And voting is now open.

13 Okay. So we're at high, 18;  
14 moderate, two.

15 CO-CHAIR ROSENZWEIG: Okay.  
16 Impact. Anna?

17 MEMBER McCOLLISTER-SLIPP: Again,  
18 I think -- I am completely incapable of  
19 finding myself through this worksheet, so my  
20 apologies for that. I don't quite understand  
21 why it's so baffling. But the potential  
22 impact for screening in terms of morbidity was

1           pretty high. And, again, we didn't have a  
2           long and extensive discussion about this on  
3           the workgroup call. But there seemed to be  
4           pretty significant agreement that the impact  
5           of doing this was potentially beneficial.  
6           Anyone?

7                         MEMBER BREEN: Yes. I'd just like  
8           to state for the record that diabetes remains  
9           the leading cause of blindness in the United  
10          States. So just to get that out there.

11                        CO-CHAIR ROSENZWEIG: Yes. I  
12          think in this case we are also considering the  
13          priority of the use of the measure, and we are  
14          not necessarily considering whether or not one  
15          or two years or three years is the best period  
16          of time. It's whether or not the measure  
17          itself might have a high priority or impact.

18                        So, any other comments?

19                        (No response.)

20                        Okay.

21                        MS. BAL: Okay. Voting is now  
22          open for high priority.

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Let's just all vote again.

There's a little delay I guess. We are at 18.

(Simultaneous speaking.)

Okay. High, 15; moderate, three; insignificant, three.

CO-CHAIR ROSENZWEIG: Okay.

Reliability of the specifications.

MEMBER MCCOLLISTER-SLIPP: In working from memory here, I think the only question we had around reliability was -- gets back to who was being measured, I mean, and how it was going to be recorded. So if you're looking at EHR data from ophthalmologists, that's pretty reliable.

If you're looking at primary care, endocrinologists, you rely on physician in many cases getting a letter from the ophthalmologist saying that the patient was seen or you're relying on the patient's memory or relying on the patient to be honest about whether or not they did it when they're embarrassed with their physician. So --

1 CO-CHAIR ROSENZWEIG: Any  
2 comments?

3 MEMBER McCOLLISTER-SLIPP: Bill,  
4 do you have anything else to add?

5 (No response.)

6 CO-CHAIR ROSENZWEIG: I think the  
7 major issue is just the -- with respect to  
8 specifications is the conflating of whether or  
9 not you are dealing with screening or you are  
10 dealing with following up of existing  
11 retinopathy.

12 Is the specification claims data  
13 or is it chart data? It's claims data? Okay.  
14 Thank you.

15 Okay. So let's vote.

16 MEMBER DUVA: Can I just add a  
17 comment?

18 CO-CHAIR ROSENZWEIG: Yes. Oh, I  
19 missed something. Sorry. Okay. Ingrid.

20 MEMBER DUVA: Sorry. The  
21 developer did submit reliability data, and  
22 they tested high.

1 CO-CHAIR ROSENZWEIG: Yes.

2 Jessie.

3 MEMBER SULLIVAN: I'm sorry. I  
4 have a clarification. Maybe it's an  
5 implementation issue. But I believe this is  
6 a hybrid measure. We certainly spend a lot of  
7 time looking for those ophthalmology charts.

8 MR. REHM: It's a choice. There  
9 are plans that feel that their admin records  
10 are sufficient, and it's because of that range  
11 of systems -- some people have legacy systems  
12 -- they can do three-quarters of it. But then  
13 for the rest of it they take over new plans or  
14 -- so that's why we have that option.

15 CO-CHAIR ROSENZWEIG: Okay. Let's  
16 vote.

17 MS. BAL: Okay. Voting is open.

18 Okay. We have high, seven;  
19 moderate, 13.

20 CO-CHAIR ROSENZWEIG: Okay.

21 Validity of the specifications.

22 MEMBER McCOLLISTER-SLIPP: The

1           validity of the specifications -- again, we  
2           didn't really cover this that much during our  
3           workgroup, because we were a little rushed.  
4           But, I mean, they seem to be valid just in  
5           terms of a process measure of doing the  
6           screening.

7                       MEMBER MILLER:  There seemed to be  
8           some high correlation for health plan level  
9           data, but the correlation was a little bit  
10          weaker for the physician level data, so with  
11          the diabetes recognition programs.  But when  
12          I wrote some notes to myself, I said that it  
13          may be reflective more of the difference in  
14          sample sizes between the levels of data,  
15          between the health plan data and the diabetes  
16          recognition plan.

17                      CO-CHAIR ROSENZWEIG:  Yes.

18                      MEMBER DUVA:  Also, same for this  
19          measure as previous.  The face validity was  
20          presented from experts, and the correlation to  
21          the other quality measures was high.

22                      CO-CHAIR ROSENZWEIG:  And is there

1 an agreement about whether or not a score from  
2 this measure is -- as specified is an  
3 indicator of quality? Screening rates in  
4 general?

5 MEMBER DUVA: Do you mean from the  
6 workgroup?

7 CO-CHAIR ROSENZWEIG: From the  
8 workgroup, yes.

9 MEMBER DUVA: In general, the  
10 conversation was that it was representative of  
11 the quality of care for the patient to be  
12 screened.

13 CO-CHAIR ROSENZWEIG: So let's  
14 vote on this, then.

15 MS. BAL: Okay. Voting is open.

16 Okay. The results are high, six;  
17 moderate, 13; low, one.

18 CO-CHAIR ROSENZWEIG: Okay.  
19 Feasibility.

20 MEMBER McCOLLISTER-SLIPP: I think  
21 feasibility was the area that we had the most  
22 discussion about, just because we don't live



1 in a system with comprehensive care. You  
2 know, people go to different physicians for  
3 different things, so, you know, again,  
4 measuring -- an endocrinologist or a primary  
5 care physician or a facility where that's  
6 given, using this as a process measure for the  
7 quality of care, while -- the fact that it has  
8 to be done by somebody else externally I think  
9 is an issue in terms of feasibility.

10 In terms of collecting the data,  
11 it is pretty straightforward, but -- from  
12 claims data. But in terms of feasibility,  
13 there seemed to be significant questions about  
14 how feasible it was to require them.

15 CO-CHAIR ROSENZWEIG: Certainly,  
16 data collection from -- you know, on a plan  
17 level seems quite feasible. But if one were  
18 to go into our -- like our medical charts to  
19 find out whether or not our individual  
20 patients had an eye exam within the past year,  
21 it becomes very difficult. So --

22 MEMBER MILLER: I think this is

1 one of the most difficult to measure variables  
2 outside of administrative plan data, because  
3 most EMRs don't have a physical field to  
4 collect to say that the -- or a lot of them  
5 don't -- to say that an eye exam was done and  
6 when it was done. And we can click that we  
7 referred the patient, but that doesn't mean  
8 that the patient actually went. So I think  
9 that on a provider or practice level I think  
10 this is extremely difficult data to capture.

11 MEMBER MAKAROFF: Yes. I would  
12 just agree with that. And also, I'm just  
13 wondering, it seems like from a feasibility  
14 standpoint -- and some patients may not use  
15 their medical insurance to get their eye exam,  
16 if they see an optometrist, use their vision  
17 insurance. Since it's not billed the same,  
18 then we're not going to capture that.

19 MEMBER MILLER: I have also over  
20 the years had many, many patients who go to  
21 Sam's Club and pay cash for their eye exam,  
22 and a letter never gets generated, you know,

1 and sent in. So --

2 CO-CHAIR GOLDEN: I have a  
3 question on the Sam's Club. I am not aware  
4 that they do diabetic retinopathy screening.  
5 They can do refractions, but --

6 MEMBER MILLER: I don't know. I  
7 have never personally availed myself of that.

8 CO-CHAIR GOLDEN: Yes. That is  
9 part of -- people think they are getting an  
10 eye exam and all they're getting is a  
11 refraction. So that's --

12 CO-CHAIR ROSENZWEIG: There are --  
13 like Pearle Vision, you know, some of those  
14 places actually do do retinal screenings as a  
15 part of it. But it varies from place to  
16 place, and the patient doesn't know the  
17 difference for the most part.

18 So let's vote on this one.

19 MS. BAL: Okay. Voting is open.

20 So we have high, two; moderate,  
21 13; low, five.

22 CO-CHAIR ROSENZWEIG: Yes. Sue?

1                   MEMBER KIRKMAN: Do I remember  
2                   correctly from this morning that another group  
3                   is looking at a measure about the eye care  
4                   professional communicating with the referring  
5                   doctor? I mean, is there a sense that that  
6                   may help some of this feasibility? Or is it  
7                   so different that it's not?

8                   CO-CHAIR ROSENZWEIG: I think that  
9                   PCPI have a number of measures where they  
10                  expect the communication from a professional  
11                  to a primary care doctor. They are doing that  
12                  with mammography, and I think they have done  
13                  that with the eye exam.

14                 DR. BURSTIN: There's a measure of  
15                 patients who have retinopathy. Was there  
16                 communication between the ophthalmologist and  
17                 the primary care clinician? I think it was if  
18                 they ever -- I mean, we can pull it up for  
19                 you.

20                 MEMBER MAKAROFF: I think there is  
21                 also a measure in the CMS of being able to use  
22                 core set for Stage 2 that is closing the

1 referral loop for all specialty care. So that  
2 would go along with that.

3 CO-CHAIR ROSENZWEIG: Oh, really.

4 Okay. Usability and use,  
5 accountability, transparency. Can we vote?

6 MS. BAL: Voting is open.

7 Okay. The results are high,  
8 seven; moderate, 11; low, two.

9 CO-CHAIR ROSENZWEIG: Okay. So  
10 let's vote on the overall measure. I hope you  
11 -- I'm not pushing you to move too fast.

12 Okay. Sorry? Oh, I'm sorry.

13 MEMBER DUVA: Sorry. It's one of  
14 those questions, again, about kind of our  
15 group process. But somebody brought up that  
16 this measure might be kind of covered in other  
17 measures. But this is very close to a measure  
18 and coordination, and I know there is a  
19 coordination panel.

20 We look at care coordination  
21 separate -- with separate measures, but this  
22 is really a care coordination measure. And

1 I'm just wondering if we'll have an  
2 opportunity to discuss that later. It's about  
3 closing the loop. Really, the problems that  
4 we have talked about is, can we get the -- can  
5 we find out if the patient is -- can we get  
6 the data? So do we have an opportunity to  
7 talk about that later or not?

8 CO-CHAIR ROSENZWEIG: I don't  
9 know.

10 MEMBER DUVA: With these other  
11 measures?

12 CO-CHAIR ROSENZWEIG: I mean, I  
13 don't see this necessarily as a --

14 MEMBER DUVA: You don't?

15 CO-CHAIR ROSENZWEIG: --  
16 coordination measure. It is basically among  
17 a specific population of patients whether or  
18 not they're in a plan or whether or not --  
19 whether or not they are under the care of a  
20 specific provider, whether or not they get  
21 their eyes checked.

22 MEMBER DUVA: Right. But it's not

1 the provider providing the exam. So then they  
2 are going somewhere else to get the exam or  
3 the screening, and then it's coming back to  
4 their provider to know that they had it.

5 CO-CHAIR ROSENZWEIG: Yes. But we  
6 are not actually -- this measure is not  
7 actually measuring whether or not the provider  
8 is being told.

9 MEMBER DUVA: Okay.

10 CO-CHAIR ROSENZWEIG: You have to  
11 take that into consideration when you're, you  
12 know, voting on the overall value of the  
13 measure. I mean, it's -- you're making a  
14 valid point, but the measure is not  
15 specifically measuring closing the loop. At  
16 least as I see it here, the way it's written.  
17 It would be if you were just looking at the  
18 physician's chart, but that's not the case  
19 here.

20 Okay. Let's vote on this.

21 MS. BAL: Voting is open.

22 Okay. The final results are yes,

1 18; no, two.

2 CO-CHAIR ROSENZWEIG: Okay. Let's  
3 take a quick break. Five minutes.

4 (Whereupon, the above-entitled  
5 matter went off the record at 3:08 p.m. and  
6 resumed at 3:16 p.m.)

7 CO-CHAIR GOLDEN: Okay. So, let's  
8 continue with measure Number 0062.

9 PARTICIPANT: Excuse me. Would it  
10 be possible to have an update on the agenda  
11 and what you expect to cover today?

12 MS. TIGHE: Yeah, absolutely.  
13 This is Lindsey from NQF. I'll just update  
14 you.

15 We're going to cover Measure 0062  
16 now, the NCQA Nephropathy Measure. From  
17 there, we're going to move to the three Joint  
18 Commission numbers 2416, 2417 and 2418.

19 After that, we'll move back to the  
20 foot exam measures. So, we'll be doing 0056,  
21 0416, 0417 and 0519.

22 We are intending to cover every



1           measure that's on the agenda today. We are  
2           going to remove the 4:30 p.m. harmonization  
3           discussion to give ourselves a little bit more  
4           time back and hopefully still get out of here  
5           as close to 5:30 as possible. Maybe 6:00.

6                           PARTICIPANT: Thank you.

7                           CO-CHAIR GOLDEN: Okay. So, this  
8           measure is titled "Comprehensive Diabetes  
9           Care: Medical Attention for Nephropathy."

10                          Bill, are you the major discussion  
11           well, wait. Do we want to hear from the  
12           developers first? Sure.

13                          DR. BARTON: So, this is the final  
14           measure today from the Comprehensive Diabetes  
15           Care Measure Set.

16                          Renal disease is another of the  
17           important downstream complications of  
18           diabetes, as I'm sure you all know, with  
19           really enormous impact on patients and  
20           families and the cost to the healthcare  
21           system.

22                          Diabetes was the cause of nearly

1 half of new cases of end-stage renal disease  
2 in 2008.

3 There are many ways to enter this  
4 measure, that is to be numerator compliant,  
5 you could have appropriate laboratory  
6 screening for urinary protein, you could be  
7 referred to a nephrologist, or you could have  
8 evidence of treatment for diabetic nephropathy  
9 with an ACE inhibitor or an angiotensin  
10 receptor blocker. So, that's it's got a  
11 multi-prong way to be compliant.

12 Thanks.

13 CO-CHAIR GOLDEN: Has this measure  
14 changed in its specifications in the last few  
15 years? Because at least as I had heard the  
16 measure in the past, sometimes existing  
17 retinopathy has been used as a denominator  
18 exclusion.

19 DR. BARTON: Yes, I believe you're  
20 right. Let me double-check right now. We've  
21 got the specs.

22 Existing nephropathy

1 CO-CHAIR GOLDEN: Existing

2 nephropathy

3 DR. BARTON: You said retinopathy,

4 but

5 CO-CHAIR GOLDEN: has been used

6 as a denominator and exclusion at least in

7 previous versions of this type of measure.

8 This may be different, but in here

9 you're including it really as a part of the

10 numerator, existing nephropathy. So, I just

11 wanted to check about that or is that a

12 separate measure or is this a new measure?

13 DR. BARTON: Let me double-check

14 that.

15 CO-CHAIR GOLDEN: Just a technical

16 question, also, for a test for a would a

17 metabolic profile with calculation of

18 glomerular filtration rate count, or that does

19 not count?

20 DR. BARTON: Does not.

21 CO-CHAIR GOLDEN: And why doesn't

22 it count?

1 DR. BARTON: The test is for  
2 urinary protein burden. So, it is looking  
3 I think it's a 24-hour urine collection if I'm  
4 not

5 CO-CHAIR GOLDEN: Okay. But you're  
6 talking the label of this was "nephropathy"  
7 as opposed to urinary protein excretion. So,  
8 it's different.

9 DR. BARTON: So, you would argue  
10 that there's a glomerular filtration rate  
11 threshold that you would use?

12 CO-CHAIR GOLDEN: Well, you're not  
13 in Stage 1 renal failure. You can do that  
14 easily by a blood test with calculation of  
15 GFR.

16 DR. BARTON: Thanks.

17 CO-CHAIR ROSENZWEIG: The EGFR  
18 would be a separate measure which actually has  
19 been approved by the that joint NCQA-AMA  
20 panel recently.

21 I don't know if it's ready for  
22 submission to us, but the use of EGFR as a

1 regular tool has I know has been approved by  
2 your joint committee, but clearly it's not a  
3 part of this measure.

4 Yes.

5 MEMBER BAILEY: And just to add to  
6 that, that there is a significant proportion  
7 of diabetic patients with established chronic  
8 kidney disease that don't have overt  
9 proteinuria let alone microalbuminuria, or  
10 further along in the spectrum it's about 30 to  
11 40 percent.

12 So, by omitting EGFR, we may be  
13 missing a significant portion of the  
14 population and also a significant opportunity  
15 to direct them to care and, hence, impact  
16 outcomes.

17 CO-CHAIR ROSENZWEIG: Yeah, that's  
18 why I was asking about the way this was  
19 constructed, because it was my understanding  
20 that the purpose of this particular measure  
21 was to promote the use of microalbumin as a  
22 screening tool.

1                   It wouldn't necessarily diagnose  
2                   nephropathy, but it would diagnose evidence  
3                   potentially leading towards the diagnosis.

4                   MEMBER BAILEY: Right, but you'd  
5                   also be missing patients that may have  
6                   decreased GFR and not have microalbuminuria.  
7                   So, you should have either/or, or both.

8                   CO-CHAIR ROSENZWEIG: You mean a  
9                   composite measure, yeah. Right now as I  
10                  understand it, they exist as two complementary  
11                  measures, but I don't know if they've been put  
12                  together as a composite measure.

13                  DR. BARTON: PCPI measure is a  
14                  physician-level measure and is not yet at the  
15                  point of being tested.

16                  CO-CHAIR ROSENZWEIG: Okay.

17                  DR. BARTON: And so, it has not  
18                  been brought to NQF yet.

19                  CO-CHAIR ROSENZWEIG: Okay. So,  
20                  were you able to clarify that issue about  
21                  numerator versus denominator just before we  
22                  had the discussion?

1                   MEMBER KIRKMAN: So, I believe it's  
2                   in the numerator. So

3                   CO-CHAIR ROSENZWEIG: Here, it's in  
4                   the numerator.

5                   MEMBER KIRKMAN: Right.

6                   CO-CHAIR ROSENZWEIG: But in

7                   MEMBER KIRKMAN: But that's the  
8                   program.

9                   CO-CHAIR ROSENZWEIG:     other  
10                  versions of this measure I've seen it in the  
11                  denominator. In other words, patients who  
12                  already have existing nephropathy don't need  
13                  to get microalbumin screening.

14                  MEMBER KIRKMAN: But that would  
15                  sort of     that's what would happen here as  
16                  well.

17                  CO-CHAIR ROSENZWEIG: No, it's in  
18                  the numerator.

19                  MEMBER KIRKMAN: Right. They  
20                  either get the test, or they have diagnosed  
21                  nephropathy.

22                  CO-CHAIR ROSENZWEIG: Okay.

1                   MR. REHM: Just to clarify again on  
2                   Section S4 Numerator Statement, patients who  
3                   received nephropathy screening tests or had  
4                   evidence of nephropathy during the measurement  
5                   year.

6                   CO-CHAIR ROSENZWEIG: Okay. So,  
7                   it's basically trying to identify people who  
8                   have evidence for nephropathy, but it's not  
9                   but your point is well-taken that it's not  
10                  clarifying whether EGFR is being measured,  
11                  which would be the third piece to that.

12                  Could you give your evaluation,  
13                  please?

14                  MEMBER TAYLOR: Yes. Our  
15                  subcommittee spent most of its time on other  
16                  measures, but generally went through this and  
17                  was very favorable toward it. I guess we'll  
18                  go through the specifics as we scroll down.

19                  The general background is what  
20                  Mary has already said that the evidence is  
21                  good, that it is important to find. And that  
22                  if you find it early, you can actually change



1 the course of events so that it makes sense to  
2 be criterion for screening with a big  
3 performance gap in disparities involved as  
4 well.

5 High priority for the reasons that  
6 Mary said with lots of chronic renal disease  
7 ascribable to diabetes.

8 CO-CHAIR ROSENZWEIG: So, the  
9 evidence quality?

10 MEMBER TAYLOR: Consider it high-  
11 quality evidence by the Subcommittee.

12 CO-CHAIR ROSENZWEIG: Comments?

13 MEMBER MILLER: I have a question  
14 and it goes back to the microalbumin EGFR. I  
15 always understood the urine microalbumin test  
16 to be a test to be a very, very early  
17 detection and identification of patients.

18 So, I guess the question, and I  
19 don't know the answer to this is, is  
20 microalbumin I know about the 30 to 40  
21 percent who don't have microalbumin. But in  
22 those who do, does that generally, I mean, I

1 think that generally happens before their GFR  
2 would drop.

