NATIONAL QUALITY FORUM

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MEASURE APPLICATIONS PARTNERSHIP

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HOSPITAL WORKGROUP IN-PERSON MEETING

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FRIDAY

DECEMBER 9, 2016

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The Workgroup met at the National Quality Forum, 9th Floor Conference Room, 1030 15th Street, N.W., Washington, D.C., at 9:00 a.m., Cristie Upshaw Travis and Ronald S. Walters, Co-Chairs, presiding.

PRESENT:

CRISTIE UPSHAW TRAVIS, MSHHA, Co-Chair
RONALD S. WALTERS, MD, MBA, MHA, MS, Co-Chair
GREGORY ALEXANDER, PhD, RN, FAAN
ANDREA BENIN, MD, Children's Hospital Association
AKIN DEMEHIN, American Hospital Association
WOODY EISENBERG, MD, Pharmacy Quality Alliance
DAVID ENGLER, PhD, America's Essential Hospitals
ELIZABETH EVANS, DNP*
LEE FLEISHER, MD
FRANK GHINASSI, PhD, ABPP
KIMBERLY GLASSMAN, PhD, RN, NEA-BC, FAAN, Nursing Alliance for Quality Care
MARTIN HATLIE, JD, Project Patient Care
JENNIFER EAMES HUFF, Mothers Against Medical Error
MIMI HUIZINGA, MD, Premier, Inc.
JEFF JACOBS, MD, The Society of Thoracic Surgeons*
JACK JORDAN
HEATHER LEWIS, MS, MBA, Geisinger Health System
MARSHA MANNING, University of Michigan
R. SEAN MORRISON, MD
ALLEN NISSENSON, MD, Kidney Care Partners
SARAH NOLAN, Service Employees International Union
ANEEB SHARIF, Service Employees International Union
KAREN SHEHADE, MBA, Medtronic-Minimally Invasive Therapy Group
BROCK SLABACH, MPH, FACHE, National Rural Health Association
ANN MARIE SULLIVAN, MD*
MARISA VALDES, RN, MSN, Baylor Scott & White Health*
LINDSEY WISHAM, BA, MPA
WEI YING, MD, MS, MBA, Blue Cross Blue Shield of Massachusetts

NQF STAFF:

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KATHERINE MCQUESTON, Project Manager, Quality Measurement
ELISA MUNTHALI, Vice President, Quality Management
ERIN O'ROURKE, Senior Director
DESMIRRA QUINNONEZ, Project Analyst

ALSO PRESENT:

HEIDI BOSSLEY, MSN, MBA
REENA DUSEJA, CMS
JOANN FITZELL
MARLIS GONZALEZ-FERNANDEZ, MD, AAPM&R*
ROXANNE JENSEN, Georgetown University
JOSHUA LAPIN
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BOB SHANER, American Academy of Pain Medicine

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ASHLEY WILDER SMITH, PhD, MPH, NCI

LISA SUTER, MD

ANGEL VALLADARES, Avalere Health

PIERRE YONG, MD, CMS

*** present by teleconference**

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

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

9:02 a.m.

CO-CHAIR TRAVIS: Well, this is Cristie Travis, for those on the phone. I want to welcome everybody back today to Day 2. If you're like me and it's your first time, it was like drinking from a fire hose yesterday.

(Laughter.)

CO-CHAIR TRAVIS: We did cover a number of different federal programs, so we got to have a variety of issues that we were able to discuss.

I also want to thank everybody for working through the decision matrix, understanding what we needed to do to give the proper recommendations and guidance, both to the Coordinating Committee for MAP and ultimately to CMS. And I think we got into a really good rhythm about understanding our four decision categories and really working hard to be consistent and to give the level of detail that we needed to. So thank all of you for kind of

working through that with us.

It's the first time we've had this particular decision category, and we have found it does take just kind of actually doing it, because things can look great on paper, but when you have to make decisions, you realize there are some nuances that you need to take into account. So thank you very much for that.

We are excited about the programs we're going to be covering today, which are primarily IQR and value-based purchasing. And then at the end of the day we will do like we did yesterday and go through the current measure sets for those two programs as well as the other two that we haven't covered yet in terms of new measures, because there weren't any new measures coming forward.

So with all of that, I'm going to turn it over to Ron.

CO-CHAIR WALTERS: Thanks again for everybody's work yesterday. We really do appreciate it. You make our job as chairs very

easy.

First thing is people that were not here yesterday that are new today filling in for someone, et cetera, et cetera, please introduce yourself and disclose any conflicts that you have. And I'm looking at Allen first.

MEMBER DEMEHIN: Good morning. I'm Akin Demehin. I'm the Director of Policy at the American Hospital Association sitting in for Nancy Foster. Glad to be with you. No conflicts to disclose.

CO-CHAIR WALTERS: Sorry. I said Allen.

Is there anybody else? Going around the table I don't see anybody.

CO-CHAIR TRAVIS: There was somebody.

CO-CHAIR WALTERS: Oh, yes.

CO-CHAIR TRAVIS: When he comes back.

CO-CHAIR WALTERS: Okay. We'll get him when he comes back.

The second thing, you got a new agenda, and that agenda is just about two minutes

old already. As you note on the agenda, on your prior spreadsheet there was one measure for value-based purchasing, and then it was not on the agenda you got yesterday. It is back on the agenda now, the Communication About Pain. So we'll deal with that later on after IQR. Just wanted to get you thinking about that early in the day. We also literally just found out about it.

The only other change I know about is that we're going to -- yesterday Nancy asked a question about the rationale of some of the design of the IQR Program. So after PROMIS and after the overview, before the public comment, Pierre is going to give a high-level response to Nancy's question. We'll still go through the measures measure by measure and not at the measure level, but kind of what they were thinking as far as IQR.

Okay. Not back yet.

All right. Well, then let's -- Melissa, do you have anything you want to say?

MS. MARINELARENA: (No audible response.)

CO-CHAIR WALTERS: Okay. We'll have to catch up with the disclosure, I guess.

CO-CHAIR TRAVIS: We have a little bit of time because we go into the PROMIS discussion. We'll do it after PROMIS.

CO-CHAIR WALTERS: Yes, we'll do it after PROMIS. Always grab time when you find it.

(Laughter.)

CO-CHAIR WALTERS: Always take those -- So, Pierre, you ready to start the PROMIS discussion?

DR. YONG: Absolutely.

CO-CHAIR WALTERS: Good. Thank you.

DR. DUSEJA: Okay. Good morning, everyone. So we wanted to use the opportunity today to talk about PROMIS. I think yesterday there was a lot of discussion about patient-reported outcomes, and our agency has been trying to think about this. And we're really early on in the process of how to think about PROs as it

relates to quality measurement. So we wanted to use the opportunity with this group to get your feedback on what we've been doing and to get your input.

I'm going to hand off to our colleagues here from Georgetown and NCI. And so, this is Roxanne. And I'll ask you to take the floor next.

DR. JENSEN: Hi, everyone. Thank you. I'm -- my name is Roxanne Jensen. I'm an assistant professor at Georgetown. And so, Ashley Wilder Smith from the Outcomes Research Branch at NCI was supposed to give these first slides, but I'm going to wing it and we'll see how I do, hopefully.

All right. So to tell you a bit about what PROMIS is, the acronym is Patient Reported Outcomes Measurement Information System. And what it is, it's a system of patient-reported outcome selection and its way of administering PROs in a brief way that's precise, valid and reliable. And there's a lot of different ways

you can administer it. And the advantages are that it goes -- not my slides.

Okay. So some of the advantages of this type of administration of patient-reported outcomes is that PROMIS is -- it goes across diseases, it's not disease-specific and yet it's flexible and it has a lower patient burden and has electronic and paper options.

And so how it was developed, it was using a thing called Item Response Theory, which is taken from educational testing and applied into the health realm. And one of the benefits of this is that you can have a lot of different items in one item bank and you can build a survey that best meets the population you're trying to assess.

Okay. So I guess one of the main concepts of PROMIS is that it is not disease-specific, it's not setting-specific, and so what these questions are is that you develop a bank of questions that measure a construct of health. And so it's a continuum.

So for example, fatigue. You have items that measure fatigue and then from there you select the items that you go into your questionnaire or your survey.

All right. So IRT methodology is used to develop something called an item bank, which I've mentioned previously. And basically what happens is that you take a number of candidate items for a construct and then these are evaluated and retained as long as they can measure across continuums. So for something like physical function, you're going to have a wide range of content that goes from people who are -- have difficulty getting out of bed, for example, to people that are able to run a marathon. And all of these items can be used interchangeably within the short forms that are administered.

Okay. So PROMIS is a system, and there are a lot of different topics that are measured using it in physical health, mental health and social health. And so, you can see the wide range of content that is available. So

for example, you can get a short form in physical function, pain intensity, pain interference, fatigue, mental health. Same idea.

And you can see the ones kind of in dark are the ones that are more commonly used as part of a profile. And they're used to kind of map common symptoms and functional issues that patients with chronic conditions may experience to get kind of a full flavor of what's going on. And then the ones that are in the light shading are more recent additions to the PROMIS kind of library of options.

Okay. All right. So to reiterate -- so I think one of the real benefits of PROMIS and administering it is that there are really as many options as you can imagine to administer. If you have electronic capabilities, you're able to do it electronically or using paper forms. You can use stuff that's available or you can create your own short forms that are tailored to, say, a specific population.

And then there's a lot of platforms

that are currently available. So REDCap for example has kind of the common standard off-the-shelf short forms that are available to administer. And then also what's being developed as part of the health measures. There's the API interface which allows for administration, say, within hospital systems

My God, I --

DR. SMITH: Should I just do it?

DR. DUSEJA: Well, okay.

DR. SMITH: Can I say one other thing about that?

DR. DUSEJA: Yes, please do.

DR. SMITH: First of all --

CO-CHAIR TRAVIS: Introduce yourself.

DR. SMITH: Yes, absolutely. Apologies. Metro, unfortunately.

So just one thing to say relative to availability, and this is going to come up at the end. First of all, there are links at the bottom of this which we can of course distribute. And just so you know, this is being updated all of

the time because our availability just increases. And the main thing for your purposes that would be useful for you to know is that we are actually embedding these instruments in two different EHR vendors.

And specifically, Epic is the roll-out for the 2016 version. It's getting updated actually spring of 2017. So anyone who had an update in 2016 will actually have both short forms. And so, the PDFs that are listed there and also will have computer adaptive testing.

And I'm not sure, Roxanne, if you explained what that was, but I'll say a word or two about it.

So, sorry if this is duplicative. What's really unique about this measurement set is that it allows for the ability to assess from a patient's perspective their health status in ways that are very low-burden. And the computer adaptive testing is something to think about moving toward in the future for assessment purposes in a variety of clinical settings

because as it is being rolled out again in medical record through MyChart, et cetera, and Epic -- and then also we're in conversation with Cerner, and that should happen later this year as well, too. So again, you can see that this is sort of a -- we're really in a sea change in terms of availability.

But computer adaptive testing allows you to ask a question based on the response to the prior question. So all of you who have children who have recently taken standardized tests or for whom you have gone back to school and taken your own standardized test recently, you've done it on the computer or they've done it on the computer. And when they get a question wrong, they get an easier question. When they get a question right, they get a harder question. And you hone in very quickly on a skill level.

We've adapted the same kind of methodology to health. So for example when you're talking about physical function, if you ask somebody can you walk around the block and

they say no, you don't ask them, can you walk a mile. You ask -- the next question is can you get out of bed? So you hone in very quickly to the person's ability level based on the responses that they had to the prior item.

That's an important methodology for you to know about because burden is a real issue, especially when one is thinking about rolling out questions to patients across the country.

So, and then the other thing I just wanted to mention is that there is the ability to -- and we can talk about this a little bit later in the last couple of slides, but the metric that I'm assuming that Roxanne covered a little bit, which is -- and she'll cover it a little bit more in some detail about some data -- is it's a scale between 0 and 100 and it has applicability across health domains so you can get scores on each of the different health domains. Regardless of the number of questions that you ask you can get a score.

So that computer adaptive test -- for

example, you could ask different questions to different people, but still get that same score because you may not want to waste their effort on questions that don't apply to them.

We also have the ability to actually compare those scores to other kinds of patient-reported outcome measures that have been used quite widely in the field. So those include things like the SF-36, for anybody who is familiar with patient-reported outcomes, and many others. The CESD for depression. There are a number of other instruments.

So what happens is even when people have been assessing using a different kind of assessment tool, they can compare it to the metric and you can actually have scores that apply to everyone regardless of what instrument they've taken. So this is another piece I just thought would be useful for you.

You want to go next?

DR. JENSEN: All right. Great. Now onto my slides, which -- thank God.

