NATIONAL QUALITY FORUM

+ + + + +

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

+ + + + +

THURSDAY
JUNE 4, 2015

+ + + + +

The Committee met at the National Quality Forum, 9th Floor Conference Room, 1030 15th Street, N.W., Washington, D.C., at 8:30 a.m., 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, FAAFP, 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 Manger
REVA WINKLER, MD, MPH, Senior Director

ALSO PRESENT:

NALINI AMBROSE

JOHN EICHWALD

MARCUS GAFFNEY

KENDRA HANLEY

FLORA LUM

WILLIAM RICH

DANIEL ROMAN

*** present by teleconference**

C O N T E N T S

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

8:29 a.m.

DR. WINKLER: Good morning everyone. Thank you for joining us for day two. It's going to look a lot like day one as we continue the evaluation of eight more Measures.

So, yesterday I think there was a good day. I hope you all had a pleasant evening. I know a goodly number of you went out to dinner. And I hope that was enjoyable for everybody.

Any comments, questions from the group before we get started for today?

(No response)

DR. WINKLER: All right. Well then, comments from our Co-Chairs?

CO-CHAIR YAREMCHUK: Welcome. We'll get started moving into the Measures. The first one that we're going to be looking at today is the Diabetic Retinopathy.

No, sorry, I had an Age-Related Macular Degeneration, 0087, Dilated Macular Examination. And that's Bill Rich is -- and

Flora Lum. Again, any comments?

DR. RICH: Yes, I think -- thank you very much. Today we're going to look at the other two leading causes of blindness in the elderly. And that's age-related macular degeneration and diabetic retinopathy.

The -- as we discussed yesterday, the natural time line for quality improvement and better outcomes is good science, education guidelines and finally, measurement and registries to actually collapse the rate of adoption from Beth McGlynn's Article that shows only a 50 percent uptick in ten years.

Both of these, the first two Measures deal with macular degeneration. They're bolstered by Level One evidence. And again, the difference in these examinations of the retina is that we are able to completely stage the course of a disease, unlike cancer or even diabetes where you want to look at kidney function.

We can actually see all the pathology, stage it. And how effective is that in affecting

the natural course of the disease, again the diabetic blindness from diabetes after the publication of the DRS trial was down 50 percent in five years.

The same dramatic results with the diabetic macular edema. And with macular degeneration, we've decreased the leading cause of blindness in the western world by 90 percent. Which is pretty dramatic.

There is still gaps in care. And we're also going to deal with a counseling Measure. And probably has the most, I think all of us at NQF are a little leery about counseling measures.

This one has Level One evidence of the efficacy of the counseling. Decreasing number -- new cases of wet macular degeneration within five years if the adoption of appropriate antioxidants is used.

That decrease of 300 thousand patients results in a savings depending upon the use of anti-VEGF agents between $2 and $12 billion over

five years. So, not only are we decreasing the cost, but we're dramatically saving vision.

So, and the last two are diabetic measures. And we'll address them when we get to them. Thank you, Ms. Chairman.

CO-CHAIR YAREMCHUK: And discussants, Scott?

MEMBER FRIEDMAN: Good morning. So, the first Measure deals with age-related macular degeneration, dilated macular exam. Age-related macular degeneration is the most common cause -- briefly the most common cause of legal blindness in adults over 75 in the United States.

And basically there's two types. There's a wet type, which is the least common or more severe type. And a dry type, which is the more common and least severe type.

So, people go through a progression. They develop mild changes. And then the natural history is it typically gets worse.

And you can develop abnormal blood vessels, which are treatable. In order to

diagnose the wet type of macular degeneration, one needs to do testing. Including but not limited to actually looking in the back of the eye.

And so, what this Measure, basically looks at is, did you look at the back of the eye. And did you define the level of degeneration, i.e., absence of macular thickening, which can be a sign of wet macular degeneration and/or hemorrhage.

It can also be a sign of wet macular degeneration. There's no scientific proof through randomized clinical trials that actually looking at the back of the eye saves vision.

But it just makes sense that in order to diagnose it, one needs to actually look at the eye and document the findings. I guess in theory you could do other ancillary tests without looking at the eye, but nobody in my opinion does that or should be doing that.

So, there is fairly good evidence that looking in the back of the eye and documenting

the level of retinopathy is advantageous in diagnosing and treating macular degeneration.

CO-CHAIR YAREMCHUK: Okay. So this is a process measure. And if you want, we're ready to vote for evidence? Or is there any discussion?

MEMBER MADONNA: I have nothing to add.

CO-CHAIR YAREMCHUK: Okay. Discussion? Go ahead Matt.

MEMBER CARNAHAN: So, just to clarify, we're saying the value of this Measure is that we're doing staging. And therefore, can add an intervention like an AREDS 2 supplement recommendation.

As opposed to diagnosing wet, which I would think the odds of diagnosing wet in a timely fashion, where you see an actual improvement, would be unlikely.

MEMBER FRIEDMAN: So I think it's two fold. I think if they have -- if you look in and they have mac -- well, it says they already have

macular degeneration.

So if you look in the back of the eye and they have moderate to severe dry macular degeneration, which again, is the more common type, then one should recommend vitamin antioxidants for treating that condition.

But if you look in and they previously have been dry and they've been stable. Then they come in and they're still -- they're still asymptomatic.

They have no change in their symptoms. But you see a little bit of bleeding in the eye that requires more testing and possibly different types of treatments.

So in order to actually diagnose early stage of wet macular degeneration, which can occasionally present without new symptoms, you actually need to look in the eye to see if there's new bleeding which wasn't there before.

CO-CHAIR YAREMCHUK: Yes, Andrew?

MEMBER FRIEDMAN: If that answers your question.

MEMBER SCHACHAT: Right. And so as far as the issue about whether you have to look in the eye to see any of this. There are alternative ways of doing it, which is screening with photographs.

That's done for diabetes. It's not been shown to work very well yet, and so it's not an option for AMD.

So this is the only option. And as far as the comment about not detecting wet, I echo what Scott says. Wet can definitely be asymptomatic. So you can see it by looking in.

And there's evidence from a number of trials that earlier treatment gets better outcomes. So, it makes sense.

MEMBER CARNAHAN: Right. I was just suggesting that perhaps the likelihood of catching a person at wet, if you're trying to do a cost effective intervention, that this would likely not -- I would say that the highest percentile not capture wet patients.

MEMBER SCHACHAT: That's right. But

it's cost effective for dry. And this is just an extra added benefit for those wets that you catch, make it even more cost effective.

Because you get the free thing. Once they're looking in, you can find the wet.

CO-CHAIR YAREMCHUK: Are we ready to vote?

MS. ROBINSON-ECTOR: Voting is now open for evidence for Measure 0087. And for those on the call, option one is high, two is moderate, three is low and four is insufficient evidence.

MS. LUONG: And Judith, you can send me an email for the voting. Thanks.

MEMBER LYNCH: I don't know that I should vote. Is this the Measure that we just started talking about?

I just got on. They kept me on hold for a very long time.

MS. LUONG: Oh, they did. Okay. All right then, thank you.

MS. ROBINSON-ECTOR: So, it looks like

we're waiting for three more votes in the room. If you guys could point your clickers at this laptop. Thank you.

Okay. Great. All the votes are in. 62 percent voted high. 31 percent voted moderate. Eight percent voted low. Zero voted insufficient evidence. So for evidence, Measure 0087 passes.

CO-CHAIR YAREMCHUK: Opportunity for improvement?

MEMBER FRIEDMAN: So the Developers gave us some data using PQRS data from 2009 to 2012. And the meaningful performance results range from 94 to 96.1 percent.

So, the people that are reporting are doing an awesome job. But out of the number of eligible professionals, only 14 to 19 percent of people are reporting.

So, it is a small number of people that are reporting. And this is a couple of things. So this is a very common condition.

And even if you increase the mean

performance result by one or two percent, you're still going to save a vision in several thousand patients.

And so as Bill alluded, save billions of dollars, depending on which anti-VEGF that you use. So it is very cost effective. You're going to save money on the back end.

And the other issue is that we think with the changes in reporting, that more people will report. And we think maybe the people that are reporting are doing a better job.

So, it's certainly plausible that the mean performance will be lower as more people report. So I think there is room for improvement.

And even if there wasn't room for improvement, a small percentage would mean a large amount of saved vison over the course of time.

DR. RICH: Just to augment Scott's comments. Again, an issue you have to report on nine measures instead of three.

And so in IRIS we're able to look at the three that were selected. But we also look and can see their performance on other measures.

And it's dramatically lower for measures that you are not focused on. And we'll be glad to supply some data if you'd like, but.

MEMBER MADONNA: Yes. I would only add to what Scott said about detecting wet AMD and saving vision there. But additionally, you get this -- you will stage persons with dry AMD and then appropriately counsel them about antioxidants, which also will lead to vision -- savings of vision.

And also, reduce the number of side effects for people who should not be taking antioxidants but do nevertheless.

DR. LUM: Just to follow up with Dr. Rich. We did actually collect information on the AMD measures.

As we said, the severity should be according to the AREDS scale. And we've known that in medicine it probably takes 17 years for

clinical trials to actually reach the bedside.

So, our performance rate, looking at electronic records and the real documentation that practices do is only ten percent. And that's because they aren't using the right severity scale.

They're not looking -- they're not documenting macular thickening. And we give them the practice pattern and it's really at the point of care and that they're being measured that they're going to change their practices.

Even though we have wonderful practice guidelines and a lot of great education, we do really find that a lot of our ophthalmologists aren't following the latest guidelines and the latest severity scales.

So that's the performance that we've seen just looking at EHR documentation across 2722 physicians in 2014.

DR. RICH: One last comment. We've all talked about physician support. Well, when a physician -- physicians are pretty competitive.

And when they see their performance rate is ten percent they howl. And we have a practice person assigned to that practice that will explain to them why their performance is terrible.

They're not meeting the guidelines. And you talk about a turnaround in the adoption of guidelines.

We were one of the first three societies to develop them in 1985. Well, all of a sudden, they get adopted pretty quickly when they see their score.

DR. WINKLER: I guess, Flora's beginning to ask this, but if the way you get into the measures is because there's an encounter with the clinician, and so, I guess I'm trying to understand the quality problem.

Because exactly around -- because aren't they examining these patients? And is it the not examining? Or is it the not documenting the staging?

And that's what I'm -- and I want --

and this Measure can differentiate that.

MEMBER SCHACHAT: Actually some of both. Because you have to put drops in. And so this will encourage putting more drops in.

So it changes the existing.

CO-CHAIR YAREMCHUK: Any other comments?

(No response)

CO-CHAIR YAREMCHUK: Ready to vote?

MS. ROBINSON-ECTOR: Voting is now open for performance gap for Measure 0087. And for those on the call, option one is high, two is moderate, three is low and four is insufficient.

MS. LUONG: Hi Vaishali, I know you just got on the line. Will you be voting?

MEMBER PATEL: I'll just sit out this one since I didn't hear the discussion.

MS. LUONG: Okay. And Judith?

MEMBER LYNCH: Yes. I'm going to wait probably until the next one as well.

MS. LUONG: Okay. Great. Thanks.

MS. ROBINSON-ECTOR: So, all the votes

are in. 69 percent voted high. 31 percent voted moderate. Zero voted low and zero voted insufficient. So for performance gap, Measure 0087 passes.

CO-CHAIR YAREMCHUK: Reliability?

MEMBER FRIEDMAN: So the Developer presented two types of testing. The first one is measure score reliability using the 500 docs from the IRIS Registry.

And the reliability rates were 0.89 to 1, which is extremely high. They also looked at data element reliability using inter-rater reliability from a single doc.

And for the denominator PQRS versus gold standard was 96 percent, extremely high. But the numerator was only 45 percent, which is moderate.

And then they used reliability, the EHR chart extraction versus gold standard. And the numerator was, this time was 97 percent. Which is extremely high.

So with exception of the one numerator

45 percent, reliability was extremely high.

CO-CHAIR YAREMCHUK: Richard?

MEMBER MADONNA: Nothing to add.

CO-CHAIR YAREMCHUK: Any other comments?

(No response)

CO-CHAIR YAREMCHUK: Are we ready to vote?

MS. ROBINSON-ECTOR: Voting for reliability for Measure 0087 is now open.

Okay. All the votes are in. 54 percent voted high. 46 percent voted moderate. Zero voted low and zero voted insufficient. So for reliability for Measure 0087, the measure passes.

CO-CHAIR YAREMCHUK: Validity?

MEMBER FRIEDMAN: So, the developers examined validity using a -- using face validity with an expert panel of 16 members who agree that the measure was valid.

And there are no threats to validity with this Measure.

CO-CHAIR YAREMCHUK: Go ahead, Reva?

DR. WINKLER: I just want to point out that the data that Flora just gave us, which says that only ten percent of the folks in the registry would meet the measure looking at their EHRs.

Yet PQRS is reporting 95 percent. And so to me that 95 percent probably doesn't represent what we think we're measuring.

So, to me that is a -- I would question the validity of the results you get in this Measure.

DR. RICH: Okay. Actually I brought that up yesterday in my initial comments. That we -- we're finding dramatically different results from PQRS, where people misinterpret it as just dilating and looking at the eye.

When you actually look at what they're doing, they're not -- we don't think they're even measuring.

So I made that point yesterday that if we're going to look at all these issues, and we

look at claims, I think you're going to find out with -- we're going to see a lot of -- we're probably the first ones to come before you with a lot of new registry measures.

We're going to see dramatic differences between the claims. And this is a great example. Docs think they're doing things and it's not fraud.

But they don't understand the demands of staging the diseases. And they don't get a score.

MEMBER STEIN: I think that's one possibility. The other possibility is whether the IRIS Registry is fully capturing the information adequately enough.

So there may be an underestimate on that end.

DR. LUM: That is true. So because it is ten percent, but because it's not counting for PQRS, people haven't been working on the documentation as much as the other measures, which are counting for PQRS this year.

So that it is probably an underestimate from the first initial mapping and extractions from electronic methods. We probably could dig deeper and there would be some better compliance.

DR. RICH: The data is the data. You know, they're not doing it.

DR. WINKLER: I guess from a criteria perspective, when we're assessing validity, what we're hearing is, depending on how the data is collected, we get wildly different results.

So, the question I would ask you is, what do we think, or how could we know what provides us with the most valid results? Because that's what we're looking for.

And that's the measurement that works. I mean, we don't really want to continue promoting a measure that doesn't provide us with valid results.

So, if there's truly an issue around, you know, different data sources give us different results, I think we need to have a

better understanding of which ones gives us, you know, valid results. If we can possibly know that.

DR. RICH: Great point. You're not going to see any claims data for this thing from now on. Because no one -- it's physically impossible for someone in practice to by claims make nine measures.

I don't know anyone in the United States that's trying to do it. It's all going to be EHR or it's going to be registry reported.

So, again and I made that point yesterday and now we're seeing the manifestation of that.

DR. WINKLER: Essentially this Measure before us is the registry measure. You're not bringing an E-Measure for this particular version.

So, we're looking at the registry. Are you saying that you're not recommending a claims version of it be part of this endorsed Measure?

DR. RICH: No. I'm saying that practically, I don't know anyone that's going to do claims.

But I think the option should be available to them that physicians are trying to do a good job. They're close to retirement. They don't have an EHR, which you need to do an extraction of data.

I just -- I couldn't do it physically. But I hate to take away that option from them.

DR. LUM: The other thing I think is we could do better education about how to use this Measure. And the Measure specification does specifically state the disease severity and the macular thickening.

And that all has to be documented. So, we could do a better job of educating people using the Measure through claims and the registry to do all those things.

That's what it means -- it means to meet the measure.

CO-CHAIR YAREMCHUK: Scott?

MEMBER FRIEDMAN: Well, one of the other possible scenarios is that the people that are reporting through PQRS are retina docs. And retina docs deal primarily with treating mac degeneration.

And general ophthalmologists may not be reporting on this. Maybe very little or not at all.

But then when we look at the registry data, we can capture that. And maybe they're doing a poor job of reporting it. That's where we need to have our emphasis and move them forward.

But clearly, all the retina doctors and I report on this Measure for example, I do not dilate 100 percent of my patients. It's kind of ridiculous for me not to because I couldn't do my job.

So I dilate 100 percent of my patients. And I'm probably in the 96th percentile because this is what I do them all. I don't do -- I do a poor job of documenting the

anterior stuff because I don't really care about it for example, as much, because it gets in my way.

So, maybe we need to get our general ophthalmologists to do a better job of documenting the findings for macular degeneration as well as the retina specialists.

CO-CHAIR YAREMCHUK: I was wondering if the PQRS would also be early adopters of both that might be the ones that are reporting. And therefore doing a better job of it.

And that's only a question. Go ahead Richard.

DR. RICH: I don't think so. As a general ophthalmologist I think Scott is right. We have 12 in my group. I don't think any of us reported this Measure. We report on other measures.

MEMBER MADONNA: Yes, I just have a couple of questions about the Measure. The first one is, we specify a dilated macular examination. But we don't specify how the dilated macular

examination is performed.

And I would think that the retina specialists would agree that that should be done stereoscopically. And so that's question one.

And the second one is that there appears to be the ability to have exclusions from -- and I just don't have a sense of how often those exclusions have been used.

You know, how often is it being reported that I didn't dilate because the patient didn't want it? Or something like that?

Patients with AMD need to be dilated. So the exclusions should be rare.

MEMBER SCHACHAT: There are all kinds of good reasons for exclusions. And some of these patients are coming monthly and don't want the other eye dilated each visit or something like that.

The other eye may already have the disc reform scarring and they don't need to be checking the other eye on that day and so on.

And as far as the first question about

a stereoscopic exam, I think that's generally covered in the preferred practice patterns and general recommendations about how to examine the retina. It's sort of basic teaching in ophthalmology.

You know, in the hemoglobin A1C measures, do you discuss how they should achieve better blood sugar? So I'm not sure the Measures get into the detail of how to do steps in the exam or the treatment or something else.

MEMBER MADONNA: Understood. But, still would be able to get a positive check on this measure by just putting drops in the eyes and not doing the appropriate examination.

MEMBER SCHACHAT: I think it says to look at the macular and make some observations. And so it would be fraud not to look.

MEMBER MADONNA: But again, without doing it stereoscopically, it's probably not going to get done.

MEMBER STEIN: The high percentages, you know, that the PQRS is generating, it's not

something specific to this particular Measure comes up. With all these measures.

It's more of a global problem of, you know, who's using PQRS to report what. And I don't think that -- I mean, I think that people are going to report on the things that they're doing a lot. And that they feel they're doing most appropriately.

But I don't think it's an issue with any of these particular Measures. It's just, you know, how the system is capturing it.

And whether, you know, by going to an IRIS Registry where you can look beyond just the folks who are choosing to report on that measure, you're going to see more variability. And you're going to probably capture quality better.

The question is whether IRIS is there yet. So, I mean, I think it's important.

CO-CHAIR YAREMCHUK: Thank you. Steve?

MEMBER STRODE: I'd also like to follow up as a non-eye doctor on the stereoscopic

eye process. Is that necessary -- is that the ideal?

Or is that necessary for an adequate exam? If it's adequate, should it not be added as a specification?

MEMBER SCHACHAT: So, you can look in the direct ophthalmoscope and see the features of wet AMD not as well. You can see the hemorrhage. You see the lipid.

You can't appreciate the elevations. So you get two-thirds of the information. And for the drusen, we can see them for grading dry AMD, either way.

It doesn't matter a whole lot to me. If you want to examine the eye better, you examine the eye better. But, again, I'm not -- in the other Measures, I don't see specifications on how you do things.

So, in blood pressure measures do you specify what kind of cuff you use and how many measurements you do? And whether you do it four places or once or twice? I'm not aware.

But I don't think so. So, I don't think these measures generally go to those levels of specificity.

DR. RICH: Steve, I'll answer. I'm a general ophthalmologist. They think over the last 30 years since the introduction of the widely available Zeiss and Volk lenses, I don't know anyone that doesn't look at the macular stereoscopically.

It's easy to do. Perhaps people that were somehow missed that, they're practicing longer then I am, and I'm almost 70, they might not do it.

But, everyone -- it's just what you do.

CO-CHAIR YAREMCHUK: I -- okay, go ahead Tammy.

MEMBER BRADHAM: I just have a simple question. So we're being asked to look at validity. And so, are we taking administrative claims, electronic clinical records, the registry and pulling it all together and taking off the

duplicates for this Measure?

Or, are you only looking at the registry? Or are you only looking at administrative claims in doing this Measure?

I'm just trying to figure out how you're measuring this. And I think the discussion's been great on the medical. But I need help understanding what we're measuring.

CO-CHAIR YAREMCHUK: I appreciate what you're saying. And Reva, you can correct me. But, when it says data source, it doesn't mean and. I mean, it means any one of those can be used.

And so, what the original question is, is that administrative claims fulfills this, but it doesn't really fulfill it.

You know, it should be easier.

DR. RICH: I think I introduced huge confusion. When I was talking about the lack of performance, when we're look -- we can actually look at the performance of someone that wants to submit this.

But we can also look at everyone's performance on these other measures. So, the performance is, these are not -- I'm not saying there's a difference between what's in the registry for a submitted one of the three.

It's the other ones that they're not reporting. That's where we see variations.

So, I think I introduced a lot of confusion. I think it was Josh or Scott said that when you report it, you do a good job.

We're saying what the other people are not reporting that measure, if they're not concentrating on it, that's where we see the performance very low.

CO-CHAIR YAREMCHUK: All right. Go ahead Josh.

MEMBER STEIN: I just want to add one comment. I think it's important to capture the source of where it's coming from. Especially if there's going to be comparison of provider A versus provider B.

Because I think, some of the sources

may do a better or worse job then others at this point.

CO-CHAIR YAREMCHUK: Go ahead Matt.

MEMBER CARNAHAN: Just a question around the measurement in terms of the staging. Is it the old staging or the new staging?

And is there a way with current coding to do the new staging, it's a 0, 1, 2? And would that effect the recommendations you give to a patient in relation to the staging you could give based on the coding available?

MEMBER SCHACHAT: Do you mean the Beckman classification as opposed to the AREDs? Well, the 0, 1, 2, is the simplified AREDS scale.

MEMBER CARNAHAN: Document that based on coding?

MEMBER SCHACHAT: No. But, in ICD-10 you can do better on all of these than you can do on them with ICD-9. But I think the idea is people are being asked to look.

And if you can't look and write something down, can't get to that point, you're

lost.

I don't think that the Measure specifies how to grade the retinopathy severity.

DR. RICH: That raises an important point. And that's the granularity of our current coding system.

So, Flora's made recommendations to our health policy committee to actually do exactly that. To actually -- we're going to be able to be staged -- different stages of open angle glaucoma that was one.

And we're actually doing this with diabetic retinopathy macular degeneration. But it's a laborious process. What does it take, about three years to get something back?

But we've already submitted it. But there is not enough granularity if you really want to risk adjust things in even ICD-10.

It's going to be a lot thinner than ICD-9.

CO-CHAIR YAREMCHUK: Are we ready to vote?

MS. ROBINSON-ECTOR: Voting is now open for validity for Measure 0087.

Okay. All the votes are in. 15 percent voted high. 69 percent voted moderate. 15 percent voted low. And zero voted insufficient. So for validity for Measure 0087, the measure passes.

CO-CHAIR YAREMCHUK: Feasibility?

MEMBER FRIEDMAN: So, the Measure is specified for several data sources as we discussed. Claims data, registry and extraction.

And then all data elements are well defined. So I don't think there's any issues with feasibility for this measure.

CO-CHAIR YAREMCHUK: Rich?

MEMBER MADONNA: Nothing to add.

CO-CHAIR YAREMCHUK: Any discussion?

(No response)

CO-CHAIR YAREMCHUK: Ready to vote.

MS. ROBINSON-ECTOR: Voting is now open for feasibility for Measure 0087.