3 CO-CHAIR ROSENZWEIG: Yes. You  
4 actually have a rise in GFR for several can  
5 be for several years. You have an abnormally  
6 high GFR that often occurs in the very early  
7 stages of diabetic nephropathy.

8 So GFR, per se, a decrease in GFR  
9 really is detecting nephropathy at a further  
10 point than microalbuminuria might be.

11 But microalbuminuria but a lot  
12 of people get nephropathy without  
13 microalbuminuria, as Bob has just indicated.  
14 Maybe 30 percent.

15 MEMBER MILLER: I just was bringing  
16 that up, you know, because of the discussion  
17 we were having about if GFR is included or not  
18 that

19 MEMBER BAILEY: If I could just add  
20 to that, so microalbuminuria identifies the  
21 high-risk group that's more likely to progress  
22 down the spectrum than the general population.

1 MEMBER MILLER: Absolutely.

2 CO-CHAIR ROSENZWEIG: When the  
3 microalbumin test was first used, we kind of  
4 thought of it as being an indicator of getting  
5 nephropathy, but now it's really considered  
6 early nephropathy.

7 MEMBER MILLER: It is.

8 CO-CHAIR ROSENZWEIG: Yeah.

9 Any other comments?

10 MEMBER TAYLOR: We can keep  
11 scrolling.

12 CO-CHAIR ROSENZWEIG: Okay. So,  
13 let's vote on this then. This one is an easy  
14 one to vote on.

15 MS. BAL: Voting is open.

16 (Pause.)

17 MS. BAL: Okay. The final vote is  
18 high, 13. Moderate, seven.

19 CO-CHAIR ROSENZWEIG: Okay.  
20 Performance gap. This is I think this is  
21 something that's actually improved over the  
22 years, but I don't know if it's

1                   MEMBER TAYLOR: Yes. We didn't  
2                   show the numbers right here, but there's a lot  
3                   of gap in general in the population, and then  
4                   disparities in particular high-risk groups.

5                   MEMBER MILLER: I had made a note  
6                   that the Medicare HMOs had the least  
7                   improvement, but they had the highest mean  
8                   percentages of performance.

9                   CO-CHAIR GOLDEN: Let me ask a  
10                  question on that. In terms of the gap, I find  
11                  that just intrinsically hard to believe.

12                  I guess my question is, is that  
13                  because they are collecting the measure  
14                  incorrectly?

15                  My data would show that 80 percent  
16                  plus of diabetics run ACEs and ARBs. So, your  
17                  potential for a tremendous performance gap  
18                  would be fairly low.

19                  So, I was just curious if they're  
20                  just measuring urine microalbuminuria, then  
21                  sure. But if they're not excluding or  
22                  accepting ACEs and ARBs as part of the

1 collection of the data, there would be a lot  
2 of variation.

3 MEMBER MILLER: I would think so.  
4 I think in a number of primary care practices  
5 there is a lot of emphasis on get the  
6 patient's urine before they leave, because  
7 that's something we can collect in the office  
8 even if the patient is going to a lab  
9 somewhere, but we can get a urine specimen.

10 But that really would raise all  
11 boats, not just the

12 CO-CHAIR GOLDEN: Yeah, but if your  
13 patient's already on an ACE or an ARB, you  
14 satisfy the measure.

15 MEMBER MILLER: That's right.

16 CO-CHAIR GOLDEN: That's why I'm  
17 confused by the performance gap.

18 MEMBER MILLER: I see. I don't  
19 have an answer for you.

20 CO-CHAIR ROSENZWEIG: All right.  
21 Let's vote on the performance gap.

22 MS. BAL: Voting is now open.

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(Pause.)

MS. BAL: Okay. The final results are high, 11. Moderate, seven. Low, two.

CO-CHAIR ROSENZWEIG: I should mention that if a person is on an ACE or an ARB when they have diabetes, it's not necessarily an indicator and a fact that nephropathy is being treated.

It could be that they're being treated for hypertension. Okay. So, that's just something that needs to be considered.

CO-CHAIR GOLDEN: True. But if you're positive for urine microalbuminuria, it makes no difference.

CO-CHAIR ROSENZWEIG: No, but the numerator is saying microalbumin, or being on an ACE and an ARB, or being referred to a nephrologist. At least that's the way I read the measure.

So, there may be some people who are on an ACE and an ARB purely for hypertension who may not necessarily have

1 nephropathy.

2 I don't know whether it really  
3 matters in terms of the value of the measure  
4 itself, but I just thought I should mention  
5 it.

6 Yes.

7 MEMBER BAILEY: There are a couple  
8 of things. The first one is that very often  
9 the ACE or ARB is titrated upwards until you  
10 get no further decrease in urine protein or  
11 the patient can't tolerate it.

12 So, from a clinical perspective  
13 there are differences. But I think from an  
14 administrative dataset perspective, there  
15 probably was not.

16 CO-CHAIR ROSENZWEIG: Any other  
17 comments?

18 MEMBER MILLER: I don't see ACE and  
19 ARBs in the numerator here. I just see  
20 patients who receive nephropathy screening  
21 tests or had evidence of nephropathy, but I  
22 don't see

1 CO-CHAIR GOLDEN: Page 16 of the  
2 document.

3 MEMBER MILLER: Okay. Thank you.

4 PARTICIPANT: Also at the very end  
5 is an algorithm.

6 CO-CHAIR ROSENZWEIG: Yeah, they're  
7 defining evidence of nephropathy as including  
8 being on an ACE and an ARB, which is not  
9 exactly technically correct.

10 MEMBER MILLER: Excellent. Thank  
11 you.

12 CO-CHAIR ROSENZWEIG: Any other  
13 questions or any other comments?

14 (No response.)

15 CO-CHAIR ROSENZWEIG: Okay. Let's  
16 vote on priority then.

17 MS. BAL: Voting is open.

18 (Pause.)

19 MS. BAL: Okay. It's high, 16.  
20 Moderate, four.

21 CO-CHAIR ROSENZWEIG: Okay. From  
22 the Workgroup, any comments about reliability?



1 MEMBER TAYLOR: Yeah, only that  
2 there was some evidence that showed that the  
3 test is reliable.

4 CO-CHAIR ROSENZWEIG: You mean the  
5 microalbumin test specifically.

6 MEMBER TAYLOR: Yes.

7 (Simultaneous speaking.)

8 MEMBER TAYLOR: The EGFR is not

9 CO-CHAIR ROSENZWEIG: Is the  
10 measure reliable?

11 MEMBER TAYLOR: We had evidence for  
12 reliability of the measure, too.

13 MEMBER MILLER: Yeah, the data had  
14 very high reliability for health plans, but it  
15 was a little less reliable for the physicians.

16 CO-CHAIR ROSENZWEIG: Oh, and less  
17 for physicians. Thank you.

18 MEMBER MILLER: Yes.

19 CO-CHAIR ROSENZWEIG: Any other  
20 comments?

21 (No response.)

22 CO-CHAIR ROSENZWEIG: So, let's

1 vote on this one.

2 MS. BAL: Voting is open.

3 (Pause.)

4 MS. BAL: Okay. We have high, ten.  
5 Moderate, eight. Low, two.

6 CO-CHAIR ROSENZWEIG: Validity.  
7 Are the specifications consistent with the  
8 appropriate evidence? Exclusions appropriate?  
9 This is where Bob Bailey's issue may come up  
10 as a potential

11 MEMBER TAYLOR: Yes, about the  
12 EGFR. We didn't talk about that in the  
13 Subcommittee.

14 CO-CHAIR ROSENZWEIG: Yeah. Any  
15 other comments, Bob?

16 Yes, Vicky.

17 MEMBER DUCWORTH: This is just, I  
18 guess, kind of my complaining in general.  
19 Again, how I use metrics to evaluate any  
20 program really depends on the different  
21 criteria within these metrics.

22 And this is just one of those

1 metrics where it's really difficult for me to  
2 tie it to any particular or specific activity,  
3 because there are so many activities in it.

4 And it was specifically the ACE  
5 and ARBs that used to drive me crazy. And,  
6 again, I know because it's more indicative of  
7 a patient who was being treated for  
8 hypertension versus maybe nephropathy.

9 So, our providers would get credit  
10 for something they weren't, in fact, doing  
11 adequately. So, yeah.

12 CO-CHAIR ROSENZWEIG: I can make a  
13 comment on that. Just most physicians  
14 prescribe an ACE or an ARB to a diabetic  
15 because it is it's a positive impact on the  
16 kidney.

17 So, it's not that they're doing it  
18 by accident and luck, but they are  
19 deliberating choosing that agent because of  
20 its beneficial kidney effects.

21 CO-CHAIR GOLDEN: One issue,  
22 though, is that a lot of physicians will put

1 people on ACE and ARBs without measuring a  
2 microalbumin at all, which that's a subject of  
3 debate in various among different  
4 guidelines.

5 Yes, Sue.

6 MEMBER KIRKMAN: But I guess, you  
7 know, if we want performance measures to drive  
8 better outcomes, you know, I mean, you think  
9 about what's going to prevent end-stage renal  
10 disease from diabetes. It's, you know,  
11 looking for it or getting people on the right  
12 therapy.

13 So, ACE and ARBs, blood pressure  
14 control, which we have measures for, glucose  
15 control, which we have measures for. So, I  
16 mean, that doesn't really bother me that that  
17 is sort of part of the because that's really  
18 part of the downstream what you would do if  
19 you found microalbuminuria anyway.

20 So, I don't think it means the  
21 care was bad or that it was accidental. It  
22 means, for whatever reason, they're getting

1           what they would need anyway if the tests were  
2           positive.

3                       So, whether the test was done  
4           doesn't matter so much. So, I think it's okay  
5           although it might drive you crazy from an  
6           analytical perspective. I mean, I think more  
7           performance measures should be like that where  
8           we're actually measuring that the right thing  
9           was done as opposed to the test was ordered.

10                      CO-CHAIR ROSENZWEIG: Yeah, and  
11           once the test is positive, frequency of how  
12           often it needs to be done after that is a  
13           subject of great debate, because it can be  
14           used to help titrate up the medications you're  
15           using to treat it, but you don't necessarily  
16           have to continue to measure microalbumins  
17           forever afterwards once you've got them on the  
18           maximum dose of ACE or ARB.

19                      Yes.

20                      MEMBER HAYDON-GREATTING: What do  
21           you do if you have a population that can't be  
22           on an ACE or an ARB and, I mean, there's a

1           certain    there's a percentage of growing  
2           African Americans that are having issues with  
3           the ACEs and ARBs.  And then the new  
4           guidelines came out with calcium channel  
5           blockers and

6                        PARTICIPANT: I think there are  
7           exclusions, I mean, if I remember correctly.

8                        MEMBER HAYDON-GREATTING: I mean,  
9           this wouldn't exclude them, because you   with  
10          those patients you would be making sure you  
11          had microalbumin, you know, tests, but

12                       CO-CHAIR ROSENZWEIG: For treatment  
13          of hypertension certainly you're absolutely  
14          right.  And, in fact, the new JNC 8 guidelines

15  
16                       MEMBER HAYDON-GREATTING: Right.

17                       CO-CHAIR ROSENZWEIG:     specify  
18          going to other agents other than ACE and ARBs  
19          for African Americans.

20                       MEMBER HAYDON-GREATTING: Right.

21                       CO-CHAIR ROSENZWEIG: So, you're  
22          absolutely right with respect to that.  But

1 for people with diabetes, they're still  
2 recommending ACE or ARBs as first-line drugs.

3 MEMBER HAYDON-GREATTING: So, I  
4 just did a six-year longitudinal study on my  
5 employer group. And my patients down in North  
6 Carolina are I'm getting a small population  
7 of African Americans that cannot be on an ACE  
8 or an ARB because they've had some sort of  
9 reaction to it.

10 So, it's just a pattern I'm  
11 watching.

12 CO-CHAIR ROSENZWEIG: And there are  
13 a large percentage of our patients who can't  
14

15 MEMBER HAYDON-GREATTING: And I  
16 think we didn't know that before. And now  
17 we're doing such a good job of putting people  
18 on them that have diabetes, I think we're  
19 starting to see more patients having some of  
20 those adverse effects

21 CO-CHAIR ROSENZWEIG: No, your  
22 point is --

1                   MEMBER HAYDON-GREATTING:    where  
2                   it used to be rare.

3                   CO-CHAIR ROSENZWEIG: Your point is  
4                   well-taken.  Some people will get cough on an  
5                   ACE and they'll go to an ARB, and then they'll  
6                   have elevated potassiums or

7                   MEMBER HAYDON-GREATTING: Yes.

8                   CO-CHAIR ROSENZWEIG:       or they'll  
9                   have an elevated creatinine

10                  MEMBER HAYDON-GREATTING: Yes.

11                  CO-CHAIR ROSENZWEIG:       and you'll  
12                  have to stop that.

13                  MEMBER HAYDON-GREATTING: Yes,  
14                  that's it.

15                  CO-CHAIR ROSENZWEIG: Your point is  
16                  well-taken, but usually those patients end up  
17                  being referred to a nephrologist so that it  
18                  would be considered

19                               (Speaking off mic.)

20                  CO-CHAIR ROSENZWEIG: Let's vote,  
21                  yes.

22                  MS. BAL: Voting is open.



1 (Pause.)

2 MS. BAL: Okay. We have high, ten.  
3 Moderate, nine. Low, one.

4 CO-CHAIR ROSENZWEIG: All right.  
5 Okay. We're on feasibility. Sorry. Anyone  
6 want to speak to the feasibility the  
7 Workgroup want to speak to the feasibility  
8 aspect of this?

9 MEMBER TAYLOR: In our brief  
10 discussion of feasibility, we didn't see a  
11 problem.

12 CO-CHAIR ROSENZWEIG: The major  
13 issue might be is that you're collecting from  
14 different databases all at once for this one  
15 measure.

16 You can collect from with  
17 respect to billings for some, then medications  
18 for others, and then lab tests for the third.  
19 All of which could come from different  
20 origins, but I guess this has been in play for  
21 a while.

22 So, you've had no problems?

1                   MR. REHM: I guess the question I  
2                   have, I've run into some plans that don't have  
3                   their pharmacy data available for mining,  
4                   because it's in a PBM.

5                   Is that an issue at all?

6                   MEMBER TAYLOR: In my former life I  
7                   used to work for AHIP, which is the trade  
8                   association, and was in their clinical  
9                   affairs. And now the PBMs are very much part  
10                  and parcel of the data flow continuum.

11                  MEMBER HAYDON-GREATTING: Also, the  
12                  large employers are creating data warehouses  
13                  where they're requiring all that data being in  
14                  their back pocket now.

15                  They're not depending on express  
16                  groups or whoever else comes up to and part  
17                  of their contracting, they're requiring an  
18                  adherence clause so that they can get those  
19                  numbers and look at that.

20                  CO-CHAIR ROSENZWEIG: Any other  
21                  comments?

22                  (No response.)

1 CO-CHAIR ROSENZWEIG: Okay. Let's  
2 vote on feasibility.

3 MS. BAL: Voting is open.

4 (Pause.)

5 MS. BAL: The results are high, 13.  
6 Moderate, seven.

7 CO-CHAIR ROSENZWEIG:  
8 Accountability, transparency, progress with  
9 respect to improvement. Do you have any data  
10 related to improvement over the last few  
11 years?

12 MR. REHM: Again on Section 1(b)(2)  
13 and importance is the performance data gaps  
14 between let's see. This is the tenth and  
15 the 90th percentile are about 13 percent in  
16 commercial. 13 to 15. 18 percent in  
17 Medicaid, and nine in Medicare.

18 And in terms of improvement on the  
19 mean, fairly stable with some improvement in  
20 PPO for commercial and in Medicare.

21 CO-CHAIR ROSENZWEIG: Okay. Thank  
22 you. Any comments by the Workgroup?

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Bob?

(No response.)

CO-CHAIR ROSENZWEIG: Okay. Let's  
vote on this.

MS. BAL: Voting is open.

(Pause.)

MS. BAL: Let's all just push the  
vote one more time. We're missing two. Thank  
you.

(Pause.)

MS. BAL: Okay. We have high, 13.  
Moderate, six.

CO-CHAIR ROSENZWEIG: Okay. Let's  
vote on the overall measure.

MS. BAL: Voting is open.

(Pause.)

MS. BAL: Yes, 19.

CO-CHAIR ROSENZWEIG: So, NCQA  
should be happy with that. Okay. So, now  
we're going to move on to 2417.

DR. BURSTIN: And we'll come back  
to the foot measures. The Joint Commission

1 folks had to fly out of town. So, we're going  
2 to do the Joint Commission measures and then  
3 come back to

4 MS. TIGHE: Yeah, we're going to  
5 start with 2417. The way their set was  
6 developed it makes more sense to start there.  
7 So, apologies for the additional confusion on  
8 top of changing the agenda around.

9 (Pause.)

10 CO-CHAIR ROSENZWEIG: Okay. So,  
11 the title of this measure is "Risk  
12 Assessment/Treatment After Fracture." And the  
13 measure developer is the Joint Commission.  
14 And would you like to describe the measure for  
15 us, please?

16 And what's your name?

17 MS. DOMZLSKI: Cathy Domzlski from  
18 the Joint Commission. Hello, everyone. With  
19 me today is Ann Watt from the Joint  
20 Commission, and Dr. Ethel Siris who is the  
21 chairperson of our advisory panel.

22 We have had these measures in

1 development for the last eight years and,  
2 unfortunately, not much has changed over those  
3 eight years in the care of the osteoporosis  
4 and fragility fracture patient.

5 Our objective in measure  
6 development is that when used together  
7 although these measures are not paired, it  
8 gives an overall picture of the care for  
9 fragility fracture patients and our approach  
10 has several steps.

11 It begins with a literature review  
12 and formation of that advisory panel of  
13 experts, and they advise us at every step of  
14 the process.

15 We issue a call for measures. We  
16 develop a framework and draft measures. And  
17 those measures when developed, are then alpha  
18 tested for phase validity.

19 We invite public comment on the  
20 measures, and we then draft and specify the  
21 final version of measures.

22 We pilot test them, we do data

1 collection, and we do that at volunteer  
2 hospitals throughout the country. The results  
3 are subsequently analyzed.

4 The advisory panel reviews those  
5 results, finalizes measures. And in this  
6 case, we have three measures to present to you  
7 today relative to the fragility fracture  
8 patient.

9 The first numerical measure,  
10 Number 2416, encompasses lab testing for  
11 underlying causes of low bone mass.

12 Given the prevalence of secondary  
13 causes of osteoporosis, we feel this testing  
14 is essential to identify and prevent further  
15 bone loss and further fracture.

16 In lieu of testing for Vitamin D  
17 levels in that measure, oral D may be given  
18 during the hospitalization.

19 The second measure which is now  
20 the first one we'll discuss, Number 2417,  
21 seeks to ensure that those hospitalized with  
22 a fragility fracture indeed receive testing or

1 treatment for osteoporosis either while  
2 hospitalized, soon after discharge, or through  
3 the auspices of a fracture liaison service.

4 The last measure, Number 2418,  
5 addresses patients seen in the ED and sent  
6 home with a fragility fracture.

7 Now, there is no reason that those  
8 patients who are sent home should be treated  
9 differently or have a different standard of  
10 care than those patients hospitalized. And  
11 so, again, we want to ensure that bone mineral  
12 density testing is performed by treatment  
13 through a fracture liaison service or by  
14 referral to a testing facility or other  
15 practitioner. And that referral would be  
16 contained in the discharge instructions to the  
17 patient or caregiver.

18 Now, the results of our testing  
19 indicate in all three measure cases,  
20 compliance with the measures is at a mean  
21 level below ten percent, which is a little bit  
22 lower than that reported in the literature.



1                   Generally speaking, 20 to 22  
2                   percent of patients are tested or treated for  
3                   osteoporosis after a fracture, but certainly  
4                   there's a lot of room for improvement.

5                   We did find a ray of hope. There  
6                   was one hospital in our pilot test group who  
7                   enacted a couple of changes to their policies  
8                   and procedures and they were able to achieve  
9                   more than a 90 percent compliance rate.

10                  And what did they do? They  
11                  educated their house staff, their ED staff and  
12                  they slightly modified their fracture order  
13                  set and their discharge instructions to the  
14                  patient. So, we feel this represents an  
15                  opportunity to really improve care for these  
16                  people.

17                  So, once again we thank you for  
18                  having us. We thank you for inviting us onto  
19                  your previous call. Thank you very much.