(Laughter.)

DR. JENSEN: Oh my gosh. All right. Now, I'm a psychometrician, or at least a practicing one, and so basically a lot of people come to me and they say, oh, Roxanne, I want to measure physical function. So now this is how I approached these questions before when someone would come to me. I would say, okay, so you want to measure physical function. That's great.

All right. How detailed do you want to get into it? I mean, is this just an overview or you want to get really into like the functional ability that people have? How much space do you have on your survey? We all know that's very precious and patient burden is important. Who do you want to compare it to? I work in cancer, so do you want to compare to cancer patients? Do you want to compare to the general population? Those are different surveys and they're different items.

So for example, if it's a general population and it's just a wide overview, the SF-

12 has six items for physical function. That will do the job just for like real bare-bones stuff. If you want to get into it, the HAQ, I mean, that's 34 questions about physical function and that will really get some detailed information.

For cancer patients, we have some broad quality of life surveys that are disease-specific, but you can see the number of questions goes up based on kind of how people respond to these questions.

All right. So now here are some of the problems with using your standard paper survey, is the response burden. As mentioned before, people have to fill these out. It takes time, especially for sick people, right?

Comparability beyond the study sample. So I have a FACT-E score of 113. What does that mean? Well, I can compare to other studies and you can get a flavor of how my patient population compares to others, but -- there might be reference values that people have created, but

these don't do a great job of painting the big picture.

Also sensitivity. If you administer five items of physical function on an SF-12, it's not going to be very sensitive to change or kind of the individual things that are going on for people.

So moving forward, this is what Ashley was alluding to. There are these new methods that came about, and I think I mentioned this earlier, too, item response theory, educational testing, these computer adaptive tests, and kind of what you need to know. Also, just as an add on, when you're taking say the GRE and the vocab is getting easier, not harder, or the math questions are getting easier, not harder, you're in trouble. Your score is going down. Okay?

(Laughter.)

DR. JENSEN: And so, yes, I even remember living in fear. It was like oh, no, CATs, like I'm in trouble.

(Laughter.)

DR. JENSEN: Fortunately, I guess it worked out.

(Laughter.)

DR. JENSEN: All right. So let's move on. So this is what happens now when people come to me to talk about PROMIS and they want to ask about physical function.

Well, the first thing I ask them is are you using a computer or do you need paper? This is a really big concern for people. And so, they tell me, oh, I need a paper. Oh, okay. If you have a computer, are you going to be able to actually run a computer adaptive test? Do you have programming capability, or do you just need the items to just show up, be answered? How much wiggle room? How fancy are we going to get? All right. Do you want to use something that's established?

Now, researchers, especially quality of life researchers, they get a little -- oh, I want to use something that's been used and validated and tested. I don't want to create my

own form. I want something that's available and I know is going to work because -- I just want something that's out there. So, all right. So there is a 4, a 6, an 8, a 10 and a 20-item short form for physical function that you can select. And what people generally do is they take a look at the content and they say, okay, this covers the range of my patient group. That makes me happy.

You can create your own and you can create -- so you can look through the item bank of 124 questions and pick any items you want and it -- you can create a score from it. And so some people do that.

Some people will -- I would -- and so how many items you actually put on. People say, well, how few can I get away with? That's like the number one question. And to be honest, you don't need that many. I mean, but it depends, right? But don't give someone 124 questions about physical function. That's just -- ah man, that's not very nice. So there you go.

And then this is a visual representation more about physical function and how this works on the continuum of 0 to 100. So people that are not able to get out of bed are going to be more towards the zero and people who run ultra-marathons, Ironmen, they're going to be the other side. And so, you can see these are some of the questions that fall across continuum. And then they're in order from highest functioning to lowest functioning.

So you can see that on the top, are you able to run five miles? Then are you able to jog two miles? And bear in mind, people are responding, they have five response options. And so, the item response theory is taking the probability of a response and the response pattern together to give you a response. And so, it's kind of taking the lid off of how we used to do questionnaires.

All right. So here's another visual representation. I'm going to talk to you today about some findings from physical function,

because quite honestly when we talk about PROMIS, we say these great things that it does. We say you can ask all the questions you want or just a few and you're going to get the same score, but, okay, in theory this is what happens, but let's take a look at what's really going on, right. I mean, let's see if it actually can do what it says it's going to do.

So let's go ahead and hit the next slide here. Interpretability. So something that we hit on a little bit. And just look at the colors, really. So this is a T score metric. I think what to take from this 10 points is a standard deviation, but it's also -- I think if you think about this in percentiles, because I think sometimes people think that way, too, this is -- also can be gridded that way.

And so, when you're up at something like 40, that's -- let's say 64 or 84, 80. And then 30 is going to be at 98th percentile. So you can see that people are really at the ends kind where as -- as these colors get more towards

red. So, and we're able to kind of mark out where clinically relevant differences are.

So a mild issue in physical function, for example, is going to be someone between 45 and 40. That's half a standard deviation below the U.S. population, right? And so, we actually know where someone falls relative to the average person in the United States, and that's really cool.

Then moderate change is from 40 and 30. So you see it's kind of in that orange zone. And that's above a standard deviation lower. So these are people that are kind of approaching that 98th percentile, or 2 percentile of physical function.

And then below that you have your severe functioning issues between 30 and 20.

Yes?

DR. SMITH: Just to that slide, actually. Can you go back?

So actually, just so you know, the bottom of the scale is for functioning. So

physical function, you see a higher-functioning person has a higher score. So the 80 is on the left. And essentially PROMIS scores are more of whatever it is that you're measuring, so a higher anxiety score means more anxiety. A higher physical function score means you are doing better.

But in terms of the interpretation for clinical purposes and other application purposes, this slide is a generic that shows you across health domains. That could be physical function, cognitive function. Symptoms are at the top; functioning at the bottom. But essentially there are fairly robust ranges for severity, meaning somebody is doing worse. And there are some individual differences for domain. And we can talk about that as well, but this is a general sort of framework for interpretation.

DR. JENSEN: Higher is more of. Just remember that.

All right. So let's take a look at what scores actually mean because we have some

information about that.

So this is from a study that we're doing validating PROMIS domains in a very broad community-based cancer sample. Seven different cancers, 5,000 people. And we asked questions about exercise and needing help with mobility.

And so, you can see that if someone's in a wheelchair they reported having a PROMIS physical function score of 28. Okay? With a cane it's 34. No help is 47. And these are -- so these are cancer patients, so you would expect it to be close to 50, but perhaps maybe a little under. And then people who are reporting five to seven times a week of exercise is above 50. So you can see they're doing better, meaningfully better than the general U.S. population.

All right. Next slide. Okay. We also -- oh, can you go back one? We can keep that, I guess. There's a lot of colors. Hopefully we can see it all here.

On the bottom though -- and so you can see this is how these scores can work. So we

have an overall lung cancer physical function score. We have a colorectal cancer score. We have a prostate cancer score. And again, I don't know what you guys' background is, but prostate cancer patients on all they probably are doing pretty average, right, generally speaking. This is after treatment.

Colorectal cancer patients, there's a bit more of a range. And so they're at 44.

Lung cancer patients typically are not doing well. And you can see they're about a standard deviation lower than the U.S. population with their scores.

And now if you can click the slide forward. I color coded, so you can see the pretty colors, and this maps into the severity level. So people that are in a wheelchair are in the red, right? Cane, you can see -- and you can see this all goes up. So green is better. And then we have some problems.

All right. And then I included this, too, so you can see the range. We also are able

to do -- and these are U.S. reference values that we've created for cancer and by stage. And so you can see the range by stage. And this is just the level of detail we can really give. So oftentimes when people don't know how to interpret a score, I mean, the thing about PROMIS is you really can because we could create scores for different diseases. You name it and there -- it -- this provides a really nice comparison that really puts things in context.

All right. Okay. All right. Just to look at this another way. So this is a self-report item, physical functional status. And people said they're normal. They said they had some symptoms. They were less than half the day on bed rest or more than 50 percent of the day on bed rest. And so you can see these are people that are about nine months post-diagnosis of cancer, seven different cancers. This is a really broad community-based sample that we collected at four sites in the U.S.

So you can see most people are feeling

good or normal. They don't have symptoms. And you'll see these bars. All of these colors are the different physical function surveys. And so you can see across the board these are doing exactly what we said they're going to do. They're measuring exactly the same way. They're within a point, which is minuscule. And you can ask 4 items, you can ask 16 items, you could ask more than that, and you're going to get the same scores. And that's what this is suggesting.

And if you click it one more time, there are my colors again. And look, this is -- quite frankly, you're not going to get a better slide than this one when it comes to physical function. It just makes me feel good as someone who does measurement, because it just goes down the continuum there. So you're able to really discriminate against -- for groups.

All right. And they left -- we left this one slide in. So part of the validation work I've done -- and we did this for eight different domains; this is physical function --

is we asked compared to six months ago how is your physical function. This is a follow-up survey. And then we measured the actual change and what people said. The effect sizes there are next to the response that people gave.

And this is quite frankly probably one of the better response graphs you're going to get when you ask this type of question. You'll see that above three is kind of what we hope -- 0.3 is what we hope for for a clinically relevant difference for an effect size. And you see that when people said they were a lot better, six -- between that six-month period, they improved in physical function about three points, or one-third of a standard deviation.

And then when you see it declines, you'll see it's much more sensitive to declines, where it's three points for a little worse and then five points for a lot worse. And this is very standard what you see for these type of metrics, and this performs absolutely like the best we could hope for.

DR. SMITH: So there's just two slides left. So this is some -- oh, and I guess we didn't incorporate the --

DR. JENSEN: No.

DR. SMITH: Okay. This was not the most up to date, but essentially what I had mentioned earlier -- first of all, there's increasing adoption for clinical care and treatment decision-making. And originally -- so these were developed from the NIH, which is a research organization. So we're really developing them for clinical research purposes.

However, in the process of this it became very clear that they were useful in clinical settings. And there have been a number of early adopters who have really, I would say, drunk the Kool-Aid themselves, and are rolling out PROMIS in fairly substantial ways.

The biggest early adopters are orthopedists, which is not entirely surprising, right? I mean, if you have a surgical outcome and someone either has knee pain or can't

function well, you want to know that from the patient. So this is the reason that you're seeing that in orthopedics. But we have it applied in a lot of other settings. Oncology Roxanne's just been discussing. And also we have in -- we've had even ICU -- surprise, surprise -- the ability to ask some questions. We've seen it being used in a lot of different ways, and in some places pretty ubiquitously in health systems.

So the availability in -- through the EHR is obviously a huge impact in terms of the roll-out and ability to use these more across the board. And there are a lot of other ways that people can access it. And frankly, you could go to the Health Measures web site now and download any PDF you want. So that's always a possibility. And as I mentioned, the availability in Cerner in something that we have negotiated, but the roll-out and the particulars are happening in calendar year 2017.

If you want to go to the next slide.

So we've been in consideration of where this might be. This is really the last slide. It's just an example to say that, what are some of the potential uses in settings? And keep in mind that these instruments were not originally developed for setting-specific comparisons or uses, but across and within specific diseases.

Those diseases are treated or functional pieces are -- of health are treated in settings. One of the things that we've been considering is are there data that we still need to understand used in particular settings? We actually have quite a lot of data that we've collected across many different investigators over many, many years, so we're pooling them a little bit differently, is part of what's happening.

But the other thing is that some of the earliest potential uses would be -- have potentially been in post-acute care. And some of the topics associated with the IMPACT Act could be addressed fairly well and quite reasonably now

with many of the different PROMIS domains. So some of the ones that could be considered are cognitive function, anxiety, physical function and mobility, fatigue, sleep disturbance, social role functioning, depression and pain. So those are the different areas that we've just been in conversation about thinking through.

And there's the ability to determine domain-specific scores for each of those health domains that I've just mentioned. But the other piece is that -- and I don't know much Roxanne covered this -- we have profile scores available, and profile scores are basically across domains. So it might be some mental health, some physical health, and you get summaries of a person's health status.

One of the things that is possible to do is to calculate some profile scores on these different domain areas that have a fewer number of questions for the specific purposes, again, of evaluating, for example, the IMPACT Act or anything else related to quality programs.

And the other thing is that there's the ability to -- when I was talking before about the ability to compare the metric to other measures that have been used, PRO measures that have been used, one can also use CMS items that have already been fielded and compare them to PROMIS scores so that there's continuity even over time, or for those folks who've been using other items to do that kind of comparison.

So that's just sort of an early example of one application, but there are many. And the beauty of this is just how flexible it is. And what it just means is that we need to be in conversation with the people who want to use it.

So the last slide just has my contact information if you'd like.

