

# NATIONAL QUALITY FORUM

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## EYE CARE, EAR, NOSE AND THROAT CONDITIONS (EENT) STANDING COMMITTEE

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WEDNESDAY  
JUNE 3, 2015

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The Committee met at the National Quality Forum, 9th Floor Conference Room, 1030 15th Street, N.W., Washington, D.C., at 9:11 a.m., Daniel Merenstein and Kathleen Yaremchuk, Co-Chairs, presiding.

### PRESENT:

DANIEL MERENSTEIN, MD, Co-Chair

KATHLEEN YAREMCHUK, MD, MSA, Co-Chair

TAMALA BRADHAM, PhD, CCC-A, Vanderbilt University  
Medical Center

MATTHEW CARNAHAN, MD, MS, The Permanente Medical  
Group

SCOTT FRIEDMAN, MD, Florida Retina  
Consultants

SETH GOLDBERG, MD, Aetna Insurance Company

JUDITH LYNCH, NP, American Association of Nurse  
Practitioners \*

RICHARD MADONNA, OD, SUNY College of Optometry

VAISHALI PATEL, PharmD, MS, US Health Outcomes,  
Allergan Inc. \*

TODD RAMBASEK, MD, ENT & Allergy Health Services

ANDREW SCHACHAT, MD, Cole Eye Institute,  
Cleveland

Clinic

JOSHUA STEIN, MD, MS, University of Michigan

MICHAEL STEWART, MD, MPH, Weill Cornell Medical  
College

STEVEN STRODE, MD, MEd, MPH, FAAEP, AR Disability  
Determination Services

JACQUELYN YOUDE, AuD, CCC-A, Healthcare  
Performance  
Partners

NQF STAFF:

ANN HAMMERSMITH, JD, General Counsel  
MARCIA WILSON, PhD, Senior Vice President,  
Quality Measurement  
SHACONNA GORHAM, MS, PMP, Senior Project Manager  
VY LUONG, MPH, Project Manager  
KAITLYNN ROBINSON-ECTOR, MPH, Project Manager  
REVA WINKLER, MD, MPH, Senior Director

ALSO PRESENT:

MARY BARTON  
ELVIA CHAVARRIA  
KENDRA HANLEY  
BENJAMIN HAMLIN  
JOY JIN  
TONI KAYE  
FLORA LUM  
SAM TIERNEY  
RICHARD ROSENFELD  
WILLIAM RICH

\* present by teleconference

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

2 9:11 a.m.

3 DR. WINKLER: Good morning and thank  
4 you for joining us. I'm Reva Winkler, I'm a  
5 Senior Director here at NQF.

6 Thank you all for joining us for our  
7 EENT measures evaluation and being members of our  
8 Standing Committee.

9 NQF has moved to standing committees,  
10 we'll draw choices between two and three year  
11 terms for you so that we have a committee  
12 available to discussion this topic area when  
13 issues come up and when we need to review  
14 measures. So, we do appreciate the time that  
15 you're volunteering and spending.

16 To kick off our introductions, I want  
17 to introduce our co-chairs, Dan Merenstein and  
18 Kathy Yaremchuk. And so, we'll be turning the  
19 meeting over to them when we get going a little  
20 bit later.

21 But, right now, I'd like to introduce  
22 NQF's General Counsel, Ann Hammersmith, and she

1 will help us do introductions and disclosures of  
2 interest.

3 MS. HAMMERSMITH: Good morning  
4 everyone. As Reva, said, we'll combine the  
5 introductions with the conflicts disclosure  
6 because it saves a little time. It's a little  
7 bit easier.

8 If you recall, we sent you a rather  
9 long form before you were named to the committee  
10 where we asked you about your professional  
11 activities in some detail.

12 What we'd like to do now is have you  
13 go around the table and declare anything that you  
14 wish to declare that you think is relevant to  
15 your service before the committee.

16 Please do not summarize your resume.  
17 You don't even need to summarize the form.

18 The idea is for you, in the spirit of  
19 openness, to disclose any activity that you've  
20 been engaged in in the last five years that may  
21 be relevant to the subject matter before the  
22 committee, but only if it's relevant to the

1 subject matter before the committee.

2 Before I have you go around the room,  
3 I want to remind you that you serve as an  
4 individual, as an expert. You're not here  
5 representing your employer. You're not here  
6 representing anyone who may have nominated you  
7 for service on the committee, purely as an  
8 individual expert.

9 Just because you disclose something  
10 doesn't mean you have a conflict. You're simply  
11 stating things to your fellow committee members  
12 and to the public that you think are relevant and  
13 important to the work that will be done here  
14 today.

15 We are particularly interested in any  
16 research that you've done that's relevant to the  
17 topic today, any grants you've received or  
18 speaking engagements, but only if it's relevant  
19 to the subject matter before the committee.

20 So, with that, I'll start with the  
21 chairs. If all of you could introduce  
22 yourselves, tell us who you're with and if you

1 have anything to disclose.

2 CO-CHAIR YAREMCHUK: I'm Kathy  
3 Yaremchuk, Chair ENT, Henry Ford Health system  
4 and I don't have anything to disclose.

5 CO-CHAIR MERENSTEIN: I'm Dan  
6 Merenstein, family physician from Georgetown  
7 University.

8 Part of my research is on sinusitis  
9 and I do work on a committee with Pew and CDC on  
10 decreasing antibiotic usage and it's primarily  
11 ENT issues.

12 MEMBER YOUDE: Hi, everybody. My  
13 name's Jackie Youde. I have nothing to disclose.

14 I am an Audiologist and I work as a  
15 consultant at Lean Six Sigma with Health Care  
16 Performance Partners, a MedAssets Company.

17 MEMBER SCHACHAT: I'm Andy Schachat.  
18 I'm a retina specialist at the Cleveland Clinic  
19 and these instructions are much broader than the  
20 instructions I read.

21 You're asking about research and  
22 grants and I've participated in 10 or 20 research

1 projects and probably written 200 articles  
2 related to the field and I've edited a journal  
3 and edited a textbook.

4 So, I'm just -- I can't begin to list  
5 them for you, although I've shared the CV.

6 MEMBER GOLDBERG: I'm Seth Goldberg,  
7 Medical Director from Aetna Insurance and I have  
8 nothing to disclose.

9 MEMBER BRADHAM: My name is Tammy  
10 Bradham and I am at Vanderbilt University. I am  
11 an NCHAM consultant, National Center for Hearing  
12 Assessment and Management.

13 I have published about, not 200, take  
14 a zero, 20 articles in the area of early  
15 intervention identification and hearing loss. I  
16 do have a current grant right now that's looking  
17 at spoken language development in children newly  
18 identified with hearing loss.

19 MEMBER STEWART: I'm Micky Stewart.  
20 I'm an otolaryngologist at Weill Cornell Medical  
21 College in New York. And I don't have any  
22 conflicts.



1 I am on the Board of -- I'm elected  
2 Director of the Board of Directors of the  
3 American Academy which is the sponsor or the  
4 steward of several of the measures but I've never  
5 been actually on a -- I've never developed a  
6 measure. I haven't been on the committee. I  
7 haven't been an author on any of the guidelines.  
8 I'm just on the Board of the Academy.

9 MEMBER STEIN: My name's John Stein.  
10 I'm at the University of Michigan. I'm an  
11 ophthalmologist and glaucoma specialist there.  
12 I'm on the American Glaucoma Society Board of  
13 Directors.

14 And my research, I'm a health services  
15 researcher. I do a lot of large health care  
16 claims, database analyses, some of which are  
17 relevant to some of the measures.

18 MEMBER RAMBASEK: My name is Todd  
19 Rambasek, allergist with ENT & Allergy Health  
20 Services and I have no relevant research or grant  
21 interests.

22 MEMBER MADONNA: Good morning. I'm

1 Rich Madonna. I'm the Chairman of the Department  
2 of Clinical Education at the SUNY College of  
3 Optometry.

4 I do consult for or on advisory boards  
5 for or speak for drug companies and instrument  
6 companies. However, I don't believe that they  
7 will have any direct relevance here.

8 MEMBER FRIEDMAN: Scott Friedman,  
9 ophthalmologist, Lakeland, Florida. I have no  
10 significant financial disclosures.

11 MEMBER STRODE: Steven Strobe. I'm a  
12 family physician from Little Rock. I did  
13 participate with the American Academy of  
14 Otolaryngology in developing a clinical measure  
15 on hoarseness and then with the AMA on sinusitis.  
16 I think both were about four or five years ago.

17 MEMBER CARNAHAN: Matt Carnahan, an  
18 ophthalmologist, the Permanente Medical Group in  
19 Northern California. I have nothing to disclose.

20 MS. HAMMERSMITH: And I understand  
21 there are some people on the phone.

22 Judith Lynch?

1 MEMBER LYNCH: I'm Judith Lynch from  
2 Milford, Connecticut. I'm a Nurse Practitioner  
3 in otolaryngology and allergy.

4 I've written several articles on  
5 different issues in ENT and allergy.

6 MS. HAMMERSMITH: Okay, thank you.

7 Vaishali Patel?

8 MEMBER PATEL: I'm Vaishali Patel. I'm  
9 a pharmacist in the Health Outcomes researcher by  
10 training and much of my research is in  
11 ophthalmology health outcomes research. And I  
12 currently work at Allergan.

13 MS. HAMMERSMITH: Okay, thank you.

14 Before I leave you, I just want to  
15 remind you that we rely on you as committee  
16 members to help us successfully deal with any  
17 bias or conflicts of interest.

18 So, if you're in the meeting and you  
19 think that one of your fellow committee members  
20 has a conflict or if you have a conflict or if  
21 you think someone is behaving in a biased manner,  
22 please do speak up. Please don't sit there and

1       then tell us six months later, well, you know, I  
2       thought so and so had a really huge conflict and  
3       we didn't know about it. We want to deal with it  
4       in real time.

5               If you want to say something about you  
6       think you have a conflict, you think someone else  
7       does or is acting in a biased manner, you are  
8       always free to speak up openly in the meeting.

9               You can go to your co-chairs who will  
10       consult with NQF staff or you can talk to NQF  
11       staff directly.

12              Any questions? Anything you want to  
13       discuss?

14              Okay, thank you.

15              DR. WINKLER: Okay. Before we get  
16       started with looking at the measures, we do want  
17       to talk about NQF's -- your role and also the  
18       portfolio of measures in this topic area.

19              The role of the committee, you all  
20       have varied backgrounds and we are going to ask  
21       you to wear multiple hats while you're here.

22              This committee is looking at a widely

1       disparate topic areas, eye care, ENT, don't  
2       really seem to have a whole lot in relationship  
3       to each other except historically when both  
4       groups of specialists belonged to the same  
5       professional society. So, there is a historical  
6       precedent for putting these two together.

7               And so, some of you may have expertise  
8       in, say eye care, but not so much the others.  
9       So, when we're talking about the measures in your  
10      area of expertise, that certainly is the hat  
11      we're expecting you to wear.

12             However, as a multi-stakeholder group,  
13      you also are able to wear several other hats.  
14      So, if eye care is not your specialty, you  
15      certainly can wear the hat of a potential patient  
16      or family member.

17             Most of you are involved in the  
18      clinical care of some type of patient. So, as a  
19      professional, an interest in moving towards a  
20      higher quality, more efficient health care system  
21      is something that we should all have a stake in.  
22      And so, you wear that stakeholder hat as well.

1                   And so, I'm asking all of you to stay  
2 engaged in all of the measures and offer what  
3 you're able. So, if you don't necessarily have  
4 that clinical expertise, put yourself in the  
5 position of a patient, a generalist or a member  
6 of the community in terms of asking how does this  
7 measure going to help drive improvements in the  
8 quality of care provided in the health care  
9 system.

10                   So, again, remember that you're  
11 representing a wide variety of interests and  
12 stakeholders. And so, depending on the topic at  
13 hand may very well be you're wearing different  
14 hats today.

15                   So, I really appreciate your thinking  
16 in those terms.

17                   As I mentioned, you will be assigned  
18 by a draw. We're going to do it, I think, after  
19 lunch today, a two or a three year term of office  
20 for a Standing Committee.

21                   In the off time when we're in actively  
22 engaged in a project, we may come back to you

1 with questions that come up around some of the  
2 measures.

3 We do annual reviews of measures.  
4 Sometimes we need to do ad hoc reviews of  
5 measures. Sometimes there are issues that arise  
6 in a topic area and we may be coming back to you  
7 and asking you for your input.

8 So, it will be less busy than now, but  
9 we certainly anticipate needing to touch base  
10 with you over that time frame until the next big  
11 review of measures with other questions.

12 Your role is with all of us to achieve  
13 the goals of this project which essentially are  
14 to look at the measures. Most of the measures  
15 that we are going to be looking at are currently  
16 endorsed by NQF and so we want to look at  
17 continuing endorsement and whether they still  
18 meet NQF's criteria.

19 We need to evaluate each of the  
20 measures against all of the criteria. After your  
21 recommendations, we will publish them and seek  
22 public comment to get feedback on your

1 recommendations.

2 We really enjoy getting the feedback  
3 to find out what's happening in the field, what  
4 folks -- the audiences out there think of the  
5 measures, whether it's practicing clinicians or  
6 other groups.

7 And also, the CSAC, the Consensus  
8 Standards Approval Committee, which is the  
9 subcommittee of the Board of Directors is sort of  
10 the end of the road when it comes to granting  
11 endorsement along with the Executive Committee of  
12 the Board. And so, they may as any specific  
13 questions or directives. And so, it's your job  
14 to respond to those as needed.

15 So, we will be guiding you through all  
16 of this process. But, again, we do appreciate  
17 your being here.

18 Does anybody have any questions on  
19 that before we move on?

20 Okay. Okay. In terms of the measure  
21 evaluation which is our primary activity for  
22 today and tomorrow's meeting is that, as I



1 mentioned, all members are expected to be  
2 involved in the review of all measures. We have  
3 gone through in the workgroups the discussants.  
4 We've sort of had a run through.

5 We will evaluate each measure against  
6 the criterion. This will be a formal process of  
7 going through each on, discussing it and the  
8 committee voting so that we do have a record that  
9 can be part of the consensus process.

10 You will be ultimately making  
11 recommendations on these measures for continued,  
12 or for the one new measure, endorsement in an  
13 ongoing way.

14 And then we're going to discuss in a  
15 few minutes the overall portfolio of measures.  
16 You're looking at the vast majority of them for  
17 review today.

18 However, we would really like to see  
19 your input and thoughts of where there are areas  
20 that measurement, we don't currently have  
21 measurement gaps, things that would be useful to  
22 drive further improvements. And we're looking

1 for your input. So, those'll be some of the  
2 conversations we have tomorrow as we finish up  
3 evaluating the measures.

4 Okay, so, I just want to briefly talk  
5 about the portfolio. And, as I said, we put eye  
6 care and ENT together. From an NQF perspective,  
7 operationally, because they're relatively small  
8 groups themselves but they do have a historical  
9 relationship. So, we're sort of relying on that.

10 But, as you have probably would do,  
11 looking at it from the perspective of eye care  
12 and ENT.

13 So, the next slide? Whoever's over  
14 there? Okay.

15 So, the eye care portfolio, and I just  
16 want to look at it in its toto and you will see  
17 there two measures for macular degeneration that  
18 you're going to talk about, three measures for  
19 cataracts, two measures for diabetic retinopathy  
20 and then I've added one measure that is not  
21 primarily the responsibility of this committee  
22 but is very much related, and that is Measure 55,

1 which is a measure for patients with diabetes  
2 that is overseen on our endocrine committee but  
3 it is the referral for an eye exam.

4 And so, I want you to be aware that  
5 that measure is also part of NQF's overall  
6 portfolio.

7 Then we do have two measures for  
8 glaucoma and we do have a new measure around  
9 vision screening that we'll discuss.

10 I'd like to point out something.  
11 We've endorsed many of these measures for a long  
12 time. I think I've mentioned to you all that  
13 I've been with NQF for more than 14 years and so,  
14 I do have the benefit of history and knowing.

15 I'd like to particularly point out  
16 some of the measures in the eye care portfolio as  
17 some of our earliest outcome measures that came  
18 through. In the early days, process measures was  
19 the main focus and there was both a technical  
20 kind of wariness of outcome measures, but we  
21 really have had some outcome measures in eye care  
22 from some of the earliest times and I do

1 congratulate the developers and the society for  
2 pushing in that direction.

3 But I'd like to specifically point out  
4 the three measures for cataracts as a  
5 particularly wonderful group of measures because  
6 what you have is patients have undergone cataract  
7 surgery, 1536 is how the patient thinks about  
8 their vision improvement after 90 days. So, it's  
9 an outcome based on what the patient perception.

10 Second is, you know, clinical  
11 assessment of, you know, whether their vision is  
12 20/40 or better afterwards, so there's an  
13 objective assessment.

14 And then there's a measure of  
15 complications.

16 So, we have three very too the point  
17 outcome measures that pretty much describe what  
18 happens for patients undergoing cataract surgery.

19 So, this is a particularly nice  
20 grouping for this subject area. And we do, NQF  
21 does put a premium on outcome measures and we  
22 certainly look for outcome measures whenever it's

1 appropriate.

2 We certainly are looking forward to  
3 seeing more patient reported outcomes such as we  
4 see here. And so, your input on the types of  
5 patient reported outcomes that might be  
6 particularly pertinent in these topic areas would  
7 be very useful.

8 So, this is our eye care portfolio as  
9 it is and we will be asking you to help us talk  
10 about the measures in the portfolio as well as  
11 opportunities to improve the portfolio.

12 The next slide is the other side of  
13 the coin which is the ear, nose and throat  
14 conditions. And, again, we're going to be  
15 talking about the group of measures around ear  
16 infections and one measure for pharyngitis.

17 I did want to point out that there is  
18 another measure that was discussed as related to  
19 this measure for treatment of children with a  
20 URI, so it is related, although it is managed by  
21 another Standing Committee in our pulmonary topic  
22 area.

1                   And then we do have several measures  
2                   for speech and hearing, so the functional sense  
3                   is there.

4                   So, that's the portfolio. And so,  
5                   again, your input in terms of other topic areas,  
6                   where there are gaps, how we might move to  
7                   outcome measures, where there are opportunities  
8                   for patient reported outcome measures would be  
9                   quite valuable in trying to, you know, understand  
10                  where this portfolio could be improved going  
11                  forward.

12                  So, any questions about the portfolio?  
13                  Because one of your roles is to oversee it.

14                  Okay, go on.

15                  So, I just want to let you know that  
16                  there were several measures as we came to bring  
17                  these topic areas to you.

18                  Three measures, the measure developers  
19                  decided not to continue to pursue endorsement, so  
20                  we really want to just be complete and share with  
21                  you the measures that will be removed from the  
22                  portfolio because they've been retired by the

1 developer.

2 Next one? Okay.

3 MS. LUONG: Hi everyone.

4 So, I'm just going to briefly go over  
5 the projects, activities and time line with you  
6 all again. I know I mentioned it during the  
7 orientation call, but just to remind everyone.

8 After the in-person meeting, there is  
9 a post-meeting webinar to go over anything that  
10 we did not cover at the in-person meeting today  
11 and tomorrow and that is on June 22nd.

12 Staff will then begin to draft the  
13 report. We'll begin shortly after this meeting  
14 as well as with the post-comment, post-meeting  
15 call on the 18 measures in this project. And the  
16 draft report will go out for commenting on July  
17 10th to August 10th.

18 During this time, member of the public  
19 as well as NQF membership can comment on any of  
20 the measures in this project.

21 The comments will be gathered by NQF  
22 staff and we will present you with the comments

1 at the August 21st meeting which is the post-  
2 comment call.

3 And during this meeting, we'll present  
4 you with the comments, the themes for the  
5 comments as well as your proposed responses to  
6 the comments.

7 NQF staff will then gather your  
8 suggestions and comments during this call and we  
9 will put it back out in a draft report with red  
10 lines and it will go out to membership for voting  
11 and that is in September, from September 9th to  
12 September 23rd.

13 So, that happens. And after NQF  
14 membership votes, we will bring all of this to  
15 the Consensus Standards Approvals Committee, also  
16 known as CSAC. And this is the next body to  
17 oversee the measures and they have a few options  
18 to vote.

19 They can vote to uphold your  
20 recommendations of the measures. They can vote  
21 not to or they vote if they have concerns with  
22 the measures for it to be brought back to the ENT



1 Standing Committee for further discussion.

2 And CSAC is expected to review the  
3 measures in this project on April 13th. And once  
4 CSAC reviews it and votes, it goes to the  
5 Executive Committee of the Board of Directors for  
6 the final measure ratification. And that's on  
7 November 13th.

8 Once the Board ratifies the measures,  
9 it goes out for appeals for a month and that's  
10 from November 19th to December 18th.

11 And we expect to have the final report  
12 published on the NQF website early in next year.

13 So, I will now give this off to the  
14 two co-chairs to discuss some ground rules for  
15 today's meeting.

16 CO-CHAIR MERENSTEIN: Thank you.

17 So, this is our first meeting doing  
18 this, being at any of the meetings, our being  
19 chairs, so hopefully, you can help us and move it  
20 along.

21 We'll try to stay on time. And the  
22 few rules are on the slide but be prepared, and

1       having reviewed the measure before hand and  
2       everyone's already participated in the phone call  
3       so I think we're okay with that.

4               Try to base evaluation recommendation  
5       on the measure evaluation criteria and guidance.  
6       So, obviously, we're going to bring in other  
7       things that just from your baseline knowledge,  
8       but try to use that and just point out when  
9       you're bringing different things in.

10              Remain engaged, Reva already talked  
11       about that. There's lots of ones that, you know,  
12       are not really pertinent to what you do daily,  
13       but still try to remain engaged.

14              And then if you guys need a special  
15       break that's not on here, just let us know. But  
16       otherwise, we'll just stick with the breaks that  
17       we have set up.

18              CO-CHAIR YAREMCHUK: And another point  
19       is to keep it concise and focused. And often  
20       times, many of us who've done research in areas  
21       and we may tend to get off on a tangent on  
22       something or another. But, remember, we're

1 looking at the measures and the applicability of  
2 the things that we're interested in.

3 And if things have been said  
4 previously, it's okay to say agreed and then just  
5 move along.

6 It's important to think about your  
7 different constituents and your constituents are  
8 your patients, your colleagues and people that  
9 will be using these measures.

10 And then, what Reva had talked about  
11 earlier was the idea of improving quality of  
12 care. You know, underutilization,  
13 overutilization and being appropriate for our  
14 patients.

15 And I think the indicated agreement  
16 without repeating what has been said, our first  
17 measure going through this because we're a group  
18 that hasn't worked together before may be a  
19 little bit more structured in terms of going  
20 through it. And by the end of the day on  
21 Thursday, I'm sure it'll be a little bit faster.

22 So, it's a pleasure to have everybody

1 here and I think Dan and I both recognize, and  
2 Reva and everybody from NQF, the amount of time  
3 it takes and energy and away from business. And  
4 often times we say we have a day job going on as  
5 well and so, trying to stay here and having your  
6 day job at the same time can be challenge.

7 MS. LUONG: So, thank you both, Kathy  
8 and Dan.

9 Now, just to go over the process of  
10 the measure discussions, I'd like to go over how  
11 it will flow.

12 You have in front of you in the packet  
13 a measure discussion script. This will help you  
14 with facilitating -- with understanding how the  
15 flow of the measure discussion will go. And I'll  
16 also speak a little bit to it now.

17 As we mentioned at the orientation  
18 call, NQF continuously strive to improve our  
19 committee meetings based on input from a variety  
20 of different stakeholder groups.

21 And we are very fortunate to enough to  
22 have our measure developers present at the

1 meeting, especially today with a full house in  
2 the back. And we will be asking them to briefly  
3 introduce their measures as their measure goes up  
4 for discussion.

5 And in the case of our measures, since  
6 they are grouped in many topic areas, they can  
7 give a brief introduction of the measure groups.

8 So, committee members are -- after the  
9 measure developers discuss their measures briefly  
10 for two to three minutes, the committee members  
11 who are the discussants on the measures will then  
12 begin to discuss the measures in relation to the  
13 NQF measure criteria.

14 We have provided a designated place  
15 for the developers on the two sides to my left  
16 right now. And they will be able to speak during  
17 their measure discussion and it allows them to  
18 answer any questions that you may have for them  
19 at a more close setting.

20 Both committee members and developers  
21 may put their name cards up, the name cards right  
22 in front of you, when they wish to respond to a

1 question raised or to correct any statements that  
2 may come up about their measures.

3 For those on the webinar, Vaishali and  
4 Judith, you can -- there's an option for you to  
5 raise your hands if you'd like to speak or you  
6 can just speak to the phone.

7 During the measure evaluation,  
8 committee members often offer suggestions on how  
9 to improve the measures and these suggestions can  
10 be considered by the developer for future  
11 improvements.

12 However, the committee is expected to  
13 evaluate on the measures in front of them and  
14 make recommendations per the submitted  
15 specification and testing.

16 As Reva mentioned earlier, the  
17 committee members, you, act as a proxy for the  
18 NQF membership. And, as such, you, as a multi-  
19 stakeholder group, brings together a variety of  
20 different perspectives and values and priorities  
21 to the discussion and that's one of the things  
22 that we are very fortunate about.

1           It is very important that we respect  
2 each other's differences of opinions and stay  
3 friendly and collegial with our interactions  
4 amongst each other and as well as with the  
5 developers.

6           So, moving forward, to recap the  
7 voting criteria, there are four to consider today  
8 for each of the measures discussed. During the  
9 discussion of the different criteria, we'd like  
10 it if you can stay within that discussion.

11           So, for example, if we are discussing  
12 performance gap within importance to measure and  
13 report, the first criteria, please stay within  
14 that discussion and not diverge to maybe  
15 usability and use. We will have time to talk  
16 about that later.

17           So, the criteria are in specific order  
18 and there is a hierarchy, there is a logic to  
19 looking at them in this specific order.

20           The first one is important to measure  
21 and report. And there are two subcriteria  
22 under it which is evidence and performance gap.

1                   Following that is scientific  
2                   acceptability of the measure's properties and  
3                   looking at -- this is looking at the  
4                   specifications as well as the reliability and  
5                   validity of the measure which are the two  
6                   subcriterion.

7                   And it's important to note that the  
8                   first two criteria and the subcriterion under it  
9                   are must pass criteria.

10                  Moving forward, criteria three is  
11                  feasibility. And the ideal goal here is to have  
12                  a measure that causes as little burden on the end  
13                  user as possible.

14                  As for criteria four which is  
15                  usability and use, the criteria is really on how  
16                  the measure can be used for decision making  
17                  regarding accountability and improvement later  
18                  on.

19                  And now, I am going to hand this over  
20                  to Kaitlynn who will be going over our voting  
21                  process and how you can use the clickers right in  
22                  front of you.



1 MS. ROBINSON-ECTOR: Hi everyone.

2 So, just to go over this quickly. In  
3 order to vote, you point your clicker directly at  
4 this laptop and each number on your clicker  
5 correlates to an option on the voting slide. And  
6 if you wish to change your vote during the voting  
7 process, simply click the number that correlates  
8 to the new answer that you would wish to put in.

9 If we stop the voting and you would  
10 like to change your vote, then just me know and  
11 I'll open voting again.

12 Thank you.

13 DR. WILSON: The other thing I would  
14 mention is, your clicker is a unique number, so  
15 it's not like Chicago where you can vote early  
16 and vote often. So, don't worry if you change  
17 your vote and sometimes we may miss a vote and we  
18 don't get to the number we're expecting so we'll  
19 say vote again. So, don't worry, you're not  
20 putting in a duplicate vote. So, just know that  
21 your clickers are unique.

22 And, yes, sir?

1                   MEMBER SCHACHAT: Could you explain if  
2 something passed if there's a majority or do you  
3 need 80 percent or what the cutoff is?

4                   DR. WILSON: We're going to get there.  
5 Is that in your slides? Do you want to cover  
6 that?

7                   MS. LUONG: Yes, I can briefly go over  
8 that. It's on the voting slide it has the  
9 consensus on it.

10                  So, overall, we have 16 Standing  
11 Committee members, one cannot attend today and  
12 two will be attending by phone.

13                  And so, in the room we have 13 people.  
14 Quorum for a Standing Committee is at 66 percent,  
15 so we have more than that right now in the room,  
16 especially with the two on the phone.

17                  And in terms of consensus not reached,  
18 it is anywhere from 40 to 60 percent.

19                  So, for the two must pass criteria, if  
20 we somehow end up in the gray zone, consensus not  
21 reached for this, we will continue to move on and  
22 we'll make a note of it in our draft report.

1           For measures, for the two, especially  
2           the criteria one and criteria two, if there are  
3           less than 40 percent of vote in favor of the  
4           measure, then it does not pass. And if there's  
5           more than 60 percent then it's a pass.

6           Do you have any questions?

7           MEMBER LYNCH: This is Judith. I'm  
8           still having problems with figuring out how to  
9           vote. I do not see any clicker on the up side of  
10          the left on anything that you have sent me.

11          MS. LUONG: Sure, Judith, yes. That's  
12          another thing that we're working on. But, in the  
13          meantime, for Judith and Vaishali, can you email  
14          me your voting results? Or, if you feel  
15          comfortable, you can just -- yes, so just please  
16          email me your voting results and we'll speak to  
17          the voting options.

18          MEMBER LYNCH: Thank you.

19          MEMBER PATEL: Yes, and that's fine,  
20          right.

21          MEMBER SCHACHAT: So, to reach  
22          consensus it's got to be 60 percent of 15 because

1 we have 13 here and two online?

2 MS. LUONG: Oh, and another thing, so,  
3 I know I mentioned this earlier, but if you'd  
4 like to speak since we're all here and we might  
5 want to say something at the same time, please  
6 use your name card.

7 And also, for the microphones, when  
8 you're done speaking, please just turn it off  
9 because there can only be three microphones on at  
10 the same time.

11 Thank you.

12 DR. WINKLER: Any other questions about  
13 the voting process?

14 As we do the first measure, we'll all  
15 have a chance to kind of go through it.

16 Is that the last slide, guys?

17 MS. LUONG: Yes, that is.

18 DR. WINKLER: Okay. All right, so I  
19 think we can turn it over to Dan and Kathy and we  
20 can get started with the first measure, 0653.  
21 So, if the measure developer representatives want  
22 to join us at the table?

1 MS. GORHAM: Before we get started,  
2 Vaishali and Judith, this is Shaconna. Did you  
3 receive my email?

4 MEMBER LYNCH: Yes.

5 MS. GORHAM: Okay. Can you access the  
6 path?

7 MEMBER LYNCH: I can.

8 MS. GORHAM: Okay, wonderful.  
9 Vaishali, are you okay as well?

10 MEMBER PATEL: I'm just checking. Oh,  
11 yes, yes.

12 MS. LUONG: Oh, so you can see the chat  
13 now? Everything is good?

14 MEMBER PATEL: No, I can't see the  
15 chat. All I have are the measures.

16 MS. GORHAM: They have the measures.

17 MS. LUONG: Okay, so if you can just  
18 email me when we vote on each criteria, that  
19 would be great.

20 MEMBER PATEL: Okay.

21 MS. LUONG: Thank you.

22 MEMBER PATEL: Thanks.

1 CO-CHAIR MERENSTEIN: So, we have two  
2 measures with otitis, so we're going to -- I  
3 think the developers are going to go over both at  
4 the same time. Is that right?

5 DR. ROSENFELD: Good morning. I'm Rich  
6 Rosenfeld. I'm a pediatric otolaryngologist at  
7 SUNY downstate in Brooklyn.

8 I've been involved with both creating  
9 the guidelines as well as the performance  
10 measures that we'll be discussing today. And I  
11 appreciate the opportunity to be here.

12 Thank you.

13 I have no conflicts of interest even  
14 though I'm -- other than I like the measures and  
15 the guidelines, but that's the conflict.

16 So, the first two are on acute otitis  
17 externa, affectionately known as swimmer's ear,  
18 not so affectionately known by the people who get  
19 it because it ruins your vacation and life very  
20 quickly.

21 It's defined as a diffuse inflammation  
22 or infection, really a cellulitis of the skin of

1 the ear canal. It can involve the ear drum as  
2 well as the skin of the external ear.

3 You know you have it because it hurts,  
4 you get itching, you get fullness, but most  
5 importantly, it is extraordinarily, sometimes  
6 excruciatingly, painful to the point that it's  
7 incapacitating and requires narcotics.

8 The reason we're interested in this  
9 from a guideline perspective and a measure  
10 perspective is it's very, very common, there's  
11 about 2.4 million annual visits in the U.S. every  
12 year. It affects roughly 1 in every 120 in the  
13 U.S. population and the lifetime chance of  
14 getting it is about 10 percent.

15 It's remarkably common. It's also  
16 remarkably mismanaged which is why we feel  
17 there's an opportunity for quality improvement.

18 The two measures that we have up, one  
19 relates to -- both relate to process and they  
20 relate to doing things in the first case that you  
21 shouldn't do. It's an overuse measure of  
22 antibiotic prescribing that the clinician should

1 not prescribe antibiotics for treating this  
2 condition, oral antibiotics that is.

3 There are two randomized trials that  
4 have looked at this and found no benefit when you  
5 add it above and beyond the topical drugs. But  
6 most importantly, the main organism that causes  
7 swimmer's ear is called pseudomonas aeruginosa  
8 and the vast majority of oral antibiotics are  
9 completely ineffective against this.

10 CO-CHAIR YAREMCHUK: Rich, we're  
11 talking 0653, so this is the topical prep -- I  
12 know, but this is the one that we are going to  
13 try to --

14 DR. ROSENFELD: I was told to introduce  
15 both --

16 CO-CHAIR YAREMCHUK: Okay.

17 DR. ROSENFELD: -- measures at the same  
18 time --

19 CO-CHAIR YAREMCHUK: All right.

20 DR. ROSENFELD: -- unless I'm doing  
21 something wrong.

22 CO-CHAIR YAREMCHUK: All right, and I



1 don't know which order that you wanted to do it.

2 DR. ROSENFELD: Okay.

3 CO-CHAIR YAREMCHUK: Okay.

4 DR. ROSENFELD: Well, does it matter  
5 which one goes first in the introduction? We'll  
6 do it on your schedule.

7 DR. WINKLER: We'll do it on the order,  
8 but your introduction can encompass both --

9 DR. ROSENFELD: Okay.

10 DR. WINKLER: -- to quickly get them  
11 into the picture.

12 DR. ROSENFELD: Sure, no, it'll be  
13 brief.

14 So, using an oral antibiotic to treat  
15 this not only doesn't work, it's actually a  
16 nocebo effect because it has lots of adverse  
17 events.

18 Roughly about 31 percent of providers  
19 seem to be doing this despite a prior guideline  
20 and the known lack of efficacy.

21 The second measure, or actually the  
22 first measure we'll speak about relates to

1 topical therapy for acute otitis externa which is  
2 supported by about 31 randomized control trials  
3 as well as several systematic reviews including a  
4 Cochrane review, all of which show very good  
5 efficacy.

6 About two-thirds to 90 percent of  
7 people, 95 percent of people are going to resolve  
8 in 7 to 10 days using these products. So, the  
9 measure encourages the use and promotes  
10 appropriate use by asking people if they are  
11 indeed using the topical preparation.

12 The topical preparations are not just  
13 antimicrobials, they can be antiinfectives in  
14 some cases, most commonly, acetic acid.

15 Even when it is an antibiotic, the  
16 risk of adverse events is extraordinarily low  
17 mainly because it's like dropping an atomic bomb  
18 on the bacteria it's so concentrated that there's  
19 really no resistance, similar to using ophthalmic  
20 topical preparations. It's that old saying that,  
21 I guess, dead bugs don't multiply. So, it's very  
22 effective.

1                   The profile of safety is  
2                   extraordinarily good and it tends to be  
3                   underused. We don't have exact data on this, but  
4                   there is clearly a gap here that people don't use  
5                   them or use systemic instead.

6                   So, that's the introduction. And  
7                   Kathy and Michael want to talk about the  
8                   evidence?

9                   CO-CHAIR YAREMCHUK: So, this was an  
10                  existing measure that was accepted and endorsed  
11                  in 2011 and so it's coming back again for  
12                  updating.

13                  There was a clinical practice  
14                  guideline that was issued by the American Academy  
15                  of Otolaryngology. So, there was a review 2014,  
16                  so the background and the history of this is  
17                  early, fresh and not outdated at this point in  
18                  time.

19                  And there was also a Cochrane  
20                  Collaborative review on this as well.

21                  So, there's been two systematic  
22                  reviews that endorse, and I'm going to talk about

1 the topical therapy measure first.

2 And so, once again, it's a process  
3 measure. It is something that can be gotten from  
4 administrative claims, administrative claims  
5 being that you have an office visit with an ICD-9  
6 or an ICD-10 code for otitis externa.

7 And then there is a pharmacy claim for  
8 topical therapy.

9 So, it is very a common problem. It  
10 tends to occur 50 percent more in the from 2  
11 years to 14 years of age, a little bit heavily  
12 weighted in terms of pediatrics.

13 At the same time, almost everybody in  
14 the room will have gotten one or has had one.  
15 Once again, it's the swimmer's ear diagnosis.  
16 So, good evidence for this.

17 CO-CHAIR MERENSTEIN: I think we stop  
18 at the evidence unless Michael has something to  
19 add about the evidence.

20 No? So, then we vote. Do we have to  
21 vote on the evidence?

22 DR. WINKLER: We first can see if

1 anyone else has questions or comments.

2 CO-CHAIR MERENSTEIN: Oh, anyone else  
3 have questions about the evidence? It's pretty  
4 straightforward, I mean. Comments? Questions?

5 DR. WINKLER: So, we'll give the voting  
6 thing a try. You get to play with your clickers.

7 So, in terms of voting, just to be  
8 sure, the evidence, you'll rate as either high,  
9 moderate or low, depending on how you evaluated  
10 the quality, quantity and consistency based on  
11 your discussions.

12 So, go to the next slide for evidence.  
13 Okay. Next one? It's not an outcome. Kaitlynn?  
14 Okay, there we go.

15 MS. ROBINSON-ECTOR: Yes, so if you can  
16 just point your clickers at me and -- yes.

17 So, voting for Measure 0653 is now  
18 open. Oh, yes, and for those on the phone,  
19 option one is high, two is moderate, three is low  
20 and four is insufficient.

21 And we're just waiting for the votes  
22 on the phone now.

1 I'm sorry, so if everyone in the room  
2 could point at me one more time and press their  
3 option, we're missing one.

4 Great, so all the votes are in and  
5 voting is now closed.

6 Eighty-seven percent voted high, 13  
7 percent voted moderate, zero voted low and zero  
8 voted insufficient.

9 So, for the criterion evidence, the  
10 Measure 0653 passes.

11 MEMBER STEIN: So, now we're going to  
12 go on to opportunity for improvement.

13 CO-CHAIR YAREMCHUK: I had mentioned  
14 from 2011, it is a PQRS measure, so an individual  
15 or a group can report.

16 And currently, from 2012, 83.9 percent  
17 of individuals that report the measure do  
18 systemic issues, they do topical antibiotics for  
19 otitis externa.

20 So, we're looking at that there is a  
21 gap of about 16 percent individuals in terms of  
22 reporting that. And so, 16 percent may not seem

1 like a huge opportunity but when you look at the  
2 volume of 2.4 million visits for this, clearly,  
3 there's an opportunity in terms of doing better.

4 CO-CHAIR MERENSTEIN: Michael, do you  
5 have anything to add?

6 MEMBER STEWART: No.

7 CO-CHAIR MERENSTEIN: Any questions  
8 about the improvement there?

9 There's a question. Rich?

10 DR. ROSENFELD: Since the PQRS is  
11 voluntary and it's probably primarily  
12 otolaryngologist, the actual gap is probably much  
13 higher than the 17 percent, although we don't  
14 know for sure.

15 CO-CHAIR MERENSTEIN: Can we open the  
16 voting?

17 MS. ROBINSON-ECTOR: Yes. So, voting  
18 for Measure 0653 is now open and voting will  
19 close when we reach 15 votes.

20 And for those on the phone, option one  
21 is high, two is moderate, three is low and four  
22 is insufficient.

1                   Okay, all the votes are in and voting  
2                   is now closed.

3                   Seventy-three percent voted high, 27  
4                   percent voted moderate, zero voted low and zero  
5                   voted insufficient.

