NATIONAL QUALITY FORUM

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PATIENT SAFETY MEASURES
STEERING COMMITTEE

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FRIDAY
OCTOBER 29, 2010

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The Steering Committee met at the National Quality Forum, Suite 600 South, 601 13th Street, N.W., Washington, D.C., at 9:00 a.m., William A. Conway and Lisa J. Thiemann, Co-Chairs, presiding.

PRESENT:

WILLIAM A. CONWAY, MD, Co-Chair, Henry Ford Health System
LISA J. THIEMANN, CRNA, Co-Chair, American Association of Nurse Anesthetists
ROBERT BUNTING, JR., MSA, CPHRM, CPHQ, MT, WellPoint
ELLIS R. DIAMOND, MD, American Academy of Neurology*
DONALD KENNERLY, MD, PhD, Baylor Health Care System
CLIFTON KNIGHT, MD, Community Hospital of Indiana
STEPHEN T. LAWLESS, MD, MBA, Nemours Foundation
ALAN LEVINE, Consumers Advancing Patient Safety
STEPHEN E. MUETHING, MD, Cincinnati Children's Hospital
JANET NAGAMINE, MD, RN, Society of Hospital Medicine
PAUL NAGY, PhD, University of Maryland School of Medicine

PRESENT: (CONT.)

DAVID P NAU, PhD, R.Ph, CPHQ, Pharmacy Quality Alliance
PAUL R. SIERZENSKI, MD, Christiana Care Health System
DANIEL SOLOMON, MD, Brigham and Women's Hospital*
IONA THRAEN, MSW, Utah Department of Health
DAVID E. TURNER, MD, PhD, MPH, Monsanto

NQF STAFF:

PETER ANGOOD, MD
HEIDI BOSSLEY, MSN, MBA
ANDREW LYZENGA
ELISA MUNTHALI
LINDSEY TIGHE
JESSICA WEBER

ALSO PRESENT:

CHRISTOPHER BEVER, MD, MBA, American Academy of Neurology*
RON GABEL, MD, AAAHC Institute for Quality Improvement
NAOMI KUZNETS, PhD, AAAHC Institute for Quality Improvement*
REBECCA SWAIN-ENG, MS, American Academy of Neurology

*Participating via telephone

C-O-N-T-E-N-T-S

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

9:08 a.m.

CO-CHAIR CONWAY: Okay, good morning. Why don't we get started? Welcome back. Hope you all had a good night. I think we could probably forego Committee and--first of all, Operator, if you could open the lines to the public, and we probably don't need to do the Committee introductions.

We have on the phone today, Dr. Solomon is back again, bless his heart, and we found Dr. Diamond, we were able to connect, so Dr. Diamond is on the phone.

And we have two guests for the first part of the morning. The first is Rebecca Swain-Eng--Rebecca? Are you--right there. And she has Dr. Bever on the phone, both from the American Academy of Neurology, who are the measure proposers for the first section this morning.

So, if we could, maybe we could begin with Rebecca, you or Dr. Bever

introducing the whole section here. Please.

MS. SWAIN-ENG: Dr. Bever, this is Rebecca. I'll start the conversation but feel free to jump in.

DR. BEVER: Thank you.

MS. SWAIN-ENG: Okay. Well, good morning. Thank you for reviewing our measures. You'll be reviewing four of the American Academy of Neurology's measures today. Two are from an epilepsy measurement set, which is part of a larger measurement set of eight epilepsy-related measures.

And, two of the Parkinson's Disease measures are part of a larger set also; there are a total of ten Parkinson's Disease measures.

To give you just a very brief background, I know you're all quite familiar with the measures, but more on the methodology, how we developed the measures. The American Academy of Neurology worked with the Physician Consortium for Performance

Improvement and followed their methodology to develop the epilepsy measures.

The AAN was the first independent measure development project run through the PCPI where, what that means is the PCPI provided us with the methodologist, with some limited support, but the AAN maintained copyright and kind of oversaw most of the measure development process.

We had a very broad stakeholder group of representatives from health insurance providers, with representatives from patient advocacy groups as well as multiple different physician organizations.

And I think the first measure that we're talking about this morning is going to be the AED side effects measure. And this was reviewed briefly at the TAP, gosh, about a month or two ago.

And some of the concerns I know that were expressed at that time were focusing on whether or not a Council measure could

actually lead to improved quality outcomes. I know, after doing a review of what NQF has endorsed in the past, NQF has endorsed seven counseling measures in the past.

And, I know that, I was at a talk yesterday for the American, or, AQA alliance, and Don Berwick was there and was supporting a smoking cessation counseling measure. So that goes to show you there is support for those counseling measures out there and we think this first measure, which is the AED side effects measure, is a very useful measure.

It's supported by seven Guideline recommendations, five of which are A-level recommendations from papers and a few other Guideline developers. Don't know if you want me to go further, talk about the additional measures, or stop there.

CO-CHAIR CONWAY: If you could just outline the whole four measures for us.

MS. SWAIN-ENG: Sure. So, the first measure is querying counseling about anti-

epileptic drug side effects. And this measure is focusing--the patient population is all patients with a diagnosis of epilepsy and within the materials that you have, it does include the relevant CPT and ICD-9 codes in the packet.

The numerator is a patient visits, a patient queried and counseled about anti-epileptic drug side effects and the querying and counseling was documented in the medical record.

There is a medical exclusion that would be relevant for this particular measure, for example, if the patient was not receiving an AED or the patient was unable to communicate and there was no informant available to do the counseling with.

The second measure that you'll be discussing this morning is a counseling about epilepsy-specific safety issues. This measure is supported by two Guideline statements, and this measure, again, the patient population is

going to be all patients with a diagnosis of epilepsy.

The numerator statement is patients or caregivers counseled, counseled about context-specific safety issues appropriate to the patient's age, seizure type and frequencies, occupation, leisure activities, et cetera.

Examples would be injury prevention, burns, appropriate driving restrictions, or bathing at least once a year. There is a system reason that would be applicable for this measure, for instance if the patient was unable to comprehend counseling about safety issues.

This measure was, the rationale behind the measures, there's specific safety issues that are relevant for those with epilepsy, excuse me, specifically dealing with driving and dealing with bathing and other issues.

And with the Guideline

recommendation support, the work group, which consisted of about twenty-six different members, felt this would be a very important measure for patients with epilepsy.

The third measure that you're going to be discussing this morning is a Parkinson's Disease measure. This is a measure that's entitled Querying About Falls. This measure, the eligible patient population are all patients with a diagnosis of Parkinson's Disease.

The numerator statement reads, patient visits with patient or caregiver queried as appropriate about falls. There are four Guideline recommendation statements that support this measure.

And the rationale behind this measure, I know there are other falls measures that do exist, but with Parkinson's Disease, there are specific concerns. And we wanted to specifically target the patient population of those diagnosed with Parkinson's Disease.

And the last measure that you'll be discussing this morning is Parkinson's Disease-related safety issues counseling. Again, the eligible patient population are those with a diagnosis of Parkinson's Disease.

And, similar to the epilepsy measure, this was developed right after the epilepsy measurement set was developed, so you can see a little bit of the same wording in this measure. Patients or caregiver as appropriate were counseled about context-specific safety issues appropriate to the patient's stage of disease, including injury prevention, medication management, or driving at least annually.

And there are five recommendation statements that support this measure as well. Similar to with Parkinson's Disease that there are specific issues that are related to the disease that affect falls, there are specific issues, overall safety issues that the panel felt were very important that warranted a

specific measure that looked at safety issues counseling, counseling them about injury prevention, medication management, different aspects that may affect their ability to live a healthy and normal daily life.

And Dr. Bever, do you have any additional comments?

DR. BEVER: No, I think that covers it.

CO-CHAIR CONWAY: Great. Thank you. And, Rebecca, you can stay there in case there's additional questions. Our primary discussion leader is Cliff Knight.

DR. KNIGHT: Yes, specifically for the first one. Then, on this one, it does look like it's got two components. It's got querying and counseling about anti-epileptic drug side effects. And then documentation of that in the medical record. So this is a process measure.

As I looked through this, apparently there's not been any testing

completed yet on this process or exactly how that would be documented and reported.

And, under the gap, in demonstrating performance, the focus was really on the variability of diagnosing and treating and so I didn't see any demonstrated gap that -- measure gap, I guess, in current practice as far as a deficiency there in that counseling.

So, those were a couple of things that I noticed as I looked at that, was that evidence then that would really show that that would effect an improvement in outcomes.

CO-CHAIR CONWAY: Great. And Steve, do you have anything to add?

DR. MUETHING: Just a couple comments. We had a chance to discuss it beforehand, so I think we're aligned in how we're thinking about this. It is a relatively large impact in that the evidence shows there's three million or so individuals with some version of epilepsy and about ten percent

of those are kids.

The gap: I agree there's no evidence that there's a gap. It was inferred somewhat by the array of providers that care for patients with seizures, so it was inferred that there most likely is a gap.

They did comment about the disparity that there's an increase in incidence of epilepsy amongst minorities, and the issue about does counseling positively affect the outcome, the evidence for that is expert opinion, but it is the expert opinion that it does relate to the outcome.

And it was recommended as, mentioned that, I believe there was at least four different countries' Guidelines that had recommended this type of counseling on an annual basis. I have the same concerns about the lack of testing.

I believe there's some testing supposed to be underway in some clinics. I believe the methodology they're recommending

is a sampling. But again, the testing is not complete.

And then I have some concerns about the usability and just, if it's going to be expected of every provider who cares for patients with seizures, or is this specific to neurologists?

And then there was a comment about the usability, that it would somehow be tied to maintenance of certification, I believe, down the road. So that's my comments.

CO-CHAIR CONWAY: Okay. Thank you, Steve. Questions or comments from the Committee members? If we could follow the process of yesterday, of putting our nametags sideways.

MR. LEVINE: Yes, in the background material I noted there's a high mortality rate of 25,000 to 35,000 individuals with epilepsy will die this year. Is that from, do we know what that's from? Is it issues related to patient safety, or is it comorbidities, or is

it basically an issue with their disorder, neurological disorder?

MS. SWAIN-ENG: I believe it was issues related to their epilepsy diagnosis.

MR. LEVINE: Okay. I was struck by the 30 to 40% of people with epilepsy have seizures despite treatment. I didn't realize that was quite as significant as it is. Anyway.

CO-CHAIR CONWAY: Iona?

MS. THRAEN: This measure is specific to AED side effects, and then the second measure that follows up is a broader category of epilepsy-specific safety issues?

MS. SWAIN-ENG: Correct.

MS. THRAEN: It seems like this one is a subset of the second. Can you comment on why this has been pulled out as a single measure versus not incorporated into the, as a subset of the second one?

MS. SWAIN-ENG: Sure. I will. Dr. Nathan Fountain was the chair of this

workgroup, who's a lead epileptologist who works, he's out of--I'm blanking, Virginia somewhere. And he, as well as the rest of the workgroup, felt that this was such a significant problem for the patients that they saw, that they weren't getting proper treatment for AED side effects, that this wasn't being asked on a regular basis, which was really leading to detrimental outcomes for their patient care.

And they felt that with the additional safety issues counseling that addressed additional issues that were so, as important as the AED side effects measures, and with this specific measure they felt that maybe somebody would choose to follow the AED side effects measure and not choose to follow the safety measure.

And they wanted to make sure that they were trying to reach the broadest, have the biggest impact by having those two measures, so they have the one that's focused

specifically on AED side effects because of the high levels of evidence with the five level recommendation statements and the two additional recommendations that go to support that.

As well as the patient safety measure, there are so many other things that are so specific to epilepsy that they felt were crucial to ensuring high-level patient care, they wanted to include those in a separate measure.

They realized, and we did discuss this quite extensively, there is some overlap there but they felt there would be different physicians that might choose to use one measure over the other, and that both measures were equally as important, so they left them both in the measurement set.

MS. THRAEN: And then just for clarification, this one does have a CPT code specific--is that correct?

MS. SWAIN-ENG: It has a CPT 2

code, and then it has specific--

MS. THRAEN: CPT 2 code.

MS. SWAIN-ENG: --which is, let me look, 6070 F. We did take these through the PMAG for review and they were approved-- gosh, when was that? February of 2009. And we did approve those. And then there was specific CPT codes and ICD-9 codes for the measures.

If you note, when you look at the measures, if you've reviewed the CPT codes, we're not focusing on those with seizures. We're focusing on those actually diagnosed with epilepsy. So there's some difference there.

So if someone has just one seizure, they're typically not diagnosed with epilepsy, they're just, it's noted with the different CPT code that they've had a seizure but they don't have the specific epilepsy CPT codes noted in their medical record.

CO-CHAIR CONWAY: Okay. How about David, Lisa, and then Janet?

DR. NAU: Sure. Perhaps you could clarify the intent of AAN developing this measure. Was it really developed for the purpose of maintenance of certification for neurologists? Was that sort of the original intent of why this was put together?

MS. SWAIN-ENG: So the academy has developed measures in the past for stroke and stroke rehabilitation, and then we've worked with the PCPI now on epilepsy and Parkinson's Disease. Maintenance of certification is part of the reason that we developed these measures, but it's not the sole reason.

One of the reasons that the Academy became a measure developer is that we felt that we could provide the most expertise with developing measures for neurological conditions. So we are trying to get these into a PQRI or a pay per performance type program.

Trying to get these incorporated into local system or regional quality improvement programming. I know we have one of

our physicians that's going to, or is in the process of incorporating all eight of the measures in the epilepsy measurement set into his system, and using it for an internal QI project.

And we do have these developed, in the process we'll be releasing in January a maintenance of certification project based upon the epilepsy and Parkinson's Disease measures that will be a web-based infrastructure that our physicians or anyone could choose to sign up and use these programs to earn their Part Four maintenance of certification performance and practice module credit.

DR. NAU: Sure. And with regards to the testing that was described that's going to take place, has that begun, or --

MS. SWAIN-ENG: Yes. We've got sites selected. WE have a testing protocol I know we've worked with the PCPI, I know Heidi was there, she can attest to this. We've worked

with Keri Christiansen at the PCPI.

We just finished up a stroke and stroke rehabilitation testing project and now we're doing two additional stroke measures in the radiology group and we're using the same methodology that we've used for stroke, applying that to our epilepsy measures as well as our Parkinson's Disease measures.

So we've got I think, five sites agreed for epilepsy so far and three for Parkinson's, and we're finishing up maintenance of certification so we can go right into testing and with our maintenance of certification we're hoping we can actually use some of the outcome data from that database that we'll be essentially developing to actually show more improvement data.

Because patients, what we'll be, the diplomates will be doing, it'll be looking at our measures, taking it pre- and post-test, seeing how well they do, figuring out where they want to do their intervention, meaning

picking which measures they want to reassess them at, themselves at, eighteen months later.

And then coming back and implementing those measures in practice and seeing if they actually do improve overall and then seeing if they get better scores and better patient satisfaction from using the measures.

DR. NAU: And the testing is done with neurologists?

MS. SWAIN-ENG: Neurologists. Well, I think they're specifically all neurologists currently. Neurological, I know we're working with Cleveland Clinic, we have one of our physicians there and a couple other large health systems, or physicians that are in large health systems, to do the testing.

DR. NAU: Okay. Thanks.

MS. SWAIN-ENG: Great.

CO-CHAIR THIEMANN: Rebecca, I have one question, just in follow-up. It's always been CMS's position regarding performance

measures that are picked up by PQRI that they should be applicable to anyone who can bill for services.

And so, as a provider who's not a physician, I'm just curious as to the limitation to just clinicians, MD/DO, for reporting for this, when there may very well be advanced practice registered nurses who may be engaged in caring for this patient population.

So is it the intent of AAN in this measure that this is only specific to physicians, or is it to all care providers?

MS. SWAIN-ENG: Currently it was limited to physicians simply just by the CPT and ICD-9 codes that are currently in the measurement set. This was something that we did discuss quite extensively when we had our in-person meeting as well as in follow-up conference calls.

We initially just wanted to get the measures out there and see how they were

implemented and then see if there really was the desire to have more advanced nurse practitioners or other individual clinicians that would like to use the measures, we'd be more than happy to have added additional codes that would allow them to use these measures in a PQRI-type program.

CO-CHAIR THIEMANN: As a follow-up, since that is CMS's perspective--position, as I understand it, I actually would probably recommend to AAN that they look at including those codes earlier rather then later, otherwise they may be at risk for not being picked up in PQRI.

MS. SWAIN-ENG: You know, that's really good to know. We haven't had that feedback before.

DR. NAGAMINE: My concern is in the usability, specifically the query and counseling. Who does it, and what does it consist of? So how do you operationalize this and know that it's happening in a manner that

you would like it to?

MS. SWAIN-ENG: This was purposefully left a little bit more open-ended so that it didn't have to be a specific type of querying or specific type of counseling. Because we felt that the physicians would have to use a clinical judgment to use the most appropriate type for the patient.

We understand, as it's currently written this is an administrative claims measure, it's a process measure. And this would create some burden, having to have someone go back through your records and look for specific information that would indicate that they did query and counsel them about AED side effects.

So, for example, if a physician saw a patient with epilepsy and he asked him, you know, have you had any side effects recently, and he said, well, yes, I'm having trouble driving, he might counsel him about maybe you should stop driving--or something like that,

would meet the measure.

So it's not specific on purpose, because they felt that the clinicians needed to have that leeway to use their clinical judgment to use the most appropriate counseling or query and counseling for the individual patient. So right now it is kind of vague just for that reason.

DR. LAWLESS: Yes. A couple things as actually a follow-up on the advanced practice nurses. I think that for most offices these days don't downplay the impact of advanced practice nurses.

I would actually say that probably most are actually doing this, and so the CPT code, the way you can bill it, it may not be reimbursed, which is a different issue, but they can actually put it down as a service provider rather than a billing provider.

And you can document it, but it's a growing field and I would think, don't, you will end up having less use because of that.

I'm a little bit concerned in your effective teaching or looking at the way you said it, in terms of effectiveness of teaching.

If counseling can vary from, I'm really having an effective teaching counseling session to, should I drive, no, don't drive, that meets the characteristic of this. I see a wide variety, and I would ask for a little more specificity about what required elements would actually be helpful or not.

Driving, and whether you should drive or not based on state regulations and things, would be a lot more of an effective teaching than, yes, you know, don't smoke, or something.

MS. SWAIN-ENG: Of course, of course. And I can see that'd be something that we might be able to be more specific as a measure is evolved and we do updates to the measure.

DR. LAWLESS: Well, I would include under the third piece would be in your

maintenance of certification trials, one of the things of Part Four of maintenance of certification is you have to look at your intervention and the impact on outcomes.

So that's a great opportunity to put that into the effectiveness of the teaching into the outcomes for the maintenance of certification, and that's where the testing would come in. Because otherwise you're not going to get the maintenance of certification.

MS. SWAIN-ENG: Yes, we do have that in our program, that will be coming out next year.

DR. NAU: Sure. And just a quick note, because we've talked about nurses, there are also a growing number of neurology practices that have clinical pharmacists involved in doing some of the same counseling functions about the drugs.

But my real, fundamental concern about the measure is that it's a two-part measure rolled into one, in the sense that

it's querying and counseling, which are two separate behaviors, which may occur on two separate encounters with the patient.

And so, I think that makes it even more challenging to really figure out how to appropriately calculate the numerator. Because if we're doing the retrospective chart review, and the patient was initiated on the drug, and, you know, the clinician said, yes, I advised the patient about potential side effects, well, that wouldn't include the querying components.

So I guess then we'd have to clarify, well, does that count in the numerator, or not? And I think that's where some of those issues would get cleared up in testing, understanding what makes the most sense.

And so that's where I'm a little bit concerned about the way this is specified. So I guess, have you actually tried to work through some of those issues of what would

count in the numerator or not?

MS. SWAIN-ENG: Well since this is what they call an "and" measure, you have to meet both parts to actually meet the measure. So you would have to do both the query and the counseling to actually successfully complete this measure.

We had discussed, you know, the reason why we included querying in there is because the workgroup felt that this wasn't being done, since there are, are a wide array of physicians that do see patients diagnosed with epilepsy, they felt this wasn't being done on a regular basis.

So if an epilepsy patient was just seeing their primary care physician every year and maybe an epileptologist every three to five years, they weren't being asked on this annual basis, are you having any side effects? And just the act of querying would prompt the act of doing some counseling.

So we felt they went hand-in-hand

and that you needed to have both in order to give optimal patient care. And this is, as you mentioned, this is something that testing will show us, whether or not if that comes back as being an issue and we'll reevaluate it at that time.

CO-CHAIR CONWAY: Dr. Diamond or Solomon, do you have any questions or comments?

DR. SOLOMON: No.

DR. DIAMOND: This is Ellis Diamond. My only comment would be that this is a measure that could be chosen as a measure by the neurologist to participate in. Other physicians, such as gynecologists and family doctors, do not have to choose this measure as one to be monitored on.

So there's an elective quality here, it doesn't effect everybody across the board who sees patients with epilepsy as it stands currently in its development. That takes the burden away from, you know, the

general population physicians who might see somebody who's got a seizure problem.

CO-CHAIR CONWAY: Other questions or comments from the Committee? Okay, shall we proceed to see where we stand on the importance to measure and report on this? In the, in 1A, the assessment of the impact of this measure, how many Committee members feel that was completely demonstrated?

Okay, we see none. How about partially demonstrated? Eleven. With myself, it would be twelve. Anyone feeling it was minimally demonstrated? Two? And, anyone here feel it was not demonstrated at all? Okay. And Dr. Diamond?

DR. DIAMOND: Partial.

CO-CHAIR CONWAY: Partial. And Dr. Solomon?

DR. SOLOMON: The same.

CO-CHAIR CONWAY: Partial. Okay. On the criteria of demonstrating a gap, how many feel that that was completely demonstrated?

Seeing none, partially demonstrated? Seeing none.

How about minimally demonstrated? Fourteen in the room. Anyone in the room feel it was not demonstrated at all? Dr. Diamond?

DR. DIAMOND: Minimally. I agree.

CO-CHAIR CONWAY: Okay. And Dr. Solomon?

DR. SOLOMON: Same.

CO-CHAIR CONWAY: Okay. And on the criteria for relationship to outcome, how many feel that that was completely demonstrated? Seeing none. Partially demonstrated? Three. Minimally demonstrated? Nine. And not demonstrated at all? Two. And Dr. Diamond?

DR. DIAMOND: I'm sorry. Yes, minimal, please.

CO-CHAIR CONWAY: And Dr. Solomon?

DR. SOLOMON: Same.

CO-CHAIR CONWAY: Okay. Dr. Solomon?

DR. SOLOMON: Minimal.

CO-CHAIR CONWAY: Minimal. Okay. All right. Now, in the overall category of the importance to measure and report on this proposed measure, we'll be voting yes or no. How many feel that this should be a yes? Please raise your hand.

There's six in the room. Okay, the chair has lost. How many feel that it has, yes? Would you raise all your hands again? Janet, what are you, a yes? Okay. Eight yeses in the room. How many nos? Six in the room. Oh, great.

Tell me what we do. Dr. Diamond?

DR. DIAMOND: Yes.