Okay. It looks like all the votes are

in. 46 percent voted high. 38 percent voted moderate. 15 percent voted low. And zero voted insufficient. So for feasibility, Measure 0087 passes.

CO-CHAIR YAREMCHUK: Usability and use?

MEMBER FRIEDMAN: So the Measure has been discussed, is currently being used in the PQRS program. And PQRS will be publically reported.

And it's also being used, I think, in the IRIS Registry. Well, it's also used in the IRIS Registry. So, it's currently being used and will have more use in the future.

CO-CHAIR YAREMCHUK: Rich?

MEMBER MADONNA: Nothing to add.

CO-CHAIR YAREMCHUK: Any discussion?

(No response)

CO-CHAIR YAREMCHUK: Ready to vote.

MS. ROBINSON-ECTOR: Voting is now open for usability and use for Measure 0087.

All the votes are in. 77 percent

voted high. 23 percent voted moderate. Zero voted low and zero voted insufficient information. So for usability and use, Measure 0087 passes.

CO-CHAIR YAREMCHUK: So, to vote for suitable for endorsement.

MS. ROBINSON-ECTOR: Voting is now open for recommendation for overall suitability for endorsement for Measure 0087.

Okay. All the votes are in. 92 percent voted yes. And eight percent voted no. So for recommendation for overall suitability for endorsement for Measure 0087, the Measure passes.

CO-CHAIR YAREMCHUK: Okay. Moving onto the next one, Age-Related Macular Degeneration: Counseling on Antioxidant Supplement. Richard? You're up.

MEMBER MADONNA: This is kind of an ideal follow up to the last Measure. Because the staging of macular degeneration, which we've mentioned as part of the dilated exam becomes very important here.

The Measure looks at the percentage of patients age 50 or older with a diagnosis of AMD. There are care givers who are counseled within 12 months of the benefits and/or risks of the AREDS formulation for the progression of AMD.

What's interesting is that the information can be discussed with all patients with AMD, even those who don't meet the criteria for supplementation. Which is intermediate AMD in at least one eye.

As there are risks in using supplements in some patients, for example in smokers, and there's no evidence of proof that supplementation is useful in persons with early AMD, counseling must be provided to all patients.

If we look at the evidence, this is a process measure based on a systematic review of two randomized clinical trials. Age-related eye disease study with AREDS and then AREDS 2.

In which treatment with antioxidants and minerals is recommended for patients who have intermediate or advanced AMD in at least one eye.

And the evidence is rated as strong.

CO-CHAIR YAREMCHUK: And our co-discussants?

MEMBER STRODE: Nothing to add.

CO-CHAIR YAREMCHUK: Okay. Any comments? So, go ahead Tammy.

MEMBER BRADHAM: What is AREDS?

MEMBER MADONNA: That's the Age-Related Eye Disease Study. So that looked at age-related diseases, macular degeneration and cataract. We're specifically looking at macular degeneration.

And it looked specifically at using antioxidants or nutritional supplementation in slowing the progression of macular degeneration.

MEMBER SCHACHAT: And so the vitamins cost about $15.00 or $20.00 a month. And for patients with a certain amount of AMD, it reduces their risk of progression and losing vision over time by about a quarter to a third.

So it's a very cost effective and safe way of preventing blindness.

MEMBER FRIEDMAN: But, we also did a study to show, and they gave, you know, we had a placebo control group. So, we did a well-designed Phase III randomized, multi-center Phase III randomized clinical trial.

And there's clear evidence that it's beneficial.

CO-CHAIR YAREMCHUK: Go ahead Matt.

MEMBER CARNAHAN: I wasn't clear. Is this saying that the recommendation for the patients is a face to face doctor's office visit?

Or is it just education that can be given if you already know what the staging was? Say they were advanced enough to need the supplements.

DR. RICH: I'm not sure of the Measure description, but this occurs face to face. You look in, 20 percent of the time they're inappropriately taking vitamins.

And there's a gap in care of 40 percent that's been documented. So, you sit down and you explain the trial to them. You no longer

have to discuss the risk of it with smokers because with AREDS 2, that's been eliminated.

So it occurs face to face at the time of the visit. And every time you see them, you ask them, you know, are you taking them? Are you taking them as prescribed?

And it's face to face. I'm not sure the Measure describes.

DR. LUM: That's correct. It's, you know, counseling. So it would be during the encounter with the -- between the physician and the patient.

CO-CHAIR YAREMCHUK: And how would you collect the data? Is there a code for this? For counseling for antioxidants?

DR. LUM: There's a G code for reporting it. That the counseling was performed or not performed.

CO-CHAIR YAREMCHUK: Tammy?

MEMBER BRADHAM: Does it matter if they're a past smoker? Or that they have to be currently smoking?

MEMBER SCHACHAT: So, once you've not been smoking for two or three years, that begins to count as a non-smoker. But --

MEMBER MADONNA: Just in following up from the last Measure. That's why it's so important that that dilated macular exam be done. And staging will be done appropriately.

Because if you have early AMD, there's been -- there's no benefit shown from taking the supplementation. And of course then you -- the risk benefit is such that you only have risk and no real benefits show.

CO-CHAIR YAREMCHUK: Okay. Are we ready to vote on evidence?

MS. ROBINSON-ECTOR: Voting for evidence, Measure 0566 is now open. And for those on the call, option one is high, two is moderate, three is low and four is insufficient evidence.

Okay. All the votes are in. 60 percent voted high. 40 percent voted moderate. Zero voted low and zero voted insufficient

evidence. So for evidence, Measure 0566 passes.

CO-CHAIR YAREMCHUK: Okay. Opportunity for improvement.

MEMBER MADONNA: PQRS data indicates that an increasing but still small number of practitioners report. With an increase of 7.8 percent in 2010 to 13.9 percent in 2012.

And a mean performance of about 92 percent for each year. Data submitted to the IRIS Registry for 2014 give a performance rate of 82 percent.

Considering the huge number of persons with AMD, improvements in performance will likely result in saving many persons from significant vision loss.

CO-CHAIR YAREMCHUK: Steve? Any discussion?

CO-CHAIR MERENSTEIN: I just have a question. Do you have any data on inappropriate use? It seems like people might be using it too early.

DR. RICH: Yes. It's only going to be

20 percent. As you can tell from talking to your patients, there's wide lately available advertisements to take your eye vitamins.

We see people 35 year old and spending $20.00 a month. So actually we spend just about as much time counseling people, should I be taking these vitamins? And they're perfectly healthy.

So, the overuse is 20 percent.

CO-CHAIR YAREMCHUK: This won't get to overuse or under-use however. It's just that there's been counseling done.

MEMBER SCHACHAT: Yes. One of the largest overuse groups are family members. Like children of patients with AMD and they see the trouble their parents have and they take the vitamins hoping they won't get it.

But it doesn't make any difference because they don't have any yet.

CO-CHAIR YAREMCHUK: Are we ready to vote?

MS. ROBINSON-ECTOR: Voting for

performance gap is now open for Measure 0566. For those on the call, option one is high, two is moderate, three is low and four is insufficient.

CO-CHAIR YAREMCHUK: Reliability?

MS. ROBINSON-ECTOR: Oh, we're still waiting for two more.

CO-CHAIR YAREMCHUK: Oh, sorry. Sorry.

MS. LUONG: Judith, if you can just email me your vote. Thanks.

MS. ROBINSON-ECTOR: Okay. All the votes are in at 14 votes. 71 percent voted high. 29 percent voted moderate. Zero voted low and zero voted insufficient. So for performance gap for Measure 0566, the measure passes.

CO-CHAIR YAREMCHUK: Okay. Reliability.

MEMBER MADONNA: We just mentioned the specifications for the Measure. The numerator is specified by CPT code. And the denominator by new ACT code. There are not exceptions.

The Developer presented two types of

testing. The Measure score reliability from 490 ophthalmologists submitted to the IRIS Registry for 2014 to PQRS reporting.

Reliability ranged from .46 to 1.0. Data element reliability was tested by an inter-rater reliability from a single ophthalmologist's office.

Reliability of PQRS claims versus chart review, the denominator was 96.1 percent agreement. And the numerator 39.2 percent agreement.

Reliability of the EHR chart extraction, which is the gold standard, was a numerator of 75.5 percent agreement.

CO-CHAIR YAREMCHUK: Steve?

MEMBER STRODE: Nothing to add. Thank you.

CO-CHAIR YAREMCHUK: Any comments? Todd?

MEMBER RAMBASEK: I'm sorry, can you clarify what 39 percent agreement means?

MEMBER MADONNA: The numerator is the

CPT code, which is the counseling. So that was the comparison of the -- this was in a single ophthalmologist's office.

So that was the claim made by the ophthalmologist versus chart review of the ophthalmologist's charts. I believe that's correct.

CO-CHAIR YAREMCHUK: Any other comments?

DR. RICH: The 39 percent is low because a lot of times that is, we don't say we sat down and discussed, we usually have little mnemonics, you know. AREDS plus, AMSLER plus, you know, that means that we discussed it.

So, sometimes chart extractors, you know, I think everyone documents how they did this differently. I don't know if you have a standard form, but.

MEMBER FRIEDMAN: So, this -- the reason I'm smiling is this maybe me, unfortunately. Only 39 percent.

As you said, I'm the -- I want to be

100 percent. So, what I think we do is our EHR in our discussion, we put in that we counsel the patient with AREDS or some verbiage.

It's probably documented in the discussion if it's a generic discussion for a typical dry AMD, it's pretty simple. If it was dictated, it's possible that it was missed.

It's also possible that the abstractor missed it as well. But certainly, that's where it is.

So, I counsel everybody on vitamins. I may not 100 percent of the time document that it was done on a routine basis.

It's possible it was done on one visit and not on another visit. And the patient was seen as Andy suggested, once a month.

So, seen 12 times, maybe 24 times because they come in twice a month.

CO-CHAIR YAREMCHUK: The specification just says counseled within 12 months. So if you did it once in 24 visits, and it was every two weeks, it should still be --

MEMBER FRIEDMAN: Right. If you did it -- if you even did it one time in months per year, it qualifies. If you didn't do it the other 23 times for this Measure, it still qualifies.

If you didn't document it the other 23 times, it still qualifies.

CO-CHAIR YAREMCHUK: Any other comments?

(No response)

CO-CHAIR YAREMCHUK: Ready to vote?

MS. ROBINSON-ECTOR: Voting is now open for reliability for Measure 0566. And for those on the call, option one is high, two is moderate, three is low and four is insufficient.

All the votes are in of 15 votes. 20 percent voted high. 73 percent voted moderate. Seven percent voted low. And zero voted insufficient. So for reliability, Measure 0566 passes.

CO-CHAIR YAREMCHUK: Our next is the validity.

MEMBER MADONNA: The supplements used were the same ones used in the AREDS 2 study in patients of the appropriate age, age 50 and older. Validity was assessed by systematic assessment of face validity.

An expert panel with 16 members have generally agreed that the Measure could extend this quality of care. There were no exclusions and there was the Measures risk-adjusted.

MEMBER STRODE: Nothing to add. Thank you.

CO-CHAIR YAREMCHUK: Any comments?

(No response)

MS. ROBINSON-ECTOR: Voting for validity for Measure 0566 is now open. For those on the call, option one is high, two is moderate, three is low and four is insufficient.

Okay. All the votes are in of 15 votes. 33 percent voted high. 60 percent voted moderate. Seven percent voted low. And zero voted insufficient. So for validity, Measure 0566 passes.

CO-CHAIR YAREMCHUK: Feasibility.

MEMBER MADONNA: Excuse me. Data is self-apparent and readily available by the EHR. Very straightforward.

CO-CHAIR YAREMCHUK: Steve?

MEMBER STRODE: Nothing to add.

CO-CHAIR YAREMCHUK: Any comments?

(No response)

CO-CHAIR YAREMCHUK: Ready to vote.

MS. ROBINSON-ECTOR: Voting is now open for feasibility for Measure 0566. And for those on the call, option one is high, two is moderate, three is low and four is insufficient.

All the votes are in of 15 votes. 80 percent voted high. 20 percent voted moderate. Zero voted low and zero voted insufficient. So for feasibility, Measure 0566 passes.

CO-CHAIR YAREMCHUK: Usability.

MEMBER MADONNA: The Measure is publically used in PQRS. And it appears to do what it's supposed to do. Just to further the goal of high quality, efficient health care.

CO-CHAIR YAREMCHUK: Okay. Steve?

MEMBER STRODE: Nothing to add.

CO-CHAIR YAREMCHUK: Any comments?

(No response)

CO-CHAIR YAREMCHUK: Vote.

MS. ROBINSON-ECTOR: Voting for usability and use for Measure 0566 is now open. And for those on the call option one is high, two is moderate, three is low and four is insufficient information.

All votes are in. 67 percent voted high. 33 percent voted moderate. Zero voted low and zero voted insufficient information. For usability and use of Measure 0566, the measure passes.

CO-CHAIR YAREMCHUK: All right. Thank you. And now to vote whether to recommend the Measure as suitable for endorsement.

MS. ROBINSON-ECTOR: Voting is now open recommendation for overall suitability for endorsement for Measure 0566. For those on the call, option one is yes and option two is no.

All the votes are in. 93 percent voted yes. Seven percent voted no. So for recommendation for overall suitability for endorsement for Measure 0566, the measure passes.

CO-CHAIR YAREMCHUK: Okay. Our next measure is 0088, Diabetic Retinopathy: Documentation of Presence of Absence of Macular Edema and Level of Severity of Retinopathy.

DR. RICH: Just a brief comment. So I think this is a Measure that shows the events in the coordination of care between a specialty and primary care.

And this is a great story and a great science. The DRS study and the ETDRS study were done on the '80s.

The guidelines were developed in '85. And within five years there's a -- was a 50 percent decrease in blindness.

Most importantly, the DCCT trial came out in '92. The Diabetic Computations of Control Trial. And the constant interaction with appropriate visits, indication with primary care,

blindness was down 70 percent.

Statements from the NEI saying that we could get up to 90 to 95 percent prevention of blindness. And having practiced long enough where I would have someone go blind about every two months in the '70s.

And my father died blind from diabetes on dialysis, it's a remarkable story. And again, science, education, time lines, instruments.

CO-CHAIR YAREMCHUK: Okay. So 0088 Diabetic Retinopathy: Documentation of Presence or Absence of Macular Edema and Level of Severity of Retinopathy. So, this -- yes, so -- okay.

Okay. All right. So, to discuss, Andrew Schachat.

MEMBER SCHACHAT: So actually, Bill's comments are very appropriate about coordinating. Because if you don't assess the stuff, you don't have anything to coordinate.

See this is what you end up telling people. And so this is a process Measure. And as Bill said, there's been an amazing advance

since the completion of these studies.

I actually cite slightly different numbers. The 50 percent five year blindness rates from before the studies. And now, if there's timely detection and appropriate treatment, the blindness rate ought to be one to two percent.

So, it's an amazing reduction in avoidable blindness. There are numerous randomized control clinical trials.

And then also large, representative national populations based natural history studies. And that has shown that these are the causes of blindness. And that the blindness can be reduced by timely treatment.

The treatment is cost effective. And the retinopathy level reliably predicts the development of proliferative diabetic retinopathy with high likelihood.

So these are relevant things to look at. Both can be asymptomatic. It's clear from randomized trials that treatment is beneficial.

And the screening that's being asked for the examinations that would be asked for here, is to identify patients for whom treatment is indicating that's the macular edema, or patients for whom there would be a benefit for closer follow up.

So for more advanced retinopathy, you get told to come back sooner. And less advanced come back later because the idea is to catch proliferative disease at the time you would treat that.

Just like AMD is the leading cause of new blindness in older people, diabetic retinopathy is the leading cause of new blindness in working age Americans. And so it's a huge problem.

CO-CHAIR YAREMCHUK: Steve? Were you finished?

MEMBER SCHACHAT: I was -- can I have a --

CO-CHAIR YAREMCHUK: Sorry, go ahead, sorry, Andrew.

MEMBER SCHACHAT: No, the rest is a -- there was one more point. And that is that the numerator is the dilated macular fundus exam. And we're all doing this.

And all ophthalmologists would accept that detection is not possible without that. Only that one could do screening photos if photos replaced doctors.

MEMBER STRODE: I've got a question. This is percentage of patients 18 years and older with a diagnosis of diabetic retinopathy. Not 18 and older with a diagnosis of diabetes?

Is there another measure that would cover the larger population of all diabetics?

MEMBER SCHACHAT: I think there is in the general medicines space that is the annual eye exam. I mean, you're -- so, the primary care provider is being informed, do your diabetes patients get an annual exam.

So there's a measure for that.

CO-CHAIR YAREMCHUK: Yes, there is in the portfolio. The overall for the eye exam.

Other comments?

(No response)

CO-CHAIR YAREMCHUK: All right. Ready to vote.

MS. ROBINSON-ECTOR: Voting for evidence is now open for Measure 0088. And for those on the call, option one is high, two is moderate, three is low and four is insufficient evidence.

Okay. It looks like we're missing one vote in the room. Thank you.

Okay. All the votes are in. 93 percent voted high. Seven percent voted moderate. Zero voted low and zero voted insufficient evidence. So for evidence for Measure 0088, the measure passes.

MS. LUONG: And I just want to note that this is part of the claims and registry version of the Measure. This applies to both the evidence. Sorry about that.

CO-CHAIR YAREMCHUK: Okay. For opportunity for improvement.

MEMBER SCHACHAT: So I really think it's the same story we heard for AMD because the score rates are very high already at 96 percent, 95 percent, that kind of level. But again, it's the PQRS doctors who are reporting. And I think there is data in the IRIS Registry that this is not scored reliably for the doctors who are reporting that. Flora, do you have that?

DR. LUM: I have a rate of about 36 percent.

MEMBER SCHACHAT: So, it's exactly the same story as the other. This is actually harder to do and so the scores ought to be lower, because there are more categories here and the findings can be more subtle.

CO-CHAIR YAREMCHUK: Any other comments? Oh, excuse, me Steve?

MEMBER STRODE: Nothing to add.

CO-CHAIR YAREMCHUK: Any comments in general? Go ahead Todd.

MEMBER RAMBASEK: I know we talked about it. Why are the PQRS putting doctors so

different from the claims doctors? Is it just retinopathy has more specialists?

MEMBER SCHACHAT: I can't say. I guess it's retina specialists. I think it's a more basic thing. If you're getting paid more to do something, you do it. And if you're not getting paid, you do it less. I mean, that's the point of the -- this pay for performance stuff.

DR. RICH: I think again, what we're looking at in the registry, we're not looking at just the three measures the doctors are reporting. We're actually looking at the performance of the other nine measures that they're not reporting. So that's -- does that make sense?

CO-CHAIR MERENSTEIN: But again, as was mentioned, they might be doing it. They're just not documenting it.

DR. RICH: Yes. But what we can document -- so in other words, if they're reporting on these, we only had to do three before. But we actually are able to measure the

performance on all of them. All the measures. And that's why you see the performance rate of about 36 percent. Next year when they have to report on nine, I would imagine it will be a little bump up. Flora?

DR. LUM: Okay. It's what you get measured on that you can focus on and improve. And as Dr. Friedman said, it's probably mainly retina specialists that are reporting on the measure. I think it was -- it's only 20 -- 16 -- 26 percent now of eligible providers are reporting in the PQRS system on this Measure.

DR. RICH: Again, a lot of docs are doing it. But since they're not reporting on it, they're not documenting it. I don't know anyone that doesn't look at the diabetic retinal exam, but, if they're not going to be reporting on it, they're not going to meet the criteria.

CO-CHAIR YAREMCHUK: Are we ready to vote?

MS. ROBINSON-ECTOR: Voting is now open for performance gap for Measure 0088. And

for those on the call, option one is high, two is moderate, three is low and four is insufficient.

All the votes are in. 53 percent voted high. 47 percent voted moderate. Zero voted low and zero voted insufficient. So for performance gap for Measure 0088, the measure passes.

CO-CHAIR YAREMCHUK: Reliability.

DR. WINKLER: And as Vy did mention, this Measure does have an e-Measure version. So as we did yesterday, we'll right now look at the criteria for the claims registry version. And we'll go back to the e-Measure.

MEMBER SCHACHAT: So for reliability, using claims reporting, the developer reported good reliability when the average number of quality events were reported. Looking through -- pulling data from the registry, there was high reliability across the board. Whether it was low, moderate or high at numbers of the reporting rates.

I have one question, comment or small

issue to mention to the developers. The denominator is defined in a group of ICD-9 codes that denote the presence of diabetic retinopathy. And I wasn't sure if 362.07 was included, because I didn't see it on the list. And I think that's one of the codes that gets used for diabetic macular degeneration.

DR. LUM: Yes. I believe we noted this comment in the pre-meeting evaluation. And we reviewed that and, in consultation with the AA, will make that determination to add that.

MEMBER STRODE: Nothing to add.

CO-CHAIR YAREMCHUK: Discussion?

(No response.)

CO-CHAIR YAREMCHUK: Ready to vote.

MS. ROBINSON-ECTOR: Voting is now open for reliability for the claims and registry version of 0088. For those on the call, option one is high, two is moderate, three is low and four is insufficient.

Okay. All the votes are in. 20 percent voted high. 80 percent voted moderate.

Zero voted low and zero voted insufficient. So, for reliability for the claims and registry version of Measure 0088, the measure passes.

CO-CHAIR YAREMCHUK: Validity.

MEMBER SCHACHAT: So an expert panel of 16 members strongly agreed that the Measure could distinguish quality of care. So that much for face validity.

There was moderate agreement on the e-Measure testing. But that is for the e-Measure discussion. Exception rates are low. One percent to five percent, respectively, based on whether you are looking at one way of reporting or another. And exceptions are the kinds of things where you can't look at the fundus because there's a vitreous hemorrhage or a cataract or something like that. Those are examples.

MEMBER STRODE: Nothing to add.

CO-CHAIR YAREMCHUK: Any comments or discussion?

(No response.)

CO-CHAIR YAREMCHUK: Ready to vote.

MS. ROBINSON-ECTOR: Voting is now open for the claims and registry version of 0088 for validity. And for those on the call, option one is high, two is moderate, three is low and four is insufficient.

Okay. 33 percent voted high. 60 percent voted moderate. Seven percent voted low. And zero voted insufficient. So, for the registry and claims version of 0088, the measure passes for validity.

CO-CHAIR YAREMCHUK: Feasibility.

MEMBER SCHACHAT: So, it's based on codes. So it's quite feasible.

MS. ROBINSON-ECTOR: Voting for feasibility for the claims and registry version of Measure 0088 is now open. And for those on the call, option one is high, two is moderate, three is low and four is insufficient.

All the votes are in. 80 percent voted high. 20 percent voted moderate. Zero voted low and zero voted insufficient. So for feasibility for the registry and claims version

of Measure 0088, the measure passes.

CO-CHAIR YAREMCHUK: Usability and use.

MEMBER SCHACHAT: It's currently used in PQRS. And will be currently reported. And it's been successfully used in IRIS.

CO-CHAIR YAREMCHUK: Steve?

MEMBER STRODE: Nothing to add.

CO-CHAIR YAREMCHUK: Any discussion?

(No response.)

CO-CHAIR YAREMCHUK: Vote.

MS. ROBINSON-ECTOR: Voting is now open for usability and use for the claims and registry version of Measure 0088. And for those on the call, option one is high, two is moderate, three is low and four is insufficient information.

Okay. All the votes are in. 93 percent voted high. Seven percent voted moderate. Zero voted low and zero voted insufficient information. So for usability and use for the claims and registry version of

Measure 0088, the measure passes.

CO-CHAIR YAREMCHUK: Now to vote for whether to recommend the Measure as suitable for endorsement.

MS. ROBINSON-ECTOR: Voting for recommendation for overall suitability for endorsement for the claims and registry version of Measure 0088 is now open. For those on the call, option one is yes and option two is no.

All the votes are in. 100 percent voted yes. And zero voted no. So for recommendation for overall suitability of endorsement for the claims and registry version of Measure 0088, the measure passes.