6                   So, for the criterion performance gap,  
7                   the measure passes.

8                   CO-CHAIR MERENSTEIN: We're going to go  
9                   on to how reliable the testing is.

10                  CO-CHAIR YAREMCHUK: Okay. In terms of  
11                  reliability, once again, we're going back to  
12                  what's been reported so far with PQRS. And this  
13                  is based on CPT 2 Codes, ICD-9 Codes, so an  
14                  electronically administered data pull which I  
15                  think is reliable.

16                  When you look at reporting of the  
17                  people that have done this for PQRS, there's 11  
18                  percent of individual clinicians that have  
19                  complete data and the minimum number of patients.  
20                  Twenty-two percent of groups had complete data.

21                  I think this is something that, once  
22                  again, is good enough, adequate in terms of



1 reporting and important enough as being able to  
2 pull the data that it can move forward.

3 CO-CHAIR MERENSTEIN: Michael?

4 MEMBER STEWART: There's very little  
5 overlap in codes or any other issue here. This  
6 is a pretty straightforward diagnosis. The  
7 straightforward ICD-9 Codes, I think the data  
8 should be very reliable from electronic pulls.

9 CO-CHAIR MERENSTEIN: I just have a  
10 question of clarification.

11 So, you said it was not required to  
12 report this, so how does this get reported? I'm  
13 confused about that.

14 MS. TIERNEY: Yes, so, the PQRS program  
15 is a voluntary reporting program. Up until 2015  
16 it was an incentive-based program, so incentives  
17 were available for those who reported.

18 In 2015, it's moving into a penalty  
19 phase so, I imagine -- and we've seen actually  
20 the numbers of reporting providers has increased  
21 over time. So, I think in 2007, it was something  
22 around maybe 17 percent. Does that sound right?

1 And I know in 2013, there were 51 percent of  
2 eligible professionals who were reporting in the  
3 PQRS program.

4 But within the program, there are a  
5 number of measures, probably close to 300  
6 measures. And so, any individual physician or  
7 eligible professional can pick from among those  
8 measures to report.

9 So, these two AOE measures are just  
10 one of those, or two of those 300 that could be  
11 reported on.

12 So, it's really up to the physician or  
13 eligible professional to determine what patient  
14 population may typically treat and if these  
15 measures would fall into that and if they'd like  
16 to report on it.

17 So, it's very up to the individual  
18 eligible professional to determine what they  
19 would like to report on.

20 MEMBER FRIEDMAN: But just to be  
21 accurate, it's still voluntary. It's gone from -  
22 -

1 MS. TIERNEY: It's still voluntary,  
2 yes.

3 MEMBER FRIEDMAN: -- incentive to  
4 penal, but it's still voluntary.

5 MS. TIERNEY: Yes, absolutely, yes.  
6 Thank you.

7 CO-CHAIR MERENSTEIN: And it sounds  
8 like it's voluntary. You get to pick which one  
9 you're good at. You perform which one you're  
10 good at, right?

11 MS. TIERNEY: That's probably what  
12 people would do, yes.

13 CO-CHAIR YAREMCHUK: Well, and the only  
14 other thing to clarify, it really -- you don't  
15 get paid whether you have zero percent or a 100  
16 percent. You get paid for reporting.

17 MS. TIERNEY: Yes, absolutely.

18 CO-CHAIR MERENSTEIN: Andrew?

19 MEMBER SCHACHAT: Thank you.

20 I understand the ICD-9 Codes  
21 specifying the diagnosis. I don't understand how  
22 you know if a drug was prescribed from the

1 administrative claim status. If you could  
2 explain because I'm eager to look at the pharmacy  
3 plan data set. And then what about patients who  
4 don't have a pharmacy plan and are just getting a  
5 prescription?

6 MS. HANLEY: So, the data that our  
7 testing has come from is the PQRS data. So, this  
8 is data that gets reported on the claim. But the  
9 physician actually puts it's called a CPT 2 Code.  
10 There's a code that indicates the topical  
11 preparations were prescribed. So, that code gets  
12 added to the claim, gets into the process and  
13 that's what's analyzed.

14 MEMBER STEIN: This may be a naive  
15 question, but are some providers prescribing both  
16 topical and oral and how does that -- how do your  
17 measures deal with that?

18 DR. ROSENFELD: The answer is yes. I  
19 don't have an exact number but it's probably  
20 about a third who give both. And that's why we  
21 have two distinct measures, one relating strictly  
22 to the systemic antibiotic and a separate one

1 relating to the topical antibiotic -- topical  
2 preparation.

3 MEMBER STEIN: But if the goal is to  
4 get people to use the topical, why not just make  
5 one measure that gets to that?

6 DR. ROSENFELD: I think we could, but  
7 if -- I think the goal is twofold. It's not just  
8 to encourage topical, it's to strongly discourage  
9 systemic as well. And unless we have some way of  
10 monitoring the use of systemics, someone -- if we  
11 just add this measure, for example, the patients  
12 who are prescribed the topical, if the clinician  
13 gave both, the topical and a systemic, they would  
14 meet the measure, even though that's bad  
15 practice.

16 So, I think you do need the two  
17 separately to really drive down the use of the  
18 systemic and drive up the use of the topical.

19 MEMBER STEIN: So, systemic only is  
20 worse than nothing?

21 DR. ROSENFELD: Yes, it's essentially  
22 a placebo because the most systemic oral

1 medications are not going to cover Pseudomonas  
2 with rare exceptions, especially in the younger  
3 population. In adults, if they're given a  
4 quinolone, perhaps it would have some benefit,  
5 but for children, there are no FDA approved  
6 commonly available antibiotics that would cover  
7 Pseudomonas. So, it would almost certainly  
8 strictly be a nocado in that situation.

9 MEMBER GOLDBERG: I think he's  
10 concerned about exceptions as well. Can you  
11 elaborate on that?

12 DR. ROSENFELD: Can you be more  
13 specific with the question about exceptions?

14 MEMBER GOLDBERG: The exceptions for  
15 the use of systemic antibiotics for otitis  
16 externa?

17 DR. ROSENFELD: The clinical  
18 perspective, and I know our AMA colleagues can  
19 give more of the methodology, but there are  
20 exceptions that we specify both in the measure  
21 and the guideline, the main being that if the  
22 acute otitis externa spreads beyond the confines

1 of the ear canal to start creating the cellulitis  
2 of the skin of the external ear or even into the  
3 face or neck that that is a situation where a  
4 systemic antibiotic would be appropriate.

5 In very rare cases where you simply  
6 cannot get a topical medication into the ear  
7 because of debris that cannot be removed or  
8 because of edema that prevents access, a systemic  
9 drug could be necessary.

10 And in certain individuals with immune  
11 deficiency, diabetes or they're on chemotherapy,  
12 other conditions that make them more susceptible  
13 to rampant infections, we do acknowledge that a  
14 systemic drug would be indicated.

15 Do you want to add to that?

16 MS. TIERNEY: Yes, so to add to what  
17 Dr. Rosenfeld said, the measure is -- both  
18 measures were designed to be sensitive to various  
19 indications in which either topical therapy in  
20 this case would not be appropriate from a medical  
21 reason or a patient reason, patient refusal.

22 And then they also -- the other

1 measure just includes medical reasons in which  
2 you might want to prescribe systemic antibiotics.

3 So, the measures were designed to be  
4 sensitive to that. I will say they are designed  
5 in accordance with the exception methodology  
6 that's been developed by the AMA Physician  
7 Consortium for Performance Improvement.

8 And so, you've probably noted that the  
9 exceptions are broad in nature. So, there's  
10 three technical buckets that you could put  
11 patients in, medical reasons, patient reasons or  
12 system reasons.

13 And for any given measure, we would  
14 work with the expert workgroups to determine  
15 whether or not those might be appropriate for  
16 that individual measure.

17 So, in this case, for the topical  
18 preparations measure, we have medical reasons and  
19 patient reasons. And the reason we've done that  
20 approach is to allow for individual decision  
21 making appropriate to the needs of the individual  
22 patient and to allow for some clinical discretion



1 as appropriate for individual patients.

2 CO-CHAIR MERENSTEIN: Andrew and then  
3 Scott?

4 MEMBER SCHACHAT: Do you have to click  
5 a button that says I prescribed the topical to  
6 populate that CPT Code or do the electronic  
7 medical records know that if you wrote a  
8 prescription for it, it clicks that for you?  
9 Because otherwise, you'll under ascertain.

10 MS. HANLEY: So, this measure specified  
11 for claims reporting. So, it would actually  
12 require that the practice indicates on the claim  
13 that that was prescribed. So, it's --

14 MEMBER SCHACHAT: I wondering how  
15 automatic that is? Do I have to click the CPT  
16 Code as part of the visit or if I write a  
17 prescription, do electronic medical records sort  
18 of do that?

19 MS. HANLEY: The CPT Code would need to  
20 be reported. Individual practices may set up  
21 systems within their practices to help automate  
22 that.

1                   MEMBER SCHACHAT: The other side of it,  
2                   on the systemic measure looking to see that you  
3                   don't use the systemic medicine, if you prescribe  
4                   one, do you have to click a button that says you  
5                   prescribed it? If you don't click that button,  
6                   then you can get away with prescribing it and you  
7                   won't be scored as having given it. Right?

8                   MS. HANLEY: For the other measure,  
9                   what is calculated as meeting the measure is  
10                  whether or not it was not prescribed. So, again,  
11                  the presence of a prescription would indicate it  
12                  was prescribed and not meet the measure.

13                  MEMBER SCHACHAT: No, there was a  
14                  prescription for that one, okay, whereas you're  
15                  telling me it doesn't know if there's a  
16                  prescription for this one?

17                  DR. WINKLER: Let's not confound the  
18                  two measures. Let's stick to the topical right  
19                  now and then we'll talk about very good questions  
20                  that should be addressed.

21                  MEMBER FRIEDMAN: Yes, I guess Andy and  
22                  I think alike. So, again, you can prescribe

1 topicals and systemics and that's not best  
2 clinical practice and you report on topicals so  
3 you get rewarded for that but you don't ding  
4 for giving systemics. And how do you get around  
5 it?

6 MS. TIERNEY: So, the measures are  
7 intended to be reported together. They are  
8 paired and that's -- we've submitted them to NQF  
9 as paired measures.

10 And, in fact, for the PQRS program  
11 have indicated that they should be reported  
12 together because of that exact reason. We want  
13 to make sure that, you know, both measures  
14 together, as Dr. Rosenfeld explained --

15 MEMBER FRIEDMAN: So, how do you know?

16 MS. TIERNEY: I mean that's the  
17 intended --

18 MEMBER FRIEDMAN: You should, I agree,  
19 you should.

20 MS. TIERNEY: Yes.

21 MEMBER FRIEDMAN: But people are gaming  
22 -- people theoretically could be gaming the

1 system.

2 MS. TIERNEY: I mean I would say  
3 there's only so much you could do as a measure  
4 developer in terms of encouraging implementation  
5 to adhere to your intended use of the measure.

6 And so, we've certainly indicated that  
7 in the PQRS specifications and we've indicated  
8 that in the NQF submission. So, anyone pulling  
9 the measure off the NQF website would see that it  
10 is paired. The two measures are paired. So, we  
11 would ideally implement them together.

12 But I suppose it's possible that that  
13 might not happen. But that's not consistent with  
14 the intent or even the way they may be endorsed  
15 if they were to get endorsed here going forward.

16 MEMBER STEIN: Just to follow-up on  
17 Andy's point. I think that linking it to the  
18 actual prescription of the medication would be a  
19 lot stronger than checking off if someone did or  
20 did not do it using the indirect CPT Code.

21 CO-CHAIR MERENSTEIN: Can I just go  
22 back to the exclusions? It seems like you're

1       being a little too lenient.

2               If it spreads outside the ear, then  
3       you have a new diagnosis called cellulitis. And  
4       just because the patient wants it, I don't think  
5       that would qualify it. I mean it's clearly  
6       indicated, as Rich explained very well, there's  
7       no indication for oral antibiotics.

8               So, even if the patient wanted it, I  
9       don't think that should be a reason for exclusion  
10      for doing clearly the wrong thing.

11              MS. TIERNEY: So, our measure  
12      development workgroup agreed. So, for the second  
13      measure, there is only a medical reason  
14      exception. There's no patient reason exception.

15              So, a patient, even if you have a  
16      patient who asks for it, you would technically  
17      fail the measure because there's no way to  
18      account for that within the measure for the  
19      systemic antibiotic measure.

20              But, for this measure, there are  
21      medical reasons and patient reasons for why a  
22      patient -- yes, please, go ahead.

1 DR. ROSENFELD: So, just for the  
2 topical, for example, there are certain, you  
3 know, elderly populations that are going to be  
4 unable to, because of dexterity or, you know, the  
5 environment they're in, administer a topical  
6 preparation.

7 Some children just simply will not let  
8 their parents put something in their ear. You  
9 literally have to press them down with velcro and  
10 have two people hold the head.

11 So, I think the intent here is just  
12 that if there is some patient-based reason that  
13 there's no way you're going to get that topical  
14 in that we don't want to sort of ding the person  
15 because of that.

16 CO-CHAIR MERENSTEIN: I guess that  
17 makes sense, though you did say it was a placebo.  
18 So, if, you know, if they're doing oral, they're  
19 probably doing more harm than good.

20 MEMBER FRIEDMAN: Yes, I'm new to this  
21 process and haven't developed measures. But it  
22 seems to me best practices plus topical, no

1       systemic, can these measures be combined into one  
2       measure and it just seems that the best practice  
3       would be percentage of patients aged two and over  
4       with a diagnosis of AOE who prescribe topical  
5       preparations and not prescribe systemic  
6       medications.

7               DR. ROSENFELD: I mean, I suppose you  
8       could but it would reduce a lot the sensitivity  
9       because there are two distinct actions that are  
10      being requested.

11              The one action is do not prescribe the  
12      systemic unless there's some very, very good  
13      reason.

14              And the second is, prescribe or  
15      recommend the topical which are two separate  
16      acts.

17              If you put them both in one, I think  
18      you lose some sensitivity there as far as being  
19      able to -- and you also lose your ability to  
20      estimate the gaps and the prevalence of what's  
21      going on with the two separate actions.

22              So, I think they could be combined,

1 but there's a lot of distinct advantages for  
2 keeping them separate. Also, the level of  
3 evidence supporting each one is a little  
4 different and the gaps, in particular, I think  
5 are something that need to continue monitoring.

6 CO-CHAIR YAREMCHUK: There was the  
7 question about, you know, self-reporting the CPT  
8 Codes and, you know, whether it's oral or it's  
9 topical. In most electronic health records, when  
10 you do a prescription of some sort, it goes to a  
11 specific type of code that'll tell you exactly  
12 the antibiotic and it'll tell whether it's  
13 systemic or if it's topical.

14 And there was one form where we looked  
15 at we saw like a thousand different ICD-9s and  
16 CPTs and that kind of thing. And I'm going to  
17 guess that in the development of this, that will  
18 include the prescription itself.

19 DR. ROSENFELD: I also think that this  
20 would be picked with e-prescribe.

21 MS. HANLEY: So, for right now, to  
22 answer that question, as we've mentioned, the



1 method of reporting is reporting that CPT 2 Code.

2 I think looking to the future, as we  
3 think about electronic specifications to query  
4 this information automatically from electronic  
5 health records, that's when we would actually  
6 develop the list of the exact antibiotics and  
7 look for that code as it gets prescribed, et  
8 cetera to populate the information for the  
9 measure.

10 MEMBER BRADHAM: I'm still having some  
11 difficulties understanding the gap that you  
12 referenced about when -- if you combined it, what  
13 is the gap in the sensitivity?

14 DR. ROSENFELD: So, if we combine them,  
15 the only thing we could measure is if a person  
16 did not give the systemic and gave the topical,  
17 which I agree: We could measure proper care.  
18 We'd have an excellent measure of proper care.

19 We would have a very lousy measure of  
20 poor care because we would not be able to  
21 separate out the use of the systemic antibiotics  
22 as a separate factor from the use of the

1       topicals.

2                   So, it's just logistically, the two  
3       separate actions and from a logistic standpoint  
4       with the coding, with the specifications, with  
5       even the rationale and, more appropriately, the  
6       exceptions become extraordinarily difficult to  
7       conceive because the exceptions are very  
8       different for both of the actions.

9                   So, yes, you can measure proper care,  
10      but I think you'd be giving up a lot in the  
11      ability to measure gaps to focus on the  
12      individual things and to have really meaningful  
13      exceptions that make sense.

14                  MS. TIERNEY: If I could also just add  
15      to what Dr. Rosenfeld said, I think when you  
16      think about the, you know, the purpose of  
17      measurement being to drive quality improvement,  
18      if you combine them into one, that certainly  
19      would -- it would be more difficult to identify,  
20      perhaps, which individual action you might need  
21      to improve upon.

22                  And so, I think from a quality

1 improvement standpoint, it's better to have them  
2 separated out as separate measures.

3 And I will say, you know, we developed  
4 a number of measures over the past ten years of  
5 our existence and there's been a lot of -- we  
6 have a couple of measures where we've sort of  
7 combined things. And so, the feedback that we  
8 get on some of those measures is that it's very  
9 challenging from a quality improvement standpoint  
10 to know where the quality gap is.

11 And so, I think combining the measures  
12 has a lot of benefits, both from a clinical  
13 standpoint, but also from a quality improvement  
14 standpoint -- of not combining the measures,  
15 sorry.

16 MEMBER FRIEDMAN: I think we should  
17 vote no. We've had a lot of discussion.

18 CO-CHAIR MERENSTEIN: Any other  
19 questions?

20 MS. ROBINSON-ECTOR: Okay, so voting  
21 for reliability for Measure 0653 is now open and  
22 voting will close when we reach 15 votes.

1                   And for those on the phone, option one  
2                   is high, two is moderate, three is low and four  
3                   is insufficient.

4                   MEMBER STEWART: I'm sorry, I should  
5                   have asked this a second ago.

6                   It's absolutely true the concern that,  
7                   in fact, people can game, you know, by saying  
8                   they did when they actually did something  
9                   different.

10                  But, if we're going to use that as a  
11                  criteria for how reliable -- I mean, are we  
12                  supposed to use that as a measure of reliability  
13                  or are we supposed to assume that people are  
14                  honestly reporting and then we're just trying to  
15                  figure out if the reporting will tell us what the  
16                  proportion of good practice is?

17                  Because I think if we take that into  
18                  account, there's a lot of measures we're going to  
19                  say, well, you know, people could manipulate and  
20                  lie and add codes. I mean, that's always  
21                  possible. I think we have to assume that's not  
22                  happening.

1                   Or are we supposed to take the  
2 gameability into our evaluation?

3                   DR. WINKLER: You know, the gameability  
4 aspect of it comes up a lot but, at the same  
5 time, I think you can't ignore it but I don't  
6 think it should be your overwhelming factor in  
7 considering, you know, the utility of these  
8 measures. We can't control what ultimately may  
9 happen out there in the world.

10                  But it doesn't mean you shouldn't  
11 bring up it when you think it's appropriate but I  
12 don't think it should overwhelm everything else.

13                  MEMBER BRADHAM: This is Tammy. Just  
14 for clarification purposes, you mentioned that  
15 this is a paired. So, does that mean that out of  
16 the 30, they have to select both of these or can  
17 they just select one of these and then select  
18 another item on the PQRS?

19                  DR. WINKLER: Right. The issue of how  
20 PQRS implements, it is distinct from how we may  
21 look at it here. So, the developers have  
22 submitted them as paired and we will consider

1       them in paired.

2                   And what that means is our expectation  
3       is that they would be used together. That's  
4       doesn't mean we have any control over what truly  
5       happens down the road and out in the field. But  
6       that's the directive we would like to see happen.

7                   MS. HANLEY: If I could just add one  
8       thing, especially for the measures that are  
9       reported via claims. Reporting misinformation on  
10      a claim is considered fraud and so that's also  
11      just an underlying incentive to report what you  
12      do and not report something that you haven't  
13      done.

14                  CO-CHAIR MERENSTEIN: Continue voting  
15      please?

16                  MS. ROBINSON-ECTOR: And voting is  
17      still open.

18                  And for those on the phone, option one  
19      is high, two is moderate, three is low and four  
20      is insufficient.

21                  Okay, so all the votes are in and  
22      voting is now closed.

1                   Thirty-three percent voted high, 53  
2                   percent voted moderate, 13 percent voted low and  
3                   zero percent voted insufficient.

4                   So, for the criterion reliability, the  
5                   measure passes.

6                   CO-CHAIR MERENSTEIN: We're going to go  
7                   on to validity.

8                   CO-CHAIR YAREMCHUK: What did we just  
9                   vote on? Okay, all right.

10                  So, validity testing, this has been  
11                  something that's been in use previously in terms  
12                  of the PQRSs that we discussed and has been  
13                  reported. So, we know that it's able to do so.

14                  And it's been in PQRS since 2009, so  
15                  it's been in effect for a while.

16                  It is electronic. It does have the  
17                  ability to evaluate the care that's being  
18                  delivered and that the specifications are fairly  
19                  straightforward.

20                  DR. WINKLER: One thing I just was to  
21                  point out in terms of thinking about validity is  
22                  that the areas around potential threats to

1 validity.

2 And I just wanted to point out some of  
3 the data that was provided around the frequency  
4 of exclusions and how frequently they are being  
5 used, that was a topic you brought up. So, I  
6 just wanted to point out that they did provide  
7 data from PQRS and PQRS GPRO. And where the  
8 overall exception rate for PQRS was about 5.7  
9 percent of reported cases.

10 CO-CHAIR YAREMCHUK: And that was for  
11 individual reporting and for group reporting, it  
12 was a little bit higher?

13 DR. WINKLER: Right, 11 percent.

14 CO-CHAIR YAREMCHUK: And there was a  
15 huge variation which is what we see in  
16 everything. So, for individual, it went from 0  
17 percent to 51 percent for exclusions and for  
18 groups it went from 79 percent to 0 percent.

19 So, as in anything, there's huge  
20 variation in terms of the person that's reporting  
21 in terms of exclusion.

22 DR. WINKLER: The other potential thing



1 to think about under validity is how the results  
2 spread and can this be used to make  
3 differentiation? Are there meaningful  
4 differences of the results?

5 And so, some data was provided to you  
6 on sort of the range and the means and this  
7 distribution of the results so you can see how  
8 well this measure may act as a tool for  
9 identifying differences among providers.

10 CO-CHAIR MERENSTEIN: Michael, anything  
11 to add? Any questions about this? We addressed  
12 some of this already.

13 No questions? We'll vote.

14 MS. ROBINSON-ECTOR: Okay. So voting  
15 for validity for Measure 0653 is now open and  
16 voting will close when we reach 15 people.

17 And for those on the phone, option one  
18 is high, two is moderate, three is low and four  
19 is insufficient.

20 And it looks like we're missing one  
21 vote so if everyone in the room could revote  
22 please? It looks like we're still missing

1 someone. Okay, great, thank you.

2 All the votes are in and voting is now  
3 closed.

4 Forty-seven percent voted high, 53  
5 percent voted moderate, zero voted low, zero  
6 voted insufficient.

7 So, for the criterion validity, the  
8 measure passes.

9 CO-CHAIR MERENSTEIN: So, Kathy,  
10 feasibility?

11 CO-CHAIR YAREMCHUK: Okay. And I think  
12 we touched on this before. It can be reported  
13 from EMR as electronic submission, CPT 2 Codes,  
14 ICD-9.

15 And this is a question to the measure  
16 developers. If an individual wants to do a paper  
17 review, can they still submit it that way?

18 MS. HANLEY: For reporting in PQRS, no,  
19 that's not an option for reporting. But they  
20 could certainly use the specifications for  
21 internal quality improvement within their  
22 practice. I mean there's nothing preventing them

1 from doing that.

2 CO-CHAIR YAREMCHUK: Okay. In terms of  
3 feasibility, once again, I think it's something  
4 that would be high in terms of feasibility.

5 CO-CHAIR MERENSTEIN: Michael? Michael  
6 agrees.

7 Any questions about that? Yes, we  
8 talked a lot about this. We can vote on it.

9 MS. ROBINSON-ECTOR: So, voting for  
10 feasibility for Measure 0653 is now open and  
11 voting will close when we reach 15 votes.

12 It looks like we have all the votes in  
13 the room. Oh, yes, and for those on the phone,  
14 option one is high, two is moderate, three is low  
15 and four is insufficient.

16 CO-CHAIR MERENSTEIN: We still need one  
17 vote.

18 MS. ROBINSON-ECTOR: So, all the votes  
19 are in and voting is now closed.

20 Eighty percent voted high, 20 percent  
21 voted moderate, zero voted low and zero voted  
22 insufficient.

1                   So, for the criterion feasibility, the  
2                   measure passes.

3                   CO-CHAIR MERENSTEIN: So, for the last  
4                   criteria, usability?

5                   CO-CHAIR YAREMCHUK: It should improve  
6                   treatment, quality of care and prevent  
7                   overutilization, appropriate utilization of  
8                   antibiotics.

9                   CO-CHAIR MERENSTEIN: Michael?   Michael  
10                  agrees.

11                  DR. WINKLER: Yes, for usability and  
12                  use, particularly measures that have been  
13                  endorsed for a while, we really want to think  
14                  about, you know, how they've been used and what  
15                  the information has been used for.

16                  Potentially, you know, what's been the  
17                  impact of this measure?   Have we really seen  
18                  opportunity, you know, seen improvement in the  
19                  quality care provided?   Have we seen improving  
20                  trends?   I mean is this a good tool for  
21                  stimulating quality improvement?   That's what  
22                  we're thinking about in terms of usability and

1 use.

2 CO-CHAIR MERENSTEIN: So, Richard, do  
3 you have anything to add with that?

4 DR. ROSENFELD: So, I agree, it's a  
5 noble aspiration. We do not have enough data  
6 over time to I think assess that. But, we're  
7 very hopeful.

8 CO-CHAIR MERENSTEIN: You said before  
9 it's what, 67 percent of people use topicals?

10 DR. ROSENFELD: I think in the PQRS it  
11 was in the 80s. It was high.

12 DR. WINKLER: Right, if we look at 2009  
13 for the performance gap, 2009 it was 72 percent,  
14 2012, it's 83. So, it's been getting use.

15 DR. ROSENFELD: I take it back, it's  
16 very usable.

17 DR. WILSON: I mean the issue is  
18 voluntary reporting. But, the voluntary  
19 reporters reported significant improvement over  
20 time.

21 MEMBER STEIN: Can you guys comment on  
22 the types of providers that are using this code?

1 Is it ENT specialists? Primary care docs?

2 MS. TIERNEY: We don't know. The PQRS  
3 program provides information about the number of  
4 eligible professionals. And so for this measure,  
5 it was around 85,000 eligible professionals. Of  
6 those, 3,200 reported on the measure.

7 So we can guess, but the number of  
8 eligible professionals, you can sort of speculate  
9 that the number of eligible professionals  
10 includes some primary care physicians.

11 But more than likely, given how small  
12 the number gets that probably it's primarily  
13 specialists and otolaryngologists who use -- who  
14 actually report on the measure.

15 But we don't know for sure and the  
16 PQRS program doesn't provide us with that level  
17 of detail related to those who report on the  
18 measure.

19 MEMBER STEWART: And practically,  
20 there's not a lot of otolaryngology measures to  
21 select. There's not a large menu is PQRS.  
22 There's probably a larger menu of PQRS options

1 for people in primary care.

2 So, I mean the reality is a lot of  
3 otolaryngologists are reporting because there's  
4 not a lot measures. That would be another bit of  
5 assumption that would probably indicate it's  
6 heavily otolaryngology.

7 MEMBER STEIN: And the people that are  
8 prescribing the oral antibiotics, are they mostly  
9 primary care docs or are they -- like, is  
10 everyone in ENT know to do things the right way  
11 and the ones that are not doing it right, people  
12 that are not ENT specialists or even within ENT  
13 there's a lot of misuse of oral antibiotics?

14 DR. ROSENFELD: I think the data,  
15 again, are pretty sparse. There is a UK study  
16 that looked at primary care docs and found in the  
17 30, 35 percent range with prescribing. But I'm  
18 not aware specifically of usable information on  
19 otolaryngologists versus emergency physicians and  
20 other folks who may see swimmer's ear with some  
21 frequency. So, the answer is we really don't  
22 know.

1 MS. TIERNEY: Can I just add, I mean I  
2 think it's important, although we don't really  
3 know what type of specialties are reporting in  
4 PQRS, there's still a gap of those who are  
5 voluntary reporting. There's a noted gap related  
6 to the actual use of topical preparations.

7 So, I think that's important even  
8 though we don't necessarily know how that is.  
9 And maybe it is more otolaryngologists but it's  
10 still important, I think, to emphasize that  
11 there's still a gap among those voluntary  
12 reporting in this program.

13 CO-CHAIR MERENSTEIN: Any further  
14 questions before we vote?

15 Okay, let's open voting.

16 MS. ROBINSON-ECTOR: So voting is now  
17 open for usability for Measure 0653 and voting  
18 will close when we have 15 votes.

19 And for those on the phone, option one  
20 is high, two is moderate, three is low and four  
21 is insufficient information.

22 It looks like we have all the votes in



1 the room.

2 Vaishali, I didn't get your vote yet,  
3 so if you want to email me the vote, thanks.

4 MEMBER PATEL: Yes.

5 MS. ROBINSON-ECTOR: Thank you.

6 All the votes are in and voting is now  
7 closed.

8 Okay, 60 percent voted high, 40 voted  
9 moderate, zero voted low and zero voted  
10 insufficient.

11 Okay, so it passes.

12 CO-CHAIR MERENSTEIN: So, I think we  
13 just do one more final vote about suitability.  
14 Is there a discussion before that? Anyone have  
15 any final questions about this?

16 So, it's just a yes or a no. I guess  
17 we can vote.

18 MS. ROBINSON-ECTOR: Okay, so voting  
19 for overall suitability for endorsement for  
20 Measure 0653, acute otitis externa is now open.

21 And for those on the phone, option one  
22 is yes and option two is no.

1 MS. LUONG: And this is for overall  
2 suitability for endorsement for those on the  
3 phone.

4 MS. ROBINSON-ECTOR: Great, so all the  
5 votes are in and voting is now closed.

6 One hundred percent voted yes and zero  
7 voted no, so for recommendation for overall  
8 suitability for endorsement for Measure 0653,  
9 acute otitis externa passes.

10 CO-CHAIR MERENSTEIN: So, unless there  
11 is any further comments, we'll take a five to ten  
12 minute break and then come back and finish a  
13 couple up before lunch.

14 (Whereupon, the above-entitled matter  
15 went off the record at 10:31 a.m. and resumed at  
16 10:44 a.m.)

17 DR. WINKLER: We had a question that  
18 may have provided some context in terms of the  
19 endorsement process.

20 NQF grants endorsement for three years  
21 and we try to review these measures on that sort  
22 of periodic basis. However, we do solicit annual

1 updates from the measure developers on all the  
2 measures to identify any updates of measures that  
3 may occur.

4 If there are material changes to those  
5 measures, it could prompt an earlier ad hoc  
6 review. And also, anybody could request NQF do  
7 an ad hoc review for a measure.

8 There have been some controversial  
9 measures. There's been new evidence come out.  
10 There's been unintended consequences out in the  
11 field. Those are the types of things that have  
12 typically prompt ad hoc reviews. So, that can be  
13 done in the intervening between the regularly  
14 scheduled review that could occur.

15 Again, as a Standing Committee, you  
16 would be available to do those ad hoc reviews if  
17 they come up.

18 So, that's kind of the implications of  
19 the endorsement. Measures that have been  
20 endorsed that you would say do not recommend for  
21 continued endorsement fall off our list. You  
22 know, how that plays out in the field with people

1 using them will be highly variable.

2 Oftentimes measures that are imbedded  
3 in programs sort of, it takes a bit of mechanics  
4 to get them out, if you will. But, nonetheless,  
5 the message is clear.

6 And when you do that, we really want  
7 to document the reasons why that we made that  
8 change and removed the endorsement status.

9 So, I know, Josh, you were the one  
10 with the question. Did I respond to your  
11 queries?

12 MEMBER STEIN: Yes.

13 DR. WINKLER: Okay.

14 CO-CHAIR MERENSTEIN: I was going to go  
15 right into the next discussion with Seth and  
16 Michael.

17 MEMBER GOLDBERG: Dr. Rosenfeld had  
18 already introduced this measures, acute otitis  
19 externa systemic antimicrobial therapy and  
20 avoidance of inappropriate use.

21 This is, again, a process measure and  
22 the numerator statement, the patients who were

1 not prescribed systemic antimicrobial therapy and  
2 the denominator was all patients two years and  
3 older with the diagnosis of acute otitis externa.

4 There was extensive literature showing  
5 the lack of evidence of efficacy of systemic  
6 antibiotics both from the Academy of Clinical  
7 Practice Guideline as well as the 2010 Cochrane  
8 Collaborative Review.

9 And so, you know, based on this, and  
10 we have two systematic reviews and we have ICD-9  
11 and CPT Codes and, again, pharmacy claims that  
12 would allow documentation.

13 Plus, we have measurement of  
14 performance with continued improvement shown in  
15 PQRS program between 2009 and 2012 with an  
16 improvement in the measure from 45 percent in  
17 2009 to 74 percent in 2012.

18 But there is still a gap in care,  
19 obviously, and as we have discussed previously,  
20 we're not quite sure which physicians are being  
21 measured. It appeared primarily the  
22 otolaryngologists and so --

1 CO-CHAIR MERENSTEIN: Seth, sorry to  
2 interrupt. We're going to vote on the evidence  
3 before we get into gap in care.

4 MEMBER GOLDBERG: Oh, okay.

5 CO-CHAIR MERENSTEIN: Sorry about that.

6 MEMBER GOLDBERG: Sorry.

7 CO-CHAIR MERENSTEIN: Michael? Do you  
8 have anything to add?

9 So, any questions about the evidence  
10 behind the measure?

11 Then we can vote.

12 MS. ROBINSON-ECTOR: Okay. So, voting  
13 for evidence is now open.

14 And for those on the phone, option one  
15 is high, option two is moderate, option three is  
16 low and option four is insufficient evidence.

17 So, it looks like we're missing one  
18 vote, so if everyone in the room could please  
19 revote?

20 Great, all the votes are in and voting  
21 is now closed.

22 Ninety-three percent voted high, seven

1 voted moderate, zero voted low and zero voted  
2 insufficient.

3 So, for the criterion evidence, the  
4 measure passes.

5 CO-CHAIR MERENSTEIN: Thank you.

6 Seth, we can now talk about the  
7 opportunity for -

8 MEMBER GOLDBERG: Okay, again, as we  
9 discussed for the previous measure, there is a  
10 performance gap. It's still significant.

11 The most recent reported performance  
12 result is in 2012 with 74 percent in compliance.  
13 There is a gain indicating that this has been  
14 effective but we are uncertain outside of those  
15 reporting physicians who is actually using this  
16 measure.

17 And so, based on the information we  
18 have, there still is room for improvement,  
19 especially based on the frequency of the  
20 condition.

21 CO-CHAIR MERENSTEIN: Michael?

22 Anything to add about that?

1                   Any questions about that? Again,  
2 we've talked a little bit about this already, but  
3 any questions?

4                   So, let's go to voting.

5                   MS. ROBINSON-ECTOR: Voting for  
6 performance gap is now open and we will close  
7 votes when we have 15 votes.

8                   And for those on the phone, option one  
9 is high, two is moderate, three is low and four  
10 is insufficient.

11                  So, all the votes are in and voting is  
12 now closed.

13                  Eighty-seven percent voted high, 13  
14 percent voted moderate, zero voted low and zero  
15 voted insufficient.

16                  So, for Measure 0654, the measure  
17 passes on criterion performance gap.

18                  CO-CHAIR MERENSTEIN: Thank you.

19                  Now, we're going to talk about the  
20 reliability of the test.

21                  MEMBER GOLDBERG: Okay. Again, we  
22 talked about reliability of the previous measure.



1 And, again, this is based on claims of the  
2 registry. The numerator is CPT 2 Code, the  
3 denominator is ICD-9 and 10 and CPT Codes.

4 We do have exclusions, exemptions.  
5 They are specified as an insufficiency, giving  
6 examples of insufficiency in diabetes.

7 The method of testing and testing  
8 results, I believe, demonstrate that this is  
9 reliable.

10 CO-CHAIR MERENSTEIN: Michael, anything  
11 to add?

12 Tammy, do you have a question?

13 MEMBER BRADHAM: I have two questions.

14 The first -- well, I think you already  
15 answered one of them, I'm sorry.

16 I have a second question. In the  
17 exclusions, does it include people with hearing  
18 aids?

19 MS. TIERNEY: So, this is Sam. So, the  
20 exclusions or the exceptions, as we call them,  
21 are broad. So, you would just put down a medical  
22 reason in something like a hearing aid if that

1 was an appropriate reason, you could put that  
2 down and that would be a reason that you might  
3 prescribe systemic antimicrobials.

4 DR. ROSENFELD: From a medical  
5 standpoint, I'm not sure that would be a valid  
6 reason unless they were so dependent on the  
7 hearing aid they couldn't function and there was  
8 a little concern about the liquid getting into  
9 the aid.

10 But, just the presence of an object in  
11 the ear canal, I think usually with acute otitis  
12 externa, it's so painful you couldn't put your  
13 hearing aid in and they probably would be fine  
14 with topical.

15 So, it's a potential exception, but  
16 probably not a particularly common one I would  
17 expect.

18 MEMBER LYNCH: I would agree with that.  
19 This is Judith.

20 CO-CHAIR MERENSTEIN: Andrew?

21 MEMBER SCHACHAT: So, this is my  
22 leftover question from the last one.

1                   Is there a CPT Code that says I didn't  
2 prescribe systemic antibiotics?

3                   MS. HANLEY: Yes, there is.

4                   MEMBER SCHACHAT: So, it's extra work?  
5 You have to click and score another thing on the  
6 medical record, so you could easily under  
7 ascertain not prescribing the antibiotics?

8                   CO-CHAIR MERENSTEIN: Yes, and I think  
9 Rich agrees with that, right? You think that  
10 probably it's probably higher than we're actually  
11 recording, I think that's what you said  
12 previously.

13                  MEMBER LYNCH: So, you're saying that  
14 I would have to click that I did not order a  
15 systemic antibiotic in order to meet the  
16 criteria?

17                  MS. HANLEY: You would enter a code on  
18 your claim indicating you did not prescribe an  
19 antibiotic for this patient.

20                  MEMBER LYNCH: Even though I ordered a  
21 topical?

22                  MS. HANLEY: Yes, because these are

1 reported separately.

2 MEMBER LYNCH: Okay.

3 MEMBER GOLDBERG: Couldn't this be  
4 picked up passively by the absence of a  
5 prescription or pharmacy report or e-  
6 prescription?

7 MS. HANLEY: So, that question, again,  
8 gets to the implementation of the measure and the  
9 implementation that we've used to test the  
10 measure has been the PQRS program.

11 And the way Medicare is designed, that  
12 program is you actually have to actively report a  
13 code.

14 But, again, a health system practice,  
15 they could design their own systems that would  
16 more in an automated way collect the information  
17 for the measure.

18 CO-CHAIR MERENSTEIN: Any further  
19 questions or comments?

20 So, I guess we'll vote on the  
21 reliability.

22 MS. ROBINSON-ECTOR: So, voting for

1 reliability for Measure 0654 is now open and will  
2 be closed when we reach 15 votes.

3 And for those on the phone, option one  
4 is high, option two is moderate, option three is  
5 low and four is insufficient.

6 Okay, all the votes are in and voting  
7 is now closed.

8 Thirty-three percent voted high, 47  
9 percent voted moderate, 20 percent voted low and  
10 zero voted insufficient.

11 So, for the criterion reliability for  
12 Measure 0654, the measure passes.

13 CO-CHAIR MERENSTEIN: Seth, validity,  
14 please?

15 MEMBER GOLDBERG: Okay. In terms of  
16 validity, it does appear the specifications align  
17 with the evidence.

18 The measure was tested for face  
19 validity. And in terms of meaningful difference,  
20 the range in performance was quite high and  
21 consistent and it does identify meaningful  
22 differences about quality.

1 CO-CHAIR MERENSTEIN: Michael, do you  
2 have anything to add?

3 MEMBER STEWART: Nothing to add.

4 CO-CHAIR MERENSTEIN: Thanks.

5 Just as a general, when we're  
6 speaking, try to speak closer because they can't  
7 hear us back there, guys.

8 Any questions about that? Again, we  
9 talked a lot about this.

10 Let's vote.

11 MS. ROBINSON-ECTOR: Thanks. So,  
12 voting for validity for Measure 0654 is now open.

13 And for those on the phone, option one  
14 is high, option two is moderate, option three is  
15 low and option four is insufficient.