20                  CO-CHAIR ROSENZWEIG: Thank you.  
21                  Thank you very much. Would the Workgroup  
22                  members like to comment on that?

1                   MEMBER KEARNS: Okay. So, I was  
2                   the lead on this measure, the first one we're  
3                   going to review, which is the assessment for  
4                   fracture risk or treatment by several measures  
5                   in patients who are actually hospitalized with  
6                   a fracture. So, not the emergency room. This  
7                   is inpatients who are dismissed and the  
8                   measure to meet the measure so, it's every  
9                   patient over age 50 from an inpatient with a  
10                  long list of potential fractures that would  
11                  meet this diagnosis.

12                  And to meet the measure, the  
13                  numerator would be had a DXA scan ordered or  
14                  performed, prescribed a medication or who were  
15                  seen by a fracture liaison or had some other  
16                  risk assessment measured if DXA was not  
17                  performed.

18                  There were a couple of exclusions.  
19                  People younger than 50, people who are already  
20                  on a treatment for osteoporosis or enrolled in  
21                  an osteoporosis trial, patients who are on  
22                  comfort measures only or those who had

1 expired, or those who had documented bone  
2 mineral density test in the last 12 months  
3 prior to the fracture.

4 So, that's the basics of the  
5 measure. I could go right to the evidence if  
6 that's okay.

7 I think the Working Group agreed  
8 that the evidence for detection and treating  
9 osteoporosis with the ultimate goal of  
10 preventing additional fractures was very high,  
11 that there's no reason to question that  
12 medications are helpful.

13 Whether there is evidence that  
14 scheduling a DXA is the same as prescribing a  
15 medication, I think, is not clear, but  
16 certainly treatment of osteoporosis goes up if  
17 there's more DXAs performed.

18 So, it may seem to be an  
19 intermediate measure that's reasonable. So,  
20 that's the evidence I think any questions?  
21 There's other concerns and things that will  
22 come up later about the process and things,

1 but I think the evidence for treating  
2 osteoporosis, especially in patients who had  
3 a low-energy fracture, is pretty solid.

4 CO-CHAIR ROSENZWEIG: It specifies  
5 specific fractures that are supposed to be  
6 fragility fractures, but what if you have  
7 fractures that are technically not fragility  
8 fractures that would have those same diagnosis  
9 codes?

10 For instance, if a person has  
11 existing prostate cancer or breast cancer with  
12 metastasis to the spine.

13 MEMBER KEARNS: That's a good  
14 question. I looked at there's a lot of  
15 codes in there. So, I'm not an expert in all  
16 the codes.

17 And I don't think that it included  
18 things that were considered pathologic from  
19 cancer treatment from my looking through  
20 there. But, again, this may be people who are  
21 more familiar with codes could speak to that,  
22 but I don't think it includes that.

1                   So, I don't think    to answer your  
2                   question, I don't think that patient would be  
3                   captured by this, but there are a lot of codes  
4                   included.

5                   CO-CHAIR ROSENZWEIG: Okay.

6                   Yes.

7                   DR. SIRIS: Well, the intent was  
8                   that these would be osteoporosis-associated  
9                   fractures. And by definition if you have  
10                  metastasis in the bone, it is not an  
11                  osteoporosis-associated fracture.

12                  CO-CHAIR ROSENZWEIG: But you're  
13                  making    you're using the DXA test in order to  
14                  diagnose osteoporosis and it's the fracture  
15                  that comes first, isn't it?

16                  DR. SIRIS: No, no, no. We're  
17                  trying    the diagnosis of osteoporosis can be  
18                  made based upon a DXA that gives you a certain  
19                  level of lowness. Or if you have low bone  
20                  mass and you've had one of these fractures,  
21                  clinically you have osteoporosis.

22                  And since these are generally

1 fractures that are operated on in the  
2 hospital, you would exclude metastasis,  
3 because that would be noted. Or if you were  
4 a patient who broke a hip in the setting of  
5 being treated for prostate or breast cancer,  
6 clearly the diagnosis would have to be made  
7 before you could call it an osteoporosis-  
8 associated fracture.

9 That is to say you'd have to  
10 exclude as part of your clinical care that  
11 there was metastatic disease in bone. I mean,  
12 that's what would happen.

13 We are not interested in pursuing  
14 fractures once the diagnosis has been made  
15 that it's due to metastatic disease in bone.  
16 That's a separate issue.

17 We're trying to capture the  
18 patient with a fragility fracture due to  
19 osteoporosis, which clinically means you  
20 either have a score on DXA that's minus 2.5 or  
21 below with the spine or hip, or you have low  
22 bone mass and you've broken one of the major

1 bones that are considered osteoporosis-  
2 associated fractures.

3 Right now those folks get the  
4 fracture fixed by the orthopedic surgeon and  
5 then they're told goodbye and good luck. And  
6 there's no further effort to reduce the risk  
7 of the next fracture for which they are at  
8 very high risk, and that's what we're trying  
9 to get past.

10 CO-CHAIR ROSENZWEIG: So, to follow  
11 up on this question, there's an Excel  
12 spreadsheet attached which we --

13 DR. SIRIS: Yes.

14 CO-CHAIR ROSENZWEIG: So, the  
15 metastatic or the pathologic fractures would  
16 be in the spreadsheet?

17 DR. SIRIS: They're excluded.  
18 Sorry. Okay. Short answer, they're excluded.

19 PARTICIPANT: Okay. I'm sorry. I  
20 may have misinterpreted the way it was set up,  
21 but I assumed that it was the fracture that  
22 was the initiating event that put the person

1 in, you know.

2 DR. SIRIS: The reason for the  
3 fracture is osteoporosis. And right now  
4 that's not being recognized.

5 So, these are people who have had  
6 the complication of osteoporosis. They've had  
7 a fracture. Generally speaking, they've never  
8 been diagnosed as having osteoporosis. And,  
9 therefore, no attempt is made to treat them to  
10 prevent the next fracture for which they're at  
11 high risk, but these are for patients admitted  
12 with a fragility fracture. That's correct.

13 MEMBER KIRKMAN: So, I guess the, I  
14 mean, just to follow up on that, I guess the  
15 only question is, is it specific enough in the  
16 measure specifications that's redundant  
17 that those people wouldn't be, I mean, I think  
18 we all get it that that's not what we're  
19 looking for.

20 But if you're measuring this, is  
21 it specific enough? Because I don't see an  
22 exclusion for metastatic cancer or



1 CO-CHAIR ROSENZWEIG: I think that  
2 that gets into specs, and not into the  
3 evidence.

4 MEMBER KIRKMAN: Yes, sorry. And  
5 ICD-10 will fix it anyway.

6 CO-CHAIR ROSENZWEIG: Okay. Any  
7 other comments?

8 Yes, Bill.

9 MEMBER TAYLOR: We're asking  
10 question about the evidence?

11 CO-CHAIR ROSENZWEIG: Yes.

12 MEMBER TAYLOR: So, could someone,  
13 an expert on this, comment on why a T-score of  
14 minus 2.5 is the cutoff for years?

15 DR. SIRIS: It's an arbitrary  
16 cutoff that the World Health Organization came  
17 up with in 1994 when a bunch of osteoporosis  
18 experts got together in Geneva, and over beer  
19 and pizza they decided that the cut-point  
20 could be minus two, or it could be minus  
21 three, and they finally concluded that it  
22 should be minus 2.5.

1                   It was arbitrary. It's not  
2                   unreasonable. The lower your T-score, the  
3                   greater your relative risk for fracture.

4                   And this became an operational  
5                   definition of osteoporosis in 1994 from the  
6                   World Health Organization as a way of helping  
7                   epidemiologically to sort out those people at  
8                   higher risk of fracture and it's what we live  
9                   with.

10                  We have just published a paper in  
11                  Osteoporosis International calling for an  
12                  expansion, that is to say a consensus group is  
13                  saying that that's one good way to identify  
14                  the patient at high risk.

15                  Osteoporosis is a disorder of  
16                  reduced bone strength that predisposes to a  
17                  high risk for fracture. The T-score is one  
18                  way to do it.

19                  Another way to do it is you say to  
20                  somebody, you just had a hip fracture and  
21                  you're 75, you have osteoporosis regardless of  
22                  T-score.

1                   If you have low bone mass not  
2                   quite at minus 2.5 and you've had certain  
3                   types of fractures, that puts you  
4                   statistically at very high risk of another  
5                   fracture and that's been well-established in  
6                   the literature. So, that's another way to  
7                   make the diagnosis.

8                   And I think you're right that the  
9                   ICD-10 codes are going to help us there, but  
10                  that's the answer to your question as to how  
11                  they picked minus 2.5.

12                  CO-CHAIR ROSENZWEIG: I think if it  
13                  was the World Health Organization, it wasn't  
14                  a meeting over beer and pizza. It was  
15                  probably wine and quiche or something like  
16                  that.

17                  DR. SIRIS: I know the people who  
18                  were there and I believe that was part of it.  
19                  And the reason it's called a T-score is  
20                  because the guy from one of the bone density  
21                  companies was named Tom, and they decided to  
22                  name it for him.

1                   They were drunk when they did  
2           this.

3                   (Laughter.)

4                   CO-CHAIR GOLDEN: So, can I follow  
5           up on your comment just so    because one of  
6           the reasons for the cut-point which actually  
7           gets to be interesting because you get into  
8           overuse, the data on using the drugs, the  
9           phosphonates in people under 2.5 because they  
10          are toxic in their own way

11                  DR. SIRIS: I would argue that.

12                  CO-CHAIR GOLDEN: Well, I mean,  
13           I've been getting different kind of  
14           depending on who you talk to, but I'm just  
15           saying I've seen actually people getting more  
16           treatment below 2.5. And I'm not sure    well,  
17           at least from my perspective in

18                  DR. SIRIS: The literature shows  
19           that a number of the clinical trials had entry  
20           criteria that included people with hip T-  
21           scores that were the basis for entry and many  
22           of those were below minus 1.6.

1                   Some of the pivotal trials  
2           included people with osteopenia who had  
3           already had a vertebral fracture. So, there's  
4           quite a bit of data indicating that these  
5           drugs do work.

6                   Risedronate studies have shown  
7           that the drug worked in people who were  
8           misclassified as osteoporosis who actually had  
9           osteopenia. And I think clinically today if  
10          you get somebody with a bad fragility fracture  
11          and the T-score is minus 2.3 instead of minus  
12          2.5, you're going to treat.

13                  We also use algorithms like FRAX,  
14          a fracture risk analysis, which doesn't  
15          necessarily require a bone density although it  
16          works better if you do a bone density. And it  
17          will show that if you're an older individual,  
18          70, 75, 80 and you're osteopenic and you have  
19          one other risk factor such as the fracture you  
20          just sustained, your risk is going to be very  
21          high.

22                  And the current guidelines

1 recommend that those patients should be  
2 treated to lower the risk of the next fracture  
3 and there's a literature that suggests for  
4 several drugs that it does reduce fracture  
5 risk in those patients.

6 CO-CHAIR GOLDEN: So, when you  
7 refer to a fracture risk assessment, you're  
8 specifically referring to FRAX?

9 DR. SIRIS: Well, FRAX would be the  
10 common one used in the United States. There  
11 are other algorithms that some people choose  
12 to use, but FRAX is the one that is sort of  
13 WHO-II. Bone density was WHO-I.

14 CO-CHAIR GOLDEN: Okay. Thank you.

15 MEMBER TAYLOR: So, just to  
16 clarify, I understand that as T-score goes  
17 down greater values below fracture risk goes  
18 up. And as FRAX score goes up, fracture risk  
19 goes up.

20 But the trials that show  
21 bisphosphonates prevent fractures, haven't  
22 they mostly been limited to people who not

1           only have low bone density, but also have had  
2           a fracture?

3                       DR. SIRIS: Some of the trials used  
4           exclusively cut-points of minus 2.5 at spine  
5           or hip as entry criteria. Other trials  
6           including those in post-hip fracture patients  
7           with the drug zoledronate, included people who  
8           had had the hip fracture and they simply had  
9           to be osteopenic.

10                      I mean, they did not require a  
11           minus 2.5, and the drug was highly effective  
12           at reducing the risk of subsequent fractures  
13           and reducing mortality.

14                      MEMBER TAYLOR: But for people with  
15           only the low bone density less than where they  
16           did not achieve a greater than 2.5 reduction  
17           and they had no fractures, those people have  
18           not been studied and shown to

19                      DR. SIRIS: No, they have, because  
20           some of the trials back when they were first  
21           enrolling people, there were differences in  
22           the two manufacturers' reference populations

1 and it turned out in retrospect that a fair  
2 number of people whose T-score was minus 1.6  
3 to minus 2.4 were enrolled. And in the  
4 alendronate trials, there was an effective  
5 reduction in risk of certain fracture types in  
6 that setting.

7 Now, of course, whether or not the  
8 drugs work in people with osteopenia who  
9 haven't had fractures is a good question, but  
10 every patient that we're talking about has had  
11 a fracture.

12 So, it's a different group of  
13 people where the risk is much higher and where  
14 we have evidence from a number of trials,  
15 particularly the zoledronate trials in hip  
16 fracture patients, that the drugs are highly  
17 effective and that you shouldn't get too hung  
18 up as to whether the T-score was minus 2.2 or  
19 minus 2.5 or minus 2.7.

20 MEMBER KEARNS: Well, I just wanted  
21 to say that I agree with the intent of the  
22 measure.



1                   If you pull up the appendix that  
2                   lists the other ways for a fracture risk  
3                   assessment, if you could pull that up, because  
4                   that is not clear to me, the measure as  
5                   written talks about DXA.

6                   Maybe it could be modified to say  
7                   bone density for which there are several ways  
8                   to assess it. I don't know, but the ancillary  
9                   information is not clear what those are in the  
10                  appendix.

11                  If they're not in the appendix,  
12                  then they should - since they are a way to  
13                  qualify for the measure, they have to be very  
14                  specified.

15                  And what I had included, an  
16                  ultrasound of the humerus or something, which  
17                  I don't - when I open it on my computer,  
18                  that's what it looks like.

19                  MS. DOMZLSKI: Our first submission  
20                  was --

21                  MEMBER KEARNS: It's in the  
22                  appendix.

1 MS. DOMZLSKI: - in ICD-9.

2 MEMBER KEARNS: It's in the  
3 appendix.

4 MS. DOMZLSKI: In the translation  
5 to ICD-10, there are additional codes that  
6 need to be supplied. But the other assessment  
7 methods that may be used are the QCT of the  
8 spine, the QUS of the heel, DXA of the  
9 forearm, a SXA or DXA of the heel, and the  
10 FRAX assessment, too.

11 And we are working on supplying  
12 the current, up-to-date codes for those.

13 MEMBER KEARNS: Yes, those sound  
14 like the right ones. Just the file that we  
15 have doesn't say that clearly.

16 CO-CHAIR GOLDEN: And just to help  
17 me again on the evidence, I know that DXA  
18 scans are very good. All of us have seen  
19 people coming in with the local heel scans in  
20 somebody's office. So, are those considered  
21 valid and useful by the evidence?

22 DR. SIRIS: There's evidence that

1 if you're very low on one of these peripheral  
2 tools, your fracture risk is elevated.

3 Clearly the preferred test is DXA.  
4 DXA right now is a relatively inexpensive test  
5 and there are a fair number of DXA machines  
6 around. So, most people are likely to get a  
7 DXA.

8 But if you lived in a place where  
9 the nearest DXA facility was three hours away  
10 and your physician, after you had your  
11 shoulder fracture, did an SXA which showed low  
12 values, that would satisfy the measure.

13 MS. WATT: Can I just clarify? I'm  
14 not sure that it's clear. This measure really  
15 is about the denominator is patients who come  
16 in with a fracture, and the numerator is  
17 patients who had either a DXA ordered or  
18 performed, or a prescription for medication  
19 while they're in the hospital, or seen by a  
20 fracture liaison service.

21 That is simply it in terms of what  
22 this measure comprises.

1                   MEMBER TAYLOR: Well, that's not  
2                   what she just said.

3                   (Simultaneous speaking)

4                   MS. WATT: Sorry.

5                   DR. SIRIS: There are other  
6                   fracture risk assessment tools which are very  
7                   unlikely to be used, because it's easier to  
8                   get these other things done.

9                   Remember this is - because this  
10                  is potentially a Joint Commission measure,  
11                  what's in most of our hearts is the hope that  
12                  right now probably the best way to get the  
13                  post-fracture patient treated for osteoporosis  
14                  is through the fracture liaison service. The  
15                  evidence for that is powerful. Kaiser has  
16                  shown it really, really works.

17                  The problem is that most hospitals  
18                  are unwilling to pay the salary of a fracture  
19                  liaison person.

20                  And if this were to become a Joint  
21                  Commission measure which will require your  
22                  approval before they will approve it, it would

1           conceivably be an incentive to hospitals  
2           admitting patients with fractures - I'm  
3           telling you something that isn't in the  
4           document you're reading, but the fracture  
5           liaison service is a powerful way to get these  
6           people managed.

7                         It's a coordination of care effort  
8           that puts the fracture fixers together with  
9           the subsequent fracture preventers. It works.  
10          There's a plethora of data.

11                        And yet, right now people are  
12          struggling to put these things in place  
13          because of the cost of hiring somebody for  
14          70,000 bucks a year to do the work.

15                        So, the hope is with something  
16          like a Joint Commission measure, that it may  
17          be an incentive to a hospital to spend the  
18          money to get fracture coordinators and make it  
19          work the way it does at Kaiser.

20                        CO-CHAIR GOLDEN: Okay. I guess -

21                        DR. SIRIS: No, no, no. They don't  
22          have to do that. They can make sure that as

1           that hospital you visited does, that they know  
2           they should do it and the endocrinologist  
3           agrees that they'll see everybody who's had a  
4           fracture.

5                         CO-CHAIR GOLDEN: One more  
6           technical question.

7                         DR. SIRIS: Yes, sir.

8                         CO-CHAIR GOLDEN: These activities,  
9           this assessment has to be done by discharge,  
10          or within 60 days of discharge? Is there any  
11          framework that it has to be before discharge?

12                        MEMBER KEARNS: All these measures  
13          to meet the criteria have to be by -  
14          according as written as the time of dismissal,  
15          but that includes just an appointment for or  
16          just an appointment with a fracture liaison.

17                        So, you don't actually have to do  
18          the DXA which comes down to a feasibility  
19          issue, not really an evidence issue.

20                        CO-CHAIR ROSENZWEIG: What about if  
21          the patient has already had this evaluation  
22          prior to the fracture like before coming into

1 the hospital?

2 Do you have like a time frame of

3 -

4 MEMBER KEARNS: As written, it says  
5 if they have a documented DXA within the 12  
6 months previous.

7 CO-CHAIR ROSENZWEIG: Previous,  
8 okay.

9 MEMBER KEARNS: Now, there are  
10 feasibility issues with that, again, but the  
11 evidence is what we're discussing, I think.

12 CO-CHAIR GOLDEN: We've covered  
13 multiple fronts here. We've covered some  
14 specification issues which will help us later.  
15 We have a point at the end there.

16 MEMBER LEE: What is the definition  
17 that you're using a fragility fracture? Can  
18 you just clarify that?

19 CO-CHAIR GOLDEN: There is a  
20 spreadsheet, apparently, that you can look at  
21 and it's probably on the SharePoint. That  
22 lists everything that you - probably more

1 than you'd want to look at.

2 DR. SIRIS: I'm looking at that  
3 right now. I think it's in front of me. It  
4 includes pathologic fracture of -- the Excel  
5 column cuts off, but it gets back to our  
6 question of just how does the measure exclude  
7 metastatic fractures. It's just not clear  
8 from this.

9 DR. SIRIS: Let me start by saying  
10 that some orthopedic surgeons if they treat an  
11 osteoporotic fracture, call it a pathological  
12 fracture because they get paid a little more  
13 if they call it that, but the intent is that  
14 these are osteoporosis-based fragility  
15 fractures not due to things like metastatic  
16 cancer.

17 Cathy.

18 MS. DOMZLSKI: The patient with  
19 pathologic fracture as Dr. Siris indicated, is  
20 very often not due to a metastatic lesion.

21 However, there are also cancer  
22 patients who the first sign is a fracture that



1           they have an underlying disorder that's of a  
2           malignant nature. And so, that doesn't mean  
3           that they should not be tested or treated.

4                        Patients who are far advanced in  
5           cancer who are on comfort measures only are  
6           excluded from the measure.

7                        CO-CHAIR GOLDEN: Okay. Let's get  
8           back to evidence. So, we have wandered around  
9           here a little bit and are we ready to talk  
10          about or vote on the evidence of this measure?