DR. YONG: So one, thank you, Roxanne and Ashley, for that sort of background about PROMIS. And so I just wanted to frame it a bit before we go into discussions, so why did we ask Ashley and Roxanne to come down and why did we

stress Roxanne out to cover --

(Laughter.)

DR. YONG: -- those initial slides, which she did a great job on.

So I think as Reena mentioned, we've -- and yesterday, right, we heard lots of talk on the gaps in all of these programs is patient-reported outcomes. So we've been thinking internally, not just at CMS, but in collaboration with our colleagues at NIH, all the way up to Francis Collins and Patrick Conway, how can we leverage some of the resources we have within the agency at HHS? And so, there's just tremendous work, as we just heard about, with PROMIS in research settings, but also have clinical application.

And so, some of the things that really attracted us to PROMIS, as Ashley and Roxanne covered, right, it's not disease-specific, it's not setting-specific; it's really adaptable. It both comes in paper and e-form, just the number of questions validated and tested. But are there

ways to think about using PROMIS and use that as a basis to turn it into a PRO, be a performance measure that then could be incorporated into one or across programs, right, that addresses some of these issues that we talked about yesterday in terms of thinking across programs and how we sort of -- how patients move across these different providers and care settings.

So what we'd love to get back from you today is really your feedback and thoughts about is there an idea here? Are there -- these aren't measure concepts per se that we've brought to you, right? There would need to be additional work to bring back an actual measure for consideration by the MAP. But are we down the right path? Are there applications that we can -- you can start envisioning?

I will also say that we are -- Ashley mentioned at the end how there are some ideas that we have around the PAC setting. We are having the discussion across all the workgroups because we are trying to think about this

broadly, so not just in the Hospital Workgroup, but also in the PAC Long-Term Care Workgroup, as well as in the Commission Workgroup.

So happy to answer any questions, but really do want your feedback.

CO-CHAIR WALTERS: Well, thank you very much. Just a second. I'll get to Allen.

Yes, this is -- thank you very much for the presentation.

One -- I really happen to be a fan of the OCM, the oncology care model. That was a good move forward. One of the things I was disappointed about was in some of the original proposals it included use of a tool such as PROMIS as one of the measures. And then that fell out somewhere along the way.

But pertinent to our discussion yesterday that's where I think -- certainly oncology world, but in general we have to start out offering these sorts of tools, educating people, because I've got a whole bunch of health services researchers who have their own REDCap

databases about tool X. Ah, this is not -- you hear all of their arguments.

It's going to take a lot of education and discussion to get this going and support that with things like a structural measure in various programs heading towards actually the outcomes measurement, which is of course what we care about more. But to get people to use tools such as PROMIS adapted to their particular circumstance and using measure development to support that so that people can start realizing, oh, my goodness, this really does have a lot of value after all.

And so, we're still very early in that, I know. And I worked at MD Anderson. And so, I really support the work that you're doing and we need to continue to move forward with exactly this kind of effort, because there's a lot of inertia and I'm glad to hear that it's being built into EHRs. I think it's a little more feasible. Thank you very much though.

Allen?

MEMBER NISSENSON: So this an area that I have spent a lot of my career working in, so I have particular interest in it. And I love the PROMIS promise --

(Laughter.)

MEMBER NISSENSON: -- and think our population -- I know there's been a little dabbling in the kidney disease population, but there -- in my view there needs to be a lot more than dabbling. I think it's the perfect population to apply this approach to.

But I have a question. Maybe this is more for Pierre. So as we think about using this and possibly somehow incorporating it into accountability metrics -- and I'll use our ESRD example, but it may be applicable to some of the other folks.

So we currently have -- for ESRD in the conditions for coverage for certifications of a dialysis facility we have to administer the KDQOL at least once a year. So KDQOL, it's an SF-36+. So we have to do that. We now have the

CAP survey.

So my question to Pierre; and it's sort of the measure bloat issue, how kind of are you thinking about when you look at individual programs and the applicability of a tool like PROMIS in terms of PROs, not just here's another thing to add on to the other stuff we're already doing, and how we can impress this, because -- and I'll use the term "burden" -- on patients is really substantial, having to administer -- and CAPS, as you know, we're actually doing CAPS twice a year. And we're doing KDQOL once a year.

And my final question is this sort of self-reporting, which I think is really great for patients, we have on the CAPS side a requirement that CAPS can only be administered by an external third party. So kind of how do you think about tools like PROMIS and patients just kind of doing this, or will there be requirements that we have to hire outside consulting companies to administer this, or what are you thinking from the agency point of view?

DR. SMITH: So the beauty is in part the metric that I was talking about relative to PROMIS. So for example, all those SF-36 items, you would not have to administer them because we would have the ability to get similar information using many fewer questions using PROMIS. The other thing is that it's self-administered. So you can hand someone an iPad and they fill it out. And you saw that that was one of the availability pieces.

So actually the idea behind trying to get a standard set using a measurement system that's applicable across both disease setting, etcetera, etcetera is that you have the ability to have scores that are -- that again can be interpreted across those different places and people.

Just to mention your comment about the need for education or training or a better understanding of interpretability, the more that you continue to use that 0 to 100 scale and people get a sense of what those scores and the

cutoffs mean across different areas, the easier it is to facilitate their interpretation and use.

So I think that -- and I'm very familiar with CAPS. We do a cancer CAPS, a linkage with our cancer registries that we provide, so I'm quite familiar with CAPS and how many questions it is. And that is not designed in the same way, so I can't really speak to that because CAPS is really more of a process measure as opposed to an outcome measure.

But I think that the idea of using this as a framework would actually substantially reduce the burden that you're thinking about. I don't think it would add.

CO-CHAIR WALTERS: I know we've got a lot of people lined up here about this, so, Karen, you're first.

MEMBER SHEHADE: I just wanted to mention yesterday we talked about the importance of looking at measures that are important to patients. And when you were speaking it made me think about the Stanford Chronic Disease Self-

Management Program, and in my past work with chronic disease management looking across chronic conditions and what are the common themes that resonate with all chronic disease? And Stanford did some of this. And I just wanted to ask you to think about how that -- the PROMIS approach could even tie into something like this, looking at things that cut across a variety of conditions. So just wanted to put that out there.

DR. SMITH: So just again to reiterate that the design of PROMIS was to be cross-disease.

MEMBER SHEHADE: Yes.

DR. SMITH: That as -- and actually that was part of the foundational reason for developing it. It was part of the NIH Common Fund or Road Map Initiative. That's by definition across disease for exactly that reason. And for patients frankly with multiple morbidities and diseases.

CO-CHAIR WALTERS: Okay. I got the

list going here. Don't worry. Everybody will get their chance. Helen gets priority though.

(Off microphone comment.)

CO-CHAIR WALTERS: Okay.

(Off microphone comment.)

CO-CHAIR WALTERS: Okay. Good.

Andrea?

MEMBER BENIN: This seems really fascinating to me and definitely right in line with what we've been talking about as needing to understand where patients stand and how they feel. It does seem to me that at this moment really far from an accountability metric, substantially far from an accountability metric, and even thinking about what that would look like is complex, I think. I think I can go -- if you think about how it is a one patient, one cancer look and how do you hold a hospital accountable for how that person's dealing and while risk-adjusting or whatever else needs to happen. I don't even know. So I think that it's far from an accountability metric right now.

I could imagine a world where there was a structural metric around using a tool like this or another kind of tool that I could imagine, but I think that is a way that if CMS felt it was wanting to support the HHS effort, I suppose. But to me this feels like a very clinical tool that should be propagated extensively in the clinical areas and -- but the payment methodology may not really be the right one for that. I'm not sure that that's -- this is the right place to put this tool right now. It doesn't feel that way to me yet.

It feels really valuable. It feels like it move things forward. I'm curious to fill it out myself, but -- yes, just the anxiety part, right? So anyway, thanks.

CO-CHAIR WALTERS: David?

MEMBER ENGLER: Thank you. So I'm a big supporter of PROs. I think it really goes to the point of patients and making it patient-centered. So congratulations on the work being done. And by the way, I'm not going to take it

today because I'm depressed as hell, so --

(Laughter.)

MEMBER ENGLER: -- as are many people around the table.

But so I support it. I wonder if there's an opportunity here to place this in a category since it's not yet ready for accountability. But I wonder if there's an opportunity for you to think about placing this in the category of emerging population health metrics. Many of our member hospitals are moving towards more and more population health, given both our mission and where they're going in terms of their steering organizations.

And it seems to me that if you broadened this just a bit and looked at the notion behind reported, self-reported measures in a population that you would be metricating and measuring something that we're not currently picking up on the clinical side.

So I offer that as both a comment about the excitement and the forward thinking

that you're bringing to the table, but also as the opportunity to look forward in terms of this being a population health metric or consideration for population health. So thanks.

CO-CHAIR WALTERS: Lindsey?

MEMBER WISHAM: So thank you for your presentation. It was interesting and exciting all at the same time.

I think though when we talk about the scores and how comparable they can be, whether it's across care settings or disease-specific conditions -- is that ultimately that's beneficial perhaps to a researcher or even a provider that's giving the care. But if this is truly meant to engage the patient, the patient's going to say so what? So what I'm a 93? What does that mean? Or how does that change the care that I'm going to receive? How does that change maybe how my providers interact with each other?

And so I think that ultimately if this is the -- a goal is getting us started down a really good path of truly making patients engaged

in their care is that we have to be able to communicate what that means back to them.

DR. SMITH: So that is something that we are already taking up, absolutely. And in fact there are a number of -- there have been a number of studies that are about both patient communication and thinking about integrating information for decision making, dose modification or whatever it is. There are definitely both the interpretation by the patient and the clinician, and getting them in a synergistic place has been a part of using these. And I would say that patients actually have been fairly enthusiastic.

Do you want to --

DR. JENSEN: So my other hat is that I actually have been developing patient-focused symptom reports. So say a breast cancer patient who's done with treatment, 35, stage whatever. They're able to look at the scores and see how they compare to someone just like them. And people not only really wanted this information,

but they see like direct application, because it's very difficult in this -- my narrow setting to understand what fatigue means to them now that they're done with treatment. And just even though maybe there isn't direct applications immediately, this is something, this is information that patients seem to really want and are enthusiastic about.

CO-CHAIR WALTERS: The feedback's very good. Keep it up. I've got everybody on.

Jack?

MEMBER JORDAN: I completely welcome this, and it's really nice when what we're trying to do in our health system is actually aligning with where CMS is going.

Our associate chief medical officer of our main hospital has essentially told people that if you're doing a research study, you will use PROMIS unless you have a compelling reason not to. We're trying to really work through in our own system thinking through -- we've had this problem in the past. They have a research study;

and their ERB captures it there and it's lost, it just passed through there, to really try to unify this so that we're actually tracking it with one data monitor. We can reuse this for different things and not have a patient take it twice.

We are an early adopter. We do have it built into our patient portal in Epic prior to it being released as a complete thing. So it exists.

I want to agree with the population health portion, too. I think looking at populations over time -- they see a model. This is a great way to have that be kind of common and thought of. And I think we're also trying to think about is -- this is a way to look at primary care panels and kind of look at kind of the risk scoring kind of a tool for looking at panels as well. So I think there's a ton of uses for this.

And I think that the standardizing on something this on a large scale so we can get things marched across the country and doing that.

So I'm completely all for this and I think there's a lot of benefits in a lot of places if we try to commonize on this where we can. And I think what we'll lose in the specific disease things are pretty small in comparison to what we gained by being able to have comparability across.

One thing I did hear that I want to make sure of is that we don't build something like this where we're officially sending it to CMS, that we don't get to keep our own data, because I think we want to use it for other purposes. If you're wanting to measure what we're doing, I would really encourage you to not set up a model where the official blessed one you trust is data then that's blinded to us and we don't get to keep. I think it's important that we get to keep and use it.

CO-CHAIR WALTERS: Thank you. Frank?

MEMBER GHINASSI: Okay. I'm going to try not to repeat anything anybody said.

Just first of all, this is -- I'm very

fond of this and I was actually part of the group that did the winnowing and thinning way back. And so it's exciting to see this one come to -- so the real PROMIS is the IRT-CAT combination, so I want to really stress if you can make that a priority, because I think that's where the magic is in this.

The second thing; it's just a concern, is are you thinking of this -- and you don't have to answer this. I'm just putting it out there for you to think about. Are you thinking about this as a graphic tool or a nomothetic tool? So is this a one patient kind of issue or are you really looking at this to measure large populations? Because I think it has implications both ways.

The third thing is, at least in my experience, within populations there are patients who consistently underreport or endorse and over report and endorse. And so, change among those populations is not the same. And when you're measuring a population, begin to think if you can

about ways to include individuals who restrict the range of their own self-report versus those who exaggerate the range, because it's a real phenomenon and it will affect this.