CO-CHAIR CONWAY: And, Dr. Solomon?

DR. SOLOMON: No.

CO-CHAIR CONWAY: Shall we move on? What's our rules of procedure here? Consensus doesn't support nine and seven, you know, but.

MS. BOSSLEY: This is Heidi. I think you need to discuss this more. So I think the only way you're going to be able to do that is

talk about the rest of the criteria.

CO-CHAIR CONWAY: Okay.

MS. BOSSLEY: Which is great. Now you can do that. This is good.

CO-CHAIR CONWAY: That's good. Okay. This group has not been there yet.

MS. BOSSLEY: At least face to face.

CO-CHAIR CONWAY: All right. Do we want to pause and discuss a little bit more here, or should we move on and vote on the specifications? Go through each one? Okay. Okay, let's move on and get a sense of where we are on the measure specifications.

And where is the pre-voting? Well, wait a minute. Okay, great. On measure specifications 2A, is the adequacy of how precisely this was specified, how many feel it was completely specified?

Okay. Okay. Why don't--okay. Let's discuss the measure specification first. Any questions or comments about that? David, are

you up or down on that card? Okay. All right. Lisa?

CO-CHAIR THIEMANN: My card isn't going to stand up. So I guess I'm not allowed to say anything. Questions about, and I realize that the measure hasn't been tested yet. But it's my understanding that currently it would be manual chart extraction, in order to capture the data right now.

And so could you describe a little bit about that and the actual level of burden of data collection on providers who choose to participate in this measure if it was endorsed by NQF, and then describe any future plans for transition into electronic data capture, because ultimately that's where NQF would like to go.

MS. SWAIN-ENG: As you just mentioned, right now this is going to be a chart abstraction measure and we realize that will cause some burden to physicians to actually abstract the data or to their, if

they have a claims person that helps them or if they have an administrative assistant that will have to kind of help them get the record and look through it for the actual statements that say they did meet this measure.

We are in the process of trying to develop electronic health record specifications. This is something that's quite new for the academy as well as many other specialty societies and organizations, to develop EHR specifications.

Right now, we're actually working on a project with the PCPI for a different measurement set, dimension measurement sets but developing EHR specifications for those measures. So, as we go through that process, it's helping us learn how we can best develop the EHR specifications for the specific measurement set.

And that's something that we really are, it's one of our priorities to do, because of the high rate of burden that this may place

on certain physicians because they have to do that chart abstraction.

CO-CHAIR CONWAY: Iona?

MS. THRAEN: I need a little clarification, and this is showing my ignorance about the CPT codes. You have CPT code category two, with a numerator and a denominator, and so it was my understanding looking at this that this was actually an electronic administrative claims opportunity.

How does that then--were you just talking about the testing right now, that you were going to do the chart abstraction?

MS. SWAIN-ENG: So right now, what's in here, there are--I'm not sure what you know about CPT 2 codes, basically what a CPT 2 code is, actually for the numerative statement. So, instead of having to write out the huge statement that the patient was queried and counseled about AED side effects and it was about driving and so on and so forth, you could actually list in your medical record the

CPT 2 code which is the 6070 F which indicates that you did meet the numerative statement for this part of the measure.

MS. THRAEN: Okay.

MS. SWAIN-ENG: That is not something that is in a lot of electronic health records, not many physicians actually, at least when we have dealt with this, dealing with our neurologists who are actually using CPT codes in their practice, it's something they'd have to get approval from, if they work for Kaiser or for another large health system, to actually get incorporated into their electronic health system.

It's something that facilitates medical record chart abstraction because they can look for those four numbers followed by the letter F and know immediately that that physician, whoever's doing the chart abstraction, did actually perform this measure, because they recorded that code in there, in their documentation.

But it's something that, at least dealing with our physicians, hasn't been something that's been able to be searchable in electronic health record from Epic or any other groups. That just, really, right now--

MS. THRAEN: So it's not a billing code?

MS. SWAIN-ENG: No.

MS. THRAEN: Okay.

MS. SWAIN-ENG: It doesn't indicate billing, it doesn't have an RVU value or anything.

MS. THRAEN: Okay. That was my confusion. I thought it was a billing code.

CO-CHAIR CONWAY: Janet, and then David.

DR. NAGAMINE: In terms of the specs and the focus on just neurologists, was there discussion or intent to broaden the providers including pharmacists, nurses in advanced practice? Or, or will it remain focused on neurologists?

MS. SWAIN-ENG: Well, it wasn't focused just simply on neurologists, it was also focused on any other physician that may see a patient specifically for epilepsy. So we had family care physicians that were on our group, we had pediatricians.

We did have representatives that, from radiology because of the measurements, that there were some MRI, EEG, CT, and so on, measures that were included in the measurement set. At the time, we were focused mostly on the physicians, because at the time we felt that those would be the people that would be more likely to use the measures.

In retrospect, looking at it, you know, specifically hearing more that CMS does like to have the advanced care providers included, I don't think the group would have any problem including additional codes that would allow them to use the measure.

MS. THRAEN: Okay. Thank you.

DR. NAU: Just to follow that vein

of thinking, you know, the CPT 2 code could be added to any encounter within the physician encounter provided that then the nurse or pharmacist was in the practice and working as part of the practice.

And that could be included, so it still could be included as part of that encounter. But the challenge then is, you know, what if the nurse or pharmacist isn't in the actual practice as part of the standard counseling and querying process? Then none of that's going to be captured.

So I think this would give an indication for assessment of the neurologist's practice, of whether they were making sure it got done. But a lot of counseling and querying about the medications may take place at the pharmacy or elsewhere.

So I think that's where it gets a little tricky in terms of interpreting the findings. So I think that counseling about these issues and querying about them is very

important.

I'm concerned, without any testing data, whether we know how, what the actual burden is, and what the accuracy and reliability rate really is of this measure.

CO-CHAIR CONWAY: Okay. Let's work our way down the table and around, starting with Steve.

DR. MUETHING: Thanks. And this probably reveals my ignorance on measurement development, but if I understand it, the intent is to understand what percent, or, what percent of patients that have epilepsy are counseled on AEDs.

But the denominator says it will be all visits for patients with a diagnosis of epilepsy. So I'm not clear on how that will work with the denominator being all visits.

MS. SWAIN-ENG: So, if you're familiar with other measures, some measures may be once a year or annually or once within the measurement period. The

temporality of the measure was something that was heavily discussed for this measure because it is more burdensome because we're asking every time that a physician would code for the specific CPT codes that they're listed in this measure itself that they do ask about any AED side effects every time they're seeing that patient for an epilepsy visit, even if there are family practitioner who's seeing them more often than their epileptologist they are going to ask them.

SO the patient population that's eligible is still those that are diagnosed with epilepsy according to the CPT code or, excuse me, ICD-9 codes that are in the measurement set.

The temporality is, every time you see that patient with the measurement set which is usually a year, from January 1st to December 31st, that you do ask them. So if you see them three times that year, we want you to ask them, have you had any side effects since

the last time I saw you, because that may lead to medication adjustments that may lead to additional counseling.

That, maybe, they haven't had a seizure for three years and then you see them January, they still haven't a seizure, you see them in March, they have had a seizure, maybe you need to reconsider driving or other issues that may be related to any side effects that they've had from their medication combined with any sort of any other indications that's going on for how their treatment's being handled.

And there are additional side effects that they get from the medications that they're taking that may lead to other issues that they need to be addressed by the physician seeing them.

DR. MUETHING: So if I see them twice in a week, and one time I counsel them and the other time I don't, is that 50%?

MS. SWAIN-ENG: No. So this is, if

you're looking at the measurement period for a year, in order to meet the measure you have to counsel them at every visit in that measurement period in order to actually meet the measure, which adds another, you know, level of complication to it.

And this again was something that was heavily discussed by the, the expert panel and they felt that it was so important that they really needed to be done at all visits.

DR. MUETHING: Thank you.

DR. SIERZENSKI: I understand the querying component needs to be verbal. The question is, does the counseling component need to be verbal?

There's a great move towards automated and as an emergency physician, we do a lot of automated discharge instructions that are a plethora of information. So, would an automated prompt suffice in the counseling component?

MS. SWAIN-ENG: As long as it was

documented in the medical record, yes, that you gave them something or that you know that this was going to be automatically given to them by the nurse before they are discharged, or -

DR. SIERZENSKI: Okay, so, so, once again, I mean, we see a lot of patients with a seizure, because when they seize, they call 911 or someone does. Every patient that gets discharged, if they have an, you know, if there's drug on there, there's a listing of side effects, or with epilepsy there's a discussion generally on most of these.

Is there then a requirement to additionally document that you know that you've provided them that, versus the fact that it is part of the medical record as a discharge instruction?

MS. SWAIN-ENG: If it's for measures generally, if it's not documented in the medical record, it didn't happen, even though it may have. That's one of the complications

with measures that has to be documented, there has to be some sort of proof.

If you can document that you know that your patient who comes into the E-D with a diagnosis of epilepsy not just having a seizure but actually has a diagnose of epilepsy was given discharge information on epilepsy something or other, and you have that documented in the medical record somewhere within that chart report and it's signed off by the physician, that would qualify.

CO-CHAIR CONWAY: Let's work our way up the left side of the table, starting with Alan.

MR. LEVINE: I have a high proportion of people that have epilepsy who are over 65. I was surprised that, almost 600,000 out of three million are on Medicare. And, as a Medicare patient myself, I believe -- oh, I'm sorry -- as a Medicare patient myself, I believe I'm entitled to get one full physical a year.

It would seem to me, it just, I would expect to get those kinds of questions during the exchange with my primary care physician. So the question is, why do we need specifically to hold my primary care physician accountable for something that he should already be doing?

MS. SWAIN-ENG: Well, it's -- well, first of all, these measures, in order to be eligible, you actually have to use one of the codes for epilepsy. So if your primary care physician is not seeing you for something, maybe they're seeing you for headaches or something not related to epilepsy and they didn't use the epilepsy code within your, within their medical record.

They wouldn't be dinged, as some people call it, for not completing the measure because they're seeing you for a different issue. The reason that they want to, that the supplies to the family practitioner is that that, that person may be the only person that

sees you that year.

You're not going to see your epileptologist. And so we wanted to make the measure more broadly available in the physician community so that other individuals who are taking care of you and maybe perhaps seeing you more regularly can help monitor your care, so that if you are having any side effects from an AED that can be more closely monitored and you can get better patient care. Does that answer your questions? Okay.

DR. LAWLESS: I've got two things, actually. One with the CPT. I would gather that most people, most physicians, are using as part of their current high level complexity or higher level CPT, that they fund counseling.

And that's one of the justifications behind going to a higher level CPT. Have you addressed the potential as the academy, there's the potential that there may be pushback? Because if they document with a

CPT 2, they may have to then down code on their primary CPT because that's not included in that counseling.

MS. SWAIN-ENG: No. There's, I don't believe We've heard of any physician having that issues. With the CPT 2 code, those are completely optional. Those are something that shouldn't impact at all with the diagnosed for CPT 1 code, because that's going to be the billing code that's going to come back to them.

DR. LAWLESS: But does CPT -- the characteristics of a CPT, if you go to a higher level, if you go to the CPT book --

MS. SWAIN-ENG: Yes.

DR. LAWLESS: Part of that will be his comprehensive history, I've done some counseling, and the word counseling is sometimes, and, and some discussions about things.

So I'm just saying is, there may be, as it rolls out, out of the academic world

into the primary world, they may say, wait a minute, why am I going to a four level down to a three level, because I've, you've done it, you've documented by an EPN or some, or pharmacist, those exact things.

I would just, I'm just saying there's a potential pushback from that --

MS. SWAIN-ENG: Okay.

DR. LAWLESS: The other thing is, with your ICD-9, ICD-9s you've chosen, why didn't you chose them for that they could be comorbidities? They're all primary ICD-9 codes for seizures, which makes it look like a primary diagnosis, to the point that, Mr. Levine mentioned.

Could it be also the codes or some comorbidity condition?

MS. SWAIN-ENG: The reason that these specific ICD-9 codes were chosen is that the, the recommendation statements are coming from guidelines that are specifically on epilepsy, those with a diagnosis of epilepsy,

not having, talking about the comorbid conditions.

And we reviewed those as workgroup and the workgroup felt that those were the ones that, those ICD-9 codes most relevant, relevantly applied to the recommendation statements from the guidelines as the, being the appropriate, eligible patient population.

MS. THRAEN: I wanted to followup on two things. Two of the logics have just been discussed. One is the discharge instructions. And, related, this is a medication specific side effect question, and how does the information that comes from the pharmacy when you go to fill your medications, that advise you on side effects, et cetera, play out in this scenario? That's the first question.

And then the second question related to the coding, more complicated upcoding for counseling and more complex care, why wouldn't that count from and electronic billing perspective as a way of being able to

monitor what's going on with the patient in relationship to this measure?

MS. SWAIN-ENG: Sure. So for your first question, you're asking about would a pharmacist who counseled a patient about AED side effects, would that counseling count as part of the measure.

And as we've discussed a little bit this morning, right now, the measure is focused primarily on physicians, and we're actually looking for physician process improvement, so it's the physician process, it doesn't include the pharmacists at this time.

So that would not count unless the physician were to be there with the pharmacist and actually do the, and review the medication with them. More than likely, that's not going to happen, so at that time, that pharmacist counseling does not count for this measure.

As to your second question, I realize that as you work through the CPT coding as you get into the higher levels

that's supposed to include the counseling.

However, as I mentioned earlier this morning, unless it's actually physically documented with words, as the measure is written now, because it is a chart abstraction, it has to be documented with saying they did some sort of querying and counseling in the measure.

Not just indicating that you used a higher CPT code, necessarily mean that you actually did the querying and the counseling for this specific measure. But it could be something that could be looked at more closely when we get our testing results back and see what CPT codes were actually used and if that did indicate more readily that they did do the counseling with the measure.

MS. THRAEN: To me, if that's a possibility, that that offers the opportunity to decrease the burden, to achieve the same end that you're trying to achieve. So that's the first thing.

But, going back to the pharmacy side effect questions, it strikes me that I understand the desire for physician improvement, performance improvement, but I also recognize that there's a team of folks caring for patients and that it sort of, the pharmacy component of filling your meds and getting, getting the information and the question that they always query, do you have any questions about the medications that you are receiving, have you taken these before, et cetera.

So there is a, a team component of this that is being either rightly or wrongly shifted over to the physician and not being acknowledged in this process. And the electronic medical records systems are moving towards pharmacy, claims data, integrated systems, opportunity if you wanted to look at least at a population perspective.

And I'm speaking from Utah's perspective because we've got all patient, all

payer data now. The opportunity to look at a population and just see how well this is being played out, both from the pharmacy perspective and then from a billing perspective. I think that, that's less onerous than chart abstraction, et cetera, that you're moving towards.

MS. SWAIN-ENG: Definitely and we discussed, you know, whether or not to create this as an individual physician level measure or to create it as a system level measure, which would take into account the system as a whole and all of those players that kind of integrate into it.

And that, again, the workgroup came back and said right now they felt like this was not something that was being done by physicians, specifically, and that was leading to detrimental patient outcomes and so they wanted to focus on this measure specifically in the, in the physician patient -- physician population to crease the, the, the times that

they are actually asking about side effects and then giving appropriate counseling for their patients.

And I completely agree, you know, would reduce burden if you had more of the system level. But that's something that maybe we could look at in the future, developing either an updated or a newer measure that would in turn be a more of a system level measure.

I know for our patient population talking about our members who are neurologists, only I believe it's 6% of practices and 3% of neurologists do have an electronic health record at this time. So for them it's a very, very low number and they don't have access to a lot of those electronic health records, medical systems that would aid them like your, in Utah, you said in your area you're able to see all that payer data.

Lot of neurologists don't do that, and again, this measure isn't directly solely

for the neurologists but, you know, this is neurological condition so those are going to be the, be the experts that we'll be seeing as patients more often than not.

MS. THRAEN: I have another question, but I forgot.

DR. NAU: Sure, and I just wanted to make sure I'm clear on the denominator in this. Form, it says that the denominator is basically any patient with a diagnosis of epilepsy. But just to get more specific, you're suggesting that would be really any encounter where the primary ICD-9 is for epilepsy --

MS. SWAIN-ENG: Correct. Yes.

DR. NAU: -- so, if it was listed as a secondary ICD-9, that encounter wouldn't get counted in the denominator, is that correct?

MS. SWAIN-ENG: If the diagnosis is listed in the medical record, it would be counted, actually. I believe. I could be wrong

on that. I am not an ICD-9 expert in that manner.

But if it, if the ICD-9 is not listed at all, and it is somebody with a diagnosis of epilepsy then the measure wouldn't count for that patient. I can double-check that fact for you on that.

DR. NAU: Well that, yes, that's a huge difference. In terms of which encounters would be included. So I think we'd want to have a clear idea of what the denominator was before we would approve this.

DR. NAGAMINE: Two points. One is a question about the ICD-9 code in the primary and secondary diagnosis. I'm a hospitalist and if I see a patient who comes in for say, A-fib or an MI but they have a history of epilepsy.

So, would that, would I be one of the physicians look to the counsel on side effects of the drugs, the querying and counseling?

MS. SWAIN-ENG: How it, my

experience with working with measures and how it works is if you include that ICD-9 code for the p measure within their medical record for that specific visit, you should be asking about AED side effects.

But if you're seeing the patient for A-fib or something that is more unlikely that you're actually going to put that, that code down, as being the prime, I think it's --

DR. NAGAMINE: Well, no, we, you know, being an internist, I list every medical condition that they have because that has implications for every medicine I prescribe.

So, you know, I see how I should and shouldn't in some ways, be accountable for that. And so that's a really important point when it comes to feasibility.

And secondly, this conversation kind of goes back to the one we had yesterday about the spectrum or continuum, about the difference between a clinical guideline, yes, neurologists should be asking this.

And, you know, if we see someone in the ER who crashed their car because they were somnolent because of a new drug, we should be asking them. But my question is back to the primary objective of this, and I believe you said it was for quality improvement of neurologists.

And, and, you know, that's, that's one thing, but that, who this applies to majorly effects the impact of this, the system level versus the individual practitioner. So, if pharmacists were included as part of the team, I think that the overall impact would be larger.

But on the other hand, it gets messy if you include too many people, like a hospitalist dealing with an acute MI. So, I just wondered, what discussions you've had around that, in terms of the primary objective versus where you might be headed ultimately with this.

MS. SWAIN-ENG: We've had our

discussions. I know Dr. Bever, who's on the line, can speak to this as well, when we've had our discussions about this measures we weren't trying to develop measures that were solely for neurologists.

We were trying to develop measures that were for physicians, more than likely, neurologists would use them more often than other practitioners. These measures, as they're developed now, I believe they're all outpatient measures, which may limit the ability for certain practitioners to use the measures.

And I apologize I don't have the actual descriptions with the CPT codes, I don't' believe you have those in your measurement set. And I believe we talked about these physicians being relevant in the outpatient setting as well as being relevant in a nursing home and, yes.

MS. BOSSLEY: Yes, outpatient -- I think they're all outpatient.

MS. SWAIN-ENG: Yes, Heidi is looking at it now, there it outpatient office counsels --

MS. BOSSLEY: It's outpatient, skilled nursing facility.

MS. SWAIN-ENG: That, that looks like that's it. So, nursing home and outpatient.

DR. NAGAMINE: And then, just, the last comment is, again, if the objective is preventing harm, which, you know, I agree that these are, to not do this, the result is big. Often death. Drowning, burning, crashing. And so I would also just mention that they may come to the ER for an MVA but the issue might be their epilepsy drug.

For, for some other trauma. And so if you want to capture an impact that specific problem, I'm not sure that just epilepsy codes would capture it. So that's just a comment.

MS. SWAIN-ENG: Oh, I agree. There, there's significant opportunities for

improvement if you were to applied it to other codes in other patient populations.

We're very kind of methodologically strict in how we develop our measures, that we looked specifically at the evidence that is available, and the evidence that is available, and the evidence that was available to support these measures was specifically for epilepsy.

Which is why we have the measurement set here before you today.

DR. NAGAMINE: And, and I don't know what the answer is, but. Yes.

CO-CHAIR CONWAY: Donald?

DR. KENNERLY: I wonder if you could comment on, all of them, the other societies have commented on the feeling that this is important to drive in terms of awareness and improvement. Do you have a sense that those discussions have moved beyond the leadership, if you will, to the rank and file, if you will, neurologists, to ask just the extent to

which those represents a significant burden in, because as you say, the relative paucity of electronic records and the lack of mapping at this point make this a non-trivial exercise.

And, and I think that sometimes leaders become very enthusiastic, and I know we look to them for guidance, but I think that, I wonder if you might comment on whether this has been in a sense put to the broader population of folks in terms of their commitments.

MS. SWAIN-ENG: This, these measures in the whole epilepsy measurement set, all eight measures were very heartily approved and embraced by the epilepsy community. I know there was a presentation last year at the American Epilepsy Society in December of 2009 given by Dr. Nathan Fountain who was the co-chair of this group. And he got nothing but good comments back on this could actually improve patient care, how the physicians said,

yes, this is what I need in my practice, I need something like this that can help me with the whole measurement set in itself to direct patient care so that I know that I'm giving my patient the best quality care.

And we've reached out to the American Epilepsy Society as well ast he National Association Epilepsy Centers and they were very big supporters of the whole measurement self as itself, in itself, that it could, it could really improve patient care.

And they're right behind it as well as we've worked with the family physicians groups, the pediatricians, a number of different groups that have given large base, broad based support for the measurement set, including this measure.

DR. KENNERLY: And, and since much of the work of neurologists has to do with counseling at a variety of levels, certainly, depending on the, sort of the control of the disease as well as the complications of

medications, treating the disease.

I wonder if, if someone would get credit, if you will, if they had, for example, a checklist of a variety of different counseling measures, or, I shouldn't say measures, but activities, if you will, so that if they had a standard sheet that had different things on it and they were to check the ones that were relevant for that particular patient, which, you know, many of us would argue would be a good standardization kind of approach, and, and, and sort of a starting point for discussions.

If you, if you said in a neurology note, counseling as appropriate, you know, for, the things that you had queried, would that suffice, or would you have to be very granular in your description of exactly what happened as part of that counseling --

MS. SWAIN-ENG: No. Right now, it's, it's left purposefully vague so if it's documented in the medical record, they did

some type of querying and counseling, and if it's documented that you gave them a counseling sheet about something to do with the side effects of AEDs, in the medical record, but it's not said I used the SF36 for dot dot dot, or whatever other testing material that you might want to use.

That would still meet the measure. It's just there has to be some indication in the medical record that you did do some type of counseling, whether it is giving them a standard sheet as you mentioned or if you went into an in depth discussion about the complication of the medication with something they're doing int heir daily life, I don't know, whatever that may be.

DR. KENNERLY: Sure. But in effect, what I think you're saying is that you, you still have to be very specific about what's documented in the record about counseling for AEDs as opposed to what I think many of us will do, would not be to list every single

thing that you describe, much as surgeons don't describe all of the risk benefit analysis, if you will, associated prior to surgery.