11                       MS. BAL: Voting is open.

12                        We have high nine, moderate ten.

13                        MEMBER KEARNS: Okay. If we move  
14          on to the performance gap, I think that the  
15          published literature would support that  
16          there's a huge performance gap.

17                        And they did do pilot studies in  
18          some hospitals and shown that there was quite  
19          a bit of a gap in the care here. So, I would  
20          rate that this is a high.

21                        We did not in our working group,  
22          get a lot of time to discuss this measure,

1           because we started with a different one. And,  
2           as you've already seen today, sometimes it's  
3           hard to get to all the measures, but I think  
4           there was a consensus that this was a high  
5           gap.

6                           CO-CHAIR ROSENZWEIG: Ready to  
7           vote.

8                           MS. BAL: The voting is open.

9                           Okay. We have high 17, moderate  
10          two.

11                          MEMBER KEARNS: Okay. And then we  
12          move on to priority, and I think that, again,  
13          if I can speak for the working group and if  
14          anyone wants to jump in and correct me, that  
15          we felt this was a high priority that this is  
16          probably an area that's been neglected in  
17          terms of performance measures and that the  
18          impact on the health of individuals and  
19          society was great enough that make this a high  
20          priority.

21                          CO-CHAIR GOLDEN: Seeing no  
22          comments, are we ready to vote?

1 MS. BAL: Voting is open.

2 The results are high 18, moderate  
3 one.

4 MEMBER KEARNS: Okay, the  
5 reliability measure. They did do testing in  
6 some hospitals and about reporting. And it's  
7 appeared to be quite a reliable way to  
8 ascertain the data.

9 CO-CHAIR GOLDEN: It gets into the  
10 issue about your specificity, I mean, how well  
11 you identify your denominator and your  
12 numerator.

13 So, any other further comments on  
14 this issue?

15 MEMBER KIRKMAN: So, am I right  
16 that there were some things that you did not  
17 do reliability testing on like the fracture  
18 liaison service and whether they were already  
19 on osteoporosis treatment and whether they had  
20 had a DXA before, the year before?

21 MS. DOMZLSKI: We tested, for  
22 reliability, we tested every data element.

1 MEMBER KIRKMAN: Okay.

2 MS. DOMZLSKI: Whether they had  
3 been tested in the previous year, everything  
4 that you see listed is a data element with  
5 reliability tests.

6 MEMBER KIRKMAN: Okay. I guess it  
7 was a staff comment that maybe it was just a  
8 mistake.

9 MS. WATT: Yes, if I understood  
10 your question correctly, it was did we see how  
11 many people were referred to the fracture  
12 liaison service versus had the DXA versus were  
13 on the medication?

14 The answer is no, because that's  
15 one data element. We didn't look for the  
16 individual component of that data element. We  
17 just looked to see if one of those was done.

18 MEMBER McDERMOTT: But I would ask  
19 do -- some of these people potentially are a  
20 refracture. It's not a first fracture or they  
21 are known osteoporosis.

22 If they are known osteoporosis -

1                   MEMBER KEARNS: They're excluded.  
2                   If they're on an osteoporosis medication  
3                   already, they're excluded.

4                   MEMBER McDERMOTT: Oh, I missed  
5                   that. Thank you.

6                   MEMBER KEARNS: And if they had a  
7                   DXA within the last 12 months, they're  
8                   excluded. So, it would only include,  
9                   hopefully, people who were not diagnosed or  
10                  treated.

11                  Now, people can be diagnosed and  
12                  not be treated, or been given a prescription  
13                  and not taking it.

14                  MEMBER McDERMOTT: Thank you.

15                  MEMBER TAYLOR: What's the test-  
16                  test reliability of the DXA?

17                  DR. SIRIS: I'm not sure I know  
18                  what you mean by test-test reliability. DXA  
19                  is a pretty precise tool. I mean, it's an  
20                  accurate and easily done test.

21                  MEMBER TAYLOR: Yes, if you do it  
22                  twice, do you get the same measure? That's

1           what I mean.

2                         DR. SIRIS: Because of the way it's  
3           calibrated, because of the way the machine  
4           works if you're trained and you know what  
5           you're doing, you should get very, very, very  
6           tight similarity in repeating the test twice,  
7           yes.

8                         MEMBER TAYLOR: And then when it's  
9           looked at and actually used, do people  
10          actually well-trained and know what they're  
11          doing, I mean, when a physician gets -

12                        DR. SIRIS: Well, I mean, a lot of  
13          them are in radiology practices today. And  
14          the radiologists seem to know what they're  
15          doing.

16                        The ones that are in endocrine  
17          offices or primary care offices, you hope that  
18          they are giving you decent data.

19                        MEMBER TAYLOR: Oh.

20                        DR. SIRIS: It's not perfect, but  
21          it's pretty good.

22                        MEMBER TAYLOR: And how about at

1 different sites, you know? The spine and the  
2 total hip and -

3 DR. SIRIS: Generally what we do is  
4 we measure the spine and the hip and you can  
5 certainly get discordance between spine and  
6 hip, but that's part of the natural history of  
7 the disease. That's not the machine.

8 Some people will be low at the  
9 spine and better at the hip. Other people as  
10 they get older and older and get more  
11 degenerative disk disease, will have spines  
12 that can't really be measured, but the hip can  
13 still be very well measured correctly.

14 And many places will include a  
15 forearm measurement which takes another 30  
16 seconds. If the spine is useless, you can  
17 look at the forearm and the hip.

18 MEMBER TAYLOR: And how about in  
19 the evidence base? Were those numbers in  
20 wrist, forearm, spine used when you gave us  
21 the T-scores that have been used to show  
22 fracture reduction with treatment?

1 DR. SIRIS: Well, no. In terms of  
2 making a diagnosis, the spine, the hip, and  
3 the forearm were the standard sites. And  
4 those are the standard sites that are still  
5 used today.

6 For clinical trials, entry level  
7 usually involved looking at spine and hip and  
8 you had to be low at one or the other.

9 If you're low at any of those two  
10 sites where there were two hip sites and a  
11 spine site, if you're low at any of those  
12 three sites at the level of minus 2.5 or  
13 below, you were called osteoporosis.

14 CO-CHAIR GOLDEN: So, again, Sue,  
15 do you have something you want to, or are you  
16 just

17 MEMBER KIRKMAN: Well, I'm still  
18 confused about your reliability testing.  
19 Because at least in 2(a) 2.3 it looks like you  
20 looked at what happened in the hospital, but  
21 not whether they came in on FDA-approved  
22 pharmacotherapy, whether they had previously



1 had a DXA in the prior year or the fracture  
2 liaison service.

3 Am I misreading that? Because, I  
4 mean, that's the same thing that the staff  
5 comment said that you didn't do reliability  
6 testing on all the parts of the numerator.

7 MS. WATT: Those are exclusions to  
8 the denominator. They never would have made  
9 it into the measure.

10 MEMBER KIRKMAN: Okay. But you can  
11 reliably pick out those exclusions, because -  
12 okay. I mean, because otherwise a lot of  
13 people are going to score poorly on this even  
14 though the patient was already on appropriate  
15 therapy. You know what I'm saying?

16 MS. WATT: I do know what you're  
17 saying, but the thing is those patients -  
18 there's the whole mass of fracture patients,  
19 and then we look for those exclusions before  
20 they ever even get into the measure.

21 We're talking about the  
22 reliability for this measure. Those patients

1           aren't in there.

2                           MEMBER KIRKMAN: I mean, don't you  
3           have to have a reliable way to find the  
4           exclusions?

5                           Maybe the NQF staff can help me  
6           here, but - so, we have to kind of take your  
7           word for it that you could reliably exclude  
8           people.

9                           MS. DOMZLSKI: For example, every  
10          one of those exclusions, for example, a prior  
11          diagnosis of osteoporosis, becomes a data  
12          element when you collect this data. And we  
13          did reliability scores on all of the data  
14          elements.

15                          In other words, how accurate was  
16          the ability to identify that particular data  
17          element?

18                          And for that particular data  
19          element, the kappa score was 0.75, which is  
20          quite high.

21                          We had a match rate of almost 95  
22          percent in terms of what we abstracted

1 compared with what the hospital had abstracted  
2 and identified as a patient with a prior  
3 diagnosis of osteoporosis.

4 So, that was one data element that  
5 was -

6 MEMBER KEARNS: So, maybe, Sue,  
7 you're asking about, I mean, there's some  
8 different questions that I have within this,  
9 but they're not part of the reliability. And  
10 one of them is it's very difficult to know  
11 whether a DXA has been done at a different  
12 center within the last year, but that's a  
13 different question in my mind than what the  
14 hospital is looking at and what you are  
15 confirming were very well-matched. And  
16 that's, to me, the reliability.

17 The feasibility and usability are  
18 different things about certain measures, but  
19 the reliability I think they did test and was  
20 found to be quite good with the limitations  
21 that the hospital may not know everything  
22 because of the nature of healthcare in this

1 area.

2 CO-CHAIR GOLDEN: Patricia, do you  
3 have something or are you just vestigial  
4 there? Okay.

5 MEMBER MILLER: Does Sam's Club do  
6 DXA scans?

7 (Laughter.)

8 MEMBER KEARNS: Not yet.

9 PARTICIPANT: Costco, I'm sure.

10 DR. SIRIS: DXA scans involve  
11 radiation so that they have to be performed in  
12 places where you have - in most states you  
13 have to have licensed x-ray technicians. And  
14 they do involve radiation and they're not -  
15 now, I suppose Sam's Club may do ultrasounds  
16 and things like that, but it's never been  
17 profitable. So, I doubt that it's being done.

18 CO-CHAIR GOLDEN: Are we ready to  
19 talk about reliability and vote?

20 MS. BAL: Voting is open.

21 High eight, moderate 11.

22 MEMBER KEARNS: Okay. So, the next

1 point to talk about is validity and that is  
2 the strength of the evidence of the different  
3 items in the measure and whether that would be  
4 a valid assessment of quality.

5 And I think, again, our working  
6 group did not get a chance to really discuss  
7 this in this level of detail, but I think we  
8 would all agree that assessing for  
9 osteoporosis by one of these measures after a  
10 fragility fracture would be a valid assessment  
11 of quality.

12 CO-CHAIR GOLDEN: Ready to vote?

13 MS. BAL: Voting is open.

14 High nine, moderate 11.

15 MEMBER KEARNS: Okay. I think the  
16 next point to discuss is feasibility and I  
17 think there is some points to discuss here  
18 potentially.

19 This is at a facility level where  
20 we're talking about inpatients. So, I think  
21 that's important to keep in mind because of  
22 the way that healthcare is structured around

1           inpatients. A lot of the tests we're talking  
2           about are not routinely done as inpatients.

3                         That's why I think allowing for  
4           some of the other measures and/or an  
5           appointment for a measure gets around that  
6           because anybody who knows DXAs, knows you're  
7           not getting a DXA as an inpatient. In my  
8           facility you can't, because the machines  
9           aren't in the hospital.

10                        One could argue about whether an  
11           appointment is the same as a measurement of  
12           it. Because in my experience with hip  
13           fracture patients when we tried that giving  
14           them an appointment, maybe ten percent of  
15           people would show up for the appointment.

16                        So, you know, that doesn't negate  
17           the importance of doing it and having a  
18           measure and certainly some populations might  
19           require a different approach. And I think the  
20           fracture liaison service nicely gets around a  
21           lot of that.

22                        So, I think, again, maybe perfect

1 shouldn't be the enemy of good here.

2 DR. SIRIS: I think you're correct.  
3 The fracture liaison service is one way to get  
4 around it.

5 The other way to get around it is  
6 to discharge the patient on osteoporosis  
7 medication if you choose to do that.

8 MEMBER KEARNS: Our surgeons do not  
9 like that.

10 DR. SIRIS: I understand. But, I  
11 mean, that is still an alternative. And many  
12 surgeons have now determined that you can  
13 safely - there's no evidence in the  
14 literature that you delay fracture healing,  
15 but you're right. There are biases.

16 But the point is it can be - you  
17 have three mechanisms. One of which is to  
18 schedule a DXA. One of which is to provide  
19 treatment. And one of which is if you have an  
20 FLS, that's the coordination of care mechanism  
21 that would work best.

22 And that's what we're sort of

1 hoping if this measure goes forward, will  
2 become easier to do.

3 CO-CHAIR GOLDEN: A question for  
4 you, Ann. Do you have a perception of what  
5 the burden of data collection is for this?

6 MEMBER KEARNS: Well, I think  
7 that's another point because there is very  
8 hard in - and so, within a system it's easy.  
9 Maybe with an electronic record, that would  
10 include DXA in it. Not all DXA machines are  
11 included in electronic records even in my  
12 expanded healthcare system.

13 So, finding out if they've had one  
14 in the last 12 months could be tricky, could  
15 lead to some duplication, which is not well  
16 thought of by most of us because that's an  
17 unnecessary thing.

18 But, again, if you have an  
19 appointment and you're liaising with a primary  
20 care physician who might know that, you'd like  
21 to think it wouldn't get duplicated, but I  
22 think it's a valid point that there is the



1 risk that there could be duplication.

2 Relying on patients to know what a  
3 DXA is, a bone scan or an x-ray is not always  
4 so reliable. I think that's a low risk, but  
5 real.

6 DR. SIRIS: Could I just comment  
7 that if you had a DXA last year and this year  
8 you broke your shoulder, it wouldn't be such  
9 a bad thing to have another DXA if it turned  
10 out that they goofed and they couldn't find  
11 out you had had one before, I mean,  
12 clinically.

13 CO-CHAIR GOLDEN: I think we're  
14 ready to vote.

15 DR. SIRIS: Yes.

16 MS. BAL: Voting is open.

17 High two, moderate 11, low six.

18 MEMBER KEARNS: Okay. And the next  
19 point is the usability and use. And I don't  
20 think - we don't have any - since this is a  
21 new measure, there's no prior usability other  
22 than the pilot studies that were done that

1           showed actually that at least in one system  
2           they were able to really step up to the mark.

3                       But I think there is definitely  
4           published data from other systems that this is  
5           a very usable system.

6                       I think, again, the same caveats  
7           about DXA and inpatients and those things  
8           probably apply, but I think this would be  
9           rated at least a moderate, if not high.

10                      CO-CHAIR ROSENZWEIG: Since this is  
11           a Joint Commission measure, is the  
12           accountability at the level of the hospital,  
13           or at the level of the providing physician?

14                      MS. WATT: These data would be  
15           aggregated at the hospital level, not at an  
16           individual provider level.

17                      CO-CHAIR ROSENZWEIG: Okay. So, if  
18           a patient had the DXA performed as an  
19           outpatient shortly after the admission, that  
20           would be okay, I assume.

21                      MEMBER KEARNS: If they had the  
22           appointment at the time of dismissal.

1 CO-CHAIR ROSENZWEIG: The  
2 appointment, okay.

3 MEMBER KEARNS: They would meet the  
4 criteria. I think the limitation is that  
5 there are - and certainly I'm learning in my  
6 institution this is an inpatient measure. And  
7 there's an ER measure that talks about  
8 fractures, but there are a group of people  
9 that we're missing with both of these who  
10 don't - and those are especially the  
11 vertebral fracture patients who present to  
12 their physician, who get an x-ray with an  
13 incidental noting of it done for other things.

14 So, this is definitely the best we  
15 have. And I think making it a facility  
16 measure is important because we've shown it  
17 doesn't happen, but this won't address all  
18 patients, in my opinion.

19 CO-CHAIR GOLDEN: Going once.  
20 Bill.

21 MEMBER CURRY: From the usability  
22 issue, I think it was mentioned that I think

1 the surgeons are going to have some reticence  
2 to be ordering tests that perhaps they think  
3 should be followed up by a patient's primary  
4 care provider.

5 I think they're going to have  
6 reticence about ordering medications that will  
7 be ongoing, prescribed maintenance-wise by  
8 their primary care provider.

9 And I think the usability of this  
10 will be difficult because of that unless  
11 there's a fracture liaison service.

12 DR. SIRIS: Which is precisely the  
13 point. In other words, it's very, very simple  
14 to reassure the orthopedic surgeons that  
15 others in the hospital are very happy to take  
16 on that responsibility. That's been shown to  
17 be highly effective, because this would be  
18 hospital policy.

19 The orthopedic surgeons are not  
20 obligated to do this. They're simply  
21 obligated to cooperate if somebody else is  
22 willing to do this, and that's worked.

1                   The reason right now there is such  
2                   a tremendous gap is precisely because the  
3                   orthopedic surgeons fixed the fracture very  
4                   well and that's it. This is an attempt to  
5                   make sure that there's the continuation of  
6                   care and the link that will make sure these  
7                   patients get treated.

8                   MEMBER CURRY: But as the measure  
9                   stands today, I think it would be difficult to  
10                  use this, because many facilities do not have  
11                  the fracture liaison service.

12                 DR. SIRIS: Right, but many  
13                 facilities, hospital facilities have  
14                 internists. And hospital facilities have  
15                 endocrinologists.

16                 And if the hospital recognizes  
17                 that this is a critical quality care measure  
18                 and that we have an epidemic of fractures, as  
19                 we do, the hospitals may simply decide that an  
20                 endocrinologist will be asked to see everybody  
21                 who comes in with a fracture the same way many  
22                 patients prior to surgery have to be seen by

1 an internist to be screened for surgery.

2 It's feasible. It's doable.

3 CO-CHAIR GOLDEN: Well, you're  
4 getting a little far afield.

5 DR. SIRIS: Sorry.

6 CO-CHAIR GOLDEN: And we're also  
7 talking about how to spend money. So, that's  
8 another interesting question as opposed to  
9 other things.

10 MEMBER BREEN: I'm just going to  
11 comment I think that's why it's important that  
12 it is a hospital-based measure, because right  
13 now the hospitals are recouping large sums of  
14 money on operating on the first fracture, the  
15 second fracture, the third fracture. It's  
16 true.

17 And I think the resources are  
18 potentially already there for some cost  
19 savings in the larger scheme of things, but  
20 the burden has to be on the hospital to  
21 coordinate the resources that many of them  
22 already have. They're just not linked, right?

1                   So, I think you're right. The  
2                   usability, it's not the easiest thing right  
3                   now, but that doesn't mean that it's not the  
4                   right thing.

5                   CO-CHAIR GOLDEN: The hospital has  
6                   its own ways of solving problems.

7                   MEMBER KEARNS: And you would be  
8                   surprised. The orthopedic surgeons have their  
9                   own initiative called Own the Bone. So, they  
10                  are more aware of it.

11                  Although they don't want to take  
12                  responsibility for doing it, in my experience  
13                  they're very willing to let me come in and -  
14                  so, I think there won't be as many barriers.  
15                  We just need a little incentive.

16                  CO-CHAIR GOLDEN: Bill, do you have  
17                  a comment?

18                  MEMBER TAYLOR: I got a question.  
19                  Is there a concern with this measure that if  
20                  all that's required is ordering the DXA as  
21                  opposed to somehow making sure the patient  
22                  gets the DXA or somehow connecting to the

1 source of care that would follow up  
2 appropriately, that there's any concern that  
3 this wouldn't get far enough to actually close  
4 the loop?

5 DR. SIRIS: No, I think right now  
6 the problem is nothing is done. And it may  
7 well be that if you go the first step, which  
8 is to even think about a DXA, you recognize  
9 that there's a clinical issue.

10 So, while ideally, you know, you  
11 want the DXA done and you want somebody to  
12 actually look at it, it's the first step  
13 toward moving into a paradigm where you're  
14 going to do the right thing, I would hope.

15 MEMBER BREEN: And I would just  
16 comment in order to order the DXA, you need to  
17 diagnose the patient with osteoporosis which  
18 is often not happening, right?

19 In order to order the DXA, you  
20 have to put down qualifying criteria. And  
21 that then enlarges your capture rate of these  
22 patients as opposed to patients just coming in



1 with "a fracture" who then leave without a  
2 diagnosis on some level of having  
3 osteoporosis.

4 So, I think the ordering, you  
5 know, in and of itself has some good things  
6 even if the test doesn't.

7 CO-CHAIR ROSENZWEIG: So, getting  
8 back to usability and use. So, do we have  
9 accountability, will it result in improvement  
10 and are benefits better than the risks?