CO-CHAIR YAREMCHUK: And now we need to vote on the e-Measure form of this?

DR. WINKLER: Yes. And similar to yesterday, we've got some limited testing at the data element -- or data element validity testing. And we're expecting to see the BONNIE testing in the simulated data set for the e-Measure as well when next we regroup.

CO-CHAIR YAREMCHUK: So, any issues or comments? Questions around E-Measure specifications or anything that might be different from the registry Measure on the e-Measure?

(No response.)

CO-CHAIR YAREMCHUK: Okay. So, are we now ready to vote?

MS. ROBINSON-ECTOR: Voting is now open for the e-version of Measure 0088 for reliability and validity. And for those on the call, option one is yes with conditions and option two is no.

Okay. So it looks like we're missing one vote in the room. So if you all could revote please. Oh, she's not -- oh, okay. Thank you. Thanks. So, all the votes are in at 14 votes. 100 percent voted yes with conditions. And zero voted no. So for reliability and validity for the e-version of Measure 0088, the measure passes.

CO-CHAIR YAREMCHUK: Okay. We're

going to go ahead to the next measure of this -- oh, sorry.

DR. WINKLER: We have to do the feasibility and use voting. And then we'll go to the others.

CO-CHAIR YAREMCHUK: Okay.

DR. WINKLER: Anything around feasibility for an e-Measure? Any discussions any concerns about the data elements being capturable in electronic health records?

(No response.)

MS. ROBINSON-ECTOR: Okay. Voting is now open for feasibility for the e-version of Measure 0088. And for those on the call, option one is high, two is moderate, three is low and four is insufficient.

Okay. All the votes are in at 14 votes. Feasibility -- oh, sorry. 93 percent voted high. Seven percent voted moderate. Zero voted low and zero voted insufficient. So for feasibility of the e-version of Measure 0088, the measure passes.

DR. WINKLER: For usability and use, do you feel that you're votes would be different for the e-Measure, versus the registry Measure? Want us to carry it over?

(No response.)

DR. WINKLER: So the last one would be your vote on suitability for endorsement of the e-Measure. And again, this would have the same conditions we talked about with the testing they're going to do in the simulated data set and bring back the results in the post-comment call.

MS. ROBINSON-ECTOR: So, voting is now open for recommendation for overall suitability for endorsement for e-Measures for the E-version of Measure 0088. And for those on the call, option one is yes with conditions and option two is no.

All the votes are in at 15 votes. 100 percent voted yes with conditions. And zero voted no. So for recommendation for overall suitability for endorsement of e-Measure 0088, the measure passes.

CO-CHAIR YAREMCHUK: Okay. We're going to go ahead to the next measure at this point in time. And it is the 0089, Diabetic Retinopathy, Communication with the Physician Managing Ongoing Diabetes Care. Discussant is Scott Friedman.

MEMBER FRIEDMAN: So this is a process measure. Looking at communicating with the primary care physician with patients with diabetic retinopathy. And we all know that as has been discussed, we know that higher levels of hemoglobin A1C and poor control of diabetes leads to more retinopathy. Better control leads to less retinopathy.

So basically, there's no level one evidence showing that if you communicate with a primary care physician that you're saving vision. But it just makes sense to me that if the patient is poorly controlled and you communicate with the doc saying that the eyes are getting worse that they would possibly encourage the patient to have better control, or change their regimen to have

better control of their diabetes, which in fact will lead to less progression of the retinopathy. But again, there is no level one evidence for that, but it just make sense to do.

I certainly do it in my practice. I think if that this is pretty obvious, that docs want to know what the level of the retinopathy is in their patients. And they certainly want to know that if the eyes are getting worse. One thing that I mention the phone call. We actually did a study where in our office, we consult the patients as to treatment for diabetes and we measured the hemoglobin A1C as a primary outcome trying to lower the level of hemoglobin A1C over a couple of years.

Our paper's been accepted but not in print yet. So I can't discuss the results yet. So, we are very as a retinal community and as an ophthalmology community, in trying to do whatever we can do to lower the level of diabetic retinopathy. And this would be one way to get at that.

MEMBER STRODE: I've got some questions for the Developers. Does this have an e-Measure associated? It does. Okay. And what is the acceptable level of documentation? Would it be a check mark saying yes, I communicated? Or would you expect to find a copy of the written communication that that was form?

MS. HANLEY: We actually do have in the Measure, e-Measures inadvertently left out of the submission form, a definition of communication. So, I'll read it verbatim. It may include documentation that the results were communicated verbally, by letter, EG. It could be any type of communication with the clinician managing the patient's diabetic care.

Or a copy of the letter in the medical record to the clinician managing the patient's diabetic care. So we would look for that documentation in the eye care provider's patient record that that information had been sent.

MEMBER FRIEDMAN: So, just to clarify, in my practice, typically I know patients are

referred. I sent a letter to the referring doctor, and I sent a copy to the primary care physician. And that's included in my EHR. It's clearly defined.

CO-CHAIR YAREMCHUK: Any other discussion?

DR. WINKLER: On the phone call, it was a conversation we talked about a little bit of different people's experiences. Because this is a traditional area where this coordination of care is really challenging. And I remember when this Measure was first discussed, it was how hard this communication issue really was.

And so, I guess a sense of how -- of whether we're really making improvements in that communication among providers. Andy, I thought it was you that maybe volunteered on the call, the way you do it in your office that's very automated. And with that, both primary care folks on the Committee as well as the specialists, we got both ends. And I'm curious to know what your experiences are. What's going

on out there in the world? How well this communication is truly happening?

MEMBER SCHACHAT: Well, with many of the new electronic medical records, it's pretty easy to do. And I can do it in an extra two seconds, and I am very pleasantly surprised with how often I get messages in my inbox that say thank you. So, messages are appreciated. I don't count how many of the letters I send that are not even looked at. We can actually look at that.

DR. RICH: It's a great question. I remember the discussion years ago. And I have document management system. And at the end of that examination, after I've discussed and counseled with the patient, emphasizing that little stuff is the big stuff, if you eliminate one's retention of lipids it can have a dramatic impact on the natural course of the disease.

We actually augment what the primary care doctor is saying. I would then have a copy of that that the patient can carry out.

Unfortunately, because of interoperability and we are dealing with many different EHRs, I have a practice, I actually fax it. It's a more reliable way. So, the ability to make this happen is dramatically better than just five or just seven years ago.

CO-CHAIR YAREMCHUK: Go ahead, Steve.

MEMBER STRODE: As again, of one family doc, that experience doesn't go very far. But actually in my current role, I'm doing lots of chart review. And it does seem that from retina specialists, general ophthalmologists and DO -- OD's that this is becoming much more of a standard of care. And it may be written, it may be electronic, but it seems increasingly to be getting out to either the endocrinologist or the primary care doctor.

CO-CHAIR YAREMCHUK: Any other comments?

MEMBER STEIN: I just one to add one more point for all this. In the discussion that came up about how communicating with the PCP is

helpful in terms of letting them know about the status of retinopathy. But the status of the retinopathy is often the surrogate for what is going on with, you know, kidney function, neurologic function and various other organ systems. So, I think it's helpful. Just focusing on evidence, it's helpful in many ways. I'd like to think. I'm not a PCP, but I'd like to think they find it useful.

CO-CHAIR YAREMCHUK: All right. Are we ready to vote on evidence?

MS. ROBINSON-ECTOR: So voting for evidence for Measure 0089 is now open. And for those on the call, option one is high, two is moderate, three is low and four is insufficient evidence. It looks like we're missing one vote. So if everyone could point their clickers. There we go.

So, all 15 votes are in. 47 percent voted high. 47 percent voted moderate. Seven percent voted low. And zero voted insufficient. So for evidence for Measure 0089, the measure

passes.

CO-CHAIR YAREMCHUK: Okay. Now discuss opportunity for improvement.

MEMBER FRIEDMAN: So the developers provided data from the PQRS from 2009 to 2012. And they're about 92 percent, up to 93 percent. So, again, the same -- it's the same story. The people that are reporting it are doing an excellent job. Most likely the people that are reporting are a paucity of the possibilities.

And those are the people that care the most, so if you look at the IRIS Registry, it may be lower. But again, it's possible there's still room for improvement. There's lots of people out there with diabetes, so if you can move the bar up a couple percents, you'd be saving -- potentially saving lots of vision on tens of thousands of patients. And it's also possible that if more people report on it, the numbers would be a lot lower. So there is ample room for improvement in my opinion.

CO-CHAIR YAREMCHUK: Steve?

MEMBER STRODE: I just wanted to follow up on what Josh said. Certainly, whoever is the ongoing diabetes provider, endocrinologist, or primary care is also expected to screen and follow the neuropathy and nephropathy. But it just seems easier to scare people into perhaps better diabetes care if you're talking about their vision. It's great ammunition.

DR. RICH: Steve is absolutely correct. I've worked with a training program that says that's the only practice for over 20 years. And people blow off heart disease now, the diabetics. And we have the discussion with them that the hemoglobin A1C, which is your hypertension control, you're going to actually decrease any retinopathy 70 percent, and 90 percent prevent blindness. They listen. So, we do -- we are able to scare them.

CO-CHAIR YAREMCHUK: I guess I have a question. When we look at from 2009 to 2012, it hasn't changed in terms of in the PQRS meeting

that. And so I guess my question is, with people thinking this is a slam dunk and very important, it hasn't changed at all.

MS. HANLEY: I would comment that the number of physicians reporting has also increased from 2009 to -- the day that we have through 2013. The reporting rate in 2010 was ten percent of eligible professionals were reporting on this measure, of those for whom this measure were eligible were reporting on this measure. And that has increased up in 2013 to 16.5 percent. So, as the numbers of eligible professionals reporting on the measures increases, that's going to have an effect on the performance rate as well.

CO-CHAIR YAREMCHUK: I mean, it's just kind of interesting because we've mentioned the electronic record has made it somewhat easier to be able to do some of these things. And so, with that change in availability, I would think that it would also then improve the likelihood of doing well, notwithstanding the fact that you had

more people reporting. So I don't know if there's any comments from the providers in the room regarding this?

DR. RICH: Well, I think the biggest thing is that you only had to report on three. And so when you report on nine, I think you'll see a dramatic jump in 2015.

CO-CHAIR YAREMCHUK: All right. Ready to vote.

MS. ROBINSON-ECTOR: Voting is now open for performance gap for Measure 0089. For those on the call, option one is high, two is moderate, three is low and four is insufficient.

All the votes are in. 27 percent voted high. 73 percent voted moderate. Zero voted low and zero voted insufficient. So for performance gap for Measure 0089, the measure passes.

CO-CHAIR YAREMCHUK: Reliability.

MEMBER FRIEDMAN: So the Developers reported reliability testing on claims and registry data. And just to summarize, the

reliability on the claims data, looking at lots of docs, was very high. And then looking at the registry data, they also had a high level of reliability. So I don't think there's going to be any issues with reliability for this Measure.

MEMBER STRODE: Nothing to add.

CO-CHAIR YAREMCHUK: Ready to vote.

MS. ROBINSON-ECTOR: Voting for reliability for Measure 0089 is now open. Oh, and for those on the call, option one is high, two is moderate, three is low and four is insufficient.

MS. LUONG: And to note, this is for the claims and registry version.

MS. ROBINSON-ECTOR: All the votes are in. 20 percent vote high. 80 percent voted moderate. Zero voted low and zero voted insufficient. And so for reliability for the claims and registry version of Measure 0089, the measure passes.

CO-CHAIR YAREMCHUK: All right. And we can talk about validity.

MEMBER FRIEDMAN: So the -- again, the Developers presented data for both claims registry and e-Measure. Do I discuss e-Measure at this time?

MS. LUONG: No, not the e-Measures.

MEMBER FRIEDMAN: Okay, so the claims and registry is done by face validity, an expert panel of 16 members. And they strongly agree the Measure could distinguish quality of care. So, from claims and registry data, there's good validity testing.

MEMBER STRODE: Nothing to add.

CO-CHAIR YAREMCHUK: Comments?

(No response.)

CO-CHAIR YAREMCHUK: I guess I have question. How do you get this from claims?

DR. RICH: I think there's a --

MS. HANLEY: You collect measure from claims. There's a CPT-2 code that's recorded on the claim.

DR. RICH: A code that says I sent the letter.

CO-CHAIR YAREMCHUK: Okay. All right. Ready to vote.

MS. ROBINSON-ECTOR: Voting is now open for the claims and registry version of Measure 0089 for validity. And for those on the call, option one is high, two is moderate, three is low and four is insufficient.

All the votes are in. 40 percent voted high. 60 percent voted moderate. Zero voted low and zero voted insufficient. So for validity of the claims and registry version of Measure 0089, the measure passes.

CO-CHAIR YAREMCHUK: Scott?

MEMBER FRIEDMAN: So feasibility?

CO-CHAIR YAREMCHUK: Right, feasibility.

MEMBER FRIEDMAN: The Measure is specified for several data sources including claims registry and e-Measure. And there shouldn't be any issues with feasibility for this Measure.

MEMBER STRODE: Nothing to add.

CO-CHAIR YAREMCHUK: Any discussion?

(No response.)

CO-CHAIR YAREMCHUK: Vote.

MEMBER CARNAHAN: Just a quick question?

CO-CHAIR YAREMCHUK: Yes. Go ahead Matt. Sorry.

MEMBER CARNAHAN: Wouldn't the 50 10F or 2P, the patient reason for not communicating, is that a fail for the provider then? What would be an example of a patient? If they didn't have a primary care? I don't know.

MS. HANLEY: It would be -- yes. If they didn't have a primary care physician, it would not be considered a Measure failure. It would be removed from the denominator as an eligible piece.

MEMBER FRIEDMAN: So, unfortunately, some of my patients don't know who their primary care doctor is. This is reality of medicine. For some reason, some patients don't want you to send the letter to the referral doctor or to the

primary care doctor. Why don't you want to do that? No, who knows. So, you can't make them do that. That could be one of the other reasons.

MS. ROBINSON-ECTOR: Voting is now open for feasibility for the claims and registry version of Measure 0089. And for those on the call, option one is high, two is moderate, three is low and four is insufficient.

Okay. All the votes are in. 80 percent voted high. 20 percent voted moderate. Zero voted low and zero voted insufficient. So for the claims and registry version of Measure 0089, the measure passes for feasibility.

CO-CHAIR YAREMCHUK: Usability.

MEMBER FRIEDMAN: So, the Measure is currently used in the PQRS program. It will soon be publically reported. And it's also used in the IRIS Registry.

MEMBER STRODE: Nothing to add.

MS. ROBINSON-ECTOR: Voting is now open for usability and use for the claims and registry version of Measure 0089. And for those

on the call, option one is high, two is moderate, three is low and four is insufficient information.

All the votes are in. 100 percent voted high. Zero voted moderate. Zero voted low and zero voted insufficient information. So for usability and use for Measure 0089, the registry and claims version, passes.

Voting is open for recommendation for overall suitability for endorsement for the claims and registry version of Measure 0089. For those on the call, option one is yes and option two is no.

Okay. All the votes are in. 100 percent voted yes. And zero voted no. So, for recommendation for overall suitability for endorsement for the registry and claims version of Measure 0089, the measure passes.

CO-CHAIR YAREMCHUK: Now for the e-Measures?

DR. WINKLER: Yes. We'll look at the e-Measures. The scientific acceptability again,

as we've done with the other e-Measures, the fact that there was a submitted data element validity testing on these measures, but we do expect to review the results of the simulated data set testing at the post-comment call. So that would be your decision to accept that and pass the criteria with the condition of review note in a few weeks.

MS. ROBINSON-ECTOR: So voting is now open for reliability and validity for the e-Measure version of Measure 0089. Oh yes, and for those on the call, option one is yes with conditions and option two is no.

All the votes are in. 100 percent voted yes with conditions. And zero percent voted no. So for reliability and validity of the e-Measure version of Measure 0089, the measure passes.

DR. WINKLER: Okay. We're kind of -- you can see we're sort of going through the same thing. So for feasibility and use and usability, is there anything new or different about this e-

Measure compared to the other diabetic retinopathy e-Measure? In terms of your sense of feasibility, use in an e-measure and use and usability? Should we carry those over from the previous vote? Great. So we can go to the last vote.

MS. ROBINSON-ECTOR: Voting is now open for overall -- recommendation for overall suitability for endorsement for the e-Measure 0089. And for those on the call, option one is yes with conditions and option two is no.

Okay. All the votes are in. 100 percent voted yes with conditions. And zero voted no. So for recommendation for overall suitability for endorsement for the e-Measure 0089, the measure passes.

DR. WINKLER: All right, thank you. Now it's time for a break. So we will do a ten minute break and then back. Thank you.

DR. RICH: I'd just like to thank the -- on behalf of the Academy, IRIS and PCPI, I'd like to thank the staff and the Members of the

Panel for their attention and their professionalism and tough stuff. Thank you very much.

(Whereupon, the above-entitled matter went off the record at 10:04 a.m. and resumed at 10:20 a.m.)

DR. WINKLER: We've got everybody together. Thank you. The last of the measures in the eye care category is a new e-Measure. This is our only new measure that has come to us, that's never been seen and used before.

As e-Measures are in the development, and I talked yesterday about, you know, this whole evolutionary process, part of NQF's support of the development of e-Measures is an approval for trial use, sort of halfway option whatever, for measures --

They're for new measures that are coming in for sort of an initial review around the importance criteria, around some of the issues and potential use and usability of the measure. But these measures have not yet been

fully tested, and so -- but by providing the approval for trial use, it allows them to have been looked at by you all, and we'll be putting them out for public comment and getting feedback.

So that it allows them to be vetted, and this supports their use in some of the meaningful use programs going forward. So we are trying to promote the implementation of the ability to conduct more robust testing afterwards. So the approval for trial use designation is not the same as endorsement.

It is just, as it says, approval for trial use, and these are free measures that are ready for implementation but not yet adequately tested, and so it applies to these new measures. We are looking for e-Measures that address important areas for performance measurement and quality improvement.

So the importance criteria is what we're going to look at. We're going to see what the evidence is and what do we know about the quality problem and performance at this point in

time, from the literature or whatever potential sources of data. We won't have anything from the measure itself.

We do want to -- they have been reviewed internally by our e-Measure technical review for the specifications, to determine that they are least technically sound for implementation, but we really have nothing in the realm of reliability and validity.

The feasibility assessment for e-Measures has been performed, and these measures are not intended to be used for accountability, not intended to be used for public reporting or payment. This is meant to just say this is an important measure still in, you know, the later stages of development, but that we do feel that it's an important measure that has great promise, and NQF will be granting approval for its trial use, to gain more experience, to understand how the measure will function going forward.

So that's how we're going to ask you to evaluate this upcoming measure. So you're

going to look at it with somewhat different lens, all right. Do you have any questions about the differences between what you have been doing for two days, and what we're looking for here.

MEMBER FRIEDMAN: So down the road, what would be the use for this measure?

DR. WINKLER: I think that's one of the things we can talk about when we get to use and usability, okay. All right. Anything about the process? Okay. Then we go on to look at the measure itself, which is -- bring up the next slide, please.

Good, all right. We've still got the old slide and we talk about the name of the measure. But it is Measure 2721, renamed Visual Acuity Screening in Children. And so Andy and Scott were the discussants for this measure. So we do want to, as we've done with all the measures, go through. So we'll start with evidence.

CO-CHAIR MERENSTEIN: The developers don't speak to this?

DR. WINKLER: I'm sorry, absolutely. Let our developers speak.

MS. AMBROSE: Well good morning, everyone. This measure, Amblyopia Screening in Children, was the original measure title and description, and the evidence actually came from the United States Task Force, the Preventive Services Task Force and the AAP. And it was initially developed as visual screening for the medical home by the AAP, and our team took the measure and actually specified it for amblyopia, based on recommendations, initial recommendations from the AAP expert group.

But in review with the NQF, we got some great feedback from our reviewers, that it will be more appropriate as a visual acuity screening measure because really the algorithm and the measure specifications were attuned to visual acuity screening and vision, to identify and detect vision problems.

So that's how the measure is being presented today, and there's -- we conducted an

evidence review, and Dan, feel free to give details. Dan is our specification lead. But there is quite a bit of evidence that visual acuity testing in kids will prevent issues like amblyopia, strabismus, etcetera.

And the measure also includes a referral component so it's not just the screening, but if a child is identified as positive, the child would then be referred to either a pediatric ophthalmologist or an eye care specialist for further eye examination.

CO-CHAIR MERENSTEIN: Andrew.

MEMBER SCHACHAT: So this was originally presented as an amblyopia screening measure, and that's a very difficult space to work in. The idea was to screen for amblyopia and if there was a concern that it was present to refer. It's clear that this is something that can be asymptomatic. It's clear that there's a large prevalence of it, and it's clear the treatment is beneficial and that there are cost-effective treatments, and the harms of missing it

are high, because you have poor vision for the rest of your life, and it's pretty preventable.

So the whole rationale of screening and detection for amblyopia is there and it makes sense. The trouble with working in this space is that state by state, there are laws on how this is done, and so to provide one measure and if the law says something else, they're going to follow the law, and so there will be variation in the scores across states. So that's a problem.

Another problem is that there's -- screening is done at school or by other places, often not in the health care system, and getting the data into the health care record is a challenge. And the data could just be entered as screening done, but I'm not sure that that's what the thing specified.

And then exactly how to screen is pretty complicated, and I'm not even sure I know how to screen for amblyopia the right way. Pediatric ophthalmologists do it. I just sort of screen for the risk of it, and then send them to

the pediatric ophthalmologist to figure it out. This was asked to be done by the pediatricians, who probably can't do it right.

So after this discussion, the developers agreed that maybe they wanted to suggest something else, and they suggested visual acuity screening, which is reasonable, because it's a first step, and if kids have normal vision, they don't have amblyopia, and if they have reduced vision, they have something, and the most common something they have is that they need glasses.

But you have to go to an eye care provider to get that worked out, and if glasses don't solve it, then there's a testing algorithm to figure out if someone has amblyopia and so on. So I support the whole idea, but the devil is in the details.

CO-CHAIR MERENSTEIN: Scott, anything to add?

MEMBER FRIEDMAN: Yes, and one quick thing. Since we have our discussions and they

modified it, for example, denominators exclusions terminating with an active diagnosis of amblyopia or blindness during the measurement period. So you're going to have kids that have an active diagnosis of refractive error. So the question is, again what Andy just said, most kids are going to have refractive error, and do you want to exclude those as well.

MR. ROMAN: We can definitely add those exclusions. Just with the timing that we had from the discussion until today, we didn't want to just add in anything that, you know -- we wanted to make sure that it was something that made sense to add.

I think that additional exclusions would be something that we would test for, with the additional testing that this measure needs. We only looked at blindness when we tested. We included amblyopia as an exclusion because originally, based off the USPSTF, this was -- that's what the measure was really, or that's what the focus was.

It made sense if a child already had amblyopia diagnosed in the record, that you wouldn't do this additional screening from. So that's why those two are included. We want 100 percent agree that there would be additional visual problems that it might include, given that this is visual acuity screening now, and at least something that we would look for in additional testing.

CO-CHAIR MERENSTEIN: And are there questions about this, because that's more of a Libby issue. Are there questions about the evidence or comments about the evidence, because we could vote on that first and then -- it's a good discussion. Josh.

MEMBER STEIN: I'm still trying to understand the new measure, or the revised measure. But is this intended for pediatricians? Can you clarify what providers would be --

MS. AMBROSE: Yes. It's intended for use in a primary care setting, so it would essentially be pediatricians.

MEMBER STEIN: So if a child is getting school screening as part of the state program, the pediatricians also are supposed to do this in addition? How are you reconciling the screenings that are going on in the schools, in that whole infrastructure with this?

MS. AMBROSE: That's one of the questions that actually came up in our discussion. So that could potentially be an exclusionary criteria for when the measure is tested in real life settings. We're also looking to test in other settings, like a school-based clinic perhaps, or even -- you know, exploring the possibility of obtaining data from school systems and EDHR systems. I think those are for the future but definitely under consideration.