But if you went over, so, I'm a little concerned that if in, there's a broad array of counseling that takes place, which I would guess would happen in many neurology visits, you have to be specific about exactly that these were attending to the side effects of medications.

MS. SWAIN-ENG: Yes. There just have to be some sort of general indication that you did counsel about AED side effects.

DR. KENNERLY: Thank you.

CO-CHAIR CONWAY: Okay, how about Lisa, Allan, and then David.

CO-CHAIR THIEMANN: Okay. Ms. Swain-Eng, two questions. One has to with performance discrimination and the other one has to do with a multi-specialty consensus process, possibly.

First one, I'm, I'd like to kind of circle back around about the intent and, as, as the driver for the creation of the performance measures since we're always looking to drive quality care across the care, the patient population.

Was this really, was this a gap in care for, that AAN identified for providers that are not neurologists, versus a gap in care that they felt that AAN members of neurologists weren't querying, combined with counseling?

Because I also heard that. And, the reason I ask this, is I had heard, I had heard Dr. Diamond earlier talk about how this was a voluntary measure, and since this is a voluntary measure for this individuals who are maybe primary care providers, other specialties that are not neurology, are we really missing out on that population?

If that's what AAN was trying, if that's the population they were trying to

drive clinical practice and improve clinical practice, we may not see that or have them even engage this measure if it's endorsed.

So, that's one question. The second question is, recognizing that AAN engaged the services of AMA PCPI in recognizing that AAN, this is a proprietary measure for AAN, I wonder if AMA PCPI may be willing to, now that they're offering consultative services to the specialty organizations, offer the ability to submit the measure to AMA PCPI general membership or post for public comment, thereby getting additional feedback and multi specialty consensus on the measure apart from neurology.

MS. SWAIN-ENG: SO I'll answer your second question first. And yes, this actually was approved by the full PCPI membership in March of 2010. So as soon as, with the independent measure development process, you still have to go, once you get the measure approved by your workgroup and we did a thirty

day public comment period during that measurement period.

And then we had it approved by our Subcommittees, Committees, our Board of directors, and then it was sent to the executive Committee of the PCPI who reviewed it. At that time they requested a few minor changes to some MRI and CT measures just as some clarification in the wording.

And then it went before, before the full PCPI membership and it was approved about March 10th or so of this year, and it did go through public comment period by the PCPI where it hear comments back.

We didn't get anything new, I know when we had our thirty day public comment period, we notified them as well so they could let their member, the full membership know and comment during that.

And it was approved with, I don't think we had any major comments or dissension at all from the full membership of the PCPI.

CO-CHAIR THIEMANN: Followup question. Just to that, do you, do you recall the specialty groups that you received comments from? Were they --

MS. SWAIN-ENG: We received about 297 comments, with comments from, I remember we received comments from AAFP, family practitioners, we received comments from radiology, we received comments from physical therapy because there was some related measures in the measurement set.

Nursing associations, a lot of individuals that were interested, either members of our association or members of the PCPI. And we responded back to all of those comments.

And the measures were modified minorly just to create some more clarifications with the intent of the individual measures were, was clear, or was clear. And, and then they were put forth for approvals.

CO-CHAIR THIEMANN: Just to, I just wanted to, because I'm trying to recall, when AMA-PCPI or puts out a public comment period on the level of detail for the measure of specifications and so forth, are they similar to NQF? I can't recall offhand.

MS. SWAIN-ENG: So, generally we set out the measurement set, which for the epilepsy measurement set, it was approximately fifty pages long, which contains the numerator, denominator, exclusions, the measure statement, the recommendation statements, that go to support the measure.

Part of this document I have in front of me, the rationale for the measure was supporting literature, evidence based to support it, calculations for performance, calculations for reporting measure specifications, which includes administrative claims data, ICD-9 CPT and at this, for this specific group of measurements --

CO-CHAIR THIEMANN: Not to, not to,

not to, not to, but I just wanted to, I just, I basically was looking for is, is, you know, where you looking, you know, have you sought other specialty groups opinions on this --

MS. SWAIN-ENG: Definitely.

CO-CHAIR THIEMANN: -- and that's really what I was trying to get at, through that process.

MS. SWAIN-ENG: Yes, that's definitely part of our AAN process, is that we follow the PCPI process which is very broad based and includes all the relevant stakeholders, including people from WellPoint Humana, Blue Cross/Blue Shield, United Health Care, large group health employers, physician groups, patient groups, everybody.

Because we know this measure will effect so many different physicians and so many different patient populations, we want to make sure we have all of those, stakeholders have their voices heard.

CO-CHAIR THIEMANN: Back to the

first question?

MS. SWAIN-ENG: Oh --

CO-CHAIR THIEMANN: Sorry, I know I ask too many questions at one time. The performance discrimination gap in care question, as to non-neurologists versus was it driven to look to improve neurology care tying querying and counseling.

MS. SWAIN-ENG: So the measures are developed to improve neurology care, for neurological condition independent of who the physician was that was seeing them. We didn't look at this and poll our membership and say, you know, what's missing in your practice.

We went to the evidence base and said, so from the guidelines that we have available, what is the evidence saying that needs to be done in practice. So taking those recommendation statements and then applying them to the literature and what did we find from our workgroup, which did consist of neurologists, it did consist of family

practitioners, radiologists, and so on.

Using their expertise as a whole to really delineate where we needed to go with measured development, looking at feasibility, of course gaps in care, what's not being done in practice for the individuals that were on our panel.

And I believe I mentioned there's about twenty-six individuals on our panel, so it was a broad representation. Using all that data together, which we're very evidence based, to then develop the individual measures that are, were in this measurement set.

MR. BUNTING: I just feel like we're so close on this and after our discussions yesterday you wouldn't have believed what an accomplishment that is. But --

MS. SWAIN-ENG: I heard it was quite inconclusive yesterday.

MR. BUNTING: I'm still stuck on two points. One is the documentation issue. You know, if, if you're going to have to abstract

charts, I, I agree with you that, you know, if it's on the discharge instructions, why put the burden back on the physicians to double document.

We need to get away from that. So, if their discharge instructions are mentioned that they gave the appropriate discharge instructions, or else a copy of those discharge instructions are with the medical record, I think that should be in compliance.

I think making a physician document about what he gave the instructions about is double documentation and I'm against that. The other thing that I want us as a group to discuss, because this certainly is outside of my realm of expertise, even though I'm very familiar with coding and running data analysis and primary secondary codes, on this measure, what would be the benefit or the harm for using only primary or only, or using both primary and secondary?

I'm trying to wrestle with, which

would be the best way of including this measure. So, any other committee member have words of wisdom about which would be the best measurement?

DR. MUETHING: Yes, I would comment that from my point of view, it would depend on what, how large the gap is. In that, if the gap is very large, then I think it would be worthwhile for some period of time to focus on the primary.

Because, you will bring in all kinds of questions and issues by bringing it in as a secondary diagnosis. If we're at 90% or 92%, we're trying to get up to 98%, then I think it brings up this issue about where are we missing it.

And then you start bringing up this issue of maybe it's in the emergency room, maybe it's in, when they drop by the pharmacy or whatever. And that's why I'm, I wish I knew what the gap was. I'd be more comfortable with that question.

DR. NAGAMINE: So, I guess it depends on what you're trying to measure. So, there's a huge difference in what those numbers would mean, depending on whether you include the primary or secondary. And I think the narrow more specific target group would be to do only the primary.

And so, if you put in secondary, you're going to get a whole bunch of other players and, and accountable for something, and it may be, it may or may not be peripheral. It gets money.

MR. BUNTING: Well, I agree with you. And one of the reasons I brought that up was your question about trauma, if you're primary diagnosis is multiple trauma, but in the secondary diagnosis is epilepsy, to me, that's like 1A and 1B.

So, I would be more interested in impacting that patient than I would somebody where the secondary diagnosis was number nine. So I think it's a fine line, and it's a

difficult issue to rationalize.

DR. NAGAMINE: It is, because that's one specific case where you're going to miss a major opportunity. But how many other opportunities, a number needed to treat, are we talking about, before you get that one really relevant, you know.

MS. THRAEN: In your application, or in this application, under purpose, intended use of the measure, public reporting is listed as number one, and then internal quality improvement. And then accountability and payment.

What is the, what is the, your agency organizations associations, motivation for wanting to take this to NQF?

If, if the focus is truly to improve care associated with neurology, it strikes me that by establishing this list there and working with your, your membership and your constituencies that that provides you the opportunity for quality improvement.

MS. SWAIN-ENG: One of the reasons that we came to NQF, and this is not the solely reason, sole reason, is that the NQF is the, you know, the ultimate vetter of measures and the stamp approval from NQF gives more credence to your measures.

Right now, in a paper performance program like PQRI, specific to neurology, there are only stroke and stroke rehabilitation measures. There are no other specific measures for neurological conditions.

We feel that our physicians don't have a lot to choose from. If they wanted to participate in a PQRI type program, in fact, we have a very low percentage of our physicians that actually do participate. So one reason is to encourage them to participate in a PQRI or pay per performance type program that would include measures that were developed by them for physicians and for other, for neurological conditions for anybody that may see those, those patients.

That's one reason, and also we've worked, we're a member of the National Quality Forum. We've worked with the National Quality, the NQF for a number of years and we really appreciate the extra vetting that the NQF does, and the process itself gives more power behind the measure to get it implemented, say, by a health plan, or to get it implemented across the Board.

And, our goal of these measures is not to hold onto them tightly and only let certain people use them. It's to really get them incorporated into different systems up here so that patient quality care can be improved.

DR. LAWLESS: Would you consider -- I think the idea of the counseling and the querying is absolutely important. I have lots of problems with documentation. What about just altering what would be a consideration, just altering to new, to the initial new onset time that this is a requirement?

MS. SWAIN-ENG: To the new onset --

DR. LAWLESS: That, a new, a patient is newly diagnosed with and is a part of the newly diagnosed time, which is an easier way to document in the system. The coding is simpler, and during that time is, did you include counseling about side effects, counseling about other things, and leave, as a start, for the gap, at least starting out, and then as a, then, then eventually going to the ongoing versus the big bang.

MS. SWAIN-ENG: So, this was something that was discussed by the full workgroup. They felt that there as a need to have this done at every visit regardless of it being the first visit or not, for the initial diagnosis visit.

We do have other measures that are specifically focused on the initial diagnosis visit for epilepsy. They felt that, you know, AED side effects, you can have problems creep up any time. This shouldn't be something

that's just done simply at the beginning.

That should be done at every visit because there are issues that could arise that need to be addressed in a timely manner.

DR. SIERZENSKI: What about the patient using incapacitated, so, I mean, I see that you had Andy Jagoda from ACEP on your workgroup, so I presume he vetted a number of these issues. But, everyone keeps talking about the trauma patient, but the trauma patient comes in, they may have a history of epilepsy, they're intubated.

Then, I need to document that the patient is intubated incapacitated and therefore was not able to discuss and counsel patient on --

MS. SWAIN-ENG: That's one of the exceptions listed for this measure.

DR. SIERZENSKI: Okay.

MS. SWAIN-ENG: So that, if you do have an exception, you can still can use the measure if you try.

DR. SIERZENSKI: Because the, the issue of the burden, the burden on the physician and I can tell you that in the world of emergency medicine, seeing the vast majority of, of variety of patients, we already are seeing ourselves with nearly a sheet and a half of having to document that we recognize, that we discussed or documented some type of quality measure.

And so, you know, I understand the importance of trying to get this information across, I just wonder if, if we're on the outer range of the bull's-eye instead of honing down and I really think that the burden of proof and the burden on the emergency physician could be fairly extensive.

Especially since if the diagnosis of epilepsy and we're trained to try, ideally, to put as much information down, is second or third on the list, and the patient is there primarily with a laceration or, or some model that complains cellulitis, are we then going

to need to document at that time if we decide to be included in this measure the fact that we've counseled them.

And I, I think that's fairly extreme. That's, that would be the vast majority of the overuse of this measure, in our environment, than just targeting the population that I think you ideally are looking at, which is patients who haven't, you know, who haven't had that counseling, and need it.

And, the last, I would, I would ask is, is what is the view then in a system process where emergency medicine often has to rely on other individuals in the system? If we're going to front load all this, I, I can tell you the burden and the world of emergency departments is going to be huge. It's going to be massive.

MS. SWAIN-ENG: Well, I believe that's one of the reasons this measure was listed -- limited primarily to outpatient CPT

codes. We, you know, we Dr. Jagoda, as you mentioned, who is on the panel and I remember him voicing some concerns similar to what you've just said about the burden of doing this if they're seeing somebody for an, a different acute situation in the ER, do they really have to do that.

Do this measure, and that's one of the reasons we limited to the CPT codes that were, or are proposed in this measurement set is to reduce those that would be forced into doing the measure. Put it that way, so that it's limited to outpatient measures and the consult codes, I don't, I know Heidi has them in front of her.

But, so that those physicians that aren't seeing them primarily for, say, primary care visit or for an epilepsy visit and they're not an epileptologist and they're not going to want to use this measure for PQRI type program, because they're going to be using other measures that are more relevant

to, say, a stroke measure in, in the ER, which all of our stroke measures are actually inpatient measures.

DR. SIERZENSKI: Just to clarify then, because some people when they talk about outpatient, they lump emergency Department in that or not and we talked about the ED. Are you saying that the ED, by the fact of the coding and that you're using outpatient and not acute ED, that E-D is exempt from this?

MS. SWAIN-ENG: I believe so. Yes. And that was something we had discussed, really looking at the setting of where the measure would apply and what would be too burdensome, and that was something you know Dr. Jagoda had led a large discussion about that specific item.

DR. NAU: Sure, and just my, my final comments on this measure. I would applaud the academy for, you know, developing this measure. I think it's an important issue, because there are a significant number of

patients who have problems with those medications and, and need attention.

What the conversation around the table is telling me, though, is that there's still some fuzziness around the denominator, and which encounters should be included. And there's some fuzziness around the numerator and what counts as counseling, or counts as querying.

So, as we're considering whether this measure is ready for public reporting, you know, I don't think the answer is yes, because there's still some uncertainties there. But I, I would suggest that, you know, continue the testing and refining this measure because it addresses an important issue.

I would though suggest that as you're thinking about what counts as querying or counseling, you know, at one point you suggested that maybe handing a sheet of paper to the patient about their medications might count, and I would encourage you not, not to

go there.

Because that would really, I think, diminish what really needs to be happening in terms of the dialogue between the clinician and patient about the medications, so. I, I think this is a worthy issue to tackle, I just, I'm not convinced that this particular measure is ready for public reporting.

MR. LEVINE: What percent of neurologists belong to the academy?

MS. SWAIN-ENG: I don't know that number off the top of my head. I know it's the majority, but I don';t know the number off the top of my head. We have 22,500 members right now. I know that number.

CO-CHAIR CONWAY: Dr. Diamond, do you have any questions or comments?

DR. DIAMOND: I think, I think, I have an incredible respect for the brainpower that, just to spite itself, it was an outstanding discussion. I certainly totally agree with the concept that simply giving a

sheet at discharge is not counseling. I totally agree with that.

But I think it's a, it's definitely an important measure. Who supports it and who stands behind it needs to be, needs to be defined.

CO-CHAIR CONWAY: Thank you. Dr. Solomon?

DR. SOLOMON: No. I've learned a lot but I don't have any further comments.

CO-CHAIR CONWAY: Okay, thank you. And any further comments or questions from the Committee? Okay. Should we proceed to grade the measure of specifications? The first category, 2A, is whether the measure is precisely specified.

Those who feel that the answer to that is completely, please raise your hand. Okay. Partially? There's one. Minimally? One, two, three, four, five, six, seven, twelve, thirteen. And not at all? And, Dr. Diamond?

(No response.)

CO-CHAIR CONWAY: And, Dr. Solomon?

DR. SOLOMON: Minimally.

CO-CHAIR CONWAY: Okay. Thank you. Sixteen. Very good. They'll reflect that you choked on the question. 2B is the extent of reliability testing. Those who feel that was demonstrated completely? Partially? Minimally? Okay -- minimally, please -- four, six. And, not at all? Six -- there's eight. Six, eight. And Dr. Diamond?

DR. DIAMOND: Yes, not at all. It's not been tested.

CO-CHAIR CONWAY: Dr. Solomon?

DR. SOLOMON: Not at all.

CO-CHAIR CONWAY: Thank you. 2C is validity testing. Those who feel that was completely demonstrated? Partially demonstrated? Minimally demonstrated? There's one. And -- two, minimally demonstrated. And, not at all demonstrated? Four, five, six, seven, eight, nine, ten, eleven, twelve.

And, Dr. Diamond?

DR. DIAMOND: Not sure. I think, not at all.

CO-CHAIR CONWAY: Not at all, okay. Dr. Solomon?

DR. SOLOMON: Not at all.

CO-CHAIR CONWAY: Okay. 2D is exclusions justified. Those that feel that was completely demonstrated? Partially demonstrated? Six. Minimally demonstrated? Five.

Not at all demonstrated? Not applicable. There were a few of those. That's, that's, I, I thought it was not applicable. Three. And, Dr. Diamond?

DR. DIAMOND: Minimally.

CO-CHAIR CONWAY: Solomon?

DR. SOLOMON: Not at all.

CO-CHAIR CONWAY: Okay. 2E is whether the risk adjustment category was demonstrated. 2E. Those who feel that was completely? Partially? Minimally? One. Not at all? On, that's on risk adjustment. Not at all

is, one, two, three, four, five. And, not applicable. Two, four, six, eight, nine. Is that more than fourteen? Oh, it's fourteen. Dr. Diamond?

DR. DIAMOND: Not at all.

CO-CHAIR CONWAY: Not at all. And Dr. Solomon?

DR. SOLOMON: Not applicable.

CO-CHAIR CONWAY: Okay. Thank you. 2F is the identification of meaningful differences in performance. Was this completely demonstrated? Partially? Minimally? That's, four, that's eight. Not at all? Three, six. Dr. Diamond?

DR. DIAMOND: Not at all.

CO-CHAIR CONWAY: And, Dr. Solomon.

DR. SOLOMON: Not at all.

CO-CHAIR CONWAY: Thank you. The comparability of moldable data sources and methods. Was this completely demonstrated? This is 2G. Partially? Minimally? One. Not at all? Five, six, seven, nine, ten, eleven,

twelve. And, not applicable. One. And, Dr. Diamond?

DR. DIAMOND: Not at all.

CO-CHAIR CONWAY: And Dr. Solomon?

DR. SOLOMON: Not at all.

CO-CHAIR CONWAY: Okay. Disparities in care, is this completely demonstrated? This is 2H. Partially? Minimally? Three. Not at all? Five, eleven. And, not applicable. Dr. Diamond?

DR. DIAMOND: Not at all.

CO-CHAIR CONWAY: Dr. Solomon?

DR. SOLOMON: Same.

CO-CHAIR CONWAY: Okay. Thank you. And for the overall category, we have to grade that according to the, for scale, completely to not at all. Do you feel that this overall category is scientific acceptability of the measure was completely demonstrated, partially demonstrated, minimally demonstrated? Two, four, six, seven, eight, nine, ten, eleven, twelve. Thirteen.

Not demonstrated at all? And, Dr. Diamond?

DR. DIAMOND: Minimally.

CO-CHAIR CONWAY: Dr. Solomon?

DR. SOLOMON: Same.

CO-CHAIR CONWAY: Okay. I think we missed one there. It may not matter. I might have miscounted. Okay. That is that category. Looking on at the usability category, are there questions or comments about that category?

Okay, should we proceed to grading that, then? Okay, we'll do that. This is in the usability category, 3A, whether the measure is meaningful, understandable, and provides useful information.

Do you feel that was completely demonstrated? Partially demonstrated? Minimally demonstrated? Two, four, six, seven, eight, nine, ten -- that's fourteen. And, not demonstrated at all. Okay. Dr. Diamond?

DR. DIAMOND: As a neurologist, I'd have to say partially. I understand --

CO-CHAIR CONWAY: All right. That's fine. Dr. Solomon?

DR. SOLOMON: Minimally.

CO-CHAIR CONWAY: Okay. In the category of 3B, harmonization. Is this demonstrated completely? Partially? Four. Minimally? One, two, three, four, five, six, seven, eight, and ten. And not at all. Dr. Diamond?

DR. DIAMOND: Minimally.

CO-CHAIR CONWAY: And Dr. Solomon?

DR. SOLOMON: Agree.

CO-CHAIR CONWAY: Okay. And 3C, the last question in this section, does this provide distinctive or additive value information? Was that category met completely? Partially? Two, five, six, eight, ten. And, minimally? Two, four. And not at all? Dr. Diamond?

DR. DIAMOND: Minimally.

CO-CHAIR CONWAY: And Dr. Solomon.

DR. SOLOMON: Minimally.

CO-CHAIR CONWAY: Thank you. Overall, for this category, then, is the extent to which the overall criteria were met. Do you feel it's completely? Partially? Minimally? Six, seven -- fourteen. Not at all, and Dr. Diamond?

DR. DIAMOND: Minimally?

CO-CHAIR CONWAY: Dr. Solomon?

DR. SOLOMON: Same.

CO-CHAIR CONWAY: Okay. That was pretty uniform. Looking at the feasibility category, is there any discussion or questions related to that? Should we move onto grading that, then?

On 4A, as to whether the data generated is a byproduct of the care process, was that demonstrated completely? Partially? Minimally? Fourteen. And, not at all? Dr. Diamond?

DR. DIAMOND: Minimally.

CO-CHAIR CONWAY: And, Dr. Solomon?

DR. SOLOMON: Agreed.

CO-CHAIR CONWAY: Okay. Pretty uniform agreement there. On electronic sources being available, is that demonstrated completely? Partially? Two. Minimally? Eight. And, not at all? Four. And, Dr. Diamond?

DR. DIAMOND: Yes, minimally.

CO-CHAIR CONWAY: And, Dr. Solomon.

DR. SOLOMON: Minimally.

CO-CHAIR CONWAY: Okay. 4C is whether exclusions were, were demonstrated. And, is that completely? Partially demonstrated? Seven. Minimally demonstrated? Six. Not at all? I missed somebody I think. Dr. Diamond?

DR. DIAMOND: Partially.

CO-CHAIR CONWAY: And Dr. Solomon?

DR. SOLOMON: Minimally.

CO-CHAIR CONWAY: Someone feel it's not applicable? All right, I think I might have miscounted once there. On 4D, the susceptibility of the inaccuracies and unintended consequences, was this demonstrated

completely? Partially? Minimally? Eight. Not at all? Six. And, Dr. Diamond?

DR. DIAMOND: Minimally.

CO-CHAIR CONWAY: And Dr. Solomon.

DR. SOLOMON: Minimally. Okay. That's ten minimal and six not at all. On 4E, data collection strategies and implementation, was that demonstrated completely? Partially? One. Minimally? Seven. And, not at all? Six. And, Dr. Diamond?

DR. DIAMOND: Not at all.

CO-CHAIR CONWAY: And Dr. Solomon?

DR. SOLOMON: Minimally.

CO-CHAIR CONWAY: Okay. Looking at this category overall, to what extent were the criteria feasibility met, completely? Partially? Minimally? Thirteen. And, not at all? Is there somebody abstaining in the room? Okay, looks like -- how about Dr. Diamond?