The next one is are you thinking about this as a treatment planning tool or are you thinking about this as a quality outcome tool in a pay-for-performance environment? Because those are two very different agencies.

And then the other question is are you thinking about a delta in these scores as the measure? And if so, is that a within-organization delta or some kind of national delta? Because there are problems on both sides of that. Organizations that are in different environments maybe work with different populations. Their deltas may look very good within their organization structures, but not so good across a larger one.

And the last point simply is I'd recommend that if you're going to do this, numbers are going to help. Millions of people

are going to be better. Hundreds of thousands. There may be 15,000. So for -- if you're going to do an accountability measure, it's probably going to be better if you do it at the payer or state level than at the provider level. Just thoughts.

CO-CHAIR TRAVIS: All feedback, aren't you?

Brock?

MEMBER SLABACH: I think prefacing my comments, I'm a hospital administrator, so I always think about things kind of operationally.

First of all, is Epic and Cerner going to be charging for this package to their offering to its hospitals and clinics?

DR. SMITH: I'm fairly certain that anyone who has the ability to -- so Cerner I don't know yet, because that's like too early for me to actually -- so the Epic piece, I'm fairly certain if you have the ability and have already selected patient reported outcomes it's part of that package. And so for those who already had

it, it's available.

And just I wanted to mention that these are also available in English and Spanish.

MEMBER SLABACH: It's available where?

DR. SMITH: In English and Spanish.

MEMBER SLABACH: Oh.

DR. SMITH: Through Epic.

MEMBER SLABACH: The other question I have is -- and maybe I missed it in part of the presentation, but is this administered to all patients? So upon admission to either a hospital or a clinic setting are they asked to interface with tool in all cases or just in certain disease-specific conditions of cases?

DR. SMITH: So you mean how is it currently being used in clinical settings?

MEMBER SLABACH: Yes, I mean --

DR. SMITH: Specifically --

MEMBER SLABACH: -- what do you perceive is the best way to do this --

DR. SMITH: Well, I --

MEMBER SLABACH: -- going forward and

how do we I guess respond to that in terms of implementation of process, because in the hospital context and the clinic context you've got to make -- you got to translate this into -- we're required to have patient portal -- a certain percentage of patients accessing our portal, for example.

DR. SMITH: Right.

MEMBER SLABACH: So is this going to be a requirement that we're going to have to have so many of these forms filled out for so many of our patients in terms of population?

DR. SMITH: So it's a little bit of a complicated question. I can tell you what's being done now and I will also defer to Pierre and also the thinking with guidance from you all and of CMS relative to developing a performance measure, because some of the questions and comments just made were incredibly poignant and important to consider in terms of how this interpretation will happen and what kind of change in one's reported abilities or symptoms

for tests, whatever it is, is going to be -- matter based on what the ultimate measure is.

But in terms of current use -- and I would say; as I mentioned, that orthopedics is the biggest starter, there are -- so for example, University of Rochester, every single orthopedic patient gets it the minute they walk in. Every time.

MEMBER SLABACH: Every visit?

DR. SMITH: Every visit. And they actually have iPads set up. And initially they thought they needed a nurse consultant or somebody to explain it, and they very quickly recognized that they did not actually need that. So they reduced that FTE burden, etcetera. The administration fees is actually pretty great.

So, yes, they use it. And they track patients over time and they make decision related to physical therapy, surgery, I mean, etcetera. So they're -- and now they are moving it into their oncology setting. Again, the second sort of high user group. But there are lots of

examples. And GI distress, for example, was one of the domain areas. That tends to be used in particular populations more. But -- and is being used in clinical settings. So there are examples all around.

Some -- I think for the most part in clinical practice the idea is to be tracking people either for flagging them for a particular -- the patient population in general for problems or for if there are decision points that are being made. And that depends on what the condition is and who the patient population is. Yes.

And the other thing is that the earliest adopters had to do a lot of their own IT-related pieces, but moving into these electronic health records, that changes that ball game completely.

MEMBER SLABACH: And I think that the key will be -- is to make sure; and I think I've heard it said, but just stating it another way, the benefits to the clinician and to the patients

have to be clearly outlined so that it will be saturated and the use of this will proliferate. Because otherwise if it's just seen as a requirement that CMS or Joint Commission or whoever requires fill this out. So that -- and I see the benefits and I see the direct outcome of the benefit, but if it's not translated in a really positive way, I think it could be seen negative.

Finally, the question I have is predictive ability. So I know in dealing with patients you get a certain condition at this moment in time. In terms of decision support, looking ahead in terms of the progress given the reality of where a patient is now, can you project certain characteristics or where this patient's path will go and will be planning for that in terms of reality of the situation? That's probably not a very well-asked question, but --

DR. SMITH: No, no, no. That's a good question.

To some extent, yes, I would say that; keeping in mind that these have been tested in so many different studies, like hundreds of studies actually, the -- looking at predictive ability for every patient type in every single situation, we're not going to have that kind of information available at this point. But there are certainly indicators for -- that have been -- that have gotten more attention or more study that we do have the ability to have a general sense of someone's trajectory and that sort of thing. I wouldn't say it would -- we could assume, oh, in three months someone's going to have a three-point change. That's not going to happen.

MEMBER SLABACH: Right.

DR. SMITH: But a general trend is potentially possible, yes.

MEMBER SLABACH: Yes, I think it could provide a real reality moment for people. And then I just think about myself and the question about filling out a form and such. It helps the feedback. Instead of denial and --

DR. SMITH: -- Right.

MEMBER SLABACH: -- avoidance, it maybe helps to craft the conversation. I think it's a really good communication tool to set up a plan of treatment that's realistic and appropriate.

DR. SMITH: And there are research studies on how to best provide the information to clinicians and helping clinicians action back what they are doing, and again in different settings.

But your comment earlier about how this gets incorporated and the sort of way in which to make it ubiquitous or such that it's easily interpreted and integrated is that if you start with; I guess the comment earlier was about structural measures, just the assessment of these and people get used to having the information and there is guidance provided just cause, here's how you can use it, and there's -- these are -- here's some information, but that isn't actually evaluating the outcome piece yet. But getting

people used to it is sort of a stepped approach. And then the potential to look at indicators either at the population level or -- depending on what you want at the individual level, too.

CO-CHAIR WALTERS: Pierre's been taking copious notes. We'll get back to him after Helen.

But, Jennifer?

MEMBER EAMES HUFF: So first of all, just congratulations on all the work. It's pretty amazing. And I think we would all agree, I think we have all agreed on the importance of patient reported outcomes and can see how it's a place where many users can come together and get benefits for a variety of reasons and leads towards a more patient-centered healthcare environment.

I want to underscore a couple of things, one around engaging the patients in using the info and the importance that has. And care delivery, and care management, and care engagement. And I think there's also a piece of

-- I know -- so I've filled out surveys, too, and I get really pissed if I don't know what happens with the results or don't see that. It just -- so if we're talking about doing even more surveys, we need a way to actually get the patients to buy in to doing that.

And I think one of the ways -- so I don't know if you're doing research on smartphones and apps and how those can play a role. And I'm thinking more of it's not the solution for everybody. And we know there are population differences, but there was a time when there was like a standard model of you mail out the survey once, twice and then you do a phone. Is there a way that we can move to apps being a part of the multi-modal way in which you reach patients? And it's not the be-all-end-all, but it serves as a really important point for a variety of reasons.

And then the other thing I want to say to CMS is I think you've done a great job already starting to create momentum in terms of using

PROs in healthcare, the voluntary option in the CJR Program. And I actually even like CPC+ because it becomes a part of the package. You get to choose the track, you choose the PROs. So I think that's really important to getting engagement and comfort with using that as starting to have it.

And I do think I find one of the challenges -- particularly as we're talking about different disease states, and if you're looking at doing aggregate comparisons across organizations, is the numbers challenge, right? Some of these places it's just small numbers to even get to the point of creating reliable and valid. It's kind of challenging. So I'd strongly encourage you to engage with the private sector in doing this towards the beginning. Is there a way in which the private sector can also be in alignment? One, for a variety of reasons it just creates having multiple signals of what's important; but two, in working together on the measure development so you're creating the

volume.

And I know that requires a lot more front-end work, but I think this is one of those places in measurement we have a key opportunity to get people on board and sort of driving in the same direction instead of having lots of different measures about the same thing. I think that's something we'd really want to avoid. So there really needs to be a lot of care from the get go in terms of having very early conversations about what people can and cannot do. From the registries to healthcare systems to the payers there's a variety of opportunities around that.

DR. SMITH: Just one quick clarification. The app is already available. So one of the things in the early slides was about that there's a PROMIS app and -- but it's available for iPad. It has not been developed for smartphone use yet. And that's where again the University of Rochester, everybody's using an iPad, distributing it, and that's how it's

specifically done.

I think one of the things -- I don't know if the iPad -- if it's in sort of an office space use, but I think as we're seeing some of the things that you're doing, we wouldn't want it tied to an office visit. It does not have to be. It can be done remotely. It can be done anywhere. I just more mean that if a hospital is, for example, doing it for every patient that walks in the door, you can do it on -- buy five iPads and you're -- and, but, yes, it can be done remotely, and that is used and can be integrated directly.

CO-CHAIR WALTERS: Wei?

MEMBER YING: Actually this year will be the third year our organization will be receiving the patient reported outcome data from our physician organization, so I can share some of the experience and the lessons learned from this exercise.

It's very exciting to hear that they're now -- PROMIS has kind of integration

with other two, but one question that we encountered when we tried to negotiate this contract is physicians are receptive to using the PROMIS tool, especially the physical function and the global tool, but they're hesitant on the mental health side. The main issue there is PHQ-9 has been out there for such a long time and they're so familiar with it. So they'll usually shy away from the mental health part.

And also another thing is a lot of times these things are -- specialist societies didn't want to use it, and we developed their own specialist-driven app. So usually, while we engage with orthopedists or oncologists, it's always PROMIS -- we offer PROMIS as one of the options, but they always want to couple it with another tool that they're more familiar.

So my question is, in terms of collaboration do you mean the collaboration was a more general standardized health status tool, SF-36, or do you mean the collaboration with some kind of the specialty society development tool?

DR. SMITH: So I should have had a slide on this. And there's actually web site about it. It's called PROsetta Stone. Very cute. It was --

(Laughter.)

DR. SMITH: It was a grant that was funded by the NCI, the National Cancer Institute, and it was specifically to develop these crosswalks between what we call legacy measures -- so SF-36 is one, PHQ-9 is also one, the CSD, etcetera, etcetera. And there's actually a list there. And we are planning additional ones in the current grant that NIH is funding now for use.

In terms of any -- and an oncology fact, for example, Roxanne had -- is used extensively. Many fact items are actually the same in PROMIS because the development of PROMIS actually came from both the identification of specific legacy measures that could be -- items could be pulled in directly from them. Then we have agreements with the authors of those

instruments to do that. And then we added additional items where there were gaps. So some of that crosswalking is fairly direct, actually.

And if there are little-used -- so the other thing I always tell the patient we understand there are many assessment tools that are -- people are very comfortable and familiar. Go ahead and use it. We can compare it to the PROMIS metric and get you a PROMIS score. If you want to change over, it's seamless. And if you want to stick with the PHQ-9 because you know it, that's fine, too.

So if there are specialty society-driven assessment tools that are more -- narrower use, I don't know that we would have crosswalking available now. It sort of depends on what it is. We've been trying to go with the most used ones first, obviously. Yes, but the methodology is there.

MEMBER YING: Oh, great. And another lesson learned we -- that we learned from this exercise is the actionability. So PHQ-9, the

reason we ran out with PHQ-9 the first two. The reason for that is there is -- I want to call it clinical guideline, but physicians sort of know if a patient gets scored within this score range, it means this. We think that's working. They know how -- what to do about it.

For the other two their argument is, yes, it's nice. I know it's 80. But what does that mean? What's the difference between 80 and 85? So they're -- if they don't know what to do about it, it's very hard to persuade physicians to actually adopt a tool into their work flow.

And another thing about PHQ-9 is there are two PHQ-9 measures that's out there. I've seen at least one of them. Maybe both of them are endorsed by NQF. Again, when we go out with these measurements, we still get a lot of pushback. So we don't use it for payment purpose. We use it sort of as a monitoring purpose. But again, there is something there that we can monitor what's going on and we can look to claims data to see what is the treatment

has that leads to different kind of improvement pre and post the survey.

So for these other choose if there is no actionability so the physician doesn't know what to do about it, it's very hard to push forward.

CO-CHAIR WALTERS: Take home assignment, everybody should visit PROsetta just to look through it.

(Laughter.)