11 MEMBER KEARNS: I would say yes.

12 CO-CHAIR ROSENZWEIG: Okay. Any  
13 other comments?

14 MS. BAL: Voting is open.

15 High seven, moderate ten, low two.

16 CO-CHAIR ROSENZWEIG: We're up to  
17 yes and no.

18 MEMBER KEARNS: I would think that  
19 we should vote yes, but I'm maybe a strong  
20 advocate for this overall.

21 MS. BAL: Voting is on.

22 Let's all try one more time.

1           We're missing one person.

2                       We still need one more. We need  
3           19.

4                       So, 19 yes.

5                       CO-CHAIR GOLDEN: Thank you.

6           Nicely done. Are we going to that one now?

7           Okay. We're going backwards.

8                       MEMBER BREEN: So, I'm so glad we  
9           changed the order of this. Can I just say I  
10          was worried we were going to start here and  
11          then go - exactly, never finish.

12                      That's what happened on our  
13          workgroup call. So, you know, I'm sorry. So,  
14          this measure is Laboratory Investigation for  
15          Secondary Causes of Fracture.

16                      This is getting at the concept  
17          that many people who come in with osteoporosis  
18          actually have a secondary reason besides  
19          having senile osteoporosis or age-related  
20          osteoporosis.

21                      And so, I'll get down into this.  
22          In terms of the background, there have been

1 studies that estimate that when you look at  
2 patients with fractures, a large percentage,  
3 anywhere from 40 to 50 percent, actually have  
4 some underlying cause that can be identified  
5 with laboratory testing that is not currently  
6 happening.

7 The numerator statement for this  
8 measure, patients who have all, actually, have  
9 assessed their laboratory tests ordered or  
10 performed prior to discharge. That's CBC,  
11 kidney function tests, liver function tests,  
12 a serum calcium, a 25 Vitamin D level or the  
13 provision of Vitamin D.

14 And that kind of gets back to what  
15 we were talking about in that kidney measure  
16 with whether you measure urinary microalbumin  
17 or whether you treat with an ACE or ARB and  
18 you get credit for both, right?

19 You get credit for the  
20 measurement, but then you also kind of get  
21 credit for just treating the assumption of the  
22 deficit.

1                   The denominator, patients over the  
2                   age of 50 who have been discharged from an  
3                   inpatient status. Again, these are admitted  
4                   inpatients with a fracture. So, it's a  
5                   similar group as the one before.

6                   And exclusion criteria, again,  
7                   comfort measures only. That's important in  
8                   this group that we're taking the amount of  
9                   people who had been enrolled in clinical trial  
10                  pertaining to osteoporosis if they had had  
11                  laboratory testing performed in the prior 12  
12                  months.

13                  So, let's talk about the data if  
14                  anybody has any larger questions. I don't  
15                  know if the developers want to talk, make a  
16                  comment at all about this particular measure  
17                  and the thought process behind this particular  
18                  measure.

19                  DR. SIRIS: Well, right now nobody  
20                  gets treated or worked up. Twenty percent get  
21                  treated or worked up. So, the assumption is  
22                  that they're not getting the testing either.

1                   I mean, we don't have evidence  
2                   that they're getting the testing with the  
3                   intention that it would be used to determine  
4                   whether it related to their fracture.

5                   You can't use medication until you  
6                   know that the patient doesn't have some other  
7                   medical condition either because the  
8                   medication won't work or because you're going  
9                   in the wrong direction. You've got to deal  
10                  with that first. So, this is sort of a  
11                  logical part of the process of assessing the  
12                  patient.

13                  MEMBER BREEN: So, for the rest of  
14                  you, this is what our entire work group time  
15                  was spent on this concept of how you parse  
16                  measures that hadn't been looked at  
17                  specifically.

18                  So, when we get into the  
19                  challenges around the evidence for this, there  
20                  is little data that has looked specifically at  
21                  what happens when you measure these laboratory  
22                  tests, because nobody does that.

1                   We have large kind of osteoporosis  
2                   studies that use these laboratory assessments  
3                   as part of their study, but nothing  
4                   specifically looking at this measure.

5                   But, again, you can't do the  
6                   treatment that we just said we need to do  
7                   without having these tests done. So, it's a  
8                   little bit of the chicken and egg.

9                   DR. SIRIS: Sometimes people do use  
10                  the treatment and that's the wrong thing  
11                  medically.

12                  MEMBER BREEN: So, there was some  
13                  just in terms of the data, there was one trial  
14                  looking at kind of getting at this whole  
15                  concept, you know, when you do all this  
16                  testing and reading, you do a lot of  
17                  interventions at the time of the clinical  
18                  event, i.e., the hospitalization and you do  
19                  the testing and you assess the fracture,  
20                  there's a higher rate of patients getting  
21                  treated down the road.

22                  So, again, I think that's the best

1 supporting evidence to suggest that testing  
2 patients for secondary fractures in the  
3 hospital during the time of their fracture is  
4 supported by the data.

5 Anybody else have any -

6 MEMBER BAILEY: Just a quick  
7 question. Why is PTH not included? It may be  
8 just my ignorance in terms of not being close  
9 to this field.

10 MEMBER BREEN: As one of Dr. Siris'  
11 former fellows, I'm going to defer to her to  
12 comment on this.

13 DR. SIRIS: If you ask a dozen  
14 endocrinologists what should the list of blood  
15 tests be, you'll get a dozen answers.

16 So, what we were trying to do is  
17 to take, you know, what do you really need to  
18 know?

19 You need to know that the calcium  
20 is not 14. You need to know that the patient  
21 is not profoundly anemic, which could be  
22 suggestive of a number of other disorders.

1                   You need to know that the patient  
2                   is not in renal failure. And it's probably  
3                   not a bad idea to also know that the patient  
4                   doesn't have liver failure at the time you're  
5                   seeing the patient with a fracture. So, we  
6                   went with the bare minimum.

7                   Now, once you've done that, you  
8                   can probably start the patient on treatment.  
9                   If you're missing normocalcemic  
10                  hyperparathyroidism, the drug is still going  
11                  to work. And hopefully because you're  
12                  treating the patient for osteoporosis, there  
13                  will be ongoing care that we'll be able to  
14                  continue to evaluate the patient, but at a  
15                  minimum.

16                  Plus, most of these tests are  
17                  things - maybe not the liver panel. Most of  
18                  these tests would be done as pre-op tests with  
19                  an eye toward not putting somebody in renal  
20                  failure into the OR to have their fracture  
21                  fixed, but it may not be thought about in  
22                  terms of its role in playing, you know, what's



1 going to happen to the patient clinically with  
2 the osteoporosis.

3 So, it's a way of forcing these  
4 standard, not terribly expensive tests to set  
5 you up. Yes, there are other tests that could  
6 be done.

7 What about 24-hour urine calciums,  
8 you know, all kinds of things, sure.

9 MEMBER BREEN: And this is the  
10 challenge when you look at the data is that,  
11 you know -

12 DR. SIRIS: Celiac screens and -

13 MEMBER BREEN: You know, for every  
14 12 bone studies, you have 12 different  
15 constellations and data pieces that they've  
16 done.

17 So, this particular constellation  
18 of data measurements has not been studied in  
19 and of itself as a standalone unit if we're  
20 looking for evidence. But my poor man's take  
21 on it was a less well-spoken version of Dr.  
22 Siris'.

1                   What do you need to know to not  
2                   kill somebody or hurt them really badly while  
3                   they're in your care and you're trying to  
4                   treat them for osteoporosis?

5                   CO-CHAIR GOLDEN: So, what you're  
6                   saying is we've covered most of the waterfront  
7                   or the important waterfront aspects. May not  
8                   be perfect, but it's good enough.

9                   MEMBER BREEN: Yes.

10                  CO-CHAIR GOLDEN: Okay.

11                  MEMBER KEARNS: I would just like  
12                  to comment about, as I'm sitting here right  
13                  now I just thought, should dialysis patients  
14                  be excluded?

15                  Because, really, that is a patient  
16                  population that is - and I think of this of  
17                  all the measures that we're talking about in  
18                  osteoporosis and it just occurred to me now,  
19                  because that is a very different patient  
20                  population.

21                  They have a high risk of fracture.  
22                  They have a complicated set of problems.

1           They're probably not really the patient  
2           population for the intent of this, but yet  
3           they're not specified as an exclusion. So, I  
4           might encourage the developers to rethink  
5           that, you know.

6                     You could make an arbitrary level  
7           of renal function, but you can certainly say  
8           patients on dialysis are not the intent of  
9           this in general.

10                    DR. SIRIS: If a patient is on  
11           dialysis, it might alter your choice of  
12           therapy. But at the same time, you need to do  
13           the assessment because it may not be a  
14           dialysis, I mean, it may not be that it's  
15           renal bone disease. It may still be  
16           osteoporosis. So, I don't know that I would  
17           exclude those patients.

18                    If you had somebody in renal  
19           failure who's fracturing and you really don't  
20           know what's going on, you would do a bone  
21           biopsy. And you might be able to determine  
22           that the patient's reason for fracturing was

1 not the renal failure, but, in fact, was  
2 ordinary osteoporosis. And that might  
3 influence you to use a drug that you can  
4 safely use in a dialysis patient.

5 I don't know what you would do,  
6 but the point is I don't want to make these  
7 patients be ignored, because they might have  
8 osteoporosis.

9 MEMBER KEARNS: Well, I agree, but  
10 how would this set of tests help you with  
11 that?

12 DR. SIRIS: It would tell you that  
13 this was somebody in renal failure, which  
14 would force you to think about what was  
15 actually going on in that patient.

16 MEMBER BREEN: And if I could just  
17 make a comment when we talk about when we get  
18 to potential harm or unintended consequences,  
19 I think that's what you're kind of getting  
20 into, the unintended consequences if you don't  
21 exclude someone who might be inappropriate for  
22 bisphosphonate therapy.

1                   But I think we also have to err on  
2                   the side of some clinical assessment that if  
3                   we're saying their renal function has to be  
4                   assessed, the next step is then you use that  
5                   assessment to drive your clinical treatment of  
6                   the fracture.

7                   MS. DOMZLSKI: Yes, patients who  
8                   have had these lab tests within the prior 12  
9                   months are excluded from the measure.

10                   So, it's likely the dialysis  
11                   patient would have had these tests, say, for  
12                   the 25(OH)D, which you can give them the  
13                   Vitamin D dose or do the test.

14                   MEMBER KEARNS: Right, but they  
15                   wouldn't be, I mean, to do a, I mean, I guess  
16                   you can do a DXA on a dialysis patient. We  
17                   don't routinely do that.

18                   MEMBER BREEN: But for this  
19                   particular measure -

20                   MEMBER KEARNS: For this one. But  
21                   for the constellation of them, you know, I  
22                   guess thinking of the prior one, the DXA or an

1 appointment for a DXA in a dialysis patient is  
2 a little bit different.

3 CO-CHAIR GOLDEN: We're getting  
4 into specifications. So, we want to -  
5 Jessie, do you have anything on evidence?

6 MEMBER SULLIVAN: I wanted to ask  
7 the developers to address why you think that  
8 giving Vitamin D while the patient is in the  
9 hospital is equivalent to testing their -  
10 testing their Vitamin D level.

11 DR. SIRIS: One of the problems is  
12 that the rest of the tests come back the same  
13 day. The 25 D level may not come back for a  
14 week and a half.

15 So, when Cathy was busy assessing  
16 all of this at the various hospitals, they  
17 were saying, gee, you know, waiting for that  
18 test to come back is going to be a problem for  
19 us. What about if we just start the patient  
20 - if we've identified that this is somebody  
21 who's got osteoporosis and they're going to  
22 have to have follow-up, we'll start them on

1 Vitamin D and at some future point they can  
2 have either the test or somebody can decide  
3 that they're adequately treated.

4 MEMBER SULLIVAN: That's the  
5 problem. It's not going to be adequate if you  
6 don't -

7 DR. SIRIS: It was a practical  
8 measure to be able to get it done while the  
9 patient was still in the hospital.

10 If you're only going to be in the  
11 hospital three or four days and that 25 D test  
12 isn't going to come back to the electronic  
13 record for a couple of weeks, it becomes a  
14 problem in terms of just making it happen.

15 If you can show that you've  
16 started the patient on D, big doses of D,  
17 that's a way around dealing with the 25 D  
18 level, which is also an expensive test.

19 CO-CHAIR GOLDEN: So, are you  
20 saying you would start therapy without any  
21 documentation?

22 MEMBER BREEN: But again it's based

1           on the - if I can ask for clarification,  
2           that's the dose of D that was settled on.  
3           Because again if you ask 12 different  
4           endocrinologists their doses of D, this dose  
5           was settled on what was considered reasonable  
6           in the public health world in terms of  
7           recommendations about what certain type of  
8           people should take for basic supplementation;  
9           is that -

10                           CO-CHAIR GOLDEN: I guess the  
11           question is going to be - all right. I guess  
12           it is an evidence question, right?

13                           DR. SIRIS: It's very hard to get  
14           anybody into trouble starting them on Vitamin  
15           D. And I think it would be within the  
16           judgment of whoever was taking care of the  
17           patient, whether it would be 50,00 units the  
18           day they came into the hospital, whether you  
19           would put them on 2,000 a day.

20                           I mean, you might take a history  
21           and find out that the patient, you know, was  
22           on a multivitamin and you might start a lower



1           dose of Vitamin D, but the point is that you  
2           want to assure that you're not missing  
3           somebody with D deficiency.

4                       And the way to do that is either  
5           to draw the blood, but you can't get it back  
6           fast enough, or simply start them.

7                       And by virtue of having them  
8           involved in this process, you hopefully will  
9           follow up with it.

10                      I think if we require the blood  
11           test, if we can require the blood test. But  
12           if we do that, the hospitals are going to balk  
13           that they can't get the result. It's not  
14           feasible. So, again, it's better to start the  
15           D or draw the test.

16                      If you've got a fracture liaison  
17           service, you'll be able to get the test  
18           report, because the fracture coordinator will  
19           get it two weeks later.

20                      CO-CHAIR GOLDEN: That gets into  
21           solutions, though. That's a different issue.

22                      All right. Any other questions on

1 evidence? Comments on evidence.

2 (No response.)

3 CO-CHAIR GOLDEN: Ready to vote.

4 MS. BAL: Voting is open.

5 (Pause.)

6 MS. BAL: We have high, one.

7 Moderate, 12. Low, six.

8 MEMBER BREEN: All right. Moving  
9 on to the performance gap. Again, for this  
10 particular measure, which is looking at  
11 laboratory assessment for secondary causes, it  
12 doesn't currently exist.

13 So, we don't really know except in  
14 the pilot when they did the pilot, they found  
15 that I think it was less than 10 percent of  
16 your hospitals were doing these assessments on  
17 patients with known fracture in the hospital.

18 So, I think there's definitely a  
19 performance gap that was demonstrated amongst  
20 the pilot project.

21 Does anyone have any other  
22 questions or additions?

1 CO-CHAIR ROSENZWEIG: The pilot,  
2 were the hospitals vigorously going back to  
3 find out if all of these tests had been done  
4 in the past year?

5 MEMBER BREEN: Well, that was a  
6 marker of exclusion, right? So, if they had  
7 had the test done in the last year, they  
8 weren't included, right?

9 MS. DOMZLSKI: That's correct.  
10 Yes, they did look for that.

11 CO-CHAIR ROSENZWEIG: No, but in  
12 order to exclude them, you need to find out if  
13 the tests were done.

14 I imagine it's kind of hard for  
15 hospitals to go back retrospectively to find  
16 out if the physicians who had been following  
17 the patients had been doing it.

18 I mean, it sounds like what the  
19 thrust of this would be to sort of tell  
20 hospitals to do all of these five tests on  
21 everybody just to cover their basis.

22 MS. DOMZLSKI: Well, typically the

1 patient who's being hospitalized for a  
2 fragility fracture is going to have surgery  
3 and most of these tests are done as a matter  
4 of course anyway. So, they are not out of the  
5 ordinary for a surgical patient.

6 And to address your previous  
7 comment about the test group gap, the median  
8 level of performance was 9.5 percent.

9 MEMBER KEARNS: I would just guess  
10 that the biggest hangup was the Vitamin D in  
11 that.

12 Seeing all the hip fracture  
13 patients at Mayo Clinic, the tests that  
14 weren't done until I demanded they be done was  
15 the Vitamin D.

16 They still don't do a calcium or a  
17 liver test. The others they do routinely on  
18 admission for a fracture. So, I think it's  
19 adding a little bit, but not a lot.

20 Getting back to your question  
21 about within the last year, again when we're  
22 operating in a hospital facility system and

1           you had an outpatient one, there is the risk,  
2           I guess, of duplication of things, because you  
3           don't know what has been done.

4                     I think what the hospitals would  
5           do is probably just order that all the tests  
6           be done on admission and a Vitamin D pill get  
7           prescribed, which is a step in the right  
8           direction, but there is, I guess, the risk  
9           that these tests were done.

10                    The facility is held responsible.  
11           They don't know they were done at your office  
12           and not at this hospital.

13                    CO-CHAIR GOLDEN: Are we ready to  
14           vote as a group?

15                    MS. BAL: Voting is open.

16                    (Pause.)

17                    MS. BAL: We have high, 11.

18           Moderate, seven. Low, one.

19                    CO-CHAIR ROSENZWEIG: Okay.

20                    MEMBER BREEN: So, importance  
21           measure. High priority. So, this stresses  
22           whether this is a specific national health

1 goal priority or data demonstrated a high-  
2 impact aspect of healthcare. And, again, this  
3 is for this specific measure, which is around  
4 laboratory measurement.

5 I think we've already assessed  
6 that missed fracture and prevention of  
7 secondary fracture is a high priority.

8 I think the challenge for this  
9 group is to figure out if this measure to do  
10 the lab testing is a high priority.

11 And, again, we come back to you  
12 can't initiate the correct therapy unless you  
13 know where your patient's basic laboratory  
14 testing are. So, I think it's linked, in my  
15 opinion, but I'd appreciate other comments on  
16 this.

17 I think we need a cookie break.

18 CO-CHAIR GOLDEN: We're getting  
19 there, yeah.

20 MEMBER BREEN: As a diabetes  
21 specialist, I'm sensing a cookie deficit.

22 (Laughter.)

1 CO-CHAIR GOLDEN: Ready to vote?

2 Voting time?

3 MS. BAL: voting is open.

4 (Pause.)

5 MS. BAL: Okay. High, six.

6 Moderate, 11. Low, two.

7 MEMBER BREEN: Excellent. Okay.

8 Moving on to reliability. Again, the data  
9 that we have from this is really from their  
10 pilot project that they did.

11 And we've already discussed that  
12 in the last session. So, I think the  
13 discussion on reliability in the last session  
14 also applies to this measure.

15 Unless anyone has any comments, we  
16 found that it was fairly reliable, I think.  
17 Good reliability of their data in their pilot  
18 study.

19 CO-CHAIR GOLDEN: Do you have a  
20 comment, Ann? Okay.

21 Are you ready to vote? Okay.

22 Voting.

1 MS. BAL: Voting is up.

2 (Pause.)

3 MS. BAL: High, six. Moderate,  
4 ten. Low, three.

5 MEMBER BREEN: Okay. Moving on to  
6 validity. Again, the data that we have is  
7 from the pilot testing. The face validity was  
8 assessed by the hospital sites.

9 The only data element that was  
10 more challenging when it came to validity was  
11 assessing the laboratory tests in the 12  
12 months prior to fracture.

13 We've already determined that is a  
14 challenge. The rest of the in-house testing  
15 seemed to have a good validity score.

16 CO-CHAIR GOLDEN: Ready to vote?

17 MS. BAL: Voting is open.

18 (Pause.)

19 MS. BAL: Okay. High, three.  
20 Moderate, 13. Low, three.

21 MEMBER BREEN: Moving on to  
22 feasibility. This is how feasible it is to do



1           this.  These are inpatients.  These are  
2           laboratory measures that we check on  
3           inpatients.

4                       And so, I think in most of our  
5           hospitals we now have electronic laboratory  
6           measurements.  So, I think that it's a fairly  
7           feasible  I don't see that many barriers to  
8           feasibility in terms of the collection.

9                       I think the challenge comes in the  
10          assessment of the 12 months prior.  And those  
11          challenges, I think, have been discussed.

12                      CO-CHAIR GOLDEN:  If no one from  
13          the Committee is going to comment, I'm not  
14          going to all on you.

15                      So, do we have any comments?  You  
16          definitely want to say something?

17                      MS. DOMZLSKI:  Yes, I just wanted  
18          to reinforce what you're saying.  This is one  
19          thing that has actually been helped by the  
20          electronic record.

21                      Particularly in an integrated  
22          health system, it's very simple to look back

1 and find what was done as an outpatient or in  
2 the physician's office or at an offsite  
3 testing facility in addition to what's done in  
4 the hospital. It's been a big improvement.

5 MEMBER BREEN: I also just want to  
6 comment that the abstraction period goes for  
7 30 days post-discharge.

8 So, even those Vitamin D levels  
9 that were drawn and not available at time of  
10 discharge will be included in that catch.