DR. DIAMOND: Minimally.

CO-CHAIR CONWAY: Minimal. And, Dr. Solomon?

DR. SOLOMON: Minimally.

CO-CHAIR CONWAY: Okay. Then we would move onto recommendation for endorsement. Before we do that, the, the choices here are to endorse, to not endorse, or to endorse with recommendations for change.

And, Lisa and I thought maybe we should discuss possible recommendations for change ahead of the final vote on this, put some of those on the table. Or at least talk about it. Or should we just do a straw vote to see if it -- yes.

How many in the room would be prepared to endorse this at the present time, as a measure? That'll take care of that discussion. Then let's formally vote on that. Do you recommend this measure for endorsement --

MS. BOSSLEY: Can we try the handheld just to try it?

CO-CHAIR CONWAY: A handheld?

MS. BOSSLEY: I'm sorry, I'm dying

to see how this works. So.

CO-CHAIR CONWAY: Okay. Would you want to explain that?

MS. BOSSLEY: Yes, Elisa or Andrew, we need to project, are we set up to do it, or did you all -- okay, so I'm going to let them explain it. I'm not a good one to explain it.

MS. MUNTHALI: Okay, so the first option is one, yes I recommend the measure as written. You will ignore probably the second option, because it, it looks like you don't have any recommendations --

CO-CHAIR CONWAY: Well, we may. We may.

MS. MUNTHALI: -- for modification, is that correct?

CO-CHAIR CONWAY: We might.

CO-CHAIR THIEMANN: If people, I think if people feel that there's modifications that they would like to see, then maybe they should vote for yes, with modifications, and then depending on the

numbers, we could see, we could have that discussion as to what the modifications would be. Does that sound --

MS. MUNTHALI: Heidi, do you think it would be better to talk about those before voting?

MS. BOSSLEY: It's hard. I mean, it's hard to tell, there's times when there may be a modification to the measure that would sway all of you and then you would say yes, you would endorse it.

So it may be worthwhile if anyone has one to at least mention it now and see if anyone else would like to further discuss it, and then if not, then I would just go ahead and vote.

CO-CHAIR CONWAY: Okay.

DR. LAWLESS: What happens if number two wins in terms of the process at NQF, do they have to resubmit it, and, because of the whole process?

MS. BOSSLEY: So -- good question.

So, what will happen is, if there are things that you think would make the measure better to the point where you could recommend it, and I wouldn't say a brand new measure, what it could be.

But if there's, you know, say, definition on what exactly you mean by querying and counseling, maybe further specifications in some way, or an acknowledgment, you know, that it does include this or this.

That type of thing would go then back to the developer, and we'd give them a few weeks to get back to you all and say whether they could make that change or not. So if they didn't, it would come to you on a call -- or, did, or didn't, actually -- it would come back to you on a call.

Yes, come back to you and you all would decide if you felt that it was adequate enough to be endorsed. So if you did decided you want to modify, you would revisit it

again. It's not like it would, you would be saying yes today and then you'd never see it again.

So, it all depends on what type of modifications you really think could be made.

CO-CHAIR CONWAY: Okay. We have two comments. Steve, on the left.

DR. LAWLESS: Out of interest of time, I think the discussion we had was pretty robust. And I think that as you would do a manuscript review, if you look at, look at the minutes of the minutes, except for the hiccup, and see what you could respond to, an itemized list of those responses or discussions they're coming back here, I would feel very comfortable with that.

CO-CHAIR CONWAY: Okay. Steve?

DR. MUETHING: Mine's more a point of clarification on voting. So, if, is testing for a year considered a modification, or is that considered a no?

MS. BOSSLEY: That's a really good

question. So, actually because there is no testing, you would be voting on this measure as a time limited endorsed measure. So your recommendation, if you did measure, put this measure forward, would be you felt it met all the criteria with the exception of the testing components under scientific acceptability.

And they would be given, I think, twelve, I think they can get it done in twelve months. So, twelve months, and then it, if that, testing information would go to the consensus standards approval committee.

They would review it, determine whether they think it was adequate testing, and then endorsement would either become, you know, endorsed, or they would remove endorsement.

DR. MUETHING: So if I would like to see modifications and testing, I should vote no?

MS. BOSSLEY: The assumption is, when you put this forward and recommend it, we

expect testing in twelve months. So you can just assume that, this is you approving it as a time limited endorsed measure, that's what you're recommending.

So, the testing piece, everyone acknowledges is not there, AAN says they haven't done it yet. That's, that's coming and that will happen.

CO-CHAIR CONWAY: Janet?

DR. NAGAMINE: So, again to clarify, if we want testing but I, I don't want them to test what's written. Certain modifications that we recommend would be tested?

MS. BOSSLEY: Right. So, if, so let's walk through what would happen. If you all said, we want this, this, and this done to the measure, goes to AAN. AAN says yes, let's say. Assuming that they agree with the changes.

That thing comes back to you all on a conference call in a month or so, a couple weeks, whenever that would be. You would then

determine whether you agreed with those changes. Those changes then, if you agreed with them, become a part of that measure, as it moves forward through the process.

And they would be expected when they come back in twelve months to test, it would be on that modified measure. So it's, I mean, once the changes are made, the changes are made. It's, you know, it's, that is the measure as it is, not the one that you're looking at right now. Does that make sense?

CO-CHAIR CONWAY: David?

DR. NAU: Yes. Just, just to clarify here. I think number two is really designed for situations where we can build consensus on a very explicitly change that we all agree on would be a, or most of us would agree on, would be the change that makes us very comfortable with this.

And, I don't know that we've got that consensus on a very specific change. It seems like there's lots of potential concerns.

So I think we should keep that in mind, that, how big a change we want.

MS. BOSSLEY: Right. And I think that's what you all need to, I think you, you need to explicitly state what you think the change would need to be, and then you need to decide if that's too big a change, and if everyone agrees, even, with the change. And then it would have to, you know, and then we'd have to see if AAN could indeed do it.

CO-CHAIR THIEMANN: Heidi, that's what I was going to, that's kind of where I was going as well, that, you know, we've had a two hour discussion on this measure, that, roughly, and, that has come up with multiple areas of concern.

And, so even though we've all been sitting around the table and on the phone and heard them all, you'd want to be, you know, if we were voting yes with modifications, we'd want to make sure that whatever the concerns individually we were making were actually

captured in there.

And if we voted yes with modifications, it may not be captured. And so, you know, and that's a concern from, from my perspective. But, if people were to vote yes with modifications at this point, AAN took it back, did make the modifications as requested by the steering committee, presented it again on the next steering committee conference call.

The steering committee members then actually would be issuing their final vote. So today is not a, it's not a final vote. It's a temporary, to take another look at AAN's attempts at making changes and so we would be issuing the final vote on this measure, on a conference call, after AAN made the, the changes, correct?

MS. BOSSLEY: That's correct. So, I would, I would actually say if you do determine you want to vote on a modification you're really just determining if you have

consensus on even moving forward and asking AAN to do the modification today.

You wouldn't be really recommending the measure, that's not until the next call.

CO-CHAIR THIEMANN: And, in followup as well, although we're going to be seeing a draft report summarizing our conversations for the past two days, and three weekish, three weeks, roughly, four weeks something like that.

Would the steering committee be able to see, if, if this was passed as yes with recommendations, would the steering committee be able to see that list that would be requested to go to AAN for modifications before they were to come back, so we could validate that our concerns were accurately -

MS. BOSSLEY: Yes, typically what we've done in the past is, for the measures where there are modifications, we put the measure as it was. We list the modifications, if we send it around.

Make sure you all agree that we captured what you intended, then it goes to the developer because otherwise it's chaos. So yes, that's what we do.

MR. LEVINE: What if there is, or have our next conference call, and they say we recommend two, what if there is a sense that there's one more recommendation that we have? Modification. What happens, just, worst case scenario.

MS. BOSSLEY: It depends. I mean, it would depend on a few things. You could, it's possible, say they did a definition and you felt that if they made one final tweak to that definition, you could put the measure forward.

If AAN could agree on the call, or within a couple days after that, then we probably could do it. If it's again, something that's go back and you know, require another week or two, then probably we couldn't.

There comes a point where you, you

know, you, yes, there's only so many times you can modify a measure to get it to the point where, so, we typically try to get it done on that call. If there's some minor tweak, then that's probably fine.

CO-CHAIR CONWAY: Okay. For Dr. Diamond and Solomon who are on the call, we were voting with an electronic gizmo and we'll get around to collecting your vote when we figure this out.

Now, the device we have in our hand, you have four choices, and then hit a send button. The first choice, number one, is yes, I recommend this as written.

MS. BOSSLEY: I'm sorry, I have Donald gesturing that he has I believe a comment, or something, on the phone.

CO-CHAIR CONWAY: Okay, sure. Is there a question on the phone?

DR. DIAMOND: Yes, actually. I wanted to ask Rebecca whether she feels that given the, given the list of concerns that

were raise, does she feel realistically that the AAN workgroup can, can accommodate these, these number and levels of concern as raised by the panel?

MS. SWAIN-ENG: I believe so. I don't know what else. Dr. Fountain, I'm still working with Dr. Fountain, who is the co-chair of this workgroup and we have a really working relationship with him.

I understand --

DR. DIAMOND: Could you talk louder? Louder.

MS. SWAIN-ENG: Yes, I understand the concerns that were addressed today dealing with, you know, the lack of having a pharmacist or an advanced care provider included within the measurements, that I think adding colludes to include those individuals could be done something very simply.

Other concerns about having perhaps a specific example of what would be considered, as, to qualify as counseling, and

querying in the measure, I do not see any issue with adding that type of example to the measure itself.

I think there was one other concern with primary or secondary diagnosis, and that's just my ignorance, that I don't know that part of the methodology and I can quickly get an answer on that. Those were the three major areas of concern, I think, that people were mirroring during our discussion this morning.

CO-CHAIR CONWAY: Okay. Now, Elisa just pointed out to me, before we vote, we should open the phones to comments from members or the public. Are there any out there? Okay. Hearing none, well, we'll move onto this device.

Number one is yes, I agree with the measure as written. Number two is yes, with modifications, to be defined later. Number three is no, I don't recommend the measure. And four, I abstain.

And Dr. Diamond and Solomon, we'll collect those numbers from you in a minute. So -- okay. So, yes. So then, hit a number and then push send. You hit a number and then push send.

MS. BOSSLEY: So we don't have a numb, an end of it, we just have a percentage. So we, we want to make sure that everybody's vote got captured, that's what I was --

CO-CHAIR CONWAY: There's fourteen, there's fourteen, there's fourteen voters in the room. Let's just, let's just validate the room. There should be fourteen in there.

DR. SOLOMON: I actually have one in my hand that I've voting in Boston.

CO-CHAIR CONWAY: That's good.

MS. BOSSLEY: So this is the fun part of it. It's only programmed through the PowerPoint slides. This is why we're, this is going to be interesting. We can't -- you can only vote once per slide. So I think we'll have to do a hand vote to confirm that we have

it correct.

CO-CHAIR CONWAY: Just a, just a tip for the future. With only fourteen people, you might not need to use a lot of technology. Okay. Let's -- could I see a show of hands? We're going to have two choices and see if it adds up to fourteen.

The first will be, yes, with modifications. Who voted that way, could I please see your hands. Five, six, seven, eight, nine. And how many voted no? Two, four, five. All right. That's fourteen. Excellent. And, Dr. Diamond?

DR. DIAMOND: Two. With modifications, please.

CO-CHAIR CONWAY: Okay. Dr. Solomon?

DR. SOLOMON: I vote no.

CO-CHAIR CONWAY: Okay. Well, it looks like the yes with modifications prevails. Now, should spend some time specifying the modifications? Rebecca, would

you mind recapping the three changes you think you heard? Let's validate those.

MS. SWAIN-ENG: Sure. I think one of the concerns that I heard was that some of the members of the steering committee wanted a specific example of what would count as querying and counseling, so giving an EG of some sort, that would demonstrate what specifically we are looking for, giving people a little bit more indication as to what type of documentation would be needed.

Secondly, I think there was some concerns, which I said was my ignorance and still is, whether or not a primary diagnosis would be the only that apply or it would be a secondary diagnosis as a workgroup member so this just an outpatient member so for those those that are hospitalist who work in in the hospital itself this measure would not apply to your practice.

And the third concern -- I'm blanking on what it was. I know there was

three. Querying and counseling, documentation -- oh, position extenders. Yes, of course, yes, making the measure applicable to an advanced nurse practitioner or other pharmacist or other care providers.

CO-CHAIR CONWAY: Okay, before, let's first take that list of three, is there any disagreement that that is what we would want to see in a revisit to this measure? Let's take those three first. There may be additions to that list, but let's resolve those three.

DR. NAU: Okay, so are you asking if those are the three that we should discuss and formulate recommendations around? Because --

CO-CHAIR CONWAY: What, what I'd like to do is resolve those three and then move on to see if there's others that are supportive.

DR. NAU: Okay, so, I guess, since we're going to need to provide explicit recommendations that we're in agreement on

for, I would suggest that with regards to the numerator, the denominator statement, that it be narrowed to include only encounters where the primary diagnosis is for epilepsy related conditions.

CO-CHAIR CONWAY: Okay. So that's a modification or a clarification of the number two issue, on, I think Rebecca just said primary versus secondary. Our request would be that we specify, this is applicable to primary. Okay. Primary encounters, or, primary diagnosis.

Okay. Other comments on these three requested changes? Okay. Dr. Diamond or Solomon, do you have any comments on those three changes? Okay. So at a minimum we would ask the, the, the, the proposing organization to specify in the denominator, this is for primary diagnoses, to give examples of, of querying and counseling and to broaden this to all providers of care.

And, Janet, do you have a comment

on these three?

DR. NAGAMINE: Yes. Just one other comment about the documentation piece. As we've already discussed, I just want to make sure that we capture the redundancy of documentation piece that if there is material given to the patient in the chart, whether we need to ask the physician to document that I gave this to the patient, or this double documenting piece.

And then secondly, the, to, to think about the effectiveness of what we're asking people to do, you know, with smoking cessation, every patient who is discharged from our hospital has on their discharge sheet, you know, discuss smoking sensation -- cessation, and you know, you check it.

But, did it really happen, how well, did it really have any impact. And so there's more and more of these just discharge forms being given out and you have to wonder how effective are we ultimately. And how well

was it done.

So, just some consideration to that question about the hierarchy of effectiveness of the things that we do. It all makes sense and you hope it's done well, but just some further consideration to addressing that. How do we know it's ultimately going to make a difference, the things that we're asking people to do.

CO-CHAIR CONWAY: So is that -- let me just clarify -- is that an addition or is that a clarification in number one providing an example of querying and counseling?

DR. NAGAMINE: Well, I think it could go under that, but I just wanted to specifically capture that, that we look at that.

CO-CHAIR CONWAY: Okay.

DR. NAGAMINE: What is querying and counseling and how is it going to be done and how effective do we expect it to be?

CO-CHAIR CONWAY: All right. So,

Rebecca, can you package that into number one?

MS. SWAIN-ENG: I'll do my best.

CO-CHAIR CONWAY: Okay.

DR. DIAMOND: I have a question. I'm really not clear why this is different than any other aspect of the discharge process, where counseling or the hospitalization doesn't work, counseling is a requirement.

MS. THRAEN: It's not applicable to inpatient, the way it's currently constructed, it's outpatient focus, unless you're talking about the ER question, whether or not you're treating it the ER, is it inpatient or an outpatient.

So it really is not applicable to your world as it's currently constructed.

CO-CHAIR CONWAY: All right. Further comments on these three modifications? Let's go clockwise, starting with Iona.

MS. THRAEN: It's, it was actually a follow up to what Janet had said. Just a response, in the patient safety world, for

example, we've worked on, on correct site surgeries as an example of changing a culture.

And what's, what we're starting to see from patients is each time they go into the hospital, we standardize a way of asking the question after I just said it's not relevant to your world, I'm just saying that form a public health perspective changing the culture of questioning actually prompts patients to begin to ask physicians themselves.

And so even though the effectiveness question, each time you say, are you smoking, are you smoking, you know, what are you doing about your smoking, you're changing the way in which we're addressing that issue in the society.

So there is some benefit, it's not a direct benefit.

CO-CHAIR CONWAY: Don?

DR. KENNERLY: I have a couple of thoughts, and again, being new to the process,

I, I'm, you know, would look for some guidance. But I wonder if, given that, in effect, we're, this creates sort of one extra round of consideration for them, given that their time limits for their response.

I, I guess to some degree I worry a little bit about whether our job is to get very granular in how, for example, we deal with Janet's question of redundancy and telling them what they should put in or not or whether our goal is to give them a general idea of the discomfort that we had around certain areas.

And to say, just come back with your best synthesis, if you will, of what we said, rather than our saying, well, you got to go do this, or you got to do that. Because, I, I, I, I think, really, I think we could spend an enormous amount of time rewriting it for them.

And, well, no, I mean that, and, I mean, that would be a constructive use of

people's time, potentially, but I'm just not sure that that's the purpose of this group, is to, is to, in a sense, be redrafting and recrafting to some extent.

I mean, I, I, and so, I, I, think it would be that we've synthesized concerns and, and perhaps passed them along to the, to the measure developer and said, now give it one more shot because we think we're close, as opposed to getting into highly refined discussions about exactly what we're going to include.

So, I mean, I, that's just my comment about just how we use our time. And, and, again, I'm open to the group's suggestion, but that's just a concern that I have. I think, secondarily, as we more specifically I guess, a second issue is, I think when you begin to start telling people what's necessary for documentation, I think it's also probably worth also explaining what won't work or be sufficient.

Because I think that's often as important because people say, well, gosh, I put this in, isn't that close enough. And so, you might want to create some description of what would not meet the threshold of being sufficient documentation.

DR. NAU: Well, just to respond to the very suggestion there, I agree that we could spend a ton of time rewriting this. I don't know that that's a great use of this committee's time, today.

But on the flipside, having been a measure developer, and having gotten feedback, it's very difficult to deal with very vague feedback saying things like, just bring us examples, without really knowing what examples are going to be sufficient and satisfactory to the majority of the members.

And so, that's where the risk we run by not giving explicit recommendations is that they could come back with examples that they've spent a lot of time developing and we

say, well, no, that's not what we want, or that's not acceptable.

So I think that, you know, and I, I voted no, because I think there's so much uncertainty here that I don't know that we've got consensus to give very explicit recommendations that if they brought those back we'd say, yes, you've, you've met that.

So I guess that's where I'm concerned, that we're going to give very vague feedback, they're going to do a lot of work and then come back and we're going to say, well, no, we're still not happy with it. So, that's where I'm concerned about the vagaries of some of our suggestions.

CO-CHAIR THIEMANN: I would agree with you there as well. One other area, and I know we, that this area, it's not one of the three that were identified, but we did talk about testing and recognizing that that AAN will be doing testing.

But I think I had head you say that

the sites that would be selected are neurologists only sites?

MS. SWAIN-ENG: No, they're large group, they're neurologists specifically that we work with in large group settings, so it's not just neurologists.

CO-CHAIR THIEMANN: Okay. My, my recommendation to AAN would be to expand that consideration so that you're getting a, assuring that you're getting a broader multi specialty testing, so that you're looking at the, really, the breadth of the gap there.

Not only within the neurologist population, that might be predominantly neurologists, but if there are family practices that counsel these individuals, or that don't have neurologists on staff, or in the practice, making sure that that gap actually is present across the entire population.

DR. MUETHING: One additional area, if I may, is that I'm uncomfortable with the

lack of clarity, and maybe it's mine, but the lack of clarity about the measurement and sampling and that I would need to see clarity on whether we're taking the approach of chart review or CPT 2 usage, and, I assume they'll demonstrate, or, create vastly different rates, or significantly different rates, so I would need to understand if we're going to allow for either or we're choosing one or the other.

MS. SWAIN-ENG: Well, it's all chart review that CPT 2 usage can aid in using the, doing the chart review. So it's not just explicitly looking for a certain CPT 2 code but while you're doing the chart review it can sometimes help you do find the information you're looking for quickly because you have a specific code you're looking for that indicates that they met the measure.

DR. MUETHING: So, every provider would need to review every chart of every patient that had the primary diagnosis of

epilepsy? Every year?

MS. SWAIN-ENG: For the measurement period that they chose, if they chose to use this measure, for every visit during that measurement period for the patient that had the diagnosis of epilepsy they would need to look in the medical record to see whether or not they documented that they queried and counseled the patient about AED side effects.

DR. MUETHING: Okay.

CO-CHAIR CONWAY: Okay. Yes? Paul?

DR. NAGY: What you're saying though is that can be done in an automated fashion? It doesn't require manual chart review.

MS. SWAIN-ENG: It's going to depend on what type of medical record system that that physician or system is using.

DR. NAGY: Right, well, first you'd query for all the ICD-9 for epilepsy and then you would, of those subset, you would ask the database which ones have that 6070F CPT code.

MS. SWAIN-ENG: You could do that if

you did happen to use the CPT 2 codes. The CPT 2 codes are required to be used.

DR. NAGY: DO you have any idea what percentage of facilities are going to be able to be using that CPT code?

MS. SWAIN-ENG: I don't know. Off the top of my head. I don't have that data.

CO-CHAIR CONWAY: Okay. Before we send Rebecca off to do three things in her association, could I just get a show of hands, are these three items, based on the discussion you've heard for the past two hours, do these three items reflect modifications that they should do on this measure?

And even if you voted against the measure, just let me see a show of hands about whether these reflect changes we'd like to see. All in favor of that. Okay. Who thinks these three measures should not be incorporated into the change? Okay. So you've got some support, to work on those.

Now, are there other modifications

that the committee would like to see on the measures that may not have been captured in those three concepts? Okay. I think we, I think we have a wrap. Rebecca, you're holding up really well. That association should give you a raise just for --

MS. SWAIN-ENG: Kathy Rydell, CEO. Let her know.

CO-CHAIR CONWAY: I'm sorry.

DR. LAWLESS: Maybe a point of protocol. Seems when you presented this initially you presented this as more of a bundle, these are all the things together. And since this, our lessons learned yesterday, since these are all very similar, and my prediction would be, is we're going to have the same discussion over and over again.

From a protocol, NQF protocol, instead of having those two hours of each one again, is there a way we can actually, or are you allowed to wrap the entire discussion and say, this may be applicable to all of them?

Save a lot of time?

CO-CHAIR CONWAY: Why don't we go through those and see if that's some of them. That's a good idea, but they may be a little bit different. Iona?

MS. THRAEN: I was the secondary reviewer on the next three, and there's some nuance differences related to, mostly related to the CPT code, code two, opportunity, that I can go over quickly and then you can decide whether or not you just want to --

CO-CHAIR CONWAY: Good idea. Steve, invoke that as we go along. Let's, let's open the discussion first. So, our next measure is patient safety measure 11 dash 10, counseling about epileptic, epilepsy specific safety issues.

And, our primary reviewer for that is Ellis Diamond. On the phone. Ellis, do you want to give is an overview of this measure?