CO-CHAIR TRAVIS: Sean?

MEMBER MORRISON: So, Ashley, you've heard this from everybody, but just to reemphasize what an extraordinary body of work the PROMIS people have done over the years. And the amount of psychometric work to get a measure set like this is extraordinary, so thank you for that. I think it's probably one of the most pragmatic things that NIH has ever done.

(Off microphone comment.)

(Laughter.)

MEMBER MORRISON: Please do not. I

still rely on you for funding.

I wanted to make really three comments. The first is that what we've seen is CMS evolve from really essentially a big insurance company to an organization that has really focused on the health and quality of life of people in this country. And that is a very, very important change. And all of the work that we have done around this table has really focused on the goal of how do we improve health and quality of life for people who sit under CMS, and all the measures that we have done are really surrogates in that.

But as healthcare has moved forward and becomes more fragmented and more personalized and we get individual treatment options, all of these multiple measures that we have are going to become obsolete because either we're going to be spending all of our time measuring every single specific small outcome or process that goes with every single individualized treatment, or we're going to have to rethink how we're doing that.

And I think what this does is really focus on -- this set of measures as what are -- what is important for the nation's health? It is the patient reported outcomes. It is what's important to know.

They don't -- my 90-year-old doesn't care what his or her glycosylated hemoglobin is. She really doesn't. What she cares about is how she's feeling. And I think that we really need to think very, very hard about how we push this forward extremely quickly, that the opportunity is here to have a set of measures that goes across diseases. It goes across settings, it goes across plans and it goes across providers in a way that's very meaningful to the people we're taking care of.

And I would love in five years to be sitting here and thinking about what are the PROMIS measure sets or what are the measure sets rather than when I'm going to be looking at is 25 different items such as alcohol use and brief -- if you provided or offered an alcohol use brief,

and multiple measures like that.

So thank you for doing that. And, Pierre, thank you for the opportunity for us to hear about it. And thank you for CMS considering this as a move forward. I think it is the right direction.

CO-CHAIR WALTERS: Okay. We're drawing near, but we'll get to Lee, then Dan and then Lindsey and then Helen and then Pierre.

Lee?

MEMBER FLEISHER: Yes, another kudos. We actually do use it on every visit for our pain practice. And one of the key questions is -- particularly we don't know in pain what works at all for many of our treatments. In fact, I would question a lot of what we do, as do my own people, which is why they've done it in 3,000 patients longitudinally with other scores. It would be great to somehow use this to actually do a comparative effectiveness trial within certain areas, because I think; Sean, I think would agree, some way to marry up payment with research

to find --

DR. SMITH: We at NIH welcome applications all the time. There are multiple receipt dates for January --

(Simultaneous speaking.)

MEMBER FLEISHER: Yes, between you and PCORI, right.

DR. SMITH: Right, yes.

MEMBER FLEISHER: So I think --

DR. SMITH: No, but really actually we do support a grant portfolio that would be very enthusiastic. I'm in a healthcare delivery research program. We're very much focused on how can we use tools like this. So additional studies, NIH funds, yes.

CO-CHAIR WALTERS: Dan?

MEMBER POLLOCK: And to that end and thinking in terms of moving this from where it is now to the measurement world for quality improvement, one of the most important dimensions of quality measures is to establish that there's a performance gap and to establish how the metric

can be used to close that gap. So I would just encourage keeping those very important parameters in mind as you move forward. Where is the performance gap? This is a vital sign. What you are developing is another vital sign. So how does that vital sign get used to actually improve patient care and where are the gaps?

CO-CHAIR WALTERS: Lindsey?

MEMBER WISHAM: So kind of having grown up through electronic clinical quality measures, I tend to look back at what are the lessons learned, what maybe we could have done differently to make that a smoother process. And I think that this is a new frontier, just as ECQMs have been as well.

I think one thing to consider from an implementation perspective is though while it seems it's very positive that it's configurable and there are so many questions that you could put together to hopefully achieve a very light score, depending on the questions you ask of course, but is it -- how do we get this data back

out of the systems? So I'd be very interested to talk with and Epic or a Cerner to see how they would potentially get the data back out in some sort of meaningful way for reporting so that initial benchmarking could be done, so that performance metrics could be developed, that it could begin to look at what these benchmarks may drive.

CO-CHAIR TRAVIS: Thank you, all. And before I turn it to Helen, there are just kind of three observations I've made about things that were interesting to me about this.

One was the whole discussion about is this for individual treatment decision making and how that may not align really very well necessarily with looking at performance measures.

I was in a conversation earlier this year around oncology actually, and the whole concept that this type of information could be used as part of the work flow and to the point about making it important to patients. I mean, if they see that what they're giving you actually

changes the treatment decisions that are being made, I think that's a significant piece. So whatever -- I would hate to think it only becomes a performance measure and is still not there for individuals treatment decisions along the way that need to be made.

Another thing I kind of picked up on -- and I'm -- I work with employers on their health, I don't work out in the industry per se, just as background -- is that there may be in other regulations, in other pieces of licensure or other regulatory processes for people who are required to do other types of patient reported outcomes. So I think being sure that as CMS looks at how do we use this that it's not just CMS programs that you're looking at, but that you understand what are the other pieces? And I think to Jennifer's point, working with others now to figure that out, whether it's an accreditation requirement, whether it's a regulatory requirement, whether it's a state requirement, so that there can be some kind of

consensus on how we move forward.

But the whole idea that we could actually have performance measurement be part of work flow versus this added thing that happens over on the side I think would be exciting, and I can kind of see how this could do that as long as it still continues to meet both needs.

And with that, I think I'll turn it to Helen.

DR. BURSTIN: Great. Thanks so much. I want to thank both of you. It was great. And Ashley and I have talked about this in the past. Just so you know, PROPMs has been a major purpose of NQF for the last several years, since very generous funding from HHS that allowed us to actually create a pathway for how do you go from the tool -- and this was a brilliant tool we talked about this morning where a series of item banks were essentially a PRO. How does that make the transition to a PRO-based performance measure is where I think a lot of our emphasis has been and I think a lot of the work is going to need to

go.

For those of you who haven't done it, I would really recommend going onto PROMIS and doing a couple of the item banks. There's nothing more instructive than actually doing itself, and we'd be happy to send those links out. And since Ashley mentioned the University of Rochester, I actually have the video from Judy Blumenauer that she shared and she allowed me to share with anyone of the work they've done of -- literally a patient sitting with their clinician looking at their PROMIS results and seeing how well they did compared to where they could be.

And what's really extraordinary is they're also using it to get at appropriateness. So they can figure out based on somebody's pre-op score how far they would actually have had to move to make sufficient improvement that surgery is every worth doing. And they can actually tell people based on what your PROMIS physical functioning score is you're actually too well off. Surgery wouldn't get you enough benefit to

take the risk on. So this is really clinically transformative in a way we're just beginning to scratch the surface of.

So as part of our PROPM work funded by HHS there was a monograph developed, which is on Amazon; I think we shared the link with you, or free paper versions of it, that explain that pathway. The lead author is David Sella, who works very, very closely with Ashley and her team at PROMIS. And again, this pathway is where I think we really need to think about how do we move from having a structural measure -- and we talked about this yesterday. Is that really satisfying enough just that you checked that to the other extreme of did you demonstrate sufficient improvement like we have with our depression measures?

And I think part of what we have to figure out is there something in between those two poles that in the interim we could move towards -- is that you used it in a clinically meaningful way might be another way to help us

get closer to actually your point about being able to use it in practice, with being able to use it for measurement and what that looks like and the promise of -- it's very easy to do that, isn't it?

(Laughter.)

DR. BURSTIN: Redact. The promise of putting it in the HR means, with all the caveats we heard from Lindsey -- it's actually in there and I hope that it actually gets used clinically beyond a check box measure. Yes, I checked that somebody has an annual KDQOL, to Allen's earlier point.

We also have some incubator work we're doing as part of the NQF incubator, developing some new PROPMs. And David Sella is working very closely with is on those as well. And there is an interesting model to Wei's earlier comment about using a generic tool like physical functioning as we're doing for a multiple sclerosis project, but then adding on a series of more disease-specific kind of items to get sort

of the best of both worlds, but not get just the addition of multiple and multiple tools. And we'd be happy to share that as well.

Since Lindsey also -- I'm sorry, since Ashley also mentioned the PROsetta Stone work, we actually have been working closely with both developers, Minnesota Community Measurement and NCQA, to actually consider moving away from the measure requiring a PHQ-9, but to allow the full range of tolls that have been covered by the PROsetta Stone analysis to show that you can do that equivalence.

There's still some work ongoing, but from our vantage point the idea of being able to have a set of tools that you don't have to force hospitals to say I've been using this for years. Well, sorry, you now going to have to switch to this. That's not what we want to do. So we're actually very excited about what could be done here.

And just lastly -- there's one other thing I wanted to say. Now I can't remember what

it was. Oh, the last thing just in terms of the private sector, since both Jennifer and Cristie brought it up, we're actually doing a joint convening in -- I think it's now scheduled for February or March with ICHOM, the International Consortium for Health Outcomes Measurement; PROMIS is part of those discussions, being co-convened by NQF and the Healthcare Transformation Task Force. So David Lansky and I are leading those efforts with the folks at ICHOM.

So again, very much trying to see whatever we can to bring all of these different forces together. This is such a remarkable approach. There's just -- we spent so much time trying to harmonize at the back end and banging our head against the well and it's just very exciting to see opportunities to very highly upstream harmonize before these measures even kind of hiccup. So thanks.

CO-CHAIR WALTERS: And a sincere thank you for everybody's thoughts and comments. You can tell people are quite energized about this.

Pierre, did you get enough feedback?

(Laughter.)

DR. YONG: We could spend the rest of the day. We can just skip the measures, right?

(Laughter.)

DR. YONG: No, I -- this has been -- I mean, wow, right? I mean, I think I loved the engagement and didn't expect anything less, but really the discussion here in the past hour I think has been tremendously valuable, not just for us, but also for our NIH colleagues as we continue to sort of think and think about the potential next steps in this. So really do appreciate that and so want to thank Ashley and Roxanne for coming and providing their expertise, and also their additional CMS staff in the room, but also back at CMS who've been working with Roxanne and Ashley closely on this.

DR. SMITH: One thing just for synergy purposes, we are also working with the FDA and they are currently evaluating PROMIS as a -- for use as a PRO in drug development trials, and

specifically they're looking at physical function. And at their request they were interested in physical function in oncology. But that's an earliest place where; speaking of industry, other side of industry, will be using these as part of their comparisons in their arms to better understand the effects of the drugs that they're testing.

CO-CHAIR WALTERS: Thank you. This is what MAP and NQF is about right here. You just saw a great example.

We have one thing to take care of first. Aneeb, would you introduce yourself and disclose any conflicts you have?

MEMBER SHARIF: Aneeb Sharif with SEIU and there are no conflicts.

CO-CHAIR TRAVIS: Okay. Well, thank you all for a warm-up. It obviously was a very engaging conversation, and I think for me is very optimistic and very hopeful for where we can go. And I do want to echo Sean's opening comments about the role that CMS is playing and really

thinking about the health of our nation and not just being a payer and how you've aligned those two things together, which brings us to our next set of federal programs that we're going to talk about today.

The first program that we're going to address today is the Hospital Inpatient Quality Program, one of the ones that is nearest and dearest to all of our hearts. It also includes the Medicare and Medicaid EHR Incentive Program for Eligible Hospitals and Critical Access Hospitals. And I am going to turn it over to who? Melissa.

(Laughter.)

CO-CHAIR TRAVIS: I can't read and talk at the same time. It's like chewing gum and walking.

So, Melissa, thank you for kicking us off.

MS. MARINELARENA: Thank you, Cristie. Okay. Let's keep that positive attitude that we just had while we go through these last programs.

(Laughter.)

MS. MARINELARENA: So as we all know, IQR, this is a pay-for-reporting and public reporting program. Hospitals that do not participate or do not meet the program requirements are -- can receive up to a quarter reduction of the annual payment update and the program rules are to progress towards paying providers based on the quality rather than the quantity of care that they give patients. And there's also a goal of interoperability between EHRs and CMS data collection, which is where you see the integration of IQR and the EHR Incentive Programs, which are separate and; I think I got the EHR Incentive Programs right, to provide of course consumers information about hospital quality so that they can make informed decisions. And I'll look to my CMS colleagues to see if I got this right.

So the Medicare and Medicaid EHR Incentive Program for eligible hospitals and critical access hospitals, which is -- was

meaningful use -- it was three different programs. So the Medicare EHR Incentive Program, that is for eligible hospitals and critical access hospitals that do not successfully demonstrate meaningful use. They receive reduced Medicare payments.