16 It looks like we have all the votes in  
17 the room. All the votes are in and voting is now  
18 closed.

19 Forty percent voted high, 60 percent  
20 voted moderate, zero voted low and zero voted  
21 insufficient.

22 So, for the criterion validity for

1 Measure 0654, the measure passes.

2 CO-CHAIR MERENSTEIN: Feasibility

3 please?

4 MEMBER GOLDBERG: Okay, we talked about

5 this previously. The data elements are defined

6 in elected fields in electronic claims and the

7 measure has been in use by PQRS since 2009.

8 MEMBER STEWART: Agree this is

9 feasible.

10 CO-CHAIR MERENSTEIN: Any questions

11 about that?

12 MS. ROBINSON-ECTOR: So, voting is now

13 open for the criterion feasibility for Measure

14 0654.

15 And for those on the phone, option one

16 is high, option two is moderate, three is low and

17 four is insufficient.

18 So, it looks like we're missing one

19 vote in the room. If everyone could please

20 revote. Thank you.

21 Great. Okay, all the votes are in and

22 voting is now closed.

1                   Sixty-seven voted high, 20 percent  
2                   voted moderate, 13 percent voted low and zero  
3                   voted insufficient.

4                   So for the criterion feasibility,  
5                   Measure 0654 passes.

6                   CO-CHAIR MERENSTEIN: Usability please?

7                   MEMBER GOLDBERG: The measure is  
8                   currently in use in the PQRS program which is  
9                   publically reported. And there is published  
10                  information that there has been improvement over  
11                  time. There doesn't appear to be any unintended  
12                  consequences with the measure.

13                  CO-CHAIR MERENSTEIN: Michael, anything  
14                  to add?

15                  MEMBER STEWART: Nothing to add.

16                  CO-CHAIR MERENSTEIN: Kathy?

17                  CO-CHAIR YAREMCHUK: I mean the only  
18                  correction, it's not publically reported. You  
19                  can submit the information and you can comply  
20                  with PQRS standards, but it isn't publically  
21                  reported.

22                  MS. HANLEY: If I could just add, I



1 would say yes. CMS is transitioning to starting  
2 to publically report some of the results on some  
3 of the measures.

4 CO-CHAIR MERENSTEIN: Any questions  
5 about that? I see people voting, so I guess not.

6 MS. ROBINSON-ECTOR: So, voting is open  
7 for usability for Measure 0654.

8 And for those on the phone, option one  
9 is high, two is moderate, three is low and four  
10 is insufficient information.

11 Okay, all the votes are in and voting  
12 is now closed.

13 Seventy-three percent voted high, 27  
14 percent voted moderate, zero voted low and zero  
15 voted insufficient information.

16 So, for the criterion usability and  
17 use, Measure 0654 passes.

18 CO-CHAIR MERENSTEIN: We need a vote  
19 for overall suitability.

20 MS. ROBINSON-ECTOR: Okay, so voting is  
21 now open for overall suitability for endorsement  
22 for Measure 0654, acute otitis externa systemic

1 antimicrobial therapy.

2 For those on the phone, option one is  
3 high and option two is no.

4 CO-CHAIR MERENSTEIN: Yes and no.

5 MS. ROBINSON-ECTOR: Oh, sorry. Yes,  
6 option two is no and option one is yes.

7 MS. LUONG: Vaishali, if you can vote  
8 via email please? Thanks

9 MEMBER PATEL: Yes, I just did.

10 MS. LUONG: Okay, great. Thanks.

11 MS. ROBINSON-ECTOR: All the votes are  
12 in and voting is now closed.

13 Ninety-three percent voted yes and  
14 seven percent voted no. So, for recommendation  
15 for overall suitability for endorsement, Measure  
16 0654 passes.

17 CO-CHAIR MERENSTEIN: Okay, so we're  
18 going to go on to the next one on otitis media  
19 with effusion. So, if you want to pull it up and  
20 with the same developers.

21 Other people coming up? Thank you for  
22 your time.

1 DR. ROSENFELD: Okay, so I'll introduce  
2 all three of these at once, is that the plan?

3 CO-CHAIR MERENSTEIN: Great plan.

4 DR. ROSENFELD: Okay, good.

5 So, now we shift -- we'll stay on the  
6 ear but we switch to kids and talk about otitis  
7 media with effusion called also middle ear fluid  
8 in lay terms.

9 And this is defined as the presence of  
10 some fluid in the middle ear space without any  
11 signs or symptoms of acute ear infection.

12 And this is essentially an  
13 occupational hazard of early childhood. If you  
14 occupy early childhood, you get middle ear fluid  
15 at some point. Between 50 and 90 percent of  
16 children will get this by the time they enter  
17 school.

18 The period prevalence over a year, so  
19 if you look over a year, 15 to 30 percent of  
20 young children get it. And there are studies  
21 that have tracked individual children and found  
22 that young children on average will get four

1 distinct episodes per year.

2 And if you follow them over several  
3 years, they spend about 25 percent of their days,  
4 have some degree of middle ear fluid. So, this  
5 is fairly ubiquitous in your children.

6 The symptoms can be subtle and, at  
7 times, may be almost completely absent. The most  
8 common one would be hearing loss that can impact  
9 speech and language development and school  
10 functioning and school performance.

11 Other symptoms could be as subtle as  
12 a lack of feeding properly or sleep disturbance,  
13 irritability, behavioral changes, some have ear  
14 pain but it definitely does affect them in many  
15 different ways.

16 The vestibular problems are also seen  
17 with this where kids are quite clumsy and have  
18 gross motor issues at a young age.

19 We don't know exactly how many  
20 episodes there are but it's been estimated on  
21 some pretty old data that there's about 2.2  
22 million episodes a year in the U.S. Those are

1 strictly new episodes. But a lot of these can be  
2 very persistent as well.

3 The three measures that are proposed  
4 are all very similar. They're all overuse  
5 measures and they all deal with various types of  
6 medical therapy, all of which recommend not to do  
7 it.

8 So, there are two, one for  
9 antibiotics, systemic antibiotics that says the  
10 physician should not prescribe it.

11 There's another on systemic steroids  
12 that also says the physician should not prescribe  
13 it.

14 And then there's one on antihistamines  
15 which says that, but also extends it to say that  
16 the physician should also not recommend  
17 anticipating the over-the-counter use of such  
18 products that extends beyond prescribing.

19 So they're all three process measures.  
20 We could potentially consider the one that says  
21 do not recommend is also falling into the  
22 communication category of quality improvements.

1 I'll just very briefly go over some of  
2 the data and gaps which we'll talk about more  
3 thoroughly with each measure.

4 We don't have the robust data that we  
5 had or somewhat robust data we had for the otitis  
6 externa measures because these have not been used  
7 and practiced to a significant extent. They're  
8 not PQRS. So, we have some limited data on the  
9 issues.

10 The antibiotics first, and the data  
11 that we do have, I will say are unpublished but  
12 fairly robust. They come to us from an  
13 individual, Jennifer Shin, who's an  
14 otolaryngologist at Harvard and has been working  
15 very fortuitously on the past several months  
16 looking at some big national databases to monitor  
17 usage of medications for otitis media with  
18 effusion.

19 This was motivated by the new clinical  
20 practice guideline that we're about to publish in  
21 the next few months that updates the 204  
22 guideline on this.

1                   So, those databases covered millions  
2 of pediatric visits in the U.S. and had about a  
3 114,000 otitis media with effusion visits in  
4 them. So, it's a fairly significant data set.

5                   For antibiotics, they found that about  
6 32 percent of encounters resulted in antibiotic  
7 prescribing even though it's not recommended to  
8 be used for that purpose.

9                   And, obviously, there are rather  
10 significant side effects and adverse effects of  
11 antibiotics ranging from individual issues,  
12 allergic reactions to the societal implications,  
13 the resistance.

14                  For antihistamines, her work showed a  
15 9.5 percent use of these products during otitis  
16 media with effusion visits. And, interestingly  
17 enough, and that includes -- this includes both  
18 over-the-counter as well as prescriptions, and  
19 about 60 percent of that 9.5 percent was related  
20 to the old first generation sedating  
21 antihistamines which actually do have some rather  
22 substantive side effects in children especially

1 since dosing is not always optimal in young kids.

2 The other 40 percent were more of the  
3 non-sedating antihistamines that typically  
4 require prescriptions.

5 And the last category of systemic  
6 steroid use is fairly low. That was 3.2 percent  
7 of otitis media with effusion visits in her  
8 analysis.

9 And those data, and actually, all of  
10 these data, unfortunately, do not break down  
11 individual prescribers. They're just an average  
12 of all the visits.

13 So, it's quite possible, and I would  
14 say very likely, that there are pockets of  
15 individual providers or group practices where  
16 there's very high prescribing.

17 So, for steroids, perhaps, 10, 20  
18 percent of visits are getting this. Whereas, in  
19 many other practices, it's very low or close to  
20 zero.

21 So, there are probably outliers here  
22 but we just cannot identify them from this data



1 set. But anecdotally, it does seem that there  
2 probably are instances of abuse going on.

3 We'll talk about the evidence in a few  
4 moments. But, there are Cochrane Reviews on all  
5 of these which do not show substantive benefits.  
6 For the antihistamines, there's absolutely no  
7 benefits, that's old news, zero benefit, again, a  
8 nocebo strictly.

9 For the systemic steroids, there is a  
10 slight benefit at one month which disappears  
11 afterwards in the Cochrane Reviews, so it's not  
12 recommended.

13 For the antimicrobials, there is a  
14 short term benefit, actually, one that goes out a  
15 few months of about a 15 percent bump in  
16 resolution rates. However, there's absolutely no  
17 impact on hearing levels or rates of ear tube  
18 tympanostomy tube insertion which are the more  
19 relevant patient-based measures.

20 So, the Cochrane collaboration  
21 recommended not to use these drugs because of the  
22 lack of the really meaningful clinical impact.

1                   So, that's the overview.

2                   Yes?

3                   MEMBER FRIEDMAN: I'm sorry, can you  
4 enlighten us as to the appropriate treatment for  
5 this condition?

6                   DR. ROSENFELD: Well, thank goodness we  
7 have three measures, all of which say do nothing.  
8 But that's a good question.

9                   Much of managing middle ear fluid in  
10 kids is sort amusing the patient while nature  
11 cures disease in the words of Voltaire. And  
12 antibiotics, steroids and antihistamines are not  
13 very good amusements because they all have side  
14 effects.

15                   So, our new guideline, for example, is  
16 going to stress a lot supporting materials to  
17 give parents so they understand the natural  
18 history is very favorable, that most cases get  
19 better on their own.

20                   And we also have a tympanostomy tube  
21 guideline that very clearly lays out the  
22 situations where if it's persistent for three

1 months or longer in both ears, particularly if  
2 it's impacting hearing or having other effects on  
3 children such as their school performance or  
4 ability to acquire speech and language, those are  
5 situations for tubes.

6 But it really boils down to either  
7 you're going to put the tubes in at some point or  
8 you're just leave them alone and just let them  
9 outgrow it on their own which is the more typical  
10 outcome with these kids.

11 MEMBER STEIN: Do you have any plan on  
12 creating a measure to capture use of tubes when  
13 appropriate?

14 DR. ROSENFELD: Yes. What we're going  
15 to work on probably are similar to a measure are  
16 the appropriate use criteria. We're going to  
17 derive from our tympanostomy tube guideline.

18 But, yes, we have a very recent  
19 tympanostomy tube guideline 2013 that has some  
20 very explicit recommendations regarding tubes and  
21 the senses. There are some real QI opportunities  
22 there.

1                   So, we will look at measures. We'll  
2 look at appropriate use criteria.

3                   CO-CHAIR YAREMCHUK: And this is a  
4 question. You're currently updating these  
5 guidelines?

6                   DR. ROSENFELD: Yes. So, the otitis  
7 media with effusion clinical practice guideline  
8 was published in 2004 and that was a joint  
9 project of the American Academy of Pediatrics,  
10 the Otolaryngologist and the Family Physicians.  
11 That's where the measures stem from because we  
12 had very similar recommendations in that. At  
13 that point, they were just recommendations.

14                   The new guideline that's in a fairly  
15 advanced for of a draft now and will hopefully be  
16 published by very early 2016 carries this concept  
17 further. It breaks it down into individual  
18 recommendations and they're all strong  
19 recommendations now against prescribing because  
20 there's been more evidence, particularly  
21 regarding antibiotics and steroids than on the  
22 first guideline.

1 CO-CHAIR YAREMCHUK: So, I guess the  
2 question that I have is it worthwhile to wait  
3 until 2016 when you have these guidelines out as  
4 opposed to doing it now based on the previous  
5 information?

6 DR. ROSENFELD: I don't think so. The  
7 thrust of the -- the measures do not change at  
8 all based on the current guidance. I think we'll  
9 be able to say perhaps there's a little more  
10 data, but those data have already been published.

11 The guideline itself is not the  
12 supporting data for the measures. It's the  
13 Cochrane Reviews and the randomized trials which  
14 are all freely accessible and have already been  
15 published.

16 MEMBER FRIEDMAN: Okay, so the next  
17 logical question is, is there any advantage to  
18 combining them into one measure? Is there any  
19 disadvantage of prescribing one versus all three?  
20 Do you care? If they're prescribing one, they're  
21 not doing appropriate care, what do you care  
22 whether they're prescribing one or all three of

1       them at the same time, which is probably even  
2       worse?

3               DR. ROSENFELD: So, yes. So, you could  
4       do a single measure and we could do, say, we  
5       could even do a single measure that says do not  
6       treat otitis media with effusion with any type of  
7       medical therapy because it fundamentally doesn't  
8       change the child eustachian tube.

9               The problem with that is these all  
10       have different adverse event profiles. And so,  
11       for example, steroids, systemic steroids, which  
12       are fairly infrequent at just over three percent.

13              The problem with those is in young  
14       kids who get this condition, there's been ample  
15       reports of disseminated varicella where kids die  
16       because they've taken steroids that they didn't  
17       need in proximity or even that they needed for  
18       asthma in proximity to a varicella or chicken pox  
19       episode and it gets disseminated. You get the  
20       aseptic necrosis. You get cataracts.

21              So, I think the adverse event profiles  
22       are very different. The prevalence is very

1 different. I think the gaps are very different.  
2 And even with though we could say the gaps are  
3 small, three percent for one and maybe just about  
4 ten percent for another, it's a very ubiquitous  
5 condition in a susceptible population of young  
6 pre-school kids.

7 And, to me, one of the advantages of  
8 having three separate measures is that, three  
9 years from now or whenever it comes time to  
10 renew, having these measures will allow us to  
11 really get the data we need to understand the  
12 real gaps and the real issues.

13 And if it turns out we're wrong and we  
14 overestimated, fine, the measure goes to sleep  
15 and disappears. But I think it's important to  
16 keep them separate.

17 CO-CHAIR MERENSTEIN: So, this is Seth  
18 and Michael again. I don't know if, Seth, you  
19 have anything to add on evidence?

20 Are we switching? Am I reading?

21 MEMBER STEWART: We'll switch. I'll do  
22 this one.

1 CO-CHAIR MERENSTEIN: Okay.

2 MEMBER STEWART: No, I think -- I guess  
3 I had -- we had a similar discussion on our call  
4 about this, the point that Kathy brought up,  
5 which was the guideline we're basing this on is  
6 basically a recommendation and not a strong  
7 recommendation.

8 But, in fact, there's been a lot of  
9 intervening evidence. There's going to be a new  
10 guideline coming out which is a strong  
11 recommendation. And so we feel the evidence is  
12 quite strong to support this, you know, since  
13 we're doing these one at a time, to support the  
14 one we're doing now which is systemic  
15 antimicrobials.

16 So, the evidence is strong.

17 CO-CHAIR MERENSTEIN: The evidence is  
18 the Cochrane Review, right?

19 MEMBER STEWART: Yes.

20 CO-CHAIR MERENSTEIN: I mean I guess  
21 there's other studies that they reviewed to make  
22 it.



1 Do you have a question, Josh?

2 MEMBER STEIN: This is more a global  
3 question. If, in general, we like a measure but  
4 there's one or two aspects of it that we don't  
5 like about it, do we have to vote the whole  
6 measure down for the developer to just change  
7 that one or two aspect? How does that work?

8 DR. WINKLER: We alluded to it on the  
9 introduction. We're asking you to evaluate what  
10 you have before. Your conversation and  
11 discussion and concerns that you raise is being  
12 heard by them. And so, they will take that under  
13 advisement for potential action down the road.

14 But we're asking you to make your  
15 decisions based on what's presented in front of  
16 you.

17 MEMBER STEIN: But for them to make  
18 that action, we'd have to vote it down, correct?

19 DR. WINKLER: Perhaps. I mean, I think  
20 each situation is different to what degree that  
21 your concern is that you would want to, you know,  
22 remove endorsement for the measure because your

1 concern is that big.

2 So, I think each situation might be  
3 different.

4 CO-CHAIR MERENSTEIN: Andrew?

5 MEMBER SCHACHAT: I just have a  
6 different question. I'm looking at a slide in  
7 front of me, not that one, and it says data  
8 source paper medical records. So, can you just  
9 remind us what the data source is?

10 MS. KAYE: So these particular  
11 measures, they are being submitted for paper  
12 medical record endorsement mostly because we need  
13 to get it endorsed based on the data source that  
14 we use to test the measures.

15 And so, for the purposes of this, we  
16 will be seeking paper medical record endorsement.

17 MEMBER SCHACHAT: But could someone  
18 just explain generally how you could ever do any  
19 of this with paper medical records? I mean are  
20 people supposed to Xerox their records and mail  
21 it to someone or what happens?

22 MS. KAYE: So, we included in the

1 materials, there is a chart abstraction tool.

2 It's a bit of a worksheet and so that would guide  
3 the manual review of medical record and then you  
4 would answer the specific questions that then  
5 would feed into the measure.

6 MEMBER SCHACHAT: Was that to do the  
7 measure or is that just to validate that someone  
8 did it? Do they just check off a box to say I  
9 did it or do they have to fill out that  
10 worksheet?

11 MS. KAYE: From what I understand, it  
12 would be that to calculate the measure, so it  
13 wouldn't necessarily be the provider filling in  
14 this worksheet. It would be the person  
15 abstracting and calculating the measure.

16 MEMBER SCHACHAT: I'm not going to  
17 monopolize the discussion but I just am skeptical  
18 about anything that relies on paper records.

19 CO-CHAIR YAREMCHUK: And this is,  
20 again, just a question for the developer.

21 The previous two measures were  
22 electronic. They were prescription and these are

1 paper. And so, I'm asking why is there a  
2 difference between the two?

3 MS. KAYE: Well, for these measures, we  
4 were able to get electronic measures or  
5 electronic data for the previous measures because  
6 they are included in the PQRS program. So, we  
7 were able to access that data.

8 However, because these are not  
9 included in the PQRS program, we had to kind of  
10 rely on some earlier data from when we originally  
11 developed these measures that included a paper-  
12 based testing project. So, we didn't have that  
13 PQRS data available to us.

14 And I guess in terms of, to answer  
15 your question about, you know, updates or if  
16 there are aspects you are concerned about, there  
17 is also, we are hearing this and, you know, in  
18 terms of endorsement, there are also  
19 opportunities through annual updates and  
20 continued maintenance of the measure to where we  
21 could take those under consideration as well,  
22 depending on the types of concerns that you may

1 have.

2 MEMBER STRODE: Let me just follow-up  
3 on that. For whatever reason, the Feds have not  
4 put these measures into PQRS. An electronic  
5 health record could have the elements that would  
6 allow you to determine how this was treated.

7 A system could decide that they wanted  
8 that software to be created or a system could  
9 say, we'll go through the extensive effort  
10 required to either do a review off of the  
11 computer screen of the raw record or do a paper  
12 chart review.

13 MS. KAYE: That is correct. That just  
14 because we were kind of limited to paper-based  
15 testing data does not mean that it couldn't be  
16 implemented in an electronic format.

17 And so, there are certainly, I think,  
18 you know, in terms of the data elements, I don't  
19 see that necessarily being not possible, it's  
20 just more that we kind of, you know, due to  
21 resources, had to use the data we had available  
22 which is how it wound up in the paper-based

1 format.

2 DR. ROSENFELD: I just want to build on  
3 that because I want to be sure that I understand  
4 the process correctly.

5 The purpose is to vote on the measure  
6 itself, not necessarily the implementation  
7 process which is going to be quite variable.

8 Obviously, some things were done to  
9 collect some data to get to this point. And for  
10 the others it was electronic through PQRS. It  
11 was paper-based but that's just to get a sense of  
12 is the measure working? How is it done?

13 Going forward, there's no intent that  
14 this just be a paper-based measure. I mean it  
15 could find its way into however the system  
16 monitor uses it, it's corrective. Whether that  
17 was in EHR or some automatic process or any  
18 other, you know, value-based purchasing system  
19 that comes down the pike.

20 Am I correct with that understanding?

21 DR. WINKLER: Yes, you are. But, in  
22 terms of being able to evaluate what we know

1 about the measure for you all to make a  
2 recommendation on endorsement, we have to use the  
3 data that's available. And that's why the data  
4 source that they have tested, specified and  
5 tested, is based on paper medical records.

6 MEMBER STEWART: So, what this slide is  
7 telling us is, the data source was paper medical  
8 records, not that the guideline group is saying  
9 this must be done using paper medical records  
10 going forward?

11 MS. KAYE: That's correct. And I will  
12 add that these were in PQRS at the very beginning  
13 but due to some kind of more stewardship-based  
14 concerns, were removed. However, there are, you  
15 know, it was implemented briefly.

16 And we are currently working, or  
17 rather our colleagues at AAOH&S, are currently  
18 working with states to try to implement this in  
19 the Medicaid population which is a little bit  
20 more appropriate because this has a pediatric  
21 focus.

22 Those Medicare-based programs, you

1 don't really get a lot of those pediatric  
2 patients in.

3 And so, one of the hurdles to clear to  
4 get into these Medicaid-based programs,  
5 incidentally, is NQF endorsement. And so, that's  
6 one of the hurdles that we are seeking here.

7 But we are seeking avenues for maybe  
8 a little bit more appropriate implementation to  
9 these measures.

10 CO-CHAIR MERENSTEIN: So, this is a  
11 really good discussion with lots of different  
12 points but right now, I think we need to vote on  
13 the evidence, not on the -- so, we'll get to  
14 those points, too. But I think we should vote  
15 just on the evidence behind the test right now.

16 MS. ROBINSON-ECTOR: So, voting for  
17 evidence for Measure 0657 is now open.

18 And for those on the phone, option one  
19 is high, option two is moderate, three is low and  
20 four is insufficient evidence.

21 It looks like we're missing one in the  
22 room. Thank you.



1 MS. LUONG: Judith and Vaishali, I'm  
2 ready for your votes any time. Thanks.

3 MEMBER PATEL: I sent mine.

4 MS. LUONG: Vaishali, I actually just  
5 got a blank for you. Can you resend that?  
6 Thanks.

7 MS. ROBINSON-ECTOR: So, all the votes  
8 are in and voting is not closed.

9 So, seven voted high, six voted  
10 moderate, two voted low and zero voted  
11 insufficient.

12 So, the measure passes for the  
13 criterion of evidence.

14 CO-CHAIR MERENSTEIN: So, Michael,  
15 we're going to talk about opportunity for  
16 improvement.

17 MEMBER STEWART: So, I think we heard  
18 very nicely -- this, we're talking about systemic  
19 antimicrobials. We have probably the greatest  
20 opportunity for improvement because this is  
21 something that is frequently prescribed for this  
22 condition.

1                   Certainly, the data that were  
2                   presented indicated that. Certainly, that's been  
3                   anecdotal experience is seeing patients who have  
4                   had this condition referred in or have not  
5                   infrequently still given antibiotics.

6                   I think there is a high level of -- I  
7                   think there's a high level of opportunity for  
8                   improvement.

9                   CO-CHAIR MERENSTEIN: Anything to add,  
10                  Seth?

11                  Any questions or comments about that?

12                  MS. ROBINSON-ECTOR: So, voting for  
13                  performance gap for Measure 0657 is now open.

14                  And for those on the phone, option one  
15                  is high, two is moderate, three is low and four  
16                  is insufficient.

17                  It looks like we have all the votes in  
18                  the room. We're just waiting on one more. All  
19                  the votes are in and voting is now closed.

20                  Forty-seven percent voted high, 53  
21                  percent voted moderate, zero voted low and zero  
22                  voted insufficient.

1                   So, for the criterion performance gap,  
2 Measure 0657 passes.

3                   CO-CHAIR MERENSTEIN: So, this is one  
4 we've already talked a little bit about but I  
5 don't know if you want to add for reliability  
6 now.

7                   MEMBER STEWART: I think that this is  
8 -- I mean there is a clear ICD-9 Code. It is a  
9 prevalent condition. I think this should be  
10 extractable from EMRs and from other systems.

11                   So, I would think that whether or not  
12 antibiotics were prescribed for this particular  
13 diagnosis should be able to be reliably measured  
14 going forward which is, I think, what we're  
15 voting on here today. Or how are we --

16                   DR. WINKLER: You want to look at what  
17 we've been able to establish by the testing  
18 that's been done. I think, you know, it's fine  
19 to consider where that may take you in the  
20 future, but the reason that we require testing of  
21 the measure in some form is to give you some  
22 actual data to work on rather than speculate.

1 DR. WILSON: Well, I think the data  
2 that was collected was collected reliably and I  
3 think there's a high level of reliability based  
4 on the data that we have so far.

5 MEMBER GOLDBERG: I agree.

6 CO-CHAIR MERENSTEIN: Any questions?  
7 Comments? We've talked a little bit about it.

8 DR. WINKLER: Yes, reliability also  
9 includes anything about specifications, if there  
10 are any comments or questions about those.

11 MS. ROBINSON-ECTOR: So, voting is open  
12 for the criterion reliability for Measure 0657.

13 And for those on the phone, option one  
14 is high, two is moderate, three is low and four  
15 is insufficient.

16 All the voting is in and voting is now  
17 closed.

18 Forty percent voted high, 27 percent  
19 voted moderate, 33 percent voted low and zero  
20 voted insufficient.

21 So, for the criterion reliability, the  
22 measure passes.

1 CO-CHAIR MERENSTEIN: So, we're going  
2 to do validity, Michael.

3 MEMBER STEWART: So, this is whether  
4 the specifications align with the evidence and  
5 whether there were issues with exclusions or  
6 comparability.

7 I think based on what we've heard, I  
8 think the validity of the diagnosis, the  
9 treatment and the data appear to be valid. So I  
10 don't know if there's other questions about that.

11 MEMBER LYNCH: The exclusions only  
12 mention medical reasons, there's nothing  
13 specific.

14 MEMBER GOLDBERG: That was my question.  
15 Could the developers comment on that further?

16 MS. KAYE: So, this is a similar --  
17 this reflects our exception methodology where we  
18 use these broad exceptions of medical reasons  
19 exceptions to allow for those other co-occurring  
20 conditions that could justify the prescription of  
21 an antimicrobial, say an existing infection.

22 Or I know Dr. Rosenfeld, if you're

1 looking a specific examples, but we utilized,  
2 again, that kind of broad exception category to  
3 allow for individual clinician judgment.

4 MEMBER GOLDBERG: So, you're stating  
5 any other diagnosis in addition to otitis media  
6 with effusion?

7 MS. KAYE: It's what it allows for. I  
8 can give some examples of what was from out  
9 testing data if that would be helpful.

10 MEMBER LYNCH: Yes, please.

11 MS. JIN: So, we went back and took a  
12 look at the data sample and then made a  
13 determination for the exception rate which was  
14 11.43 percent for Measure 0657.

15 And there were a couple of different  
16 types of reasons for the exceptions.  
17 Specifically, individuals reported acute otitis  
18 media SNAP script, SNAP Omnicef and then  
19 sinusitis as well.

20 MEMBER LYNCH: Why not use those  
21 specifically instead of just medical reasons?

22 DR. ROSENFELD: I think there's a host

1 of reconcurrent things that could drive an  
2 antibiotic. So a child has a concurrent  
3 streptococcal pharyngitis, they have a concurrent  
4 bacterial sinusitis, they have a concurrent skin  
5 problem or cellulitis.

6 There's a lot of other reasons that  
7 kids would get antibiotics. I think trying to  
8 come up with a completely inclusive list would be  
9 very onerous.

10 I think the general point is that the  
11 antibiotic is being prescribe for a reason other  
12 than the otitis media with effusion.

13 MEMBER LYNCH: Okay.

14 CO-CHAIR MERENSTEIN: Go ahead, Andrew.

15 MEMBER SCHACHAT: Does the CPT Code  
16 that says I didn't prescribe an antibiotic just  
17 say that period or does it say I didn't prescribe  
18 an antibiotic for otitis media, in which case  
19 that solve that.

20 MS. KAYE: I think I can call on Kendra  
21 who is our specifications expert for this  
22 particular coding question.

1 MS. HANLEY: The code is general but  
2 it's intended to be used in conjunction with this  
3 measure. So, it says systemic antimicrobials not  
4 prescribed. It would need to be linked, yes.

5 MEMBER STEWART: It does seem that this  
6 could be improved by in not stating it not as for  
7 medical reasons but the antibiotics were -- the  
8 exclusion is not just for quote, medical reasons,  
9 the exclusion is to treat another problem or  
10 something along those lines which would be a  
11 clearer -- it would give people less leeway to  
12 say, well, in my medical opinion, I thought this  
13 patient did, if there's another problem needing  
14 antibiotics.

15 MS. KAYE: One thing that we can  
16 consider, and many of our measures we do, we  
17 provide examples to kind of clarify the intent of  
18 the exception with the understanding that those  
19 examples would not be an exhaustive list of all  
20 possible medical reasons but rather just to give  
21 a flavor of potential medical reasons.

22 Because, like Dr. Rosenfeld mentioned,



1 I think it's a little onerous to try to create an  
2 exhaustive list of all of the reasons.

3 MEMBER STEWART: I wasn't suggesting an  
4 exhaustive list, I was suggesting the different  
5 terminology instead of just for medical reasons,  
6 like if the exception was to treat another  
7 condition or something like that. Make it an  
8 active instead of a -- not to list all of the  
9 conditions.

10 CO-CHAIR MERENSTEIN: Any further  
11 questions?

12 So, we should vote on validity.

13 CO-CHAIR MERENSTEIN: Yes, one thing  
14 before we vote.

15 DR. ROSENFELD: So, in the data that I  
16 mentioned that we have on the ambulatory care  
17 visits, and this may help address the issue that  
18 was raised.

19 The prescribing was 32 percent of all  
20 visits, of OME visits. They also looked at  
21 prescribing for non-EMO visits, so all the other  
22 times a child showed up and that was 13 percent.

1           So, we could potentially anticipate  
2           that as much as 13 percent of the time, there any  
3           be a reason for giving another antibiotic, not  
4           necessarily because those children are showing up  
5           for that reason. The other ones are showing up  
6           for OME.

7           But even if we look at the -- take  
8           that out, we've still got a gap of about 20  
9           percent at the worst case scenario that's being  
10          strictly given for the OME.

11          CO-CHAIR MERENSTEIN: Can we vote now  
12          please?

13          MS. ROBINSON-ECTOR: Okay. Voting for  
14          validity for Measure 0657 is open.

15          And for those on the line, option one  
16          is high, two is moderate, three is low and four  
17          is insufficient.

18          All the votes are in and voting is now  
19          closed.

20          Twenty percent voted high, 47 percent  
21          voted moderate, 33 percent voted low and zero  
22          voted insufficient.

1                   So, for the criterion validity,  
2 Measure 0657 passes.

3                   CO-CHAIR MERENSTEIN: So, Michael,  
4 we're going to go on to feasibility.

5                   MEMBER STEWART: It seems that these  
6 data elements required are generated during  
7 delivery. It seems that this would be feasible  
8 measure to implement in practice based on what we  
9 heard, based on the group discussion we had on  
10 our call.

11                  CO-CHAIR MERENSTEIN: Seth, anything to  
12 add?

13                  MEMBER GOLDBERG: I agree. They've  
14 been paper-based in the past but they are easily  
15 transferrable to electronic medical records.

16                  MS. KAYE: And I would just add that  
17 building on, you know, when these were in the  
18 PQRS program, there are existing claims  
19 specifications for this measure. It's just that  
20 because of to match our testing data, we weren't  
21 able to include those but those do exist and that  
22 helps.

1 CO-CHAIR MERENSTEIN: Any further  
2 questions about this?

3 MS. ROBINSON-ECTOR: So, voting for  
4 feasibility for Measure 0657 is now open.

5 And for those on the line, option one  
6 is high, two is moderate, three is low and four  
7 is insufficient.

8 All the votes are in and voting is now  
9 closed.

10 Thirty-three percent voted high, 27  
11 percent voted moderate, 33 percent voted low and  
12 seven percent voted insufficient.

13 That's grey zone.

14 DR. WINKLER: Yes, that falls into a  
15 consensus not reached. This is not a mandatory  
16 having to pass to move on. But there does seem  
17 to be lack of consensus in the feasibility of  
18 this measure among the committee.

19 Anybody want to comment on that?

20 MEMBER SCHACHAT: I may have  
21 misinterpreted the question, but since it's a  
22 paper measure, I didn't understand how you could

1 use electronic sources.

2 DR. WINKLER: You know, I mean I think  
3 there is the what they tested, that's really the  
4 data, hard data that you have versus personal  
5 experience, the sense of how things could  
6 potentially be implemented can factor into your  
7 thinking.

8 MEMBER SCHACHAT: So, if we're allowed  
9 to look forward to whether it could be  
10 implemented electronically, I'm happy to vote in  
11 favor of it. But I thought the question I was  
12 having was the measure as written.

13 CO-CHAIR MERENSTEIN: Yes, I think it  
14 is.

15 MS. KAYE: If I can speak to, you know,  
16 in terms of the data, the elements required for  
17 the measure, we certainly agree that I think it  
18 could be implemented electronically.

19 And in terms of paper medical records,  
20 just kind of to highlight that the NQF criteria  
21 themselves don't favor one modality over another  
22 in terms of, you know, because the testing data

1 was paper isn't necessarily a strike against it  
2 for feasibility as long as it could also be  
3 captured electronically.

4 DR. WINKLER: Do they want to revote  
5 it?

6 MEMBER STEWART: Yes, I'm sorry, I  
7 thought that, at least what we said earlier,  
8 which is that, yes, it was done through paper,  
9 but what we were voting on is today, is this a  
10 feasible measure?

11 DR. WINKLER: Well, if someone -- I  
12 think, think of it this way, is the concept of  
13 feasibility is how easily is it to implement this  
14 measure? What are the burdens associated with  
15 implementation?

16 What you have in specifications that  
17 would allow you to implement it with chart review  
18 has been the way that they've tested it. So,  
19 that's what we know from experience and we have  
20 hard data. All right?

21 So, the question to you is, how  
22 feasible is this measure to be used?

1                   MEMBER SCHACHAT: I just think chart  
2 review and using paper is generally not feasible.  
3 But I can't believe people going forward would do  
4 that. I'm sure that people will do this  
5 electronically. So, I'd be happy to support it  
6 if we could be forward looking.

7                   MEMBER STEIN: So, this is an example  
8 where I think we're trying to tell the developer  
9 to do it a different way but we may not want to  
10 vote down the whole measure.

11                  MEMBER FRIEDMAN: So, we probably all  
12 agree that electronically, this is easy to  
13 implement. But the way it is right now, with  
14 paper, it's difficult.

15                  So, based on that, that's what we're  
16 asking, is do we vote feasibility favorable or  
17 unfavorable?

18                  DR. WINKLER: I think the fact that  
19 you're not able to say totally one way or the  
20 other reflects that what you just said is what we  
21 know about the measure and the limited experience  
22 with the measure is being done, you know, through

1 the paper, through the specifications as is.

2 We don't have experience with the  
3 measure, although it seems likely. We don't have  
4 that experience.

5 So, the fact that you're not able to  
6 really feel comfortable one way or the other  
7 probably reflects the reality of it.

8 MEMBER STEWART: I would disagree that  
9 we are uncomfortable with the reality. The data  
10 for this was measured in 2004. So, we were  
11 forced to use paper records.

12 I think today, we're voting on the  
13 feasibility of this measure going forward. And I  
14 don't think there's people thinking, I don't know  
15 if this is feasible to be measured in today's  
16 world. I don't think anybody has any doubt about  
17 that.

18 We're not -- this is an old -- data  
19 for this are relatively old, EMRs were not widely  
20 in use at that time. So, I don't think that the  
21 spread of votes is because there's concern about  
22 the feasibility going forward. I think the



1 spread of votes is about the concern that data  
2 records were used, paper records were used for  
3 2004 which I'm not sure is the pertinent question  
4 today.

5 MEMBER GOLDBERG: And just to give a  
6 concrete example, I don't see that it would be  
7 any problem with the developer going to an  
8 organization like Kaiser and saying, could you  
9 test this for the next year? And they could  
10 easily do it because they are electronic.

11 DR. ROSENFELD: I think we can make an  
12 analogy between this and the measure we just  
13 voted on for acute otitis externa which was  
14 basically a similar concept, don't give the oral  
15 antibiotic.

16 Both acute otitis externa and otitis  
17 media with effusion have a very specific CPT  
18 Code, it's 381.10 for otitis media with effusion.  
19 It's an unambiguous CPT Code.

20 We have the existing CPT 2 Code for  
21 not prescribing the antibiotic. So, from just a  
22 conceptual sense going forward, if there's a

1       desire to come up with some specs and get this  
2       into an EHR or a health care system, it would  
3       seem to be very straightforward. Famous last  
4       words, but it's basically completely analogous to  
5       the acute otitis externa, I think, experience.

6               MEMBER STEIN: So, there is like a  
7       post-call period and then we're going to have an  
8       opportunity to revote? Is this something that  
9       the developer can go and test electronically and  
10      then report back to us in a month or two?

11             MS. KAYE: I mean with testing projects  
12      like that, they're very time and resource  
13      intensive to plan, implement, analyze, you know.  
14      We, unfortunately, are measure developers but not  
15      implementers. So, we rely on external partners  
16      to conduct these testing projects as we don't  
17      have access to electronic data ourselves as  
18      stewards.

19             And so, you know, there's a lot to it  
20      rather than -- I don't think that's something we  
21      could certainly do before the, you know, the  
22      post-comment call. Those are pretty -- it's a

1 pretty intensive process.

2 MEMBER MADONNA: So, based on that,  
3 what you're saying is it may be quite a long time  
4 before the data source changes to electronic  
5 record? So, should we then be voting on what's  
6 going to happen in 2019 or are we going to be  
7 voting on what's in front of us right now?

8 MS. KAYE: I mean, one exception to  
9 that would be if, you know, if there's a registry  
10 out there or a system would chose to implement it  
11 electronically and then make their data available  
12 to us.

13 And so, but for us to have our own  
14 accord to go and kind of start the testing  
15 project from our end is a little bit of a  
16 different -- you know, to try to get the measure  
17 implemented versus an implementer choosing to  
18 implement that measure and then providing the  
19 data that we could then test.

20 MEMBER CARNAHAN: So, is this more of  
21 a question of is it feasible or do we believe  
22 it's feasible with an EMR just because the study

1 has a paper and we're saying it's very similar to  
2 the prior measure so it should be very feasible.

3 What we don't know is, is it usable?  
4 Because maybe there's no PQRS or someone to take  
5 this extracted data. That's not how it should be  
6 done.

7 MEMBER FRIEDMAN: And if you look at  
8 the -- point of clarification -- if you look at  
9 the verbiage here, it says under feasibility,  
10 could be captured without undue burden.

11 So, if we believe that electronically  
12 it could be captured, then we vote favorably for  
13 this.

14 MEMBER STEWART: I think that's the  
15 whole thing, could this be captured? I don't  
16 think we need to ask them to go back and do a  
17 study to see if it could be captured. Because if  
18 your ICD-9, this is all extracted from the  
19 record, it could be done.

20 The data is old, it was done with  
21 paper. We're not saying it must be done with  
22 paper. That's all they had.

1 CO-CHAIR MERENSTEIN: So, can we revote  
2 with a note that we're voting on the ability for  
3 them to capture electronically?