MR. ROMAN: I think another thing to consider here is how the measure's implemented. So this measure is only an e-Measure, and it was developed for consideration for use in the EHR incentive program, which is only looking at what eligible professionals are doing.

So what happens in the school, I'm not sure how we'd factor that in. When we look at the programs across states, they vary when screening's supposed to occur. Some are not -- some don't have any policies at all actually some states. Some states have very specific guidelines or recommendations, or just they're -- these are the policies. It does again vary whether or not it's just a recommendation or it's an actual policy.

Some are very specific at what age it should occur, some are not. Some do not include pre-school vision screening. So I think the goal with this measure is that we're looking for when a physician is seeing a child any time from ages three to five, that they do the visual acuity screening at least once.

So the hope is that, or the goal is that it's getting children screened before school. So the school programs, again, don't all include the age that this measure is focused on, which is ages three to five, or before they turn

six.

MEMBER STEIN: The other key component to this is, you know, doing the screening is one thing, and the key thing is whether the child actually gets to the provider, the pediatric ophthalmologist or the, you know, the eye care specialist, and the active screening and evaluating, and even saying you need to see an eye care specialist, if you don't close the loop than that's still problematic.

MR. ROMAN: So in our testing, the limited testing that we were able to do, since this is an e-Measure, our data source is the electronic health record. We asked the sites that we tested with for feasibility, I think we had -- what they had available.

So getting information about whether or not visual acuity screening occurred yes, that was easy. Whether or not there was a referral that you could actually track the data to see that a referral was made when one was needed, that was also a possible. I don't believe all

the sites were able to do it, but EHR vendors said it is possible.

As far as the follow-up, that third crucial piece, that's the piece that in the EHR, it's difficult to see whether or not it occurred. I think if you were doing a plan level measure, where you're looking at claims data and kind of the whole, everything that's available, you could do that.

With the EHR data and from the perspective of one provider reporting the data that occurred, what they did for one patient, it's really tough to get that data. So for this measure's purpose, there wasn't -- we decided not to include that follow-up, just because we don't think that the data's actually there.

MEMBER STEIN: Do you think this would be better as a plan measure than as an individual provider measure? We discussed a plan measure yesterday, right?

MR. ROMAN: I think there also potential for a plan level measure. I mean

that's not really -- that wasn't in the purview of the work that we were doing. We were focused on the EHR measures. I think it's possible, and potentially the plan level measure you would do even more than just a visual acuity screening. But again, that's kind of outside the scope of this measure or what we were contracted to do.

MS. AMBROSE: There's also under Meaningful Use, there are other measures. There's a measure for closing the referral loop. So when we looked at developing this measure and adding that follow-up component, one of the recommendations from our team was that this measure could be used in conjunction with a measure like closing the referral loop, which will then capture what you're talking about.

CO-CHAIR MERENSTEIN: Any further comments before we vote on evidence? Sorry.

MEMBER SCHACHAT: I'm not even clear. Are we voting on whether screening helps vision, helps avoid vision loss in the future, or are we voting on whether --

DR. WINKLER: Yeah. This is a process measure that is about visual acuity screening in children. So the evidence you're looking for is what do we know about the relationship between doing that screening and outcomes for children, assuming it's indeed a vision outcome. So think of other screening measures. There are many of them, and obviously it relies on the appropriate follow-up of the abnormal screen.

But screening is a commonly measured concept, screening of various things, blood pressure screening, pap smear screening, mammography screening, you know, all of them. So this is a similar kind of thing. So you're looking what's the relationship to the outcome or vision outcomes for patients?

MEMBER SCHACHAT: I'll just say that it's absolutely clear that some children are helped. What we don't really know is the sensitivities, specificity and efficiency of the whole thing and so on.

MEMBER CARNAHAN: Yes, and I would

echo that. I think we've done testing looking at glaucoma screening, and they found it really wasn't cost effective. You do capture some people that have glaucoma, but a huge percentage of patients don't, and a huge percentage of these children will be falsely identified as having vision problems. Or a lot of them just, I mean the ones that I see just weren't screened, and most of them have perfect vision.

MEMBER BRADHAM: So this is Tammy. So what is our false positive rate for sensitivity, specificity for screening?

MR. ROMAN: So really it depends on what screening method is used, and it's all over the place.

MEMBER STEIN: I think it's an evolving area, and there are different screening tools that are being tested. I think the cost effectiveness is a little different than with glaucoma, because identifying a child with a potentially sight-threatening condition early in life, that they're going to live the rest of

their life with poor vision is different than identifying someone in their 60's and 70's with peripheral vision loss. So I think -- I'm sure that the study is looking at cost effectiveness, and it should be very cost effective. I don't think that's the issue here.

MEMBER BRADHAM: So this is Tammy again. So does this measure specify which hearing screening tool that will be used? Vision, I'm sorry. I'm an audiologist here, what vision screening tool will be sued?

MR. ROMAN: Currently, it does not. It only is looking at that a visual acuity study is done. That's the code that it is using. There are no codes specific to the different types of wall charts or eye acuity screening test that you might do. We have one code that is capturing kind of all the visual acuity that might -- visual acuity studies that might occur.

The other, the only other option we have right now I think would be to put in some additional guidance around what type would be

acceptable. Currently the e-Measure, the text of the e-Measure provides some guidance linking to some of the specialty societies and what they recommend on what's passing, what's failing and what tests to use.

MEMBER MADONNA: I'm not sure. Excuse me, I'm not sure this is the right time, but I'll bring it up anyway. In listening to the comments and in listening to all of the problems that screenings are subject to, doesn't it make sense to consider that visual acuity screening may not be the right thing to do for children, but that children should have complete eye exams done by an eye care professional at some point between, in this case, three and six years old, as opposed to screenings?

CO-CHAIR MERENSTEIN: Follow-up to that, Michael?

MEMBER STEWART: I guess if I'm looking in this, the measure worksheet here, it looks like the AAP had simply an expert opinion guideline or recommendation, but the USPSTF said

there is at least Grade B evidence to support this. So if we're just talking about the evidence, I'm sorry, maybe I missed it, I haven't heard that presented yet.

Everybody keeps saying oh, but this is good. Well, who's against it right? But I mean what's the evidence? Looks like Grade B, but am I interpreting that correctly, because it also kind of sounds like everybody thinks this is so obvious that it's not really been looked at from a cost effectiveness or an evidence-based perspective --

MS. AMBROSE: Yeah. I mean I think -- I think this measure was initially conceptualized as being able to capture possible vision problems in the primary care setting, and an eye exam measure I think will be very valid, but probably could be a follow-on measure to a referral screening measure.

And as far as evidence and then there were other studies that pointed to, I think, the reason why we selected this measure and was also

initially a measure that been developed by the AAP, that we can follow through.

MEMBER STEWART: I mean I'm for this, okay. I'm not against it. I'm just saying every time the question gets asked about evidence, the answer is well, everybody thinks this is a good idea. I'm just asking is there -- what is the level of the evidence to support it, because we have to at least vote on that. That doesn't mean we don't do it. I'm for doing it, but --

CO-CHAIR MERENSTEIN: Although a Level B from the task force is pretty high.

MR. ROMAN: And some of the other specialty organizations have their recommendations that are very similar to this, and it's because they're all based -- they all kind of point back to the USPSTF recommendations. So the level of evidence is B, and it doesn't really matter what organization you look at, because most of them all point back to the USPSTF and their review of the evidence.

CO-CHAIR MERENSTEIN: Any other

comments?

MEMBER FRIEDMAN: Does that evidence come with a certain type of vision screening as was questioned before?

MR. ROMAN: So the guideline, sorry. The recommendation says amblyopia screening, but everything -- this is why our measure, the wording on our measure was difficult, and why we used amblyopia screening. They're essentially recommending visual acuity screening before age six.

They say amblyopia screening and they qualify it in a lot of ways. But they evidence they look at is visual acuity screening in those ages. I think that they have -- there's some additional testing evidence that they reviewed, but it's essentially it's talking about visual acuity screening in the early ages.

CO-CHAIR MERENSTEIN: It says ages three to five I think. Rich.

MEMBER MADONNA: Yes, just a comment on that. Again, for the group who weren't privy

to the initial conversations on this, you really can't screen for amblyopia. You're screening for visual acuity, and if visual acuity is decreased, then you have to send somebody for an eye exam, who then that person does a refraction, which again, as Andy said before, is the most likely reason why the vision is reduced.

You screen for binocular problems, you screen for ocular health problems, and after that, that's the only time that you can really say someone has amblyopia or not. So I think it's really important that we make that distinction between visual acuity screening, which could be done under the set up that we have here, versus actually making a diagnosis of amblyopia, which can only be done by an eye care professional.

CO-CHAIR MERENSTEIN: You took amblyopia out, right? There's no mention of amblyopia --

MR. ROMAN: Yes, yes, we removed it, and again that's our fault for following kind of

the wording of the USPSTF recommendation, which talks -- it says amblyopia screening. So that's the wording we used. What we tested in the limited testing we did is whether or not visual acuity testing was done. That's the coding that was used at the sites we worked with. That's what they were looking at when they considered whether or not a child needed a referral or not, is visual acuity study.

So the wording change that we made really aligns with what was done and the intent anyway, because it is that you do this visual acuity. There are basic screening that primary care, in the primary care setting first, so you can find some indication that there might be a problem that needs to be examined, that needs to be looked at by an eye care professional.

CO-CHAIR MERENSTEIN: So I think there's going to be a lot more discussion points as we go on, but let's vote on the evidence, so we can move on.

MS. ROBINSON-ECTOR: Voting for

evidence for e-Measure 2721 is now open, and for those on the phone, Option 1 is high, 2 is moderate, 3 is low and 4 is insufficient evidence.

MS. LUONG: And this is about the trial use approval?

MS. ROBINSON-ECTOR: Yes.

MS. ROBINSON-ECTOR: All votes are in. 7 percent voted high, 60 percent voted moderate, 20 percent voted low and 13 percent voted insufficient evidence. So for evidence, for the trial use e-Measure 2721, the measure passes.

CO-CHAIR MERENSTEIN: Opportunity for improvement, Andrew.

MEMBER SCHACHAT: There is ample data that a tremendous amount of treatable diseases are overlooked, and that's the reason that states have passed laws requiring it.

CO-CHAIR MERENSTEIN: Anything to add?

MS. ROBINSON-ECTOR: Voting is now open for --

CO-CHAIR MERENSTEIN: Would you like

to add something? Yes, sorry.

MEMBER FRIEDMAN: No, I have nothing to add.

CO-CHAIR MERENSTEIN: Oh, okay.

DR. WINKLER: I'm just going to ask one question. Is there anything about disparities issues in what we know about access to screening and visual care follow-up?

MEMBER SCHACHAT: So if you mean in poorer, poorer children and disadvantaged families, absolutely. So in the Cleveland area, for example, we have a whole big screening program, and determined that the screening didn't work because we detected all kinds of stuff and they didn't get the care.

And so we changed the program to take -- stop screening, and it's now screening and treatment sort of on the spot. So as the screening, when they found the problem, they do the next exam and give them free glasses. So by putting all the care in with the screening, it solves that problem. But there are huge

disparities.

MEMBER STEIN: Yes. We had a similar experience in Michigan, that closing the loop is the biggest issue, and there are in the literature reports of disparities between different -- children of different races and socioeconomic levels.

MEMBER MADONNA: So again it sounds to me like it makes sense to promote eye examinations and not screenings, because that immediately closes the loop.

CO-CHAIR MERENSTEIN: Then again, I think that the usability issue that's going to, yeah. So if we go to opportunity for improvement.

MS. ROBINSON-ECTOR: The voting's now open for performance gap with the trial use e-Measure 2721. For those on the phone, Option 1 is high, 2 is moderate, 3 is low and 4 is insufficient.

All the votes are in. 67 percent voted high, 27 percent voted moderate, zero voted

low and 7 percent voted insufficient. So for performance gap for the trial use e-Measure 2721, the measure passes.

DR. WINKLER: Just in terms of this measure, we're talking about an e-Measure who does not have testing for reliability and validity particularly. We do want to look at the specifications, though, and you know, what exactly is being measured, who's the denominator population, what exactly is being captured in the numerator. So that's what you're really looking at for this part of the evaluation under this conditions.

MEMBER SCHACHAT: Okay. So the numerator is children who received visual acuity screening to detect the presence of vision problems between their third and sixth birthdays and necessarily were referred, and if that means receives screening by the pediatrician, fine. If it means received screening at all and that they had screening done at school and the pediatrician could just check off mom said they did it, I

could accept that.

But I don't know if that's what's specified, and so maybe -- maybe we can answer in a second. And in the denominator, it's children who turn six of age during the measurement period and had at least one of these done during the measurement period. So the denominator is okay.

MEMBER YOUDE: So when I'm looking at this, I'm almost seeing two process measures, the first one being children who are screened, and the second one being children who needed of referral against children who are screened. I'm not clear how the metric looks, or when we say and if necessary, what does that mean in terms of looking at the data and can -- if that data is what we're using, how is that actionable? Separating out the two would make it very clear and understandable and actionable, where we could say are they getting screened, are they getting referred.

MR. ROMAN: Okay. So this measure, again it's an e-Measure. So the way that that

works is all in the e-Measure logic. So first you're looking to see that screening was done, and if it was -- if the physician said that the child's vision was normal, or if there was a referral needed.

So it's kind of screening, and then the second tier is normal or a referral needed, and it's only e-Measure logic. This again originally was a screening measure. We had some suggestions from experts to expand it and try to include that follow-up component, because screening it fine, but it would be nice to see that if there was a problem found, that there's a referral made.

So it is -- it's one process, and it's kind of options of what you do once you have your findings, is why it looks when you read it like that. But it's in the e-Measure logic that it, kind of all the work happens.

MEMBER YOUDE: I like where it's going. I just think that because we have that second step in, it seems natural to separate the

two, so that you can clearly look at Part 1 and then clearly look at Part 2.

CO-CHAIR MERENSTEIN: Tammy, then Scott.

MEMBER BRADHAM: So wouldn't the denominator be the children who failed the screen, and then the numerator be the referral?

MR. ROMAN: No. The denominator right now is all children who turned six during the measurement year, and because of the requirement with CMS and the e-Measure program, we also include in there that they have a visit with the physician during the year. That's not for any reason other than it's a requirement of the e-Measure program. I think it's to establish eligibility and kind of a relationship with the provider. So it's all children before the age of six, and it's whether or not they got screened.

If they -- if they're screened and they're normal, then that passes. If they screen and they fail that screening, then they have to have a referral to pass. So it's the provider.

The provider passes if the screening happened and it's normal, or if the screening needed a referral and a referral was made. So that's the two ways that the physician passes the measure.

MS. AMBROSE: Right. That was one of the reason why we combined the two together, because it just wasn't enough if a physician was screening a children, but also taking the next step and referring.

MEMBER FRIEDMAN: So it's kind of semantics. So patients -- what we want to do is want to prevent vision loss. So the way to do that is to screen kids. You screen kids and it's abnormal. You hope to get referred, and then they get referred and then they get treated.

So there's all these different processes for a kid to ultimately prevent vision loss. So you hope that patients that are screened that had abnormal vision are referred. So I mean you hope that docs aren't saying oh, you're vision's blurry, but I'm not going to do anything about it. That's kind of ridiculous.

So you could even do this -- you could even say, I mean, that they were just screened, and so you want to make sure all the kids were screened properly, because if they're screened and it's abnormal, then they're going to take a step. But what they added is if they're screened, were referred appropriately. Well again, you can say well, were they referred inappropriately. That's kind of ridiculous too. But so I mean it's kind of all these different steps.

But you can -- it's kind of semantics and again, I think we could even leave out were referred appropriately, and just kids that were screened, because if they're screened and their vision is blurry, I would hope that they're being referred appropriately and treated appropriately.

CO-CHAIR MERENSTEIN: Josh.

MEMBER STEIN: I'm still not clear how this overlaps or deals with what's going on in the schools in each of the states. Is the idea if a kid got screened at school, that the

pediatrician's going to check off a box saying I don't need to screen them today, because they got -- they had a school screening? Or are they going to replicate and do more unnecessary evaluation of that kid, so they can meet the measure? How do you reconcile what's going on outside the pediatrician's office?

MS. AMBROSE: I think at this point, the measure specifications do not address that. But I think there's opportunity to expand the specifications to include just that. If there is documentation from the school, for instance, that a vision screening has been done, then there could potentially be a data element included in the EHR to capture that.

I think we talked about it, and there were several other questions that came up. I mean is it enough if there's documentation that the school completed the screening? Should there be evidence of what the screening entailed, what the scores were, and how those scores were interpreted and so on? So I think because of

those questions, we decided to keep it simple, at least for this level of the measure. But I think there's opportunity to expand.

MEMBER MADONNA: Excuse me. Can the referral come from the school directly?

MS. AMBROSE: Yes. I mean I think that's another possibility that we thought about. There could be a school clinic, for instance, that's screening kids and making that referral directly to an eye practitioner.

MEMBER MADONNA: How would that be captured then?

MS. AMBROSE: That would have to be captured through information that's provided from the school to a primary care physician and recorded as such.

MR. ROMAN: It sort of -- for the purpose of this e-Measure, it really does depend on where it's implemented. So if it's implemented in the CMS/EHR Meaningful Use Program, the school is not an eligible professional who can be included. So there's --

that's not a source of data for the program.

The source of data are eligible professionals, which include medical doctors, I think ophthalmologists and optometrists. So those would really be the only providers who could be a source of data for that program. If this were implemented in a Medicaid/CHIP program, I think that would be something that we would have to consider, of how we would expand it, and it's also something we'd have to look at in testing.

So like Melanie said, I think it's something that in the future of this measure we could look at. For the purposes of it, how it's specified right now, it is not something that the measure can handle, school referrals.

MEMBER MADONNA: I'm just a little concerned, because there's the school system and then this measure, that kids are going to fall through the cracks, and it's going to look like they got properly screened when they didn't have it at either place. So I'm just posing that

concern.

MEMBER BRADHAM: Since most kids don't start school until they're five, and this measure is from three to five, we're talking about pre-schoolers or we're talking about kids in daycare settings. So I don't think that that is much of an issue.

MEMBER MADONNA: But detecting amblyopia earlier has much better outcomes. So they should be getting screened in preschool.

MEMBER BRADHAM: It depends on like if a parent has them in a private daycare setting, they may not be doing screenings. So it would be back to the pediatrician to do it. Plus with the poor sensitivity and specificity outlined in the U.S. Preventative Service Task Force recommendation, I can still see the pediatricians repeating the screenings.

MEMBER STEIN: I just think the key to this whole thing, for it to be successful, is the coordination of care, and if there's not good coordination among the pediatrician, the school,

the patient and their parents, and the eye care providers, then it's not going to be successful.

And I'm not sure whether this is going to get us there. I mean certainly the idea that pediatricians are checking vision is a good thing. I just am a little concerned about unintended consequences and people coding things and it making it look like a kid really got adequate attention. That kind of gets to Richard's point a little bit.

MEMBER STRODE: As a family doctor, I just feel obliged to remind the group that in addition to pediatricians, that family doctors and physician assistants and advanced practice nurses care for kids. I understand this is a pilot EHR, but I think these issues make it all the more germane, since it's a pilot, a pilot's measure that we're discussing here.

I understand what you all contracted to do, but working for CMS, I would hope that you might take the message back to CMS, that here we're looking at the future of checking the

electronic health record of the optometrist, the ophthalmologist, the pediatricians, the family docs and the midlevel surveyor, with people who not only may be getting screened in schools, but it may just be a community effort that isn't involved with the school district at all.

And each state has their own rules. But who has more influence over this mess than CMS? But I hope that they might be able to carry the message back, that we see this as messy but real, and the more than CMS can influence all of those entities, schools, I mean the Medicaid rules for each of 50 states and encouraging the schools and community screenings and whoever's doing the screenings, Lions Club, to feed that into the providers.

The problem with the providers is that I could see when it does move from is there the measure built into your EHR to document that there has been a screening, there has been a referral, if proper, to being paid on the basis of that, then I would expect that most of us as

primary care physicians would turn out with horrible scores, because people are being screened elsewhere and we're not getting the information about it.

MR. ROMAN: Yeah. I think a recommendation for future testing for the measure would be how we'd incorporate information from the school, or evidence, and this is a suggestion we had from our original expert who helped us develop it, is just how you incorporate that the patient might already be seeing an eye care professional.

We did look at that in the limited testing we had, and there was -- that data is not in the EHR. But that the child might be already under the care of another eye care professional. So we're limited and we didn't include that. But I think that with additional testing, those two things would be something that we would look at.

CO-CHAIR MERENSTEIN: So I don't know if really you want to add anything, but all these points are usability still, I think. I mean

they're all really important points, but I don't know if we've talked about specificity yet, the specifications. I guess we did at the very beginning, so if people want to vote on it. Seeing no other questions, we'll vote on it now.

MS. ROBINSON-ECTOR: So voting for measure specifications for trial use e-Measure 2721 is now open. For those on the phone, Option 1 is high, 2 is moderate, 3 is low and 4 is insufficient.

All the votes are in. 7 percent voted high, 47 percent voted moderate, 27 percent voted low and 20 percent voted insufficient. So this would fall in the gray.

DR. WINKLER: So I think there's a lot of concerns about the way the measure is specified. You've heard the conversation. So I think we would certainly be willing to entertain, you know, revisions in the future that might can deal with some of these issues. But that's sort of the purpose for this kind of preliminary review, is to get this sort of feedback for you.

But Todd.

MEMBER RAMBASEK: I'm just hoping someone can explain to me, and as Dan pointed out, there seemed to be some conflation between the usability discussion and maybe the evidence discussion. But why does the U.S. Preventative Services Task Force say vision screening for children is level of evidence B? But we're voting that the specifications are not consistent with the evidence. I'm -- perhaps I'm missing it.

DR. WINKLER: A question.

CO-CHAIR MERENSTEIN: Sounds like the ophthalmologists in the room did not agree with the task force, because the task force didn't say visual acuity. They said amblyopia screening, and it sounds like your discussion on the call was that you disagree with that, right?

MEMBER RAMBASEK: But we just said that you can't do amblyopia screening, because you can't do it. A pediatrician can't do that.

MEMBER FRIEDMAN: So we all agree

that screening for -- treating amblyopia is beneficial. Amblyopia is a rare condition and it certainly is treatable, and you can save a lifetime's worth of vision. And so in order to diagnose the amblyopia, you need to detect it. You need to screen for vision.

So is screening for vision ultimately going to potentially save vision from amblyopia? The answer is yes. So in my perspective, I think the measure is getting better, but it still needs to be tweaked a little bit. So you're heading in the right direction. Keep it up. Eventually I think we'll find something that's palatable.

And one other thing. So we talked about coordination of care. The question is whether the sensitivity specificity of screening in schools and whether screening extra twice as much is going to be deleterious, and maybe it's better. Maybe the sensitivity will go up if there's more screening done. Presumably from a statistical viewpoint, that could be beneficial. But I mean I think we all agree that screening

for vision loss, amblyopia and rarely other even bad diseases is going to be helpful. The question is how do we do it?

CO-CHAIR MERENSTEIN: I think the question is where do we do it too though. I mean with the dental exam, the primary care doctor is not doing that. So I think as Rich said, maybe it should be -- the recommendation should be that they see an eye doctor before they're five years old.

DR. WINKLER: I would just like to circle back to Todd's comment was, you know, the question is are the specifications that they presented to us consistent with the evidence that was discussed, and just be sure that that vote represents a response to that question. If you'd like to rethink it, we could certainly redo.

MEMBER STEIN: Well, we're not voting on reliability and validity and things like that. So I think a bunch of these issues and nuances and how it's actually are going to happen, at least for me. I'm using this as my means of

conveying my opinions about that.

DR. WINKLER: So do you feel like maybe we want to, you know, revisit, focus -- yes. I mean Todd was obviously right. The question is are the specifications consistent with the evidence you discussed?