For the Medicaid EHR Incentive Program those eligible hospitals and critical access hospitals that only participate in the Medicaid EHR Incentive Program, which is state-based, and do not bill for Medicare are not subject to any kind of payment adjustments.

Then there's the Medicare and Medicaid EHR Incentive Program. I think I got this right. So hospitals, eligible hospitals and critical access hospitals that participate in both and do not meet meaningful use, they are subject to payment adjustments, is that correct? I think so, yes.

Okay. And of course the goal is to promote the adoption and meaningful use of interoperable information, technology and

qualified EHRs and to accelerate the adoption of HIT and utilization of qualified EHRs. So we have measures that were -- are introduced into the program for both IQR and the EHR Incentive Program, and then some are just for IQR. We have separated them out.

Here's a slide provided to us by our colleagues from CMS. And we have again the NQF's priorities on the left. And you have -- all these measures on the right that were introduced in the MUC. The ones in the parentheses are the ones that are just the EHR Incentive Program, but we will -- those are the ones that we're voting on last, so we'll make that every clear when we go through them.

This is the current state of the IQR EHR Incentive Program, and we have it lined out where there's the ECQM only measures. And you can see the progress of the IQR Program over time. There used to be -- like when I started all of this there was a lot of chart-abstracted measures. There's very few left.

The slide that you have now, I did update it with the measures that are slated to be removed within in the next couple of years, but we start off with your COTIs, COPSIs, your claims-based measures.

If we go to the next slide, these are more the claims-based measures, and I tried to like lay them out my mortality or the readmissions measure, excess days in acute care measures. So these again are all based on sort of themes.

Keep going. We have a whole lot. So here's your ECQMs. Those are the ones that are -- can qualify either in the EHS Incentive Program or some of the ones that the IHR IQR Program can use as part of meaningful use.

Now the ones that are highlighted in purple; and I have it, those are finalized for removal. So the original slides that you saw back during the web meeting, I did include those, but now I've put those back in so you could see what CMS has scheduled to move out. So those are

scheduled to move out, so we don't look at those as gaps. They've been taken out. And you have it in your handout as well.

So these are the only chart-abstracted measures that are left. So CMS is really moving towards either the ECQMs or claims-based measures. And we have your patient surveys and some structural measures. And then there's two that are scheduled to be removed as well.

And there's a quiz afterwards --

(Laughter.)

MS. MARINELARENA: -- to name all the measures.

CO-CHAIR TRAVIS: Thank you. That will take a while.

(Laughter.)

CO-CHAIR TRAVIS: Before we go to public comment, Pierre, I know you wanted to make some comments based on some feedback you got yesterday. So if you would like to make some comments, or to -- whatever you're prepared comments are, those are the right ones.

DR. YONG: Thanks, Cristie.

So just wanted to offer just some general context for the measures we're about to discuss for IQR, so hopefully that will be helpful for you all as you're thinking about why we put these measures on the MUC list for IQR. And I'm just going to cover this at a very high level. Obviously if you have specific questions during individual measure discussions, we can certainly cover that.

But, so one of the things that folks have been -- I know many folks around the room do follow closely our regulations, but in last year's IPPS rule for the Inpatient Quality Reporting Program one of the questions we did ask for feedback on was -- generally we noted that based on some MedPAC analyses about a third of psychiatric hospitalizations for Medicare beneficiaries actually occur not in inpatient psychiatric facilities specifically, but in acute care general hospitals. So there's a substantial amount of psychiatric-related conditions that are

taken care of in general hospitals.

And so one of the questions we asked for feedback in last year's rule was -- or earlier this year was should we consider more behavioral health-specific measures in the IQR Program? And we did get a variety of responses that were quite supportive of that concept, but then also got some comments just cautioning again you needed us to consider general implications for work flow and effort, if you will.

But so what we did in this year's -- when putting together this year's MUC list is we looked at -- as you know, yesterday we discussed the measures for the IPF Program, the Inpatient Psychiatric Facility Program. So we looked at the measures there that may be applicable to the Inpatient Quality Reporting Program. So for example, acute care hospitals.

And so you'll see a number of those measures on the MUC list, and they are all implemented into the IPF Program. So that's what was generating that and driving those decisions

to put those on the MUC list. And so we want your feedback on those. And are those the right measures? And so that's what we're here to discuss.

I think yesterday we also had a robust discussion and expect that we will have another robust discussion, as I'm sure Sean will lead the way on -- in certain terms of pain and opioid questions, but as we all know the opioid epidemic in this country is something that's garnered a huge amount of attention. And so we do have a couple of questions relating to pain management and opioid use. And so that's what's driving those particular questions being -- or measures, excuse me, being on the MUC list, and we'll have a discussion around that.

And then we also look generally across general gaps, so nutrition for example, there's a collection of four -- a set of four questions relating to patient nutrition and malnutrition status that are on there. There are some questions around tobacco use and other sort of

questions along those lines to fill those kind of gaps. So hopefully that will provide some general high level context for the decision making that went around measures that went onto the MUC list. So thank you.

CO-CHAIR TRAVIS: Well, thank you. That's very helpful for us to really think about how we go through these measures when we do.

So before we get started with the measures I'm going to open it up for public comment.

Operator, will you see if there's any public comment on the phone?

OPERATOR: Thank you. At this time if you would like to make a comment, please press star then the number one on your telephone keypad. We'll pause for just a moment.

(Pause.)

OPERATOR: And there are no public comments at this time.

CO-CHAIR TRAVIS: Public comment in the room? You may go ahead.

DR. SUTER: Can you hear me? Okay. Hi, my name is Lisa Suter. I'm the -- oversaw director -- I was -- directed measure development for the informed consent measure that you're actually going to be hearing about later, but the NQF staff indicated that we had new information relevant to today's discussion. They had new information relevant to the MUC 16-262 measure, the informed consent measure, and the NQF staff asked me as the developer to present during public comment.

So we have information relevant to the hospital level measure result reliability testing. We performed split sample test/retest. I'm happy to share documents if people want to see this in front of them. But this is where we took hospital level data for the informed consent measure, which we'll discuss later. We split the patients at each hospital randomly into two 50 percent samples. We ran the measure results in both 50 percent samples and then calculated interclass coalition coefficients to determine

measure result at the hospital level reliability.

If you're looking just at the mean score, the ICC is 0.94. If you're looking at the proportion of informed consent quality scores at that hospital that were over a quality threshold of 5, a score of 5, the ICC was 0.73. And if you're looking at the proportion of informed consent quality scores over a threshold of 10, the ICC was 0.95. So I'll be happy to discuss this later, but the staff asked me to present this early during public comment. Thank you.

CO-CHAIR TRAVIS: Thank you.

MS. BOSSLEY: Hi, Heidi Bossley. I'm speaking on behalf of AMA. Their staff unfortunately couldn't make it today; asked me to read a couple comments for them.

Specifically, I believe the two HCAHPS pain measures are for discussion, not for votes. Or is one for vote and one's -- okay. Either way we're going to provide some comments on both.

(Laughter.)

MS. BOSSLEY: Pain is a high priority

when treating a patient and should be assessed frequently, but the measures and questions as drafted imply that it is the first and foremost topic of conversation. The questions still only highlight prescription medications as a sole option for managing pain when alternatives may also be effective such as physical therapy, non-prescription medications and so forth.

The questions associated with specifically the 263, the Assessing Pain During the Actual Stay, seemed very open-ended. And the second and third questions that are associated with that same MUC number, the ones dealing with has the hospital talked to you about how much pain you've had and then have they actually talked to you about how to treat that pain are not realistic since the scoring aspect is -- be always by patients?

We also suggest that instead of asking whether hospital staff explained side effects of any prescribed pain medications the question should ask if the hospital staff explained how to

safely use the medications. Therefore, there is a need for CMS to complete testing and bring the measures back to the MAP for careful review after the testing results and revised measures are developed to ensure the measures are valid and they do not lead to unintended consequences.

Second measure, the Safe Use on Opioids. They just wanted to briefly comment as well that they support the intent of the measure, but are very concerned that it will lead to unintended consequences that patients that legitimately need concurrent opioids prescribed will have an access issue primarily due to the fact that physicians might be penalized for prescribing those. Thank you.

CO-CHAIR TRAVIS: Thank you both very much. Oh, we have another one.

MR. SHANER: One more. Thank you. Hi, I'm Bob Shaner. I'm here on behalf of the American Academy of Pain Medicine, which is the AMA-recognized specialty society in pain medicine. And we want to say us, too.

I think we endorse the comments that were just made on behalf of the AMA. We think it would be a terrible mistake to change the existing measures and adopt a new set of measures that simply puts more focus on medication. Quality pain control in the inpatient setting is a lot more complicated than a yes/no choice on opioids.

And in fact, there's been tremendous progress in the last 20 years on inpatient pain control, and much of it has very little to do with opioids. Sometimes it's opioids in conjunction with other therapies. Sometimes it's other therapies instead of opioids. But to come back with five questions, two of which now basically focus on did you get medication or didn't you get medication, and did they talk to you about side effects or didn't they talk to you about side effects? Just vastly oversimplifies a complicated part of quality inpatient care.

So we would urge you as the AMA has to hold off on the five that you have proposed, do

more work, gather more input, and our academy would be more than happy to participate in that. We submitted a very lengthy statement to CMS in connection with the de-linkage of the quality measures for pain for payment purposes, and I'd like to make that available to you and hope you'll have a chance to share that among your colleagues. So thank you very much for the opportunity to weigh in on this.

CO-CHAIR TRAVIS: Well, thank you.

Are there any other comments in the room?

DR. GONZALEZ-FERNANDEZ: Hi, yes. I am Marlis Gonzalez-Fernandez. I'm a physiatrist, Johns Hopkins School of Medicine, and I'm here today to give comments representing the American Academy of Physical Medicine and Rehabilitation.

CO-CHAIR TRAVIS: Okay.

DR. GONZALEZ-FERNANDEZ: We also --

CO-CHAIR TRAVIS: Yes, I'm sorry. Go on.

DR. GONZALEZ-FERNANDEZ: We also agree

with the comments that AMA and AAPM just put forward. We further suggest that expanding the scope of the options for managing pain is incredibly important, especially, as we mentioned before, the opioid epidemic is upon us.

So those things that are beyond medications include activity, behavioral modifications, mindfulness, medication counseling, psychological support, physical occupational therapy. So and the measures are not addressing any of those interventions.

Further, we would suggest that MUC 16 -- the 263 and 264 should better represent the intent of testing the communication of pain, rather the treatment of pain. So we would suggest that changing the how often questions in HP-2 and HP-3 to, for example, quote, "During the hospital stay did the hospital staff discuss ways to treat your pain with treatments other than medication," and perhaps saying, for example, "During this hospital stay did the hospital staff ask about the effectiveness of your pain

treatment" would be a little bit more open and help patients tell us if pain has been in the forefront, not just in the medicational realm, but overall.

So thank you for your consideration.

CO-CHAIR TRAVIS: Thank you. Are there any other comments on the phone, operator?

OPERATOR: There are no comments at this time.

CO-CHAIR TRAVIS: Okay.

MR. LAPIN: I believe I have a comment, if I'm able to right now.

CO-CHAIR TRAVIS: Sure.

MR. LAPIN: So, I'm Joshua Lapin. I'm at the Society of Hospital Medicine and I just wanted to I guess forward the comments from the AMA on the 263 and 264, the HCAHPS measures. Hospitalists are frequently in the position of treating pain for hospitalized patients, and we strongly appreciate that CMS has been working to address some of the unintended consequences and pressures around the HCAHPS questions.

And similarly, to the AMA's comments, we think that there's an opportunity to continue working on the measures to be able to focus more on the communication of pain and the wide range of non-opioid options available for pain management for hospitalized patients and for pain management post-discharge.

CO-CHAIR TRAVIS: Okay. Thank you very much.

I'm going to pause one moment to see if there's anybody else out there before we close public comment. Any other comments?

OPERATOR: And there are no further comments.

CO-CHAIR TRAVIS: Thank you, operator.

All right. Well, thank you to all of those who made comments and we really appreciate your perspectives as we begin to look at these particular measures.

The first set of measures that we're going to be looking at address alcohol use and drug use as well as one smoking prevalence

measure. I didn't get any notification ahead of time as to whether anyone wanted to pull these measures, but we will go measure by measure to see if anybody would like to pull them.

The first one is Alcohol Use Screening, which is MUC 16-179. It was originally and is being recommended to support a rulemaking. Is there anyone that would like to pull that measure? Okay. Akin says yes. Okay. That's great. So that measure's pulled.

The second one is Alcohol Use Brief Intervention Provided or Offered and Alcohol Use Brief Intervention. The recommendation on the consent calendar is support. Would anybody like to pull that? Mimi. Okay.