DR. DIAMOND: Okay. The, the issues here are really, it is very similar to the

concerns with these very similar to the concerns with these very similar to what was discussed regarding counseling, querying and counseling for, both for agents.

But, this measure, patient safety measure, is 011-10, counseling about epilepsy specific safety issues, and it relates to concerns that have to be addressed on a once a year basis regarding community safety issues to include particularly driving restrictions, bathing issues for safety, bathtub versus shower, and through prevention, burns, particularly cooking, barbequing, safety around potential, potentially burn prone devices.

And any other injury prevention, you know, avoidance of heights, sports activities, all of the various exposures to possible injuries should someone have a seizure that's not controlled by medications.

Again, this is a measure that's not, that has not been actually recorded or

measured, but it is, as I understand it, they AAN anticipates the measurements to take place.

I think all of the concerns that were realized regarding the previous measure apply in this instance, as well. Rub, Rub, I would ask Rebecca, are there other comments that you would add, having been actively involved, or Dr. Bever, having actively involved in the creation of the measure?

CO-CHAIR THIEMANN: Dr. Diamond, Rebecca had to step away for a few moments. If you don't have any additional questions concerning these at this time I'd ask for secondary discussion leader Iona Thraen to go ahead and add any additional comments.

DR. DIAMOND: I'm sorry, I, I can't hear you. I'm sorry.

CO-CHAIR THIEMANN: Oh, I'm sorry. Rebecca had to step away for a few moments, so she'll be back in a moment, so I would just now ask secondary discussion leader Iona

Thraen to go ahead and add her additional opinions regarding PSM 11 at this time. Okay great thanks.

MS. THRAEN: Couple, just couple of observations. One was that the in terms of the evidence for improvement there wasn't much evidence presented on the percentage of injuries that you're counseling about, how they're related, what percentage of those injuries are related to seizure activity.

So I didn't see anything in that area. The, there is the same kind of idea of using a list of ICU 9 codes specific to those diagnoses and Office codes and then this CPT 2 coding system that they talked about. But you have the same problem in terms of capturing that data and having to do chart review, et cetera.

I was a little bit confused, and Rebecca's back now, so maybe she'll be able to clarify this in her comments, about the level of evidence, I saw evidence based guideline

and then expert opinion, and again, I was, you know, it's sort of the common sense idea of the contribution of this disorder to these risks, or the risks of this disorder in terms of these kinds of issues with a lot of societal infrastructure already in place in terms of laws about driving and more vehicle risks, et cetera.

Whether or not that, that, that evidence is strong enough outside of, in, above expert opinion. There was some evidence grade C related to the chronic effects of epilepsy and it's treatment regarding drug side effects, drug-drug interactions, effect on bone health, contraceptive family planning and pregnancy and menopause.

And then, level D, secondary evidence related to driving and safety issues. So again, the quality of the evidence was a question mark in my mind. They used the same methodology, the PCPI methodology for achieving this.

They had broad system support and clinical representation support with the number of different organizations that they previously mentioned in the, in the previous measure. And, plan, testing's not been done, as already previously mentioned, but is in the planning works.

There is no reliability testing. The CPT code modifier that they, is mentioned here, is 44330F/3P, and again, this is, from the previous conversation, it's not a billing code. So the electronic opportunity is limited, so you're back to manual chart review.

There is a statement regarding public reporting. The statement is the measure is not currently in a public reporting initiative, it was submitted for consideration of inclusion in the PQRI 2011 program.

Currently developing a maintenance of certification performance and practice toolkit program that will be, will use this

measure, very similar to the one previously. Coding and abstractions performed by someone other than the person obtaining the original information is the recommended feasibility requirement for data collection. And, that's it.

CO-CHAIR CONWAY: Okay. Thank you. We could open this up for discussion of the points of the measure, the measuring and reporting on this. And, go ahead, David.

DR. NAU: Sure. Just a, a question about the numerator statement. Was the numerator statement derived from the CPT 2 code definition, wherein the --

MS. SWAIN-ENG: I think there's a little bit of a confusion about what a CPT 2 code is. The CPT 2 code is developed after you develop the measure, I know we have Dr. Gabel here, who is the chair of the performance measurement advisory group.

And what the CPT 2 code is basically operationalizing the numerator

statement with a simple number. So it's not associated with billing, it's not, we're not trying to fit this measure into an existing code.

This was a brand new code that was created for this specific measure.

DR. NAU: Right, but this, every CPT 2 code does have a definition statement to decide what it is, and that's just what I'm wondering, if that definition is identical to the numerator statement --

MS. SWAIN-ENG: Yes, yes.

DR. NAU: -- okay. Because it seems misleading here that the numerator describes this as appropriate counseling, and I guess that's really where we can't truly assess whether it was appropriate counsel, we just know that counseling was done and that the box was checked, that, you know, add the CPT 2 code.

So, I would prefer that we just narrow the numerator statement to be what we

really know, is that, you know, there was this counseling occurred. I'm not going to make a big stink over that, because I know that lots of the codes are defined as saying that it was appropriate counseling or appropriate querying. I'm just, it may be this concern more about the way definitions are selected.

MS. SWAIN-ENG: I know, we worked with the PCPI's methodologist to help us really with the wordsmithing of this measure and the word appropriate is referring to the patient's specific disease. So, not all epilepsy patients need the same type of counseling.

Somebody who is five with epilepsy's going to need different counseling than someone who is twenty five and driving with epilepsy. What's appropriate to the individual patient, kind of really making that specific to the patient and what they need, its not necessarily saying whether its appropriate overall, just maybe the better

word is to say, you know, specific to the patient, but that was the wordsmithing that our methodologist came up with, which is the same one again that the PCPI works with.

DR. NAU: And, and that's fine. I just think specific to would be better than appropriate to, but, minor point. Thanks.

DR. NAGAMINE: I was going to say, or, age appropriate.

MS. THRAEN: Actually they say context specific, is the, is how they frame it. Context specific safety issues.

CO-CHAIR CONWAY: So, further questions or discussions around the issue of importance of the measure? Dr. Diamond or Solomon, do you have any questions or comments about importance of the measure?

DR. SOLOMON: No.

DR. DIAMOND: No.

CO-CHAIR CONWAY: Okay. Steve?

DR. LAWLESS: Yes, I just, want to ask again, in a very curious way, you've

mentioned a bunch of times the pay per performance methodology. You hinted once before. The purpose of all the measures here, tell me, from the society's standpoint, are, for the overall patient population good, or is it, is the purpose of the measures, qualify for pay per performance, we need measures that are identified.

MS. SWAIN-ENG: It's a combination of things. So overall, the reason that we develop measures is to improve care for patients that have a neurological condition, regardless of how that's done, how the measure is implemented.

If it's in an internal QI program, if it's in a pay per performance program, if it's in any other type of performing me that's more of a system based program. But it, there aren't a lot of measures, as I mentioned earlier, for neurological conditions that currently do exist.

And epilepsy is one of the leading

causes of mortality and morbidity and decreased quality of care for our patients. And it's something that we really felt that needed to be addressed.

DR. LAWLESS: So, what, what, the gap that you're seeing in care, I'm, I'm trying to think of, what was the driver in the gap or the gap in care versus the gap in we're not being rewarded for this?

MS. SWAIN-ENG: It's more in the gap of the patient's not getting the care they need. Versus that the patient, that the physician is not getting paid for it.

DR. LAWLESS: And there's strong evidence of that?

MS. SWAIN-ENG: Our, our workgroup, yes, found that evidence, I don't have it in front of me at this moment, but yes.

DR. LAWLESS: Was it included in the documentation?

MS. SWAIN-ENG: There should be some references in your documentation that would

support that. And I know, what, Iona had -- here we go, sorry.

MS. THRAEN: The citations for the performance gap are listed as website, NINDS, National Government Institute of Health, .gov, disorders, epilepsy.

And, accurate diagnosis of type of epilepsy a person has is crucial for the treatment, and it goes on actually the focus of the evidence that was presented on the gap.

And I actually, I had some questions about this, is more about the diagnosis of epilepsy rather than the risks associated with the diagnosis and the treatment of the epilepsy.

So, it didn't really provide much evidence to support that, that question. It's more about diagnosis than -

MS. SWAIN-ENG: I, that's one of the things that we'll, you, you'll always find with safety issues, I'm sure you've encountered this with other measures, that the

steering committee has reviewed that often times the evidence that you have available to support isn't going to be a level-A randomized control trial.

Because you're not going to randomize somebody, for example, to jumping on a plane with a parachute and without to see whether or not a parachute actually saves lives. So it's hard to get that high level evidence to go to support safety specific measures.

So what you're reliant on are the measures that are available, or, excuse me, the recommendation statements that are available from guidelines which, sometimes, as in this case, are, is a consensus based process that was developed by Dr. Pugh and was a very reputed study and is very well known.

But it does go to support the, the recommendations that were used to support this measure, and after having, you know, our very broad based stakeholder panel, the beginning

of the conversation going of, you know, what's missing, for, for your patients with epilepsy, what do they really need.

It's bringing all that information together and really realizing that this isn't being done in practice. You think it's being done, it's common sense you would ask about safety issues with somebody who does have epilepsy, but it's not being done, it's not being done on a regular basis, and it's something that really has an opportunity to improve quality of care for those patients.

MS. THRAEN: There's also the same problems that you have with the early one about the, who's providing the service, it's specifically aimed at physicians, MD's and DO's, and then the question of care settings, it's emergency clinics, nursing homes, and hospital outpatient specific.

DR. BEVER: This is Chris Bever. Can I make a comment on the earlier question?

CO-CHAIR CONWAY: Sure. Yes.

DR. BEVER: I just wanted to point out that there are four references in the packet that went out to you under the rationale for the measure that are articles primarily related to driving safety and epilepsy, and they do address the gap in care issue.

CO-CHAIR CONWAY: Alan?

MR. LEVINE: That was -- actually that was -- questions directed at that point, in terms of data on driving accidents -- my question was related to that point about data on driving accidents, work -- work related seizures, things that may fall under occupational health data that CDC might maintain, whether -- they did reference something in the document that I, where was that in the document?

CO-CHAIR CONWAY: Page three.

DR. MUETHING: It's actually under impact, not under gap.

CO-CHAIR CONWAY: The top of page three. Steve?

DR. MUETHING: And just to reiterate on this point, it is under impact, and I did not read the four references there, I, I, my assumption is, those are describing the significance of -- of doing this counseling.

But unless I'm missing it, I don't see any evidence that there is a defined gap, that x percentage of neurologists or primary care providers provide counseling and x percentage do not, which is something we have with each of the measures yesterday, current state, we don't have a -- evidence about current state.

DR. NAGAMINE: Which would go back to the issue of testing, possibly.

DR. MUETHING: Right.

CO-CHAIR CONWAY: Other questions or comments about the importance of the measure? Okay, should we proceed to grading the measure on importance? 1A is the degree to which it

demonstrated high importance. Those who feel that was completely demonstrated, please show your hands. Partially? Five, six, seven -- nine. Minimally? Five. And, Dr. Diamond?

DR. DIAMOND: Partially.

CO-CHAIR CONWAY: Dr. Solomon?

DR. SOLOMON: Partially.

CO-CHAIR CONWAY: Okay, thank you. 1B is the demonstration of the gap. Those who feel that was completely demonstrated? Partially demonstrated? Minimally demonstrated? Seven. And not at all demonstrated? Seven. And Dr. Diamond?

DR. DIAMOND: Partially.

CO-CHAIR CONWAY: And Dr. Solomon?

DR. SOLOMON: Partially.

CO-CHAIR CONWAY: Okay. Thank you. And, 1C is the evidence supporting the relationship to outcome. Those who feel that was completely demonstrated? Partially demonstrated? One. Minimally demonstrated? Seven. And not at all demonstrated? Six. And

Dr. Diamond?

DR. DIAMOND: Minimally.

CO-CHAIR CONWAY: And Dr. Solomon?

DR. SOLOMON: Not at all.

CO-CHAIR CONWAY: Okay. And looking at this category, overall, was the threshold of importance to measure and report met, the answers to that will be yes or no. Those who feel that that was demonstrated, please vote yes.

Okay, those who feel it was not demonstrated, please vote. Three, six, nine, twelve, fourteen in the room. Dr. Diamond? There was, there was fourteen nos in the room, for Dr. Diamond and Solomon. Dr. Diamond?

DR. DIAMOND: No.

CO-CHAIR CONWAY: And Dr. Solomon?

DR. SOLOMON: No.

CO-CHAIR CONWAY: Okay, thank you. Then that measure would not move forward based on the importance criteria. We can move on to patient safety measure, 12 dash 10, querying

about falls in patients with Parkinson's disease. And, Rebecca, do you want to have any opening comments on how this might be different than the seizure category?

MS. SWAIN-ENG: Sorry. The patient population for this measure, we're switching the last two measures that you'll be discussing from the Academy this morning are Parkinson's disease measures, so that is the patient population that would be eligible for this specific measure.

This measure is for all visits for patients with a diagnosis of Parkinson's disease, and then the numerator statement, where the patient was queried, patient or care giver, as appropriate, was queried about falls.

I know there's currently, I believe, an NQF endorsed falls measure, however I believe that's a geriatrics measure that only applies to those sixty five years old and older.

And since falls are so prevalent in patients with Parkinson's disease and Parkinson's disease can begin earlier than sixty five, the workgroup felt that that necessitated the creation of this measure.

CO-CHAIR CONWAY: Thank you. Our primary discussion leader is Ellis Diamond, on the phone.

DR. DIAMOND: Again, this is the querying about falls in Parkinson's disease patients. The measure requires querying about falls where appropriate, if the patients or the care givers, it's a safety issue, it's a patient experience type of measure.

It's a public reporting, quality improvement accreditation payment incentive and accountability purposes. I think the rest of it is pretty self explanatory, as mentioned by Rebecca, so if we could go to discussion.

CO-CHAIR CONWAY: Okay, thank you. And additional comments from Iona?

MS. THRAEN: A couple of things. One

is that there's been no testing. It's very similar to the epilepsy measures. This one and then the next one. So this is a specific process measure aimed at getting at information specific to falling.

And then the followup one is a more broad measure aimed at looking at context specific patient safety, or, yes, patient safety issues. No testing has been done on this at this -- up to this point. The prevalence is 1.5 million incidents, 60,000 new each year.

Cost, about $2,500 a year in meds, 5.6 million dollars annual cost related to the falls. With falls, you have the risk of head injury, hip fracture, et cetera. Eighty percent of the falls are due to freezing and postural instability, with 25% of falls resulting in injuries.

There is in the gap question some evidence regarding gap, patients receive appropriate care related to Parkinson's

disease using ten, the ten indicators -- indicators of Parkinson's disease about 69% of the time.

There's large variations by process of care with specialists delivering care in racial and ethnic disparities. Annual assessments of important symptoms of Parkinson's includes falls, depression, hallucinations, orthostatic hypotension.

When those assessments were conducted, only 35-to-60% of the time were those, these items assessed in the annual -- annual visits. And then a movement disorder specialist was associated with appropriate care, it was delivered 78% of the time.

However, in two thirds of patients in one study, they were never seen by a movement disorder. So it looks like you have wide variation in the practice that the association is trying to address.

It's a process measure, not an outcome measure. They're looking for

documentation, at least annually, regarding the occurrence of falls. The strongest predictor for a fall is having had one fall. So that's an important component.

Level-B evidence, in terms of the strength of the evidence that's out there. Broad support in the -- in a variety of communities, and they have applied as of March 30th of this year, they did apply for a designated CPT code similar to what you saw in epilepsy but as of this writing had not received it. I didn't know if that had changed or not.

MS. SWAIN-ENG: Yes, we have received it.

MS. THRAEN: Okay. So, again, not a billing code, but I would call it a designation code for flagging charts, is available at this point. And they're looking at an annual measure. And they are planning for testing again as a chart review process just like the ones previous, and I think

that's all I have.

CO-CHAIR CONWAY: Okay, thank you. And Alan Levine was our other secondary discussant. Do you have any additions to that?

MR. LEVINE: No.

CO-CHAIR CONWAY: Okay. We have questions or comments on the category of importance? Let's go counter clockwise. Cliff and then --

DR. KNIGHT: In general, on this one, I think there's more of a defined gap that's been demonstrated, and I like the fact that the measure itself is more defined from the standpoint that it's more of a yes no, did you query about it or not, rather than did you counsel.

And counsel is such a broad based area, so personally, I find this one more valuable in general and more demonstratable importance as far as that goes.

DR. LAWLESS: Just a clarification. Actually for you. Mentioned about the CPT A

code or whatever, the --

MS. SWAIN-ENG: Two.

DR. LAWLESS: Two, code, sorry, that you got, that you have. It's being published now, or just accepted as a code?

MS. SWAIN-ENG: So the CPT code was released by the PMAG earlier, was it this year, which the code is actually, I have it, it's 6080F, is the code. And then if you have a modifier, there's one exclusion for this measure, which is a patient is unable to respond and no informant is available, so you can code that as 6080F-1P, 1 -- being the patient level. Yes.

DR. LAWLESS: And I -- I'm not sure about the coding piece, I'm talking about, so it's approved, it's gone through RUC, it's gone through everything, it's going -- it's published?

MS. SWAIN-ENG: It's been approved by, well, PMAG is the group that approves the codes. It's kind of more of a RUC --

DR. LAWLESS: It's, generally, it's out there.

MS. SWAIN-ENG: It's out there, yes. It's on the PMAG website, which is part of the AMA website.

MS. BOSSLEY: It's -- I should give you the caveat, my last job was with the AMA, I was a Director at the Physician Consortium. So what happens with the CPT category 2 code, it's the same process in many ways as the category one codes. So it goes to the editorial panel.

Everything goes through the CPT editorial panel. So this, if it has a number, and it's out there, it's been through the editorial panel, yes.

CO-CHAIR CONWAY: Don?

DR. KENNERLY: I think, although, again, it's -- it may be easier to get some of this information, one of the things that concerns me a little bit is -- is the notion of even though there may be a gap in

documentation, I wonder whether there's really a gap in asking those questions.

Because in a sense, I mean, in some respects, it's like asking cardiologists, did you ask about chest pain. And deciding to pay, you know, whether you put them in, now, again, they'll probably do it, but the question of whether or not the absence of documentation reflects necessarily the absence of the process of care itself.

And so as we begin to start thinking about this, I wonder if, because there's no intervention involved, clearly, I think most neurologists are aware of the issue of falls, is this going to generate a greater awareness on the part of physicians to be doing, asking about this, and, again, I don't know that there's really been much in the way of findings that would support that in fact that this will actually be changing physician behavior along those lines and, and, and again, I agree, I think, with Cliff, from the

perspective that the absence of a counseling makes it easier, but I guess I'm not so sure that if people don't say well, gee, maybe, you know, your, you should have assistance with regard to your walking on an ongoing basis, that just asking about, it's going to make much of a difference in terms of how the patients ultimately do.

So I feel kind of ambivalent about that and wonder about your thoughts along those lines from the developer's perspective.

MS. SWAIN-ENG: I think the reason that -- one of the reasons that this measure was developed is that by simply asking about falls, if they've had a fall since their last visit, you are assessing their risk for having a future fall, a past fall is a greatest, as Iona had mentioned, from the data, a past fall is the greatest risk factor for actually having a future fall.

So it's important to ask those questions so that you're preparing that

patient, specifically with Parkinson's disease, which is a movement disorder disease, to know that they need to be more careful. This starts the conversation. It's not the end of the conversation, but just by the querying, there is future interventions that may take place as a result of the conversation.

I know we do have -- in the additional measure that we'll be discussing shortly, that is more of a broad based safety measure, which does include the counseling in that measure, but having Parkinson's disease and having the risk of falls being such a major problem for them and being specifically focused due to their disease or to their condition, the workgroup felt there was a need for this measure and that there was a significant enough gap to necessitate the creation of this measure and that this wasn't being done in general practice, working with the different neurologists and working with the different family practitioners, and

similar to the epilepsy workgroup we had a very broad based stakeholder group.

I think we had twenty four on this workgroup representing all the specialty societies that would have a vested interest in this patient population and may be seeing a patient with Parkinson's disease, and they felt that this was not being done in practice.

DR. KENNERLY: You just, just a point of clarification, that, the question wasn't being answered or the chart didn't reflect that the question was being answered? Because I'm wondering, in a sense, what we're presuming is the absence of documentation presumes the absence of asking the question, and I think many of us will wind up documenting that a fall happened, we'll ask about it, if it happened we'll put it in the chart, but we may not say there was no fall over the course of the last year.

And so I guess, sort of the absence of proof isn't the proof of absence, and so I

just wonder is -- does your group feel as though, really, the practice of asking questions is uncommon, as opposed to the documentation of having had that discussion uncommon.

MS. SWAIN-ENG: I don't know that I would use the word uncommon, but I would say it's not as high as it should be. It's not actually being asked. And for this measure and any measure that's been developed by either, other outside organizations, if it's not documented in the medical record it didn't happen.

And so for following additionally so if that patient was able to go to see another physician and the physician looks at the medical record, if it's not in there that the physician asked about falls and, yes, Mr. Smith had a fall two weeks ago, how are they going to know to change maybe perhaps their course of care when they're seeing that additional physician.

DR. KENNERLY: Well, I, I'll take a little issue with the notion that the absence of documentation means it didn't happen. You can't --

MS. SWAIN-ENG: Just for the purpose of measurement --

DR. KENNERLY: No, I understand, by my point is that if we're trying to understand the degree to which this may have impact, then I guess we -- it would be helpful to get a sense of whether it really wasn't happening, that is, in a sense if one were to go into situations where it was not documented in the chart and find out that in fact those patients had falls.

I think that would be very compelling. On the other hand, in the absence of at least some evidence along those lines, I would be a little concerned that what we're dealing with is a documentation issue and not necessarily the practice itself.

Although, again, good practice is

good documentation. I'll grant you that.

CO-CHAIR CONWAY: Steve, and then Alan, and then the left side of the table.

DR. MUETHING: Thanks, I think my question is for Dr. Diamond. I see the evidence that 70% of Parkinson's patients will have a fall in the first eight years, and so my question is about the impact.

If there's already a endorsed measure that all patients over 65 should be screened on this, it takes away half the patients already, they're already covered by that measure.

So for the remaining patients that are under 65, do we have any evidence of when the falls occur? Are they more prone in the over 65 patients, and are the patients under 65 have the same rate of fall, or is it different?

DR. DIAMOND: I think there's considerable evidence that the younger a patient starts the worse -- the severity of

the disease increases, so that the patients who start younger, they tend to do considerable worse clinically than patients who are older. I would use the cutoff at age 60 as the cutoff for that discussion.

DR. MUETHING: So I think I can take from what you're saying is that there is a potential significant impact for patients under 65 with Parkinson's?

DR. DIAMOND: Yes.

DR. MUETHING: Thank you.

MS. SWAIN-ENG: And I believe that geriatric measure also is only a once during the measurement period, so it's a different temporality to the measure as well, if I recall correctly.

MS. THRAEN: One of the things that I noticed I was sort of following up on the logic that Dr. Kennerly was talking about, not so much in terms of documentation but what's the -- what's the intervention here.