MEMBER SCHACHAT: Does this vote, if it stays this way, stop it? Well, I don't think it should be stopped, because it's a good thing. I just think that what -- the details aren't there yet, to know that it's going to work right. But if pilot things don't have to work right, then I'm happy to change my vote. I just think what we have right now isn't going to work, but they should go ahead and do something.

DR. WINKLER: Well, I mean that's essentially -- you know, what we're trying to do is evaluate whether the measure is measuring something important, that basically is evidence-based in the way it's constructed, and certainly we expect them to learn more when they do the formal testing for reliability and validity in

terms of the results.

MEMBER STEIN: So I think it's great that we're doing this pilot thing and giving you guys feedback, and I agree with Andy, that if this is going to stop discussing rest of it, so you don't get more feedback, it kind of defeats the purpose. So if we have to vote a certain way just to be able to get through more questions. See, it seems like a Catch-22, right?

DR. WINKLER: Yes.

MEMBER STEIN: Like why not give them feedback on usability, because it's a pilot thing, just because of how we voted on this?

DR. WINKLER: Right. Well, it's a little bit more than just providing feedback, because you're ultimately going to determine where NQF should approve it for trial use. You will be making a recommendation. So these are the things that are feeding into it, and these are your evaluation of it. So again, that's why I think Todd's question is spot on, and does your vote represent your sense of whether the

specifications are consistent with the evidence.

MEMBER SCHACHAT: So how quickly can they -- if we say we don't like this, but show us something else, how quickly can that process go and let them do something, and I don't know if they have funding to do that.

MR. ROMAN: It depends on the request.

MEMBER SCHACHAT: Right. You know, is there a way to have this -- something further by the next, or that conference call two months from now?

MR. ROMAN: It would really depend on what the request is. I mean if it's changing some wording or adding coding, or you know, just changes to the spec itself I think are possible. But adding in stuff that would require testing, that probably is out of the scope of what we'd be able to do.

MEMBER SCHACHAT: It's just that for me the biggest -- I think measuring vision by pediatricians is probably a good thing, and so I'm happy to approve that. For me, I'm more

focused on what Josh was talking about, and that is what about all the stuff that's going on in schools, and how is that brought in here, and is there a way to put it all together.

Do we want one screening system going and just let the schools do it, or do we want two, or is this -- it is clear that -- well maybe you can just tell us. I don't know how many states have rules, and of those, how many require anything in the preschool age, and support this here, this is in the preschool age. Then the evidence I'd like to know is is it more important to do it in the preschool age, in which case maybe states should all change their laws and not do it in schools? I mean I can go on and on, and I apologize.

MR. ROMAN: With regard to states, I mean, not all the states have a policy about it. There are a handful that have no policy at all. Most do have some policy. Again, they vary on whether or not they're actually a policy or a guideline.

Not all of them recommend it in preschool age. Some are like second grade and ninth grade. Others are pre-K and earlier, so as soon as they're in school or as soon as they're in any type of preschool-type activity. But it's not uniform, unfortunately, and that's why this measure is focused on the preschool age, because that is what the recommendation is, is that doing it at that age is really kind of the sweet spot to find the issues early, before they get more developed, because by the time they're in school, it's getting dangerous or problematic.

CO-CHAIR MERENSTEIN: Josh, then Todd, and then maybe we consider re-voting this.

MEMBER STEIN: I was just going to say that I'm willing to reconsider my position until we can give them more feedback.

MEMBER RAMBASEK: It sounds like the major concern is coordination between the state screening programs and what the pediatricians are doing. But I think I heard in the discussion it said that the pediatrician should just be able to

check a box that says "school screening was done."

So, and then the only hurdle they have to jump through to get this measure positive would be to make the referral. I don't see why the pediatrician can't just -- or the family practitioner or nurse practitioner or primary provider -- can't just say "mom, dad, bring me in the school result," or just call the principal and say, "fax all 500 over," and just do referrals that are appropriate, and then that would be even easier for them.

Then they'd have 500, a stack of 500 tests sitting on their desk, and they could just look at the abnormal ones and have the nurse contact them. I'm not sure that's a big -- it doesn't seem like a big deal.

CO-CHAIR MERENSTEIN: Any comments? Do you want us to re-vote?

MR. ROMAN: I agree. I don't think it's a big deal. I think, really, more though it's how you -- what you're going to incorporate

into the spec, because I think just seeing that it was done from the provider perspective isn't really sufficient for a measure.

You want to see that it was done and what are the results. So you need to have some -- I think the way we have to work it in is that the physician at least acknowledge that the results are normal or they're abnormal or there are referrals needed. Just seeing that a screening is done is kind of a low bar measure.

So that's the only thing. I think, in implementing it and putting it in the spec, we'd have to figure out how we would incorporate that the physician has to acknowledge what the result was. Because just seeing that it was done, it wouldn't really be sufficient.

MEMBER PATEL: This is Vaishali on the phone. I probably should have asked this earlier. Can somebody clarify are the current school screenings just for amblyopia, or do they screen for all kinds of vision problems? And who is the screening done by?

MR. ROMAN: As we stated, you can't screen for amblyopia. You can screen for decreased vision. And then, again, the most common cause of decreased vision is going to be refractive error, myopia more commonly, and hyperopia secondarily. So you can't screen for amblyopia. And then who does the screening, I can't speak for that.

MEMBER PATEL: Is it eye care professionals or is it primary care providers or is it some other professional?

MEMBER MADONNA: It could be just about anybody, including mom, who's the head of the PTA. It could be just about anybody screening, providing the vision screening at a school.

MEMBER PATEL: Okay. Thank you. Thank you for the clarification.

MR. ROMAN: The requirements by the states vary. You're exactly right. It really varies by state.

MEMBER PATEL: Okay. Thank you for

the clarification. And also as a -- not so much as an eye care professional, because I'm not one, but as a mom, I would say I like the idea of, you know, proper vision screening, either in a primary care professional office or in an eye care professional office.

CO-CHAIR MERENSTEIN: I think we should re-vote this to give us more feedback.

MS. ROBINSON-ECTOR: Okay. So voting is now open for performance step with the trial use e-Measure 2721 for measure specifications. And for those on the call, Option 1 is high, 2 is moderate, 3 is low and 4 is insufficient.

All the votes are in. Thirteen percent voted high, 67 percent voted moderate, 13 percent voted low, and 7 percent voted insufficient. So, for measure specifications for the trial use e-Measure 2721, the measure passes.

CO-CHAIR MERENSTEIN: We're going to go to feasibility. Andrew, is there anything to add about feasibility? Turn on your mic.

MEMBER SCHACHAT: We've been told that

some preliminary evaluations have been done. Obviously, it's feasible to score if pediatricians do something. Is there a code created for it that says I did it?

MR. ROMAN: Yes.

MEMBER SCHACHAT: Yeah. And there could be a code -- there's a code saying that I referred also?

MR. ROMAN: Yes, there's a way that referrals are represented in the EHR.

MEMBER SCHACHAT: So it's quite feasible.

CO-CHAIR MERENSTEIN: Anything to add?

MEMBER FRIEDMAN: No. Just given the caveats that we're previously described about duplication of screening, I think it's very feasible.

CO-CHAIR MERENSTEIN: Any comments? Josh.

MEMBER STEIN: One more piece of feedback, since this is going to be an e-measure. You should be able to capture that a referral was

made, assuming the referring doc is in the system. That's why I think this would be a better plan measure. But for docs, you know, where if a pediatrician has a working relationship with an ophthalmologist and sends a patient, there's some way of capturing that in the electronic health record.

Then that would be, to me, more powerful than just saying "I referred a patient," to see that the referral was made, or that an action was done.

MR. ROMAN: So, the way that you measure specification works, that particular data element is looking to see that a referral was made. I think that the way it gets implemented, it varies per EHR. But that is the intent of that data element in this measure, is that, if there's a problem found, that the child is referred.

It's not just saying that a referral is needed. It's saying a referral was made. The part that we were not able to incorporate is that

any follow-up from the eye care specialist happened, in this version of the measure.

MEMBER FRIEDMAN: Again, it gets into semantics. So, a referral is necessary. So, you could say that. A referral is made, you schedule the patient. You don't know if the patient actually showed up. And then the patient showed up, was a referral necessary, was there feedback, was there something done? You know, there's all these other issues that go on.

CO-CHAIR MERENSTEIN: Let's vote on feasibility.

MS. ROBINSON-ECTOR: Voting for feasibility for trial use e-Measure 2721 is now open. And for those on the call, Option 1 is high, 2 is moderate, 3 is low and 4 is insufficient.

Okay. All the votes are in. Twenty percent voted high, 67 percent voted moderate, 7 percent voted low and 7 percent voted insufficient. So, for feasibility for the trial use e-Measure 2721, the measure passes.

CO-CHAIR MERENSTEIN: Okay, usability. We've been talking about that. Steve?

MEMBER STRODE: Do you know how CMS plans to use this? If it's put into the meaningful use basket, and it does turn out that the pediatricians, family docs, and others have really low scores, reflecting, as we would suspect, poor coordination of care in this sphere, then that would be valuable information that the pilot would show.

On the other hand, if it's going to be implemented and then it's going to tie in to reimbursement for those providers, in the face of what we suspect is really poor coordination of care, then that bothers me. Do you know what the intent is when this rolled out?

MS. AMBROSE: Our understanding is that the measure is planned to be implemented as part Medicaid CHIP programs, state programs also. Again, I don't know what the applicability would be in the EHR incentive program because of the age range. But I think the intent was really to

encourage kids in Medicaid CHIP populations to get screened, because there was a gap in screening for those children.

MEMBER STRODE: And recognizing that SCHIP can vary from state to state, but is your impression that a check saying, "screening was done by me," or momma said screening was done somewhere, would be sufficient for payment?

DR. WINKLER: Steve, let me just jump in. Remember that this is simply an approval for trial use. And NQF's approval specifically says this measure is not yet ready for accountability purposes. So it's to learn to use it, find out what it can do. It needs to come back with all of that information for consideration for a full endorsement. So that's part of the fact that it's trial use, and that's an element of it.

CO-CHAIR MERENSTEIN: Josh.

MEMBER STEIN: I just want to follow up on Steve's point. I actually see this potentially as an excellent opportunity, because you've got 50 states that are doing things in

very different ways, and we know that a lot of kids are falling through the cracks and not getting screened, by either a Lions Club or the school or the pediatrician or someone and they show up at age seven with amblyopia that was undetected, and there's nothing we can do about it at that point.

So the challenge for you guys is, how you can you get all the states on board to do this the right way, where you don't have 50 different ways of doing it, but one way that CMS endorses that will convince the states to buy into to do it the right way?

MEMBER MADONNA: So, earlier today we talked about diabetics, who are a vulnerable population, and we talked about measures to improve the care of diabetics.

Now we're talking about a vulnerable population, kids, and yet we didn't talk about screening diabetics. We're examining diabetics. Why aren't we examining kids? Why are we just screening them and having all of these different

types of screeners? As Josh just said, this could bring -- this could kind of pull it together.

If the screening's done by a thousand different types of people, many of whom have really no clue what they're doing, and then they've got to send that information to the pediatrician, who may or may not go through the forms that they're given, that may or may not check off a box, and then the pediatrician must then take the next step and send for an eye examination.

It just seems to me, again, I'll go back to what I said before, that it would be a lot simpler to promote eye examinations. And my fear is that having a screening in place may reduce the number of children who are adequately examined.

MEMBER SCHACHAT: So I think the reason is that we don't have the data yet that doing exams on all kids has reasonable sensitivity and specificity and cost

effectiveness. If the vision's normal, if we knew the vision's normal, the other things we're looking for are not common enough that it makes doing an exam on everybody --

MEMBER MADONNA: And we may or may not know that.

MEMBER SCHACHAT: As long as these visions are reliable visions. I think there's evidence in favor of measuring vision but maybe not do a whole exam. Anyway, it's a different issue, because it's not part of this measure.

MEMBER PATEL: So, this is Vaishali on the phone again. So, you know, I completely agree with actually doing this, again, as a mother, doing it in the eye care professional's office. And if we don't have the data to say, you know, how many kids are going to actually get diagnosed if we have the requirement of directly sending all kids between the age of three to five to eye care professional's office.

So if you screen 100 kids, how many -- or a thousand kids -- how many are you going to

identify with vision problems, how many are you going to identify with amblyopia screening? We can do that testing.

I mean, it costs time and money, but it can be done. And I would recommend it, as opposed to doing that same screening of, you know, another thousand kids in the primary care provider's office and, you know, then referring patients and seeing how many actually make it to an eye care professional office and get identified with some kind of problem.

You know, you can do that, too. So, that can be done, and I would encourage doing that as part of the testing. But my gut feeling tells me that without doing that kind of screening, that if you send kids directly to an eye care professional's office, you are more likely to have more people go and get screened and get, you know, diagnosed, even without doing the testing.

CO-CHAIR MERENSTEIN: Todd.

MEMBER RAMBASEK: I just want to make

a cultural point that we, as a society, spend about twice as much per capita on health care as patients, people in Japan, and they live longer than we do. And it reflects a cultural problem with how we value and allot health care dollars.

And if somebody who's published 200 articles has said there's not data to say that that's cost effective, then we probably shouldn't recommend it.

MEMBER PATEL: So, again, as a health services researcher, I completely see your point. But we are talking about vision problems in kids. So, yeah, I see the point that, yes, we should do the testing before we make decisions, and I'm all in favor of doing that. So, then if we're considering two different options, there should be testing done.

CO-CHAIR MERENSTEIN: So I think they're taking notes of this, but that's not really what's at the table right now. I mean, at the table is vision screening in the primary care office and the usability of that.

Comments before we vote? I think we've had a lot of comments, but, okay, one more comment.

MEMBER RAMBASEK: Just a quick question. So, is the pediatrician allowed to check off what the school did according to this measure?

MR. ROMAN: It's not in the spec right now, no.

MEMBER RAMBASEK: It's not specified or they're not allowed to?

MR. ROMAN: It's not specified, and as far as whether or not they're allowed to, that's a question that we would have to look at through more research and probably with discussions with some of CMS and others, because, you know, for the purposes of the measure that we are talking about, it's what a provider did or an eligible professional did in their office.

Whether or not they can say that they passed the measure because the school did something, I'm not sure and I can't answer that

question. Right now, the measure does not include it.

MS. AMBROSE: Yeah, it becomes a question of attribution to that particular provider, I think. But if there's an opportunity to expand the measure, I think, from a specification perspective, it would be doable to add a data element to capture that.

CO-CHAIR MERENSTEIN: So, that's a recommendation, but the vote is not -- that's not a possibility for the vote. So let's --

MEMBER LYNCH: This is Judith. I need a clarification. Are we voting on screening for vision testing or screening for amblyopia?

CO-CHAIR MERENSTEIN: Vision testing.

MEMBER LYNCH: Okay, thank you.

MS. ROBINSON-ECTOR: Voting is now open for usability and use for the trial use e-Measure 2721. And for those on the phone, option 1 is high, 2 is moderate, 3 is low and 4 is insufficient information.

MS. GORHAM: We're just waiting on

Judith.

MS. ROBINSON-ECTOR: Okay. All the votes are in. Thirteen percent voted high, 40 percent voted moderate, 27 percent voted low, and 20 percent voted insufficient information. So this would fall in the gray zone, but it's not a must pass.

CO-CHAIR MERENSTEIN: So we're voting on use? I mean, recommendation for endorsement.

(Pause.)

MS. ROBINSON-ECTOR: Voting for overall suitability for approval for trial use for e-Measure 2721 is now open. And for those on the call, option one is yes and option two is no.

All the votes are in. Sixty-seven percent voted yes and 33 percent voted no. So, for recommendation for trial use for e-Measure 2721, the measure passes.

MR. ROMAN: Thank you.

DR. WINKLER: We're going to switch gears and bring out our last set of measure developers. And we're going to talk about

hearing screening.

(Pause.)

CO-CHAIR MERENSTEIN: Kathy was supposed to do all the ophthalmology, but I agreed to switch for that last one. I don't know why. It looked like it was going to be easy.

So we're going to do Hearing Screening Prior to Hospital Discharge. If you can just introduce yourselves and give us some background.

MR. EICHWALD: I'm John Eichwald. I'm with the Center for Disease Control's National Center on Birth Defects and Developmental Disabilities.

MR. GAFFNEY: Hello. My name's Marcus Gaffney. I'm also with the CDC National Center on Birth Defects and Developmental Disabilities.

CO-CHAIR MERENSTEIN: Do you want to introduce the measure, or all the measures? Either way. You can just do the first one or all of them.

MR. GAFFNEY: Okay. I believe we have three measures that are going to be discussed

today. The first is 1354, Hearing Screening Prior to Hospital Discharge. And then I believe after lunch we're also going to be discussing Measure Number 1360, Audiological Evaluation No Later Than Three Months of Age, and Measure Number 1361, Intervention No Later Than Six Months of Age.

DR. WINKLER: If they're happy with that, that's fine.

CO-CHAIR MERENSTEIN: All right. We'll go on. So we're going to go to evidence. It's myself and Tammy. The evidence, I think, is pretty straightforward. There's three randomized controlled trials, one observational trial, a few recommendations from NIH panels and AAP panels, and then the United States Preventative Services Task Force Grade B evidence is the evidence behind screening. Do you have anything to add about that, Tammy?

MEMBER BRADHAM: Just one comment about the U.S. Preventative Task Force is that they did inactivate this particular measure for

hearing screening because there had been no new evidence published since the last time they had done their statement. And so that was done in 2008.

CO-CHAIR MERENSTEIN: Any questions or comments about that? So we'll vote on the evidence.

MS. ROBINSON-ECTOR: Okay. So voting for evidence for Measure 1354 is now open. And for those on the call, option one is high, two is moderate, three is low and four is insufficient evidence.

All the votes are in. Sixty percent voted high, 33 percent voted moderate, 7 percent voted low, and zero voted insufficient evidence. So for Measure 1354, the measure passes on evidence.

CO-CHAIR MERENSTEIN: Opportunities for improvement. So, on this one, there's not really that much. The CDC says that 97 percent of newborns in the United States were screened, and of those that were screened, 1.8 percent did

not pass the final or more recent hearing.

There is some disparities. The only people that aren't screened are the births that are occurring in small and rural facilities or outside the hospital. So, we talked a lot about this yesterday. My bias is that there's not much room for improvement, but they've done such a good job that I'm not interested in voting against it. But that's obviously open for debate. Tammy.

MEMBER BRADHAM: We are at a ceiling effect with this particular measure because it's hearing screening within one month. Something to consider would be maybe hearing screening prior to hospital discharge. That may add some opportunities there to look at.

But we are running into issues, as mentioned in here, regarding disparities, where we have families that live in border states, so they may be born in another state, and so that information doesn't cross over to the state that they reside in. Or the other opportunity here is

to capture babies that are born through midwives.

CO-CHAIR MERENSTEIN: So, just to clarify, I think this is just before discharge. So it is before discharge. Because the only exclusion for this one is death in the hospital. So I don't know if there's -- yeah, questions about it?

MEMBER RAMBASEK: Well, this is going to come up in same discussion as yesterday, which is do you need to keep a rule in place or will there be slideback?

CO-CHAIR MERENSTEIN: And again, I'm open to listen to others. Just my view is that it's a little different than yesterday, in the sense that the physicians themselves have stopped using steroids. This is, I think, sort of the hospitals have changed in practice, and I think they changed because this has been looked at.

But you're right. There's not much room for improvement. The question is if they stop checking it, will there be slideback?

MEMBER STEWART: Yeah, I would say

this one is different, because this is now -- in most states it's a regulation. It's actually gone around the world now. And quite frankly this is in many ways an unfunded mandate, that this must be done, but there's no resources to do it.

So if you don't measure it, then hospitals are going to find ways to not do it, or they're going to find ways to, you know, ensure that the patient has the availability for follow up, but they're not going to actually do the screening.

So I think that this is one where if you don't measure this, it will definitely fall off. It will be a problem.

MEMBER YOUDE: I agree with Mickey.

MEMBER LYNCH: This is Judith. I agree as well.

CO-CHAIR MERENSTEIN: Any other thoughts about this one?

MEMBER FRIEDMAN: Okay. For all of us lame ophthalmologists, what are the current

guidelines for screening right now? What are the requirements?

MEMBER BRADHAM: So, the screening in the hospital, they either have to have an otoacoustic emission or an automated ABR, which are tests that are routinely done either by the nurses, or they maybe have an audiologist that does it, or they may have volunteers that do it. But they have to be signed off by the physician.

So they are regulated. They have to be trained to be able to do this procedure. There is good sensitivity and specificity for these measures. We do run into some risk of, if the hospital does otoacoustic emission, that we may miss auditory neuropathy spectrum disorder children.

MEMBER FRIEDMAN: Okay. So, basically, screening is required right now. Why are we -- what will this measure do to enhance that? If the measure doesn't get passed, screening is still required. Is that correct?

MEMBER BRADHAM: At this current time,

it is still required, but families can opt out to not have it done, and we're starting to see a slight trend with this pattern because of the cost. And so they may have to -- because the programs that are coming into the hospital to provide the screenings, they may be out of network for the family, and so then they get passed the charge or they can just elect not to have it done.

CO-CHAIR MERENSTEIN: But if you have a quality measure, they can still opt out of it, presumably. I think John has to answer that.

MR. EICHWALD: One of the issues is this is state regulation, and there's only 44 states that actually passed legislation. So we've got six states and some territories that have no legislation in place.

Also that legislation varies considerably by jurisdiction. Some only recommend. Some of them basically say, "We'll only keep screening if you maintain such and such level." So there's no real one standard of

regulatory, of having it done.

MEMBER FRIEDMAN: So, again, this dovetails to the discussion that we had on the last measure. There's some state input. The states are variable. The question is, do you attack that by creating a quality measure, or do you have legislation done at the federal level, or do you go to these individual states and say, "We need to have a uniform state requirement"? And then all 50 states have requirements and they're all the same, and then you're done.

MR. ROMAN: There is no federal regulation. So this is just state-based.

CO-CHAIR MERENSTEIN: Todd.

MEMBER RAMBASEK: Forty-four states have laws saying you have to do this. So, 12 percent of states have laws that you don't. So there's only three percent are not getting screened. So apparently, even in the states where there's no law, there's still a lot of this happening?

MR. EICHWALD: Yeah, the screening

still continues even without state regulation.

CO-CHAIR MERENSTEIN: Tammy.

MEMBER BRADHAM: So, all states have an EHDI program, or Early Hearing Detection and Intervention program. And so there is somebody hired at the state level that coordinates these efforts, and they collect, maybe by fax, maybe by email, maybe by whatever mechanism, information from the hospitals as well, as we'll learn later, audiologists and early intervention providers.

They collect that information and then they send it on to CDC for reporting. This information's really important, though, for the reauthorization for the fundings that the states get for the reauthorization for these programs.

CO-CHAIR MERENSTEIN: Josh.

MEMBER STEIN: I think one of the fundamental differences between this and the last one, though, is here most patients are getting it appropriately, and we're up in the 90s and we want to maintain that.

With the vision screening, it's not

clear how -- it's certainly not up in the 90s, and one needs to develop a system to try to get good vision screening. So I think that they're different, even though the states are supposedly involved.

CO-CHAIR MERENSTEIN: Any other comments or questions about this? Yeah, sorry. Todd.

MEMBER RAMBASEK: Yeah. If we did pull back, what's the -- we just watch it and then reinitiate it when it falls below -- you know? How does that -- how would that process work should anybody move in that direction?

MR. EICHWALD: Well, we would still -- we would probably still collect the data. Endorsement by NQF obviously creates a quality measure here that people respect and basically would continue to follow.

So, I mean, endorsement, I think, is what really helped this, and it also helped this get accepted by CMS as one of the meaningful use measure. So we look forward to maintaining NQF

endorsement.