The third one is Alcohol and Other Drug Use Disorder Treatment Provided or Offered at Discharge and Alcohol and Other Drug Use Disorder Treatment at Discharge. And the recommendation is do not support. Would anybody like to pull that measure for discussion?

(No audible response.)

CO-CHAIR TRAVIS: Okay. Seeing none, it stays on the consent calendar.

And the final one is Patient Panel Smoking Prevalence IQR, which is MUC 16-68. Recommendation of do not support on the consent calendar. Anyone want to pull it?

(No audible response.)

CO-CHAIR TRAVIS: Okay. So we have two measures that are remaining on the consent calendar. They are MUC 16-180 and MUC 16-68.

Are there any general comments that anyone would like to make about these measures before we see if we can just accept the consent calendar? Akin?

MEMBER DEMEHIN: Since we pulled this I did want to give a --

CO-CHAIR TRAVIS: Oh, no, we're not there yet.

MEMBER DEMEHIN: Oh, okay.

CO-CHAIR TRAVIS: Sorry about that. We're just considering -- we'd like to offer an opportunity for people to say something about the

consent calendar measures in case there's a burning desire to do so. So that's where we still are.

Okay. I don't see anybody based on their card to do that. So are there any objections to accepting the consent calendar with those two measures on there?

(No audible response.)

CO-CHAIR TRAVIS: I don't see any objections. So now we will move to looking at the particular measures that have been pulled for discussion. And the first one is Alcohol Use Screening, MUC 16-179.

And, Akin, if you'd like to open us up with your rationale for why you had it pulled.

MEMBER DEMEHIN: Thanks, Cristie. So it was helpful to hear from Pierre some of the rationale for putting measures on the IQR list, one of which was looking at the IPF measure set and seeing if there was an opportunity to incorporate measures from that.

I'll be pretty blunt and say that we

aren't a fan of this measure in the IPF measure set and we're not particularly big fans of it in the IQR measure set either.

In raising concerns about this I certainly don't want to convey the impression that we don't believe alcohol abuse is an important public health topic, because it most certainly is. I just think we question the extent to which a measure like this, which is really offering a brief intervention during a hospitalization, during a time when a lot is happening for a patient -- just how much of a downstream impact this has on overall rates of alcohol abuse.

It seems to us that this is kind of a process measure. It's more of a check-the-box thing that something that has a strong linkage to outcomes. So from our perspective the effort to collect the measure doesn't seem to pay off downstream. So our recommendation on this would be do not support.

CO-CHAIR TRAVIS: Thank you, Akin.

And just as a clarification we do have several alcohol measures here. This particular one is a screening measure, but we will get to the brief intervention measure in a moment. So thank you for that.

And so his thoughts are do not support. Are there other comments on this measure? Mimi?

MEMBER HUIZINGA: We agree with the AHA that the effort required to submit and collect the information for this particular measure doesn't seem to be paying off, I guess, in actionable and proven evidence.

Again, like the AHA, we don't like this measure in the current program that it's being used in and think that better understanding of the impact across a broad range of different types of acute care settings is needed before going forward.

CO-CHAIR TRAVIS: Thank you.

Sean?

MEMBER MORRISON: Oh, I just want to

offer a counter-argument. Alcohol screening is something that is not done well in hospitals. The risk of not identifying it is acute alcohol withdrawal syndrome, which is often missed and can be deadly. And one of the reasons actually to keep this is in is to ensure that people with a history of heavy alcohol use are screened and appropriately targeted, not to develop a brief alcohol intervention while they're in the hospital. I would just urge consideration to keep it for that reason, not for a brief alcohol intervention.

CO-CHAIR TRAVIS: Thank you, Sean.

Marty?

MEMBER HATLIE: Just to reinforce that, there were comments made by the Joint Commission and public comments about how important this is because the problem is very real. So I'm just supporting Sean's analysis.

MEMBER SULLIVAN: This is Ann on the phone. I just want to echo what the last two individuals have said. There's a high use of

alcohol in the elderly especially and often not noticed, not asked, not pursued, and I think causes lots of trouble actually in their ongoing medical care, and even as was mentioned the possibility of missing it and having a severe outcome.

But I really do think you need to be screening for this like you would for anything else that you're concerned about the elderly, especially since it's so unidentified. So I would support particularly the screening measure.

CO-CHAIR TRAVIS: Thank you, Ann. Nice to hear your voice this morning.

Are there other comments? Ron?

CO-CHAIR WALTERS: I agree with Sean and Ann, and I do distinguish between the screening measure and the intervention measure. There obviously are a subset of people who come into the hospital, either their first time or without direct connection to other outpatient programs.

I believe this is -- this underlies

the Joint Commission's stewardship of the measure that it's an important place of capture. The attribution in that sense can only be to the facility for doing it. The Joint Commission is obviously going to keep this as a belief that they have that it is a responsibility; I'm not speaking for them, by the way, of hospitals to do as a potential point of marking people for intervention, I would say. And I would urge that we support this, the preliminary analysis of supporting for rulemaking.

CO-CHAIR TRAVIS: Thank you, Ron.

Yes, David?

MEMBER ENGLER: Can you hear me now? Great. Thanks. Sounds like a commercial.

So with respect to Ron's comment, I'd like to support that, on 178 in particular. A number of hospitals have a significant burden of drug and alcohol abuse, a disease burden in our particular populations. I'll give you a number. It's over 30 percent of patients that we're serving that have underlying drug and alcohol

issues affecting their conditions, and chronic conditions at that.

I did have a question on -- and I'm glad the developer is on the line today. I did have a question because I'm pretty much encouraged by what I see in terms of the ability of brief interventions to have some sort of impact on alcohol use in the long term. And if in fact that is the case and if in fact we can do brief interventions and have these opportunities to reduce the burden of disease in the population, which by the way is a horrible disease, then I think it's up to us to support 178 as we go forward. So those are my comments. Thank you very much.

CO-CHAIR TRAVIS: Well, thank you. And let's please keep David's thoughts in mind when we do address 178. It's a little confusing here I know because we're kind of doing both of these, but they've both been pulled. So we will have the opportunity. So if we can, let's think about the screening component so that our vote is

clean at the end of this conversation.

So, Mimi?

MEMBER HUIZINGA: Thank you. I forgot to add that we would be much more interested in this measure if it was eSpecified. So we feel that if -- right now this is a manual extraction measure and the effort required to manually extract this is what we're concerned about from the screening perspective. However, if it was eSpecified, that would alleviate some of those concerns.

CO-CHAIR TRAVIS: Well, thank you for that. Just as a question I had had in my own mind was where's the burden? Is it on finding out whether you did the screening or is it on the screening, because there appears, at least from my perspective, to be support for doing the screening from a clinical standpoint. So, Mimi, am I interpreting you correctly that it's maybe more burdensome from the data collection standpoint?

MEMBER HUIZINGA: It's burdensome on

both. So in this standpoint -- but particularly on the data collection. So in this case it required it to be an approved measure, so you need to ensure that from a work flow standpoint that you built out the process to collect that information and to prompt that.

But when -- then when you're going back through as an abstractor and trying to -- you have to find what note it was performed in. It could be a nursing note or a physician note. So it's in multiple places in the EHR, because it's not eSpecified.

Then the reviewer must know whether or not the tool that was used is a validated tool. And you could use different tools for different age groups and what qualifies as validated versus not validated could be debated.

And then lastly, what happens if the tool is not completed? Maybe the patient answered or the person recorded only a few parts of the question.

So these are some of the very really

challenges that we have with abstraction of the screening tool in the current program. And we don't feel that those have been adequately resolved to move this to a broader program. Even though we totally understand and agree with what everybody said that alcohol screening is critically important, we would be more in favor of this if this were eSpecified and maybe further delineated.

CO-CHAIR TRAVIS: Thank you. That's helpful.

Okay. Any other comments before we go to a vote? Yes?

MEMBER JORDAN: Well, I would like to propose then for No. 2 that we have the ability to vote to say -- the clarification would be to develop a new measure as the -- what we're voting for with conditional support, the condition of an eMeasure be developed and --

CO-CHAIR TRAVIS: Okay. And I'm going I thank you for that, Jack. I'm going to look to staff around that as to whether that would be a

refine and resubmit or whether that would be a conditional support.

MS. MARINELARENA: That would be a different measure. So you have to vote on the measure.

CO-CHAIR TRAVIS: We're going to vote on the measure. We're trying to decide if we vote one, two, three or four.

MS. MARINELARENA: Right.

CO-CHAIR TRAVIS: So the question is would refine and resubmit -- if we wanted it to be an eMeasure would it fall under refine and resubmit? So it doesn't even fall under that?

MS. MARINELARENA: Well, that's --

DR. FITZELL: Hi, I'm Joann Fitzell. I'm one of the nurses that works at CMS. I'm one of the measure leads on this. So this is currently being eSpecified by SAMHSA, and TJC is consulting with them.

(Off microphone comment.)

DR. FITZELL: Well, for -- right, for one of the measures we actually have quite a bit

of data. The two -- sub two and sub three, the time frame is not -- well, not yet. We're --

CO-CHAIR TRAVIS: We're early use. I mean, the screen.

DR. FITZELL: Right. So -- pardon?

(Off microphone comment.)

DR. FITZELL: Yes. Yes, it is.

CO-CHAIR TRAVIS: I'm sorry. I couldn't hear Helen's question. So I --

(Off microphone comment.)

DR. FITZELL: On, not it's not. It is not complete yet, no.

CO-CHAIR TRAVIS: And when we says is it done yet, meaning toward eSpecification, is that --

DR. FITZELL: Right.

CO-CHAIR TRAVIS: -- the content? I wanted to be sure. There are all these sub-conversations going on so it's difficult for us to all year.

So I'm going to go back to the same question: The fact that there may be an interest

in an eSpecified measure would not therefore be anything that could get you into two or three?

MS. MARINELARENA: It can capture that you -- if you support this measure now and then make -- and capture the report that you strongly support the eSpecification of this measure that is in process.

DR. BURSTIN: So that would be yes.

MS. MARINELARENA: Right. So the recommendation for this one now is support for rulemaking, this measure now. And then know that the workgroup really wants the eMeasure, which is in process.

CO-CHAIR TRAVIS: That's great. I can't read the whole room, but what if the answer is -- I guess we could make that comment no matter what we voted on. So if we voted -- it can't be a condition or a refine and resubmit is what you're telling us? Okay. That's what I wanted to give clearly since that was the question Jack brought up.

Okay. We've still got some cards

going up. So I know this has been a little confusing and I want to be sure we get there.

Marty?

MEMBER HATLIE: Just given the magnitude of the problem that several of us have spoken to today, I would urge us to support this measure and not wait for the eMeasure with the strong comments that we've talked about, the importance of how an eMeasure would reduce burden, but I think this is one of those areas where we really have the opportunity to make a difference by using that hospitalization opportunity to address this national problem. So please let's support this one.

CO-CHAIR TRAVIS: Thank you, Marty.

Brock?

MEMBER SLABACH: I would probably say it the other way, that we need to not support but strongly recommend that this be eSpecified and brought back for inclusion in the program.

CO-CHAIR TRAVIS: Right, I mean, I think we've got that. I think that whatever we

say people are going to -- might to put a strong urging that an eMeasure be associated with this. So that can be kind of a side comment. It won't come into the voting, but it'll come in as a side comment.

Mimi?

MEMBER HUIZINGA: Well, thank you, and I agree with Brock. Of course, I mean, I want people to understand that if you put this measure in now, and even if we get conditional support, there is a history that CMS would take that forward and put that into a payment program. And so hospitals would build an entire abstracting team and program, train people, invest lots of money in making this happen. And then maybe it sounds like next year we would be talking about an eMeasure. So I would strongly support people not to support this and just do it right the first time and not have a runabout process.

MEMBER SULLIVAN: This is Ann.

CO-CHAIR TRAVIS: Yes, Ann?

MEMBER SULLIVAN: Could I just get

some clarification here? They said the eMeasure is in process. I mean, does that mean that it's going to be done very, very soon, or not?

And the second thing is I don't know the -- I would still vote for approving this and then saying that we strongly support getting the eMeasure. Because again, putting it off is something -- it interferes with the -- now you can be a long time before you do alcohol screening.

And I would just like to echo what other people have said. We have used taught processes. I know they can be difficult. I know they're a little burdensome, but this is a big issue. And I don't think it's very wise of us to not approve it now, but maybe with a very, very strong recommendation that the eMeasure move along. And I'm not so sure that CMS would put this out as an eMeasure. We're almost ready, I would assume, although maybe I shouldn't, that they would then do it as an eMeasure.