4 MS. ROBINSON-ECTOR: Okay, one moment,  
5 please. Let me clear the --

6 MS. LUONG: So, we will be revoting on  
7 feasibility.

8 And for those on the phone, if your  
9 votes for feasibility remains the same, please  
10 just let me know and if not, then please email me  
11 your new votes.

12 Vaishali -- okay, great.

13 MS. ROBINSON-ECTOR: All the votes are  
14 in and voting is now closed.

15 Thirteen percent voted high, 60  
16 percent voted moderate, 27 percent voted low and  
17 zero voted insufficient.

18 So, for the criterion of feasibility,  
19 Measure 0657 passes.

20 CO-CHAIR MERENSTEIN: We'll do  
21 usability.

22 MEMBER STEWART: So, I guess this one

1 is tough because it's not being publically  
2 reported now, so we don't have any data on which  
3 to base this.

4 It's a very prevalent condition with  
5 a clear diagnostic criteria seen frequently in  
6 primary care specialist offices.

7 I guess, certainly on the call, the  
8 group felt this was usable. But we didn't have  
9 data to support that.

10 So, I guess the question is, what are  
11 we voting on today, what the data tells us or do  
12 we think that this is a usable measure going  
13 forward?

14 DR. WINKLER: The use and usability  
15 criteria includes several things. The question  
16 is, how is it currently being used? You know, is  
17 it being used in programs? Is it being used for  
18 QI? Is it being publically reported? So, that's  
19 one element.

20 The other element of use and usability  
21 is what have we learned from the use of the  
22 measure over time. Have we seen trends? Have we

1       seen -- or what might be the impact of the  
2       measure? And the other thing would be, do we  
3       know of any unintended consequences?

4               So, use and usability covers those  
5       variety of issues that can impact the usability  
6       of the measure.

7               MS. KAYE: And, again, I guess I might  
8       just reiterate that while they currently are not  
9       in PQRS, again, because it's a little tougher to  
10      find a home for pediatric measures when they  
11      aren't captured in that Medicare population.

12              And so there are currently efforts  
13      underway to get them in the Medicaid programs  
14      with states, to try to get these used in the,  
15      hopefully, near term future. So there are some  
16      things underway, we just, unfortunately, don't  
17      have anything concrete at this moment.

18              CO-CHAIR YAREMCHUK: So, I have a  
19      question. There are also HEDIS measures, and  
20      that applies to the Medicaid population. So, has  
21      this been used in the Medicaid population for  
22      NCQA?

1 MS. KAYE: Not that I am aware of.

2 But that would be something that maybe I would  
3 need to confirm.

4 CO-CHAIR YAREMCHUK: Okay.

5 MS. KAYE: But off the top of my head,  
6 I'm not sure.

7 CO-CHAIR YAREMCHUK: Okay. And then my  
8 other question is to Reva. And this is kind of a  
9 Committee question. But how often are measures  
10 going to come forward to this Committee? Is this  
11 going to be an annual type? Is it once every  
12 four years?

13 DR. WINKLER: The typical review is  
14 three years. If something were to come up in the  
15 intervening timeframe, a material change to the  
16 measure, including additional data sources or  
17 someone externally requests an ad hoc review  
18 because of an issue that has arisen, unintended  
19 consequences, new evidence, something out there,  
20 then we might do it sooner.

21 MS. KAYE: And I guess to add a little  
22 bit to your HEDIS question, the NCQA, who kind of



1 governs, they do a lot of their own measure  
2 development. And so, for that program, they  
3 usually do homegrown measures rather than  
4 incorporating those developed by other.

5 CO-CHAIR YAREMCHUK: Reva may be able  
6 to speak to the -- many of the HEDIS measures are  
7 NQF and there's a harmonization of some of the  
8 measures.

9 DR. WINKLER: Certainly. And you're  
10 going to see one in a little bit. You know, NCQA  
11 brings a lot of their HEDIS measures to NQF for  
12 endorsement.

13 But we see measures developed by a  
14 wide variety of developers who have, you know, a  
15 particular niche, oftentimes, and different  
16 relationships with how measures get implemented.  
17 And we don't have a -- we don't limit that. And  
18 so we do see measures coming in that do have  
19 different characteristics.

20 MEMBER CARNAHAN: So, the previous  
21 measures all had a legacy to them and that made  
22 it easier for us to know they'd be implemented.

1           And so for newer measures where they  
2       don't really have a set program, you can't really  
3       get that going unless you have a measure. So,  
4       how do you balance that when we're looking at  
5       usability?

6           DR. WINKLER: I think that there's the  
7       issue between new measures, which I think those  
8       questions are quite valid because we wouldn't  
9       have much of a track record, versus measures that  
10      have been endorsed and have been available for a  
11      while. I suppose one of the questions might be,  
12      you know, what are the limitations on it being  
13      picked up for use? Why don't we have much of a  
14      track record? I think they've spoken to a  
15      certain amount of that.

16           And the question of, is there  
17      potentially a path going forward that can change  
18      that? Can we anticipate things being different  
19      down the road? And, again, I think they've  
20      spoken to that as well.

21           MEMBER STEWART: I would say,  
22      certainly, that, you know, going forward this

1 seems quite usable. It's just that we don't have  
2 a track record because it's a pediatric condition  
3 and Medicare didn't pick it up in PQRS. And so,  
4 you know, we can't base it on the data.

5 But certainly it seems like, if  
6 endorsed, this measure would be usable and  
7 useful, because, in fact, it is a prevalent  
8 condition where treatments are frequently over  
9 prescribed that have harm and costs.

10 CO-CHAIR MERENSTEIN: We can vote on  
11 it, unless there's other questions or comments.

12 MS. ROBINSON-ECTOR: Thank you.  
13 Voting for usability and use is now open for  
14 Measure 0657.

15 And for those on the phone: option one  
16 is high, two is moderate, three is low and four  
17 is insufficient information.

18 MS. LUONG: Vaishali, if you can email  
19 me your votes, thanks.

20 MS. ROBINSON-ECTOR: All votes are in  
21 and voting is now closed.

22 Seven percent voted high, 80 percent

1 voted moderate, seven percent voted low and seven  
2 percent voted insufficient information.

3 For the criterion of usability and  
4 use, the measure passes.

5 CO-CHAIR MERENSTEIN: Any discussions  
6 before we vote on the last one?

7 MS. ROBINSON-ECTOR: Voting is open for  
8 overall suitability for endorsement for Measure  
9 0657.

10 And for those on the phone, option one  
11 is yes and option two is no.

12 All the votes are in and voting is now  
13 closed. Eighty-seven percent voted yes, 13  
14 percent voted no.

15 So, for recommendation for overall  
16 suitability for endorsement for Measure 0657, the  
17 measure passes.

18 CO-CHAIR MERENSTEIN: Let's go on to  
19 the next one before lunch.

20 We're going to do Otitis Media with  
21 Effusion, systemic corticosteroids. And feel  
22 free to ask questions, but I think we've talked a

1 lot about it. Maybe the usability and  
2 feasibility we can agree on from before, but  
3 we'll see what happens. Todd?

4 MEMBER RAMBASEK: Should I shorten that  
5 part of the discussion?

6 CO-CHAIR MERENSTEIN: I think you  
7 should. I mean, it's up to you, but I think  
8 we've talked about it.

9 MEMBER RAMBASEK: I agree with you  
10 wholeheartedly.

11 So, this is a process-based measure  
12 suggesting that we limit the use of systemic  
13 steroids for otitis media with effusion.

14 The evidence is strong, based on ten  
15 randomized control trials published in Pediatrics  
16 in 2004. So I think there is little question  
17 that there is strong evidence based on the fact  
18 that systemic steroids provide little benefit and  
19 significant harms. So, I think we can vote on  
20 that.

21 CO-CHAIR MERENSTEIN: Anything to add,  
22 Kathy?

1 CO-CHAIR YAREMCHUK: The other thing  
2 that we've talked about is -- and I'm looking at  
3 what the 2004 guidelines and the 2011 Cochrane  
4 Review -- and they lumped together antimicrobials  
5 and corticosteroids. And so I think it's been  
6 raised before whether we need two different  
7 measures, or one measure and lump those two  
8 together.

9 DR. ROSENFELD: Just to respond to  
10 that, in the 2004 guideline, I think primarily  
11 due to lack of experience -- and people weren't  
12 thinking about performance measures in 2004 --  
13 actually, probably in 2002 when that process  
14 started it was more just in the conceptual  
15 thought of, yeah, let's condemn a whole bunch of  
16 medicines in one statement.

17 Since then, the evidence is a little  
18 more robust and the importance of having  
19 actionable guideline statements that can be a  
20 basis for a valid measure has become paramount.

21 So, that's why it's split into three  
22 separate ones. And, as I mentioned, the

1 currently unpublished update of that guideline,  
2 to be published probably in January or February  
3 of 2016, will have three separate strong  
4 recommendations, individually, for the different  
5 medications.

6 CO-CHAIR YAREMCHUK: And I guess  
7 that's just my question when I had asked Reva  
8 before about how often we're going to do this,  
9 because it would be nice if we had the 2016 now  
10 that had the three different recommendations and  
11 we could probably get different information about  
12 it.

13 CO-CHAIR MERENSTEIN: All right, we're  
14 going to vote now on the evidence.

15 MS. ROBINSON-ECTOR: So, voting for  
16 evidence is now open. And for those on the line:  
17 option one is high, two is moderate, three is low  
18 and four is insufficient.

19 All the votes are in and voting is now  
20 closed.

21 Sixty percent voted high, 33 percent  
22 voted moderate, seven percent voted low and zero

1 voted insufficient.

2 So, for the criterion of evidence, the  
3 measure passes.

4 CO-CHAIR MERENSTEIN: So, we're going  
5 to go opportunity for improvement.

6 MEMBER RAMBASEK: So, I feel the  
7 performance gap is the most difficult part here  
8 that will require more discussion.

9 So, we have data presented by the  
10 developers that show, in 2008, in Otolaryngology-  
11 - Head and Neck Surgery, we have a ten percent  
12 use rate for steroids. So, that's one data  
13 point, 10 percent in 2008. And then Dr.  
14 Rosenfeld has helpfully shared more data with us  
15 that we're now down to 3.2 percent.

16 So, my understanding of that database  
17 is that, recently, looking at over 100,000 OME  
18 visits, that 3.2 percent of those patients got  
19 steroids.

20 And, as I understand it, probably some  
21 perhaps small fraction of those patients had a  
22 condition for which they may have needed



1       steroids. So, maybe somebody with otitis media  
2       with effusion also has asthma that day and had a  
3       valid reason for steroids.

4               So, that 3.2 percent that got  
5       steroids, maybe if we say a small fraction  
6       actually needed them, maybe 2.9 of patients with  
7       otitis media with effusion were inappropriately  
8       given systemic steroids.

9               So, I think that really calls into  
10      question whether we want to expend the energy to  
11      chase that two to three percent.

12              CO-CHAIR MERENSTEIN: Rich?

13              DR. ROSENFELD: I agree completely that  
14      the absolute number is somewhat depressing and  
15      not probably enough to just on itself sway this  
16      erudite body. But I think, in this condition, it  
17      has to be looked at a little differently.

18              If we, again, look at the prevalence  
19      of this condition, which is somewhere between 50  
20      and 90 percent of children get this in their  
21      early childhood. We have 25 million kids  
22      currently under five -- is it under five, let me

1 get the number right -- no, that's -- yes, under  
2 five, 25 million children under age five in the  
3 U.S.

4 So, even if we go with 50 percent,  
5 that's about 12 million cases a year. If we take  
6 three percent and apply it to that, it's about  
7 360,000 children a year potentially getting  
8 systemic steroids, a very minute portion of  
9 which, or maybe not so minute, could suffer  
10 things later in life, such as cataracts, immune  
11 suppression, aseptic necrosis of the femoral  
12 head.

13 And, again, to me, the most of concern  
14 is the disseminated varicella, chicken pox, which  
15 does kill kids and there are ample reports of  
16 that. And there is this ridiculous anti-  
17 vaccination trend going on which makes that ever  
18 potentially more of a concern.

19 So, I think the number is small, but  
20 the condition is highly prevalent. And the  
21 downsides of even a small amount of systemic  
22 steroid prescribing for this have the potential

1 to be very, very serious in children.

2 I don't know how you balance all that  
3 in thinking about this, but, again, to me, the  
4 real benefit of having a little benefit of the  
5 doubt here and getting this measure through is  
6 that it will encourage dissemination of  
7 knowledge, that this is a bad idea, and we will,  
8 down the road, have data as this gets picked up  
9 and used.

10 And in three years, if we find out  
11 it's a non-issue, so be it. The measure  
12 disappears. But we may never know the answer to  
13 this question of what's the variability among  
14 practitioners unless we put some incentive out  
15 there for people to actually tell us what they're  
16 doing.

17 CO-CHAIR MERENSTEIN: So, I guess I  
18 would disagree. I would agree with Todd that no  
19 one's arguing that it's a bad idea to do it, it's  
20 just you have this limited amount of resources.  
21 It seems like to me we should be going over  
22 against antibiotic overuse, which is much more

1 prevalent, is a much more serious issue.

2 Three percent, to me, is almost a  
3 hundred percent. I mean, you can't get any  
4 better than that. Now, that's not published  
5 data; the published data we have is ten percent,  
6 right?

7 But three percent, no matter what NQF  
8 does, I don't know how you get better than three  
9 percent of usage, really.

10 MEMBER MADONNA: The other thing that  
11 I would add is that we appear to have a trend, if  
12 we take those two data points, and the trend  
13 drives with the story and the evidence.

14 There were some initial studies that  
15 suggest a little benefit. People started doing  
16 it. And then more studies came out saying maybe  
17 there's an initial small benefit, but no long  
18 term benefit. So the practice patterns have been  
19 changing independent of us, independent of what  
20 we do.

21 So, CME and medical education is  
22 already working, it's already disseminating the

1 information, and we might not need to push harder  
2 on something that's on the needle that's already  
3 moving in the right direction.

4 CO-CHAIR YAREMCHUK: I agree with what  
5 Todd and what Dan has said about this.

6 CO-CHAIR MERENSTEIN: Steve?

7 MEMBER PATEL: So, this is Vaishali on  
8 the phone. I have a question, actually.

9 How sure are we, you know, that three  
10 percent, that number from the claims database,  
11 actually is an accurate number that's associated  
12 with, you know, use of steroids in this  
13 condition? Could it be from other things, too?  
14 Because if that's possible, then even the three  
15 percent is too high.

16 DR. ROSENFELD: There is some limited  
17 data on that. Part of the analysis that was done  
18 was also to look at the rate of systemic steroid  
19 prescribing in all of the non-otitis media with  
20 effusion visits, which was about half that. It  
21 was about 1.7 percent.

22 So, at the very least, there's a gap

1 of about 1.5 percent. It's probably much higher  
2 than that because the 1.7 percent receiving  
3 steroids for their primary diagnosis are probably  
4 not the kids with OME. They're kids showing up  
5 with croup. They're showing up with asthma  
6 attacks and other reasons for steroids.

7 The OME one of 3.2 percent is with a  
8 primary diagnosis of OME. So, some of it may be  
9 due to other conditions. If we get the most  
10 generous possible, it's about 1.5 or 1.7 percent.  
11 But it's probably a small number.

12 MEMBER PATEL: Yeah. Okay, thank you.

13 CO-CHAIR MERENSTEIN: Steve?

14 MEMBER STRODE: Yeah, continuing on  
15 that, the ten percent figure from 2008 was  
16 otolaryngologists. The more recent data where it  
17 gets down to three percent, 1.7 percent, is that  
18 still a population of otolaryngologists or does  
19 that include primary care pediatricians and  
20 family doctors?

21 DR. ROSENFELD: Let's see. So, it  
22 includes -- the only thing they looked at

1 initially on these data are the otolaryngologists  
2 versus the emergency physicians. And the  
3 otolaryngologists on this were about 2.5 percent.  
4 Oh, we have some more data. The non-  
5 otolaryngology visits were 3.6 percent. For just  
6 strictly the non-otolaryngologists. So a little  
7 higher if we look at that group.

8 MEMBER STRODE: But would that be a  
9 non-ENT population that was just emergency  
10 physicians?

11 DR. ROSENFELD: No, this database had  
12 millions of encounters in it. 114,000 of those  
13 were otitis media with effusion. A small portion  
14 of that was otolaryngologists. So, this would  
15 include everybody else, the 3.6 percent, the non-  
16 otolaryngologists.

17 CO-CHAIR YAREMCHUK: Do you know if  
18 that was the only ICD-9 that was reported for  
19 that, or were there other associated? Because  
20 the question comes back, were the kids also with  
21 asthma and did they have other issues?

22 And so if the only ICD-9 was otitis

1 media with effusion versus primary diagnosis of  
2 OME, the second one was asthma exacerbation, the  
3 third one was something else, does it muddy the  
4 waters?

5 DR. ROSENFELD: I don't think -- the  
6 analysis hasn't been done at this point to look  
7 at the prevalence of the concurrent conditions.

8 CO-CHAIR MERENSTEIN: Josh?

9 MEMBER STEIN: It seems like these  
10 measures are mostly being done by ENT docs. I  
11 mean, I know you couldn't answer that question or  
12 the earlier one. So, if the ones that are  
13 misprescribing the steroids are not the ENT docs,  
14 are we really capturing the quality and the  
15 intended audience? Do you guys want to comment  
16 on that?

17 DR. ROSENFELD: I think what's been  
18 done in the past is, as we've discussed,  
19 extremely limited as far as the paper-based. But  
20 this condition is a mainstay of pediatric  
21 practice and family practice as well.

22 You know, I understand maybe about 20,



1 30 percent of family physician visits are kids,  
2 and probably the most common thing among those,  
3 other than the typical viral upper respiratory  
4 infection, would be some form of otitis media.

5 So, it's ubiquitous. It's seen in the  
6 emergency departments, as well. I think probably  
7 a minority of otitis media with effusion care is  
8 provided by otolaryngologists in real world  
9 practice. It's even seen by audiologists as  
10 well.

11 MEMBER YOUDE: Yeah, I have a couple of  
12 comments. First is a clarifying question just to  
13 make sure I'm understanding it. So, that ten  
14 percent that we originally looked at was ENTs  
15 alone and then that three percent that we looked  
16 at was ENTs plus other fields.

17 I would actually be more interested in  
18 the patient number associated with those  
19 percentages. Because while we're seeing ten go  
20 down to three, we're also changing what we're  
21 including.

22 And so, if that's possible, to know

1 the actual patient numbers associated with those  
2 percentages or what the grouping is there, that  
3 would be interesting because we may actually see  
4 a reverse trend.

5 Also, I know that we have limited  
6 resources and just in my practice alone,  
7 obviously, I'm not an ENT, I'm an audiologist,  
8 but I have seen children prescribed with, you  
9 know, steroids and whatnot.

10 And so, as an audiologist, knowing  
11 that that's not right, I'm sitting here looking  
12 at who is my patient and what are they going  
13 through? And then I look at it as a mother and  
14 I'm like, okay, if my kid's getting steroids this  
15 young, I would be furious.

16 And so I know that we're looking  
17 possibly at a small percentage, and I know that  
18 we're looking at limited resources, but I can't  
19 help but -- I don't want us to lose sight of who  
20 this is and who this impacts given the  
21 consequences that are associated with it.

22 CO-CHAIR MERENSTEIN: I would agree

1 with you that viral pharyngitis, I think, just  
2 from anecdotal evidence, is you would prescribe  
3 steroids a lot more than this. If we could do  
4 three percent, I'd be happy with that for viral -  
5 - I think it's much, much higher.

6 So, I think there's better numbers to  
7 decrease -- I'm not arguing that we should  
8 recommend steroid use for these things that are  
9 overused. I just think that the numbers are  
10 relatively low for this.

11 MEMBER PATEL: This is Vaishali on the  
12 phone. I would also agree with that.

13 CO-CHAIR MERENSTEIN: Can we vote on  
14 it, then?

15 MS. ROBINSON-ECTOR: Voting for  
16 performance gap for Measure 0656 is now open.  
17 And for those on the phone: option one is high,  
18 two is moderate, three is low and four is  
19 insufficient.

20 All the votes are in and voting is now  
21 closed.

22 Thirteen percent voted high, 20

1 percent voted moderate, 40 percent voted low and  
2 27 percent voted insufficient.

3 So, for the criterion of performance  
4 gap, the measure does not pass.

5 DR. WINKLER: Given the conversation,  
6 there's another twist for this. This is an  
7 endorsed measure. We do see measures being  
8 somewhat successful out in the field as a result  
9 of either change in practice, whatever.

10 But if the measure is still a good  
11 measure, we do have the opportunity of giving it  
12 a tag of inactive endorsement such that it stays  
13 on a list of endorsed measures, but we're sending  
14 the signal that, hey, the opportunity for  
15 improvement here may not be all that great and  
16 you really want to be careful about implementing  
17 something that could not have a great cost-  
18 benefit ratio.

19 So, any endorsed measure that fails  
20 opportunity for improvement is then eligible to  
21 go into this inactive endorsement status. And so  
22 that would mean, you know, being sure that it

1 passes all the rest of the criteria, and then you  
2 could recommend it for that inactive endorsement  
3 status.

4 CO-CHAIR MERENSTEIN: Is that a  
5 question? Or are you saying we should go on?

6 DR. WINKLER: Well, does anybody have  
7 any comments or questions before I move on? I  
8 said a lot of stuff. Okay.

9 So, we want to go through the  
10 remainder of the questions and criteria, and then  
11 you're final question would be, do you want to  
12 recommend it for inactive endorsement?

13 CO-CHAIR MERENSTEIN: So, we'll do  
14 reliability.

15 MEMBER RAMBASEK: Okay. So, the  
16 denominator here is patients two months to 12  
17 years with otitis media with effusion and the  
18 numerator is the number not treated with  
19 steroids. And the exclusions were generally the  
20 coexistence of another steroid requiring  
21 condition.

22 The reliability was measured amongst

1 two large pediatric networks. And, in doing  
2 that, there were 114 re-abstractions performed,  
3 and there's a high rate of correlation between  
4 the re-abstractions. When one person abstracted  
5 a chart, when a second reviewer re-abstracted  
6 that chart, they almost always got the same  
7 answer as indicated by the kappa statistic of  
8 0.85.

9 So, I think the reliability is high,  
10 and unless there's questions, we can vote on  
11 that.

12 CO-CHAIR MERENSTEIN: Kathy, anything  
13 to add? Any questions? We can vote.

14 MS. ROBINSON-ECTOR: Voting for  
15 reliability for Measure 0656 is open. And for  
16 those on the line: option one is high, two is  
17 moderate, three is low, and four is insufficient.

18 All the votes are in, and voting is  
19 now closed. Sixty-seven percent voted high, 33  
20 percent voted moderate, zero voted low and zero  
21 voted insufficient.

22 So, for the criterion reliability, the

1 measure passes.

2 CO-CHAIR MERENSTEIN: Validity?

3 MEMBER RAMBASEK: So, there are a  
4 large number of studies suggesting to us that  
5 this is clearly aligned with the evidence. This  
6 was assessed primarily using face validity by  
7 asking members of the American Academy of  
8 Otolaryngology Patient Safety Committee. And  
9 they basically gave it a very high rating. It  
10 had very good face validity to members of that  
11 committee that, if this indeed was done, if  
12 systemic steroids were avoided, that that  
13 probably had a high correlation with good quality  
14 care.

15 So, there were very few exclusions  
16 with regard to threats to validity. Really, the  
17 only main exclusion being coexistence of another  
18 steroid-requiring condition. And there was no  
19 risk adjustment performed because I don't think  
20 that's really appropriate for this sort of  
21 measure. Kathy?

22 CO-CHAIR YAREMCHUK: Nothing.

1 CO-CHAIR MERENSTEIN: Any questions  
2 about this before we vote? Okay, we'll vote.

3 MS. ROBINSON-ECTOR: Voting for  
4 validity for Measure 0656 is now open. And for  
5 those on the phone, option one is high, two is  
6 moderate, three is low and four is insufficient.

7 All the votes are in. Forty percent  
8 voted high, 60 percent voted moderate, zero voted  
9 low and zero voted insufficient. So, for  
10 validity of Measure 0656, the measure passes.

11 CO-CHAIR MERENSTEIN: So the question  
12 was, should we just use the same votes for  
13 feasibility? Or do you have anything else to add  
14 about the electronic --

15 MEMBER RAMBASEK: No, nothing else to  
16 add. We can use the same votes, that's fine.

17 CO-CHAIR MERENSTEIN: Same? Do you  
18 want to vote again, or do you just want to use  
19 the same vote? Just use the same vote? Everyone  
20 okay with that? And usability. It's really the  
21 same issues for the next one, too.

22 MEMBER RAMBASEK: Yes.



1 CO-CHAIR MERENSTEIN: All right, so  
2 we'll go to the last vote.

3 MEMBER LYNCH: I'm sorry, what are we  
4 voting for now?

5 CO-CHAIR MERENSTEIN: So we're  
6 actually not voting yet. We're going to vote for  
7 the overall suitability for endorsement.

8 DR. WINKLER: And just with the caveat  
9 that this would be an inactive endorsement  
10 status. It's still endorsed, but the inactive  
11 status indicates your concern about the  
12 opportunity for improvement is high, and so it  
13 should be used with caution.

14 CO-CHAIR MERENSTEIN: There's a  
15 question.

16 DR. RICH: I think you're actually  
17 touching on something that's really important --

18 CO-CHAIR MERENSTEIN: I'm sorry, you  
19 need to introduce yourself.

20 DR. RICH: I'm sorry. My name is Bill  
21 Rich, Medical Director of Health Policy, and I'll  
22 be meeting you all after lunch.

1 But if you have a really good measure,  
2 even if there's not an area for improvement,  
3 there's really robust evidence that says that if  
4 you drop the measure the performance immediately  
5 falls. There's an article in British Medical  
6 Journal where Joe Selby from Kaiser, when he was  
7 at Kaiser, took the Kaiser database and the UK  
8 database and showed that once a measure was  
9 removed from P for P, the performance immediately  
10 falls at about three percent a year.

11 Unpublished data from Kaiser in  
12 Colorado, they had the best outcomes in the  
13 United States for control of hypertension. Once  
14 they hit that, they dropped it, their control  
15 fell. So I think that's one thing to be aware of  
16 if you have a good measure, like Dr. Winkler  
17 pointed out, there are some consequences if it's  
18 no longer active.

19 CO-CHAIR MERENSTEIN: Any questions or  
20 comments? Tammy?

21 MEMBER BRADHAM: Depending on how the  
22 vote goes, can the group come back and resubmit?

1 DR. WINKLER: Sure, we can always  
2 reactivate it, depending if there's new  
3 information or something to work on, new data.  
4 Again, absolutely. This is very dynamic, it's  
5 been a process that comes and goes. As new  
6 information becomes available, certainly.

7 That's one of the benefits of having  
8 you all constitute as a standing committee: if  
9 something comes up, we can come back and bring it  
10 back in.

11 Also the other thing is, with your  
12 recommendations, we may get feedback from public  
13 comment that you may want to factor into your  
14 final decision. When we regroup after the call,  
15 there may be public comment that may influence  
16 how your recommendations go.

17 CO-CHAIR MERENSTEIN: Josh first.

18 MEMBER PATEL: So before we rush  
19 through and finalize this -- this is Vaishali on  
20 the phone -- you know, I have to say I was a  
21 little bit confused about us being out of  
22 sequence earlier for voting on this measure

1 overall as opposed to going one step at a time,  
2 reliability, validity, et cetera. So I would  
3 request, if it is possible, to do a re-vote on  
4 this measure.

5 And then, again, the other comment is  
6 I agree -- I think that was Bill Rich -- and I  
7 agree with his comment wholeheartedly that, you  
8 know, if we have a good measure which is actually  
9 giving us outcomes, removing that measure may  
10 actually have things go in the reverse direction.  
11 So that is something to be aware of.

12 And my other comment is that, yes, we  
13 can get -- I think it's in line with Bill's  
14 comment, again -- is we can look at claims  
15 databases and we can estimate rates of  
16 utilization of steroids, but the one big  
17 limitation with that is that steroids, if they're  
18 oral, they're prescribed and they appear in  
19 pharmacy claims data, and the actual diagnoses  
20 codes don't appear in pharmacy claims data; they  
21 appear in medical claims data, okay?

22 So, at best, you can only draw

1 correlations of what it might be used for, but  
2 you don't know 100 percent. And claims  
3 databases, unless you have evidence from 10  
4 different claims data that all point to the same  
5 thing, it's really risky to make a decision based  
6 on one claims database study or two claims  
7 database studies that the utilization, with  
8 certainty, is only three percent, or only 10  
9 percent. And this is coming from somebody who  
10 does a lot of claims database research.

11 CO-CHAIR MERENSTEIN: So, we have two  
12 comments. I would just say that we have voted,  
13 and it really wasn't that close, that one part.  
14 So unless there's someone that would second that,  
15 I don't see any reason to re-vote that issue.

16 DR. WILSON: Could I just suggest that  
17 we clarify what we did just vote on for this  
18 specific measure, for the transcript and for the  
19 record. This is what we've done, not going back  
20 through the votes, but we have voted on  
21 importance, we have voted on scientific  
22 acceptability. And my understanding is that the

1 group elected to, for feasibility and usability,  
2 vote as they did on the last measure. Have I got  
3 that clear?

4 CO-CHAIR MERENSTEIN: Yes, which means  
5 it passed. Yeah.

6 DR. WILSON: Correct. I just wanted  
7 to clarify, because it sounded like there was  
8 some confusion about what we had voted on for  
9 this particular measure. Thank you.

10 CO-CHAIR MERENSTEIN: All right. Josh,  
11 then Andrew.

12 MEMBER STEIN: I just wanted to  
13 clarify the process. If the developer wants to  
14 tweak the measure, can it be re-assessed on the  
15 post-call so it may not get to a point where it's  
16 taken out of practice?

17 DR. WINKLER: Yes, there can be  
18 responses during the whole process where you have  
19 the opportunity to change your recommendation.

20 CO-CHAIR MERENSTEIN: Andrew?

21 MEMBER SCHACHAT: I wanted to  
22 understand the implication of putting it in

1       reserve status. Does that mean that Medicare is  
2       not likely to use it, or -- so, my anxiety is  
3       that, even though there's no opportunity for  
4       improvement, the argument makes sense to me that  
5       if you stop measuring it, that performance is  
6       going to go down. Why not keep things?

7               DR. WINKLER: That's definitely the  
8       discussion for you all to determine.

9               MEMBER PATEL: So, again, this is  
10       Vaishali, and I'm confused. So have we voted on  
11       the actual, you know, the measure approval? Yes  
12       or no?

13              CO-CHAIR MERENSTEIN: No, we haven't  
14       voted on that yet. We are going to vote on that.

15              MEMBER PATEL: Okay, so why was there  
16       comment regarding the fact that we're voting on  
17       us, you know, liking the measure only, not really  
18       keeping the measure?

19              MS. LUONG: So, with the measure, we  
20       voted on the first criteria, which includes two  
21       sub-criterion under it. Evidence passed, while  
22       performance gap did not, it was voted down. And

1 so the whole discussion right now, Vaishali, was  
2 that Reva brought up an option for the measure to  
3 still go forward, and we can vote for it as  
4 reserve status. And Reva, you can speak a little  
5 bit more to the reserve status.

6 MEMBER STEWART: Can I ask a question  
7 too about -- and it follows on what Andy was just  
8 asking. I think Dan brought up the point, well,  
9 we have limited resources, so why should we  
10 support something where we've already achieved  
11 the goal? But I guess the question is, what  
12 resources would we use if we kept it as an active  
13 measure? I mean, are we really using resources?  
14 Because it's already an active measure, is there  
15 any negative consequence to us continuing to  
16 endorse it?

17 DR. WINKLER: The resources we're  
18 talking about, the cost-benefit balance, is about  
19 the cost of collecting data, analyzing data, and  
20 reporting data. And so there is a cost  
21 associated with actual measurement. And so, you  
22 know, all measurement has costs.



1                   MEMBER SCHACHAT: But those are  
2 optional costs. Anyone who doesn't want to do  
3 the measure doesn't have to do the measure, and  
4 they avoid the costs, I guess.

5                   I just think that -- I buy the  
6 argument that if you stop measuring things,  
7 performance goes down, and this doesn't seem to  
8 be all that difficult to allow it to continue.

9                   So what I'm putting on the table is  
10 your rule set about if the performance gap is  
11 small, you shouldn't endorse things. And I'm not  
12 sure that makes sense, especially when there's a  
13 large --

14                  MEMBER PATEL: I agree.

15                  MEMBER SCHACHAT: -- when there's a  
16 large n. It's a very common disease.

17                  DR. WINKLER: That's why it's a  
18 discussion point for you all, but one of the  
19 criteria is around opportunity for improvement,  
20 and so you need to weight that. There are no  
21 absolutes. So that's one of the questions for  
22 you all to determine.

1                   MEMBER MADONNA: Isn't that just a  
2 philosophical thing for every measure that we  
3 look at? I mean, ultimately, this is about  
4 improving care, so what we really want to do is  
5 get everything up to, you know, theoretically,  
6 100 percent. If Bill is correct, and I'm sure he  
7 is, that is a measure is dropped, performance  
8 goes down, then, you know, you're looking at  
9 thousands of children who are going to be over-  
10 treated with corticosteroids.

11                   So I think this is really -- going  
12 back to the first thing I said, and piggybacking  
13 off of Andy, really this is philosophical in  
14 terms of every measure.

15                   CO-CHAIR MERENSTEIN: Josh first.  
16 Todd, I'm sorry.

17                   MEMBER RAMBASEK: That's okay. So I  
18 think that's a key point: when you stop measuring  
19 something, does it regress? But this is not  
20 publicly reported now, is my understanding, so I  
21 see this as being used in the ABIM maintenance  
22 and certification, but I haven't seen it as

1 publicly reported anywhere. So is it really  
2 something that is already pushing on practice  
3 patterns, in its current incarnation, in the way  
4 it's been -- in other words, did the 10 percent  
5 go to three percent because of this? Or because  
6 of general dissemination of information? And I  
7 think that would require someone in the field of  
8 care to answer that.

9 MEMBER FRIEDMAN: So, I think we're  
10 going back and forth. So, if people want to take  
11 this measure and vote whether it should be active  
12 still, then we probably have to go back and look  
13 at opportunity for improvement again and re-vote.  
14 And if we think that we voted incorrectly on  
15 that, we can go back and improve it, and then we  
16 can move forward with active endorsement.

17 Right now, the way it stands -- and  
18 Reva you can clarify it -- opportunity for  
19 improvement was voted down. So at this point, we  
20 can't vote for an active endorsement. We can  
21 either put it in reserve, or just nix it at all.

22 DR. WINKLER: You said it better than

1 I could.

2 MEMBER YOUDE: Yeah, I do have a  
3 comment. So when I'm looking at this process  
4 metric -- and I look at process metrics an awful  
5 lot -- I think of process metrics as, where are  
6 we at in holding the gains? And so what's going  
7 on is like, okay, so let's say that went 10  
8 percent to three percent. That's awesome. Now  
9 let's take it away.

10 What happens when you take away  
11 process metrics is people start going all willy-  
12 nilly doing what they want to do, practicing how  
13 they want to practice, how they feel is fit. And  
14 so we do have the risk of falling backwards. So  
15 basically the process metric is holding the gains  
16 that we're seeing. If we're saying it's 10 to  
17 three, then we're holding at three. And from  
18 what I'm understanding in this discussion is  
19 three is pretty great.

20 CO-CHAIR YAREMCHUK: Okay. And I  
21 guess it's going back to what Todd had said: it's  
22 not clear that the process measure, if it's not

1 publicly reported, is what's driving it, or is it  
2 public knowledge?

3 And I appreciate that if you don't  
4 measure it, you don't get to perfection. At the  
5 same time, we use the example of immunizations.  
6 We've been measuring that forever, and part of  
7 the issue is there's been a change in culture or  
8 issues or whatever you want to describe, and  
9 that's -- the measuring of it hasn't changed, you  
10 know, the incidence of it or the prevalence of  
11 it. What's changed is an outside factor.

12 So, I think measurement is one process  
13 that drives improvement. I don't think it's the  
14 only process that drives change in patterns,  
15 change in performance and that kind of thing. So  
16 I think the question that was raised is, since  
17 we're not publicly reporting this, but there's an  
18 awful lot out there about this measure.

19 And then the other think that's kind  
20 of mixed into this is that we don't know that the  
21 steroids in the incidents that we're looking at  
22 is solely for the otitis media with effusion, or

1 is it there's some other comorbidities and other  
2 visits that are going in. So, much like when you  
3 see a kid that has serous otitis media, is it  
4 because of that they're getting the steroids, or  
5 was it something else at the time they were seen?  
6 So that's the only concern.

7 CO-CHAIR MERENSTEIN: Michael, and  
8 then Josh, then we should try to vote again, I  
9 think.

10 MEMBER STEWART: I was just going to  
11 respond to Todd's question. I believe, as an  
12 otolaryngologist who pays attention to this, that  
13 the success here has been because there's been an  
14 Academy-endorsed evidence-based guideline, and  
15 that people believe the guidelines, they believe  
16 the process, there's a respect for the process,  
17 and it's been disseminated and it's been  
18 discussed, and people look at it and say, oh,  
19 wow, the guidelines says I shouldn't do this,  
20 maybe I shouldn't do it. Not because it's been  
21 publicly reported, because there was actually an  
22 evidence-based guideline that made the

1 recommendation. That's been the improvement.

2 MEMBER STEIN: Just, again, to  
3 clarify. Our voting it down as an active measure  
4 now, it can be re-voted on in the post-call  
5 period and be determined to be an active measure  
6 once the developer has fixed some of these  
7 issues, correct?

8 DR. WINKLER: Or if there is other  
9 feedback that makes you reconsider your position.  
10 That would be one. You know, I'm not getting a  
11 sense that the developer has something specific  
12 to do with the measure per se that would change  
13 things. It's more the fact that the data on  
14 whether this is a true quality problem, at this  
15 point in time, to justify measurement. I think  
16 that is the discussion you seem to be having.

17 CO-CHAIR MERENSTEIN: Matt.

18 MEMBER CARNAHAN: I think Todd makes  
19 a good point. I come from an organization where  
20 we have measure fatigue. And we have so many  
21 competing measures that, anything that happens,  
22 an act of Congress, and we kind of get reduction

1 in everything and we're trying to do everything.  
2 So you have to really pick the important ones.

3 And this is important, we agree to  
4 that, would the amount of value that this  
5 approved measure would make may not be as great  
6 as the improvement that an organization can make  
7 by saying to its members, "this is the best  
8 practice." And so maybe we do focus on the  
9 antibiotics and other ones where there's more  
10 area to gain and not get the measure fatigue  
11 associated with it.

12 CO-CHAIR MERENSTEIN: So, is there a  
13 reason -- do people want to re-vote this one, or  
14 just vote for the last one? I mean, it seems  
15 like, to me, we just go to the last and vote,  
16 unless there are people who want to re-vote. I  
17 don't think this vote is going to change that  
18 much.

19 MEMBER STEWART: Is it feasible to  
20 have three options? So, right now, we're either  
21 being asked, you know, inactive or no. Can we  
22 allowed to vote on keep it active, inactive, or



1 no?

2 DR. WINKLER: The way to do that would  
3 be to re-vote the opportunity for improvement,  
4 just as Scott described. So the question is, do  
5 you want to do that? Does anybody feel that they  
6 would change their vote to the -- we've got the  
7 results up there. Based on the last discussion,  
8 does anyone feel that they would change their  
9 vote?

10 MEMBER PATEL: I would.

11 MEMBER YOUDE: Okay. So I think we've  
12 had some new information come to light since we  
13 previously voted. And while we may not  
14 understand what that means at this point in  
15 time, the fact that we've had that discussion, to  
16 me, warrants a re-vote, just because there's been  
17 new information presented.

18 CO-CHAIR MERENSTEIN: I think that's  
19 fine. Let's just re-vote this one question here,  
20 and then we'll go to the last question.

21 MEMBER LYNCH: Are we voting now?

22 MS. ROBINSON-ECTOR: So, voting for

1 performance gap for Measure 0656 is now open.

2 And for those on the line: option one is high,  
3 two is moderate, three is low, and four is  
4 insufficient.

5 MS. LUONG: Yes, Judith, you can send  
6 me your votes.

7 MS. ROBINSON-ECTOR: All the votes are  
8 in. Seven percent voted high, 27 percent voted  
9 moderate, 40 percent voted low and 27 percent  
10 voted insufficient. So, the measure does not  
11 pass performance gap.