And what struck me, again, going

back to the performance gap, was the notion of a movement disorder specialist. So you have a -- you have a patient with this particular condition who's had a fall, and in the performance gap they talk about that in one -- in one measure movement disorder specialist was associated with appropriate care delivered 78% of the time.

However, about two thirds of patients in the study were never seen by a movement disorder specialist during the seven year study period, and these patients were significantly less likely to receive appropriate care compared to those with movement disorder specialist involvement.

So the question for my -- in my mind is that if you're asking the question, if you have a patient who's fallen, and if the first fall is a predictor of future falls, that's an important piece. And then if you have a first fall, then the referral in terms of the movement specialist and whether not

that is the safety question, as opposed to the documentation of the query. Back to the conversation that we had yesterday.

CO-CHAIR CONWAY: Janet?

DR. DIAMOND: I'd like to suggest that I was not involved with the measure, but I don't think that was an intention. It -- I don't think most patients with Parkinson's are seen by a movement disorder specialist, and certainly not on a regular basis.

They -- oftentimes they'll be referred for an opinion, but then followed up by your family physician, your internist, or a, you know, regular neurologist. But I don't think that was the intention.

CO-CHAIR THIEMANN: Iona, can I just ask you a point of clarification. I understood you just -- that your comments to more mean that, you know, the measure isn't intending to indicate that you then would need to make a referral as a followup because right now the measure doesn't ask for any action. You're

just citing the evidence that they were basically saying that that those patients who were referred did perform better.

MS. THRAEN: It goes back to the conversation yesterday about -- when I asked the question about well, what would you consider a medication safety measure, and the response was that you've gotten information and you didn't act on it, you didn't take the next appropriate step to resolve that lab or resolve that medication problem.

And so I saw this in that sort of same kind of paradigm based on this evidence, but that this measure is not addressing that on any level. It's addressing the documentation of querying, and so kind of raising that question again, is this really a safety measure, given sort of the paradigm that you talked about yesterday about once you have documented that there's a fall, or you've asked the question that there, whether or not there's been a fall, you have a first fall,

then what's the next step in terms of minimizing that safety risk, really is what I was looking at. But, no, this measure does not address that.

CO-CHAIR THIEMANN: Right, and so you -- so I'm getting the sense that I'm hearing you say that it's -- it doesn't go far enough.

MS. THRAEN: I'm a little reluctant to say that, but yes.

DR. NAGAMINE: My question was along those lines exactly. So if someone says no, what would you expect to happen, and has there been discussion around that? Because yes and no, I mean it's good to ask, but then do they act on that risk and mitigate it in some way?

MS. SWAIN-ENG: So it is assumed that if the physician finds that the patient does have a -- patient that says, yes, I've fallen, they'll take the appropriate action. The evidence base for this measure is simply

asking if the patient has had a fall. So, again, we're very evidence based and we're looking specifically at what's out there.

This is seen as being a really great first step. It will probably evolve into a more complicated measure in the future, but for right now, this is a really great first step to actually give the physician a better idea of what the patient needs by asking them about falls, and if they've had any since their last visit.

CO-CHAIR CONWAY: Okay. Other questions or comments on importance --

DR. NAGAMINE: Just a followup to it. So you said that it -- it's assumed that there would be some action taken, and I didn't look through the testing piece, so what will you be looking for?

MS. SWAIN-ENG: Well, to meet the measure, just to simply meet the measure they need to document in the medical record that they queried about falls.

There is no follow up that they needed to refer them to, say, a movement disorder specialist, simply because they felt that this measure, by the simple act of asking about falls, you were getting a better idea of your patient needs, and that there would be some action.

But the measure itself, based upon the evidence that was available, was simply about querying.

DR. NAGAMINE: Thank you.

DR. KENNERLY: Well, could I suggest, you know, when you're testing, it might not be a bad idea to be asking or looking at those other things as well, thinking about sort of future development, I think that's what Janet was hinting at, is that if you're going to be testing, then it might be a good idea, as you're getting that information, to try to start collecting mitigation kinds of information, not relevant to this particular measure, but in a sense

beginning to think about the evolution that you've already discussed.

MS. SWAIN-ENG: Similar to what we're doing with epilepsy this also is incorporated into a maintenance of certification program similarly to what we discussed earlier, where those types of questions will be asked with interventions and outcomes and data provided back to the patient on their individual score.

And then we're looking at doing benchmark data, too, so they compare themselves either to the group that within they work -- within -- excuse me, within the group that they work in, and then within the group that have completed the MOC part four program.

CO-CHAIR CONWAY: Okay, Drs. Diamond or Solomon, do you have any questions or comments around the issue of importance to measure?

DR. DIAMOND: No, I think the points

raised are all very valid.

DR. SOLOMON: No further questions.

CO-CHAIR CONWAY: Okay. Does the Committee have any further questions or comments around importance to measure? Then should we move onto grading that? The first, 1A, on the -- whether high impact was demonstrated. Those who feel that was completely demonstrated please show your hands. We have one. It was partially demonstrated? Ten. Whether it was minimally demonstrated? There's three. I think that's everybody in the room. And Dr. Diamond?

DR. DIAMOND: Partially.

CO-CHAIR CONWAY: And Dr. Solomon.

DR. SOLOMON: Minimally.

CO-CHAIR CONWAY: Okay. 1B is whether a gap was demonstrated. Those that feel it was completely demonstrated? Partially demonstrated? Seven. Minimally demonstrated? Six.

There's one missing, is it not at

all demonstrated? Have an abstainer. One abstention. Okay. You're messing up my count, Steve.

DR. MUETHING: Sorry.

CO-CHAIR CONWAY: Dr. Diamond?

DR. DIAMOND: I think partially.

CO-CHAIR CONWAY: And Dr. Solomon?

DR. SOLOMON: Minimally.

CO-CHAIR CONWAY: Okay. Thank you. And then 1C, this is the category on the -- whether the outcome would be Affected. Those who feel that was completely demonstrated? Partially demonstrated? Minimally demonstrated? Eleven. And not at all demonstrated? Two. And one more partial. Okay, that's everybody in the room. Dr. Diamond?

DR. DIAMOND: Minimally.

CO-CHAIR CONWAY: And Dr. Solomon?

DR. SOLOMON: Minimally.

CO-CHAIR CONWAY: Okay. Thank you. And for the overall grading of this section on the importance to measure, those that feel

that this measure is important to measure, please signify by -- raising your hand yes. There's two yeses. And those that feel the answer to that is no, please raise your hand. Six, seven, eight, nine, ten, twelve nos. And Dr. Diamond?

DR. DIAMOND: Yes.

CO-CHAIR CONWAY: And Solomon?

DR. SOLOMON: No.

CO-CHAIR CONWAY: Okay. That measure fails to meet the threshold of importance to measure. And let's move on to the last in this section, patient safety measure 13-10, Parkinson's disease related safety issues counseling related to that.

And our primary reviewer is Ellis Diamond.

DR. DIAMOND: I'm going to defer to Iona. She really was very thoughtful in the previous one, I think, her --

MS. THRAEN: A punt. All right. I did my homework. This is a process measure,

this is similar to the second measure, very much like the second measure for epilepsy which is a broader category of counseling over a number of issues, what they call context specific safety issues appropriate to the patient stage of the disease, injury prevention, medication management, or driving at least annually.

The use is for public reporting, quality improvement, accreditation, payment incentive, and accountability. No testing has been completed. Same incidence and prevalence related to Parkinson's disease as previously stated.

Lots of functional difficulties related to the disease state, including motor function, visual perception, reaction time, information processing, that tend to impact driving and using equipment. Same gap information related to the, receive appropriate care related -- as a result of those -- measured by those ten indicators of

Parkinson's disease.

And the same gap associated with referral to a movement specialist. Information was cited, type of evidence, I thought, in this instance, type of evidence is listed only as expert opinion and not guidelines. I don't know if that's a typo, or if that's the truth.

Let's see. I mentioned already, it's annual. Also in this, it indicated that they had applied for a CPT code, and I, as of this writing, had not received it. They have one now? Same office codes and diagnostic codes as previously described.

Testing is planned, again, chart review. For the future. Care settings include ambulatory care, office, clinic, hospital outpatient and nursing homes. Is it intended that -- it is not currently in a public reporting initiative, but has -- was submitted for consideration and inclusion in the PQRI 2011 program.

Third party coding and abstraction

necessary for feasibility. And broad support from a variety of sponsoring organizations. That's it.

CO-CHAIR CONWAY: And Don Kennerly was another secondary reviewer. Anything to add, Don?

DR. KENNERLY: Far be it from me to add to Iona's -- no, I think -- I think she did a very nice job, and I do think, you know, this is likely to have sort of a similar profile to the parallel discussion that we had as it related to a -- patients with seizures.

CO-CHAIR CONWAY: Okay. The section importance to measure, are there any questions or comments for that section? Any on the phone? Okay, should we move on to grading this section?

Those that feel that this measure demonstrated high impact, please show your hands for completely. Partially? Minimally? Twelve. That's everybody in the room. And Dr. Diamond?

DR. DIAMOND: Minimally. I have to agree.

CO-CHAIR CONWAY: Dr. Solomon?

DR. SOLOMON: The same.

CO-CHAIR CONWAY: Okay. Thank you. And, 1B, whether a gap was demonstrated. Those that feel it was demonstrated completely? Partially? Three. Minimally? Seven. And not at all? Two. Dr. Diamond?

DR. DIAMOND: Partially.

CO-CHAIR CONWAY: And Dr. Solomon.

DR. SOLOMON: Minimally.

CO-CHAIR CONWAY: Okay, thank you. And then, 1C, whether the link to outcomes was demonstrated completely? Partially? Minimally? Nine. And not at all? Three. And Dr. Diamond?

DR. DIAMOND: Minimally.

CO-CHAIR CONWAY: Dr. Solomon?

DR. SOLOMON: Same.

CO-CHAIR CONWAY: Okay. Then for the overall category, whether this measure is important to measure and report on, those that

feel that should be adopted, please signify by raising your hand yes. Those who feel the answer to that is no? Okay, there's twelve in the room, and Dr. Diamond?

DR. DIAMOND: I have to say yes.

CO-CHAIR CONWAY: And Dr. Solomon?

DR. SOLOMON: No.

CO-CHAIR CONWAY: Okay. And that measure does not move forward. What if we grab some lunch, and then the awful thought would be to work through colonoscopy during lunch.

I'm sorry, what? Oh, sorry, sorry. Are there any members or public comments to hear at this point? Okay, we'll have colonoscopy for lunch.

(Whereupon, the above entitled matter went off the record at 12:05 p.m. and resumed at 12:23 p.m.)

CO-CHAIR THIEMANN: Since we still have five performance measures, I believe it is, up for consideration this afternoon, and I know everyone's chuckling, it's almost 12:30.

So, like to reconvene, like to welcome Dr. Ron Gabel, who is here representing AAAHC Quality Institute.

And we would go ahead and move on to performance measure 14, colonoscope processing personnel instruction. Dr. Gabel, would you like to provide a few introductory comments regarding the AAAHC's performance measure, please?

DR. GABEL: Sure. I'll be half of the presenting team. Naomi Kuznets is the Director of the AAAHC Institute for Quality Improvement, and she should be on the phone, and so she and I will share the responsibilities for answering questions. Naomi, are you there?

DR. KUZNETS: Yes, I am.

DR. GABEL: Okay. The general concept of these three measures is that there is a clear need for measures to measure the quality of colonoscope pre-processing.

This -- these measures were chosen

actually based upon a clear gap in care, which we can talk about when the time comes. The evidence is anecdotal, coming from news releases about events that occurred in VA hospitals and ambulatory centers approximately a year ago.

You probably know all about that. The inspector general found some abysmal practices. The VA inspector general found some abysmal practices. CMS has been on the issue of infectious disease control in ambulatory facilities, and an article appeared in JAMA in June that showed serious deficiencies.

And so we've got both scientific and anecdotal evidence that problems exist, so we started with gap in care. We worked with the CDC and dealt with -- had conference calls with the coauthors of the CDC guideline for disinfection and sterilization in healthcare facilities.

Another part of the CDC team that we spoke with were the senior author and the

first author on the JAMA article that subsequently came out because the CDC had been out in field gathering data, so we basically got a preview of the data that eventually were reported in JAMA.

So we feel strongly that there is a need out there to measure specific aspects of colonoscope processing that have a serious impact on the quality of patient care. So that's where we started.

And we thought the gap in care was there. We chose these three measures as a start, and we did this cognizant of the fact that in the Tax Relief and Health Care Act of 2006, the Congress mandated that the same sort of quality surveillance be applied to ambulatory facilities as to hospitals.

We've had our ear to the ground, or to the tracks, and the implementation of that program for ARCs was supposed to have taken place in January of 2009. It did not, and we did some probing to try and find out, and

informally we have been told that the reason was that there are not sufficient quality measures that passed CMS's muster.

So and I learned that that which is mandated by Congress can be modified by, in quotes, the Secretary, and so that initiative has not gone forward in part for lack of appropriate quality measures. So we felt that we might be able to assist in that as well, so that's general background on what we've done and why we've done it.

CO-CHAIR THIEMANN: Terrific, thank you. Dr. Kuznets, do you have any additional comments that you'd like to supplement?

DR. KUZNETS: Yes, just to let you know, the choice of the three topics that we are addressing here really came very directly from a discussion with Drs. Rutala and Weber, the authors of the CDC guideline, in coordination with Drs. Perz and Shafer from CDC who had done the -- who had accomplished the research in the pilot states in the JAMA

article.

CO-CHAIR THIEMANN: Great, thank you. I'd like to turn it over to primary discussion leader Dr. Conway.

CO-CHAIR CONWAY: Thank you. I have primary for fourteen, and Jan Allison had fifteen and sixteen and turned over her notes to me when she left yesterday, so I think I'll take, as far as importance, I'll take all three of these together, and the importance of appropriate endoscopy maintenance has, in the past few years, been really brought to light in some famous exposures.

The biggest being the VA hospital system discovering that many of its facilities had inadequate cleaning procedures and having 10,000 veterans exposed to possible viral infections. There were -- but they're not alone. There were similar outbreaks in a hospital in California as well as in Pittsburgh involving thousands of patients.

The V.A. has done the

most work on this, as far as the gap goes. They then started to examine some number of their facilities, and found that only 42% of the reprocessing units had adequate standard operating procedures and documentation of competence in place.

And this is the V.A., this isn't just anybody. So, that's probably a high -- that could be a high water mark on the issue of gap. Virtually any study of viral outbreaks from this procedure have been linked back to improper cleaning procedures.

So, that does happen. The other interesting thing in the work of the V.A., after they insisted that all facilities have competencies in place and standard operating procedures, they went back and audited their organizations and found that none were in compliance.

So they moved from a 42% gap and showed that they could eliminate that through this. Regarding the actual procedures, the

measure set doesn't exactly define competence, partly because it varies by equipment and device.

But the manufacturers of all these provide instructions for maintenance and cleaning of the equipment, they'll often train the staff on introducing the equipment, and some of them even provide an annual competency service to organizations. I checked with ours, and that's what we use.

The specifications are pretty well defined. Usability and feasibility, I think are pretty straightforward. Anybody can do this, this really won't add much expense, a short competency review of the staff on an annual basis is not a large expense load for any organization.

So, that's kind of an overview of all three of those categories, and the differences are fourteen asks that you document that the staff received instructions annually. Fifteen asks that the organization

update its standard operating procedures on an annual basis, and sixteen which I think is a higher requirement, is that they actually demonstrate staff competencies for anybody that's using the endoscopy equipment.

And, for people not familiar with that procedure, that aren't operating healthcare organizations, that means you have a reviewer observe the staff person going through all the steps in a scope cleaning procedure, and articulating the importance of each step and their knowledge base.

So, it's a pretty -- competency is a pretty high bar to ask for. So that is quick overview. We have secondary comments, too.

CO-CHAIR THIEMANN: Thanks. At this time, because we're considering PSM-014 initially, I'd like to ask the secondary discussion leaders, Dr. Knight and Mr. Levine, if they had any additional comments.

MR. LEVINE: Questions, should I want until we have questions, or?

CO-CHAIR THIEMANN: No, that, that's, why don't we finish with opening comments first and then we'll go onto questions.

DR. KNIGHT: I would just say that for this one specifically the numerator statement is that this is colonoscopy processing personnel at ambulatory surgery centers who receive device specific reprocessing instructions at least annually to assure that they've had this training.

So, I see this similar to requirements for fire safety training, for CPR, and if you think about those, the impact -- likelihood of impact with that requirement of training versus somebody who's actually doing this on a daily basis and the impact, the importance I think on being able to affect safety for patients, this is, seems to me, to be a high priority.

CO-CHAIR THIEMANN: Mr. Levine, do you want to, would you like to ask your

questions?

MR. LEVINE: The joint Commission has conditions and standards relating to health and safety and everything else, and CMS does lookback reviews at hospitals after joint Commission is there on regular basis.

In terms for the oversight or accreditation of ambulatory surgical centers, is there, I don't, I'm not sure, there's an organization, private accreditation organization probably does that, I'm not positive but, I don't know which one it is.

But their accreditation process, I'm sure they have conditions, standards, whatever. Do any of those currently on the books relate to following the manufacturer's recommended procedures for cleaning this device?

DR. GABEL: let me for a moment step back from that question because it has to do with whether there is a standard for a given process. And, CDC does in fact have a

standard, the, the, guideline from which these performance measures were derived is a CDC standard.

I'm sure that the joint Commission has standards relating to appropriate, following appropriate manufacturer recommendations and maintaining equipment and things of that sort.

However, those are standards and not performance measures, and of course, the difference is, that standards are -- compliance with standards is determined through the survey process, whereas performance measures are required reporting from the organization.

So, one is sort of a pull, and the other is a push, if you will. AAAHC which is the organization that I represent that developed these measures, is an accrediting body for ambulatory surgical centers, and recently, you probably know that CMS has required the deemed status accreditors to

follow a much more rigorous process in assessing the performance of, or the compliance with, the standards that CMS has for infection control.

So, yes, it is a part of the accrediting process, but it, these are not performance measures. So the intent, you know, if CMS does in fact get to the point where they have a series of required performance measure reporting, as a part of qualification for updating the annual payment scheme, as hospitals do, then this could be used for required reporting.

But it's different from a surveyor going into a hospital or an ASC and determining whether the, the requirements of the standards are in fact being met. Does that make sense?

MR. LEVINE: Yes, in, in a way, yes.

CO-CHAIR THIEMANN: I'd also add in addition to AAAHC doing ambulatory

accreditation, joint Commission also has an ambulatory program as well. But, most of the times, the, the accrediting standards are not very granular, as Dr. Gabel points out.

They tend to be the facility will have a policy for x, y, z. Rather than, you know, the facility will demonstrate that personnel clean colonoscopes. So it's not to that level. It will be generally maintenance equipment, the facility or the organization maintains its equipment appropriately, things of that nature.

So, it's not going to necessarily hit the individuals who are handling and processing colonoscopes at this point.

MR. LEVINE: Yes, I guess I would just say, and I can understand the difference between a performance measure and a condition, but it seems to me that there's something that allowed the, in the V.A. system, or in non governmental hospitals this kind of adverse event to happen, then, the accreditation

process itself is not doing the kind of job it was designed to do. And that's the end of my comment.

CO-CHAIR THIEMANN: Well, there's other influencing factors as well here, and I think that these performance measures are at least initially attempting to get at those factors. One of the groups that I work with is a safe injection practices coalition, as well.

Which, GI clinics, unfortunately in the past couple years have been one of the sources for blood borne pathogen transmissions, due to unsafe injection practices. And, so, working with the CDC staff who consulted with AAAHC QI on this issue.

And, part of the problem that we have is a lack of knowledge, and so although people may have received that education at some point in time during their training, they don't retain that. And so that's where it gets at that competency, the continued competency element.

And that's the attempts I believe by these performance measures is to try and tie into that, because although when you first were hired or when you first became a practitioner, whoever that individual is, you quote unquote had these minimal competencies, but over the course of time, you've lost them.

So I think that's part of what AAAHC is trying to get at here, not, I'm, Dr. Gabel, if you would--

DR. GABEL: I couldn't have said it better.

CO-CHAIR THIEMANN: Okay. Opening up to questions. I think Dr. Lawless, we'll start and come up this way.

DR. LAWLESS: Yes, I actually, this is one way I don't think they go far enough. This is a bigger problem than you're saying it as, because you're hitting ambulatory places only, and I think it's any, any instrument that actually goes, is used on multiple people.

This should be a regulatory issue. This is -- it feels not right to me that you can have office practices that would be exempt from this, when it should actually be one of those givens that you think everybody is going to be using a clean scope, when they actually probably don't, or they don't use it properly.

So, I'm a little bit hesitant, my own hesitancy is that it doesn't go far enough, and I think if the CMS doesn't use its deem status, doesn't use it as a condition to participation, or OSHA doesn't do something with this, it's an embarrassment to them, that you have to go to NQF to start the process rolling if they haven't done it already.

DR. GABEL: One way this could be easily expanded would be to apply the Office space practices, we wrote is specifically for ASCs because those would be the organizations that would come under the CMS aegis under the current legislature, so the need is there.

It could easily be expanded to

include Office space practices, because, because AAAHC and presumably the Joint Commission do accredit those organizations, in fact I, I just got back from a survey in rural Indiana that I did earlier this week.

It was a one, one person practice, a neurologist who did pain management, and so we do, AAAHC just does as rigorous an assessment of, of Office space practices as of ambulatory surgical centers. So, we could certainly modify the denominator to include those as well.

And I think it would be appropriate -- Naomi, you, may I ask her to respond as well, because she, she really is the employee of AAAHC. I'm, I'm a helper.

DR. KUZNETS: Yes. I agree that we would like to see this as regulatory. We would like to see this as expanded beyond colonoscope processing to instrument processing. We thought this was a good place to start, because we know that the number of

colonoscopies that are Occurring in an ambulatory setting is far beyond that, in a hospital setting.

And we also know that the number one reason for any of these infections issues is a problem with processing, and competency in processing. And I'd just like to add, that in addition to the 10,000 folks at the V.A., we know because if you look at our list of participants in this workgroup, that private corporation that manages surgery centers has had recently to inform 40,000 patients from NAC regarding colonoscope processing issues and possible infection.

CO-CHAIR THIEMANN: Thank you. Dr. Kennerly?

DR. KENNERLY: Thank you. And I, perhaps just a protocol question, I wonder, and I'm very happy to pursue the discussions we would normally have it, but it seems as though this set of, of measures really might be considered as a bundle, and where instead

of necessarily thinking of these individually, I think, I, it would be hard for me to imagine that you'd say, well, we'll do these two, but not the third.

And, and so, I think this, again, I don't know what the, what your thoughts are with regard to these. I know that you've thoughtfully developed them as individual metrics.

But whether you'd have some consideration of advancing them as, in a sense, saying the degree to which all of these conditions are, are met because it seems so clear that they're beneficial.

DR. GABEL: Well, when, when we were in the process of developing these, we discussed that option, and we knew that, that, we felt that the safest course was to do them individually, and then, and then deal with the issue of bundling if in fact that came up.