11 MEMBER KEARNS: Doesn't it also  
12 just allow for the ordering of the test, not  
13 necessarily the performance? Was that part of  
14 it, too?

15 Tests had to be performed or an  
16 order for the test at the time of dismissal.  
17 So, that could even be an outpatient follow-up  
18 of a Vitamin D level ordered as an outpatient.

19 CO-CHAIR GOLDEN: All right. Vote.

20 MS. BAL: Voting is up.

21 (Pause.)

22 MS. BAL: Okay. High, one.

1 Moderate, 16. Low, two.

2 MEMBER BREEN: Usability and use.

3 So, the accountability and transparency of  
4 this measure if this is new, which it is, the  
5 improvement, are we going to show progress?

6 Again, we didn't get time to  
7 discuss this on our workgroup call since we  
8 were so busy thinking about different data  
9 elements, but I don't see any unintended  
10 consequences of this, but this would be the  
11 time to talk about patients not clinically or  
12 appropriately excluded from treatment if  
13 people worry about a reflexive treatment of  
14 patients in order to check a box off.

15 MEMBER SULLIVAN: I'm sorry, I  
16 guess I just wanted to raise again that I  
17 think everything we've just said in the last  
18 few minutes is a reason to not allow giving  
19 Vitamin D instead of ordering the test,  
20 because, you know, and I just think it's going  
21 to make it less useful, because people will  
22 leave the hospital taking a vitamin that they

1 don't know they really need. So, they won't  
2 keep taking it.

3 And their doctor won't really know  
4 they really needed it. So, they won't

5 MEMBER BREEN: So, you're worried  
6 that the potentially substandard treatment of  
7 a potentially real Vitamin D deficiency

8 MEMBER SULLIVAN: Yes.

9 MEMBER BREEN: could actually  
10 add to harm. Because as a

11 MEMBER SULLIVAN: Because they  
12 allow you to get out of ordering the test by  
13 giving the vitamin while they're in the  
14 hospital.

15 But, I mean, I think it's still,  
16 you know, it's still good, but I just think,  
17 you know, you gave people you didn't need to  
18 throw them that anyhow.

19 CO-CHAIR GOLDEN: Is that Patricia  
20 on the end? Is your card up? Okay.

21 MEMBER McCOLLISTER-SLIPP: One  
22 question I have as somebody who just finished

1 a course of Vitamin D, oral Vitamin D, and  
2 really liked it and was excited about the  
3 energy I got, the doctor told me that I needed  
4 to stop because of potential implications for  
5 kidney stones, which is a compelling reason.

6 But is there a possibility that, I  
7 mean, and I don't know, I really this is

8 MEMBER BREEN: I think that the  
9 doses recommended here that people get credit  
10 for, they were fairly low and benign doses  
11 that it would be very hard to invoke some harm  
12 at Vitamin D 800 units.

13 I think when you deal with the  
14 bigger doses of Vitamin D, the ergocalciferol  
15 50,000 units in the little gel or green tab  
16 that you probably the gel cap, that's where  
17 you can potentially have some more clinical  
18 negative impacts if you're not treating that  
19 person appropriately.

20 But I think, again, it gets back  
21 to, you know, did we give people a way out?  
22 Did we make it too easy for them to get their

1 Vitamin D assessment credit by allowing them  
2 to have just the basic, cheap Vitamin D  
3 supplementation?

4 CO-CHAIR GOLDEN: Jessie, can you  
5 turn off your mic?

6 MEMBER KEARNS: Well, I would just  
7 like to share a little of experience that I  
8 have from trying to do this in my institution  
9 before I realized this was a measure.

10 And I can tell you that from  
11 looking at hip fracture patients, that very  
12 few patients were actually dismissed on  
13 Vitamin D, but a simple education of the  
14 orthopedic team and discussion with the  
15 endocrinology team we were able to improve  
16 that.

17 Now, we chose a strategy to  
18 measure and treat. And that might be because  
19 we're the Mayo Clinic and we have access to  
20 labs that can be back within 24 to 48 hours,  
21 but there was a discussion and promoted by  
22 some that every patient who comes in with a

1 hip fracture should get 50,000 units of  
2 Vitamin D on admission.

3 On dismissal, they're put on a  
4 thousand units a day and it's a done deal.  
5 You don't have to spend \$250 measuring a  
6 Vitamin D level.

7 So, there were alternative  
8 strategies at my institution that were  
9 discussed. And for a variety of reasons  
10 mostly having to do with stakeholders in the  
11 orthopedic and endocrine community, we opted  
12 for a test-and-treat strategy.

13 I can tell you that in the hip  
14 fracture patient population in our institution  
15 depending on how you define Vitamin D  
16 deficiency, which again maybe Dr. Siris can  
17 help us there, there's still not agreement in  
18 all sectors that it's somewhere between 50 to  
19 70 percent even in those people who say  
20 they're taking something when they are  
21 admitted to the hospital.

22 So, I think there's a lot of

1 strategies to achieve the same thing. And I  
2 think that, you know, beginning somewhere is  
3 a good idea and I don't I'm not averse to  
4 just treating people with Vitamin D at these  
5 levels.

6 You won't hurt anyone. Will you  
7 optimize some people? Maybe not a couple.

8 MEMBER BREEN: Most hospitals will  
9 I don't want to speak for most hospitals,  
10 but I can see panels being developed, right?  
11 So, if a fracture panel is developed, Vitamin  
12 D will go on it and then you get your  
13 assessment, right?

14 So, let's say they get a reflex of  
15 800 units of Vitamin D and they get the test  
16 done and, oh, yes, it comes back two weeks  
17 later severely deficient.

18 One would hope that that will  
19 translate along and catch up with the patient  
20 down the road if it's part of a panel that's  
21 being done.

22 CO-CHAIR ROSENZWEIG: In Minnesota



1 in the winter, I imagine there's a pretty high  
2 level of D deficiency.

3 MEMBER BREEN: We should all be  
4 taking 50,000 like every day.

5 (Laughter.)

6 CO-CHAIR GOLDEN: Are we ready to  
7 vote? So, Ann, are you okay with this?

8 MEMBER KEARNS: Yeah, I would be  
9 okay with this. And I was actually one of the  
10 people who advocated for just treating at my  
11 institution.

12 CO-CHAIR GOLDEN: Can we vote?

13 MS. BAL: Voting is ready.

14 (Pause.)

15 CO-CHAIR GOLDEN: We have I think  
16 someone on the phone is typing. If you can  
17 mute, that would be great.

18 (Laughter.)

19 MS. BAL: Let's all try again. We  
20 only got 16 here.

21 (Pause.)

22 MS. BAL: All right. There we go.

1           So, high, four. Moderate, 14. Low, one.

2                       CO-CHAIR GOLDEN: Okay. Ready for  
3 the big picture.

4           MS. BAL: Voting is ready.

5                       (Pause.)

6           MS. BAL: We have yes, 16. No,  
7 three.

8                       CO-CHAIR GOLDEN: Thank you, Tracy.  
9 Now, we go to Bill Curry. And no cookies for  
10 you. I'm sorry, Tracy.

11                      MEMBER CURRY: This is Measure  
12 2418, Discharge Instructions, Emergency  
13 Department.

14                      So, this is looking at the portion  
15 of patients over 50 who have fractures as  
16 we've talked about in previous measures, who  
17 have been discharged from the emergency room  
18 to home, who have received written discharge  
19 instructions or their caregivers have received  
20 discharge instructions with a need to follow  
21 up with a primary care physician, hospital  
22 outpatient department or specialists for

1 possible osteoporosis to reduce the risk of  
2 future fracture, or who were contacted by a  
3 fracture liaison service.

4 So, the numerator is patients or  
5 caregivers who receive discharge written  
6 discharge instructions regarding the need to  
7 follow up, or that were seen by, contacted by  
8 or linked to a fracture liaison service.

9 The denominator are patients age  
10 50 or over discharged to home from the ED with  
11 one of the ICD-9 codes and soon to be ICD-10  
12 codes for one of the fractures that we've  
13 talked about in the Excel spreadsheet that are  
14 listed in the SharePoint.

15 So, the discussion that we had was  
16 that we think that certainly this is an  
17 important measure. And I think it falls in  
18 line with the comments that we've had with the  
19 previous two measures that we've looked at.

20 But the big concern that was  
21 raised was that there's great evidence that  
22 supports the use of the fracture liaison

1 service, but there's very little evidence that  
2 would support giving the patient discharge  
3 instructions to follow up with their primary  
4 care physician or other hospital-based or  
5 outpatient-based provider for their care after  
6 a fracture to get tested for bone mineral  
7 density or for treatment.

8 Initially when we looked at this,  
9 we did not have any meta-analyses that helped  
10 us with that information, but there were  
11 several comments from folks advocating for the  
12 review and approval of this study or this  
13 measure.

14 And one of the articles that was  
15 cited by those advocates was a study by Ganda  
16 in February of 2013 in Osteoporosis  
17 International. And this group looked at four  
18 models of care for fracture evaluation  
19 treatment.

20 And they went from a Model A which  
21 include fracture liaison service, Model B  
22 which is similar to fracture liaison service,

1 but there was an assessment and recommended  
2 treatment made to the primary care provider.

3 The third model was that the  
4 patient received education and the PCP  
5 received communication through a variety of  
6 mechanisms to let them know about the event  
7 and their visit to the emergency department  
8 and the need for follow-up testing and  
9 treatment.

10 And then the fourth model was some  
11 sort of education piece or a recommendation to  
12 the patient to be seen by their primary care  
13 provider.

14 And certainly Model A is the best  
15 of those models in the meta-analysis that was  
16 done with significant improvement in both bone  
17 mineral density testing and also treatment.

18 Model B and Model C also showed  
19 some improvement, but there was really no  
20 improvement in the providing the patient an  
21 education piece and asking them to follow up  
22 with their primary care physician.

1                   And so, although we agree that the  
2                   fracture liaison service as part of this  
3                   measure is an important part of it, we find no  
4                   evidence to support on the discharge of a  
5                   patient just to receive in a discharge  
6                   instruction that that's going to improve their  
7                   chances of getting bone mineral density  
8                   testing or treatment.

9                   So, based on that, it's kind of  
10                  there's two places that we can go. So, the  
11                  first part with just the discharge  
12                  instructions, we think the evidence is low to  
13                  support that.

14                  With the fracture liaison service  
15                  contacted at the time of discharge from the  
16                  ED, we think that the evidence is high to  
17                  support that.

18                  So, that was our challenge as we  
19                  looked at this measure for evidence.

20                  CO-CHAIR GOLDEN: So, your  
21                  committee was mixed or less than happy.

22                  MEMBER CURRY: Well, again, the

1 evidence is mixed, but we ran out of time.  
2 So, we didn't have a lot of time to discuss  
3 this.

4 CO-CHAIR GOLDEN: Okay. Other  
5 comments from the Committee.

6 MEMBER BREEN: I think it would  
7 help if maybe the developers gave some insight  
8 as to why these two were linked together as  
9 almost comparable.

10 CO-CHAIR GOLDEN: I just want to  
11 give the Committee a shot.

12 MS. DOMZLSKI: Thank you. There is  
13 another measure that is currently NQF  
14 endorsed. It calls for a transition record to  
15 be given to discharge patients with specified  
16 elements.

17 One of those elements is follow-up  
18 regarding tests or treatments that need to be  
19 done following discharge.

20 And so, this measure in a large  
21 form, addresses the specific wording and  
22 information that needs to be in that discharge

1 instruction that's already endorsed for the  
2 other measure.

3 In addition, there is a  
4 publication from 2010 for safe practices and  
5 it recommends that discharge systems be in  
6 place.

7 It says, a written discharge plan  
8 must be provided to each patient at the time  
9 of discharge, it's understandable, and it  
10 needs to include, dah, dah, dah, dah, dah,  
11 coordination and planning for follow-up  
12 appointments that the patient can keep, among  
13 other items.

14 CO-CHAIR GOLDEN: So, just to  
15 clarify on the discharge, is that for ER  
16 discharge, or hospital discharge?

17 MS. DOMZLSKI: Just the transfer of  
18 the patient care from a hospital to primary  
19 care or other community providers. It doesn't  
20 specifically state hospital or emergency  
21 department, inpatient or ED.

22 So, that is from the NQF



1 publication of safe practices. And we feel  
2 that this measure in addition to fulfilling  
3 those items, rounds out, if you will, and  
4 gives the same care to ED patients that the  
5 patients in the hospital are going to receive  
6 via the other two measures.

7 CO-CHAIR GOLDEN: I believe,  
8 though, we're talking about two different  
9 things. It's different to give a patient a  
10 discharge instruction with the recommendation  
11 to follow up with their primary care physician  
12 versus coordinating that care.

13 When a patient of mine is seen in  
14 the emergency department in my institution,  
15 before they leave that department they have an  
16 appointment and follow-up with me. That's  
17 coordination of care.

18 Or if it's after hours and they  
19 can't get that appointment, there's a list  
20 that's provided to the medical office  
21 assistants in my practice, in all of our  
22 practices, about patients that need follow-up.

1           That's coordination of care.

2                         But as the measure is written,  
3           we're not talking about coordination of care.  
4           We're talking about giving a handout that  
5           suggests that they see their family physician.

6                         I think there's a nuance there and  
7           I think it's different.

8                         MEMBER KEARNS: Well, I think if  
9           we're just talking about the evidence and the  
10          intent of the measure to improve osteoporosis  
11          treatment, I think we all agree that anything  
12          we do will be an improvement.

13                        But if we're really strictly  
14          talking about the evidence that giving  
15          information will achieve that, I mean, we have  
16          to really look at what's there and it's just  
17          not there.

18                        Now, maybe the climate has changed  
19          since the original studies were done that are  
20          included in the meta-analysis. Maybe it would  
21          be more received. But I think for that  
22          particular item it's hard to say that there's

1 good evidence that will change.

2 And that's very different than the  
3 evidence for a fracture liaison service which  
4 is outstanding that that works.

5 And I think the low bar is what  
6 people will go for here. And I think that's  
7 where the evidence is the weakest.

8 CO-CHAIR GOLDEN: Tracy.

9 MEMBER BREEN: I have a question  
10 just I also have some guidance from our NQF  
11 leadership.

12 You referenced that it is already  
13 an NQF measure that documentation is given  
14 about a patient's disease state when they  
15 leave. And that your thinking including this,  
16 was that you wanted to define and make that  
17 language precise as it relates to their  
18 fracture in the hospital.

19 So, are we saying that that  
20 measure kind of was already out there in a  
21 general thing, we're just making it disease-  
22 specific?

1 MEMBER KEARNS: Right.

2 CO-CHAIR GOLDEN: This is an ER  
3 measure.

4 MEMBER BREEN: This is an ER visit,  
5 right? But isn't that documentation burden  
6 still at the level of the ED as well? Meaning  
7 if the patient isn't admitted and they visit  
8 an ED, they're also required to have some kind  
9 of documentation about why they were, you  
10 know, why did you come to the ED, you know?  
11 What's your follow-up plan?

12 So, I might be getting off topic,  
13 but that's my question.

14 MEMBER MILLER: I just wanted to  
15 clarify there was discussion whether it's ED  
16 or inpatient discharge, but the measure is  
17 called "discharge instructions, ED."

18 CO-CHAIR GOLDEN: Do we have other  
19 comments on evidence? And I'll ask Janice to  
20 put her card down.

21 All right. Ready to vote.

22 MS. BAL: Voting is open.

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(Pause.)

MS. BAL: We have moderate, seven.

Low, ten. Insignificant, two.

CO-CHAIR GOLDEN: Okay. NQF staff.

MS. TIGHE: All right. This

measure does not meet the importance criteria and it will not be recommended for endorsement.

CO-CHAIR GOLDEN: So, having said

that, are we finished on this measure? Okay.

So, we will I think that the measure can be revised and returned and so forth. So, yeah, those are done.

MEMBER HAYDON-GREATTING: So,

you're only going to create a measure for people that are going to go home, not to a bridge program, reach program, rehabilitation program post any intervention at the hospital?

Sometimes the elderly patients

come in, they have a fracture. The family doesn't feel like they can make sure they get to their rehabilitation center. So, they send

1           them for three to six weeks, depending on what  
2           the doctors have ordered.

3                       MEMBER KEARNS: So, this is from  
4           the emergency room.

5                       MEMBER HAYDON-GREATTING: Right.

6                       MEMBER KEARNS: Is that what you're  
7           talking about?

8                       MEMBER HAYDON-GREATTING: Right.  
9           Yeah, sometimes they're sent from the in  
10          that elderly population that kind of needs  
11          extra care. So, I wouldn't eliminate it to  
12          just a caregiver and home.

13                      CO-CHAIR GOLDEN: You know, the  
14          other thing

15                      MEMBER HAYDON-GREATTING: Yes, this  
16          measure

17                      CO-CHAIR GOLDEN: And the other  
18          thing is

19                      MEMBER HAYDON-GREATTING: Right. I  
20          know. But when they go to revise it, I just  
21          wanted them to just to think about what's  
22          happening out there in the future.

1 CO-CHAIR GOLDEN: I think that's a  
2 good point.

3 MEMBER HAYDON-GREATTING: Right.  
4 Yeah.

5 CO-CHAIR GOLDEN: I think a large  
6 percentage of these people are going to be  
7 going to long-term care facilities. Either  
8 intermediate or long-term.

9 MEMBER HAYDON-GREATTING: Right.  
10 For short-term since it yeah.

11 CO-CHAIR GOLDEN: Some sort of  
12 liaison that way should be part of the  
13 measure.

14 The other thing just to keep in  
15 mind when you revise is that if you're in an  
16 ER, that may not be connected to your PCP and  
17 you make an internal referral to your liaison  
18 service. You get into issues of insurance  
19 coverage and approvals and so, that gets  
20 real complicated also.

21 MEMBER BREEN: But I think the  
22 bottom line is there just wasn't evidence to

1 support it. Like you said, you know, I think  
2 that until there's some evidence established  
3 that's credible

4 MEMBER CURRY: Or it's written that  
5 there is an active attempt to make an  
6 appointment with the PCP or orthopedics clinic  
7 or another hospital clinic. If the  
8 appointment is made

9 MEMBER BREEN: So, you want more  
10 teeth in it.

11 MEMBER CURRY: Right. Yes.  
12 Because the rest of the measure, we thought,  
13 stood well.

14 MS. WATT: Well, we'll be back.

15 (Laughter.)

16 CO-CHAIR GOLDEN: It's 5:15 for  
17 people on the phone.

18 MS. TIGHE: Operator, if you could  
19 see if anyone on the line has a public  
20 comment?

21 OPERATOR: At this time if you  
22 would like to have a comment, please press



1 star and the number one on your telephone  
2 keypad.

3 (Pause.)

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

6 CO-CHAIR GOLDEN: Tell you what.  
7 Why doesn't everybody just stand up for a  
8 couple seconds? Give yourselves a little  
9 break.

10 I am told we're going to do one  
11 more measure before we are given a so, if  
12 you want to just walk around or get up for a  
13 second, it's

14 (Whereupon, the above-entitled  
15 matter went off the record at 5:20 p.m. and  
16 resumed at 5:23 p.m.)

17 CO-CHAIR ROSENZWEIG: Measure 0056,  
18 the diabetes foot exam. The measure steward  
19 is the NCQA.

20 If you'd like to discuss it?

21 MR. REHM: Sure. Just a quick  
22 comment. In contrast to the other five

1           measures you reviewed, this is only a  
2           physician-level measure. So, it's not in  
3           HEDIS Health plan.

4                     And, again, it's used in our  
5           diabetes recognition program and it's also  
6           used in the PQRS program.

7                     It's a fairly straightforward  
8           measure looking at foot care and appropriate  
9           examination.

10                    CO-CHAIR GOLDEN: So, I can present  
11           this. So, the numerator is     the denominator  
12           are patients of 18 to 75 who by the end of the  
13           year had a diagnosis of diabetes. And had an  
14           exam during the measurement year or the year  
15           prior to the measurement year     sorry, had  
16           diabetes during that year.

17                    And the numerator is people who  
18           this is important. It's a three-part     it's  
19           a three-part requirement to fulfill the  
20           numerator.

21                    You have to have a visual  
22           inspection, which I would assume would be a

1 description of the deformities and so forth,  
2 a sensory exam of the monofilament, and a  
3 pulse exam during the measurement period. So,  
4 there's three things you have to do to pass  
5 the numerator.