12 CO-CHAIR MERENSTEIN: Do we just go to  
13 the last vote, then?

14 MS. ROBINSON-ECTOR: Yes.

15 MS. LUONG: So, for those on the  
16 phone, that's reserve status.

17 MEMBER LYNCH: Could you please  
18 clarify the different votes on this?

19 MS. ROBINSON-ECTOR: Yes. So, option  
20 one is yes, and option two is no. And voting is  
21 now open for recommendation for reserve status  
22 for Measure 0656.

1 MEMBER LYNCH: Thank you.

2 MS. ROBINSON-ECTOR: All the votes are  
3 in. Eighty-seven percent voted yes and 13  
4 percent voted no. So, the measure does pass for  
5 recommendation for reserve status.

6 MS. LUONG: Operator, can you open the  
7 line now for public and member comments? And for  
8 anyone in the room, if you would like to speak,  
9 please come up to the microphone.

10 OPERATOR: At this time, if you would  
11 like to make a comment, please press star, then  
12 the number one.

13 There are no comments from the phone  
14 line.

15 MS. LUONG: There are no comments in  
16 the room, either. So, I'm sorry for the delay in  
17 time, but we will break now for lunch.

18 Okay, so, before we break for lunch,  
19 if you're still having problems accessing  
20 SharePoint, please raise your hand so we can just  
21 take a record vote of that.

22 CO-CHAIR MERENSTEIN: We're going to

1 try to restart at five after 1:00, if we can, so  
2 that we'll only be 20 minutes late.

3 DR. WINKLER: And also, lunch is back  
4 here in the back of the room.

5 MS. LUONG: Yes. So, five after one.  
6 Thank you, all.

7 (Whereupon, the above-entitled matter  
8 went off the record at 12:38 p.m. and resumed at  
9 1:05 p.m.)

10 MS. LUONG: So everyone, I hope  
11 everyone's coming back soon. We will start off  
12 the afternoon session with selection of terms. I  
13 believe Shaconna has walked around the room and  
14 you all have selected from this jar just a paper,  
15 a little paper with either a two-year or a three-  
16 year term. For those that have not, can you  
17 please raise your hand, and I'll walk around.

18 And for Judith and Vaishali, I will be  
19 the proxy and do it for you right now. Judith,  
20 you have two-year, and Vaishali you have two-year  
21 as well, and we had one committee member who  
22 wasn't able to make the meeting today, John

1 McClay, so I'm going to do it for him as well.

2 So John McClay has two years, too.

3 So now we will go around the room to  
4 disclose how many -- what your term is for the  
5 remaining of -- either two or three years, and  
6 if you object to more than two years, if you have  
7 a three year and you think that you can only do  
8 two years, please let staff here at NQF know via  
9 email, that would be fine, or pull us aside and  
10 you can discuss with us then. So I guess we can  
11 start now with the two co-chairs. So Kathy's  
12 three. Three. Dan's three, okay. Now Matt?  
13 Two? Steve? Two. Scott is two as well. Rich  
14 is three, Rich Madonna. And can you just speak  
15 into the phone? I can't see you.

16 MEMBER RAMBASEK: Todd, three years.

17 MS. LUONG: Three years? Okay great.  
18 I didn't see a three.

19 MEMBER STEIN: Josh, three.

20 MS. LUONG: Josh, three.

21 MEMBER STEWART: Micky, three.

22 MEMBER BRADHAM: Tammy, three.

1 MEMBER GOLDBERG: Seth, three.

2 MEMBER SCHACHAT: Andy, three.

3 MEMBER YOUDE: Jackie, two.

4 MS. LUONG: So that concludes the  
5 selection of terms. Now I will hand it back to  
6 the Co-Chairs to start the discussion of 0655.

7 CO-CHAIR MERENSTEIN: So we're going  
8 to start it again with again, another--last  
9 otitis media with effusion, this is  
10 antihistamines or decongestants. You guys  
11 already spoke, do you have anything to add? All  
12 you guys are good? All right, so we'll go  
13 straight to Kathy and Todd.

14 CO-CHAIR YAREMCHUK: So once again,  
15 this is I'm going to say the last one of otitis  
16 media with effusion, and it's regarding  
17 antihistamines or decongestants, and I think  
18 we've talked about in terms of the evidence, it's  
19 the same background, very common situation for  
20 population. Previously, the 2004 guidelines, as  
21 well as the Cochrane review in 2011 looking at  
22 the use of antihistamines and decongestants for

1 treatment of serious otitis media.

2 So the majority of these physicians do  
3 the watchful waiting that we've talked about, and  
4 about 14 percent of physicians in otolaryngology  
5 prescribes antihistamines or decongestants for  
6 pediatric patients. And I'm only going to add  
7 that probably the majority of these  
8 antihistamines and decongestants are over the  
9 counter, and won't be prescription in nature.  
10 Anything?

11 CO-CHAIR MERENSTEIN: So again on the  
12 evidence, unless there's questions about the  
13 evidence for this measure.

14 MS. ROBINSON-ECTOR: Evidence is open  
15 for measure 0655, and for those on the phone,  
16 option 1 is high, 2 is moderate, 3 is low, and 4  
17 is insufficient evidence.

18 MS. LUONG: For those on the phone,  
19 can you please vote via email? Thanks. Just to  
20 confirm, do we have Vaishali and Judith back on  
21 line?

22 MEMBER LYNCH: Yes.

1                   MEMBER PATEL: I'm listening, but I  
2 missed the discussion, sorry.

3                   MS. LUONG: Oh okay, that's fine. You  
4 can just sit out for this, and then the  
5 discussion will continue with performance gap.  
6 Thank you.

7                   MS. ROBINSON-ECTOR: So all the votes  
8 are in. 10 voted high, 3 voted moderate, 1 voted  
9 low, and zero voted insufficient. So for  
10 evidence for measure 0655, the measure passes.

11                  CO-CHAIR MERENSTEIN: So for  
12 opportunity for improvement?

13                  CO-CHAIR YAREMCHUK: When it talks  
14 about opportunity for improvement, there were --  
15 I'm looking for the percent of providers that  
16 continued to use -- 14 percent of physicians in  
17 otolaryngology prescribed antihistamines and  
18 decongestants. So I'm going to say that that  
19 would be the opportunity in terms of decreasing  
20 that number.

21                  CO-CHAIR MERENSTEIN: Any questions  
22 about that before we vote on it? I'm sorry,



1 someone has a question? Yes, comments are fine.

2 DR. ROSENFELD: I would just say that  
3 what's not apparent, as necessarily as obvious  
4 with the antihistamines decongestants are the  
5 adverse events that you also get that are maybe a  
6 little more obvious with steroids. And before  
7 coming here, I just did a little literature  
8 search, found a bunch of articles about adverse  
9 events, and it's related to the sedating  
10 antihistamines in particular, and the  
11 decongestants.

12 One article in 2004 and 2005, they  
13 looked at 1,500 emergency department visits,  
14 including three deaths, most of which occurred  
15 from overdosing, giving inappropriate doses to  
16 young kids, and a number of other articles talk  
17 about all the sedating and soporific properties  
18 of these drugs. As Kathy said, most of them,  
19 about 60 percent in the new data we have seem to  
20 be the over-the counter, and we do have a CPT-2  
21 code that currently exists that allows tracking  
22 as to whether you prescribe or recommend these

1 drugs. So there is a code for it. Thanks.

2 CO-CHAIR MERENSTEIN: All right, we're  
3 going to vote on it now?

4 MS. ROBINSON-ECTOR: Voting for  
5 performance gap for measure 0655 is now open, and  
6 for those on the phone, option 1 is high, 2 is  
7 moderate, three is low and 4 is insufficient.  
8 All the votes are in. 27 percent voted high, 67  
9 percent voted moderate, 7 percent voted low, and  
10 zero voted insufficient. So for performance gap,  
11 measure 0655 passes.

12 CO-CHAIR MERENSTEIN: Reliability?

13 CO-CHAIR YAREMCHUK: Reliability is--  
14 this was done on paper charts, and so the data--  
15 reliability was tested 2008, 2009, 98 percent  
16 agreement for the numerator, 95 percent for the  
17 denominator, so a high reliability in terms of  
18 testing chart extraction for this.

19 CO-CHAIR MERENSTEIN: I have a  
20 question. When you say chart extraction, this is  
21 just in ENT doctors, or this is in all doctors?

22 CO-CHAIR YAREMCHUK: It said pediatric

1 networks, and so I would think it could be  
2 pediatricians, it could be pediatric  
3 otolaryngologists.

4 MS. JIN: So for the population that  
5 was included, it includes all qualifying  
6 providers that are able to report or report  
7 information on those measures--that measure.

8 CO-CHAIR MERENSTEIN: But what kind of  
9 doctors are those that are qualified?

10 MS. JIN: There's no--we weren't able  
11 to gather specifics because we randomly sampled  
12 the charts, so we didn't take a look at the exact  
13 providers that were providing the information.  
14 But they were from the two pediatric network  
15 groups.

16 CO-CHAIR MERENSTEIN: Any other  
17 questions or comments about that? Then I guess  
18 open for voting.

19 MS. ROBINSON-ECTOR: Voting for  
20 reliability for measure 0655 is open, and for  
21 those on the call, option 1 is high, 2 is  
22 moderate, 3 is low, and 4 is insufficient. All

1 the votes are in. 20 percent voted high, 80  
2 percent voted moderate, zero voted low and zero  
3 voted insufficient. So for reliability for  
4 measure 0655, the measure passes.

5 CO-CHAIR YAREMCHUK: Okay, so  
6 feasibility--okay. Validity in terms of this is,  
7 you know, discussion of the ability to find that  
8 it's important. There is exclusions for medical  
9 reasons that we've talked about previously  
10 regarding this. The data measures diagnosis and  
11 treatment, so validity for this, I would say is  
12 high.

13 CO-CHAIR MERENSTEIN: Do you want add  
14 anything? The question is, is this the same as  
15 the other two? Do we have to--we can use the  
16 same two votes as we did for validity and  
17 feasibility, or it's different? You have to  
18 speak in.

19 MEMBER RAMBASEK: I would tend to feel  
20 that way.

21 CO-CHAIR MERENSTEIN: Any other  
22 comments or questions before we vote on validity?

1 We talked a decent amount about this--paper  
2 issues.

3 DR. WINKLER: I guess the question I  
4 would ask is do you have concerns about the fact  
5 that many antihistamines are over the counter  
6 medications in terms of capturing the data?

7 CO-CHAIR YAREMCHUK: And I guess my  
8 response to that is that if you're looking at the  
9 chart, the person who's going to abstract it and  
10 look at it and say I recommend antihistamine or  
11 Claritin or Sudafed or something like that, and  
12 similarly if we do it electronically, if there's  
13 a CPT code and that's your recommendation, you'll  
14 capture it that way as well.

15 CO-CHAIR MERENSTEIN: I think we can  
16 open voting.

17 MS. ROBINSON-ECTOR: Voting is now  
18 open for validity for measure 0655, and for  
19 those on the phone, option 1 is high, 2 is  
20 moderate, 3 is low and 4 is insufficient. All  
21 the votes are in. 7 percent voted high, 93  
22 percent voted moderate, zero voted low and zero

1 voted insufficient. So for validity, measure  
2 0655 passes.

3 CO-CHAIR MERENSTEIN: So Reva is okay  
4 with us using feasibility and usability from the  
5 previous two votes, unless someone, Kathy or Todd  
6 or anyone else has an objection to that.

7 CO-CHAIR YAREMCHUK: Are there any  
8 other issues that are different than what you've  
9 already discussed for these measures compared to  
10 the others? That would be the issue.

11 MS. LUONG: So on the record, we are  
12 applying the same feasibility and usability  
13 voting from the previous measure onto this one,  
14 and now we will be voting on overall suitability  
15 for endorsement, for those on the phone.

16 MEMBER CARNAHAN: Didn't the  
17 antibiotic one have a high usability, and the  
18 steroid one have a low usability?

19 CO-CHAIR MERENSTEIN: We'll put it to  
20 vote.

21 MS. ROBINSON-ECTOR: Voting for  
22 overall suitability for endorsement for measure

1 0655 is now open, and for those on the call,  
2 option 1 is yes, and option 2 is no. All the  
3 votes are in and the voting is closed. 100  
4 percent voted yes, and zero percent voted no, so  
5 for recommendation for overall suitability for  
6 endorsement, measure 0655 passes.

7 CO-CHAIR MERENSTEIN: So we're going  
8 to switch now to get some new developers. Thank  
9 you. Just so you know, it's appropriate testing  
10 for pharyngitis. Start whenever you're ready.

11 MR. HAMLIN: Good afternoon, I'm Ben  
12 Hamlin, I'm the Director of Performance  
13 Measurement, NCQA. Is this better? Sorry. I'm  
14 Ben Hamlin, I'm the Director of Performance  
15 Measurement at NCQA.

16 DR. BARTON: And I'm Mary Barton,  
17 Vice-President for Performance Measurement.

18 MR. HAMLIN: So this measure is a  
19 health plan measure of percentage of children two  
20 to 18 years of age who are diagnosed with  
21 pharyngitis and dispensed an antibiotic, who then  
22 received a streptococcal test. So basically,

1 effectively looking for appropriate testing  
2 following a diagnosis and administration of the  
3 antibiotic for the measure.

4 The measure's been in HEDIS for  
5 several years. It was developed some time ago,  
6 and I believe there's a number of--there's some  
7 more recent performance data in your forms I  
8 believe, I don't know how much more you want us  
9 to go into now.

10 CO-CHAIR MERENSTEIN: Okay, this is  
11 mine, so for the evidence, both the IDSA and the  
12 American Heart Association guidelines recommend  
13 that a throat culture or a rapid test is done  
14 before treating. So the evidence to me is the  
15 biggest issue, the reason is because the American  
16 Academy of Family Physicians, the ACP and the CDC  
17 recommend, unless developers know differently, on  
18 a decision rule, where you get five points and if  
19 you have zero to one point, it's a virus, you  
20 don't do anything.

21 If it's five, you treat with an  
22 antibiotic without testing, and then if it's two,



1 three and four, you would follow these guidelines  
2 to do testing. So that is the only -- the major  
3 problem I have with the evidence, or the question  
4 I have with the guideline considering that  
5 there's other groups that don't recommend it. I  
6 don't know if Jackie has anything to add. Any  
7 other questions or discussions about the evidence  
8 behind actually doing this? Developers, you have  
9 anything with that?

10 MR. HAMLIN: I should have added one  
11 more thing, that it is an administrative claims-  
12 based measure, so many of the decisions that you  
13 were discussing are not able to be captured in  
14 claims.

15 MEMBER FRIEDMAN: I'm sorry, so the  
16 evidence shows that you should treat them this  
17 way or you shouldn't treat them this way?

18 CO-CHAIR MERENSTEIN: Well, that's the  
19 debate. The IDSA and the American Heart  
20 Association recommend not treating with  
21 antibiotics unless you have a positive quick  
22 strep or a positive culture. The other recommend

1 use a decision rule, where you get different  
2 points for different clinical characteristics,  
3 and if you have zero to one, then you say it's a  
4 virus; you don't do anything.

5 If you get two, three or four, then  
6 you would follow this guideline and do the  
7 testing, and if you get five you just  
8 automatically treat without testing. And so I do  
9 think you get that from the administrative data.  
10 You would get if they were treated with  
11 antibiotic and diagnosed with pharyngitis without  
12 testing. You would get that from this data set.

13 MR. HAMLIN: Yes, you would get the  
14 diagnosis on the antibiotic, you would not be  
15 able to attract the decision, the scoring you  
16 mentioned through the --

17 CO-CHAIR MERENSTEIN: Exactly, yes,  
18 but you would -- that's my point. You would get  
19 -- they would be considered doing it incorrectly.  
20 If the physician was following the CDC Academy of  
21 Family Physicians and the patient got five  
22 points, they would treat them with antibiotic

1 without testing, and then guideline would say  
2 they're doing it incorrectly, right? That's  
3 correct.

4 MEMBER MADONNA: Just for  
5 clarification, so the order here is present with  
6 pharyngitis, strep test, antibiotic if the strep  
7 test is positive, correct?

8 CO-CHAIR MERENSTEIN: Yes, or a  
9 culture which--

10 MEMBER MADONNA: Yes, either way.  
11 Then why is it written the way it's written? Why  
12 doesn't it say the percentage of children blah  
13 blah blah who are diagnosed with pharyngitis  
14 receive the group A strep test for the episode,  
15 and then were dispensed an antibiotic if that  
16 test were positive. Isn't that what we're  
17 getting at?

18 MR. HAMLIN: So the order is a little  
19 different, the order is actually pharyngitis,  
20 antibiotic, strep test in the claims, because we  
21 do not -- we're not looking for the result of the  
22 test itself, we're just looking at if the

1 antibiotic --

2 MEMBER MADONNA: Okay, so it's --

3 MR. HAMLIN: -- was dispensed, the  
4 test was performed.

5 MEMBER MADONNA: Okay. That's  
6 actually an important point. They don't get that  
7 -- we'll talk about that later too. That's not  
8 an evidence issue, but yes.

9 MEMBER RAMBASEK: Do we have any  
10 evidence of what percentage of children with  
11 pharyngitis are going to have five points?  
12 Because that might be an unusual presentation and  
13 if it's only three percent, it might not affect  
14 it as much as we would worry.

15 MR. HAMLIN: We're looking for it  
16 right now.

17 MEMBER FRIEDMAN: So even if it's a  
18 small number, I still don't want to be dinged for  
19 doing what I think is best clinical practice. If  
20 it's one percent of the time, you're going to  
21 ding me for doing what I think is best practice  
22 for this patient? I'm just --

1 CO-CHAIR MERENSTEIN: It's not just  
2 what you think, what's been recommended by a  
3 major group, so.

4 MEMBER FRIEDMAN: Can you elaborate on  
5 that, whether you agree with what Dan's saying or  
6 disagree or --

7 DR. BARTON: What is a little bit  
8 ironic is that the purpose of the AFP and CDC  
9 decision rule is to make sure that antibiotics  
10 are not being used in children who should not be  
11 treated with antibiotics, right? That's the  
12 reason for defining the decision rule with five  
13 gradations, is to say reserve for the people with  
14 the highest prior probability of strep  
15 pharyngitis, reserve those people to get the  
16 antibiotics.

17 Our measure is coming at it from sort  
18 of a perpendicular direction, but also has the  
19 same goal, which is to make sure that children  
20 are not being treated with antibiotics  
21 unnecessarily. I think from the point of view of  
22 a health plan measure, it's often the case that a

1 claims based measure is an approximation of what  
2 a clinical guideline in a physician's office  
3 might say.

4 And that has been something that has  
5 worked very well over the last 25 years to hold  
6 health plans accountable for providing good  
7 quality care to their members, and it's not  
8 always something that has been, as you say--maybe  
9 it was not you, Dr. Friedman, someone else who  
10 used the word dinged, you know, so it's not  
11 necessarily the intention of NCQA to say that the  
12 health plan should be assessing each particular  
13 case necessarily, as though there was a clear  
14 line of right and wrong.

15 This is, again, there are many, many  
16 children who present with fever and sore throat.  
17 And so that's what this measure pulls on, are  
18 those claims in order to say did you mostly do  
19 the right thing at the right time, which is test  
20 for, you know, not four out of five necessarily,  
21 I don't know if the distribution of kids is in  
22 the decision rule, but the majority of kids that

1       you did the right thing and tested before  
2       presumptively treating.

3               MEMBER FRIEDMAN:   Could you get around  
4       that by doing what they did for the last few  
5       measures and say avoidance of inappropriate use,  
6       and make it an overuse measure?   So the  
7       percentage of children who are diagnosed with  
8       pharyngitis who didn't need antibiotics and were  
9       not given antibiotics.   So that's basically what  
10      you're trying to do, is avoid overuse of  
11      antibiotics, is that correct?

12             DR. BARTON:   Yes, but I'm not exactly  
13      sure how that -- how this measure -- how  
14      inverting or emphasizing one different part of  
15      the numerator or denominator would solve the  
16      problem that you're talking about, so I might  
17      need a little more coaching on that.

18             MEMBER SCHACHAT:   I just interpreted  
19      this as not necessarily a measure trying to avoid  
20      antibiotic overuse, but a measure trying to  
21      encourage strep testing, which presumably would  
22      reduce inappropriate use, but I'm okay with the

1 whole thing. I think the concern about being  
2 dinged relates to how this gets used, because  
3 this gets used different ways by different  
4 people. So like Medicare, they'll just pay you  
5 more or less if you report, and it doesn't matter  
6 what your grade is, as long as you're reporting.  
7 So you don't get dinged there.

8           Some other group may be looking at  
9 your quality performance, and you might  
10 effectively be being dinged, but then if the  
11 number of -- five out of five kids is similar  
12 across all people, everyone's getting dinged  
13 equally. Probably though, different providers  
14 have different case mix; that is, maybe doctors  
15 in the ER have seen more five out of fives and  
16 they get dinged more than family practice people  
17 in a simple office; I don't know. So it would be  
18 nice if it could account for that.

19           CO-CHAIR MERENSTEIN: Any other  
20 questions or comments? I'm sorry, I don't have  
21 much more information to--

22           MEMBER YOUDE: I have a question on



1 the denominator statement. So looking at it, it  
2 looks like we're including children that carry  
3 strep, anytime you test those kids, it's going to  
4 be positive. So why not exclude them?

5 MR. HAMLIN: Again, we're not looking  
6 for the actual performance, the actual result of  
7 the test, we're just looking that the testing was  
8 performed, and there is probably a case where,  
9 you know, to be made for not testing a certain  
10 subset of children, but I think it probably  
11 increases more noise in the measure at the health  
12 claims level than it probably does solve the  
13 problem of children carrying strep.

14 MEMBER YOUDE: I guess when I look at  
15 it, if I know my patient has strep, and trust me,  
16 I'm speaking as a non-ENT here, so if I'm using  
17 different words, I apologize. But if I know my  
18 patient has strep, I have no reason to test them.  
19 So wouldn't I be increasing the cost of  
20 healthcare by testing kids I know don't need  
21 testing?

22 MEMBER LYNCH: How often does that

1       happen, though?

2                   CO-CHAIR YAREMCHUK:   And I'm going to  
3       say that's probably the question.   I mean the  
4       incidence of carriers I think is very low, would  
5       you say single digits?   So very, very low, and  
6       I'm just looking at what the mean is in the  
7       Medicaid population, it's like 66 percent of  
8       people doing it, and for the commercial it's 79  
9       percent, so you   gap is, depending on--20 to 30  
10      percent, and it's clearly not   what the percent  
11      of carriers are.

12                  MR. HAMLIN:   And I also want to add to  
13      that that the end there is health plans, not  
14      patients when you're talking, so there's 400  
15      plans, not 400   patients in those.

16                  CO-CHAIR MERENSTEIN:   So I guess we  
17      should vote on the evidence and going forward  
18      with this.

19                  MS. ROBINSON-ECTOR:   Voting for  
20      evidence for measure 0002 is now open, and for  
21      those on the phone, option 1 is high, 2 is  
22      moderate, 3 is low, and 4 is insufficient

1 evidence. All the votes are in. 13 percent  
2 voted high, 53 percent voted moderate, 27 percent  
3 voted low, and 7 percent voted insufficient  
4 evidence. So for -- oh yes, so the measure  
5 passes.

6 CO-CHAIR MERENSTEIN: We're going to  
7 go on for opportunity for improvement. Kathy  
8 already took what I was going to say. One, so  
9 there is differences between the Medicaid and the  
10 commercial rates. The rates still aren't very  
11 high. They report that the level of performance  
12 indicates the clinical guidelines addressing  
13 testing for our group A strep infection prior to  
14 treating pharyngitis with antibiotic are not  
15 followed in about 25 percent of cases on average,  
16 and this is likely an underestimate.

17 So there's no question that there's  
18 overuse of antibiotics and inappropriate usage,  
19 so I think that was a huge indicator. If we  
20 think this is a good measure to measure it is the  
21 question, but there's no question there's room  
22 for improvement I think. Jackie, anything to

1 add?

2 MEMBER RAMBASEK: Just clarification.  
3 You said 25 percent of patients who present with  
4 pharyngitis get testing?

5 CO-CHAIR MERENSTEIN: No, no. 25  
6 percent are treated with antibiotic -- are not --  
7 wait, let me -- prior to treating pharyngitis  
8 with antibiotic are not followed, so 25 percent  
9 of the time, they're just treating them without  
10 testing. Is that--yes, so theoretically, they  
11 have a clinical guideline you have to score a  
12 five, or it could just be they're just treating  
13 people with viral pharyngitis.

14 MEMBER RAMBASEK: But we didn't  
15 clarify what that number is yet, did we?

16 CO-CHAIR MERENSTEIN: No, we don't know  
17 what that five is. It's definitely not 25  
18 percent though, you would think.

19 MEMBER RAMBASEK: Probably five?

20 CO-CHAIR MERENSTEIN: Yes, that would  
21 be my guess clinically, but that's just an  
22 anecdotal clinical guess. Any questions about

1 the room for improvement? We can vote.

2 MS. ROBINSON-ECTOR: Voting for  
3 performance gap for measure 0002 is now open, and  
4 for those on the line, option 1 is high, 2 is  
5 moderate, 3 is low and 4 is insufficient. All  
6 the votes are in. 40 percent voted high, 47  
7 percent voted moderate, 13 percent voted low, and  
8 zero voted insufficient, so performance gap for  
9 measure 0002, measure passes.

10 CO-CHAIR MERENSTEIN: So going on to  
11 reliability. This is health plan and  
12 administrative data claims, Jackie is going to  
13 talk about some of the exclusion criteria and the  
14 questions about those. The one thing it was  
15 clear is the data were very consistent over time,  
16 and it didn't really change for the last 10-year  
17 data, so it looks like the rates, they're getting  
18 what they're recording. You have anything to add  
19 about that?

20 MEMBER YOUDE: I just had a few  
21 questions about the exclusions. One, and we may  
22 have touched on it earlier, so what about kids

1 who get the rapid strep test, but we don't wait  
2 for the results, we just--we give them  
3 antibiotics regardless. How does that work into  
4 it, and then I've already brought up the one  
5 about those who carry strep.

6 MR. HAMLIN: So in the first scenario,  
7 the patient who received the antibiotic and was  
8 tested will meet the measure criteria. I should  
9 also mention there is a separate measure that's  
10 looking at using antibiotics in children with  
11 upper respiratory infections. That is a separate  
12 HEDIS measure, and that is getting more at the  
13 overuse of the antibiotic issue. So -- and  
14 again, we know of the carrier issue, but it's--

15 MEMBER YOUDE: Okay, so I guess this  
16 goes back to our original discussion that this is  
17 truly just about testing, and it's not about the  
18 result of the test, so if this kid had a virus,  
19 and we tested him anyway because hey, we were on  
20 like that two or three number scale that we had  
21 just talked about, turns out kid has a virus, but  
22 we gave him antibiotics just in case, this person

1 would still be okay because they did the test?

2 MR. HAMLIN: We hope it would lead  
3 towards the next time do better rule, and--

4 DR. BARTON: Or you call the family  
5 and tell them the test was negative and stop  
6 taking the meds.

7 CO-CHAIR MERENSTEIN: Yes, but that's  
8 the major problem, that we just don't know that.  
9 This test doesn't tell us that. It doesn't tell  
10 us.

11 MEMBER STEIN: Can you comment on, you  
12 know, one doc -- it's possible one doc codes for  
13 the pharyngitis, and another doc codes for the --  
14 prescribes the antibiotics, the data sources  
15 you're using, is that linking the same doc, or  
16 could someone code for one of these and then get  
17 dinged because a different provider is doing the  
18 other part?

19 MR. HAMLIN: So the claims that we are  
20 using are linked to the episode, so whenever the  
21 patient appears on the claims record for that one  
22 patient, regardless of which provider actually

1 submitted the claim around that date, those  
2 would be linked together by the health plan  
3 itself, so--

4 MEMBER STEIN: But in real practice,  
5 they may not be linked, right?

6 MR. HAMLIN: We don't get this at the  
7 practice level, the plans are responsible for  
8 summarizing the claims around each episode to  
9 define the episode of care, and they submit the  
10 final aggregate to us, so we don't have that  
11 level of measurement at the actual practice level  
12 of their behaviors. It's just -- it's a plan  
13 level measure, not the practice level measure.

14 CO-CHAIR MERENSTEIN: Any other  
15 questions about this, about the reliability? And  
16 you had some questions about the codes, right?

17 MEMBER YOUDE: I did have a question  
18 about the codes. So I am not an ENT, obviously,  
19 and so when I got this lovely measure about  
20 pharyngitis, I did the first thing I knew what to  
21 do, and that was go to my laryngologist friends,  
22 and I had them take a look at the codes because



1 the codes are not something that I'm familiar  
2 with, and they had brought up that at least three  
3 codes that they looked at on first glance were  
4 missing.

5 Had to do with acute pharyngitis and  
6 another one, and there's another one, but it was  
7 at least three known codes that are commonly used  
8 were missing. How did we come up with the codes,  
9 where do they come from, and do you think that  
10 there are potentially any missing, or is this an  
11 exhaustive list?

12 MR. HAMLIN: So the codes are  
13 initially developed when we test the measures, we  
14 look at the series of diagnoses and then we have  
15 several modes of updating those code lists every  
16 year, and we have a policy clarification support  
17 system where people provide us -- suggest missing  
18 codes.

19 Through implementation of the health  
20 plans, they can suggest missing diagnoses that we  
21 might want to code, and then there's a regular --  
22 there's several expert reviews with a coding

1 panel and a clinical panel that review the codes  
2 that need for each of these. And so I'm not  
3 familiar with the codes you mentioned and why  
4 they're not necessarily included, but it's  
5 usually sort of -- it's part of the process, they  
6 either were not found to be reliable enough  
7 across the different health plans, or they may be  
8 missing for some other reason because of the way  
9 the coding practices are.

10 CO-CHAIR MERENSTEIN: Any other  
11 questions or comments before we vote on this?  
12 Open voting.

13 MS. ROBINSON-ECTOR: Voting for  
14 reliability for measure 0002 is now open, and for  
15 those on the line, option 1 is high, 2 is  
16 moderate, 3 is low and 4 is insufficient. All  
17 the votes are now in. 7 percent voted high, 73  
18 percent voted moderate, 13 percent voted low, and  
19 7 percent voted insufficient. For reliability,  
20 the measure passes.

21 CO-CHAIR MERENSTEIN: So we move on to  
22 validity. And so I had some previous questions,

1 I have some more, but I think for validity, it's  
2 definitely getting at what they want to get out  
3 of questions if that's a big thing, but what they  
4 did is they look at five different plans,  
5 geographically varied, and did medical record  
6 extraction, and they found that there was  
7 agreement 86 percent of the time, so I think  
8 that's a pretty high agreement.

9 And if Jackie has anything else to add  
10 about that? So I think that with the -- they're  
11 answering the question they want answered, we've  
12 got to decide if that's the feasible question,  
13 but -- and for validity, I think they are. Any  
14 questions about that? All right, we're going to  
15 vote.

16 MS. ROBINSON-ECTOR: Voting for  
17 validity is now open for measure 0002, and for  
18 those on the line, option 1 is high, 2 is  
19 moderate, 3 is low, and 4 is insufficient. So it  
20 looks like we're missing one vote from someone in  
21 the room, so if you all could re-vote, please.  
22 Still waiting on one person. Thank you. 27

1 percent voted high, 73 percent voted moderate,  
2 zero voted low and zero voted insufficient. So  
3 for validity for measure 0002, the measure  
4 passes.

5 CO-CHAIR MERENSTEIN: So maybe I  
6 misinterpreted, I just got whispered, but I was  
7 going to talk about the feasibility, and you're  
8 saying how easy it is at the clinic. So it's  
9 easy to do an admin thing, I guess since maybe I  
10 missed it I'll add it now. My main worry is--the  
11 whole point of this testing is to make sure  
12 people use antibiotics appropriately.

13 And I guess I'm not convinced that the  
14 way you're doing it is -- that's answering the  
15 question, all you're really getting is for people  
16 to make sure they order the quick strep or the  
17 strep culture, and then they can do whatever they  
18 want, and they're considered appropriate care.

19 And to me it seems like today, just like you were  
20 talking about at Kaiser and other EHRs, there's a  
21 better way to get the data we want to get  
22 appropriate use of antibiotics. But I think I

1 brought that up at the wrong place.

2 CO-CHAIR YAREMCHUK: I agree, and I  
3 think we've touched on that throughout the  
4 discussions, but I agree entirely.

5 DR. WINKLER: I think that's the  
6 appropriate--usability and use is probably the  
7 appropriate place to talk about that. So  
8 feasibility is really about the data source, how  
9 the data is generated and transmitted and  
10 implemented.

11 CO-CHAIR MERENSTEIN: So that, I mean  
12 I think it's -- there's no question it's  
13 generated by the plans, it's administrative data,  
14 it's been very consistent over time, there's  
15 really no question about that I think. So I  
16 guess we can vote on that. Oh there is a  
17 question, I'm sorry. Josh?

18 MEMBER STEIN: Is it showing any  
19 improvement over time?

20 CO-CHAIR MERENSTEIN: It is a slight  
21 --let me pull it up.

22 MEMBER YOUDE: If we're looking at the

1 commercial rates and Medicaid rates, is that what  
2 you're pulling up?

3 CO-CHAIR MERENSTEIN: Yes.

4 MEMBER YOUDE: If we're looking at the  
5 mean, it stayed within about -- it stayed within  
6 one percent for the commercial rate. If we're  
7 looking at Medicaid, we've stayed within two  
8 percent for the mean since 2012 to 2014 in both  
9 types of insurance. So this may relate back to  
10 our earlier conversation about, you know, we have  
11 a process metric, we keep it in place because it  
12 holds the gains, but my question about this then  
13 comes to what's the expectation?

14 CO-CHAIR MERENSTEIN: I guess we have  
15 to vote on feasibility, and that's a usability  
16 question I guess. So let's just vote on this,  
17 and then we'll talk briefly.

18 MS. ROBINSON-ECTOR: Voting for  
19 feasibility for measure 0002 is now open, and for  
20 those on the line, option 1 is high, 2 is  
21 moderate, 3 is low and 4 is insufficient. And  
22 we're still waiting for those on the phone to

1 vote.

2 MEMBER LYNCH: I voted.

3 MS. ROBINSON-ECTOR: Thank you.

4 Great, so all the votes are in. 33 percent voted  
5 high, 67 percent voted moderate, zero voted low  
6 and zero voted insufficient. So for feasibility  
7 for measure 0002, the measure passes.

8 CO-CHAIR MERENSTEIN: So usability,  
9 you heard my issues, and Jackie I don't know if  
10 you want to repeat anything, but you heard  
11 Jackie's issues too, with the problem with that.

12 DR. WINKLER: One question I would ask  
13 the developers, since they are the implementers  
14 of this measure, a question that's coming up on  
15 these measures that have been around for a while  
16 and have been used, particularly since we have  
17 data over time, is how are you assessing the  
18 impact of the measure? What do we know is really  
19 the benefit of this measure being in place in  
20 health plans? How--are you making any  
21 assessments of that impact in terms of what's  
22 happening in the quality sphere? Is it making a

1 difference, if so, how?

2 DR. BARTON: Our committee on  
3 performance measurement has shown an interest in  
4 having such information, and we agree. We have  
5 been trying to understand how, of course, the  
6 span of 70 plus measures that we use in HEDIS so  
7 that we cannot necessarily commit a large amount  
8 of resources to each one each year, but we are  
9 trying, in a rotating fashion, to gather tales  
10 from the field to help both our committees that  
11 volunteer their time to help us keep these  
12 measures up to date, in the loop. I think that  
13 there's no question that measures that have, for  
14 example, found their way into the Stars program  
15 have had a rapid acceleration of their  
16 improvement, and this is not one of those  
17 measures.

18 However, there are currently efforts  
19 afoot, including collaboration between NCQA and  
20 NQF to work on the issue of antibiotic overuse,  
21 and so I think that as we think about health  
22 plans accountability, which is only one part of



1 course of the entire issue of antibiotic overuse,  
2 that this is a valuable tool for health plans to  
3 use.

4 And we also have in the upcoming  
5 measures that will be used in the quality ratings  
6 system for the marketplace plans, which of course  
7 won't be public for another year or two, this  
8 measure is included in that group. It will be  
9 interesting to see how it plays out in that  
10 setting and additionally in Medicaid over the  
11 course of the next few years as the Medicaid and  
12 the marketplace settles out.

13 CO-CHAIR YAREMCHUK: I guess my only  
14 question is this really doesn't measure  
15 antibiotics, because you don't know if it was  
16 prescribed or not prescribed. You're assuming  
17 that if it comes back negative, they won't get a  
18 prescription, but you really don't know that. So  
19 the question of over-use and under-use is  
20 hypothetical, I'm going to say. And we were just  
21 talking that in terms of the change as far as  
22 measurement, it hasn't budged a whole lot in a

1 couple years.

2 DR. BARTON: I'm not sure, but I think  
3 measure 002 means that it was first endorsed by  
4 NQF a very long time ago.

5 MR. HAMLIN: Again, at that paired  
6 measure, it actually does look at antibiotic  
7 overuse as a very similar slow rate of  
8 improvement. So I think it probably is something  
9 to do with the area of antibiotic use.

10 MEMBER YOUDE: Is there--like when I  
11 look at a process measure, and I'm like okay,  
12 what do I need to do, when do I need to do it,  
13 that type of thing, what am I being held  
14 accountable for? When I look at this, to me it  
15 says you need to test. You need to do more tests  
16 and test, test, test, test, test.

17 Is there any concern that we could be  
18 increasing health care costs because we're doing  
19 more and more and more testing? Especially given  
20 the evidence seems to conflict with practice  
21 patterns where on that decision point scale, if  
22 somebody's telling me to test and I'm going to be

1 reimbursed on tests, I'm going to test. But it  
2 might not be appropriate testing.

3 MR. HAMLIN: The cost of this  
4 particular test pales in comparison to the cost  
5 of the antibiotics that are being dispensed, so I  
6 think --

7 CO-CHAIR MERENSTEIN: I didn't hear  
8 you.

9 MR. HAMLIN: I said, the cost of the  
10 test itself is actually -- it pales in  
11 comparison to the cost of the antibiotics that  
12 are even being dispensed, so I think that we need  
13 to think of it as low cost test that is not going  
14 to be driving over-utilization. And again, it in  
15 the context of the thinking about prescribing  
16 antibiotics in the first place for these kinds of  
17 ---

18 CO-CHAIR MERENSTEIN: Although I would  
19 argue that because it's so inexpensive that now  
20 you just told every clinic just test before the  
21 doctor walks in the room, and then you've got  
22 your answer because it's not going to cost you a

1 lot of money anyway, just test and then the  
2 doctor, whenever the doctor does, the doctor's  
3 fine.

4 MR. HAMLIN: But if you've already  
5 prescribed the antibiotics, then you can to think  
6 about the long-term consequences of antibiotic  
7 overuse. So it's the chicken and egg there in  
8 that argument.

9 CO-CHAIR MERENSTEIN: Well yes, I'm  
10 not arguing you should give the antibiotics, I'm  
11 saying that you still would look on the  
12 measurement if you tested the quick strep before  
13 I even walked in the room.

14 MR. HAMLIN: Well, the measure only  
15 takes in if you've been dispensing antibiotics in  
16 the first place. So you would have already had  
17 to administer the antibiotic and then give for  
18 the test, and then you'd be in compliance for  
19 this particular measure, so.

20 DR. BARTON: You're right.

21 MR. HAMLIN: You don't need to  
22 convince a doctor to stop antibiotics, you just

1       need to test, that's the point.

2               DR. BARTON: No, no, you're right that  
3       the scenario you described would result in  
4       perfect performance on the measure, but it would  
5       be an extremely inefficient way to do that.  
6       Because you'd end up testing a whole lot of  
7       people you would never even consider giving  
8       antibiotics to.

9               CO-CHAIR MERENSTEIN: Any other  
10       questions or comments about this? I guess we'll  
11       vote on usability.

12              MS. ROBINSON-ECTOR: Voting for  
13       usability and use for measure 0002 is now open  
14       and for those on the call, option 1 is high, 2 is  
15       moderate, 3 is low, and 4 is insufficient  
16       information. All the votes are in. Zero voted  
17       high, 53 percent voted moderate, 40 percent voted  
18       low, and 7 percent voted insufficient. So, this  
19       would fall in the gray zone.