DR. WINKLER: This is actually an e-measure, and I think that the registry version of the measure is a reflection of the EDHI program. The e-measure is at a facility level. We don't have a lot of hospital level data. Some states were able to provide it, but in general, it's collected within the state. And so there's this aggregate population level, less so the actual provider level, that looks that perhaps the e-measure version may provide an opportunity to see, to get more granular down at the hospital level, where we may begin to see differences, particularly regionally or wherever those hospitals might be.

CO-CHAIR MERENSTEIN: Rich.

MEMBER MADONNA: Just a quick question. Help me answer that question that's up there right now. I know the measure is -- we have a ceiling effect right now. But are there disparities right now? Is it just the state by state disparity or rural/urban disparity? Okay.

MEMBER BRADHAM: There are disparities because of -- depending on -- not all children get born in a hospital, so trying to capture the midwives births, the rural settings, the border pregnancies. So there are some opportunities there.

MEMBER STEIN: Will this address the kids born outside the hospital?

MEMBER BRADHAM: This measure is for hearing screenings within one month. So it doesn't --

CO-CHAIR MERENSTEIN: This is before discharge. So it will not address the ones born outside the hospital.

MR. EICHWALD: Yeah, the measure is screening before hospital discharge. There are hospitals that do go below a percentage, often -- I'll bring as an example military hospitals. When you have a change in command, oftentimes hospitals will not start reporting that data back to us. Once again, it's nice to have that national standard that we can look at and make

sure that every hospital within a jurisdiction is is meeting the national standards.

CO-CHAIR MERENSTEIN: So I think we should vote. I mean, I think people -- the points are clear.

MS. ROBINSON-ECTOR: Voting is now open for the performance gap for Measure 1354. And for those in the call, option one is high, two is moderate, three is low and four is insufficient.

All the votes are in. Seven percent voted high, 60 percent voted moderate, 27 percent voted low, and 7 percent voted insufficient. So, for performance gap for Measure 1354, the measure passes.

CO-CHAIR MERENSTEIN: So, reliability. So, it's pretty straightforward. It's all live births during the measurement period that are screened for hearing loss. The numerator/denominator is all live births that are discharged from the hospital. I don't think there's any coding issues.

The way it's reported is by states. So the states report it to -- the hospitals report it to the state and then you collect it from the states. And again, the only exclusion is neonatal death. I don't know if Tammy has anything to add about that.

MEMBER BRADHAM: I would just encourage looking at are there feasibility studies and looking at claim-based data, kind of starting to look in that direction.

DR. WINKLER: Just to reiterate, we have two versions of the measure. We're talking now about the registry measure that's part of the EDHI program. Again, tends to be focused more at a higher population level. We will talk about the e-measure next.

CO-CHAIR MERENSTEIN: Comments or questions about the reliability? I guess we'll vote on that.

MS. ROBINSON-ECTOR: Voting is now open for reliability for the registry version of Measure 1354. And for those on the call, option

one is high, two is moderate, three is low and four is insufficient.

All the votes are in. Sixty percent voted high, 40 percent voted moderate, zero voted low and zero voted insufficient. So for reliability for the registry version of Measure 1354, the measure passes.

CO-CHAIR MERENSTEIN: So, for validity, you're not going to be surprised because we talked about it. There's room for improvement and they did two state checks. On Vermont they checked, and they found 3.3 percent errors in the charts when they did the medical record check. In Tennessee, 0.2 percent. In New Jersey, the lowest hospital score is 96 percent, the highest, and 33 hospitals actually reported 100 percent compliance with hearing, and there's no risk adjustments. Do you have anything to add?

MEMBER BRADHAM: And just to point out, New Jersey the -- yeah, New Jersey -- was it New Jersey is the state that does not have

mandated -- or it was Vermont that does not have mandated newborn hearing screening, and they still had a really good reporting.

CO-CHAIR MERENSTEIN: Questions about that? Then we'll vote on that.

MS. ROBINSON-ECTOR: Voting is now open for validity for the registry version of Measure 1354. And for those on the call, option one is high, two is moderate, three is low and four is insufficient.

All the votes are in. Eighty-seven percent voted high, thirteen percent voted moderate, zero voted low and zero voted insufficient. So for validity for the registry version of Measure 1354, the measure passes.

CO-CHAIR MERENSTEIN: So, feasibility. I might need some help from the developers, because is one part that's a little confusing. It sounds like the states fax them the answers. And we're not talking e-measures, so that was a little strange to me. And we haven't talked about the e-measure, and maybe that will correct

some of the problems. But is that how it's actually done?

MR. GAFFNEY: Are you meaning reporting from hospitals to the state, or the state to us?

CO-CHAIR MERENSTEIN: Yeah, yeah, no.

MR. GAFFNEY: From hospitals to the state? There's various ways. A lot of reporting is done electronically now, either through web-based systems or a weekly, maybe even a monthly upload directly to the state, depending on how that data system's set up.

We do see in some of the smaller facilities, there may be faxing of the results, or maybe even mailing. There is predominantly more reported in an electronic format. To us, we have a web-based survey we conduct once a year. So the states report using that web-based survey.

CO-CHAIR MERENSTEIN: Anything to add? Yeah, Josh.

MEMBER STEIN: This came up with the last measure. Do you guys plan on looking at --

not necessarily with this measure, but are you planning on looking at the kids who fail the screening, getting seen by the ENT doc? Is that --

MEMBER BRADHAM: That's the next measure. There's another measure.

CO-CHAIR MERENSTEIN: The next two measures.

MEMBER STEIN: Okay.

CO-CHAIR MERENSTEIN: Any other questions? So we'll vote on this.

MS. ROBINSON-ECTOR: Voting is now open for feasibility for the registry version of Measure 1354. And for those on the call, option one is high, two is moderate, three is low and four is insufficient.

All the votes are in. Eighty percent voted high, 20 percent voted moderate, zero voted low and zero voted insufficient. So for feasibility for the registry version of Measure 1354, the measure passes.

CO-CHAIR MERENSTEIN: Then usability.

Not that much. I can't think of many unintended consequences for this test. It's pretty easily used and it's tied to meaningful use. So that's probably why you see the rates so high. And it's publicly available, right? Yeah, it's publicly available. Tammy.

MEMBER BRADHAM: Agree.

CO-CHAIR MERENSTEIN: Any comments? I guess we'll vote on it.

MS. ROBINSON-ECTOR: Voting is now open for usability and use for the registry version of Measure 1354. And for those on the call, option one is high, two is moderate, three is low and four is insufficient information.

Great. All the votes are in. Ninety-three percent voted high, 7 percent voted moderate, zero voted low and zero voted insufficient information. So for usability and use for the registry version of Measure 1354, the measure passes.

CO-CHAIR MERENSTEIN: Any further comments before we vote? We'll vote.

MS. ROBINSON-ECTOR: Voting for a recommendation for overall suitability for endorsement for the registry version of Measure 1354. And for those on the call, option one is yes and option two is no.

All the votes are in. Ninety-three percent voted yes and 7 percent voted no. So for a recommendation for overall suitability for endorsement for the registry version of Measure 1354, the measure passes.

CO-CHAIR MERENSTEIN: Let's see. So, do you want do the e-measures, Reva?

DR. WINKLER: Yeah. This measure also has an e-measure version that has just been included in meaningful use for hospitals for next year, I think it is? Yes. And this measure hasn't been formally tested. So we have the same issue we have with the ones we talked about yesterday, with the eye care measures. And the developers have agreed to do the simulated data set testing and provide the results back to us in our call in August.

So that would be the condition by which you could approve or pass the criterion for this measure. Does anybody have any questions about specifications for the e-measure? Or, John, did you want to talk about anything about the e-measure? I know you've been working on it for a while.

MR. EICHWALD: Yeah, we've been developing this for several years. Actually, this measure was started out -- our original intent was this to be an e-measure and it's just taken us a while to get there. Once NQF endorsed it, CMS did pick it up. It was actually CMS' -- we're now on Version 4 of it. It's been a little bit of a moving target.

We've also tried to harmonize it with the other newborn e-measures, and so our denominator is essentially the same in that. And that would be the three measures NQF -- let me get my glasses on -- about breast feeding, NQF Measure 488, which is -- the measure steward is the Joint Commission. There's another measure on

newborn hearing screening, which is 1354, the one you're reviewing now. And then healthy newborns, NQF 716, which CMS is the measure steward.

So whenever there's been any kind of discussion of changing what the data measure is, we're trying to make sure that we're harmonizing this so, again, reducing the burden on hospitals to report this kind of measure.

DR. WINKLER: Any other comments or questions about the e-measure version of this, in terms of scientific acceptability?

MS. ROBINSON-ECTOR: Voting is now open for reliability and validity for the e-Measure 1354. And for those on the call, option one is yes with conditions and option two is no.

All the votes are in. Ninety-three percent voted yes with conditions and 7 percent voted no. So for reliability and validity for the e-Measure 1354, the measure passes.

DR. WINKLER: In terms of feasibility of the e-measure, John, do you have any comment on the use of the data elements in the usual

players in the EHR vendor space?

MR. EICHWALD: Well, we've actually been working with some vendors. We're working with an organization called Integrating the Healthcare Enterprise. And we've actually just published a document that's out for public comments, and this basically takes the measure that is defined here and it's sort of the how-to. How do we create the content using a quality reporting document architecture, QRD-8 architecture, and then being able to take the individual quality report, the quality report at the individual level, combine that, aggregate that into a quality measure at the population level.

So, that profile is out right now for public comment. We specifically built it so that it worked for EDHI, but we're really trying to make sure that it will work for other quality measures as well.

DR. WINKLER: Any questions or comments about the feasibility of an e-measure

version of this measure? Okay.

MS. ROBINSON-ECTOR: Voting is now open for feasibility for e-Measure 1354. And for those on the call, option one is high, two is moderate, three is low and four is insufficient.

All the votes are in. Ninety-three percent voted high, 7 percent voted moderate, zero voted low and zero voted insufficient. So, for feasibility for e-Measure 1354, the measure passes.

DR. WINKLER: Is there anything about the usability and use that was going to be different on the e-measure compared to the registry measure?

MEMBER YOUDE: I am a huge fan of this, because there's a significant amount of time processing paperwork with the registry version, and this will ease the usability considerably.

DR. WINKLER: Let's vote on usability.

MS. ROBINSON-ECTOR: Voting is now open for usability and use for e-Measure 1354.

Option one is high, two is moderate, three is low and four is insufficient information.

All the votes are in. Ninety-three percent voted high, 7 percent voted moderate, zero voted low and zero voted insufficient. So for usability and use for e-Measure 1354, the measure passes.

DR. WINKLER: Anything overall about the e-measure before we vote? No. Sorry, okay.

MS. ROBINSON-ECTOR: So recommendation for overall suitability for endorsement for e-Measure 1354 is now open. Option one is yes with conditions and option two is no.

DR. WINKLER: Just as a reminder, the conditions are that they bring back the results of the testing in the simulated data set.

MS. LUONG: Vaishali, if you can email me your votes, thanks.

MEMBER PATEL: Yes, Vy.

MS. ROBINSON-ECTOR: All the votes are in. One hundred percent voted yes with conditions and zero voted no. So for

recommendation for overall suitability for endorsement for e-Measure 1354, the measure passes.

MS. LUONG: Operator, at this time we'd like to open up the line for public comments.

OPERATOR: Okay. At this time, if you'd like to make a comment, please press star then the number one.

(No response.)

OPERATOR: There are no public comments at this time.

MS. LUONG: Thank you.

DR. WINKLER: Okay. Lunch is here. A little fuel for the brain cells, a little break. We're scheduled to reconvene at 12:30.

MS. LUONG: Yes. So for those on the phone, we're scheduled to reconvene at 12:30. And, Vaishali, I've got your email, so thank you for participating for the past two days, and when you come back, we won't be discussing measures anymore.

MEMBER PATEL: Great, thank you.

MS. LUONG: Thanks, bye.

(Whereupon, the above-entitled matter went off the record at 12:01 p.m. and resumed at 12:30 p.m.)

MS. LUONG: So before we start the conversation on the Measures discussion, just for logistical purposes, I know a lot of people are traveling to either Dulles or Reagan for their flight. And if you can, I think it will be a good idea to maybe take the cab together since you guys are at the same hotel, so just coordinate amongst each other because I know some of you are flying out around 5:00 or 6:00, which is around the same time as most people. Thanks.

CO-CHAIR YAREMCHUK: So, the other question is expense reports. Can you also just let people know in terms, are they going to be sent electronically to everybody?

MS. LUONG: So for reimbursement, but I'm sure our meetings department will be sending out an email to everyone here within the next few

days by the committee members with directions on reimbursement. And for the people that were at last night's dinner, if you can just make a note in there that Kathleen was the person that handled the check. Thanks.

CO-CHAIR YAREMCHUK: Okay. So the Measure that we're going to now, 1360 Audiological Evaluation no later than 3 months of age.

CO-CHAIR MERENSTEIN: Developers want to say anything about that?

CO-CHAIR YAREMCHUK: They're not listening.

MR. GAFFNEY: I don't think at this point. Just the measure is about audiological evaluation before 3 months of age. Happy to address any questions.

CO-CHAIR MERENSTEIN: So Tammy, I guess you're by yourself on this one.

MEMBER BRADHAM: So the evidence for this is basically is follow-up to once a baby's been seen in the hospital and they get a refer,

then they are supposed to be referred to an audiologist no later than 3 months of age for audiologic testing. And during that time, the audiologist is expected to make a diagnosis at that point.

And so there are reliable measures out there to be able to test a baby's hearing sensitivity by 3 months of age and Joint Commission of Infant Hearing Position Statement, which is made up of multiple organizations have endorsed this practice.

CO-CHAIR MERENSTEIN: Any questions about the evidence? I guess we'll vote.

MS. ROBINSON-ECTOR: Voting for Evidence for Measure 1360 is now open. And for those on the call, Option 1 is High, 2 is Moderate, 3 is Low, and 4 is Insufficient Evidence.

So all the votes are in. So 11 voted High, 2 voted Moderate, 0 voted Low, and 0 voted Insufficient. So for Evidence for Measure 1360, the Measure passes.

CO-CHAIR MERENSTEIN: Opportunity for Improvement?

MEMBER BRADHAM: So the opportunity improvement in looking at the national data. When they first started, what they're reporting is that back in 2007 at or around 66 percent and the national data is showing in 2012 we're at 69 percent of audiologists completing the audiological evaluation by 3 months of age. As far as disparity data, there isn't much disparity between whites, blacks, and Hispanics in getting the audiological evaluation by 3 months of age.

CO-CHAIR MERENSTEIN: This is great data, it says it's 54 percent for whites, 51 percent for blacks, 52 for Hispanics. But overall, it's 71 percent.

MR. GAFFNEY: I just want to clarify. You're saying 71 percent overall for --

CO-CHAIR MERENSTEIN: That's what it says, again, is that -- are you looking at that Tammy? It says the performance gaps is 70.8 percent in 2011.

MEMBER BRADHAM: I do not see that. I just see whites, blacks, and Hispanics, 54.8 percent for white, 51 percent for black, and 52.2 ---

MR. GAFFNEY: How's the group 70?

CO-CHAIR MERENSTEIN: But then the average should be close to, like, 54 percent, 53 percent.

(Off mic comment)

CO-CHAIR MERENSTEIN: Any questions or anything about the Performance Gap? There hasn't been much change in the last five years.

DR. WINKLER: Yes. I mean, in all honesty, what I did is they had given us the links to the various data and I had tried to abstract it. And it's possible that when I did that I may have not quite caught on. We can see. It could have been my abstraction error.

CO-CHAIR MERENSTEIN: Any other comments? So we vote on Performance Gap.

MEMBER BRADHAM: I guess the only other comment that I'll make about this is that most

states don't require an audiologist to report their results to the state and so there are opportunities there to continue to monitor this to see that reporting improve.

MEMBER STEIN: Can you clarify can these kids be seen by someone other than -- appropriately seen by someone other than an audiologist? Like, if they went to an ENT doc?

MEMBER BRADHAM: They really need to see an audiologist for the hearing testing and then they go to the otolaryngologist if hearing loss is identified for the medical work-up. But it requires the audiometric testing.

There may be some ENTs that do the actual hearing test or may have some techs, but typically for pediatrics, they usually have an audiologist do the testing. And also this does require use of electrophysiology testing at this age, at 3 months, and so the audiologist has to interpret those test results.

MEMBER STEIN: So what's your explanation for the performance gap? It sounds

like it's around 50 percent. Is it the parents just aren't taking the kids in?

MEMBER BRADHAM: That is part of it. Part of it is also some of those babies haven't even been released yet from the hospital. So they may have failed the newborn hearing screening, but they're still in the PICU or something like that and so there are other reasons for that.

MEMBER STEIN: Do you think those kids should be excluded from the denominator?

MEMBER BRADHAM: We actually asked this question about maturation because if we're looking at prematurity, we do adjust for that during testing and that is not something at this point that they're adjusting for.

MR. ROMAN: If I can point out one or two things. Sort of the data as it stands right now is about 69 percent of kids are get evaluated before 3 months. That's based on documented data, so it is likely it's even higher than that. But this is just based on what the states can

actually document in their systems.

We have recently made a update to the survey, it doesn't yet reflect in the data that's being shared here, where states can account for those children that were in a NICU for greater than 30 days. So that's kind of setting us up to get a start to address some of that issue there. And that is just a recent change that's just been implemented.

MEMBER BRADHAM: One of the other issues is that hospitals didn't know where to refer babies and so in 2013 in the spring, they released EHDI-PALS, which is a website where they can go to, to find audiologists for the testing. And so I'm hoping that as data becomes more available, we might actually see some improvement there as well. And that's a national registry of facilities and what type of equipment they have, et cetera.

CO-CHAIR MERENSTEIN: Any other comments? So let's vote on the Performance Gap.

MS. ROBINSON-ECTOR: Voting is now open

for Performance Gap for Measure 1360. And for those on the call, Option 1 is High, 2 is Moderate, 3 is Low, and 4 is Insufficient.

All the votes are in, 79 percent voted High, 21 percent voted Moderate, 0 voted Low, and 0 voted Insufficient. So for Performance Gap for Measure 1360, the Measure passes.

CO-CHAIR MERENSTEIN: Tammy, Reliability.

MEMBER BRADHAM: Next one is looking at reliability. The states report this data to, we mentioned this earlier, the states report this data to CDC. The states are getting reports from the audiologists or the facilities where they work. A lot of time this is faxed information. It could be an upload of their equipment to the state. But the actual testing procedure that's done, ADRs are -- that whole diagnostic process has very high sensitivity and specificity for detecting mild and greater hearing losses.

CO-CHAIR MERENSTEIN: Comments? All right. We'll vote on Reliability.

MS. ROBINSON-ECTOR: Voting for Reliability for Measure 1360 is now open. And for those on the call, Option 1 is High, 2 is Moderate, 3 is Low, and 4 is Insufficient.

Okay. Votes are in, 50 percent voted High and 50 percent voted Moderate. So this would fall into the grey zone.

CO-CHAIR MERENSTEIN: No, it passes.

MS. ROBINSON-ECTOR: Oh, sorry. It passes. Oops, sorry. So the Measure passes for Reliability.

CO-CHAIR MERENSTEIN: Validity?

MEMBER BRADHAM: I was, like, what? Okay. So validity, they did testing, they looked at Tennessee State Early Hearing Detection Information System of 24 audiology facilities and found that 97 of the 3,892 records, which was 2.5 percent, were found to have errors, including inconsistent values among diagnosis, diagnostic code, and/or missing values. They did exclude infant death in this measure. There's no information on missing data.

CO-CHAIR MERENSTEIN: That's pretty good. Any questions about that? Let's vote on Validity?

MS. ROBINSON-ECTOR: Voting on Validity for Measure 1360 is now open. And for those on the call, Option 1 is High, 2 is Moderate, 3 is Low, and 4 is Insufficient.

All the votes are in, 57 percent voted High, 43 percent voted Moderate, 0 voted Low, and 0 voted Insufficient. So for Validity for Measure 1360, the Measure passes.

CO-CHAIR MERENSTEIN: Feasibility?

MEMBER BRADHAM: So the feasibility is that the data is collected through the EHDI program. All the data elements are available for the audiologist to report based on the testing that they do. The one comment that I think is worth mentioning here is that all states require that if you've identified a child with hearing loss through Child Prime that they have to report it. So if they do identify hearing loss, it has to be reported at that point. So it's there.

They have a mechanism to provide that information.

MEMBER STRODE: Who's that reported to?

MEMBER BRADHAM: It varies by state. But most states either report it to their Department of Health or their Department of Education. Usually it's in the Department of Education though.

CO-CHAIR MERENSTEIN: Any other comments or questions about Feasibility? I guess we'll vote on it.

MS. ROBINSON-ECTOR: Voting for Feasibility is now open for Measure 1360. And for those on the call, Option 1 is High, 2 is Moderate, 3 is Low, and 4 is Insufficient.

71 percent voted High, 29 percent voted Moderate, 0 voted Low, and 0 voted Insufficient. So for Feasibility, Measure 1360 passes.

CO-CHAIR MERENSTEIN: Usability?

MEMBER BRADHAM: Usability and use, these are publically reported on a lot of the

EHDI state websites. The information is available.

CO-CHAIR MERENSTEIN: Any comments, questions? We'll vote on this one.

MS. ROBINSON-ECTOR: Voting is open for Usability and Use for Measure 1360. Option 1 is High, 2 is Moderate, 3 is Low, and 4 is Insufficient Information.

Votes are in, 93 percent voted High, 7 percent voted Moderate, 0 voted Low, and 0 voted Insufficient Information. So for Usability and Use, Measure 1360 passes.

And voting for Recommendation for Overall Suitability for Endorsement for Measure 1360 is now open. Option 1 is Yes and Option 2 is No.

Okay. Looks like we're missing one vote in the room. Thank you. It's still not coming up. I should have 14. It's 13 now? Oh, so we should have 14 votes, yes. So we're missing someone inside the room. There we go. Thank you. Okay, 100 percent voted Yes and 0

voted No. So for Recommendation for Overall Suitability for Endorsement for Measure 1360, the Measure passes.

CO-CHAIR MERENSTEIN: Okay. Our last intervention. Intervention no later than 6 months of age. Developers have anything to add before we start?

MR. GAFFNEY: Just that this is the first step in the process is what this is reflecting for those kids that have been identified with a permanent hearing loss, how many are actually getting intervention before 6 months, which is the recommended benchmark.

CO-CHAIR MERENSTEIN: Okay. Judith, you can start.

MEMBER LYNCH: Okay. This is an outgrowth of the past two Measures under consideration. And this will set the proportion of infants with permanent hearing loss who have been enrolled in intervention services no later than 6 months.

The evidence is pretty much the same

as it was in the previous Measure, the Joint Commission on Infant Hearing Position Statement and a systemic review of the literature on early intervention that looked at 168 studies of various types. The evidence seems to be pretty strong at a Level III. But the big problem that our call had on this was the definition of intervention.

CO-CHAIR MERENSTEIN: Yes. I guess we'll get to that more further along. But what about the evidence behind it, you said it's a Level III, you thought?

MEMBER LYNCH: Yes. At Level III.

CO-CHAIR MERENSTEIN: Jackie, you have anything to add about that?

MEMBER YOUDE: No. Nothing to add.

CO-CHAIR MERENSTEIN: Any questions or comments about the evidence? So we'll vote on the -- oh sorry, my fault. Tammy?

MEMBER BRADHAM: So just a comment on the evidence. A lot of this is based off of Christine Yoshinaga-Itano's research back in the

late '90s, early 2000 in which babies that were identified with hearing loss by 6 months of age and started getting intervention were basically on target when they started school for language skills. Whether it was sign language or oral or whatever.

So the evidence is there. Mary Pat Moeller also has published on this topic. These have been sample sizes of around 100 children, but it has been replicated in cochlear implant research that once they do get appropriate intervention that these children do make marked improvements in their linguistic and communicative abilities.