I'm an individual member of the, of PCPI and when, when the issue of bundled

measures was discussed there, it was a highly contentious issue as to whether you really wanted to have an all or none measure, or whether you would weight various factors.

And, we heard what some people considered to be compelling arguments against an all or none, because you really want, would like to have more granularity, to be able to identify a specific area where an organization was deficient.

One way or another, we would be totally open to the recommendations of this Steering Committee if you felt collectively that, that bundling would be in the greater good, we would certainly do what, what you advise to do.

We had thought that leaving them separate and more granular would have, would have benefit from the standpoint of reporting and identifying where the problems lie. Many people consider performance measure reporting as being sort of a continued identification of

gaps in care.

And, and if you're seeing one narrowing and the other not narrowing, it would give society the medical community, if you will, an opportunity to know where to apply corrective action. So, you know, those were the sorts of things that came into our, our thinking when we were developing these.

And we would, we're open to other suggestions.

MS. BOSSLEY: This is Heidi, if I could just follow up, though, I think, and I don't want to interpret what you're saying, but one other option, as opposed to doing, I think you were headed more toward the composite all or none, is kind of a bundle where you cold move these measures forward and all three would need to be used together, they'd be reported out separately, and it would be endorsed, but it would be endorsed as, we call them paired, which is not the best thing because technically you have three

measures.

But, and I, I think that would be another option--

DR. GABEL: Well, that would probably be the best of all possible worlds. You know, because we wouldn't lose the granularity, there's no question that these should be reported together, but I think they should probably be reported individually, but how, absolutely, that makes good sense.

CO-CHAIR THIEMANN: Iona Thraen?

MS. THRAEN: In Utah, we have variation in types of practices that may or may not be accredited by JCAHO or may not, may or may not be accredited by your organization, so the fact that this would be, possibly could be an NQF endorsed measure, set of measures, from a state public health perspective, would help us in terms of trying to get at those entities that don't fall under the accreditation areas.

They're licensed in our states, but

they may not be accredited, and so it would help inform our licensing process in terms of, of being able to investigate those areas.

I will also say that we were part, Utah was part of the pilot effort to look at infection practices in a small group of states, eight or eleven, eight or ten states, I can't remember how many. Anyway, and we found a wide variation in infection practices in the ambulatory surgical world.

They tend to be mom and pop stores, or maybe one physician starts a practices and then he might bring in a second or a third and it becomes a group practice. And then somewhere along the line, they might decide to get licenses, and ambulatory surgical center, and that sort of evolutionary process.

And the industry, the sector is at a place now, it seems, and I'm speaking from what I know locally and I think nationally, where they're ready to be included in the continuum of care and acknowledge that there's

a responsibility that comes with that in terms of upping their standards and their practices, et cetera.

And so I think even at in our rural communities, we're starting to get some traction with upgrading the, the, the, the standards and the practices in those environments.

So, I would support having something to look to as a state agency, a public health agency, that was not necessarily accreditation associated only.

DR. GABEL: Well, this is very encouraging to hear, because we didn't quote know what kind of a reception we were going to receive. But, you know, as Naomi said, this -- the point is that, we've been, we've honed down on these three measures.

We had, we had five general categories. I mean, we thought this was the most fruitful, and, but, if you, if we've got a winner in these three, we'll follow the

model because, you know, patient safety is of incredible importance. We, we all agree on that.

And, you know, if we've got a template here that we can expand usefully, with the support of NQF and, and others, we'll continue, continue diligently to do that. If you can tell us, you know, what we need to make these better, we'll make these better.

And if you, if you tell us as I think you're telling us, that more of the same might be useful, we're good to go. We've, you know, the mission of IQI, the AAAHC institute for quality improvement, is to improve quality.

And we know that accountability measures is one way to improve quality, and, and these are clearly accountability measures.

CO-CHAIR THIEMANN: Mr. Bunting?

MR. BUNTING: A dozen or so years ago, I was in charge of infection control at a hospital system and my first read of this was,

why are we still having this problem. I mean, you would think, twelve years ago, the staff that I had, they did this, you know, religiously.

And they did it for ten years that I was over them, so when I first read this, I was almost taken aback that, here we are a dozen years later talking about it. But I really shouldn't be that surprised because Florence Nightingale discussed the same issue in the 1850's.

So, we've not exactly made a lot of progress in this area. A little levity works this late in the afternoon, but. One of my things is, I don't know every measure that exists, so if we as a group pass these measures, I'd be interested in seeing a similar measure for endoscopes.

Because, if you're going to do colonoscopes, why not do endoscopes. So, I don't know if there's already a measure that's out there, but bronchs, endos, anything that

goes in an orifice like that, should have the same type of criteria, in my opinion.

DR. GABEL: And that's exactly what I was saying, that, that we could with that. Part of the V.A. by the way, the V.A. problems, was in, in an antique clinic, and so part of the, that outbreak was not colonoscopes. Most of it was, and that's why we focused here, but you're actually right.

And it would be easy to expand these, that's why I say if, we've got a template, and it's a matter of now, this seemed to be the, the greatest gap in care, if you will, the, the idea would be then to go down the priority list.

And general endoscopes would, would also fit into there. Just by way of clarification though, for endoscopes that are in fact sterilized, it's a very different set of circumstances than, than flexible endoscopes, which these are.

So, you know, we would want to do

some, some stratification of the endoscope world because I think we probably won't find anything nearly the gap in care with rigid endoscopes that by practice are in fact sterilized. The main problem here is in the disinfection and following manufacturer's, manufacturer's recommendations.

Sterilization is, is, gaps in sterilization are relatively rare. So, but, you know, we'll go back to the drawing boards and see if the scientific data support my inclination. But there are flexible endoscopes other than colonoscopes that we would probably want to focus in on next.

CO-CHAIR THIEMANN: Dr. Nagamine?

DR. NAGAMINE: A question that I had about the deceive manufacturers. Because what we've encountered is, you get a new scope, or a new manufacturer. There are nuances that are very relevant. The materials, the little nooks and crannies and the little screws that you're supposed to.

And that's what's, what's causing the trouble here, is the variability. So how closely have the device manufacturers worked with CDC to mutually agree upon these standards? Or is it simply the manufacturer who's doing this?

And then secondly, what role have the manufacturers played in pushing out the new incoming information that they're getting about their devices? Because, I think we all know, we get manufacturer fatigue, because we get all these alerts about devices.

And sometimes, you know, you miss these important things. So, I think that's another piece to think about and consider.

DR. GABEL: I don't know what CDC's relationship is with manufacturers. But I do know that, that we included manufacturer specific training here, because that's vital, as you've pointed out, every device has different, they have subtleties in design, and they really require different protocols to

ensure that they are appropriately disinfected.

And, so, you know, what works for one manufacturer, if you follow the very same protocol on another one, you might not adequately disinfect. So, it, it has to be manufacturer specific and you're also correct that the manufacturer has a vested interest in ensuring that their device is disinfected properly.

There may be a way down, downstream to involve manufacturers in, in performance measures. We hadn't really thought about that, right now the, the burden is, is on the individual facility to make sure that they are following manufacturer's recommendations.

DR. NAGAMINE: Right, because they often have a pulse of what's going on with their device, and we don't know that in Ohio, that this happened, and so, you know, we always want to keep a pulse on emerging information about their devices.

And, and I don't think that the communication has been as, as quick and prompt.

CO-CHAIR THIEMANN: Sure, go ahead.

DR. KUZNETS: The issue with, one of the major issues is that the V.A. was a new scope and somebody who apparently had gone on vacation and come back to a new scope, and, so, yes, training and manufacturer's instructions are very, very important.

Alternatively, one of the, and that, actually, manufacturers fall under the FDA, unfortunately, is sort of a Division of the bureaucracy in our federal government. But alternatively, some of the issues that we've seen from the JAMA article and from the corporation that I mentioned earlier, are actually issues and following standard protocols for all, all colonoscopes and those would be, as mentioned in the, JAMA article, things like free cleaning. So, very basic issues, so, it's, it does seem to be a

combination of greater technical issues but also of going back to the basics.

CO-CHAIR THIEMANN: Thank you. Dr. Lawless?

DR. LAWLESS: Yes, I'm trying to read through it and just see, does this include cleaning and decontamination?

DR. GABEL: Naomi, go ahead.

DR. KUZNETS: Yes, that is part of that whole process. The whole process, and if you look at the descriptions, we've got cleaning, inspection, wrapping, sterilization, storing, sterilization or disinfection and storing are included in the processing issues.

So, they're in the definitions in each of these. So there's a whole range of different issues within this that are part of the reprocessing processes.

DR. LAWLESS: And, I'm, I'm, maybe more technical. The cleaning decontamination after the use, immediately, does it address, because leaving it up to manufacturer

specifications, one of the big variations that occur is that if somebody allows the scope to sit for a while before they clean it, the secretions, whatever, get caked on and you can't get it off.

So the --

DR. KUZNETS: Right--

DR. LAWLESS: So the idea would be, is there a, is there enough specificity in the instructions by the manufacturers that you found that that would be covered?

DR. KUZNETS: Yes, manufacturers as Ron was saying, are fairly specific in that they want to protect themselves from associated liability. So, anything that they now, and they, because they've had such a range of experiences with the different uses of their products, anything that they know that may lead back to them, they are very, very specific about those particular issues, including timing, temperature, the actual fluids that are being used for the high level

disinfection in terms of the temperature and amount of time.

All those things where you store, the process, all those things are within instructions because they know that those are places where there are issues. And if they're also within the guidelines that are referred to in this, in each of these measures, so it's guidelines and manufacturer's instructions.

CO-CHAIR THIEMANN: Dr. Kuznets, also have a real quick question about the use of the word current. And since it's an annual measure, an annual reporting, this kind of goes back to what Dr. Nagamine was talking about, or I think Mr. Bunting was talking about the problem where someone had gone on vacation and came back and that's where the break had been.

And, so, how is AAAHC operationalizing current, and how do they intend to measure current on a month to month basis so that there isn't that gap, in that

break? Since it's only an annual reporting.

DR. KUZNETS: It will be at least annually, and if you're looking at competency for instance, when that person returns back, to the, to that particular V.A. facility, there should have been, from the competency aspect of this, review of the competency with each of the pieces of equipment, competency would mean appropriate and independent actually processing in front of them and up over, as was discussed earlier.

DR. GABEL: Actually I think that could be more spec. I'm just reading this over. The competency colonoscopy reprocessing personnel who are documented to be competent at reprocessing colonoscopes on initial assignment and at least annually thereafter.

It may be that, Naomi, we should modify that to say, to specify that anytime the protocol is changed, that competency needs to be remeasured. It would be an easy modification to do, it would just be a matter

of expanding the numerator statement. What do you think?

DR. KUZNETS: Right. Well, that depends on the NQF's willingness to allow us to do that modification and still review this measure as such.

CO-CHAIR THIEMANN: If, if you didn't hear that, Naomi, we're saying yes, we realize we have that ability. So, we're --

DR. GABEL: Why am I not surprised?

CO-CHAIR THIEMANN: So, are there any other, I think, Dr. Nagy, or Dr. Sierzenski? Not sure --

DR. SIERZENSKI: So, would that statement cover new equipment, by the presumption that it's a new process, or is the overall process the same, and the new piece of equipment, that may have subtleties in disinfection, wouldn't be picked up by that expanded --

DR. GABEL: Well, we'd want to make it iron clad. I mean, as ironclad as one

could. So, it would, it would require wordsmithing to, to say what we mean, and I think we all have heard the intent, namely, if you get a new piece of equipment, then anybody who goes near the processing of that equipment needs to have demonstrated competence. So, it, it's a matter of refining PSM 18.

DR. KUZNETS: And or equipment.

CO-CHAIR THIEMANN: And this also would effect PSM 14, in addition, because of the word current talks about the current device, the manufacturing instructions.

DR. GABEL: Absolutely.

CO-CHAIR THIEMANN: So the clarity needs to be there as well, please. Sorry, any additional questions? Dr. Nagamine?

DR. NAGAMINE: I'm struggling with the current piece, and, and, how to operationalize that. I would think that the burden would be large to require more frequently than twelve months. However, is there a way to put in a process where new

incoming emerging information is more quickly fed out to people to alert them before a twelve month, you know, cycle? So, I'm just struggling with that question.

CO-CHAIR THIEMANN: Well, I'm not sure from a --

DR. KUZNETS: Sorry, that speaker is cutting out, I cannot hear her.

DR. NAGAMINE: Okay. Can you hear me now? Okay. So, I said I was struggling with the, how to, how to remain current on incoming new emerging information that perhaps comes with a new device or a new piece of equipment.

And the burden would be high if we ask ASC's to do this more than once a year, and so, is there a mechanism that could be written into this where we could reliably know that new, emerging information would be fed out to the people using the device.

DR. KUZNETS: Well, let's see. One thing it could be within the last twelve months or --

DR. GABEL: Well, I wonder if -- I wonder if we, if we should, should mess around with the twelve month reporting because that would be, I mean, we want to, to keep it, keep a, we don't want to increase the burden of reporting.

However, we want to ensure that the reporting covers what we want it to cover, and so, again, it would require some wordsmithing that right now it, it says, personnel who receive device specific instructions at least annually.

Again, if we built into that that at least annually or when any, and I'll just choose some words that need to be more carefully worded, but, or when any substantial change in equipment requiring a modification in, in process occurs.

So, that the intent is that it'll be an annual reporting, but it will report more information basically, not only that the processors have received annual training, but

that they have, have in fact received training whenever there's a modification in the equipment or the manufacturer's recommendations for processing that equipment. Does that, does that get at what you're suggesting?

DR. NAGAMINE: It sort of does, but I guess I'm leaning more on the manufacturer's side and their role in communicating that reliably to the people who use their device.

Because we've experienced, it's like, oh, you knew this? You know, and so, you know, they know of emerging problems but don't reliably, necessarily, feed it out. Maybe after all of this media, they've gotten better, but I don't know how reliably we get timely information that's really relevant and could reduce the number of exposures by months.

DR. KUZNETS: If I could interject here. The FDA did issue information on the STERIS 1, and the time lapse between that and

calls that we got at, at AAAHC was less than twenty four, four, less than twenty four hours.

So, we do know that, that the FDA is able to make it's presence known and the ambulatory surgery arena.

CO-CHAIR THIEMANN: Okay. Assuming that you subscribe to FDA MedWatch and device recall.

DR. KUZNETS: Let's not start into that.

CO-CHAIR THIEMANN: Dr. Turner? I think you were up next.

DR. TURNER: Yes. Thank you. I just wondered if you could comment a little bit about the testing that you have in mind. I know that none has been completed at this point, but the testing phase, are you going to be looking specifically at outcomes and maybe reduced infections as a result of this measure being implemented?

DR. GABEL: I'll just speak

generically that the intent is to use the survey process for the testing, but I'll let Naomi add the meat to the bones on that one.

DR. KUZNETS: Yes, currently we actually do in the AAAHC institutes colonoscopy study, which has about 90 organizations across the country, 90 ASCs and or Office based practices across the country.

We do have the questions that are in your packets and a general information form that we've requested that people fill out for the study, and we are monitoring their ability to answer those questions, and do it in a consistent manner, and whether they have any questions about that and how useful when we report it we'll also ask about how useful they find this information.

With regard to the outcomes, one of the issues with outcomes in ambulatory surgery setting, as you may very well know, is tracking outcomes. In our studies, we track for a very short period of time after the

colonoscopies, patients are contacted by telephone interviews to find out whether they've had an unscheduled contact.

Now, the sort of tracking that you might have to do for instance for something associated with processing, is something as we know that comes out month later, unfortunately, so we would not be able to very well track that, because there's a lack of the closed system.

So there isn't an easy and good answer to the outcomes issue.

CO-CHAIR THIEMANN: Dr. Kennerly?

DR. KENNERLY: I think this has been a great discussion and so I think I take that I heard that the, the term current can in the sense be expanded to involve new equipment, potentially, because in a sense that would change a currency issue.

And, I wondered too, as it relates, you know, I think to Dr. Nagamini's comment about the role of communication in all of this

in helping to raise the bar, whether, again, although the metric may not want to reflect it, I wonder if your organization might help make it easy in some respects by integrating some of the information that is collected from, from manufacturers, if you will, with regard to what might be substantive changes and recommendations so that it would make it more readily available, if you will, perhaps through electronic means or others, push it out or in a sense let it know that there has been a significant change.

And indeed, perhaps to sometimes take the manufacturer's recommendations which are often lengthy and sort of more legal, legalistically oriented, and to try to use the eyes of your professional society, if you will, to be trying to pull out the most important aspects of those that are going to be relevant for the front line clinicians.

DR. KUZNETS: We have worked with a number of the specialty societies that are

represented on the AAAHC Board, for even the development of this, of these particular measures. And I think, many of them would be very interested in that suggestion and the implications in that assistance would offer their members.

CO-CHAIR THIEMANN: And from a Steering Committee perspective as well, the Steering Committee as we close up our conversations with out met, identifying areas needing improvement and so forth so there's also that potential, you know, opportunity from the Steering Committee's perspective to encourage manufacturers to enhance communication with facilities and clinicians as well on these issues.

Any additional comments, questions at this point? If now, we should move into assessing whether or not the performance measures developer met the burden for importance to measure and report. Looks like it's good.

If we want to move onto evaluating and taking out votes, on 1A, whether the performance measure demonstrated a high impact to healthcare on this performance measure? Oh, sorry--

MR. BUNTING: Are we voting on all three as a bundle, or each one individually?

CO-CHAIR THIEMANN: I think individually is what we have to do first, then we can make the recommendation for AAAHC QI to consider it as a paired, for NQF, if that's what the group would like to. So we'll do individual, and then consider them together if that's what the group would like to do.

So, has the performance measure completely met the burden for high impact to health care, completely? Eleven, because, we have a late comer. I think I have eleven, right? Eleven.

Partially? One. And then that's it. No -- Dr. Solomon? Dr. Solomon, are you still on the line?

OPERATOR: Dr. Solomon is not on the line.

CO-CHAIR THIEMANN: Thank you operator. So we are twelve. Okay. And, then, concerning the opportunity for improvement, performance measure met the burden for complete, by completely, met, meeting that? Completely? Six--seven. Partially? Five. And that's twelve.

And then, evidence linking outcomes? Completely? Sorry, I had--partially? Right? Seven. Okay. Great. So, taking the vote as to whether or not the importance to measure and report threshold has been met, does the group say yes? I think that--okay.

So now we move on to discuss scientific acceptability, feasibility, usability of the measure.

MR. LEVINE: The Department of Health and Human Services--I'm sure it includes CDC--has a workgroup on health care associated infections and they put out a five

year plan and it may behoove you all if you haven't already talked to someone like Don Wright who's the head of the departmental committee on quality assurance in HHS to touch base with them in terms of this initiative.

DR. GABEL: Could I just respond to that? And, and in their candidate measures, the following appears: By December 31st, 2015, all certified accredited ambulatory surgical centers will demonstrate 100% adherence to the following measures contained within current infection control worksheet.

And there are five of them and the fourth of the fifth is items undergoing sterilization and high level disinfection, as precleaned properly. So, this is among their candidate measures to be achieved by December 2015.

DR. KUZNETS: They are looking to the NQF to potentially endorse endoscopy reprocessing measures, it says, December 31st, 2015, within two years of National quality

forum endorsement all certified accredited ambulatory surgical centers will have implemented any new applicable health care associated inspection related measures, e.g, endoscope processing, immunization, et cetera.

CO-CHAIR THIEMANN: Terrific. Moving on to the scientific acceptability, anyone have any questions for the measure developers concerning scientific acceptability? I don't see any, so I think we're probably ready to go onto voting for this one, then.

So, concerning 2A, was the measure precisely specified, for the numerator here? And denominator and, not exclusions, but, was it completely met? Six. Partially? Five. Minimally? Zero. Not at all? Does that--are we missing one? Did somebody--oh, okay.

All right. We, but we're good, we have eleven, correct? We need, a quorum is eleven, for us. So we are at twelve seated, so that means we have, what, forty five minutes before the next one leaves? Exactly.

So, it appears that, okay, I think we can--do we want to go back and get his vote when he comes back in, or, okay. All right. So, and, looking at 2B, for reliability testing.

Completely met? Partially met? Six. Minimally met? Four. And, not at all? Or--yes, not at all. One. Validity testing, 2C. Completely met? Zero. Partially met? Two. Minimally met? Eight. And, not at all? One.

Okay. And, 2D, exclusions. Completely met? Zero. Partially met? Zero. Minimally met? Zero. Not at all? Did I say--not applicable? Sorry. I think that looks like everybody.

Okay. Risk adjustment for outcomes resource. Completely? Partially? Minimally? Not at all? Not applicable? I'm sorry, I shouldn't chuckle, but I can see the hands waiting.

2F, identification of meaningful differences in performance. Completely?

Partially? Minimally? One, two, three, four, five. Not at all? Not applicable? Six. So that would be eleven, correct?

2G, comparability of multiple data sources. Completely? Partially? Minimally? Not at all? I have one minimally. Yes, no? One minimal. Not at all? Not applicable? I think that's everybody else.

2H, disparities in care. Completely? Partially? Minimally? Not at all? Not applicable? So, we had one not at all. And the rest were not applicable. So, voting for the overall section of scientific acceptability, the criterion was met, yes? For the overall scientific, because now we're voting on the entire area, right?

CO-CHAIR CONWAY: We do all three though. See--

CO-CHAIR THIEMANN: Oh, sorry. Complete. Yes. Sorry. I'm already voting on the measure. Complete? Partially? There's eleven. And I think that's that, right?

Because Don's not back.

All right, going on to usability. Any questions for the performance measures concerning usability? I do have one. This, the measure is intended for use in all facilities, not only those that are accredited by AAAHC or other accrediting agencies, is that correct?

DR. GABEL: It is correct.

CO-CHAIR THIEMANN: Okay. Thanks. Any questions? Mr. Levine? No? Okay. I saw your little name up, so. All right, moving on to voting, then, for usability. 3A, meaningful understandable, useful? Measure developer met it completely? Partially? Nine. And that's everybody.

3B, relation to NQF endorsed measures, harmonization. Completely? Partially? Five. Minimally? Four. Not at all? Not applicable? Two. Not specific to colonoscopy, but for reprocessing I think there for handling, right, isn't there? For other? Heidi? Heidi?

MS. BOSSLEY: I was just getting asked if I was taking notes of if I'm doing something else, and I was like I'm totally multitasking. I'm sorry. So I missed it, I apologize.

CO-CHAIR THIEMANN: The question was, are there any, any NQF performance endorsed measures that are related in any way to the measure being discussed.

MS. BOSSLEY: I'll check again, but no.

CO-CHAIR THIEMANN: Okay. Thanks. Distinctive or added, additive value. So, completely? Zero. Partially? Nine. Minimally? Not at all? Not applicable? Okay, did we not have--two abstained. Okay. That's fine. I think that's fine, right, even though we didn't have a quorum on that one? Okay.

So that added, that's all of them. Dr. Kennerly, did you want to come, at all, did we need his vote, since he had stepped away? I don't know if he, you could get it

afterwards? Okay. All right.