20              DR. WINKLER: This is a consensus not  
21       reached decision, but this again is not a binding  
22       one in terms of moving forward. So I guess the

1 question is based on this, does this prompt any  
2 further discussion from this committee?  
3 Certainly, we will anticipate feedback from  
4 public comment, but also you'll factor in your  
5 evaluation of the criteria as you go to your next  
6 vote on suitability for endorsement.

7 CO-CHAIR MERENSTEIN: I guess maybe  
8 I've already said this, I think it is a really  
9 important measure if they can do it correctly,  
10 and I just don't think it is done correctly. So  
11 that would be my vote for the next one too. So I  
12 don't want the take-home message to be it's a  
13 bad think to check. I think it is a really  
14 important thing to check, but I'm just not sure  
15 it's being done correctly.

16 MEMBER FRIEDMAN: Can you make some  
17 recommendations on how you would make -- and I  
18 already addressed this myself, that I don't think  
19 -- I think it could be stated differently as  
20 well. So how would you state it to where it  
21 would be done better?

22 CO-CHAIR MERENSTEIN: I think you need

1 a way, a measurement that says when the test is  
2 positive, is an antibiotic given and when the  
3 test is negative, is an antibiotic not given?  
4 Somehow you need to get that data. Because  
5 there's not that many people that argue a  
6 positive test doesn't need an antibiotic.

7 MEMBER RAMBASEK: Are people going to  
8 come back and say they can't collect that data?  
9 Or is that going to be, if they write that way,  
10 is that going to be the argument pushback, it's  
11 not usable because we're not going to be able to  
12 get the data on the test result?

13 MR. HAMLIN: The test results are not  
14 available, so that's --

15 CO-CHAIR MERENSTEIN: You can't get  
16 that from laboratories?

17 MR. HAMLIN: Not the direct laboratory  
18 feed, no. We get the paid claim for the testing  
19 form and the result itself, the numeric result,  
20 is not available in that data.

21 CO-CHAIR MERENSTEIN: Even in a place  
22 like Kaiser Data?

1 DR. BARTON: If we were only examining  
2 Kaiser, we would be in a very different  
3 situation.

4 CO-CHAIR YAREMCHUK: I have a question  
5 about that. Because for diabetes, for example,  
6 hemoglobin A1c, you actually have to get a level,  
7 LBL, you actually have to get a level. So,  
8 there's got to be some way that you get the  
9 levels to know if the patient is in or out on  
10 those things. And so for this, this would be a  
11 positive or negative. So I guess I'm wondering  
12 when we talk about that, you're talking about  
13 paid claims versus results but for these other  
14 measures, you get results.

15 DR. BARTON: That's an excellent  
16 point. We do require a certain number of  
17 measures that require chart review. So, anything  
18 that requires a test result or an evaluation  
19 result, like blood pressure result, requires  
20 actual chart review. And health plans then  
21 sample from among their eligible patients to  
22 report a rate. The advantages and disadvantages



1 of an administrative claims measure, health plans  
2 are extraordinarily loathe to add another chart  
3 review measure to what they say is a considerable  
4 burden of chart review that they do each year for  
5 HEDIS. When we have an administrative claims  
6 measure, we feel confident that it can examine  
7 performance, not just in a sample of patients,  
8 but in all the eligible patients. So there are  
9 pros and cons to each approach, but we are  
10 absolutely limited in the number of chart review  
11 measures that we can require plans to voluntarily  
12 participate in, and this has not been the public  
13 comment that we've had. The expert panels that  
14 we've convened have not indicated that this  
15 measure is one that would be so improved by chart  
16 review that they would think it worth doing that.  
17 At least that has historically been their point  
18 of view.

19 MEMBER RAMBASEK: So basically we said  
20 it's not very usable and then we suggested a  
21 change and you're saying the health plans would  
22 say our change is not very usable?

1                   MEMBER STEIN: Can you explain a  
2 little more? If it's a health plan, shouldn't  
3 they have access to the lab results?

4                   MR. HAMLIN: Sometimes yes and  
5 sometimes no. Reliably across all the different  
6 health plans that report, no. They do not always  
7 have access to the labs. Different designs  
8 obviously have much more access to that  
9 indiscrete data than others, but usually when  
10 they go and do the medical record review, they  
11 have to the paper medical record and look up the  
12 411 charts to find those results. And diabetes  
13 is 528 so, it's a considerable number of records  
14 that they have to actually go in and look in the  
15 actual record itself for the lab result, not from  
16 a laboratory feed or from some kind of electronic  
17 system.

18                  CO-CHAIR MERENSTEIN: Any other  
19 comments? I guess we'll do the final vote.

20                  MS. ROBINSON-ECTOR: So the vote for  
21 overall suitability for endorsement for measure  
22 0002 is now open and for those on the line,

1 option 1 is yes, and option 2 is no. All the  
2 votes are in. 33 percent voted yes and 67  
3 percent voted no. So for recommendation for  
4 overall suitability for endorsement, measure 0002  
5 does not pass.

6 DR. WINKLER: I'll just say that this  
7 is a measure that's been around a long time.  
8 It's being used out there. I can anticipate a  
9 significant number of comments during the public  
10 comment period, and so we will revisit this issue  
11 more than likely, based on that.

12 CO-CHAIR MERENSTEIN: Do you have a  
13 comment?

14 MEMBER SCHACHAT: Is there a process  
15 for revisits? I mean if you get a bunch of  
16 people complaining, is there going to be another  
17 meeting and another vote?

18 DR. WINKLER: Not necessarily another  
19 meeting. That's the point of public comment is  
20 feedback. So, you will reconvene by conference  
21 call in August to review the comments and I'm  
22 just predicting that this is likely to prompt

1 some comments and that would then be on your  
2 agenda for revisit.

3 CO-CHAIR MERENSTEIN: Todd?

4 MEMBER RAMBASEK: So, I guess the  
5 basic push-back that is being given is that  
6 people will order the test and it will be  
7 negative, and they'll prescribe the antibiotics  
8 anyway is what people are worried about? Do we  
9 have an idea of how often that actually happens,  
10 that people are using the test as just, you know,  
11 and not respecting it, not listening to it?

12 CO-CHAIR MERENSTEIN: Happens every  
13 day in my clinic. I don't know about other  
14 clinics but it happens every single day in my  
15 clinic. It's ordered before you get there. So I  
16 would say that sometimes it's ordered when I  
17 think it's a virus and should never have been  
18 ordered, and then other people are going to do  
19 antibiotics no matter what they order, so they  
20 don't care what the tests are. They say, you  
21 know, looks positive to me, I'm going to treat  
22 it. So, I imagine it's going on.

1                   MEMBER RAMBASEK: So, I have anxiety  
2 about that. Is it being ordered by like a  
3 resident or fellow or by a non-M.D.?

4                   CO-CHAIR MERENSTEIN: By the  
5 administration. The nurse orders it before you  
6 even get there. The nurse, you know--

7                   MEMBER RAMBASEK: Okay, so, the nurses  
8 are allowed to order tests?

9                   CO-CHAIR MERENSTEIN: Yes, the nurse  
10 is already doing the test before you get there,  
11 yes. Considering all the tests they order,  
12 urine, x-rays, things like that, I'd say this is  
13 number one that I would say is a mistake.

14                  MEMBER RAMBASEK: Are there issues  
15 about having the test paid for if it's ordered  
16 and you found it wasn't needed, you're supposed  
17 to cancel the charge? How does that work?

18                  CO-CHAIR MERENSTEIN: Maybe someone  
19 else can answer that, I don't know. I mean, I  
20 think they don't order if someone doesn't say  
21 they have a sore throat or a runny nose or some  
22 kind of respiratory---

1                   MEMBER RAMBASEK: I just work in a  
2 different sphere. All my patients have Medicare  
3 and I don't have nurses. And so, if someone  
4 orders a test that I decided I didn't need, it's  
5 a big problem, and all kinds of bells go off and  
6 we have to discuss, how do you even order that,  
7 you shouldn't have pressed the button and it's  
8 complicated for us to cancel the charge when we  
9 cancel the charge. But when the charge is  
10 cancelled, that raises red flags about cancelled  
11 charges because--anyway.

12                  CO-CHAIR MERENSTEIN: So unless there  
13 are any other comments, we'll go on to some  
14 ophthalmology issues.

15                  MEMBER FRIEDMAN: I just have one more  
16 quick question for Reva. So, with the public  
17 commenting period, how often does that change the  
18 voting?

19                  DR. WINKLER: I wouldn't say often,  
20 but we will ask you to very seriously consider  
21 the comments that you get. But it can and has  
22 changed.

1 MS. LUONG: And to add on to that, if  
2 you have any specific requests for the measure  
3 developer, either now or for the June 22 call or  
4 for the post-comment call in August, please let  
5 us know and we can work with the developer to  
6 come up with a response, if possible.

7 DR. WINKLER: Okay, and if you didn't  
8 think we had a lot of information for you, I'm  
9 going to add a little more. In the eye care  
10 measures, among the group that we're going to be  
11 reviewing this afternoon and tomorrow morning, we  
12 will now be seeing a new animal called a true  
13 eMeasure, and I want to be sure that everybody's  
14 clear what we mean by that. eMeasures are a type  
15 of measure that are very specifically defined,  
16 that use electronic health records. But the  
17 eMeasure is specified in a very specific fashion.  
18 It is not just using--querying your EHR and  
19 getting the data. That is using your medical  
20 record as you would a paper medical record, if it  
21 happens to be electronic, that's nice.

22 An eMeasure is very specifically

1 written and specified in a format that's an  
2 industry standard. It's called HQMF. It also  
3 uses very specific definitions around the quality  
4 data model, and it also has the value sets. In  
5 other words, the acceptable values for each data  
6 element through the National Library of  
7 Medicine's Value Set Authority Center. So, we  
8 aren't talking just measures that can be done in  
9 your EHR, we're talking about measures that are  
10 specified in a very specific fashion. And so  
11 those HQMF specifications have been included with  
12 the submission for those measures that have an  
13 EHR version as well as say perhaps a registry and  
14 maybe even a claims version. So, we're seeing  
15 sort of a mixture of both.

16 MEMBER SCHACHAT: So, the EHR vendor  
17 would have to opt to insert that electronic  
18 structure into the electronic medical record for  
19 it to work?

20 DR. WINKLER: Perhaps. There needs to  
21 be some ability of the EHR to utilize the  
22 appropriate HQMF specifications. So go to the



1 next one. I just want to show you, if you  
2 haven't seen them, these are what they look like.  
3 This is the output for the measure authoring tool  
4 which is a sort of facilitated way of creating  
5 these HQMF specs. This is the human readable  
6 file. If you open a couple of the other files,  
7 you'll find it's totally computer language and I  
8 hope you enjoyed it. So move on to the next one.  
9 So if you go through the human readable side, you  
10 see all of the different elements of the data  
11 elements--and go on to the next--and there were  
12 some--next one. Here again are the QDM data  
13 elements and the last one are the value sets.  
14 So, I just wanted you to be aware that when we  
15 talk about an eMeasure, it means it has this  
16 particular set of specifications. All right,  
17 next slide.

18 Development of eMeasures has been an  
19 evolutionary journey over the last, I don't know,  
20 six, seven, eight years, whatever it's been.  
21 Really got launched when the HITECH Act was  
22 enacted in 2009 to promote the adoption and

1 meaningful use of HIT. I think everybody's  
2 probably familiar with the meaningful use  
3 concept. And so, first IONC and now at CMS there  
4 have been the incentive programs to develop and  
5 adopt, to adopt and utilize, in meaningful  
6 fashion, programs from the federal government and  
7 most commonly called meaningful use. They have  
8 them for hospitals, it is for eligible  
9 professionals as well.

10 The purpose is to gain experience with  
11 the development use of eMeasures and use of  
12 measurement within an electronic health record,  
13 using these particular specifications, the HQMF.  
14 So as part of getting going with that, there were  
15 eMeasure specifications created for existing  
16 quality measures; so they're called retooled  
17 measures, all right? So there was a regular  
18 measure, call it claims, paper, registry,  
19 whatever, but then the eMeasure specifications  
20 were created. So when we refer to retooled  
21 measures, that's what we're talking about. And  
22 so this whole program is meant to encourage the

1 development of more and more eMeasures hopefully  
2 that will begin to use the unique capabilities of  
3 EHRs.

4 But we are still in the midst of this  
5 journey and transition, all right? So, I think  
6 the hopes and dreams of pretty much everybody in  
7 the EHR space is that we'll get someday to a  
8 point where they really do a lot of wonderful  
9 things. And we're not totally there yet. The  
10 development and testing of these eMeasures has  
11 been quite challenging. The testing of the  
12 eMeasures is hindered by a lot of things, but one  
13 is the limited use in the field. For instance,  
14 PQRS allows measure to be submitted through EHRs  
15 but in the most recent data in 2013, only 66 eye  
16 care specialists, probably ophthalmologists,  
17 submitted data to PQRS using EHRs. The vast  
18 majority of them used it through either the  
19 claims or registry option.

20 So we don't have a lot of big data  
21 working. There are some folks who are  
22 particularly working the registry space,

1 developing it, but we are still in transition.  
2 And in fact, in the meaningful use program, a lot  
3 of the problems with data is the fact the  
4 eMeasures are reported by attestation. They're  
5 saying yes, I can do it. But the actual data is  
6 not transmitted, so there's no collection of a  
7 data set that someone can do some statistical  
8 analysis for liability and validity so, we're  
9 really stuck. So, these are the challenges that  
10 my colleagues in the measure development world  
11 are dealing with. So we're going to find sort of  
12 an awkwardness and a difficulty in trying to  
13 understand how well these measures, the eMeasure  
14 versions meet the criteria. Next slide.

15 Okay, so NQF's current criteria for  
16 the evaluation of eMeasures is we do look at  
17 these measures distinctly. So even though you  
18 had one measure worksheet that had information  
19 for both the registry measure say, and the  
20 eMeasure, we will be considering them differently  
21 because the issues around reliability and  
22 validity, the issues around feasibility, and use

1 and usability are distinct for the eMeasures  
2 versus, say, a registry measure. So, we will be  
3 doing those independently.

4 We have provided--our staff has  
5 provided a technical review of the eMeasure  
6 that's included in your worksheet so, that will  
7 apply to the eMeasure. And in general, the  
8 eMeasures are expected to meet the same criteria.  
9 So it's the same things you've been going  
10 through. There are some special applications for  
11 eMeasures, in a perfect world, we really would  
12 like to see testing for liability and validity in  
13 more than one EHR system, or a system from  
14 different vendors, so we can see how well it  
15 works. That's very hard to achieve, actually.  
16 And then also the feasibility assessment that  
17 addresses the data elements and the measure of  
18 logic. And so that's where there are some  
19 specific issues for feasibility for these  
20 measures.

21 As it turns out, we've got six  
22 retooled measures that are on the table for

1 evaluation alongside their endorsed, sort of  
2 original version, either registry or claims. And  
3 so we will evaluate them distinctly. We  
4 acknowledge the transition, we acknowledge the  
5 challenges, and so we've made some sort of  
6 adaptations, if you will, to the criteria for these  
7 particular retooled measures that have this long  
8 history of trying to evolve with the rest of the  
9 industry. So, next slide, please.

10 So, these retooled measures can  
11 actually come into the same number because they  
12 are used in federal programs under the same  
13 number, so that's why they're all kind of grouped  
14 together, but we will look at them separately. I  
15 know that it's clumsy, but at this point we  
16 really do want to talk about the measures  
17 independently even though we do carry them under  
18 the same number. We are looking for ways of  
19 being able to indicate the two different versions  
20 in the number without totally upsetting the  
21 federal rule making process that actually  
22 indicates the number of the measure when it's

1 included in federal programs. So we will be  
2 looking at them independently.

3 Absolutely, totally new, since so many  
4 of the developers are struggling to get these  
5 measures tested in more than one EHR system, new  
6 guidance that is allowing an option for testing  
7 of these measures, the retooled measures, in a  
8 simulated data set. There is a tool that CMS has  
9 created, MITR actually created it, that allows  
10 you to create a simulated data set and run the  
11 data that you have from your EHR to test the  
12 measured logic and be sure that it operationally  
13 can create and give you an answer. And then  
14 there will be the ability to compare the results  
15 from the automated EHR versus whatever you  
16 programmed for your simulated data set. So we've  
17 just been advised the major developers of that  
18 new guidance, and so they haven't had the  
19 opportunity to do it. But in discussing it with  
20 them, that is certainly an option they may choose  
21 to take and they might be able to get it done  
22 like while we're out for comment.

1                   And so this is something that you can  
2                   consider as on the table and under the conditions  
3                   that would be acceptable to recommend the  
4                   eMeasures for endorsement. Is that my last  
5                   slide? I can't remember. Okay. So with that  
6                   sort of introduction about eMeasures, does  
7                   anybody have any questions about what I just  
8                   said? So we do understand that there are these--  
9                   that eMeasures are very specific; it doesn't mean  
10                  just doing your measurement in your EHR. Okay.  
11                  Alrighty, with that, eye care measures.

12                 DR. RICH: All right, I think that  
13                 I'll start with some introductions and then I'll  
14                 give you some general thoughts about the role of  
15                 the Academy and what we are doing here. So, my  
16                 name is Bill Rich, I'm Medical Director of Health  
17                 Policy for the American Academy of Ophthalmology.  
18                 I practice in Northern Virginia, and I'm also the  
19                 Chair of the Measure and Development group for  
20                 our IRIS clinical registry. Flora?

21                 DR. LUM: I am Policy Director of  
22                 Quality Care and Knowledge Based Development and



1 I was actually the original staff on these eye  
2 care measures when they first came through with  
3 Reva. Yes, you remember that?

4 MS. CHAVARRIA: Thank you. I'm Elvia  
5 Chavarria, I'm with the American Medical  
6 Association Physician Consortium for Performance  
7 Improvement and I will--if necessary, I will  
8 invite other PCPI colleagues to answer any  
9 questions that you might have, that they might be  
10 better suited answer.

11 DR. RICH: Thank you. On behalf of  
12 the American Academy of Ophthalmology, I'd like  
13 to thank all of you for taking time away from  
14 your families and practice to be here, the staff  
15 for their diligent work, and after listening to  
16 the description of eMeasures, I'm glad there are  
17 a lot of ENT docs in the room, because people are  
18 going to start spinning the number two pencil in  
19 their ear. So what we're going to be talking  
20 about are several measures that deal with the  
21 leading causes of blindness in the Medicare  
22 population, macular degeneration, diabetic

1       retinopathy, and glaucoma. We're going to be  
2       talking about a cross-cutting communication  
3       measure dealing with sending a report to the  
4       primary care docs. We're going to be looking at  
5       an intermediate outcome measure in diabetic  
6       control, and finally, two patient-centered  
7       outcome measures that will be publicly reported  
8       next year.

9                       We look at the ability to improve  
10      quality and better outcomes as a continuum from--  
11      you have to start with great science. Number  
12      two, you have to have dissemination and  
13      education. And that's where we've been in the  
14      past. Now we're moving into an area where we can  
15      hopefully measure and then a registry further  
16      give rapid feedback to performance improvement.  
17      So if you look at some of the outcomes, the  
18      process measures, you have three before you that  
19      we'll be discussing later in diabetic  
20      retinopathy, macular degeneration, and glaucoma.  
21      So the question is, how effective has that been,  
22      these process measures, you don't look at the

1 retina, you actually stage disease. So, if you  
2 have cancer of the throat and tongue, you get CAT  
3 scans and a lot of other work-up, we can actually  
4 look in the eye, educate docs on the staging of  
5 the disease to incorporate better outcomes and  
6 appropriate therapy.

7           How effective? Well if you look at  
8 the gold standard for clinical trials, it was  
9 diabetic retinopathy study and the EDTRS study in  
10 the early 80's. The Academy then aggressively  
11 promulgated the knowledge base, we communicated  
12 with about 80 percent of primary care staffs  
13 around the country and within five years, we  
14 decreased blindness from severe macular  
15 degeneration 50 percent and we're approaching 70  
16 percent now, and with 18 percent less resource  
17 use. So even with the education and staging,  
18 we've made great strides. We feel very strongly  
19 with measures and then testing them and then  
20 implementing and measuring in the registry, we're  
21 going to even consolidate and address the gaps in  
22 care.

1           The other thing I'd like to address is  
2     the perceived gaps in care and the ability to  
3     improve. All the measures we're going to be  
4     discussing today are based on 2013 claims data  
5     whereas a physician, you had to report on 50  
6     percent of three measures, and so obviously,  
7     you're going to report on the measures you're  
8     most proficient in. And the reality is that when  
9     you look at the data, only a small percentage of  
10    physicians eligible to report actually report it.  
11    That's about 56 percent of ophthalmologists that  
12    if you throw in another 30,000 optometrists, you  
13    can see that looking at administrative claims  
14    data does not give you a picture at all as to the  
15    gap in care or the ability to improve.

16           Starting this year, we have to report  
17    on nine measures and when we look at the ability  
18    to report on nine measures, you'll actually see  
19    the tremendous gaps in care, and we'll be glad to  
20    address that in the registry. So I think that  
21    looking at 2015--2013 claims data doesn't give us  
22    an idea of what's happening today in 2015. There

1 will be no more claims reporting, you cannot  
2 report; so it's either going to be EHR reporting  
3 or through a registry. And so I think when you  
4 look at that, when we look at that data--and  
5 Flora has a lot of data--you'll be able to  
6 appreciate there's lots of gaps in care and area  
7 to improvement. So having said that, I'd like to  
8 look at also--I briefed the address at the last  
9 meeting. What happens if you actually sunset  
10 measures? And I will again distribute that  
11 article in The British Medical Journal by Joe  
12 Selby, where once you take it out, performance  
13 drops about three percent a year. Put it back in  
14 and hemoglobin A1c level performance improves 48  
15 percent. So I think that we have to look very  
16 carefully about our assumptions about area of  
17 improvement based upon old claims data.

18           So the first couple of--I'll talk  
19 about the cataract measures first, and then we  
20 can move on to the glaucoma ones later on at the  
21 Chair's. The cataract measures were designed as  
22 measures of surgical competence. 20/40 was

1 picked because that's functional level in our  
2 society as the basis of the FDA approval for  
3 intra ocular lenses, getting driver's license and  
4 actions associated with higher levels of visual  
5 functioning. The ability to--it's not risk  
6 adjusted because we didn't feel we had the  
7 ability to risk adjust it. So, we took out  
8 everything. It's a measure of pure surgical  
9 competence which will be publicly reported. So,  
10 this is a patient-focused measure to help  
11 patients evaluate, i.e. the results of the  
12 surgery, and i.e. the surgeon's results when they  
13 choose them.

14 If you look at the second measure,  
15 it's the complications of cataract surgery. We  
16 turn to the OR This is something that can easily  
17 be recognizable from claims data from the EHR and  
18 this is actually something that I did wrong as a  
19 surgeon. The percentage rate is only about two  
20 percent, the complications are greatest,  
21 expensive and results of somewhere between 60,000  
22 and 100,000 people a year. Again, that will be

1 publicly reported too. As far as the ability to  
2 improve, the claims data shows 163 physicians  
3 reporting the cataract measure. However, as we  
4 move toward register improvement in EHR  
5 reporting, last year we had 600,000, this year  
6 800,000, and I think we have about 600,000  
7 cataracts for this year alone in 2014. So you  
8 can see the distortion that will occur if you  
9 look at 163 in the administrative claims database  
10 in 2013. The same thing, and the reason why the  
11 data is so low is that those measures are  
12 registry reporting and we didn't get our registry  
13 up and running until 2014. So again, you're  
14 looking at a very small end in the 2013 database.  
15 Flora, any comments before?

16 DR. LUM: Yes, thanks Dr. Rich. I  
17 just wanted to reinforce to you guys that in  
18 2013, only 138 providers, that when you see that  
19 performance rate, it only reflects 138 providers  
20 and for the complication rate, is only 77  
21 providers. So that performance rate is high, but  
22 it probably reflects the cream of the crop who

1 chose to report on that measure. The second  
2 thing, I did want to address the eMeasures. As  
3 we said, IRIS registry is a certified EHR  
4 technology, which means we had to pass all the  
5 ONC tests. We have successfully integrated  
6 across 26 different EHR systems and successfully  
7 submitted the ECQM data for 2,722 physicians last  
8 year. So, I think we have shown that we have  
9 successfully created the measures, passed it to  
10 CMS's specifications and submitted those for our  
11 physicians.

12 The other thing I was just going to  
13 mention is, I know the ophthalmologists think a  
14 lot of these are best practice and we look at the  
15 other measures, but they are for every eye care  
16 practitioner, so we're just getting at 20 percent  
17 of eligible providers reporting these measures  
18 through claims in 2013. So as we open it up and  
19 we get more and more providers, especially  
20 optometrists as well as ophthalmologists, we will  
21 see variations in those performance rates. As  
22 Dr. Rich said, whatever performance rates are



1       this year, they will be publicly reported. So,  
2       as of this year, they are on the hook and they  
3       will see those rates being publically reported on  
4       the physician compare site next year.

5                   CO-CHAIR YAREMCHUK: I guess I'm going  
6       to suggest that we move along and go with our  
7       first measure at this point in time. So, our  
8       measure that we're going to be looking at for  
9       ophthalmology, Cataracts 20/40 or Better Visual  
10      Acuity within 90 days following cataract surgery.  
11      And if we can go through the algorithm that we've  
12      done with the other ones, and Matt are going to  
13      be the lead on this?

14                  DR. WINKLER: I'd like to interject  
15      just one thing. This is the first outcome  
16      measure we've looked at today, and I just want  
17      to point out to you that the criteria for an  
18      outcome measure for evidence is different than  
19      for a process measure. For an outcome measure  
20      essentially there just needs to be a stated  
21      relationship, sort of an actionability if you  
22      will, that there is some process or structure or

1 something that can be done to effect that  
2 outcome. It is not the same as required the  
3 quality, quantity and consistency of the body of  
4 evidence that you would for a process measure.  
5 So just to--it's more focused.

6 MEMBER CARNAHAN: Okay. So, just the  
7 thorough description of this. Patients 18 years  
8 or older with a diagnosis of uncomplicated  
9 cataract--those are all the exclusions we'll talk  
10 about later--who had cataract surgery and no  
11 significant ocular conditions impacting the  
12 visual outcome of the surgery, and had a best  
13 corrective visual acuity of 20/40 or better at  
14 distance or near achieved within 90 days  
15 following cataract surgery. And as was stated,  
16 the 20/40 number was picked based on a common DMV  
17 number, a common FDA amount used as a success  
18 target literature, as well as the Salisbury Eye  
19 Study saying if 50 percent of the functioning  
20 happened at the 20/40 level.

21 And I guess my only question on this  
22 was, some of the other statements made within the

1       measure where The Eye Care Measure Development  
2       Work Group opted to develop a measure of  
3       accountability addressing cataract surgery  
4       outcomes that relates to the safety and  
5       appropriateness of cataract surgery. I wasn't  
6       clear on the relationship there because nowadays  
7       we see younger and younger people having cataract  
8       surgery at better and better visions, below 20/40  
9       to start. The measure is based on improving  
10      patient functional and visual outcome  
11      satisfaction and quality of life, excellent  
12      visual acuity after cataract surgery is achieved  
13      consistently through careful attention, through  
14      the accurate measurements of axial length,  
15      corneal power, appropriate selection of an IOL  
16      calculation formula. And those are all true, but  
17      I just have some concern that this measure  
18      captures that. Meaning that if I as a surgeon  
19      create a sentinel event, so I go ahead and I  
20      wanted the patient-- the patient wanted to have  
21      near vision and I gave them distance vision, and  
22      they were 20/20 distance vision best corrected,

1       then I succeed and I've done a sentinel event  
2       that isn't captured to get this high-quality.

3               And the other piece is, if I have a  
4       patient that starts out 20/30 and I have some  
5       sort of issue that comes up and they end up  
6       20/40, I'm still successful. So I don't know if  
7       that's a wording issue within the description of  
8       the measure. I'm not even sure how you would  
9       correct that. But again, we just see more and  
10      more surgeries happening at better and better  
11      visions and so I wonder how we can make it so  
12      that this measure does what it's intended to do,  
13      which is highlight success as well as highlight  
14      opportunity for further success from others.

15             DR. RICH: I'll respond first.  
16      Basically, you should get excellent vision. If  
17      you don't, something happened. So that's the  
18      intent, you know, to address the issue of the  
19      target, and that's what's your talking about with  
20      the distance and near, is another measure that  
21      we've developed. I don't believe it's approved  
22      yet but it is in the registry of the QCDR where

1       it's actually, how close did you get to your  
2       target refraction. So, that solves the problem.  
3       We would have had a very cumbersome measure to  
4       try to address all these issues that you raised.  
5       But basically, if you didn't get to 20/40,  
6       something's wrong. And so our entire intent was  
7       not to risk adjust.

8               We now have a large amount of data  
9       that shows the results of about 460,000 U.S. and  
10       370,000 in Europe, all comers with no exclusion  
11       and it's about 84 in Europe, 86 here. But that's  
12       very complicated because then you have macular  
13       degeneration, a whole bunch of things of  
14       confounding, underlying diseases that would  
15       preclude you from seeing 20/40. So the intent  
16       with this is to be a patient-focused measure that  
17       the patient can look at in public reporting and  
18       say, this person gets 86 percent, this person 96  
19       percent. So that was the purest way that we  
20       could define a surgical competency measure.  
21       Eventually, obviously we'll be able to risk  
22       adjust this and look at people with diabetic

1       retinopathy and things, but we actually have no  
2       basis to do that right now.

3                   CO-CHAIR YAREMCHUK:   Okay.   I guess  
4       what I was talking about and I'd asked Reva  
5       about, this is an evidence-based--the first thing  
6       that we vote on is evidence, and there's outcome  
7       and process measures.   This is an outcome measure  
8       and it says report whether there are processes of  
9       care that can influence the outcome.   Nothing  
10      more is required about evidence for outcome  
11      measures.   So, I guess the question is, is this a  
12      process of care issue you're talking about?

13                   MEMBER CARNAHAN:   So it sounds like  
14      there are measures to do what this measure is  
15      asking to do, but this measure may not have the  
16      evidence to do what it's supposed to do.   Because  
17      it doesn't actually tell you if a patient has  
18      better vision than when they started, and it  
19      doesn't tell you if the target that was hit was  
20      the one that the patient wanted.   So you can do  
21      atrocious things and succeed at this measure.   So  
22      is that evidence of a successful measure?

1                   MEMBER SCHACHAT: So those scenarios  
2                   you're speaking about can happen, but fortunately  
3                   they are vanishingly rare as you know. So the  
4                   wrong implant and giving the wrong, like a so-  
5                   called sentinel event, the rates on that are  
6                   minuscule. It's a lot because there are a  
7                   million cataract surgeries or whatever, but the  
8                   rate is minuscule. And as far as worrying about  
9                   operating on people better than 20/40, I'm not a  
10                  cataract surgeon, but there are Medicare  
11                  exclusions. You can't get paid for operating on  
12                  people who are better than 20/40 unless there are  
13                  very special things met. So there aren't many of  
14                  those.

15                 MEMBER STEIN: I'm the other lead on  
16                 this one. I think in terms of the evidence, it's  
17                 clear that improving someone's vision with  
18                 cataract surgery is a good thing. It improves  
19                 quality of life, it improves ability to be  
20                 productive, ability to drive. So I think the  
21                 issue with the evidence, let's not bring in some  
22                 of these other issues with the measure and just

1 focus on the evidence first.

2 CO-CHAIR YAREMCHUK: Okay. So, can we  
3 do a vote on this?

4 MEMBER CARNAHAN: We're saying the  
5 evidence here shows the patient had an improved  
6 vision, even though we don't know that to be  
7 true?

8 CO-CHAIR YAREMCHUK: That they're not  
9 any worse.

10 DR. WINKLER: The evidence criteria,  
11 if you recall is that there is a rationale that  
12 supports the relationship of this outcome with  
13 some healthcare process service intervention. So  
14 in other words is it actionable? Can you affect  
15 the outcome? Is there something that anybody can  
16 do that could that could affect the outcome?  
17 That's all you need. It's basic for evidence for  
18 an outcome measure.

19 DR. RICH: I'll point out that when  
20 you look at large numbers like we are now, there  
21 are huge variability between surgeons on this  
22 measure. Again, this is a patient-focused



1 measure with public reporting.

2 CO-CHAIR YAREMCHUK: So, just to  
3 follow up, because of the criteria difference,  
4 your voting options are yes and no. There is the  
5 rationale.

6 MS. ROBINSON-ECTOR: So, voting's now  
7 open for evidence for measure 0565, and for those  
8 on the call, option 1 is yes, and option 2 is no.  
9 Oh, it's up here. I don't know why it's not  
10 there, but it's up here. I can see it. Okay so  
11 all votes are in and voting is now closed.  
12 Sorry, I can see it in not private, yes. So 93  
13 percent voted yes, and 7 percent voted no. So,  
14 for evidence, measure 0565 passes.

15 MS. LUONG: And this is with 15 votes  
16 from the committee?

17 MS. ROBINSON-ECTOR: Yes.

18 CO-CHAIR YAREMCHUK: Opportunity for  
19 improvement?

20 MEMBER CARNAHAN: Sure. So, there's a  
21 lot of data out there. The PQRS data, again,  
22 small numbers in voluntary reporting and so

1       forth, 90.6 percent in 2010, 94.8 in 2011, in  
2       2012 92 percent. So it's definitely not a trend  
3       that's been showing success in and of itself. So  
4       although I guess the flip side is, does that mean  
5       the measure is not effecting positive change? We  
6       don't know. The CRS had some data, 85.5 percent,  
7       so it kind of falls in that range. And with over  
8       three million cataracts per year across the U.S.,  
9       that's hundreds of thousands of patients. That's  
10      a lot of potential for improvement and a lot of  
11      patients that are impacted.

12                   CO-CHAIR YAREMCHUK: Anything to add?

13                   MEMBER STEIN: No, I think that's well  
14      stated.

15                   MS. ROBINSON-ECTOR: So voting is open  
16      for performance gap for measure 0565 and for  
17      those on the call, option 1 is high, 2 is  
18      moderate, 3 is low, and 4 is insufficient. Okay,  
19      all the votes are in. 60 percent voted high, 40  
20      percent voted moderate, zero voted low, and zero  
21      voted insufficient. So performance gap for  
22      measure 0565, the measure passes.

1 CO-CHAIR YAREMCHUK: Okay,  
2 reliability?

3 DR. WINKLER: Now just--for right now,  
4 I'd really like to focus on the reliability of  
5 measure in the registry. Just in the registry.  
6 We'll talk about the eMeasure version afterwards.  
7 Okay? So, right now, focusing in on the  
8 information around the reliability of the measure  
9 as a registry measure.

10 MEMBER CARNAHAN: So with clear-- well  
11 I guess the big thing is the exclusions, and  
12 there's a long list of exclusions, but I would  
13 say almost all that have the potential to cause a  
14 vision reduction in and of themselves. So if you  
15 didn't have those exclusions, then you would have  
16 a significant reduction in the results and I  
17 think that when looking at the exclusions, it led  
18 to about a 50 percent reduction in the volume of  
19 surgeries that we're counting. Sorry. Anyone  
20 hear any of that? So, there's a long list of  
21 exclusions and they are all vision threatening  
22 exclusions or vision reducing exclusions above

1 and beyond the cataract itself. So as Dr. Rich  
2 said, it keeps the data more clean to focus on  
3 just where the opportunity is around the  
4 cataracts. It would be a separate measure if it  
5 included all the exclusions. With the exclusions  
6 not being counted, it reduced the volume to about  
7 half and with the results we've already talked  
8 about.

9 MEMBER STEIN: I had a few issues with  
10 reliability, none of which I think are major  
11 issues, but things for the developers to think  
12 about. Matt brought up the point about patients  
13 who start off with better than 20/40 or better  
14 vision. And could someone game the system by  
15 operating earlier to improve their chances of  
16 being successful? It might be good in a future  
17 iteration to exclude those from the denominator.  
18 The issue of when the measurements are being made  
19 is another--if someone's coming in multiple times  
20 at what visit they're to get the--if someone  
21 comes in ten times, their chances of getting  
22 20/40 or better vision is better than someone who

1       only comes for one or two post-op visits; so  
2       incorporating that in.

3               I'm not sure how good the registry--I  
4       think that fine tuning how the vision is being  
5       captured in terms of manifest refraction, best  
6       corrective visual acuity, different providers may  
7       be capturing different things, so just to make  
8       sure that you're capturing the same thing and  
9       that provider A is being compared against the  
10      same metric as provider B. And then, it wasn't  
11      clear why, if we have all these exclusions, why  
12      not also exclude people with a more severe  
13      cataract, the 66982 as another exclusion and just  
14      focus on the people with the 66984?

15             DR. RICH: Great questions. There's  
16      three things that you addressed. Number one is  
17      gaming operate on someone with less than 20/40.  
18      There's a word for that, it's called fraud. That  
19      will enable you to visit one of those long states  
20      in the middle of the country. And as far as when  
21      we look at the registry, we can actually map out  
22      when the vision is measured, and I think the

1 average number of visits is about 3.5. Flora?

2 DR. LUM: Right. It's within that 90  
3 day period.

4 DR. RICH: In that 90 day period.  
5 What was the third one, Josh?

6 MEMBER STEIN: Why not exclude 66982?

7 DR. RICH: Oh, because there's no  
8 underlying disease that precludes you, that's a  
9 complicated cataract. That's one that's tough.  
10 We thought that's a measure of surgical  
11 competency. There's no underlying co-morbidities  
12 that would prevent you from seeing 20/40. So we  
13 felt it was important to leave that in.

14 MEMBER FRIEDMAN: So, a couple more  
15 comments. Measuring vision is somewhat  
16 subjective. For those of us that--there's ways  
17 to specifically quantify vision and be certified,  
18 et cetera. We don't do that. This is the best  
19 way to measure vision given the limitations of  
20 measuring vision in general. The reason we  
21 exclude a lot of patients is there's a lot of  
22 people out there that don't have a vision

1 potential of 20/40, but clearly benefit by  
2 cataract surgery. So there are a lot of people  
3 that are only going to see 20/60, but this is  
4 going to be their better seeing eye than the  
5 other eye that can only see light and dark. And  
6 to get them from 20/200 to see the big E, to  
7 seeing 20/60, is markedly going to improve their  
8 quality of life. They're not going to be able to  
9 drive in most states, but they will be able to  
10 read with better reliability and they're going to  
11 be happier and the quality is going to improve.  
12 But that's why there's so many exclusions for  
13 this measure.

14 MEMBER MADONNA: Just getting back to  
15 what Josh said about multiple visits and you said  
16 3.5 is the average, but isn't it possible then  
17 that somebody comes in at day eight and has 20/30  
18 vision, then develops cystoid macular edema and  
19 at the end of 90 days has 20/100 and perhaps they  
20 never recover 20/40 vision again. So they would  
21 pass this, but yet that's going to be a very  
22 unhappy patient.

1 DR. RICH: Well you know, that would  
2 be a failure if your developed CME and I guess  
3 the measure does say within 90 days.

4 MEMBER BRADHAM: This is Tammy and I'm  
5 coming at this as a parent with a daughter with  
6 significant vision issues. And when I go in for  
7 those evaluations, they always test monocular and  
8 then both of the eyes together. And when I read  
9 this definition it doesn't come out and say--it  
10 says cataract surgery, but are you getting at the  
11 vision tests with both eyes or just one eye?  
12 It's not---

13 DR. RICH: Just the surgical eye.

14 MEMBER BRADHAM: Right, but it's not  
15 clear in the description.

16 DR RICH: I don't think, you know, we-  
17 -once we're in that 90 day period, we're not even  
18 checking the other eye.

19 MEMBER BRADHAM: I know, but from a  
20 parent--if this is written for the consumer, it's  
21 not clear. I'm just saying that.

22 MEMBER CARNAHAN: It does state though



1       that each eye is a separate episode, and so I  
2       think that's how they're saying, they're  
3       clarifying that piece of the---

4                   CO-CHAIR YAREMCHUK:   Steve?

5                   MEMBER GOLDBERG:   Does the development  
6       of cystoid macular degeneration following  
7       cataract surgery though related to how it's  
8       performed, or is it an unavoidable complication?

9                   MEMBER FRIEDMAN:   I think it can be,  
10      certainly.  If someone's spending more time  
11      taking the cataract out or has poor surgical  
12      technique, I think it's possible certainly to  
13      have a greater risk of cystoid macular edema.