6 Now, in terms of the evidence,  
7 this is where things get kind of strange. So,  
8 I think that the committee or subcommittee  
9 discussed this. And I think everybody agrees  
10 that some sort of a foot exam or some sort of  
11 assessment of risk for the foot is important.

12 You can talk about different  
13 patients at different levels of risk depending  
14 on the condition of the foot, but then the  
15 issue comes up to do you have to do a sensory  
16 exam or the monofilament?

17 The evidence for the monofilament  
18 exam, which is cumbersome and often not done  
19 because it's cumbersome, is about is fairly  
20 weak.

21 There are alternative methods.  
22 For example, the Ipswich Touch Test which was

1 in Diabetes Care July 11, is comparable and is  
2 a lot simpler to do and to do in the office.

3 So, we have some concerns about  
4 the level of evidence to acquire that a  
5 sensory exam be done with the monofilament,  
6 per se, which itself would be a potential  
7 burden and barrier to completing the exam.  
8 So, that would be a question on the evidence  
9 on this issue.

10 The need to, you know, foot exams,  
11 obviously diabetes ulcerations and diabetic  
12 amputations are a serious problem. Foot  
13 injuries are slow and expensive to heal. I  
14 don't think anyone would disagree with the  
15 evidence for that.

16 The question of exclusions about  
17 this has to be done for everybody, whether or  
18 not they have already been shown to have  
19 neuropathy or not, is an interesting question.  
20 But, again, it's a three-part exam and the  
21 question is, is the monofilament an evidence-  
22 based requirement that that's the only way to

1 get this done?

2 That would be the sum of my  
3 comments. And, Sue, do you want to make some  
4 comments on that?

5 MEMBER KIRKMAN: So, just this is  
6 going to be a recurring theme, I think, when  
7 we talk about the other foot measures  
8 tomorrow. And that is that the evidence that  
9 exists for ulcer prevention is typically of a  
10 very sort of comprehensive program that kind  
11 of starts with risk assessment and then, you  
12 know, higher risk people get some sort of more  
13 comprehensive care. And then, you know, on  
14 down the line there are fewer foot ulcers.  
15 It's actually mostly foot ulcer prevention.

16 And one of the problems is trying  
17 to isolate out, you know, is there evidence  
18 that doing the foot exam with X, Y and Z  
19 versus not doing the foot exam, you know,  
20 prevents ulcers.

21 It's just very difficult, because  
22 the evidence is all for a more comprehensive

1           thing. And it's a little bit like the  
2           measuring the hemoglobin A1C, except that I  
3           think that's, you know, definitely a little  
4           bit more clearly linked to the evidence chain.

5                        So, that was just a limitation  
6           that we found with all these foot measures is  
7           that the evidence for any specific exam is  
8           difficult to come by.

9                        CO-CHAIR GOLDEN: And is it a  
10          screening test for everybody, or is there a  
11          subset?

12                       MEMBER KIRKMAN: Right. Right.

13                       CO-CHAIR ROSENZWEIG: I would just  
14          say that I guess I'm a little surprised to  
15          hear that the use of monofilament is a  
16          difficult or onerous test. It's incredibly  
17          easy and much easier than almost any other  
18          test that one can devise.

19                        It's certainly a lot easier than  
20          using a tuning fork or    and it has the  
21          advantage of really being able to be a yes or  
22          no kind of    because the filament bends.

1                   It was developed in the Carville  
2                   Center for Hansen's Disease down in Louisiana  
3                   and it has been widely adopted.

4                   It just seems to me it is one way  
5                   of at least making the sensory examination  
6                   somewhat objective. Because otherwise, you're  
7                   either picking the prodding someone too  
8                   deeply or too little with a needle.

9                   So, and it has been in a number of  
10                  studies, shown to be a fairly good measure of  
11                  not evidence for neuropathy, per se, but  
12                  evidence for clinically significant neuropathy  
13                  to the foot that might lead to an ulcer.

14                  MEMBER KIRKMAN: Right.

15                  CO-CHAIR ROSENZWEIG: So, as a  
16                  screening tool.

17                  MEMBER KIRKMAN: Yeah, it's  
18                  probably a better as good or better  
19                  predictor of future ulceration than the other  
20                  tests that are typically done.

21                  CO-CHAIR ROSENZWEIG: Yeah.

22                  MEMBER KIRKMAN: I don't know the

1           one that you mentioned, but

2                           CO-CHAIR ROSENZWEIG: So, I mean, I  
3           don't know why, I mean, it seems to me that if  
4           one is going to do a test for clinically    to  
5           actually screen for clinically significant  
6           neuropathy that could lead to an ulcer, that's  
7           about the easiest test to do.

8                           And we certainly have lots of  
9           patients, you know, we'll get to the gap of  
10          care later, but there are large numbers of  
11          people who are seen by physicians in their  
12          offices with diabetes who never get    that  
13          never take off their shoes.

14                          CO-CHAIR GOLDEN: As I said, I had  
15          looked around at the evidence, looking for the  
16          evidence for the test.  It's about a level 2B  
17          or a level 3 evidence.  I didn't find too  
18          many.

19                          And I also checked with a couple  
20          of my primary care colleagues and other  
21          Medicaid medical directors and they were all  
22          in agreement with what I just said that it's



1           cumbersome and difficult and not that useful  
2           to them.

3                        So, I don't know. It's just a  
4           matter of in the primary care community, you  
5           know, the rates haven't been improving. So,  
6           are there other ways of getting this done?  
7           That's my only comment.

8                        CO-CHAIR ROSENZWEIG: I do it on  
9           every patient.

10                      MEMBER SHWIDE-SLAVIN: There's the  
11           LEAP screening tool which is very well-  
12           defined, very simple to use and is extensively  
13           used, I think, within diabetes education  
14           programs, diabetes educators, as well as  
15           physician's offices using the monofilament.

16                      DR. PACE: So, can I just clarify?  
17           Because I presented some evidence. Are you  
18           saying that there's evidence that they did not  
19           present, or that you    you're grading this  
20           evidence as low quality? I'm not sure

21                      CO-CHAIR GOLDEN: The evidence, I  
22           just    I did my own review of the    of looking

1           around.  So, looking at the ratings.

2                       As I said, I found an alternative  
3           method.  That's all I was  I was saying it  
4           exclusively picks one particular technique.  
5           That was my concern.

6                       MEMBER KIRKMAN:  And I think, you  
7           know, again, like I said, you know, there may  
8           not be specific evidence for the foot exam  
9           versus no foot exam, but there's evidence for  
10          the foot exam identifies people who are at  
11          higher risk.

12                      And if you take the people that  
13          are at higher risk and you implement, you  
14          know, some sort of comprehensive care for  
15          them, then there is reduction in ulcers.

16                      I think it's reduction in deep  
17          ulcers that is statistically significantly  
18          reduced, but, you know, but again it's, you  
19          know, sort of like the exam is necessary for  
20          that risk assessment.  But the exam itself,  
21          you know, hasn't really been studied and  
22          probably never will be at this point, because

1           you're not going to randomize people to never  
2           take their shoes off versus the foot exam, you  
3           know.

4                           CO-CHAIR GOLDEN: Yes.

5                           MEMBER SHWIDE-SLAVIN: I'm just  
6           looking at the ADA's 2014 guidelines and  
7           there's actually B level evidence on using  
8           on the monofilament listed here.

9                           CO-CHAIR GOLDEN: Any other  
10          comments?

11                          MEMBER DUDL: Yeah, Bill. This is  
12          a question. I think the monofilament is one  
13          way to go and it's well-documented.

14                          So, the question is, would this go  
15          into the low category because it doesn't cite  
16          always to go, or a second way to go and that  
17          it forces people in one direction?

18                          I'm just a little unclear about  
19          how much this second method degrades the fact  
20          that the one does work.

21                          CO-CHAIR GOLDEN: You know, again  
22          that's something for the Committee to reflect

1 on. I think that later on we'll see that  
2 there hasn't been great improvement in this  
3 area.

4 So, the question is, is the  
5 monofilament going to be a barrier to  
6 completing the exams on other alternatives  
7 that achieve the intent on doing appropriate  
8 doing some sort of assessment of how the  
9 foot is performing and so forth?

10 That's my concern. Are there  
11 other ways of fulfilling the intent of what  
12 needs to be done?

13 MEMBER MILLER: I don't think it's  
14 a test-specific question or problem. I think  
15 it's more an office process problem and a time  
16 management problem, the time that it takes for  
17 the patient to take off their socks and shoes.

18 And I know in our practice if we  
19 have the patients if we have the medical  
20 assistants tell every single patient in the  
21 office to take off your socks and shoes,  
22 there's a higher rate of completion, period.

1                   And I think some of it is  
2                   seasonal, too, because this time of year  
3                   patients say, I'm not taking that off, no, you  
4                   know, not with my boots.

5                   MEMBER BREEN: A comment about  
6                   process and there's been a ton of evidence to  
7                   say that simple process measures make a big  
8                   change in this, you know, whether you  
9                   incorporate your office staff to do these  
10                  things with the LEAP scores, whether if you're  
11                  on a paper record you put a sticker on the  
12                  chart with a big foot ahead of time that says,  
13                  look at the foot.

14                  So, I don't think these should be  
15                  onerous measures. There's a lot of data out  
16                  there to say that simple, easy steps can do  
17                  these.

18                  MEMBER MILLER: Certainly if we  
19                  keep bombarding the patient every single time,  
20                  too, that they know when I go in it's the  
21                  expectation. And I think that we've got to  
22                  change the expectation for the patient, for

1 the office staff and for the providers as  
2 well.

3 CO-CHAIR GOLDEN: Again, my comment  
4 about the evidence is just on the monofilament  
5 piece itself.

6 CO-CHAIR ROSENZWEIG: The data that  
7 was presented in here suggests that, I mean,  
8 the monofilament and the biothesiometer  
9 vibratory sense probably have equal positive  
10 and negative predictive value, but the issue  
11 is that the monofilament is so much easier to  
12 do. I mean, you don't need complicated  
13 equipment.

14 MEMBER MILLER: And they're a lot  
15 lighter weight to carry around in your pocket  
16 than the tuning fork.

17 CO-CHAIR ROSENZWEIG: Yes. I still  
18 have one of the original ones, you know, that  
19 was produced from Louisiana, you know, that I  
20 keep, but now we always use disposable ones,  
21 you know, that are available.

22 But anyway, it seems to me that, I

1 mean, I think it's, you know, as far as I know  
2 it's part of the most guidelines that have  
3 been developed.

4 The ACE guidelines as well, I  
5 believe, mention it.

6 MS. BAL: Voting is up.

7 (Pause.)

8 MS. BAL: Okay. We have high,  
9 four. Moderate, 13. Low, three.

10 CO-CHAIR GOLDEN: So, we go next to  
11 performance gap. So, performance gap, I think  
12 that there is a fair amount of understanding  
13 that foot exams are underperformed.

14 And there are ongoing issues  
15 well, obviously there are ongoing issues with  
16 diabetic foot care, but that there was no  
17 great concern about there not being a  
18 performance gap.

19 MEMBER KIRKMAN: Is this where we  
20 talk about the age limit, or is that under  
21 validity?

22 CO-CHAIR GOLDEN: That's under

1 DR. PACE: It could have come under  
2 evidence, what does the evidence say? But  
3 you'll talk about that in validity, is the  
4 measure specified consistent with the  
5 evidence?

6 MEMBER KIRKMAN: Okay. So, just  
7 the evidence is that amputation rates are  
8 absolutely the highest in older people. So,  
9 and very devastating, very costly to Medicare,  
10 et cetera, et cetera, et cetera.

11 DR. PACE: So, let's hold that for  
12 validity. Let's talk about this performance  
13 gap. Any additional

14 CO-CHAIR ROSENZWEIG: Any comments?  
15 (Pause.)

16 CO-CHAIR ROSENZWEIG: Then let's  
17 vote.

18 MS. BAL: Voting is open.  
19 (Pause.)

20 MS. BAL: Okay. The results are  
21 high, 14. Moderate, five. Low, one.

22 CO-CHAIR ROSENZWEIG: So, we'll



1 move on to importance of the measure.

2 Bill.

3 CO-CHAIR GOLDEN: It's a major  
4 issue, major problem in diabetes. Prevention  
5 of foot ulcers would be a nice thing.

6 CO-CHAIR ROSENZWEIG: Let's vote.

7 MS. BAL: Open.

8 (Pause.)

9 MS. BAL: Okay. We have high, 17.  
10 Moderate, three.

11 CO-CHAIR GOLDEN: All right.  
12 Reliability. This one gets a little more  
13 tricky. I'd like to hear a little bit from  
14 the developer as well in the sense of, you  
15 know, again it requires three things to  
16 happen.

17 And I guess the question is, are  
18 the data extracted consistently? And is the  
19 documentation consistent? And would you have,  
20 quote, a normal exam be considered adequate?  
21 And are there specific things that have to be  
22 documented to pass the exam, to pass the

1 measure and the numerator?

2 And it's unclear how this gets  
3 extracted to pass the measure.

4 MR. REHM: Can I respond? So,  
5 again, there's the measure and then we have a  
6 program.

7 And the way our program works is  
8 that clinicians get their sample, they look at  
9 the patients, they look in their medical  
10 record, they can either extract from their  
11 EHR, registry, whatever they wish to use, and  
12 they would be looking that those three things  
13 occurred.

14 Not or, not this and or that and  
15 or this, but just do these three things and  
16 you've done a foot exam. And that's the  
17 measure.

18 CO-CHAIR ROSENZWEIG: No, I just  
19 think that, yes, it is very important to avoid  
20 a scenario where a physician has a box that  
21 says "foot exam" and they check it off, which  
22 is

1 MR. REHM: In our program, that's  
2 not the way our program works.

3 CO-CHAIR ROSENZWEIG: Yes.

4 MR. REHM: I'm not speaking about  
5 other programs that may have that dimension to  
6 it.

7 CO-CHAIR ROSENZWEIG: Well, that's  
8 why I'm saying

9 MR. REHM: That's their choice.

10 CO-CHAIR GOLDEN: One concern was  
11 it has not been tested in a primary care  
12 community, only in folks who want the  
13 recognition.

14 I don't know if anyone from a plan  
15 who collects this data they're in the  
16 primary care recognition program as opposed to  
17 a general population.

18 So, I was just curious if health  
19 plan has done reviews of this measure, I'm  
20 curious how the extractions have gone.

21 MR. REHM: It's not a health plan  
22 measure. I doubt they would want to collect

1           it just independently, because it's not in our  
2           domain.

3                        People are free to ask health  
4           plans. I'm just saying it's not a measure  
5           that's used in that setting.

6                        CO-CHAIR GOLDEN: So, it's used in  
7           is it used in PQRS?

8                        MR. REHM: Yes.

9                        CO-CHAIR GOLDEN: Have there been  
10          any data validity with PQRS?

11                       MR. REHM: The PQRS data is  
12          included in the submission. It looks very  
13          much like the same kind of data that we see,  
14          because it's a self-selected group of  
15          physicians deciding to report from a  
16          constellation of measures, measures  
17          appropriate for their practice. Generally  
18          speaking, it would be people who take care of  
19          patients with diabetes.

20                       CO-CHAIR ROSENZWEIG: Just wanted  
21          to ask does the measure specify which pulse is  
22

1                   MR. REHM: No, it leaves that open.  
2                   So, in the medical record it could probably  
3                   read a short note, you know, looked at the  
4                   foot, this is what I found, did a  
5                   monofilament, you know, here's the result and  
6                   took a pulse.

7                   CO-CHAIR ROSENZWEIG: Because the  
8                   way I read it, it suggested that perhaps you  
9                   could measure    the question was does it have  
10                  to be the two    it wasn't clear that it had to  
11                  be the foot pulses from the way it was defined  
12                  in the beginning, but I assume that was the

13                  MR. REHM: Yes, no.  If the

14                  CO-CHAIR ROSENZWEIG: In other  
15                  words, you couldn't do a femoral pulse and get  
16                  credit for this or

17                  MR. REHM: No, it's a foot pulse.

18                  CO-CHAIR ROSENZWEIG: Okay.  I  
19                  mean, it sounds silly, but

20                  MR. REHM: Yes.

21                  CO-CHAIR ROSENZWEIG: Okay.  So,  
22                  should we vote on reliability then, I guess?

1 MS. BAL: All right. Voting is  
2 open.

3 (Pause.)

4 MS. BAL: Okay. The results are  
5 high, three. Moderate, 13. Low, four.

6 CO-CHAIR ROSENZWEIG: Validity.

7 CO-CHAIR GOLDEN: So, the question  
8 here would be are the specifications  
9 consistent with the evidence? Is there  
10 sufficient specificity in the codes? And is  
11 the age inclusion consistent with the  
12 evidence?

13 That gets to your age question.  
14 That's part of the validity question.

15 CO-CHAIR ROSENZWEIG: Janice.

16 MEMBER KIRKMAN: Is this where I  
17 can talk about age?

18 CO-CHAIR ROSENZWEIG: Sue, go  
19 ahead.

20 MEMBER KIRKMAN: Sorry. This is  
21 where I can talk about age? Yes, I think the  
22 upper age limit is a big problem. I don't see

1 any justification for it.

2 I can see, like, microalbumin  
3 screening where you're talking about a  
4 complication, you know, 10, 15, 20 years down  
5 the line in a 90-year-old might not be  
6 worthwhile, but, you know, foot ulcers can  
7 develop relatively quickly, have a huge impact  
8 on quality of life and mortality and costs and  
9 so forth.

10 So, I don't know what the history  
11 was behind this other than a lot of the  
12 measures seem to be 18 to 75, but I don't  
13 think the upper age limit is justified.

14 I think it's actually kind of  
15 almost discriminatory. I mean, it's the  
16 people that need it the most that will be  
17 excluded.

18 CO-CHAIR ROSENZWEIG: I think  
19 that's a good point. I mean, decubitus ulcers  
20 occur in greater amounts in most elderly  
21 patients.

22 MR. REHM: Can I respond to that?

1 CO-CHAIR ROSENZWEIG: Yes.

2 MR. REHM: Sue, thanks for that.

3 You know, this is an interesting moment where  
4 you have an artifact of a program, because  
5 remember those were created around a program.

6 And just not that this is a health  
7 plan-level measure, but from the health plan  
8 side we had so many different indicators. We  
9 have 10 indicators for health plan measurement  
10 and diabetes and some of them you don't want  
11 to be doing over 75.

12 And we just looked at all of them  
13 and tried to get at essentially the best  
14 common denominator on age. We don't include  
15 foot exam in that. So, I want to make sure  
16 that's separate.

17 So, this is a classic case where  
18 we're comfortable having the measure endorsed  
19 with no upper age limit. In terms of the use  
20 and the program that we happen to have, we  
21 would probably constrain it because we're  
22 looking at A1C is less than A, A1C is greater,



1           you know. That's our choice to stratify, you  
2           know.

3                       We created the measure. We have  
4           the IP on the measure. NQF endorses the  
5           measure with an upper age limit of none,  
6           right? That's fine. We can use the measure  
7           in our program accordingly, as does any  
8           measure user out there.

9                       So, you can measure something and  
10          not    you can choose to measure different  
11          components of that population or stratify it  
12          to meet the needs of your thing.

13                      People don't necessarily

14                      DR. PACE: I need to weigh in on  
15          that from an NQF standpoint. NQF endorses a  
16          measure as specified, and that's what's the  
17          NQF-endorsed measure.

18                      MR. REHM: That's fine, yes.

19                      DR. PACE: We don't have control  
20          over how people implement it, but generally if  
21          it's not implemented how it's endorsed, it  
22          wouldn't be implementing the NQF-endorsed

1           measure.

2                       So, but again, you know, NQF only  
3           can control what it endorses and what the  
4           specifications are.

5                       CO-CHAIR ROSENZWEIG: But endorsing  
6           a measure with an upper limit doesn't  
7           necessarily mean that we're saying that you  
8           shouldn't do it at higher age levels.

9                       DR. PACE: Well, you have to think  
10          about, you know, that's why we have the  
11          evidence criterion, that's why we look at  
12          specifications and validity is that this is  
13          supposed to be an indicator of quality of  
14          care.

15                      And so, if you all are saying the  
16          evidence indicates that this process should be  
17          performed on patients regardless of age, then  
18          it wouldn't be logical to then endorse a  
19          measure that you thought didn't match the  
20          evidence.

21                      So, we would, you know, suggest  
22          that, you know, if this is how the evidence

1 falls out that there should be no upper limit,  
2 then you can you have some options.

3 You can ask the developer if  
4 they're willing to, you know, change the  
5 specification. I mean, that's a very limited  
6 thing, but, you know, and generally it doesn't  
7 happen during an endorsement process, or you  
8 can, you know, vote up or down on the measure  
9 as it's currently specified.