CO-CHAIR MERENSTEIN: Okay. We're going to vote on the Evidence.

MS. ROBINSON-ECTOR: Voting for Evidence for Measure 1361 is now open. Option 1 is High, 2 is Moderate, 3 is Low, and 4 is Insufficient Evidence.

MEMBER LYNCH: Okay. Oh, I'm sorry.

CO-CHAIR MERENSTEIN: Just one second,

okay?

MS. ROBINSON-ECTOR: Okay. All the votes are in, 57 percent voted High, 43 percent voted Moderate, 0 voted Low, and 0 voted Insufficient. So for Evidence, Measure 1361 passes.

CO-CHAIR MERENSTEIN: So Judith, on Opportunities for Improvement?

MEMBER LYNCH: Yes. This is not so dissimilar from the previous Measure in that the CDC data from 2006 to '12 shows between 66.4 percent and 69.1 percent. So it seems as if there is a real need for improvement in this area. As far as disparity data, whites 54.8 percent, blacks 51 percent, and Hispanics 52.2 percent.

MEMBER YOUDE: I'd also like to --

CO-CHAIR MERENSTEIN: Jackie?

MEMBER YOUDE: -- add to Judith's comments about the average performance being 67 percent across the nation that the range is actually 100 percent. So there's incredible

variability.

MEMBER LYNCH: Absolutely. Thank you.

CO-CHAIR MERENSTEIN: Is this variability where there might not be providers to do this? I mean, we think there's rural places where there's no providers to provide this.

MR. GAFFNEY: I think some of that variability may be access to services. I think some of it is also, probably a large part, reporting requirements. Privacy regulations can make it difficult for state EHDI programs to confirm from the Part C EI programs and for the Department of Education to confirm if those children referred actually are receiving services.

So I think this goes to back to this documented issue again. Data that's being presented here reflects these kids are actually documented to get these services. There's probably a lot more kids getting services due to privacy laws and other things.

MR. EICHWALD: And just also, this is

again based on state rules and regulations. Eligibility changes by state and so that's probably where we're seeing a lot of the variability.

CO-CHAIR MERENSTEIN: Tammy, anything?

MEMBER BRADHAM: It does vary by state. Some states if you have a unilateral hearing loss or a mild hearing loss, then you don't qualify for services. And so we're missing those kids and it is very clear in the Joint Commission Statement that these children need to be included in early intervention and so this is definitely an opportunity for improvement.

CO-CHAIR MERENSTEIN: Any other questions about -- sorry, Steve?

MEMBER STRODE: Do you know why the U.S. Preventative Services Task Force said we're not going to review evidence for this Measure anymore?

MEMBER LYNCH: Yes. They considered it outdated.

MEMBER STRODE: And didn't have new

evidence to review?

MEMBER LYNCH: Right.

MEMBER BRADHAM: There's just no new, I mean -- babies are being screened. We know that there are consequences if they don't get early identification. There really isn't a lot of new evidence right now.

MR. GAFFNEY: If I can just mention one thing. We are currently supporting ongoing research. The findings haven't been published yet, but that is something that's being worked on, being funded.

CO-CHAIR MERENSTEIN: Any other questions or comments about Opportunities for Improvement? So we'll vote on that.

MS. ROBINSON-ECTOR: Voting is now open for Performance Gap for Measure 1361. For those on the line, Option 1 is High, 2 is Moderate, 3 is Low, and 4 is Insufficient.

All the votes are in, 79 percent voted High, 21 percent voted Moderate, 0 voted Low, and 0 voted Insufficient. So for Performance Gap for

Measure 1361, the Measure passes.

CO-CHAIR MERENSTEIN: Judith, we're going to talk about Reliability.

MEMBER LYNCH: Okay. This is our clinical database registry. And the data is available in Early Hearing Detection and Intervention Information Systems in the states. However, only one state data set was used for validity and that was from January to December 2014.

CO-CHAIR MERENSTEIN: We're doing Reliability, but yes. Jackie, you have something to add about Reliability?

MEMBER YOUDE: Yes. So if we're looking at the numerator and denominator statements, the numerator statement, I have a couple of questions on. Stated as is, "Numerator contains the number of infants born during the time window that have been diagnosed with permanent hearing loss whose age is less than 6 months at the time of enrollment into intervention services."

I have three questions. One, how are we defining age? Is it chronological age or corrected age? Two, we're saying the time of enrollment. Can we clarify what that means? And three, given that we're looking at the time of enrollment, but the Measure is called "Intervention no later than 6 months of age," can we discuss that slightly?

MEMBER LYNCH: You know, I keep coming back to the fact that we don't know what the intervention is.

MEMBER BRADHAM: And I would also like to comment on the fact that, what population are you really looking at? Just the Medicaid population?

CO-CHAIR MERENSTEIN: So lots of questions for the developers, yes. Maybe one at a time.

MR. GAFFNEY: Okay. I'll try to address your question first once again. I believe there was a first for age. Most likely chronological age is what's being addressed at

the moment. For enrollment, the definition now, what we consider enrollment is assigned IFSP plan as reported by the state. So that's what we're using as our marker for enrollment. And I believe the third point was, exactly what intervention --

MEMBER YOUDE: Yes. So why are we looking at enrollment when the Measure is called "Intervention no later than 6 months of age?"

MR. GAFFNEY: To be honest, that's just the way our data collection is set up at the moment, to what the states can report. And using enrollment as, I guess, would imply the beginning of intervention services. And that's what the benchmarks are for ensuring intervention starts by 6 months. So that's why it's set up the way it is at the moment.

MEMBER YOUDE: Two more questions following up on that. One, is there any data to tell us the length of time between enrollment status and actual intervention? Two, is there any data to tell us the percent of enrollees that

receive intervention?

MEMBER LYNCH: I would add to that who is doing the enrollment and how is it collected?

MR. GAFFNEY: I'm going to answer this second question first. Enrollment is being reported usually by the intervention program. That's the program that has the IFSP date, so that's usually typically who's reporting back to an EHDI program saying, yes this child is enrolled. So that's who's reporting that back. Does that address the question on the phone?

MEMBER LYNCH: Yes.

MR. GAFFNEY: Okay. And then --

MEMBER LYNCH: But I'm still worried about what the intervention is and nobody is answering that.

MR. GAFFNEY: And, I mean, that's a great question. There is variation in what can be considered intervention. Part of the variation is going to be driven by what the parents decide is best, what are they going to go with. And a lot of times that comes down to the

parents' decision. Also recommendations from the providers.

Also availability of services. I mean, there are definitely difference probably between if you're in a rural area what you have access to, to if you're in a large metropolitan area what services you're going to be able to have. And we are not collecting that specific data right now. But the enrollment in EI is probably the first step towards getting the outcomes on these children. Enrollment, that's the first step in this process.

MEMBER YOUDE: So it sounds like we're using the enrollment as a proxy for intervention and I'm still curious if there's any data to tell us the length of time between enrollment status and intervention? Whatever that intervention may be considering that it has to be with the child and not with the parent.

MR. GAFFNEY: Right. There's no data that we currently have about the average age between when the IFSP starts and when it's signed

and when services begin. Nothing anywhere large scale that we have to report other than --

CO-CHAIR MERENSTEIN: Who are you measuring? You're measuring the primary care doctor if they've signed them up for enrollment? Or how do you --

MR. GAFFNEY: No. It's the Part C intervention program, they administer the IFSP. So they work with the families and the families actually have to sign the IFSP from how I understand it with the Part C EI programs. It doesn't usually involve the PCP or the medical home at the IFSP stage.

MEMBER YOUDE: One other thing that I do have, just speaking on strictly field experience, so if you have data to contradict this, I welcome it because I want to be contradicted. So I have seen families sign an IFSP, I've heard about this IFSP, I've been there for it, but signing it and getting to intervention, I have seen anywhere from days to months to up to a year in terms of actually being

enrolled and receiving intervention.

And so when I'm looking at the title of this Measure, which is called "Intervention no later than 6 months of age" and we're using a proxy for enrollment by 6 months, but we have no data to tell us the average length of time or any length of time at all between enrollment and intervention, I have a lot of trepidation about that.

MR. EICHWALD: The point I'd just like to make is that Part C is available under Department of Education in every state. So that's why we chose this. There are parents that choose to go private, but that's very difficult to capture. And that's not necessarily available in every state.

And then the second part of that, since we're using children that are enrolled in a program that is run by the Department of Education, we have different privacy rules than we do in healthcare and that's the FERPA, Family Educational Rights and Privacy Act. And then on

top of that, the Part C has their own privacy rules.

And so that's part of the reason it's difficult to try to get to that data where you're saying, we've got a signed IFSP, when did that child actually receive the service, what kind of services. And it gets sort of to the duration, length of time.

MEMBER YOUDE: Yes. And I know it's difficult to collect. There's a lot of people involved in early intervention. There's a lot of coordination of care going on.

And so what I'm wondering then, taking it the next step, that if we can only look at enrollment, but really what the evidence is suggesting is that we need to look at the time of intervention and it needs to be before 6 months of age, chronological or corrected, why not look at claims data and define intervention across the field? So in audiology, it could be time of first fit for cochlear implant or hearing aid. For SLP, it could be time of first therapy

appointment. So on and so forth.

MR. GAFFNEY: And I'm going to preface my answer by, this may not be a complete answer. What I know on the claims data, we have been working a little bit with claims data, market scan database. Again, I'm not an expert on it.

I'm not sure, data may be in there for, like, kids that have been fitted with a cochlear implant, maybe it'll pull billing codes on that, maybe even hearing aid fittings. But for things like speech language therapy, other services like that and the non-medical devices, I'm not sure that's going to show up in the billing codes. It may, but I'm not sure if it will.

So that's -- while looking at the billing codes may help with part of this, I'm not sure it would give us a complete picture of how many kids are receiving EI. And especially because some of these services are things a lot of states that are directly provided from the state Part C programs. Again, I'm not sure how

that shows up in billing codes when a state Department of Education is providing the services. I'm just not sure how that shows up. So --

CO-CHAIR MERENSTEIN: Tammy?

MR. GAFFNEY: -- a partial answer.

MEMBER BRADHAM: Yes.

CO-CHAIR MERENSTEIN: All right. Tammy has a question.

MEMBER BRADHAM: So just a -- and I guess this is my professional hat. Do you have any data on disparity or socioeconomic of the children in Part C that are getting those services? Because we do know that a lot of families are electing to go private or they may get a cochlear implant and so they're going to get their intervention services through that program and won't sign up with the Part C program.

Or the other thing to keep in mind is that the Joint Commission says that they need to be provided with early intervention services by a

qualified provider. Well, Part C, the program, the way it's designed is to be able to help the parent navigate the systems to help the parent understand maybe how to use a hearing aid or to start learning basic sign with the parent. And so it's not necessarily direct intervention per se with the child.

Plus some of those early interventionists are people with high school degrees and don't have that expertise in dealing with linguistic and communicative competencies. And so I guess we're kind of pushing back a little bit because the Measure is calling for intervention, but really what we're measuring is just that they've signed the form.

MEMBER YOUDE: When I'm looking at -- and Tammy, I entirely agree with what you said. When I'm looking at the current state of this Measure, I think it reliably measures the date of enrollment for the Part C population for those who qualify for early intervention.

I don't think that it reliably looks

at the bigger population and the time of intervention. It doesn't tell us what's going on outside of Part C and it doesn't tell us what the actual time of intervention is and I just have a lot of trepidation around that.

MR. EICHWALD: I'd just like to make the point that, I mean, that making legitimate statements here. What we really want to get to is outcome. This is just a process Measure. We recognize that. But it is a standardized process Measure that we can measure in every state.

We do want to start looking at the outcomes of these children that have gotten and that's really the direction we want to go. It's just we don't have a measure for that yet. How we define what is intervention? The dosage of the intervention.

I've been struggling with that and trying to figure out what -- and I use that word dosage a little, I mean, what's the duration? Who's the provider? How often does it occur? How soon? I mean, so it's something we're still

struggling with to try to get to outcomes. We look at this as a process measure.

MEMBER YOUDE: And it is and I appreciate all of the thought that has gone into this and I entirely agree with the intent of measuring intervention before 6 months. I entirely agree with wanting to measure outcomes. This may be the first step in getting there. I just don't know that because we're looking at such a specific subset of patients. That said, it's important and if that's what we have data to work with right now, that's really where we're at.

MR. GAFFNEY: And if I may just add one thing to that. As John said, I mean, we acknowledge this as a process Measure and there are things that could be done. I do think it represents the place it makes the most sense to start with this. I think it's the best way to start measuring this at the moment based on what's available actually from states. And I could comment, I wish I had the information I

could pull off because they are very, very valid questions. And we do have some efforts on the way too that will hopefully help advance that.

I will say for the population, while Part C does not properly serve everybody, I think it does serve a large portion of the kids that do have permanent hearing loss. I mean, we've got a pretty captive population there and we look at our data, like, number of kids, if we back out from just number of kids that have a permanent hearing loss and number of kids getting intervention, I mean, it's a lot of kids states are able to document, yes they're getting some type of intervention. So I think it speaks to we're at least getting a lot of the group. And so I would put that out there.

CO-CHAIR MERENSTEIN: Josh, you have a question?

MEMBER STEIN: For those of us who are not in this field, it sounds like both of you, Jackie and Tammy, have an issue with what the title is and what's being measured are two

different things. So I guess the question for you guys is, is what's being measured important? Like, is capturing enrollment or whatever's being measured, is that something useful? If someone's being enrolled, is that important for having intervention?

MEMBER STEWART: I mean, I know you're asking them the question. I think that you have to get referred before you can get the intervention, so, I mean, this is one of these stepwise processes. That's a very good point that in fact what we're measuring is referral for intervention, not the actual intervention. But the referral's a necessary step.

MEMBER YOUDE: Right. And you have to be enrolled before you can get intervention. That's just part of it. And I would be fine using enrollment as a proxy for intervention if I knew how long it takes from enrollment to first treatment. And that date is not available at this point in time. And based on experience, so this is anecdotal, I have seen it vary from days

to months to over a year. And I just -- that really just kind of makes me hesitate.

MEMBER STEIN: So would you guys feel comfortable with this Measure if the title was just changed to reflect what's actually being captured?

MEMBER YOUDE: I think that we would need to go and change the month as well to kind of accommodate for that lag time or the lead time to actually getting intervention. So if we were to change it to "Enrollment no later than 4 months of age," I'd feel pretty good about that.

Because then I have a two month buffer and in my professional opinion, if we've identified the hearing loss at age 3 months, the enrollment form should be sent at that point in time, during that appointment. So technically, we should have a three month period of time for that intervention to start, but given that life happens, I would be fine having "Enrollment status no later than 4 months of age."

MEMBER BRADHAM: I'm going to push back

a little bit there though, Jackie. Because Mary Pat Moeller's research shows by 11 months of age that they were enrolled in early intervention and Yoshinaga-Itano's research shows that they were identified by 6 months.

So even if it could be considered that "Enrolled in intervention no later than 6 months of age," I would be fine with that. I think the enroll intervention would be key there. If we're going to measure intervention, then I think we need to look at numerator and denominator.

MEMBER YOUDE: And I appreciate the push back, because I really love spirited conversation. That said, those two studies I'm sure were accounted for in the systematic review that was presented in this evidence which was rated as High and passed.

And so given that the evidence presented up front suggests that intervention no later 6 months of age is the best practice or is necessary to have the best outcomes, I appreciate those two studies, but I'm going to put them in

the bigger context of the evidence presented.

CO-CHAIR MERENSTEIN: Any other questions or comments?

MEMBER FRIEDMAN: Again from a layperson, the Measure's not perfect, but at least it's a start. And based on what I've heard, I think it's a reasonable thing to do. Obviously, if they're not referred, it's a moot point. Now, you can go -- the intervention may be inappropriate too and we're not commenting on that.

So just because they're getting intervention doesn't mean that you're actually ultimately helping the patient as well. But it's a start and based limited what their capability of doing, this is what they're trying to measure and I think it's a good starting point.

MEMBER YOUDE: I agree with you. It's a great starting point. It's not perfect, but it is what we're working with. At the same time, to be consistent with the evidence and we have had that conversation about intervention, I just get

nervous that we're looking at a form.

We're measuring has the form been filled out? Has the form been filled out by 6 months of age? If the form was filled out, what happened after that? And we don't know. So to me, this looks like we're measuring a form or administration.

MEMBER FRIEDMAN: So, we've been saying that for the last two days. We've been saying that for the last two days constantly. Well, does it make a difference? I have no idea. Referral, does it make a difference? I have no idea. We don't know. But at least it's a start. I mean, if you don't even do that step, you know they're not going to get better, in theory. But we have to start at some point.

CO-CHAIR MERENSTEIN: Josh and then Tammy.

MEMBER BRADHAM: This is Tammy and I just want to add one piece to it and then I'll be quiet, I promise. Is that the issue is the consumer perspective, the parent perspective, the

conversations that I've had with them.

Because they're talking about intervention no later than 6 months of age and they're just now getting that phone call from the Part C provider so they can get that form signed, but then they find out it's going to take them six months before they can get their hearing aid. And then it's going to take another three months to start their intervention because they don't like to start speech therapy until they're 12 months of age.

And so that's where the issue is, is when I'm based with that family and they're going with the state program and that's how the state program works. And so this metric needs to reflect intervention by 6 months of age so I can make sure that, that child gets their hearing aid or gets with the speech pathologist or that deaf mentor or enrolled in a sign language class by 6 months of age. That's why this is such a hot thing.

MEMBER YOUDE: I agree with Tammy.

MEMBER FRIEDMAN: So basically what you've told us is that based on the way it's written here, they're not doing that? And so that's pretty obvious, we vote it down. Because they're not doing what they're saying they're doing. They're just referring within six months, but they may not get intervention at all. And they're not capturing the data. Is that correct?

CO-CHAIR MERENSTEIN: Josh?

MEMBER STEIN: I just wanted to, I guess, follow up on that. I mean, I think it sounds like from -- as we're pretty much lay in this, that the issue is with the wording and that it may be misleading to consumers and to other groups that an intervention was performed. So certainly the title and probably some of the content needs to be modified to better reflect what's actually going on.

MEMBER STEWART: And I think we're -- with all the passion and argument about how this is not happening, we're in danger of losing this quality Measure, because of all this discussion.

I mean, is that really what we want to do here?

MEMBER STEIN: This came up earlier, I think there's a post discussion period where they could make some changes very quickly and get it in the right format and then probably approved.

CO-CHAIR MERENSTEIN: It seems like to me that if we changed the title, we would be okay with it. I mean, because I sort of agree that it's not fair for a state to say they're doing this if they're not really giving interventions till a year. But if they are enrolling, they should get credit for that. And so it seems like to me it's a title issue more than a --

MEMBER YOUDE: I think there's --

CO-CHAIR MERENSTEIN: -- a general --

MEMBER YOUDE: I think there's a couple of issues. One, you're spot on. There's really solid methodology behind measuring the enrollment for this population. We can measure the enrollment.

I think the issue that Tammy brought up earlier though is that the evidence is

pointing towards intervention. And kind of going back to what Micky was saying, we have to start somewhere. We know this is important. Is it perfect? No, not in my opinion.

But I also don't want to lose what is possible because if we're not going to measure it and we can look into the validity here in just a little bit. But we don't want to lose those patients. We don't want people being like, oh no, I don't have to fill out a form in time, nobody's going to hold me accountable, so I'm not going to do it until I have the time to do it and nobody ever has time. And so I don't want to lose what we've got. But I also know that there's some caveats here, in that we're not really measuring intervention.

MEMBER GOLDBERG: It seems that we really have a separate performance Measure that needs to be developed and that is time from enrollment to time from the intervention. And so, I mean, we're looking at enrollment and calling it intervention. So maybe the title

should be changed.

MEMBER YOUDE: If we could --

CO-CHAIR MERENSTEIN: Before --

MEMBER YOUDE: -- change the title and then start measuring time of enrollment to time of first intervention, whatever that intervention may actually be as long as it's with the child and not with the parent, that would be two very interesting ways to do it.

CO-CHAIR MERENSTEIN: Yes. Although I don't think we can vote on that. I mean, they don't know how to measure the intervention yet. But they know how to measure the enrollment so they could change the title. Anybody else have anything to say before we vote?

MEMBER LYNCH: So we're going to vote on the Reliability as it is now, not what the outcome should be in the future, correct?

CO-CHAIR MERENSTEIN: I think we have to, yes.

MEMBER LYNCH: Okay.

MEMBER STEIN: So just to clarify, if

the developers are comfortable changing the title, we still have to vote it down so they can change the title to bring it back up? Or can they say that now and then we can --

DR. WINKLER: No. If --

MEMBER STEIN: -- vote on it?

DR. WINKLER: -- they're willing to entertain that, that's a suggestion that they could follow up with.

MR. GAFFNEY: And just to clarify, we're definitely willing to entertain that.

CO-CHAIR MERENSTEIN: Let's vote on it, on the Reliability.

MEMBER YOUDE: Just to make sure I'm clear. So the developers have said they're willing to entertain changing the title. So we are voting on the Reliability with a possible suggested title change?

DR. WINKLER: Keep in mind the title does not reflect your specifications. The Reliability is about how the Measure's implemented with those specifications. So the

title is important in terms of messaging and communication, but it does not drive the specifications of the Measure. So keep those two things separate.

CO-CHAIR MERENSTEIN: All right. We're going to vote the Reliability of the Measure, enrollment.

MS. LUONG: I think Judith has a question.

CO-CHAIR MERENSTEIN: Judith?

MEMBER LYNCH: No. I'm still confused about what the voting will mean. So if we vote down Reliability, does that mean that we have to throw it out or is this not a specific one that has to be passed?

CO-CHAIR MERENSTEIN: No. It would be thrown out then. The Measure would be thrown out. Micky?

MEMBER STEWART: And just to clarify further, it actually says in the Measure, "enrolled in intervention." So we're just suggesting that the title should reflect what it

says in the Measure.

MEMBER LYNCH: Right, okay.

MS. ROBINSON-ECTOR: Voting is now open for Reliability for Measure 1361. Option 1 is High, Option 2 is Moderate, 3 is Low, and 4 is Insufficient.

Okay. All the votes are in, 7 percent voted High, 79 percent voted Moderate, 14 percent voted Low, and 0 voted Insufficient. So for Reliability for Measure 1361, the Measure passes.

CO-CHAIR MERENSTEIN: Judith, we're going to talk about Validity.

MEMBER LYNCH: Okay. The Measure was tested on our clinical database registry. As I said before, one state EHDI dataset from January '14 to December '14 was done and data from the 2012 TDCJ Screening Hearing and Follow-up Survey was done to test the ability to identify different. In 2014, 25 out of 74 records or 33.8 were found to have inconsistencies between the diagnosis code and the enrollment status.

In other words, the diagnosis code

indicated the patient does not have hearing loss, but the enrollment status is "Yes." In addition, 19 records had inconsistencies or missing information was found by comparing information between the state EHDI with the other system, which is the Tennessee Patient Tracking Billing Management Information System. So it looks like there may be some issues with validity. And I think, Jackie, was this where you had some problems with all the coding?

MEMBER YOUDE: You know, when we were first on the call, we did have some problems with coding. But the developers have since updated it and there's no problems with the codes anymore.

MEMBER LYNCH: Good.

MEMBER YOUDE: Also, adding to that, I know we say there are some problems with validity and I think it is worth noting that those 25 of the 74 or the 34 percent of the records that had some inconsistencies between diagnosis codes and enrollment status make sense. Because kids can be referred for EI and still have normal hearing

for any other diagnosis code.

That said, of the 49 records of those who actually do in fact have hearing loss, there was 19 records or 26 records that had inconsistencies, leaving 30 records that were valid, or 61 percent of those 49 records with permanent hearing loss. So when I looked at that, I said, okay well that's 2014 and I'm not really sure how many kids in 2014 were diagnosed with permanent hearing loss.

What I do see is going against the records referred for EI, but I don't see it into the bigger context of the picture for the state of Tennessee and I was wondering, do you guys have any information on that?