14                  MEMBER SCHACHAT:   So the answer to  
15      that is it's some of both?  Overall the rate of  
16      visually significant cystoid macular edema over  
17      the past few days, ends up being one percent.  
18      About thirty percent of patients have some of it  
19      but it doesn't affect their vision, but affecting  
20      the vision is about one percent.  And some of it  
21      relates to messy, botched, longer, more tedious  
22      surgery,  and a lot of it relates to other

1 conditions that got facilitated. So it's  
2 probably about half and half, but the overall  
3 rates are low.

4 I just wanted to make a comment about  
5 the concern about the multiple visits in 90 days  
6 and what Josh was trying to get at is should the  
7 vision be specified as measuring at a certain  
8 time point rather than getting a positive score  
9 for any time in the 90 day period, and then the  
10 whole thing wouldn't work because there's too  
11 much variation on the timing of visits. If you  
12 want to measure at 90 days, so many patients  
13 don't have to come back at 90 days, some would  
14 have to come back from Chicago to Cleveland to  
15 get measured at that 90 day visit approximately  
16 when they don't actually need it. So I think  
17 there's going to be a little mess in variation in  
18 the measure that I would accept to allow patients  
19 to have flexibility on their visit time.

20 MEMBER STEIN: Yes I don't think any  
21 of these issues I brought up are critical, major  
22 issues. It's just things for the developer to

1 think about to enhance the tool they have.

2 CO-CHAIR YAREMCHUK: Any other  
3 questions?

4 MEMBER FRIEDMAN: One more quick  
5 comment. So just getting back to the CME.  
6 Basically, CME is very rare and it's usually  
7 treatable. It usually goes away but if there's a  
8 provider that has, who's an outlier that has a  
9 significant number of his patients developing  
10 CME, that's a problem and that's what we want to  
11 try and identify.

12 CO-CHAIR YAREMCHUK: So, are we ready  
13 to--oh excuse me. Go ahead.

14 MEMBER CARNAHAN: Just back to the  
15 first point that it seems like the measures that  
16 you're working on to say how close are you to  
17 your refractive goal and maybe did you have an  
18 improvement in vision after cataract surgery.  
19 Because even the patient who is not fraud, who is  
20 a 20/40 cataract and comes out 20/40 who you  
21 think theoretically he'd be seeing better  
22 afterwards, is going to be a success here even

1       though they saw no better after surgery. But if  
2       the measure was saying an improvement over pre-  
3       operative vision, or met the target within half a  
4       diopter or whatever the new measures are you're  
5       working on, I think that would be really clean.  
6       And so perhaps once those kind of measures come  
7       along, then this measure falls to the wayside.

8                   MEMBER FRIEDMAN: So again, for those  
9       of us who do clinical research, there's different  
10      ways to measure visual function. One way is  
11      known as acuity, which is what 20/40 means. You  
12      can also look --- there are people with 20/40  
13      that have a lot of glare. They can't drive at  
14      night, for example. So they go from 20/40 to not  
15      being able to drive at night, to 20/40 being able  
16      to drive at night; their quality improves  
17      markedly. We're not measuring that actually, but  
18      so there is an indication for people that are  
19      20/40 to have cataract surgery in lieu of not  
20      actually having a visual improvement or  
21      improvement in their -- acuity, but their visual  
22      function does in fact improve.

1 DR. RICH: There's a separate  
2 independent measure that --- and you know, I  
3 don't want to prolong this discussion, but looks  
4 at the patient reported outcome pre and post op,  
5 separate from this.

6 CO-CHAIR YAREMCHUK: Right. Are we  
7 ready to vote on reliability?

8 MS. ROBINSON-ECTOR: Voting for  
9 reliability for measure 0565 is now open and for  
10 those on the line, option 1 is high, option 2 is  
11 moderate, option 3 is low, and 4 is insufficient.  
12 All the votes are in. 13 percent voted high, 80  
13 percent voted moderate, 7 percent voted low and  
14 zero voted insufficient. So for reliability,  
15 measure 0565 passes.

16 CO-CHAIR YAREMCHUK: Okay. Validity?

17 MEMBER CARNAHAN: So for validity, to  
18 report on when it was tested. It was looked at  
19 in a single practice and I think that was an area  
20 of contention for some people because it was  
21 three physicians and one EHR, but it had a 92.6  
22 percent agreement. The PQRS was evaluated with

1 454 physicians, with 403 having enough data to  
2 submit for this, and the only trouble with that  
3 was it didn't identify the exclusion piece of  
4 things. And as we talked about before, the  
5 exclusions, the potential threats were that 47.8  
6 percent of data remained after all the exclusions  
7 were included. And I guess the missing data  
8 again, I would say would be a pre-operative  
9 comparison or a vision target.

10 And, again, back to Scott's comments,  
11 as long as you had an improvement in vision, then  
12 you would --- I don't know how you'd quantify  
13 that, 20/40 can be different kinds of 20/40, but  
14 I would say that now you get a larger pool of  
15 patients. You get all the glaucoma patients and  
16 macular degeneration patients who go from 20/400  
17 to 20/80 and they're still a success. And so you  
18 have done them a good as opposed to their being  
19 excluded in these kinds of situations. And so  
20 they may be put to the wayside. Hopefully not.

21 CO-CHAIR YAREMCHUK: And can you just  
22 talk up a little bit. Josh, do you have

1 anything?

2 MEMBER STEIN: The other validity test  
3 they did was the face validity with an expert  
4 panel of 16 members and found good validity that  
5 way.

6 CO-CHAIR MERENSTEIN: I'm just going to  
7 need all of you to speak up. They can't hear us  
8 back there.

9 CO-CHAIR YAREMCHUK: So, any comments?  
10 Ready to vote on validity?

11 MS. ROBINSON-ECTOR: Voting is now  
12 open for validity for measure 0565 and for those  
13 on the line, option 1 is high, 2 is moderate, 3  
14 is low, and 4 is insufficient. Okay, all the  
15 votes are in. 20 percent voted high, 80 percent  
16 voted moderate, zero voted low, and zero voted  
17 insufficient. So for validity, measure 0565  
18 passes.

19 CO-CHAIR YAREMCHUK: Okay.  
20 Feasibility?

21 MEMBER CARNAHAN: This has a very  
22 specific category, two codes that would identify

1 a best corrected vision of 20/40 or better,  
2 distance or near, achieved within 90 days and a  
3 separate code if it was not achieved, so it would  
4 be very feasible that this would be easy to pull  
5 the data on.

6 MEMBER STEIN: No, I think that Matt  
7 summed it well.

8 CO-CHAIR YAREMCHUK: Okay. Ready to  
9 vote on feasibility?

10 MS. ROBINSON-ECTOR: Voting for  
11 feasibility for measure 0565 is now open and for  
12 those on the call, option 1 is high, 2 is  
13 moderate, 3 is low, and 4 is insufficient. All  
14 the votes are in. 60 percent voted high, 40  
15 percent voted moderate, zero voted low, and zero  
16 voted insufficient. So, for feasibility, measure  
17 0565 passes.

18 CO-CHAIR YAREMCHUK: And the last  
19 metric is usability and use.

20 MEMBER CARNAHAN: As we talked about,  
21 there's PQRS data for this. It goes to IRIS  
22 registry and publicly reported as a result. We



1       talked about the room for improvement with it  
2       being in the low 90's right now and that being  
3       hundreds of thousands of patients concerning the  
4       high volume. And I think just the only  
5       unintended consequences would be it might falsely  
6       identify a good surgeon who wasn't because there  
7       was no vision change potentially. As is also  
8       mentioned, it may end up increasing return visits  
9       so that you can get a successful outcome by just  
10      bringing them back until you finally get a 20/40,  
11      more than you would have otherwise.

12                   CO-CHAIR YAREMCHUK: Comments?

13                   MEMBER STEIN: The only other  
14      unintended consequence would be a surgeon not  
15      wanting to operate on someone that they didn't  
16      think could get to 20/40, but hopefully that's  
17      not going to happen. Hopefully, that wouldn't  
18      happen that much. I don't think that's a major  
19      issue.

20                   CO-CHAIR YAREMCHUK: Any other  
21      comments? Then we can vote.

22                   MS. ROBINSON-ECTOR: Voting for

1 usability and use for measure 0565 is now open  
2 and for those on the line, option 1 is high, 2 is  
3 moderate, 3 is low, and 4 is insufficient  
4 information. All the votes are in. 60 percent  
5 voted high, 40 percent voted moderate, zero voted  
6 low and zero voted insufficient information. So  
7 for usability and use for measure 0565, the  
8 measure passes.

9 CO-CHAIR YAREMCHUK: Okay. Last vote.  
10 Whether to recommend measure as suitable for  
11 endorsement. Any comments from anyone?

12 MS. LUONG: And this is for just  
13 clarification purposes, the registry version of  
14 measure 0565.

15 MS. ROBINSON-ECTOR: The vote is now  
16 open for recommendation for overall suitability  
17 for endorsement for measure 0565 for those on the  
18 call, option 1 is yes, and option 2 is no. All  
19 the votes are in. 100 percent voted yes and zero  
20 voted no. So for recommendation for overall  
21 suitability for endorsement for measure 0565,  
22 measure passes.

1 MS. LUONG: Again, to note that is for  
2 the registry version.

3 CO-CHAIR YAREMCHUK: All right, go  
4 ahead.

5 DR. WINKLER: As I mentioned --- go to  
6 the next slide --- as I mentioned, this measure  
7 does have an eMeasure version, in the way we  
8 discussed prior. So the issue around evidence  
9 and gap shouldn't be any different, so we don't  
10 need to revisit that. So we do want to talk  
11 about the potential concerns or issues or  
12 questions around the reliability and validity,  
13 the scientific acceptability of the eMeasure.  
14 Because this measure is one of the original  
15 retooled measures, they haven't -- and as I  
16 talked about earlier, this measure hasn't been  
17 tested widely. We do have limited testing data in  
18 one EHR system. We've already talked with the  
19 developers, they're willing to provide us the  
20 information for the simulated data set. And that  
21 sounds like something that can come back soon-  
22 ish, like the next time we meet, and so you could

1 see that. And that would be acceptable at this  
2 point in time.

3 We're certainly hoping that as more  
4 and more eMeasures are used and we're collecting  
5 data, we can actually do better reliability and  
6 validity statistical analysis on the data  
7 generated from eMeasures, but at this point in  
8 time, it's pretty much a limitation across the  
9 field. So we're just living in a transition  
10 time. So, what I'd like to do is just have the  
11 group talk about whether you believe that what  
12 information we have on reliability and validity,  
13 it's a single vote, for the eMeasure is  
14 acceptable with the conditions we've talked  
15 about. And then --- so Kaitlynn's going to put  
16 that one up. So does anybody have any comments  
17 about the eMeasure version from the committee  
18 first? Flora, I'll give you a chance.

19 DR. LUM: Brief comments from the  
20 developer. This was discussed before. We have  
21 extracted it for 2,722 physicians in 2014 across  
22 26 different EHR systems. And all our files were

1       accepted successfully by CMS. So we haven't had  
2       any difficulty in extracting the data. And in  
3       addition, we review the rates with the  
4       physicians, and ophthalmologists are very  
5       compulsive, so if patients are failing the  
6       measure, they can look back on which patients are  
7       failing the measure and we look back to look at  
8       the measure to see if there's any problems with  
9       the calculations. So, they all approve of what  
10      we've submitted on behalf of the --

11               DR. WINKLER: So I am -- as I said,  
12      because we are considering it, I am going to ask  
13      you to vote, we're going to combine reliability  
14      and validity into one question. It's a yes/no  
15      question. Is the information that we have about  
16      eMeasure acceptable for scientific acceptability  
17      with the conditions we're going to get the  
18      additional information from the simulated data  
19      set?

20               MS. ROBINSON-ECTOR: So voting is now  
21      open for reliability and validity for the e-  
22      version measure of 0565 and for those on the

1 call, option 1 is yes with conditions, and option  
2 2 is no. All the votes are in. 100 percent  
3 voted yes with conditions and zero percent voted  
4 no. So for reliability and validity, the  
5 eMeasure version of 0565 passes.

6 DR. WINKLER: So when it comes to  
7 feasibility, there are often feasibility issues  
8 or concerns raised in the discussion about use of  
9 an eMeasure or any potential way the measure is  
10 specified in terms of data elements, whether  
11 these are routinely collected and whether -- so  
12 those are the considerations. I think Flora's  
13 provided you some information about their  
14 experience. But in terms of your assessment of  
15 feasibility of the actual use of this particular  
16 eMeasure in EHR systems is the question for  
17 feasibility for the eMeasure. Questions,  
18 comments? Okay, it sounds like you're ready to  
19 vote.

20 MS. ROBINSON-ECTOR: Voting is now  
21 open for feasibility for the e-version measure of  
22 0565 and those on the call, option 1 is high, 2

1 is moderate, 3 is low and 4 is insufficient. All  
2 the votes are in. For feasibility, 60 percent  
3 voted high and 40 percent voted moderate, zero  
4 voted low and zero voted insufficient. So for  
5 feasibility for the eMeasure version of 0565, the  
6 measure passes.

7 DR. WINKLER: Okay, now for usability  
8 and use, this is one where perhaps your previous  
9 conversation would apply. Is there anything  
10 different about the eMeasure or would you like to  
11 just transfer your votes from the prior --- from  
12 the non-eMeasure version and have it apply here  
13 as well? Does anybody have any --- does that  
14 seem accurate and a reflection of your thoughts?  
15 Okay. Then we'll stipulate the use and usability  
16 and then the last one will be the recommendation  
17 for endorsement with the conditions we get the  
18 follow-up information.

19 MS. ROBINSON-ECTOR: Oh sorry. So  
20 this is the side that we'll be voting on. Voting  
21 is now open for overall suitability for  
22 endorsement for eMeasures for measure 0565 and

1 for those on the call, option 1 is yes with  
2 conditions and option 2 is no. All the votes are  
3 in and voting is now closed. 100 percent voted  
4 yes with conditions and zero percent voted no.  
5 So for overall --- recommendations for overall  
6 suitability for endorsement for the e-version  
7 measure of 0565, the measure passes.

8 DR. WINKLER: Just for the transcript  
9 record, the condition is that they will bring  
10 back the testing from the simulated data set  
11 using the Bonnie tool at the next time we meet  
12 after the comment period for you to evaluate.

13 CO-CHAIR YAREMCHUK: We were supposed  
14 to have break at 2:30 and it's 3:08. So yes,  
15 it's break. The question is when do we  
16 reconvene? 20 after? Okay, 20 after, reconvene.

17 MEMBER LYNCH: This is Judith, I'm  
18 going to have to sign off for today; I'll be back  
19 on in the morning.

20 [Whereupon, a break was taken from  
21 3:02 p.m. to 3:16 p.m.]

22 CO-CHAIR YAREMCHUK: Okay. I'm hoping to gather



1 everybody back around the table. I have two  
2 requests. I guess I'm going to call these  
3 housekeeping requests.

4 One is to speak in the microphone.  
5 And speak loudly enough. One, the people behind  
6 us are having difficulty hearing.

7 And there's also someone transcribing.  
8 And so it's difficult for them to be able to  
9 transcribe. So, to make a conscious effort to do  
10 that.

11 And we can now go to the -- is  
12 everyone back? Yes? I think so. Okay.

13 So then the next measure for  
14 consideration is 0564, Complications Within 30  
15 Days Following Cataract Surgery Requiring  
16 Additional Surgical Procedures. And so Matt,  
17 you're up again.

18 MEMBER CARNAHAN: All right. So,  
19 these again are the same population of people, 18  
20 years and older. Have an uncomplicated cataract.  
21 And there's a long list of those. And I guess  
22 we'll talk about that later on for the exclusions

1 piece.

2 Who had one of a number of situations  
3 arise after surgery. Retain nuclear fragments  
4 and endophthalmitis, dislocated or wrong power  
5 interocular lens, wound dehiscence.

6 But the one question that came up for  
7 our group was retinal detachment. Meaning that  
8 you could definitely induce a retinal detachment  
9 during surgery.

10 But at the same time, I would venture  
11 that most of the retinal detachments that happen  
12 after surgery are probably in patients who may  
13 have had them anyway.

14 And so the question is, are we  
15 identifying anything around a less safe surgeon  
16 who, perhaps, has a perfect surgery and yet, has  
17 a patient with retinal detachment? So --

18 MEMBER SCHACHAT: So, the rate of  
19 retinal detachment after cataract surgery needs a  
20 time denominator. It's ever increasing and it  
21 goes up forever.

22 And it has to do mainly with the time

1 of their developing PVDs, posterior vitreous  
2 detachment for the retinal -- for the ENT  
3 doctors.

4 And those that occur within 30 days  
5 are a very small fraction of the overall number  
6 that are going to occur. And I think they're  
7 more likely to relate to surgical mess ups, as  
8 opposed to just the routine kind of retinal  
9 detachment.

10 It's going to happen from PVDs, which  
11 happens at a regular rate forever. I think.

12 MEMBER CARNAHAN: And that goes along  
13 with I think another measure they have around  
14 posterior capsular rupture, which would  
15 definitely increase your rate of retinal  
16 detachment.

17 CO-CHAIR YAREMCHUK: Okay.

18 MEMBER CARNAHAN: So, just putting  
19 that out there for the evidence piece.  
20 Exclusions we talk about later, correct? Okay.

21 So we're just trying to identify  
22 complications that can reasonably be attributed

1 to the surgery or the surgeon. And reflect  
2 situations that if untreated, generally result in  
3 avoidable vision loss.

4 CO-CHAIRMAN YAREMCHUK: And once  
5 again, this is an outcome measure. And so what I  
6 had read before report, whether there are process  
7 of care that can influence the outcome.

8 Nothing more is required about  
9 evidence for outcome measures. Okay. Do we need  
10 to vote on this?

11 MS. ROBINSON-ECTOR: Yes.

12 CO-CHAIR YAREMCHUK: Okay.

13 MS. ROBINSON-ECTOR: Okay. So voting  
14 for evidence is now open for Measure 0564. And  
15 for those on the line, option one is yes. And  
16 option two is no.

17 MS. LUONG: And to note, this is not  
18 for the E-version of the measure.

19 DR. WINKLER: It applies to both.

20 MS. ROBINSON-ECTOR: And we're just  
21 waiting for the calls -- the people on the line  
22 to vote. Yes, so we're just waiting for one.

1                   Okay. All the votes are in. And  
2                   voting is now closed. 93 percent voted yes. And  
3                   seven percent voted no. So for the evidence of  
4                   Measure 0564, the measure passes.

5                   CO-CHAIR YAREMCHUK: All right. Do  
6                   you want to discuss opportunity for improvement?

7                   MEMBER CARNAHAN: Sure. So looking at  
8                   the PQRS data from 2010 through 2012, there's  
9                   actually been a higher percentage from 3.4 to 4.4  
10                  to 5.2, which would indicate a lack of  
11                  improvement. And therefore, a greater  
12                  opportunity for improvement over time.

13                  And looking at the registry numbers,  
14                  it goes from zero to one in terms of with a  
15                  median of zero. But still, there are those with  
16                  a high opportunity for improvement.

17                  So, I would say that there's  
18                  definitely room considering the huge three  
19                  million plus population of patients we're talking  
20                  about.

21                  MEMBER STEIN: Yes, I think given that  
22                  cataract surgery is the most common surgery there

1 is, you know, three to five percent means that  
2 there are many patients experiencing these  
3 issues.

4 You know, the fact the rates are going  
5 up over time, it's a little hard to interpret  
6 whether that is -- that people are having more  
7 complications or that our coding of complications  
8 is getting better with EMRs and other captures.

9 DR. RICH: I think it's a small sample  
10 size, Josh. A very, very small sample.

11 MEMBER STEIN: Right.

12 MEMBER FRIEDMAN: I think just as Bill  
13 suggested, you have to look at the confidence  
14 intervals around those numbers. If the  
15 confidence intervals are very large, they could  
16 be not -- they could just be noise and not  
17 meaningful differences.

18 CO-CHAIR YAREMCHUK: All right. Are  
19 we ready to vote?

20 MS. ROBINSON-ECTOR: Voting is open  
21 for performance gap for Measure 0564. And for  
22 those on the line, option one is high, two is

1 moderate, three is low and four is insufficient.

2 All the votes are in and voting is now  
3 closed. 36 percent voted high. 64 percent voted  
4 moderate. Zero voted low and zero voted  
5 insufficient.

6 So for performance gap, Measure 0564  
7 passes.

8 CO-CHAIR YAREMCHUK: Okay. Validity?  
9 Oh, sorry, reliability?

10 MEMBER CARNAHAN: So, looking at the  
11 reliability, the numerator statement has a list  
12 of certain procedures and a certain diagnosis.  
13 And then there's like I said, a large list of  
14 exclusions.

15 I mentioned the retinal detachment  
16 piece already. But in terms of the exclusions,  
17 it includes things like mature cataracts, senile  
18 cataract, glaucoma.

19 I would wonder if those were all  
20 necessary exclusions. And then Alpha-1 blocker  
21 use, definitely it can be a problem. But I would  
22 imagine that at least 15 percent of the time it

1 wouldn't be.

2                   So, I'm just wondering if we're over-  
3 excluding, any -- just the easiest of the easy  
4 cataracts that people can therefore be successful  
5 to measure, as opposed to truly identifying those  
6 who may need some help?

7                   CO-CHAIR YAREMCHUK: Go ahead. Josh?

8                   MEMBER STEIN: This came up with the  
9 previous measure, too. That I don't think it's  
10 necessarily a fundamental problem with this  
11 measure.

12                   But I'd like to see in subsequent  
13 measures to expand the number eligible. You  
14 know, have one measure for complete uncomplicated  
15 cataracts. And then another for cataracts with  
16 issues.

17                   And hopefully, the developers are  
18 looking to do that sort of thing.

19                   DR. RICH: We're doing exactly that.  
20 We'll be able to look at people with  
21 pseudoexfoliation. You know, all those issues  
22 we're actually collecting massive amounts of data



1 now.

2 We'll have over a million next year.

3 So we'll be able to stratify those.

4 DR. LUM: I just wanted to add that I  
5 know the analysis you were provided looked at  
6 Medicare claims data over 70,000 procedures. But  
7 the IRIS Registry is the ECQM, which is all  
8 patient populations.

9 So, the claims were limited to  
10 Medicare Part B, only fee for service. So we had  
11 over 300,000 procedures.

12 And the exclusion was much lower. It  
13 was 27 percent for that measure. So, we are  
14 including many more patients.

15 And as Dr. Rich said, we provide the  
16 rate for both complicated and uncomplicated  
17 patients to our participants, so that they can  
18 look at improvement in quality and look at those  
19 patients that had a complication. And really dig  
20 down and see what was causing it.

21 And it's really for their own quality  
22 improvement purposes.

1 CO-CHAIR YAREMCHUK: Steve?

2 MEMBER STRODE: The previous measure  
3 was at 90 days. And this is at 30 days. And my  
4 question is, would 30 days capture most of those  
5 complication surgeries?

6 Recognizing that the timing of such  
7 surgery goes beyond the recommendation of the  
8 ophthalmologist. It might have patient issues.  
9 It might have health insurance approval issues  
10 and others.

11 DR. RICH: The vast majority of the  
12 return to the OR is going to occur from surgical  
13 error. And statistically, all most all of them  
14 are somewhere around ten days or less.

15 Or certainly up to 30 days. In 90  
16 days, you might be picking up a couple of people  
17 that had an incidental retinal detachment.

18 So we felt that it was -- we could  
19 actually capture most of those surgical errors  
20 that led to the complications and we return to  
21 the OR. They can be captured both in EHR and the  
22 claims data within 30 days.

1 CO-CHAIR YAREMCHUK: Are we ready to  
2 vote?

3 MS. ROBINSON-ECTOR: Voting is now  
4 open for reliability for the registry version of  
5 Measure 0564. And for those on the line, option  
6 one is high, two is moderate, three is low and  
7 four is insufficient.

8 I'm just waiting on one more vote.

9 MS. LUONG: Vaishali, if you can just  
10 email -- thanks, got it.

11 MS. ROBINSON-ECTOR: Great. All the  
12 votes are in. 43 percent voted high. 57 percent  
13 voted moderate. Zero voted low and zero voted  
14 insufficient.

15 So for reliability, the registry  
16 version of Measure 0564 passes.

17 CO-CHAIR YAREMCHUK: Okay. Can we go  
18 on to validity?

19 MEMBER CARNAHAN: This is very similar  
20 to the prior measure where the expert panelists  
21 16 strongly agreed the measure could be  
22 distinguished as a quality of care measure.

1           There's also this small claim -- the  
2           small group of one practice, one EHR that was  
3           evaluated with a 99 to 100 percent agreement.  
4           Then there's the registry patients with a high  
5           level of agreement.

6           So, we already discussed the  
7           exclusions piece of things. And then there was  
8           some socioeconomic questions as to if that was  
9           taken into account. And maybe that would be  
10          something the IRIS Registry would be able to  
11          stratify as well in the future.

12          MEMBER STEIN: Yes, I don't think  
13          we're ready for risk adjustment yet. But I'd  
14          like to see it in the next round when this comes  
15          up.

16          Risk adjustment as clearly, for  
17          example, Asian Americans have more myopia and are  
18          more prone to retinal detachments in some of  
19          these issues. So, I think in the future that  
20          would be something important to incorporate.

21          DR. RICH: Exactly what we're doing.

22          CO-CHAIR YAREMCHUK: All right, are we

1 ready to vote?

2 MS. ROBINSON-ECTOR: Yes. The voting  
3 is now open for validity for Measure 0564, for  
4 the registry version of the measure.

5 Oh, sorry. And for those on the line,  
6 option one is high, two is moderate, three is low  
7 and four is insufficient.

8 All the votes are in. 21 percent  
9 voted high. 79 percent voted moderate. Zero  
10 voted low and zero voted insufficient. So for  
11 the registry version of Measure 0564, the measure  
12 passes validity.

13 CO-CHAIR YAREMCHUK: Usability and  
14 use?

15 MEMBER CARNAHAN: Feasibility? So,  
16 just like the prior Measure, very feasible. All  
17 the diagnosis as well as all the procedures have  
18 distinct codes that can be easily data mined.

19 So, I guess if there was -- it says,  
20 indicate whether any feasibility concerns such as  
21 fees for registry, participation, I suppose there  
22 is, as you would have to have an AAO membership

1 to participate in the IRIS Program.

2 But, otherwise you can do it through  
3 the PQRS. And that should be easily mined from  
4 any EHR I would think.

5 CO-CHAIR YAREMCHUK: Josh?

6 MEMBER STEIN: Nothing to add.

7 CO-CHAIR YAREMCHUK: Okay. Vote?

8 MS. ROBINSON-ECTOR: Voting is now  
9 open for feasibility for the registry version of  
10 Measure 0564. And for those on the line, option  
11 one is high, two is moderate, three is low and  
12 four is insufficient.

13 All the votes are in. 64 percent  
14 voted high. 36 percent voted moderate. Zero  
15 voted low and zero voted insufficient.

16 So for feasibility, for the registry  
17 version of Measure 0564, the measure passes.

18 CO-CHAIR YAREMCHUK: Okay. Now,  
19 usability and use.

20 MEMBER CARNAHAN: As we talked about  
21 the PQRS options, the IRIS options, there's the  
22 meaningful use component of things. So this

1 should be very easy, usability and use would  
2 minimally impact any practice.

3 MEMBER STEIN: Nothing to add.

4 CO-CHAIR YAREMCHUK: Vote?

5 MS. ROBINSON-ECTOR: Voting is now  
6 open for usability and use of the registry  
7 version of Measure 0564. And for those on the  
8 call, option one is high, two is moderate, three  
9 is low and four is insufficient information.

10 Okay. All the votes are in and voting  
11 is now closed. 50 percent voted high. 43  
12 percent voted moderate. Zero voted low and zero  
13 voted insufficient information.

14 So for usability and use of the  
15 registry version of 0564, the measure passes.

16 CO-CHAIR YAREMCHUK: Okay. Should we  
17 vote on E-measures? Or that's after we do the --

18 MS. ROBINSON-ECTOR: After we do this.

19 CO-CHAIR YAREMCHUK: Okay. So we'll  
20 vote on endorsement now for the measure.

21 MEMBER CARNAHAN: Let me make one more  
22 comment. Just that the panel had suggested that

1 the title actually should be selective  
2 complications as opposed to complications.  
3 Because it would indicate that someone wasn't  
4 having other complications.

5 And yet, I think this is, perhaps, the  
6 minority of complications that happen. I think a  
7 posterior capsular rupture is much more common  
8 than any of these things combined.

9 Another piece of it is that you have  
10 to have both hits to have a trigger. And I would  
11 venture to say that over half the time, and I  
12 think I'm being generous, a patient who has a  
13 wrong lens implanted is not going to go back and  
14 have a lens exchanged.

15 They're going to have laser vision  
16 correction procedure that's not going to trigger  
17 this. Just because that's the way the world  
18 works.

19 So, I don't think you can fix that.  
20 I don't think that's possible. But I just think  
21 that's reality.

22 DR. RICH: Yes. I think in the --



1 actually out in the community, people would  
2 exchange that lens, rather than taking them back  
3 for a second procedure.

4 MEMBER CARNAHAN: Are they just  
5 wearing it?

6 DR. RICH: Yes.

7 MEMBER CARNAHAN: On a laser and they  
8 put a multi-focal lens in and it's not quite  
9 right, they're not going to take it out and put  
10 another one in. They're going to do the PRK  
11 which costs them \$350, versus losing money and  
12 doing a whole new cataract.

13 And that seems like it should be  
14 recentered.

15 DR. RICH: So I think we could -- the  
16 afternoon is getting late, but --- I think I'll  
17 let that one pass. The whole idea of having  
18 selective complications is you could actually  
19 quantify them with claims data.

20 So these are things that you can't  
21 fudge. There's going to be a return to the  
22 operating room.

1                   And that's why we have a separate  
2                   measure for vitreous loss, specifically. But,  
3                   see that's much harder to track. And -- but  
4                   these are much easier to track.

5                   They're made more -- and they're a  
6                   little more serious things --- wrong eye well,  
7                   dropped nucleus, all the things that Scott sees  
8                   in his office after.

9                   MEMBER FRIEDMAN: I don't see any of  
10                  those. So, one more question. I just started  
11                  thinking, how do you differentiate returning to  
12                  the operating room that isn't related to the  
13                  complications?

14                  So the patient gets surgery. Then  
15                  they go to the operating room within 30 days, but  
16                  it's not a complication of the cataract surgery?

17                  MR. RICH: On an eye procedure?

18                  MEMBER FRIEDMAN: Well, yes. Diabetic  
19                  macular edema.

20                  MR. RICH: I don't know that I can  
21                  answer that. Flora?

22                  MEMBER SCHACHAT: I think the safety

1 catch on your concern is that most or probably  
2 the overall majority relate to the surgery. I  
3 mean, the one that I would worry about is stuff  
4 on the other eye.

5 But there are eye modifiers that let  
6 us crack that.

7 MEMBER CARNAHAN: And it does have  
8 very specific diagnosis for the returns. Not any  
9 return to the OR in 30 days.

10 It's removal procedures, excision of  
11 adhesions. Tap and inject for the ophthalmitis  
12 one lens procedures. Retinal repair, but not  
13 necessarily a vitrectomy.

14 So it doesn't go through every  
15 possible return to the OR. But only selective  
16 ones I imagine they felt would be related to the  
17 very select diagnoses of that.

18 MEMBER STEIN: The use of modifiers  
19 should be able to distinguish that. You know,  
20 it's conceivable that someone could have such a  
21 dense cataract that you can't see what's going on  
22 behind it.

1                   And then you take it out and realize  
2                   there are other issues that require additional  
3                   surgery. But the modifiers should sort that out.

4                   CO-CHAIR YAREMCHUK: Okay. Are we  
5                   ready to vote on endorsement? Okay.

6                   MS. ROBINSON-ECTOR: So, the voting is  
7                   now open for recommendation for overall  
8                   suitability for endorsement for the registry  
9                   version of Measure 0564. And for those on the  
10                  call, option one is yes and option two is no.

11                  Okay. All the votes are in. 100  
12                  percent voted yes. And zero percent voted no.  
13                  So for recommendation for overall suitability for  
14                  endorsement for the registry version of Measure  
15                  0564, the measure passes.

16                  DR. WINKLER: All right. This measure  
17                  also has an eMeasure version. So as we did with  
18                  the last measure, we do want to look at any  
19                  particular issues that might be specific to the  
20                  eMeasure.

21                  That evidence and gap should be the  
22                  same as for the other. So we're talking about

1 scientific acceptability.

2 We have the same issues that they will  
3 be doing the additional testing in a simulated  
4 data set and providing us the information from  
5 the results of that testing when we regroup after  
6 the comment call.

7 And so, the voting is as before for  
8 scientific acceptability of the eMeasure, you  
9 know, with those conditions.

10 Does anyone have any comments or  
11 questions about the eMeasure specifically in  
12 terms of reliability and validity? That may be  
13 distinct from the registry measure? Okay.

14 Ready to vote on measures. Yes or no,  
15 and once again, yes is with conditions. And the  
16 condition is bringing back the information from  
17 the testing of the simulated data set.

18 MS. LUONG: And this is for the  
19 eMeasure version of 0564. So Vaishali, one is  
20 yes with conditions and two is no.

21 MEMBER PATEL: Oh, sorry. I thought  
22 I already voted. Sorry.

1 MS. ROBINSON-ECTOR: Great. All the  
2 votes are in. Okay. For reliability and  
3 validity, for the eMeasure version of 0564, 100  
4 percent voted yes. And zero voted no. so the  
5 measure passes.

6 CO-CHAIR YAREMCHUK: Next up is  
7 feasibility of the eMeasure. Does anyone have  
8 any questions, concerns, comments about  
9 feasibility of this as an eMeasure?

10 Okay. Then we'll ask you to vote on  
11 that.

12 MS. ROBINSON-ECTOR: Voting is now  
13 open for feasibility for Measure 0564, for the  
14 eMeasure version. And for those on the line,  
15 option one is high, two is moderate, three is low  
16 and four is insufficient.

17 Okay. All the votes are in. 64  
18 percent voted high, 36 percent voted moderate.  
19 Zero voted low and zero voted insufficient. So  
20 for feasibility for the eMeasure version of 0564,  
21 the Measure passes.

22 DR. WINKLER: Now, as we did before,

1 is there anything different or distinct about the  
2 eMeasure as to usability and use that you would  
3 want to vote it separately? Or should we just  
4 use the same voting you did for the registry  
5 version for usability and use?

6 Anybody have any objection to using  
7 the same results? Excellent.

8 So we can move on to the  
9 recommendation for endorsement. Again, this is  
10 the -- with the conditions of the additional  
11 information that will be brought back around the  
12 simulated data set.

13 MS. ROBINSON-ECTOR: So, voting is now  
14 open for recommendation for overall suitability  
15 for endorsement for the eMeasure version of 0564.  
16 And for those on the call, option one is yes with  
17 conditions and option two is no.

18 All the votes are in. 100 percent  
19 voted yes with conditions. And zero voted no.  
20 So for recommendation for overall suitability for  
21 endorsement for the E-Measure version of 0564,  
22 the measure passes.

1 CO-CHAIR YAREMCHUK: So we are next --  
2 for our next measure, is this also an eMeasure?

3 DR. WINKLER: No, it's not.

4 CO-CHAIR YAREMCHUK: Okay. So 0563,  
5 Primary Open-Angle Glaucoma: Reduction of  
6 Interocular Pressure by 15 Percent or  
7 Documentation of a Plan of Care, American Academy  
8 of Ophthalmology. And who is going to discuss  
9 this? Okay.

10 MEMBER STEIN: So we're discussing the  
11 evidence now?

12 CO-CHAIR YAREMCHUK: Correct.

13 MEMBER STEIN: Okay. So there are  
14 several large landmark randomized clinical trials  
15 that have shown that lowering eye pressure can  
16 prevent worsening of vision and blindness from  
17 glaucoma.

18 The American Academy, as a preferred  
19 practice pattern that recommends lowering of eye  
20 pressure of 25 percent or more. In the clinical  
21 trials that are out there, show levels of 18 to  
22 42 percent.



1                   And it's a Grade A, Level Two  
2 evidence. So I think there's evidence to support  
3 the measure.

4                   CO-CHAIR YAREMCHUK: Is there someone  
5 that's your assistant or is also on this?

6                   MEMBER PATEL: Well, yes. Vaishali  
7 Patel on the phone. So I'm the other discussant  
8 for this measure.

9                   So, I agree with Josh that there's  
10 enough evidence. Plenty of enough evidence to  
11 show importance of lowering IOP for treatment of  
12 glaucoma.

13                   And it's the only modifier of this  
14 factor. And so from that perspective, it's, you  
15 know, an important thing to do than to lower.

16                   CO-CHAIR YAREMCHUK: Okay.

17                   MEMBER PATEL: ---- and to measure.

18                   CO-CHAIR YAREMCHUK: Any comments?

19 All right we can --

20                   MEMBER STEIN: There's a comment.

21                   DR. RICH: Yes, just a point of  
22 information that was discussed in the call was

1 the plan of care. And we felt it was very  
2 important to have the failure in there.

3 And if you look at that, that's  
4 actually consistent with all of our other  
5 Measures. The hemoglobin A1c measure, the  
6 hypertension measures.

7 There's a certain number of people  
8 where you make the value judgment that you're  
9 going to have more complications. And so you're  
10 willing to follow them.

11 So, that's why that plan of care is in  
12 there. And we were asked to document how many  
13 people passed the measure by looking at a plan of  
14 care when they didn't get there.

15 And we looked very carefully and the  
16 number was 30 percent. So, that's actually kind  
17 of consistent with the -- our other chronic  
18 disease measures that have a goal in mind.

19 CO-CHAIR YAREMCHUK: Okay. Are we  
20 ready to vote? Evidence?

21 MS. ROBINSON-ECTOR: Voting is now  
22 open for evidence for Measure 0563. And for

1 those on the call, option one is high, two is  
2 moderate, three is low and four is insufficient  
3 evidence.

4 Okay. All the votes are in. 64  
5 percent voted high. 36 percent voted moderate.  
6 Zero voted low and zero voted insufficient. So,  
7 for evidence of 0563, the measure passes.

8 CO-CHAIR YAREMCHUK: Okay.  
9 Opportunities for improvement?

10 MEMBER STEIN: So, according to the  
11 information provided by the developer, the mean  
12 performance from 2009 to 2012 is 93 to 95  
13 percent. So there is some room for improvement.

14 DR. LUM: I'd just like to add that  
15 was -- that number at least in 2013 only  
16 represented 15 percent of the eligible providers.  
17 So we're still talking about a very small  
18 minority of patients.

19 The other thing I wanted to bring up  
20 I think is we're really going through a  
21 transformational demographic trend. And we  
22 haven't talked about disparities in care.

1           But I think this issue, and we'll get  
2           to diabetic retinopathy, are huge issues for us  
3           in eye care. And just for the non-eye care  
4           professionals, I just wanted to explain that  
5           we're going from 2.71 million people with POAG to  
6           7.31 million in 2050.

7           And the largest demographic group is  
8           changing from older white women to Hispanic men.  
9           And that's by 2035. We're going to double per  
10          capita rates of POAG in key states like New  
11          Mexico, Texas and Florida because of the  
12          demographics.

13          And we already know that Hispanics  
14          have less access to care. In fact, Dr. Stein  
15          wrote an article showing the odds of ancillary  
16          testing for glaucoma are less in Hispanics.

17          So I do want to keep that focus on  
18          these population groups that potentially have  
19          less access to care, are in rural areas, under-  
20          served areas and potentially with providers who  
21          are less knowledgeable.

22          CO-CHAIR YAREMCHUK: And I guess the

1 second part is this -- it says briefly discuss  
2 any data on disparities.

3 DR. RICH: Yes. And then African  
4 Americans have a threefold higher rate of  
5 blindness and incidents of glaucoma. And so this  
6 has been a major focus of the Academy.

7 We are doing well in the -- if you  
8 look at the last 15 years, we've decreased  
9 blindness by 50 percent. The rate of blindness.

10 However, there is still marked  
11 differences in African Americans and Hispanics.

12 MEMBER GOLDBERG: Is the goal of this  
13 to get patients referred to ophthalmologists by  
14 their primary care doctors?

15 Yes, is the goal of this to get  
16 primary care physicians to refer to  
17 ophthalmologists? Or is this a measurement of --  
18 for ophthalmologists?