10 But I think you need to have more  
11 discussion in terms of whether you agree on  
12 this should not have an upper limit and then  
13

14 MEMBER SULLIVAN: So, if I  
15 understand I just want to clarify we could  
16 ask the developer, please change the limit.  
17 And the developer could say, okay. And we  
18 could proceed with the vote even though that's  
19 not usually what happens, because it's self-  
20 specific. You'd let us do that?

21 DR. PACE: Yes, but it would be up  
22 to the developer to say whether they could do

1           that at this point in time, because a lot of  
2           times they have implications and have to go  
3           back to their committees and their  
4           constituency.

5                         MEMBERS SULLIVAN: No pressure.

6                         MR. REHM: Well, I think you'll  
7           recall I made the recommendation.

8                         MEMBER BREEN: If I can just weigh  
9           in, I think this is a really interesting  
10          opportunity.

11                        Because if you look at the other  
12          measures, the reason we have the age limit is  
13          for patient safety, right? We put those  
14          because we don't want to hurt old people,  
15          right?

16                        And the irony here is by having an  
17          age limit, we may end up hurting old people,  
18          because we're basically implicitly stating  
19          that they're out of the view box as it were.  
20          So

21                        MEMBER KIRKMAN: Yes, we don't  
22          either we don't want to hurt old people or

1           there may not be benefit once you reach a  
2           certain, you know, limited life expectancy.

3                       But here, I think there is no harm  
4           and there potentially is benefit, you know,  
5           unless you're going to die tomorrow.

6                       So, I mean, yes, I mean, I would  
7           hope you would be willing to, because I  
8           wouldn't want to vote down the measure based  
9           on this.

10                      MEMBER BREEN: Especially with the  
11           aging population. When you look at the map of  
12           those numbers, just the total N of patients,  
13           we're going to be over 75 in the next few  
14           years.

15                      MEMBER KIRKMAN: So, more than half  
16           the people with diabetes are over 65. I'm not  
17           sure about over 75, but it's a big chunk.

18                      CO-CHAIR ROSENZWEIG: It's a big  
19           number. All right. Does that mean we have to  
20           actually create an amendment or something?

21                      DR. PACE: So, we've heard from Bob  
22           that NCQA is willing to remove the age limit.

1 Is there any objection from the steering  
2 committee?

3 (No response.)

4 DR. PACE: Okay. Then why don't  
5 you proceed with the rest of your voting

6 CO-CHAIR GOLDEN: I have a  
7 secondary question.

8 DR. PACE: Okay.

9 CO-CHAIR GOLDEN: The other, I  
10 mean, that's one issue. The other issue about  
11 validity, again this is I have a question  
12 about the exclusions in that somebody with  
13 already known neuropathy or foot issues or  
14 already under care, would they be excluded?

15 Or would that be if they were I  
16 guess if they're seeing podiatry, they would  
17 be in the numerator automatically?

18 DR. REHM: The specification was  
19 designed around ambulatory care and people  
20 going through that. So, that is not an  
21 exclusion currently. I mean, I don't think we  
22 presented an exclusion for that.

1 CO-CHAIR GOLDEN: Because if  
2 somebody already has known already has a  
3 known abnormality, to continue to repeat the  
4 testing

5 MR. REHM: Well, they may have an  
6 abnormality on one limb, not the other. I  
7 mean, I don't know if there's I think you  
8 get into sometimes we say do we specifically  
9 put an exclusion for a double amputee?

10 And some people say, well,  
11 actually you still need to, you know. It's  
12 kind of where do you start and where do you  
13 stop.

14 CO-CHAIR ROSENZWEIG: I think under  
15 the circumstances usually if the person is  
16 totally anesthetic in both feet, then you  
17 start testing further up on the leg basically  
18 and document the level.

19 I mean, that's what a lot of  
20 people would normally do.

21 MEMBER KIRKMAN: I think there is  
22 zero evidence for that, though. I mean, I

1           agree. I mean, there are     if they can't feel  
2           that monofilament at all, they're already so  
3           high risk that, you know, I'm not sure it  
4           matters whether they start feeling it at their  
5           knee or halfway to their knee.

6                         MEMBER MCCOLLISTER-SLIPP: Again,  
7           just chiming in on the patient perspective as  
8           somebody I have neuropathy. I have pretty  
9           good sensation in my feet, but I get pain.

10                        I mean, the level of sensitivity  
11           does fluctuate from visit to visit and it, I  
12           mean, it can often fluctuate with significant  
13           episodes of, you know, high glucose around  
14           really stressful events or something.

15                        So, I do think there would be  
16           merit in repeating it maybe not every time you  
17           see the doctor, but once a year or something.

18                        So, again, this is just anecdotal.  
19           It's not based on the evidence presented, but  
20           I don't think it's unreasonable given how  
21           inexpensive this particular test is.

22                        CO-CHAIR ROSENZWEIG: Any other



1           comments?

2                           (No response.)

3                           CO-CHAIR ROSENZWEIG: Okay. Let's  
4           vote on validity then.

5                           CO-CHAIR GOLDEN: And, again,  
6           voting on the validity with the understanding  
7           that there will be an amendment, correct?

8                           CO-CHAIR ROSENZWEIG: Correct.

9           Correct. Yes.

10                          MS. BAL: Voting is open.

11                          (Pause.)

12                          MS. BAL: So, high, eight.

13           Moderate, nine. Low, two.

14                          CO-CHAIR ROSENZWEIG: All right.

15           So, well go on to feasibility.

16                          CO-CHAIR GOLDEN: Again, this is  
17           extent to which the specifications include  
18           measure logic, data readily available, could  
19           be captured without undue burden and  
20           implemented for performance measurement.

21                          We've kind of gone around in  
22           circles about that already.

1 CO-CHAIR ROSENZWEIG: Yes, Bill.

2 MEMBER CURRY: So, in the PQRS  
3 measure it's just a foot exam. Neurologic  
4 examination of the foot and ankle. And yet,  
5 this measure has three parts to the  
6 examination.

7 And if a provider or if practices  
8 are going to try to capture this information  
9 from their EMR, they'll have to have some way  
10 to create or accommodate an element for each  
11 of those three parts of the measure, or  
12 they're going to have to do chart reviews.

13 So, I just I think that's a  
14 problem in terms of the feasibility especially  
15 for smaller practices that perhaps don't have  
16 the resources to do this kind of work.

17 Even for larger practices it's  
18 going to be a chart review, because most of  
19 our EMRs don't have an accommodate and element  
20 set with those three pieces in it.

21 MEMBER BREEN: If I can just  
22 comment, the feasibility sounds a lot like the

1 ophtha report feasibility, right? So, I mean,  
2 this is the exact same discussion we had about  
3 how to pull those ophtha reports, the  
4 ophthalmology reports of the diabetic eye  
5 exam, right?

6 So, anyone who has gone through  
7 NCQA certification in their practice knows  
8 there are two roadblocks. So, again,  
9 documentation and the eye exam.

10 So, I think the same discussions  
11 we've had about that topic play right in here,  
12 because it's you're right. There are very  
13 few EMRs that have those discrete data fields  
14 that you can pull that data from.

15 CO-CHAIR ROSENZWEIG: I could  
16 guarantee, though, that if a measure like this  
17 is approved, then the EMRs would include that  
18 granularity very quickly.

19 MEMBER CURRY: And I do believe  
20 that this is a better overall assessment of  
21 the patient's lower extremity than what the  
22 PQRS is going to measure.

1                   So, just a lot of difficulty  
2                   collecting it until the EMRs catch up.

3                   CO-CHAIR ROSENZWEIG: Yes, Janice.

4                   MEMBER MILLER: Okay.

5                   MEMBER McCOLLISTER-SLIPP: Yes, and  
6                   my question was primarily around data  
7                   extraction as well.

8                   I mean, I just see     and maybe I'm  
9                   looking at the wrong list of codes, but I only  
10                  see ICD-9 codes in what must be more like CPT  
11                  codes or something since it's a procedure.

12                  I mean, I would think that this  
13                  would be relatively cumbersome to extract.  
14                  And as somebody who works with EHR companies,  
15                  I think they might take a little bit longer to  
16                  come up with some sort of composite measure  
17                  that would be built into the base.

18                  MEMBER KIRKMAN: Yes, it's part of  
19                  the physical exam. So, it would just be part  
20                  of the E&M visit. It wouldn't be a separate  
21                  CPT code.

22                  MEMBER MILLER: I was going to make

1 the same comments about it being the same as  
2 having a distinct field for retinopathy  
3 screening, but I also think exactly what you  
4 said, Jamie. This is the only thing that's  
5 going to drive EMR developers to create a  
6 distinct field.

7 And I think if we look at what is  
8 our overall goal of this, our overall goal is  
9 to drive the quality improvement and to have  
10 this conducted and recorded so that it can be  
11 measured.

12 So, rather than saying, well, give  
13 the rubber stamp that it's too difficult to  
14 record, I think that we need to push the  
15 envelope on this.

16 CO-CHAIR ROSENZWEIG: Just as an  
17 aside, you have no idea how far behind the  
18 developers are in meeting these opportunities.

19 Any other comments? Oh, yes,  
20 Patricia.

21 MEMBER McDERMOTT: That's what I  
22 was going to say about abstraction and

1 thinking that an EMR modification is going to  
2 happen quickly.

3 So, you're developing a measure  
4 that's going to require manual chart review  
5 for quite some time. And I thought I heard  
6 that there is another measure, PQRS, that's  
7 going after the same concept. It's just not  
8 as granular. So, I guess at some point we  
9 talk about harmonization, yes.

10 And I don't know whether that  
11 other measure is already endorsed by NQF, but  
12 that's been one of the things that has driven  
13 a lot of these discussions as well is things  
14 that are basically going after the concept,  
15 same concept and how does a provider then  
16 figure out which thing to do. Just a thought.

17 CO-CHAIR ROSENZWEIG:

18 Harmonization, I think, is tomorrow.

19 MS. TIGHE: We actually so, we're  
20 moving the two APMA measures to the call that  
21 we have scheduled for March 12th. The  
22 developer had to leave. And then we'll

1 discuss the 0519, the CMS measure tomorrow.  
2 0416 and 0417, the developer had  
3 to leave. And so, he has asked that we  
4 discuss these measures on the call that we  
5 have scheduled for March 12th. It's from 1:00  
6 to 3:00 Eastern. I believe you all have  
7 calendar appointments already.

8 We had hoped to give it back to  
9 you, but unfortunately we won't be, but 0519  
10 we'll discuss tomorrow morning.

11 CO-CHAIR ROSENZWEIG: Any other  
12 comments on feasibility?

13 MR. REHM: Just a quick one. There  
14 may be more than one foot care measure in  
15 PQRS. This measure is in PQRS.

16 I believe last year they put an  
17 "or" instead of an "and." We didn't catch it.  
18 It's an "and" in future world it's been  
19 approved. So, I just wanted to let you know  
20 that there is concordance with that.

21 Now, remember that program uses  
22 either G codes or CPT 2 codes to do that. The

1 infamous check the box, that's their choice  
2 for how they do that measure.

3 So, to the extent that you believe  
4 that physicians would be faithful about doing  
5 the exam and then doing that and then that's  
6 the method of getting that data, that  
7 certainly is more feasible.

8 People have issues with the kind  
9 of the integrity underlying it. So, that's  
10 not discussion we want to weigh in on, but  
11 okay.

12 Bill.

13 MEMBER TAYLOR: It is a discussion  
14 that we ought to have though, right? I mean,  
15 if there are if there's no good evidence  
16 that actually putting a measure like this in  
17 place actually results in an outcome that  
18 we're trying to achieve and if this is pushing  
19 the envelope in terms of what developers would  
20 have to do on EMRs and so on, and if this  
21 questions even if you can't raise them, that  
22 we could about is this actually going to



1 result in physicians really doing this work or  
2 merely checking some box or doing something  
3 else rather than doing something that's going  
4 to result in the outcome we're looking for,  
5 and if there's the opportunity cost if you do  
6 this, you don't do something else, and if  
7 there's pushback in the physician community  
8 that we're requiring them to do things where  
9 there isn't evidence supporting it, well, then  
10 certainly this is exactly the kind of thing  
11 that we should not support and go ahead on.

12 MEMBER MILLER: This is also  
13 something that doesn't need to be done by a  
14 physician or nurse practitioner. You know, we  
15 have I've trained nurses to do this and to  
16 document it in notes.

17 CO-CHAIR ROSENZWEIG: I think there  
18 is evidence. I would disagree about the issue  
19 of evidence.

20 I think as we've mentioned in the  
21 ADA guidelines, they're talking about Level 2  
22 evidence; is that correct B evidence, yes.

1 Yes.

2 So, I'm not sure the issue,  
3 obviously, we're talking about feasibility.

4 So, the issue here is whether or not data  
5 capture will be feasible.

6 We have it in our electronic  
7 medical records. I just don't see why it  
8 would be a difficult thing to capture this  
9 kind of information, myself.

10 DR. PACE: So, we're on  
11 feasibility. So, are we switching back? Does  
12 someone want to go back to evidence or

13 CO-CHAIR ROSENZWEIG: No, no, no.

14 DR. PACE: Okay.

15 CO-CHAIR ROSENZWEIG: But someone  
16 mentioned Bill mentioned the fact that there  
17 wasn't evidence for it. So, I just

18 DR. PACE: Okay. Thanks.

19 MEMBER MILLER: And if we think  
20 about the process of it going back to the  
21 process again even that we don't have distinct  
22 data fields for it, practices have figured out

1           how to do it for PQRS for financial  
2           incentives.

3                       So, if they're figuring out a  
4           process to do it without a distinct field,  
5           they're figuring out a process.

6                       MEMBER SULLIVAN: I wanted to ask  
7           Bob if you could just clarify. I got confused  
8           by the last thing you said.

9                       So, not the other measure that's  
10          in PQRS, but this measure, your measure is in  
11          PQRS. So, it is specified with G codes, but  
12          we don't have them?

13                      MR. REHM: It's the no, it's  
14          included. We don't we don't give you the  
15          codes for that program. That's the program  
16          choice to use those codes, I guess.

17                      And because we have limited data  
18          from the PQRS program, we presented our data  
19          from our own recognition program. So, there  
20          are CPT 2 codes that are, in this case, that  
21          capture this requirement.

22                      I can look them up on our

1 specifications. I mean, they're there.

2 MEMBER SULLIVAN: I thought we were  
3 being asked to endorse a measure that was  
4 being used in two places in PQRS and then  
5 but we don't actually have the PQRS  
6 specifications; is that

7 MR. REHM: So, I'm sorry Helen is  
8 not here. And maybe some folks from NQF can  
9 speak to the issues around endorsement around  
10 these coding, check-the-box approaches,  
11 because and so, that's why we specify the  
12 the measure intent is to go after these three  
13 things. And how you can collect that in  
14 different programs is up to the program  
15 developer.

16 And I'm so, I just will leave it  
17 there and the Karens can maybe respond.

18 DR. PACE: So, you're bringing this  
19 measure to us with the medical record  
20 specifications, not the G code specifications.

21 MS. JOHNSON: So, just FYI, the  
22 spreadsheet that you guys submitted with your

1           measure has a G code for the foot exam. So,  
2           I think you did provide it to us.

3                   MR. REHM: Yes, we added that in as  
4           a concession to those clinicians who are using  
5           it, but that's not in our program, that's  
6           not this dominant collection. It was a  
7           courtesy, if you will, to help those that were  
8           40,000 physicians in the PQRS program, 3,000  
9           or 4,000 in our particular program.

10                   CO-CHAIR ROSENZWEIG: Well, if it's  
11           in PQRS, it presumably has already been  
12           approved by the NQF.

13                   DR. PACE: Not all measures in PQRS  
14           have been approved by NQF. And this one was  
15           the difficulty is that some of the measures  
16           that were originally endorsed did not have the  
17           testing. And I guess the testing data you've  
18           been presented with is from the recognition  
19           program using the specifications for the  
20           medical record abstraction.

21                   So, I think what you need to do is  
22           think about the measure as Bob has described

1           it, the medical record abstraction. That's  
2           what the testing is from.

3                       And I will have to clarify if  
4           there's any implications for the PQRS program  
5           or how to deal with that. We can come back to  
6           that tomorrow with Helen.

7                       MEMBER SULLIVAN: I think there  
8           will be implications for our discussion of the  
9           other measures tomorrow.

10                      I wonder, Karen, is it possible  
11           you could show us where are these here?

12                      Do discuss them.

13                      CO-CHAIR ROSENZWEIG: Well, these  
14           are the ones that have been tabled? Okay.

15                      CO-CHAIR GOLDEN: The ones that  
16           were tabled were from the podiatrists. The  
17           PQRS measure is tomorrow.

18                      CO-CHAIR ROSENZWEIG: Oh, okay.

19                      MEMBER KIRKMAN: The podiatry  
20           measures are PQRS measures.

21                      (Pause.)

22                      CO-CHAIR ROSENZWEIG: This is the

1 NCQA, okay.

2 So, I don't know what the  
3 specification of that particular code is.

4 Does that include the three parts of the

5 MEMBER CURRY: It says, foot exam  
6 performed includes examination through visual  
7 inspection, sensory exam with monofilament and  
8 pulse exam. Repot when all of the three  
9 components are completed.

10 CO-CHAIR ROSENZWEIG: So, it's  
11 consistent, yes. Okay. All right. Okay.  
12 So, I think let's vote on feasibility at this  
13 point.

14 (Laughter.)

15 MEMBER SULLIVAN: Including the  
16 HCPC code specification for PQRS, because  
17 that's how it was given to us, right? Okay.

18 MS. BAL: Voting is open.

19 (Pause.)

20 MS. BAL: Okay. We have high, one.  
21 Moderate, 15. Low, three.

22 CO-CHAIR ROSENZWEIG: So, we go to

1           usability. And usability, again, is the  
2           potential for potential audiences could use  
3           or will use performance results for  
4           accountability and improvement to achieve the  
5           goal of high-quality, efficient healthcare for  
6           individuals or populations. So, the impact in  
7           value for quality improvement.

8                           CO-CHAIR GOLDEN: So, the  
9           usability, that's in red from what the  
10          Workgroup determined?

11                          CO-CHAIR ROSENZWEIG: Yes, I think  
12          that it was there was, I mean, a few issues  
13          here and there, but generally the sense was  
14          that it was a usable measure.

15                          CO-CHAIR GOLDEN: Let's vote oh,  
16          wait. No, someone has their Jessie.

17                           (Laughter.)

18                          CO-CHAIR GOLDEN: Nobody wants to  
19          slow us up now. All right. So, let's vote on  
20          usability.

21                          MS. BAL: Voting is up.

22                           (Pause.)



1 MS. BAL: Okay. So, we have high,  
2 seven. Moderate, nine. Low, two.

3 CO-CHAIR ROSENZWEIG: All right.  
4 So, we're now voting on the overall measure  
5 with the caveat no upper age limit, and then  
6 we're presumably also having this potential  
7 for certainly for NCQA, but that the  
8 alternative PQRS could be

9 DR. PACE: Well, I think, you know,  
10 given that the specifications were provided  
11 and the comment to vote on it with those  
12 specifications, but we'll just clarify it  
13 tomorrow.

14 CO-CHAIR ROSENZWEIG: Okay. Thank  
15 you.

16 MS. BAL: Voting is open.

17 (Pause.)

18 MS. BAL: Okay. We have yes, 16.  
19 No, three.

20 CO-CHAIR ROSENZWEIG: Okay.

21 MS. TIGHE: All right. So, a  
22 little bit of housekeeping. We will plan to

1 start at 8:00 a.m. tomorrow so that we don't  
2 run into this situation with you all running  
3 to the airport to catch your flights.

4 So, thank you all for soldiering  
5 through today. I know it's been a really long  
6 day. We really appreciate it to our developer  
7 colleagues. Also, we very much appreciate you  
8 sticking around for this. The two audience  
9 members remaining, also, thank you.

10 We'll have breakfast at 7:30 for  
11 all of you. Please enjoy your evening. I'm  
12 sorry we kept you so long, and we look forward  
13 to talking to you all again tomorrow.

14 MS. BAL: And please leave your  
15 vote clickers next to your name tags. I'll  
16 come get them. Thank you.

17 MS. TIGHE: Feel free to leave  
18 papers in the room or anything that you want  
19 to revisit tomorrow.

20 (Whereupon, the above-entitled  
21 matter went off the record at 6:14 p.m.)  
22

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In the matter of: Endocrine Measure Endorsement

Before: NQF

Date: 02-26-14

Place: Washington, DC

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