So, looking at the section for entirely for usability, not voting on the measure entirely, as I tried to earlier. Performance measure met the burden for usability completely? Partially? Is that everybody? Yes, that's everybody.

Moving onto feasibility. Data generated is byproduct of care processes? Measure developer met it completely? Partially? Yes. One, two, three, one, two three, four, five, six. Minimally? Five. That's eleven.

Electronic sources. Met this completely? Zero. Partially? Zero. Minimally? And, not at all--or, yes. Not at all. Wait.

PARTICIPANT: They're planning to develop an online system.

CO-CHAIR THIEMANN: But it doesn't exist yet, so. And--is that every--no, we're missing two, so. Not applicable? That one doesn't have a not applicable. It doesn't, I'm

just saying it doesn't--you vote, because we do have that power.

So, exclusions? Sorry. Met that completely? Exclusions, 4C. Completely? Zero. Partially? Zero. Minimally? Zero. Not at all? Zero. Not applicable? This one has an N/A on it. Okay. Thank you. Eleven.

Susceptibility to inaccuracies, 4D. Met that Completely? Zero. Partially? Zero. Minimally? Eleven. Great. Moving onto 4E, data collection strategy implementation. Met that completely? One. Partially? Oh, question.

MS. THRAEN: So, the data collection, I'm, you said that, you're planning on a website reporting it, self report, but I also heard that there was--it was going to be part of the accreditation process. I guess I need some clarification.

DR. GABEL: We can't guarantee that it will be a part of the accreditation process, because that has to go to the accreditation committee and the standards

committee of AAAHC so it's a chicken and egg situation. Okay.

CO-CHAIR THIEMANN: And, and, I just wanted to clarify that as well, because I brought up a, because the measure can be used by those, by those facilities that are not currently accredited by AAAHC or other programs, it's not mandatory to be accredited therefore it couldn't be tied necessarily to only being measured by an accreditation process.

There would have to be an, a mechanism for that facility to measure it themselves, and report it themselves.

DR. GABEL: Right, and the only thing we can guarantee and, and pledge to do, and that is, that, that AAAHC institute is in fact an organization that creates organizational benchmarks.

So, we can, as soon, and in fact we have similar questions as a part of the survey process to establish those benchmarks and we

will when we get these pinned down, then incorporate that into our survey process, and make them national bench marks for, you know, coming out of the institute, which are available to non-ASC, or, non accredited organizations, but we have our limited--Naomi, can you, can you tell the steering committee how many organizations are currently in your colonoscopy study group?

DR. KUZNETS: Yes, I believe there are about 90 organizations in that study. We do it by six month period now, so there are about 90 now. They don't have to be accredited to be participating in the study, and we also published the reports and those are available for folks also.

CO-CHAIR THIEMANN: Terrific. Thank you. Moving onto--

DR. KUZNETS: The data collection for the studies actually is through an online survey.

CO-CHAIR THIEMANN: So moving onto

the overall, whether the performance measure met the criteria on feasibility, so we're voting on that whole section. Did they completely meet that? Zero. Did they partially meet that? And that's eleven.

So now, do you want us to play with this at all? No. I waved this. So now, we are looking at overall recommendation for endorsement on the measure. Yes, yes with modifications, no, or abstain. Those would be your four options.

Now, we've talked about several modifications for this--we're not going to use that, we're at, because we didn't have numbers reflected. That's why everyone laughed at me, because I held it up.

So, are we ready to vote, or do we have any additional recommendations for Dr. Gabel and Dr. Kuznets, for modifications on this?

MS. THRAEN: Could he repeat back what he heard, the recommendations were for

changes?

DR. GABEL: I won't try to wordsmith, but the concept that we pledged to build into it, and I understood, was what you requested, with which we concur, is to accommodate a change in either equipment or in recommendations from the manufacturer for a given piece of equipment.

So that the measure 14 and 16 both reflect that those changes that occur within the twelve month period will be taken into consideration in the training and competence.

CO-CHAIR THIEMANN: And refining the definition for current. Which I think was encompassed in that. But--

DR. GABEL: It, yes, that should be done as well. But the numerator statements, the two numerator statements should clearly reflect our intent on that as well.

CO-CHAIR THIEMANN: Dr. Lawless? I think you--

DR. LAWLESS: I think we also talked

a little about the idea of expanding the definition. You talk about colonoscopes as a start, but the potential of saying, flexible scopes, or are you using more than just colonoscopes.

DR. GABEL: Well, our scientific evidence breaks done at that point. I think, we would be happy to go back to the drawing boards and expand that to include, for example, endoscopes used in other parts of the body. But I--we don't have the scientific evidence for that in this application.

And, quite frankly, we'd rather go back to the drawing boards and ensure that we have the requirements for an NQF endorsed measure, namely, the gap in care, the scientific evidence, et cetera.

CO-CHAIR THIEMANN: And we could, and from a steering committee perspective, that's where, in our final report, draft report for future recommendations, and how to address additional gaps in care, that may be

where we capture that. Mr. Levine?

MR. LEVINE: Yes, I wasn't sure what I heard about new employees. Is that covered by any of these?

DR. GABEL: Yes, that's already, that is already covered.

CO-CHAIR THIEMANN: Are we ready to vote?

CO-CHAIR CONWAY: Can I just-- modified proposal, or do we have to vote for modifications?

CO-CHAIR THIEMANN: You're being difficult. No, I think, similar to the one that we did last time, what we'll do is, you know, that, you know, assuming that, I know we can't assume, but that AAAHC will take these back and consider the recommendations that we should vote as yes, yes with the modifications as currently defined and proposed, no, or abstain. Is everyone comfortable with that?

CO-CHAIR CONWAY: So, yes is yes for what was written--

CO-CHAIR THIEMANN: Was what, for what's in your document. Yes with modifications are with the refining current, adding new equipment--

DR. GABEL: Or new instructions for existing equipment.

CO-CHAIR THIEMANN: Existing, and then office space, that was the other element, expanding it past ambulatory to office space, I believe.

DR. GABEL: That would be fine. Naomi, do you see any problem with that? I don't, it's just a matter of, of redefining the denominator statements.

DR. KUZNETS: No, I'm fine with that.

CO-CHAIR THIEMANN: Okay.

DR. KUZNETS: We get office space in our studies, and I'm sure that they have similar issues, whether we would have enough to differentiate on the evidence, I'm not sure.

CO-CHAIR THIEMANN: So are we--

DR. KUZNETS: But that might be also for future measures, be -

DR. GABEL: Another observation is, that, there really is a grey line between an office based endoscopy facility and an endoscopy center that mimics an ambulatory surgical center. It, it, you know, I've surveyed both, and quite frankly, AAAHC applies the same standards to both, and whether you call it an endoscopy, an ASC specializing in endoscopy, or an office based endoscopy practice, is usually a pretty grey zone.

An office based practice is more likely to have one endoscopy room in the suite and an endoscopy center is more likely to have three or four, so, to some extent, it's size related. But it isn't a clear distinction, so it shouldn't be any problem to lump them together.

CO-CHAIR THIEMANN: Dr. Lawless?

DR. LAWLESS: I, I think this, the intent here is what my intent is, it's the safe practice. So if it's the wordsmithing over what is, we're trying to expand it. So we have any idea, saying whether it can be feasible or not, the recommendation where you can address it later, whether it is or not. From the influence, where, influence me, is, we're trying to actually expand this to make it as safe as possible, so whether its not in the evidence or not, a recommendation may come out later on and you guys can say how feasible it is, but I wouldn't try to knock it down.

DR. GABEL: That's fine. It is, it is scalable, it is expandable, easily, with, with just rephrasing the denominator statement.

CO-CHAIR THIEMANN: All right. So -- Ms. Thraen?

MS. THRAEN: Just so, just so that you know, the, at one state example, the regulatory authority varies though. So, in

the, the individual physician office practice fall sunder Department of commerce, Division of professional licensing. The ASC licensed site falls under the Department of health in our state, under the Department of health certification and licensing.

So you have different authority and different regulatory bodies that govern this area, if at some point this becomes part of a regulatory approach. Just so you understand that there's differences there.

CO-CHAIR THIEMANN: Thank you. Okay.

DR. SIERZENSKI: Just a quick question. Did, is this ever outsourced, or is this usually done at the point of, I mean, I would think most of the time it's point of care, but is there anyone that's outsourcing this service? Well, I mean the actual cleaning, as well.

DR. GABEL: Never say never, but it's almost inconceivable, because, because

these are very expensive pieces of equipment, they may have to be turned over as rapidly as possible, so, you know, to send them out would be very difficult.

Now, whether, whether there is subcontracting for somebody to come in and do the cleaning, that would be conceivable, but on the other hand, if that's the case, the standards would be, the performance measures would apply.

Because it doesn't specify that they have to be employees of the ASC or of the office space practice. So that's, that's not specified, so that would be exploited by these.

DR. KUZNETS: Specifically with the idea that they may be subcontracting. But yes the, these are, this equipment is something that they need to turn over as quickly as possible, it's extremely expensive, so they're not going to be having it off the, off the premises.

CO-CHAIR THIEMANN: Thank you. If there's no more further comments, questions before voting for this, by the steering committee members, I'd like to see if there's any public members on the call that would like to make a comment.

Hearing none, are we ready to vote? Okay. So the vote, once again, a reminder. Yes is for the performance measure, as written and specified that you received and we've reviewed. Yes, with modifications are the modifications that have just been recommend, recommended to AAAHC QI to make.

No is, no is no. And abstaining is abstaining. So, any steering committee members voting yes? Steering committee members voting yes, with modifications? Yes. I'm in there, yes. That's 100%. Okay. Thank you. So this one passes.

How many steering committee members are leaving? I don't know what everyone's schedule is. I know of one who's leaving I

think in, in just a couple, two o'clock. One's leaving at two, anyone else? 2:15? Okay.

So we have -- that's what I'm -- reason, I'm, we're just discussing whether or not we should even proceed on and engage in the next one, that's our concern is, is that we're not going to have a quorum.

MS. MUNTHALI: In the next, in the next topic of measures?

CO-CHAIR THIEMANN: Yes.

MS. MUNTHALI: What I may suggest is, we have a call scheduled for the 19th of November, and that's when we're doing the followup. We may have to discuss those measures during that call, but since you're still talking about the colonoscopy measures and, well, not bundling, pairing them, perhaps you should continue that discussion and go through the criteria for the other two measures.

CO-CHAIR THIEMANN: So, recognizing our time limit, not trying to restrict

conversation, but that I'm going to defer introduction of the measures by the primary and secondary discussion leaders. Heidi?

MS. BOSSLEY: I'm, I'm sorry. Did you all vote to pair those three measures together?

CO-CHAIR THIEMANN: Is that -- that's what you're going to do next -- okay, I'm --

MS. BOSSLEY: We still have to approve the other two --

CO-CHAIR THIEMANN: Oh, I'm sorry, I lost track --

MS. BOSSLEY: And then we've got to come back and circle.

CO-CHAIR THIEMANN: I've lost track of where you are. I'm sorry. So, recognizing the time constraints, moving onto PSM 00 15, which I will just ask Dr. Conway to very limited introduction.

CO-CHAIR CONWAY: Nothing more to add. We've covered everything.

CO-CHAIR THIEMANN: We've covered everything. SO this one is colonoscopy processing currency. Correct. Yes. And so this, so, do we have any questions concerning PSM 00 15 of the performance measure developers, on this issue?

So -- go on, I'm sorry -

DR. SIERZENSKI: I, I, I just, I just find the term currency clumsy. It, it just doesn't seem ideal. I, I mean, I, I understand the goal, it just doesn't seem like an ideal term.

DR. GABEL: I've got a great thesaurus online but I'm not online, so. But we'd be happy to seek a, a, a better term. I agree, currency, you know, let's, let's, let's look first, and then, because currency means different things. Money. Blah blah. Okay. We'll work on it.

CO-CHAIR THIEMANN: Would the group, many of the same issues apply here, as far as, I would think the group would feel that way,

as far as applying it to office space, expansion.

We've already heard the issue of refining currency, similar to current. Trying to better operationalize that and what that actually means. And, I'm looking to see if there's anything -- and then the new equipment issue as well. For this one.

So, a lot of the same issues with the last one would, would, the recommendation would be to carry those through and thread these through the rest of these, if they're applicable from a steering committee perspective. Would people agree? Okay.

Any questions? Are there any additional questions concerning importance to measure area? And I've just been notified by NQF staff that we do not need to weigh in on the subcriterion for each of the areas. We can just do the main criteria.

So, the four sections. Okay? But I don't think we have a quorum around the table

anymore, do we? We have ten seated, and we need eleven. So we need a returning steering committee member. We only have ten at the table.

In the interest of time, I know we're jumping around, but trying to make sure that we have all the questions answered in a, in ahead of time. Are there any questions concerning the next performance measure, that AAAHC has on the docket? And that one is concerning competency.

Any questions there, for the performance measure developers? Or do we want to wait?

DR. LAWLESS: Is the way it's written, the competency, is it less, is this creating less of a standard than would be competency right now, in terms of cleaning, and any other professional organizations? Would this set the bar lower than what currently is out there?

DR. GABEL: Oh, no, I don't think

so.

DR. LAWLESS: Okay.

DR. GABEL: I, I think this will raise the bar.

MR. LEVINE: This, question I actually had earlier, but if you'll allow me to ask it. Is there a particular skill set or training or certification these individuals have?

DR. GABEL: It would be nice if there were, because then you could, you could just require certification. But this may be, that may be the next step for this measure, you know, to become a criterion for certification, and, one, one of the criteria for certification. So, no, this is doing something that is not out there.

MS. THIEMANN: Are we back to eleven, I believe, now? All right, we have a quorum re-established. So, looking at, since we're no longer going to vote on the subcriterion, we're only going to vote on,

provided no one has additional comments about PSM 00 15 for the measure developers. I don't see any. Comfortable to move on for voting? Okay.

Whether the entire category for importance to measure the threshold has been met. We have to look at that first. So, steering committee members voting yes, that all conditions have been met for importance to measure? All right. Raise your hand again, please, if you're voting yes, that importance to measure. Is it eleven? There's one hand down. Okay, great.

If, if ever your vote is more important than right now. All right. Section two, scientific acceptability. Has the performance measure developer met the criterion of, of scientific acceptability. If you're voting yes.

Question? Do we have a -- sorry. I keep doing this one, with the scientific acceptability. Sorry. Completely? Partially?

Eleven. Okay. Usability? Completely? Partially? That's everybody, eleven.

Feasibility. Completely? Partially? Eleven? Okay. Now we can vote on -- now we can vote on whether or not the performance measure will be endorsed or not endorsed, or with modifications, okay? So, recall your vote for yes is as written and as specified, or yes -- question?

MS. THRAEN: Same modifications as the last one, right?

CO-CHAIR THIEMANN: Yes. With the wording for currency versus current on this one, expansion of office space, any addition of new equipment added, if applicable. And we've heard confirmation that this would also apply to the next one, as well, so these same recommendations, AAAHC will look at PSM 00 16 for the same type of modifications. Okay?

So, ready to vote? Yes, as written? Zero. Yes, with the modifications? That's eleven. That's number two, okay, terrific.

Moving onto PSM 00 16, which is colonoscopy processing competency. And we've already started to, to start to talk about this intermittently through the past two measures.

Does anyone have additional questions for the measure developers on PSM 00 16 at this time? Seeing none, then are we prepared to move onto voting of the criteria? Okay. Great. Importance to measure. Has the threshold been met by the performance measure?

Yes? No, no, we're not doing the subcriterion. So, yes. Okay. No? How did we get twelve? Oh, we've got -- sorry. Moving onto scientific acceptability. And, scientific acceptability, has the performance measure met that Completely? Zero.

Partially? Twelve. All right. Twelve. WE'RE good there. Usability. Met that completely? Partially? Twelve, okay. Feasibility. Has the performance measure met that completely? Partially? Eleven. Not at all

-- or, minimally? Sorry. One. I think that's twelve.

So, moving onto the steering committee recommendation for endorsement. Voting yes? For endorsement of the overall measure? Voting no? Are we, oh, sorry, yes. With modifications, I'm sorry. Apparently I'm going into a coma after lunch. So that's everybody.

Sorry, at least I can laugh at myself. So that measure moves forward, I don't think we need to, that's everybody. So, that's all three of AAAHC's. Question, Dr. Lawless? That's where we, the triading. Okay.

Do we need to open for public comments first, before, if there's any public comments for the three measures? Not hearing any. So, moving forward with whether the steering committee wants to make a recommendation for pairing of these measures, which conceptually -- Heidi, I don't know if you want to add in, but we've already noted

the distinction between composite bundling and pairing.

NQF refers to them as pairing, even though there's more than two, where it wouldn't be necessarily an all or none, it's a, you would measure for each of those and report together.

MS. BOSSLEY: Correct. So, if it's implemented, all three must be implemented together and all three must be reported out. Separately, but reported out together. Yes.

CO-CHAIR THIEMANN: So we'll open the floor to discussions on that. Preference, from the steering committee perspective? For the recommendation to do that? Ms. Thraen?

MS. THRAEN: I so move.

CO-CHAIR THIEMANN: I so move?

MS. THRAEN: Only because in our patient safety work, what we've seen is that what is in policy may not be in practice. And, also vice versa, what's in practice may not be supported by policy. So, it really needs to be

a combined effort in terms of what the policy states, what the practice is, and then how that practice is being judged from a competency perspective. So, I recommend that they be paired.

DR. SIERZENSKI: Yes, I would agree. I mean, individually, they're, they're teeth together, they're a bite, and you know, fourteen means nothing without fifteen, and ultimately we vote that 16 is the most significant, but fourteen really without fifteen has no significant impact, I think.

CO-CHAIR THIEMANN: Any additional thoughts, comments? Okay. And just to, this would be a recommendation to AAAHC to pair them, but even if the recommendation went forward, they would, they don't necessarily have to do that. So that everybody's aware of that.

Okay. Are we ready to vote on a recommendation to pair? Yes? It's a yes no. Okay. Recommendation is on the table to

request that AAAHC pair these three performance measures, PSM 00 14, 15, and 16 together. If you say yes, please raise your hands. That's eleven. Great. All right. Thank you very much.

DR. GABEL: Thank you.

DR. KUZNETS: Thank you.

CO-CHAIR THIEMANN: So we, at this point, I think, summing up, seeing if there's any additional closing remarks. Yesterday, we did a summary, as to, you know, some of the thoughts. I'm sorry. Public. Is there, are there any public comments, concerning the measures that were just discussed?

No? Thank you though. And, so at this point, I'd like to do a summary wrap up. We will be deferring PSM 043 and 044 onto the next conference call. The next conference call is going to be where the HIV measures will also be considered that we're, that were deferred.

That is scheduled for Friday,

November 19th, I believe. And, do you know what time? Two to four? So we're probably going to have to expand that, given that we have, because I think both of these measures probably are going to initiate some discussion, 43 and 44.

So we'll probably have to expand that time. And then there's also another conference call on November 16th, correct?

MS. MUNTHALI: And that's to discuss the draft report comments from the HAI measures, and so that's from two to four as well, and I think it'll just take about two hours.

CO-CHAIR THIEMANN: Do we have a sense on how many public comments, or member comments we're receiving yet?

MS. MUNTHALI: They typically come in in the last week, the day before. So we don't, right now, we just have one, but we have received some input from folks saying that they will be submitting comments.

CO-CHAIR THIEMANN: So, any closing remarks? I'm, I've, don't want to talk on behalf of you, Dr. Conway, but we greatly appreciate everybody's coming here, spending your time, spending your weekend reviewing measures, and you know, giving your time, because we know this is a voluntary thing.

And greatly appreciate all of the comments and all of the expertise that's around the table. Thank you.

DR. KENNERLY: One thing, I just would like to perhaps return to at some future date is this notion of our role in identifying gaps and being proactive around gap identification, and wonder if we might want to be thinking about some future agenda item as it relates to becoming more active, I guess as it relates to encouraging metric development in certain areas, with certain kinds of characteristics that we might feel would be beneficial in the long term.

CO-CHAIR THIEMANN: Heidi, I don't

know if you can speak to the new group potentially that might be forming about driving some measure of, you know, suggestions and, through HHS, and --

MS. BOSSLEY: The HHS, the measure application partnership?

CO-CHAIR THIEMANN: Yes.

MS. BOSSLEY: That one is being run through a different Department which also does the National priorities partnership priorities. What I can say right now, is that we do know we have a group that will be looking overall at where we want to see measures go, and implemented.

There will also be smaller groups that look at more topic specific content. It's still very vague as to what all the work will be, but we know that everything that you all do will funnel through to that group and then hopefully it becomes more of a feedback loop as well.

Our hope is to have measures come

out of both what's advocated out of that group, as well as through the implementation efforts. Beyond that, there's not much more that we can say.

DR. KENNERLY: I just think that in in in some respects it sounds like there's going to be a lot of activity and it'll be important to integrate that, but part of the charge to this committee as it stands is in fact to be identifying gaps, and I'm not sure we'd want to step back from that and just say, oh gosh, other people are going to be doing that.

So maybe part of that is, is to be waiting to some degree to get some guidance about where there is going to be advocacy and to lend our voice to that, if it appears that that's going to happen. Or, alternatively, to, to, if it seems to be happening slowly or in a direction we might think would be at odds with what we think is important that we could perhaps at least comment on those things.

I know we don't have a responsibility, a singular responsibility, but I think we might want to be at least having an informed discussion about that.

MS. BOSSLEY: I mean, we ask all steering committees, and this is part of what will come out of your final report, to look at where you think, first of all, the measures you have where you think they need to head next, and also what's just missing, like, have we, and I think we've missed a lot of areas to deal with patient safety.

So, part of what we'll do, and we'll have to figure out when we do that, we want you to have a conversation as to where you think there's new research needed, where there's new measures needed. All of that, I can tell you, has been pulled out and provided to other groups as well, and used, and then again, feeds back through.

So we still want you to have that conversation. It just will probably be on a

conference call.

DR. NAGY: If there's, if anyone has five minutes and any interest, I'd be happy to give them a five minute physics tutorial on CTDI volume and DLP, which may help them, assist them in their evaluation of the next two metrics.

DR. NAGAMINE: Along the lines of your comment of being more proactive, I was talking to Heidi about, could you guys sponsor like, a matchmaking event, where you get people who are clinical and who, or societies who want to do measures like SHN, we have a lot of ideas about what measures.

But we're not developers, we don't have the bench capacity to, to do that. But we would love to be aligned with people who are in the business of making measures.

And so if you could help those groups meet, we might be able to come up with things that are the high volume, high risk things that we would really like to see

addressed, and that would have broad impact.

Consumers, professional societies, coming together, to, to maybe define the areas, as well as create the measures.

MS. MUNTHALI: And I just wanted to thank everyone on behalf of the staff for all of your time and your commitment to this project, and to thank everyone on the line and to apologize to the measure developers, that did plan to participate today and we didn't get to your measures but we promise to do so in the next few weeks.

So, safe journey, and we will be sending you expense forms, probably by the time you get home, you should have it in your inbox. So, thank you so much again.

CO-CHAIR THIEMANN: And thank you all for your leadership.

(Whereupon, the above-entitled matter went off the record at 2:02 p.m.)