19 DR. LUM: For ophthalmologists and  
20 optometrists. But it's really to improve the  
21 care and make sure that we are focusing on  
22 interocular pressure reduction.

1           Because we have shown studies and  
2           that's in the rationale of the Measure that you  
3           know, maybe 50 percent of patients aren't having  
4           their IOP reduced by 15 percent.

5           I think Dr. Stein has also had written  
6           articles to that effect. That when we look  
7           across and we look at patient records, we aren't  
8           seeing the interocular pressure reduction.

9           And that's the only -- as Vaishali  
10          said, the only modifiable risk factor that we can  
11          do anything about to affect the ultimate outcome  
12          of glaucoma and prevent blindness.

13          CO-CHAIR YAREMCHUK: Are we ready to  
14          vote?

15          MEMBER PATEL: I would like to add one  
16          more thing. To answer the question of, you know,  
17          is there a gap in care that warrants a National  
18          Performance Measure.

19          So, you know, even though we see high  
20          rates of reporting or meeting this Measure, you  
21          know, being 90 plus percent. Keep in mind that  
22          that -- about 70 percent of that is actual, you

1 know, meeting the 15 percent lowering of target.

2 Which I think is already very good.  
3 70 percent, if people are meeting that criteria  
4 alone, 70 percent, that's already very good. But  
5 it can always be better.

6 So, that's why it's a good idea to  
7 continue to, you know, measure that. But, you  
8 know, don't -- I do think that the good portion  
9 of that 30 per -- you know, 95 percent is because  
10 of the second part of that wording which is Plan  
11 -- Document of Plan of Care.

12 So, if there is any way to separate  
13 the two in the future, you know, I would be in  
14 favor of that so that we can clearly see how many  
15 physicians are actually meeting the level of  
16 lowering the IOP versus how many times, you know,  
17 is a documented Plan of Care. And measure those  
18 two separately.

19 DR. LUM: And I think Dr. Rich had  
20 mentioned that we looked at our IRIS Registry  
21 data. This is the manual registry.

22 And 30 percent -- so for everybody who

1 claimed that they met the performance, 30 percent  
2 met it with plan of care. But 70 percent met it  
3 by reducing IOP.

4 So that probably reflects just that  
5 complicated situation, you know, that the  
6 patients come in, they're advanced age. Are you  
7 going to add another medication or surgery?  
8 Probably not.

9 You might have a plan of care of how  
10 to address it. The patient can't afford  
11 medication. You might have a plan of care.

12 You can't always add another  
13 medication or surgery to get that interocular  
14 pressure down in a year's time. And so, that's  
15 why that plan of care was provided.

16 But it still keeps their focus I think  
17 on reducing the interocular pressure. And  
18 looking out for that patient and monitoring that  
19 patient.

20 And that was the intent of the  
21 measure.

22 MEMBER PATEL: Yes. No, no, I -- so



1 I agree completely. I think that's a good idea.  
2 And I'm glad that in the IRIS Registry there is a  
3 way to separate the two.

4 I'm saying also, if in the quality  
5 measure, there is a way to separate the two, you  
6 know, for future purposes, that's something that  
7 should be considered.

8 DR. LUM: Well, certainly that can be  
9 separate. I don't -- CMS doesn't report it out.  
10 But there's different codes for reporting either  
11 a plan of care or a reduction of IOP.

12 So you can definitely separate it out.

13 CO-CHAIR YAREMCHUK: Are we ready to  
14 vote for opportunities for improvement?

15 MS. ROBINSON-ECTOR: Voting is now  
16 open for performance gap for Measure 0563. And  
17 for those on the phone, option one is high, two  
18 is moderate, three is low and four is  
19 insufficient.

20 All the votes are in. 64 percent  
21 voted high. 36 percent voted moderate. Zero  
22 voted low and zero voted insufficient. So for

1 performance gap, Measure 0563 passes.

2 CO-CHAIR YAREMCHUK: Okay.

3 Reliability?

4 MEMBER STEIN: So I think for the most  
5 part, it's a reliable measure. You know, I think  
6 Vaishali brought up the issues of the plan of  
7 care.

8 And I think in a future iteration it  
9 would be nice to tease that out. I think that  
10 the devel -- and I don't want to speak for the  
11 developers, but I think their intention is to  
12 come up with a measure that where the goal is to  
13 get 100 percent.

14 And there may be ways to do the  
15 measure where the goal doesn't have to be 100  
16 percent. And you can capture some of these other  
17 circumstances and have it where, you know, 90  
18 percent should be, you know, should be good  
19 performance.

20 And maybe those who are getting 100  
21 percent are over-utilizing or doing too much.  
22 But, I think for the most part it's a pretty

1 reliable measure.

2           You know, I think that I would  
3 encourage in the next iteration, for risk  
4 adjustment, clearly, with the increasing number  
5 of minorities with glaucoma, some of these  
6 patients are more difficult to care for. And  
7 achieving of 15 percent pressure lowering can be  
8 more challenging.

9           And you'd hate to have a provider who  
10 is practicing in a setting where you've got much  
11 more challenging patients not do as well because  
12 of their patient population and their  
13 demographics.

14           So, I think risk adjustment and  
15 hopefully with IRIS and -- will enable that to be  
16 possible.

17           DR. RICH: Yes. One of the issues of  
18 risk adjusting is it takes away the focus of the  
19 adverse outcomes of those populations at risk.  
20 So, you've got to balance risk adjustment with  
21 keeping the focus on the outcomes from people  
22 with -- Hispanics and African Americans.

1                   But, we will be able to do that. We  
2 have eight million people in the Registry now.  
3 We're planning that probably 48 million by 2017.  
4 So we'll be able to look at large stratified data  
5 on what's unique about these populations with the  
6 plan of care.

7                   And it -- that's actually not that  
8 hard to collect.

9                   CO-CHAIR YAREMCHUK: Any other  
10 comments?

11                   (No response)

12                   CO-CHAIR YAREMCHUK: Are we ready to  
13 vote on reliability?

14                   MS. ROBINSON-ECTOR: Voting for  
15 reliability for Measure 0563 is now open. And  
16 for those on the phone, option one is high, two  
17 is moderate, three is low and four is  
18 insufficient.

19                   Okay. All the votes are in and voting  
20 is now closed. 43 percent voted high. 57  
21 percent voted moderate. Zero voted low and zero  
22 voted insufficient. So, for reliability, Measure

1 0563 passes.

2 CO-CHAIR YAREMCHUK: Okay. Validity?

3 MEMBER STEIN: So for validity, the  
4 Developer used an expert panel, the 16 glaucoma  
5 specialists. And 15 of the 16 members, based on  
6 face validity, found it to be valid.

7 CO-CHAIR YAREMCHUK: Any other  
8 comments?

9 MEMBER MADONNA: Yes, I'd like to ask  
10 the Developers, although lowering IOP is  
11 obviously an admirable goal. Why was it 15  
12 percent chosen as opposed to 25 percent? Or  
13 something else?

14 Even in the ocular hypertension  
15 treatment study, patients who have not developed  
16 glaucoma, there was a 20 percent goal IOP  
17 reduction. So, why 15?

18 DR. RICH: I'll let Flora start and  
19 I'll comment.

20 DR. LUM: So, you're right. And as  
21 Dr. Stein mentioned, the randomized control  
22 trials did show higher rates. But those are all

1 randomized control trials in a very particular  
2 setting.

3 You know, that may not translate into  
4 real world. As Dr. Stein's mentioned, there are  
5 minority populations. Populations that we're  
6 concerned about medication adherence. And that  
7 really affects the amount of interocular pressure  
8 reduction that you can have.

9 So it was really designed as kind of  
10 a floor -- a floor effect. A failure effect that  
11 you really -- 15 percent was -- really could be  
12 reasonably expected for the patient and on the  
13 part of the physician without going to  
14 extraordinary needs and having the most ideal  
15 patient that came in for every follow up visit.

16 MEMBER MADONNA: Well, I would think  
17 that the plan of care covers that. And if I were  
18 looking at my own patients and looked at 15  
19 percent, I would think that they would be under-  
20 treated in almost all cases with the current  
21 state of the art with prostaglandin and analogues  
22 and so forth.

1 DR. RICH: Yes. The fact of the  
2 matter is that somewhere between 50 and 60  
3 percent are not under control currently. So, you  
4 have to start someplace with the pressure  
5 lowering.

6 And again, you don't have -- it took  
7 cardiology eight years to develop the guidelines  
8 for hypertension working with other primary care  
9 groups. You know, we're trying to address, you  
10 know, a pressing need.

11 We can't wait eight years to develop  
12 new evidence based guidelines. Now they've got  
13 competing guidelines, but I won't get into that.

14 So, we thought that this was a  
15 reasonable Measure. If you look at other  
16 Measures, other intermediate outcome Measures in  
17 chronic disease, it's -- if you take a 15 percent  
18 cut of the vast majority of people with  
19 hypertension that are outside, you're going to  
20 have them inside your 140 over 90 guideline.

21 So, is there Level One evidence that  
22 this is the number? The answer is no. But, we

1 have a huge gap in care when somewhere between 50  
2 to 60 percent of people under treatment have  
3 inadequate levels.

4 DR. STEIN: Richard, I think your  
5 point is well taken. I think one of the  
6 challenges is with caring for patients with  
7 glaucoma in general is that, you know, there's  
8 patient related factors.

9 There's provider related factors. And  
10 there's system related factors that are all going  
11 to impact what someone's pressure is on a given  
12 day.

13 And patient adherence is known to be  
14 a huge issue in glaucoma. So, how well one -- I  
15 think there needs to be some flexibility to deal  
16 with factors that are beyond the control of the  
17 provider.

18 I think that was part of the intention  
19 with choosing the 15 percent number.

20 DR. RICH: It resulted from extensive  
21 discussions with outcomes researchers like Josh  
22 and others in the glaucoma community. So, this



1 was a consensus figure.

2 But again, it's not an evidence based  
3 guideline like NHLBI originally came up with.  
4 You've got to start somewhere.

5 CO-CHAIR YAREMCHUK: Are we ready to  
6 vote? Or any more comments?

7 (No response)

8 CO-CHAIR YAREMCHUK: Okay. Ready to  
9 vote on validity.

10 MS. ROBINSON-ECTOR: Voting is now  
11 open for validity for Measure 0563. And for  
12 those on the call, option one is high, option two  
13 is moderate, three is low and four is  
14 insufficient.

15 All the votes are in. 7 percent voted  
16 high. 79 percent voted moderate. 14 percent  
17 voted low. And zero voted insufficient. So for  
18 validity for Measure 0563, the Measure passes.

19 CO-CHAIR YAREMCHUK: Feasibility?

20 MEMBER STEIN: I think that, you know,  
21 eye pressures are captured pretty well in  
22 electronic health records. So it's a reasonably

1 feasible, I mean Measure in my opinion.

2 CO-CHAIR YAREMCHUK: Any other  
3 comments?

4 MEMBER CARNAHAN: Yes, there's  
5 specific codes both for the 15 percent reduction  
6 as well as for the plan and care piece of it.  
7 So, it can be clearly documented.

8 And I think that's the good thing. I  
9 guess the other part of it, which is a different  
10 section, is, you can almost always find one of  
11 these plan of care options that would work should  
12 you not have the target pressure.

13 CO-CHAIR YAREMCHUK: Okay. Was there  
14 another comment on this side?

15 (No response)

16 CO-CHAIR YAREMCHUK: Okay. All right.  
17 Good. We're ready to vote on feasibility.

18 MS. ROBINSON-ECTOR: Voting on  
19 feasibility for Measure 0563 is now open. And  
20 for those on the phone, option one is high,  
21 option two is moderate, option three is low and  
22 four is insufficient.

1 All the votes are in. 64 percent  
2 voted high. 36 percent voted moderate. Zero  
3 voted low and zero voted insufficient. So for  
4 feasibility, Measure 0563 passes.

5 CO-CHAIR YAREMCHUK: Usability and  
6 use?

7 MEMBER STEIN: This data is captured  
8 in the IRIS Registry and electronic health  
9 records. And you know, with claims data it  
10 doesn't capture eye pressures.

11 But, it looks like we're moving away  
12 from using claims data as the other capture  
13 means. And it should be pretty usable.

14 CO-CHAIR YAREMCHUK: Any other  
15 comments?

16 DR. WINKLER: I have one question. Is  
17 there any plan to publically report these  
18 Measures? Since these are from your Registry and  
19 not -- this one's not part of the federal  
20 programs.

21 DR. LUM: Everything in PQRS will be  
22 reported, right? In 2015 for -- yes.

1 DR. RICH: Next year. In 2015.

2 DR. LUM: Yes.

3 CO-CHAIR YAREMCHUK: Okay. Ready to  
4 vote.

5 MS. ROBINSON-ECTOR: Voting is now  
6 open for usability and use for Measure 0563. And  
7 for those on the call, option one is high, two is  
8 moderate, three is low and four is insufficient  
9 information.

10 Okay. All the votes are in. 43  
11 percent voted high. 50 percent voted moderate.  
12 7 percent voted low. And zero voted  
13 insufficient. So for usability and use, Measure  
14 0563 passes.

15 CO-CHAIR YAREMCHUK: Okay. Now, vote  
16 on whether to recommend that Measure as suitable  
17 for endorsement.

18 MS. ROBINSON-ECTOR: Voting is now  
19 open for recommendation for overall suitability  
20 for endorsement for Measure 0563. For those on  
21 the call, option one is yes and option two is  
22 not.

1                   And it looks like we're missing one  
2                   vote in the room. If you all could revote  
3                   please?

4                   Okay. Now all the votes are in. 93  
5                   percent voted yes. 7 percent voted no. So for  
6                   recommendation for overall suitability for  
7                   endorsement for Measure 0563, the Measure passes.

8                   CO-CHAIR YAREMCHUK: Okay. Thank you.  
9                   And this isn't an E-Measure. So we don't need to  
10                  vote separately for it.

11                  The next Measure is Primary Open Angle  
12                  Glaucoma, 0086, Optic Nerve Evaluation.

13                  Evidence? Pardon me? Okay. Sheli?

14                  MS. LUONG: Vaishali, would you like  
15                  to speak to this Measure?

16                  MEMBER PATEL: The optic nerve damage  
17                  Measure?

18                  MS. LUONG: Yes. As a -- the 0086.  
19                  The optic nerve evaluation.

20                  MEMBER PATEL: yes.

21                  MS. LUONG: Yes.

22                  MEMBER PATEL: So, --

1 MS. LUONG: Just the evidence for now.

2 MEMBER PATEL: Yes. Give me one  
3 minute. So, regarding the evidence to support  
4 the Measure, the evidence, it cites the IOP  
5 practice pattern as assessing guideline -- you  
6 know, evidence Grade A for the Measure, which I  
7 agree with.

8 And then also, there is evidence  
9 that's cited in the IOP practice pattern that's  
10 based on -- it's actually, you know, based more  
11 on the case series rather than the large  
12 randomized controlled trials.

13 But there are enough large randomized  
14 controlled trials that also use the optic nerve  
15 damage as an assessment for glaucoma. So I would  
16 say the evidence is there to support the Measure.

17 CO-CHAIR YAREMCHUK: Any comments?

18 DR. RICH: One other -- I'll just add  
19 a quick note. And that is, when we were looking  
20 to address, there is a disparity.

21 About ten years ago we tried to find  
22 a "cheap, less invasive way" of looking at

1 populations at risk. This was -- and so, in  
2 detailed by an examination of the optic nerve was  
3 shown by Hopkins -- by Dunbar Hoskins in the '90s  
4 to actually be able to identify people at risk.

5 So, there was a glaucoma detection  
6 benefit was passed with the -- for people --  
7 African Americans and Hispanics in the family  
8 history of glaucoma to assess their possibility  
9 of having glaucoma.

10 And it was to preventative benefit  
11 designed by ourselves, the National Eye  
12 Institute, the American Glaucoma Society. The  
13 validity was approved by CMS and the CBO. And  
14 the cost savings were scored profit -- positively  
15 by CBO.

16 So, low tech is good.

17 CO-CHAIR YAREMCHUK: So, are we ready  
18 to vote evidence?

19 MS. ROBINSON-ECTOR: So, voting is now  
20 open for evidence for Measure 0086. And for  
21 those on the phone, option one is high, two is  
22 moderate, three is low and four is insufficient

1 evidence.

2 Okay. All the votes are in 43 percent  
3 voted high. 50 percent voted moderate. 7  
4 percent voted low. And zero voted insufficient  
5 evidence. So for evidence, Measure 0086 passes.

6 CO-CHAIR YAREMCHUK: Okay.  
7 Opportunity for improvement?

8 MEMBER PATEL: So, the current  
9 reporting for the Measure is in the 90 plus  
10 percent range. But, I think it's contin -- you  
11 know, there is still opportunity for improvement  
12 toward 100 percent.

13 And I also think, as it was mentioned  
14 before in the other, you know, Measure, it's  
15 important to continue to measure this so that it  
16 remains high.

17 DR. RICH: Another comment. There's  
18 previous literature showing the other -- the  
19 failure to document the optic nerve and this is a  
20 chronic disease.

21 It would be nice in hypertension to  
22 look at what's happened in the blood vessels in



1 the heart. Well, we can do that looking in the  
2 eye.

3 And second of all, the performance  
4 rate was really only 79 percent when we actually  
5 looked at charts and looked at the electronic  
6 record. Flora?

7 DR. LUM: Yes, that percentage was  
8 much lower when we actually looked at it. And  
9 we've talked to practices and they don't.

10 The two things that we look for in the  
11 E-Measure specification, which are also in the  
12 Measure specification for registry, is cup to  
13 disc ratio and documentation of optic nerve  
14 appearance. And we talk to practices all the  
15 time and they don't document that.

16 So, that's -- that is a gap for  
17 improvement.

18 MEMBER PATEL: Okay. So you're saying  
19 even though it's reporting PQRS as 90 plus  
20 percent, when you looked yourselves you found it  
21 be lower?

22 DR. LUM: Right. Because as you know,

1       that's attestation. So if they put a claims code  
2       that said they did a dilated eye exam, which what  
3       the bare minimum of the Measure specification  
4       says.

5               But we actually in the Measure  
6       rationale we say when you look at the nerve, you  
7       need to document -- look at the cup to disc ratio  
8       and document the optic nerve appearance.

9               And those will really give you a guide  
10      on how to treat the patient. Whether management  
11      needs to be added or, you know, stepped up.

12              So, those are the things that we look  
13      for in the electronic health record. And we  
14      don't find them really, well, a higher percentage  
15      of the time.

16              CO-CHAIR YAREMCHUK: Todd?

17              MEMBER RAMBASEK: So, if I'm  
18      understanding correctly, you can do an optic  
19      nerve head evaluation and not document the cup to  
20      disc ratio?

21              DR. LUM: Well, yes. That's what  
22      we're saying. Is in the claims and registry

1 process, the doctors are saying that they've done  
2 it. They probably in, you know, they think  
3 they've done it.

4 But if you actually look at those who  
5 have electronic health records, there is no  
6 documentation of the cup to disc ratio or  
7 appearance.

8 MEMBER RAMBASEK: So, is that what the  
9 Measure should be? That if you have a diagnosis  
10 of POAG that you need to document the cup to disc  
11 ratio?

12 DR. LUM: It is in the Measure, in the  
13 details of the Measure description from which the  
14 E-Measure specification has it. We just are very  
15 -- were much more precise in what we extract from  
16 the EHR.

17 MEMBER FRIEDMAN: So, just a quick  
18 point of clarification. So if they say they doc  
19 -- they say they looked at it, how did they  
20 document that they looked at it?

21 I mean, you can write down, I looked  
22 at the optic nerve. But is there any evidence

1 that they actually did do what they said they  
2 did?

3 DR. RICH: Well, it's pretty good --  
4 this was one that was not registry reported. It  
5 could be reported on claims. So it was an  
6 attestation.

7 Our point is, when you actually look  
8 at the performance electronically, it's not  
9 there. So, there's a huge area for improvement  
10 and a gap in care.

11 So, you know, no one's going to be  
12 reporting this on claims this year. They're only  
13 going to be reporting it electronically.

14 And so, the performance is overstated.  
15 But what we've learned in the claims for this  
16 particular Measure. And there are some problems  
17 that we'll get into about the Electronic Measure  
18 later on.

19 MEMBER MADONNA: Yes, I was just going  
20 to ask, the Measure says optic nerve head  
21 evaluation. Are they evaluating it by fundus  
22 photography and making a comment about the fundus

1       photos? Or by OCT?

2               MEMBER PATEL: Am I on? I cannot hear  
3 whatever is being discussed with the phone.

4               CO-CHAIR YAREMCHUK: No one's saying  
5 anything right now. We're waiting for someone to  
6 come up to the microphone.

7               MEMBER MADONNA: Differently, it is  
8 appropriate to get an OCT which has a cup to disc  
9 ratio on it and utilize that instead of actually  
10 -- because this just says optic nerve head  
11 evaluation.

12               And that could be done a number of  
13 different ways.

14               DR. LUM: So, as mentioned before, it  
15 includes the cup to disc ratio and the structural  
16 -- the exam for structural abnormalities.

17               DR. WINKLER: But in the code set for  
18 the numerator like what for an examination, don't  
19 the optic nerve photographs and OCT codes also  
20 count in that as a way to document the optic  
21 nerve?

22               DR. LUM: I think we do -- I mean,

1       that is part of the preferred practice pattern,  
2       is that we do tell the ophthalmologist to look at  
3       the optic nerve by dilated eye examination. In  
4       addition, they can do ancillary testing.

5               It's considered part of the eye exam,  
6       yes.

7               MEMBER MADONNA: Yes. Even though I'm  
8       kind of almost contradicting what I said, I mean,  
9       I do think it's important that you look -- that  
10      you actually look at the optic nerve head because  
11      of the presence or absence of trans-hemorrhages.

12              So, in that sense, I really do think  
13      you should. But there seems to be -- and it  
14      seems to be in this wording that optic nerve head  
15      evaluation could be done a number of different  
16      ways.

17              MEMBER STEIN: You know, we've looked  
18      at claims data. And I think this 95 percent for  
19      in terms of performance is a way over estimate.

20              In claims data it's more in the 30  
21      percent range. And I think part of it is, is the  
22      devil's in the details, as you were getting to,

1 as to what constitutes an examination of the  
2 optic nerve head?

3 You know, does doing an OCT test  
4 count? Does -- how descriptive a definition is  
5 it? Is it just a check off sheet, yes, I did it?

6 So, I think it's important to clarify  
7 exactly what counts and what does not count.

8 MEMBER GOLDBERG: Do you include 92133  
9 and 92134 in your data collection?

10 DR. RICH: Did you throw those number  
11 out as my brain is befuddled?

12 DR. GOLDBERG: 92133 is for ophthalmic  
13 diagnostic imaging post resegment of the optic  
14 nerve. And then 92134 includes the retina.

15 Are you including that in your --

16 MEMBER STEIN: It's the 331 that's  
17 relevant here. The 341 is for diseases of the  
18 macula.

19 CO-CHAIR YAREMCHUK: Any other  
20 comments? Questions?

21 (No response)

22 CO-CHAIR YAREMCHUK: And are we ready

1 to vote?

2 MS. ROBINSON-ECTOR: Voting is now  
3 open for performance gap for Measure 0086. And  
4 for those on the call, option one is high, two is  
5 moderate, three is low and four is insufficient.

6 All the votes are in. 50 percent  
7 voted high. 50 percent voted moderate. Zero  
8 voted low and zero voted insufficient. So for  
9 performance gap for Measure 0086, the measure  
10 passes.

11 CO-CHAIR YAREMCHUK: Reliability?

12 MEMBER PATEL: Okay, sorry, I was --  
13 I'm here. Sorry, I was on mute.

14 So, I would say we have all of the  
15 stated.

16 MS. LUONG: Vaishali, just to know,  
17 right now we're talking about reliability. What  
18 the claims and registry version of Measure 0086.

19 MEMBER PATEL: Okay.

20 MS. LUONG: And then we'll talk about  
21 reliability and validity together for the E-  
22 Measure version later. Thanks.



1 MEMBER PATEL: Got it. Okay. Yes.

2 So, I would say there was extensive reliability  
3 information provided by the Developer, which is  
4 great to see.

5 Reliability was measured using, you  
6 know, claims, the PQRS data set as well as the  
7 registry. And reliability seems high from the  
8 claims data even though, you know, it's important  
9 to note that not all -- there were a total of 45  
10 thousand physicians in the data set.

11 Of which only nine, you know, about  
12 ten thousand were eligible for the reliability  
13 testing. So, that's I would say is a limitation.  
14 But I can see the reason for doing that.

15  
16 And likewise from the registry, it's  
17 -- there's also reliability information provided.  
18 So I would say the reliability data is high  
19 quality.

20 CO-CHAIR YAREMCHUK: Any questions?  
21 Comments?

22 (No response)

1 CO-CHAIR YAREMCHUK: Are we ready to  
2 vote on reliability?

3 MS. ROBINSON-ECTOR: Voting is now  
4 open for reliability for the claims and registry  
5 version of Measure 0086. And for those on the  
6 call, option one is high, two is moderate, three  
7 is low and four is insufficient.

8 Okay. All the votes are in. 43  
9 percent voted high. 57 percent voted moderate.  
10 Zero voted low and zero voted insufficient. So  
11 for the claims and registry version of Measure  
12 0086 for reliability, the Measure passes.

13 CO-CHAIR YAREMCHUK: Validity?

14 MEMBER PATEL: For the face validity  
15 of the Measure was assessed by an expert panel of  
16 16 members. And -- who agreed that this Measure  
17 could distinguish quality of care.

18 And, I would agree with that approach  
19 for assessing face validity. Of course, I'll  
20 repeat that it's nicer to see a larger sample.  
21 But, I think that this is good.

22 CO-CHAIR YAREMCHUK: Any comments?

1 (No response.)

2 CO-CHAIR YAREMCHUK: Ready to vote on  
3 validity?

4 MS. ROBINSON-ECTOR: Voting for  
5 validity for the claim and registry version of  
6 Measure 0086 is now open. For those on the call,  
7 option one is high, two is moderate, three is low  
8 and four is insufficient.

9 All the votes are in. 21 percent  
10 voted high. 79 percent voted moderate. Zero  
11 voted low and zero voted insufficient. So for  
12 validity for the claims and registry version of  
13 Measure 0086, the measure passes.

14 CO-CHAIR YAREMCHUK: All right.  
15 Moving on. So, next is to be discussed is  
16 feasibility.

17 MEMBER PATEL: So I would say this  
18 data can be captured as we discussed, from claims  
19 and from registry. So it's feasible to capture.

20 And I would say we've already  
21 discussed the limitations of capturing it from  
22 the claims. Regarding the legal of granularity

1 we can have with the data, it would actually be  
2 better to capture this from registry then claims  
3 is the only comment I would make.

4 But it's feasible.

5 CO-CHAIR YAREMCHUK: Comments?

6 (No response.)

7 CO-CHAIR YAREMCHUK: And I guess I  
8 just have a question. Are we capturing the right  
9 data? Because I've heard it go back about cup to  
10 disc ratio.

11 We've talked about other I'm going to  
12 say descriptive terminology versus just that they  
13 did the exam. And the question is, in this  
14 Measure, are we going to be capturing the data  
15 that we feel comfortable with?

16 DR. LUM: So as we discussed, the  
17 Measure rationale does talk about what needs to  
18 be looked at in the dilated eye evaluation. And  
19 refers back to the preferred practice patterns  
20 which talks about the characteristics of the  
21 optic nerve and what should be noted.

22 And that's the appearance and the cup

1 to disc ratio are the two salient things. So  
2 that's already in the Measure rationale.

3 And hopefully when people do report  
4 it, you know, that they are doing those things.

5 DR. RICH: Flora, can you just --

6 MEMBER PATEL: Yes, and you know, I  
7 would comment on that also. To say that, you  
8 know, even if we can get patients to come in for  
9 the required number of times per year and we can  
10 even document that an optic nerve head exam was  
11 done that's already a win.

12 Because a lot of times the issue may  
13 be that patients are not even coming in.

14 DR. RICH: Just to further answer your  
15 question, Rich raised the thing, does a photo,  
16 and the answer is no. We want you to look. And  
17 then if you want to follow them longitudinally.

18 So, the codes for the OCT are not  
19 included. So, we are capturing what we thought.  
20 But we just had -- it's late in the day and we  
21 had to look it up.

22 CO-CHAIR YAREMCHUK: Josh?

1                   MEMBER STEIN: Do you think that's  
2 good thing?

3                   DR. RICH: Well, sometimes it is.  
4 Sorry. The Hoskins paper suggests that that's  
5 adequate. Now, for longitudinal follow up, I  
6 think that, you know, probably photos and OCT are  
7 appropriate.

8                   MEMBER STEIN: And then one other  
9 comment. I think getting at a point raised  
10 earlier, you know, getting patients in, since  
11 there are differences in access to care among  
12 patients of different sociodemographic profiles,  
13 I would encourage the next iteration for risk  
14 adjustment.

15                   Because clearly, we're seeing this in  
16 the claims data, patients of certain profiles  
17 don't follow up for regular exams as often as  
18 others. And you don't want the provider to be  
19 impacted based on, you know, the types of  
20 patients they're caring for.

21                   DR. LUM: Okay. I was just going to  
22 add that the dilated eye evaluation and

1 documentation, we know that OCTs and photos are  
2 useful for follow up. But this is only required  
3 once over the whole year.

4 So we're saying that, you know, there  
5 should be a look into the eye at least once a  
6 year for that patient. No matter the other  
7 follow ups and ancillary testing.

8 DR. RICH: And as you pointed out, you  
9 and Paul in previous papers, there's a huge gap  
10 in care that the optic nerve is looked at. I  
11 think our number of 79 percent is surprising to  
12 us.

13 CO-CHAIR YAREMCHUK: Go ahead.

14 MEMBER MADONNA: You mentioned that  
15 the preferred practice patterns mention cup to  
16 disc ratio and a description of the nerve. But  
17 what's actually captured when we capture the  
18 data?

19 Is it just the cup to disc ratio  
20 because that's the easiest thing to pull of the  
21 EHR?

22 DR. WINKLER: Right now we're talking

1 about the claims and registry version. Not the  
2 EHR. So, what's the data element specifically  
3 for the claims and registry?

4 DR. LUM: Okay. It's the dilated look  
5 at the optic nerve. Right. It's a G Code that  
6 the --

7 MEMBER MADONNA: Just whether that it  
8 was done or not.

9 DR. LUM: Right.

10 CO-CHAIR YAREMCHUK: Okay. Are we  
11 ready to vote on feasibility?

12 MS. ROBINSON-ECTOR: So, the voting is  
13 open for feasibility for the claims and registry  
14 version of Measure 0086. For those on the phone,  
15 option one is high, two is moderate, three is low  
16 and four is insufficient.

17 All the votes are in. 21 percent  
18 voted high. 57 percent voted moderate. 21  
19 percent voted low. And zero voted insufficient.  
20 So for feasibility of the claims and registry  
21 version of Measure 0086, the Measure passes.

22 CO-CHAIR YAREMCHUK: Okay. Usability



1 and use?

2 MEMBER PATEL: So, the Measure is  
3 obviously currently in use. And is shown to be  
4 usable, you know, in the PQRS program. And also  
5 the EHR -- well, I guess I won't say with the  
6 registry.

7 But the PQRS program and also reported  
8 in the IRIS registry.

9 CO-CHAIR YAREMCHUK: Any comments from  
10 anyone?

11 MEMBER STRODE: At risk of being  
12 repetitious, but for my clarity, the aim is to  
13 see that at least there's a description once a  
14 year of a cup to disc ratio and the appearance of  
15 the disc.

16 But what's actually being captured in  
17 the registry is simply the attestation. I looked  
18 at the back of the eye or I didn't.

19 DR. LUM: That is correct for the  
20 registry and claims. Obviously if you were to be  
21 -- if the physician were to be audited, they  
22 would have to provide evidence in the medical

1 record that they did look at the optic nerve.

2 And they, you know, we would expect  
3 that there would be documentation of its  
4 appearance. I think that's what the auditors  
5 would look at if they were looking if they were  
6 to audit the records.

7 DR. RICH: And in the registry, we  
8 actually have a chart to do data validity and  
9 auditing. So we -- and we do have the ability to  
10 actually see the physician's electronic record  
11 and what was recorded.

12 MEMBER MADONNA: Does this in some way  
13 negatively impact the performance of visual field  
14 testing? Particularly in patients who have  
15 advanced disease where looking at the nerve is  
16 probably is little utility, where a field has  
17 much more utility.

18 And someone sitting very close to me,  
19 I know, published the paper about the reduction  
20 in the use of visual field testing, correct?

21 Yes, so. Anyway.

22 DR. RICH: I'll defer to Josh. But --

1                   MEMBER STEIN: Well I think it -- as  
2                   a glaucoma specialist, I think it's important  
3                   both to assess the optic nerve and assess a  
4                   visual field. And maybe there's a measure that's  
5                   under development to look at rates of visual  
6                   field testing.

7                   I don't think we should knock this  
8                   Measure because it doesn't include visual field.  
9                   But, I think both are important. And there are  
10                  probably a small subset of patients that either  
11                  you're not going to get that much additional  
12                  information either from assessing the nerve or  
13                  doing the field.

14                  Because some patients you just can't  
15                  get a reliable field on. In some patients, your  
16                  view of the optic nerve may not be that good.

17                  But I think designing a Measure that's  
18                  going to capture the majority of patients that mo  
19                  -- I think most of us would agree that the  
20                  majority of glaucoma patients, we should be  
21                  looking at their nerve.

22                  CO-CHAIR YAREMCHUK: All right. We're

1 ready to vote for usability and use.

2 MEMBER PATEL: Yes.

3 MS. ROBINSON-ECTOR: Voting is now  
4 open for usability and use of the claims and  
5 registry version of Measure 0086. For those on  
6 the call, option one is high, two is moderate,  
7 three is low and four is insufficient  
8 information.

9 All the votes are in. 57 percent  
10 voted high. 36 percent voted moderate. 7  
11 percent voted low. And zero voted insufficient.  
12 So for usability and use of the claims and  
13 registry version of 0086, the Measure passes.

14 CO-CHAIR YAREMCHUK: Okay. Next is  
15 for the Committee to vote on whether to recommend  
16 Measure for endorsement.

17 MS. ROBINSON-ECTOR: Voting is now  
18 open for recommendation for overall suitability  
19 for endorsement for the claims and registry  
20 version of 0086. For those on the call, option  
21 one is yes and option two is no.

22 Okay. All the votes are in. 93

1 percent voted yes. And 7 percent voted no. So  
2 for the recommendation of overall suitability for  
3 endorsement for the claims and registry version  
4 of Measure 0086, the Measure passes.

5 DR. WINKLER: Go to the next slide.  
6 All right, this Measure also does have an E-  
7 Measure version. And I think if we think about  
8 the scientific acceptability, the issues around  
9 specifications.

10 So, I just want to go back to the  
11 comments you've made already about how you  
12 compared the claims to the information in the  
13 EHR. And so, the EHR specification -- E-Measure  
14 specifications are more detailed or more specific  
15 then the claims and registry.

16 Could you just describe that a little  
17 bit more clearly? So we understand that.

18 DR. LUM: That's correct. So, in the  
19 EHR specification, we have to look for cup to  
20 disc ratio specifically in the record. And we  
21 have to look for an optic nerve appearance that's  
22 documented in the record.

1                   So that differs, you know, as we said,  
2                   in terms of the registry.

3                   DR. RICH: Yes. And that's going to  
4                   be the operative way of collecting this Measure.  
5                   Because it's not going to be done by claims this  
6                   year.

7                   MEMBER STEIN: Flora, can you clarify?  
8                   So, if a provider is drawing a picture of the  
9                   nerve in the EHR, that is number one capturable?  
10                  And number two, will get credit?

11                  DR. LUM: Yes, that's right.

12                  MEMBER STEIN: Okay.

13                  DR. WINKLER: Though similar to the  
14                  other E-Measures in the past, we combined  
15                  reliability and validity into scientific  
16                  acceptability with the same thing. We're going  
17                  to see the results from testing on the simulated  
18                  data set.

19                  MS. ROBINSON-ECTOR: So, voting is now  
20                  open for reliability and validity for the E-  
21                  Measure version of 0086. And for those on the  
22                  call, option one is yes with conditions and

1 option two is no.

2 Okay. All the votes are in. 100  
3 percent voted yes with conditions. And zero  
4 percent voted no. So for reliability and  
5 validity for the E-Measure version of 0086, the  
6 Measure passes.

7 DR. WINKLER: All right. So we'll  
8 also talk about the feasibility of the E-Measure.  
9 Any questions or issues about that?

10 (No response)

11 DR. WINKLER: So we'll vote on that  
12 one.

13 MS. ROBINSON-ECTOR: Voting is now  
14 open for feasibility for the E-version of 0086.  
15 And for those on the call, option one is high,  
16 two is moderate, three is low and four is  
17 insufficient.

18 Okay. All the votes are in. 64  
19 percent voted high. 36 percent voted moderate.  
20 Zero voted low and zero voted insufficient. So  
21 for feasibility of the E-Measure version of 0086,  
22 the Measure passes.

1 DR. WINKLER: Okay. So for usability  
2 and use, there were some differences that we just  
3 talked about between the claims and registry.

4 So, perhaps it would be good just to  
5 take the vote on usability and use specifically  
6 for the E-Measure so that you could potentially  
7 vote differently, I think.

8 MS. ROBINSON-ECTOR: So, voting is now  
9 open for usability and use for the E-version of  
10 0086. And for those on the call, option one is  
11 high, two is moderate, three is low and four is  
12 insufficient.

13 All the votes are in. 36 percent  
14 voted high. 64 percent voted moderate. Zero  
15 voted low and zero voted insufficient  
16 information. So for the E-version of 0086 for  
17 usability and use, the Measure passes.

18 DR. WINKLER: Go ahead.

19 MS. ROBINSON-ECTOR: Okay. Voting is  
20 now open for recommendation for overall  
21 suitability for endorsement for the E-Measure  
22 version of 0086. And for those on the call,



1 option one is yes with conditions and option two  
2 is no.

3 Okay. All the votes are in. So 100  
4 percent voted yes with conditions. And zero  
5 percent voted no. So, for recommendation for  
6 overall suitability for endorsement for the E-  
7 Measure version of 0086, the Measure passes.

8 MS. LUONG: Great. So we ended our  
9 review of the Measures for today on -- five  
10 minutes early.

11 Operator, can you open the line up for  
12 our member and public comments on the phone? Or  
13 if anyone wants to speak in the conference room,  
14 please feel free to do so.

15 OPERATOR: All right. At this time,  
16 if you would like to make a public comment,  
17 please press star then the number one on your  
18 telephone key pad.

19 And there are no public comments at  
20 this time.

21 MS. LUONG: Well, we just wanted to  
22 thank everyone on behalf of NQF for being so

1 courteous with the timing and all the technical  
2 difficulties. And for our thoughtful discussions  
3 for day one.

4 We do have reservations in place for  
5 a restaurant, which I'll email everyone for 6:00  
6 p.m. today for the Standing Committee Members.  
7 It will be a good chance for you all to get  
8 together to interact and to talk about your day.

9 So, I'll email out the location now.  
10 If you guys can make it. Can I just get a show  
11 of hands just to see?

12 Who -- it's like two blocks away.  
13 Happy hour and dinner.

14 Yes, for both.

15 CO-CHAIR YAREMCHUK: I think you got  
16 a few more votes.

17 MS. LUONG: Yes. Sounds good. It's  
18 two blocks away. Right down the block.

19 So, I'll send out that information  
20 now. Thank you everyone.

21 MEMBER PATEL: Thank you, everyone.

22 DR. WINKLER: All right. Tomorrow

1 morning we'll start just a tad earlier. If you  
2 notice on the agenda, just so that everybody gets  
3 here on time.

4 The continental breakfast is at 8:00  
5 and we'll reconvene for discussion at 8:30.  
6 Okay. So it's a half an hour earlier.

7 Thank you all very much. Have a good  
8 evening. We'll see you tomorrow.

9 MS. LUONG: And thank you, the  
10 Developers as well.

11 (Whereupon, the above-entitled matter  
12 went off the record at 4:42 p.m.)  
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C E R T I F I C A T E

This is to certify that the foregoing transcript

In the matter of: Eye Care, Ear, Nose and Throat  
Conditions (EENT) Standing Committee

Before: NQF

Date: 06-03-2015

Place: Washington, D.C.

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