MR. GAFFNEY: You mean, overall identified in Tennessee?

MEMBER YOUDE: With permanent hearing loss in Tennessee in 2014.

MR. GAFFNEY: No. We have 2013, we do not have 2014 yet. We run about two years behind in our usual collection.

MEMBER YOUDE: So because we saw that the 25 of the 74 had inconsistencies between diagnosis code, meaning that they were referred but they had normal hearing because they had some other diagnosis going on, is there any mechanism in place to make sure that the work between EHDI and EI is solid so that we aren't having any of those variables accounted for in the process metric?

MR. GAFFNEY: On a state by state level, I mean, there are different procedures in place. And I'll say, I think some states do a better job than others with their linkage with EI and the type of working relationship they have. Some have data sharing agreements in place that make it a lot easier to check the completeness and the accuracy of the data, but there is some variation.

MEMBER YOUDE: Thank you.

CO-CHAIR MERENSTEIN: So just can you -- I mean, it seems like to me there's a lot of errors in the data. Am I missing something here?

Any other questions about Validity?

CO-CHAIR YAREMCHUK: I guess this is a question about a two year lag and my question is why does it take two years?

MR. GAFFNEY: It takes two years based on the way we collect the data. Main reason is, take for example a child born in December of 2014, end of the calendar year. We want to give them a year to get through the EHDI process, screening, diagnostic, and intervention. To get through the process before the state reports that data to us.

So in 2016, we're going to go back -- January 2016, we'll go back and collect 2014 data because that will give all those kids born in December of that end of the year, at least a year to work through the EHDI process. So it's very deliberate on our part because we want to try to get the most complete data and make sure kids have had time to go through the process.

CO-CHAIR YAREMCHUK: Is this a rolling year or do you do it by calendar year?

MR. GAFFNEY: By calendar year.

CO-CHAIR YAREMCHUK: And I guess that's a question in and of itself, why you would do that as opposed to a rolling.

MR. GAFFNEY: To be honest, we found the calendar year has worked best for us for ease of reporting for the states, for reporting the data out for comparison sakes. States are able to do an update mid-year to the day-to-day reported if for some reason they come with some corrections. But that is the process we've been using since we started collecting data several years ago.

MR. EICHWALD: I'd just like to point out that, so the child born in December will be 1 year of age. It's that child that was born in January of that year, will be 2 years of age. And so we have to have that two year delay.

CO-CHAIR MERENSTEIN: Any other comments, questions on Validity before we vote? We're going to vote.

MS. ROBINSON-ECTOR: Voting is now open

for Validity for Measure 1361. Option 1 is High, 2 is Moderate, 3 is Low, and 4 is Insufficient.

All the votes are in, 0 voted High, 79 voted Moderate, 21 voted Low, and 0 voted Insufficient. So for Validity for Measure 1361, the Measure passes.

CO-CHAIR MERENSTEIN: Judith, Feasibility please?

MEMBER LYNCH: Feasibility. Hospitals and practices provide data to the state who in turn upload the data. Many states still use faxes and then these are turned into electronic forms. This other data system may lead to errors in reporting as well as manual data entry and inconsistencies on measures collected.

CO-CHAIR MERENSTEIN: Jackie?

MEMBER YOUDE: I have nothing to add. She did a great job.

CO-CHAIR MERENSTEIN: Okay. Any questions about Feasibility? Comments? We'll vote on that.

MS. ROBINSON-ECTOR: Voting for

Feasibility is now open for Measure 1361. Option 1 is High, 2 is Moderate, 3 is Low, and 4 is Insufficient.

All the votes are in, 21 percent voted High, 71 percent voted Moderate, 7 percent voted Low, and 0 voted Insufficient. So for Feasibility for Measure 1361, the Measure passes.

MEMBER LYNCH: Okay. And finally, Usability and Use. This is electronic data which is reported by the CDC, so I don't think there's probably very much of a problem with usability.

CO-CHAIR MERENSTEIN: Jackie?

MEMBER YOUDE: Nothing to add, Tammy?

CO-CHAIR MERENSTEIN: Reva?

DR. WINKLER: Yes. I just have one question. This Measure takes us out of the realm of very clearly who's being measured. So it's clear that we measure this at the state, but who else, level of analysis, who else is really being measured by this Measure?

Are there specific providers that get a percent performance? Facilities? Health

plans? Who actually is being measured? Or is it really something that is done at the state level? Which is fine, it's a population health measure and that's acceptable, but I think it's important to know who actually is being measured by this Measure.

MEMBER BRADHAM: We are measuring the Part C service coordinator.

MEMBER LYNCH: Right.

MR. GAFFNEY: Which we think, it is the state level, that's what's being measured. The state.

DR. WINKLER: So it's state.

CO-CHAIR MERENSTEIN: Any other comments, questions about that? All right. We're going to vote on that then.

MS. ROBINSON-ECTOR: Voting is now open for Usability and Use for Measure 1361. Option 1 is High, 2 is Moderate, 3 is Low, and 4 is Insufficient Information.

All the votes are in, 50 percent voted High, 50 percent voted Moderate, 0 voted Low, and

0 voted Insufficient Information. So for Usability and Use for Measure 1361, the Measure passes.

And we are now opening voting for Recommendation for Overall Suitability for Endorsement for Measure 1361. Option 1 is Yes and Option 2 is No.

MS. LUONG: Judith, can you resend me a vote? It's a blank in the email. Thanks.

MEMBER LYNCH: Oh, I'm sorry.

MS. LUONG: It's okay. Thank you.

MEMBER LYNCH: You got it?

MS. LUONG: Yes.

MEMBER LYNCH: Okay.

MS. ROBINSON-ECTOR: All the votes are in, 93 percent voted Yes and 7 percent voted No. So for Recommendation for Overall Suitability for Endorsement for Measure 1361, the Measure passes.

CO-CHAIR MERENSTEIN: Just to clarify, will they come back to us at the next call or something with the change in the title or how is that going to work?

DR. WINKLER: You can let us know if you want to retitle it.

MR. EICHWALD: I'd like to actually work with the some of the members of the panel to make sure that we've got consensus here. I was just thinking that perhaps we change to something that -- and we'll work on this, "Proportion of infants with permanent hearing loss who have a signed IFSP no later than 6 months of age." At least that would be a cleaner title. But I'd rather just get consensus from those involved.

DR. WINKLER: I think we can work with them to work with the involved, passionate members of the Committee.

MR. EICHWALD: That's one thing that I've learned, is that we have passionate people involved. I mean, that makes life much more enjoyable.

DR. WINKLER: Okay. Thank you all very much. Well, that's the end of the measures that we have to evaluate.

We've got a little bit more time

before we're due to close. And an important thing that I'd ask you to do is to reflect on the measures we've looked at that are in this portfolio. And I know we've got two very distinct areas, in eye care and ENT, but from sort of a close-in perspective right now, we'd love your input and feedback on where you see opportunities within the topic area for, you know, newer measures.

Where is the next wave of measures? Are there topic areas that haven't been considered or measured? Are there types of measures? You know, we may have a lot of process measures. Are there opportunities for outcome measures or patient-reported outcome measures?

So, in eye care measures, I think, you know, we saw in four different conditions as well as screening for children. As you were thinking about the measures, for the eye care folks, are there any real gaps in the work you do where quality problems are a problem that you think, you know, might be fruitful areas for new

measures? Todd?

MEMBER RAMBASEK: I asked this question at dinner last night and someone suggested I bring it up here, but antibiotics for viral upper respiratory infections. Meaning, not prescribing. I don't know if that's in a primary care portfolio already.

DR. WINKLER: It is. We do have the appropriate use, or inappropriate use of antibiotics in kids with upper respiratory infection. I'd have to go see if it's kids or adults.

MEMBER RAMBASEK: And adults?

DR. WINKLER: Yeah, I have to go see that. That's a good question.

CO-CHAIR MERENSTEIN: For the eye one, I think we talked about that maybe someone needs to look if there's evidence -- maybe unless you know there's not -- that there should be an eye exam by a professional in ophthalmology or optometry before age 5.

They have that in dentistry now,

that's a recommendation, and I think probably the evidence is as good probably for the eye doctors. So, some group needs to look into that and make it a measure, I think. Unless the evidence is not there, I don't know.

MEMBER YOUDE: Tammy and I had a pretty good discussion about this yesterday as well. Do you want to share your thoughts on what we can with adult hearing aid or adult amplification quality measures?

MEMBER BRADHAM: I was actually thinking pediatrics or adults, reliability of the hearing aid fittings. There are some metrics that are out there that can be used. Some research that's coming out of a multi-center study has shown that children with mild to severe hearing loss, a lot of them are being actually underfit with amplification. And so having some type of an outcome measure that children are being appropriately fit would be good.

I know that our association has talked about vestibular metrics that they want to have

some discussions about. And then I'm also curious about the ANOM system that ASTRA has developed, is that something for an opportunity for NQF to review?

MEMBER STEIN: So, would the IRIS registry now becoming available that's capturing care by most ophthalmologists, I think that in the near future we will have opportunities to look at outcome measures in ophthalmology a lot more easily. Information that's captured a lot better than in claims.

So, also, with the new staging systems for glaucoma severity, one can look at levels of eye pressure for patients with different severities of glaucoma. Yesterday, someone asked about visual field. That would be a process measure, but that's an important measure of assessing the status of someone's glaucoma. So I think there are a number of different measures that can be done in ophthalmology's sphere.

CO-CHAIR MERENSTEIN: Steve?

MEMBER STRODE: We've talked in a

number of these measures about referral, did the evaluation actually take place as an appropriate intervention? And I think it would be a next step in process measures, given that our health care system is not becoming any more simple for the consumer. And that we're also moving to health systems, then I would expect that that data might help drive those systems to the idea of the patient navigator who could help somebody get through all the confusion, to ultimately get what's needed for the good outcome.

MEMBER STEIN: One thing that I noticed in us going through all these measures, it looks like the folks who are writing the guidelines for ENT have developed guidelines capturing, you know, flagging inappropriate use. I mean, almost all the guidelines that are in the portfolio. Whereas, in ophthalmology, it's trying to capture appropriate or quality use. So I think that there may be opportunities for some of the eye guidelines to capture inappropriate use and for the ENT to capture quality or appropriate use.

CO-CHAIR MERENSTEIN: Scott?

MEMBER FRIEDMAN: So, just to embellish on that, the Academy, I've been on a couple of meetings and groups where we did talk about overuse, which is a big deal with the NQF, as you know. For example, inappropriate use of glaucoma drops for people that don't have glaucoma, is one example. So I think that is something that we will look at in the future.

Also, composite measures for ophthalmology, for example. So, we do a referral. Well, did the referral actually take place? Did the referring doctor receive the referral? Did he change the treatment and did it affect the outcome? That could be something that we can look at.

Also, you have on this list cost and resource use measures. So, we're gathering data for treating a disease. We can treat it with a Drug A, which is very cheap, or Drug B, which is very expensive. And when you look at efficiency measures, are we getting our bang for our buck?

If we give them a more expensive drug, is the outcome much better? Is it significantly better to justify the cost? Those are things that we can also start looking at as well.

MEMBER BRADHAM: And I wanted to suggest maybe a late talker for speech. Because that can be indicative of a progressive hearing loss or multiple things.

DR. WINKLER: I wanted to ask some of the otolaryngologists, the measures for adults -- and there really isn't even many for adults -- it's really limited to ear infections. I mean, what are the other big topics you guys take care of that might be fruitful areas?

CO-CHAIR YAREMCHUK: I mean, one is also sinus. And that kind of crosses lots of different specialties. And I think it also goes to appropriate and inappropriate use, overutilization, underutilization. It has imaging. It has antibiotics. And I think that that would get to some of the things that you talked about.

And then I think there's another thing that came up, and I can't remember if it was -- I think it was New England Journal of Medicine about the Choosing Wisely Campaign, which a lot of specialties have paid attention to. But what they dinged ENTs specifically about, and I'm going to say orthopedics as well, is surgical procedures, and I think you mentioned it, on cataracts. You know, are you doing cataracts too early? And are there guidelines in terms of appropriateness for certain procedures? That kind of thing. And so I think that that's something that I think would have some value to look at.

MEMBER STEWART: Yeah, I complete agree, sinusitis is one that's not represented well. One of the big problems with sinusitis is that there's not any FDA -- all antibiotics we use for sinusitis are off-label for chronic sinusitis because the FDA cannot agree on what is the definition of chronic sinusitis.

So we have a definitional diagnosis

problem in these conditions. Is it inflammatory? Is it infectious? How do you prove it? For how long? Et cetera.

So, one of the problems I think we have in sinusitis, and one of the reasons it has not leant itself well to guidelines, is because we don't have an absolute measure of who has it and who doesn't. But clearly it's a prevalent problem where there is controversy, overuse, unnecessary surgery, overuse of antibiotics, et cetera.

CO-CHAIR YAREMCHUK: I think it's also the issue of imaging. And so I think acute sinusitis and the issue of viral versus bacterial in the guidelines is addressed. Chronic sinusitis and the appropriate diagnosis of chronic sinusitis and treatment is, I'm going to say, a separate issue. But acute sinusitis, I think there's some good information about that.

And then there's a recent tonsilitis guideline as well. And I think if we take to heart the article, I think was New England

Journal of Medicine, regarding appropriateness of surgical procedures, the tonsillectomy guideline kind of gets to that. And that would be an appropriate one to look at in terms of overutilization.

CO-CHAIR MERENSTEIN: When you're talking about acute sinusitis, though, there's new ENT guidelines. They recommend it's about two to ten percent bacterial, and if you look at the data, over 90 percent of the time antibiotics are prescribed. So acute sinusitis is a really big issue.

MEMBER STEWART: Acute would be easier to do, there's no doubt about it. And you're right, we have a guideline on that.

CO-CHAIR YAREMCHUK: And that one just came out and that was recently updated. So there have been a guideline, and I think it was four years ago, it was recently updated. Clearly, acute sinusitis there's more agreement, more studies, more information about that versus chronic sinusitis.

MEMBER RAMBASEK: I hear what you're saying about chronic sinusitis, and that there are no drugs of any kind, especially antibiotics, approved for it. But I don't see how that makes it difficult to lend it to a guideline. It just seems that "antibiotics should not be used for chronic sinusitis" would be an easy and helpful guideline. Is that --

MEMBER STEWART: You'd have to define what chronic sinusitis is. Is that the presence of symptoms for three months? Is it a CT scan? Is it endoscopy? I mean, if you're going to have a guideline, you've got to have entry criteria, that's the problem.

MEMBER RAMBASEK: Either one.

MEMBER STEWART: Yeah.

CO-CHAIR YAREMCHUK: But, I mean, I think the current guideline does say symptom more than 12 weeks. And so they have defined the diagnosis of what falls into that bucket of chronic sinusitis going forward. So I think those are all opportunities.

And I think also the issue of imaging is a problem, mostly because there's more and more evidence coming out about over-radiation and experience over a lifetime experiencing it. And I didn't realize this, but there's something going on with, quote-unquote, the epidemic of thyroid surgery. And the question is, there is some evidence that relates that to CT scans. And we always think, "Oh, it's only one CT scan," but over a lifetime, the dental, the CT and the others start to add up and that may be contributing to thyroid cancer.

MEMBER RAMBASEK: I have seen overuse of it as well, especially in children.

CO-CHAIR MERENSTEIN: The one other thing I would add is the ENT people seemed upset that we did not vote for their steroids for serous otitis, but if you look into viral pharyngitis, I think it's probably a much higher rate of steroid use than on serous otitis.

MEMBER STRODE: Is there a problem with inappropriate prescribing of hearing aids

for adults? And if somebody's paying out-of-pocket, that's their privilege. But if your health plan or the feds are paying for it, then it becomes a different issue. Is that an issue or not?

CO-CHAIR YAREMCHUK: I mean, I'm only going to say hearing aids aren't a covered benefit for Medicare. So they don't pay for hearing aids. I don't think they pay for glasses either, do they?

MEMBER YOUDE: I like where you're going with the hearing aid discussion. There is a big difference in care between those who -- or not difference in care, sorry -- a difference between those insurances that pay for hearing aids and those who pay out-of-pocket on the rates of people getting hearing aids.

So, people with insurance typically get the hearing aid, it's paid for, no big deal. But when you are out-of-pocket, it becomes a is this absolutely a necessity to do? If it's not a necessity, it could be perceived as a luxury

because these are not inexpensive devices.

And I would actually take a different angle on it, saying let's look at the care being -- or not the care, but the fit of the hearing aid rather than the prevalence, if you will, between the two different populations, where some audiologists do real ear measures on a fitting, others will be just like, "Hey, do you think this sounds good? Are you hearing better?"

And so there's a huge difference where best practice indicates that you should always be doing real ear at first fit. And so it goes along with what Tammy was saying where let's perhaps put in a process metric where we're saying -- a very simple one, best practice indicates real ear should be done at all first fits for all adults unless there's some sort of pathology going on where you can't actually get the hearing aid in the ear, in which case you'd be doing a BAHA or something else.

But is real ear being done or not? And then we can start there and then we can build

off of that saying, "Okay, is it to target? If it's not to target, why?" And start building off that, much like we're building off of the IFSP enrollment status.

MEMBER STRODE: So do I understand that as doing some audiological testing at that fitting and not just, "Gee, you're better now that you've got that stuck in your ear?"

MEMBER YOUDE: It's not necessarily audiologic testing. When I hear audiologic testing, I think of like a hearing test, you know, "Raise your hand," that type of thing. When I'm thinking of real ear testing, what we're actually doing is putting a probe mic in the ear and we're fitting the hearing aid to prescription, if you will. And so we're inputting the hearing test and then we're measuring the output of the hearing aid to make sure the output matches the appropriate amplification for that hearing loss.

CO-CHAIR MERENSTEIN: Judith, do you have a comment?

MEMBER LYNCH: No.

CO-CHAIR MERENSTEIN: All right. Josh?

MEMBER STEIN: For the ENT folks in the audience, are there any surgical procedures that might lend itself well to quality measures? Or any reason why there aren't any that are either being proposed or under consideration?

MEMBER GOLDBERG: Stapedectomy has been held up as one. Once upon a time, most otolaryngologists were trained to do ear surgery, including stapedectomy, and now it appears that only otolaryngologists who have done otology fellowships should be doing them. And the outcomes from those cases could be measured.

CO-CHAIR YAREMCHUK: I mean, I think tonsillectomy would be one. And I think tubes would be the other one that could be measured. And I think we'd get a large number of providers within ENT that do that.

MEMBER STEWART: And sinus surgery. Getting beyond the indications with complications, appropriateness.

MEMBER GOLDBERG: Especially appropriateness.

CO-CHAIR MERENSTEIN: Andrew, any comment?

MEMBER SCHACHAT: I was going to ask if there are crisp, agreed-to outcome measures for those surgeries?

CO-CHAIR YAREMCHUK: I think it's more based on indications in terms of tubes and for tonsils. When Micky's talking about sinus surgery, I think it's return to operating room, 30 days. And the one thing we didn't talk about it, and we've kind of, but is the issue of patient satisfaction or shared decisionmaking or that kind of thing.

How many people that have sinus surgery are happy afterward? Because there's a whole lot of it going around, and I don't know if you see, but I see patients back that go, "I didn't get any better. I don't feel any different." And so I think there's two parts. Are you operating on the X-ray? Are you

operating on the patient? And does the patient feel better afterward?

MEMBER GOLDBERG: And patient-reported outcomes are very important.

DR. WINKLER: I have pages, so, thank you. We should be able to write something very nice about it. So, we do appreciate it. And we do look forward.

So, the other ask I have of you is, wherever you're out there in your home, think about how your practice may be being measured. Are there measures being used in your realm that potentially is something that could be a measure that could be more broadly applicable and rise up to a national level that could augment this portfolio?

As I say, one of your roles on the Committee is to oversee this portfolio. And so it's not just what's in it, but also help us solicit and drive the things that should be in it. And so those sorts of feedback and input is very valuable. And your discussions with your

colleagues and what's going on in your world can help kind of drive this thing as well. And so we do kind of ask that of you as you leave this little room and go back to your practices.

CO-CHAIR YAREMCHUK: I guess the only other thing I wanted to say was we talk about this in terms of PQRS, we talk about this for public reporting, but I'm going to say, as a specialty, one of the other things, one is maintenance of certification. You have to practice improvement module. So some of these measures could be used for that.

The other part of it is, if you are in a hospital, there's FPPE and OPPE, which are Joint Commission requirements. Focused Practice Performance Evaluations and Ongoing Practice Performance Evaluations. And the idea being that you just don't rely on your credentialing cycle, but that there's an ongoing measurement of each provider in terms of the procedures they're doing and what they're doing.

And I don't know, Micky, if you have

anything to say for your department or your institution in terms of doing this, but as ENT, I'm struggling with coming up with measures for people that are on staff at University of Michigan, anybody else that's on staff somewhere, on how they're dealing with those requirements.

Josh, you're nodding your head, are you --

MEMBER STEIN: I just had a follow-up question. How expensive is it for someone to bring a measure to you guys for approval? I know there's obviously a lot of paperwork involved.

DR. WINKLER: That's variable. It depends. I mean, there are organizations, such as NCQA, Joint Commission, PCPI, that's their business. So there are the costs of just having people around doing business. The expertise required to develop a measure is somewhat specific. The type of specifying a measure, understanding data elements and calculation algorithms, understanding evaluation of reliability and validity for measurement, you

know, doing some basic testing in the field for feasibility.

So, those costs are going to be highly variable. Bringing it to NQF costs you nothing. We do open calls for measures, you fill out the form, you're there. But the actual getting the information, taking a concept, fully specifying so you have good, crisp, coded data elements, there are people who are skilled at this. And you don't do it over lunch on the back of a napkin. So there is some element there.

But in many large systems and big institutions, you've got people kind of doing that. So it really depends on where that might be coming from. And we see measures developed from within universities. Not a huge number of them, but we do see that. As well as the more traditional professional societies are becoming big in that. But also the traditional measure developers.

But often some of the big, big systems, and that's not here -- I'm an old Kaiser

doc, so I know that they've got their own system. Some of the bigger systems -- how about Michigan, you got measures you're doing internally? Yeah, I mean, so the question of whether you could respond to the questions to meet the criteria, we'd welcome it.

All right. I think we may have exhausted that, but we're supposed to do public comment one more time.

MS. LUONG: Operator?

DR. WINKLER: Just check and see if any of us --

MS. LUONG: Hi, Operator. Can you open up the lines for public comments?

OPERATOR: Okay. At this time, if you would to make a comment, please press star and then the number one. There are no public comments at this time.

MS. LUONG: Thank you.

DR. WINKLER: So, anyway, thank you all very, very much. It's been enjoyable meeting all of you. We will be in touch and we will have

follow-ups and we'll let you know. And so Vy's going to tell you what comes next.

MS. LUONG: Okay. Great. I know I said this earlier and I'll be brief. Thank you again so much. We really appreciate the thoughtful discussions for the past two days. As a reminder, in two weeks we will be convening on June 22nd for the post-meeting call. Following that is the draft report for commenting. That will be posted on the ENT project page from July 10 to August 10. So feel free to share this within your network.

There will be another call in August to review the comments from the commenting period. We then will have an updated draft report with redlines based on the comment call, and that will be posted for membership voting in September.

After membership voting, we will go to CSAC in October. Following CSAC, we will go to the Board for measure ratification of the measures in this project, and that's in November.

And then the project will wrap up with appeals from November to December of this year. And we expect to have the final report published on the NQF website early next year.

So thank you again, everyone, and we look forward to speaking with you in a few weeks.

DR. WINKLER: Thanks, everybody.

(Whereupon, the meeting in the above-entitled matter was concluded at 1:55 p.m.)

F

G

M

T

W

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: 06-04-2015

Place: Washington, D.C.

was duly recorded and accurately transcribed under my direction; further, that said transcript is a true and accurate record of the proceedings.

Neal R. Gross

Court Reporter