CO-CHAIR TRAVIS: Thank you. We'll

get clarification again. Can you all speak to the eMeasure?

DR. YONG: I mean, the eMeasures we're working with SAMHSA on this and eSpecifying it. That's -- I don't have a specific timeline.

CO-CHAIR TRAVIS: Oh, so there's no specific timeline on when the eMeasure would be available.

So unless it's something different than has already been said, Akin -- because I think we're being a little repetitive. So I want to be sure it's additive.

MEMBER DEMEHIN: This is a slightly -- this is more a question especially for the clinicians in the room. So this particular measure has as time window of three days within admission to screen for problem alcohol use. Does it make it -- and I know one of the points that was made was around this could be helpful in terms of identifying alcohol toxicity and its downstream impacts on patients, but does that three-day window make it any more or less useful

for that purpose?

CO-CHAIR TRAVIS: Sean?

MEMBER MORRISON: Yes, speaking as a clinician, the -- if you're looking at alcohol withdrawal syndrome, the window is 48 to 72 hours. And unlike opioid withdrawal syndrome, alcohol withdrawal syndrome kills. Opioids, typically withdrawal doesn't kill. Alcohol does.

CO-CHAIR TRAVIS: Okay. Well, I think that we have kind of addressed -- and we see the two issues that are before us. So I think it's time to move to a vote. As a realistic issue, our vote really is support and do not support at this point because the eMeasure development is not suitable for conditional or refine and resubmit.

Just to I guess -- I'm looking at whether we should just vote on those two, or should we include -- okay.

So we're going to just give you the option, unless I hear differently from you all, because I want to give you a chance to vote in

any category. But it looks like it's going to be support or do not support. And unless there's an objection, those are going to be the two options.

MS. MARINELARENA: Before you vote I just want you to take a look at the measures that are in the current set now. There's only six chart-abstracted measures, so I don't know if that makes a difference. I remember the days when there was a whole lot. So if CMS is moving towards -- there's less chart-abstracted measures. So I don't know if that makes a difference in decreasing the burden, but I was there when you were doing --

(Simultaneous speaking.)

CO-CHAIR TRAVIS: Well, thank you. No, I think that is helpful. So thank you very much for adding that.

(Laughter.)

CO-CHAIR TRAVIS: Okay. I think we'll go on and move -- and we're only going to vote one and four.

MS. QUINNONEZ: Yes, before you cast

your votes I just want to do a quick reminder for the sake of those who may not have been with us yesterday. When you cast your vote, everyone, I want to make sure everyone who is voting has their voting clicker, yes, in the room? Okay. If you -- when you are ready to vote, when we open the vote, if you could just point your clicker towards me.

And also to remind you that your last click that you do make will be your vote. Okay? So you can click as many times as you want, but the very last click that you do make will be your final vote.

And we may have to do this more than once. Hopefully not. But thank you for your patience. Okay?

So we are now voting on Hospital Inpatient Quality Reporting for Consent Calendar No. 6. This is Measure -- the Alcohol Use Screening measure, and that's MUC 16-179.

You have two options. For those who are on the phone, you can cast your ballots

through our chat system. Option No. 1 is support. Option No. 4, do not support. So you have two options for MUC 16-179, the Alcohol Use Screening measure. And Option No. 1 is support; Option 4, do not support.

(Voting.)

MS. QUINNONEZ: Thank you, Marisa and Ann.

Okay. Voting is now closed. Okay. Wow.

(Laughter.)

MS. QUINNONEZ: For the results of Alcohol Use Screening measure, MUC 16-179, the results are 61 percent voted for support, 39 percent voted do not support. This moves forward with support.

CO-CHAIR TRAVIS: Well, the only thing I can say from a project -- I mean, a meeting management standpoint, I'm relieved that we at least came down one way or the other on this measure --

(Laughter.)

CO-CHAIR TRAVIS: -- because we were going to have to go back and talk about this even more. So, but thank you. And I do hope that those who voted do not support understand that your thoughts were heard and they will be -- they are being communicated directly, but also will be considered as we move forward. So thank you all for that.

The next measure that's been pulled is the Alcohol Use Brief Intervention Provided or Offered and Alcohol Use Brief Intervention. I think it means happening. But anyway, and this is MUC 16-178. We've had a little bit of discussion because these things are so close already, but I know that Mimi pulled this.

So if you would like to talk with us about the rationale behind pulling it.

MEMBER HUIZINGA: I think that the rationale has already been well-stated, so I'll just review at a high level. Offering a brief intervention during the hospital stay is already a measure in another program and we haven't

necessarily seen the payoff from having that measure as we would like to see.

There is a tremendous amount of effort that goes both into implementing this intervention, tracking it, even determining if it's been offered. The amount of training, which I feel like maybe I didn't spend enough time speaking on, and the cost to a hospital of training abstractor -- first developing the process, defining the protocol, developing the abstraction tools, training all the abstractors, having to fill in the abstractors when somebody can't be there is a tremendous amount of time and effort and money. And so every time we put in a chart-abstracted measure, even if there's only six, is still -- just maintaining them on an annual basis is a phenomenal amount of time and effort.

This not only -- even if this was eSpecified, we would still have concerns about it due to several of the comments that David and Akin both made earlier about just the overall

benefit of having the brief intervention compared to the effort that is required to capture this particular measure.

CO-CHAIR TRAVIS: Okay. And I apologize for this. I did not do this earlier. It gets confusing up here, believe it or not. But we do have some lead discussants that were engaged with this set of measures. David is one of them and has raised his card, so I'll probably start with you. But either Marsha or Jennifer want to add any comments, we would like to hear from you, if you can, regarding what your thoughts were.

So, David?

MEMBER ENGLER: Thank you. Thank you.

And thank you, Mimi, for your comments as well.

My -- I had as a lead discussion I had -- hopefully the developer is on the line today. Am I thinking correctly? Are they --

CO-CHAIR TRAVIS: I don't --

MEMBER ENGLER: Are they not with us

today?

CO-CHAIR TRAVIS: No, they're not with us today.

MEMBER ENGLER: Oh, okay. Because I was hopeful for a little bit more conversation about whether or not the interventions in hospitals, these brief interventions have been proven to impact alcohol abuse in patients that are being served. And it's a question that I have that was raised by some of my staff and some of my members, whether or not that has been tested on the inpatient side. My notes suggest that it has been effective in primary care settings, but I do not know. And this is a question that I'd be interested -- and perhaps Mimi can chime in on this. I'd be interested in knowing it hasn't had any impact on the use in inpatients; that is, does brief interventions have any impact on long-term use of alcohol? Thanks.

CO-CHAIR TRAVIS: Well, why don't we, if that's okay, go on and try to see if we can

get some additional information on that, and then we'll go to the other lead discussants if they have any additional comments.

I'm looking at CMS. Do you all know what the evidence is related to the brief intervention in an inpatient setting in terms of the effectiveness?

(Off microphone comment.)

CO-CHAIR TRAVIS: Okay. I don't know if any of the Committee members on the phone have any comments. Ann, I don't know if you have any work in this area or know of any that might be helpful.

MEMBER SULLIVAN: I think the major studies have been done in primary care. To tell you the truth, I'm not sure if they've looked at absolute outcomes from individuals who are actually in the hospital and get brief interventions. So I'm sorry I can't really help with that issue.

CO-CHAIR TRAVIS: No, that's fine. Thank you.

It's my understanding there may be some additional information in our detailed summaries of this measure, but I don't have that in front of me. So would somebody who's looking at it like to read what it says? I don't know if that's Helen, Melissa, Ron.

CO-CHAIR WALTERS: So, yes, I'm reading in the measure description itself and down in the -- it's actually called the Endorsement and Public Comments. And what it says is, "The Committee noted that the majority of the evidence generally is related to the outpatient setting, however, following substantial discussion Committee members agreed that certain evidence could be generalizable from the primary care setting to the inpatient setting and that sufficient evidence was presented related to the inpatient setting based on the USPSTF and Cochrane Review evidence to support the measure."

We don't have the actual data, but that's the statement that's made.

CO-CHAIR TRAVIS: Okay. I think that's helpful. Is that helpful to you, David?

(Off microphone comment.)

CO-CHAIR TRAVIS: Yes. Is that related to this, Sean? Okay.

MEMBER MORRISON: So a brief PubMed search found two RCTs in the inpatient setting of the effectiveness of a brief alcohol intervention in the hospital with highly statistically significant results.

CO-CHAIR TRAVIS: So to us non-researchers does that mean it is working?

MEMBER MORRISON: I'm sorry. What it means is, yes, there are two randomized control trials that have shown that a brief alcohol -- oh, man.

(Laughter.)

(Simultaneous speaking.)

MEMBER MORRISON: A hundred and twenty-four large confidence intervals, but statistically significant.

CO-CHAIR TRAVIS: Okay. So I guess

one thing -- I mean, there's two things that I'm taking away from that: There are some PubMed results that show that it was effective, albeit people may be looking at the numbers, but that in the standing committee they did feel that the evidence from primary care -- they felt after looking at it would also apply in this setting. So I think we've given you the answers that we can give you relative to David's concerns.

I do want to give a moment, if any of the other lead discussants had any comments that they wanted to make relative to this particular measure, MUC 16-178. And it's okay to say no. Okay. I just didn't want to not honor the work that may have been done in advance.

Okay. So because I have been thinking and not looking, I'm just going to start down at the end of the table with Marty and work my way up on this side. And then those of you over there can start thinking about whether you want to have any comments.

So, Marty?

MEMBER HATLIE: Okay. Since we don't have the Joint Commission with us on the phone, they did file a very significant and strongly-worded comment. Clinical trials have demonstrated that brief interventions, especially prior to the onset of addiction, improved health, but also reduced cost. So there's a cost element here that I wanted to highlight that we haven't really talked about except for the effort side of the equation. Thank you.

CO-CHAIR TRAVIS: Thank you, Marty. We're glad you're looking at those comments, so thank you very much.

Brock?

MEMBER SLABACH: This measure I think illustrates, and Mimi talked about the very important parts of data collection, but I'm going to move upstream now and suggest to you that there's about 1,500, 1,800 small and rural hospitals that have a very difficult time in terms of staffing to be able to provide this intervention. So the first question I ask is

who would do this in a particular facility?

And usually, like in the tobacco cessation requirements, it's respiratory therapy. We say you go up to talk to the patient. This is even more difficult I think in terms of a conversation, especially if family is involved and they're in the room and you're in a two, three, four-day acute care stay dealing with important acute care issues that are going all on at the same time. And now you're trying to talk with them about some systemic issue that is going to go on well beyond that short stay. And it needs to be done well, I guess is my point.

And then this becomes a check-the-box program. And then the value of it I think diminishes despite some of the evidence to the contrary. I just know how this is operationalized in a facility.

CO-CHAIR TRAVIS: Thank you.

Mimi?

MEMBER HUIZINGA: Thank you. So I wanted to clarify the points about the data that

we were looking for, and then also because I'm an epidemiologist and I can't -- I feel like I can't let Sean's comments go unspoken to.

The first piece of it, what we were specifically talking about was evidence of the use of this measure. So not a randomized control trial. But this measure has been in use and we're very interested how this measure has impacted long-term alcohol use, and we don't feel that that has been publicized. And if it has, CMS, we would love to see that information and data and I would love to be corrected.

Second, when we look at this measure and how it aligns to just the Cochrane study, the Cochrane Review was a 14 randomized control trial. Cochrane does a great job. It only shows a benefit for heavy alcohol users, which is not what this measure is. This measure is anyone with unhealthy alcohol use. There are multiple studies that show -- randomized control trials that show that use and light drinkers or at-risk drinkers does not show benefit.

And so we've taken a population where there is evidence for -- we've expanded in this measure creating additional work and effort that again doesn't have the support. I know this isn't our place to debate the scientific merits of the study; and Helen's shaking her head at me, but it was opened up and there was a question that was asked, so I felt that it's worthwhile to respond then to you.

CO-CHAIR TRAVIS: Thank you, Mimi.

Brock, anymore comments or --

MEMBER SLABACH: No.

DR. BURSTIN: Operator, could you please open the line for Ann Watt from the Joint Commission?

(Pause.)

DR. BURSTIN: Ann, are you with us?

(Pause.)

DR. BURSTIN: Operator, are you with us?

OPERATOR: Ann has not dialed in. We do have Alvera Ryan on with the Joint Commission.

DR. BURSTIN: Okay. Maybe they switched. Go ahead.

(Pause.)

DR. BURSTIN: Good morning.

MS. RYAN: Hi, this is Alvera Ryan.

DR. BURSTIN: Wonderful. Are you able to speak to the questions that have been raised about the alcohol intervention measure?

MS. RYAN: I can't really speak in terms of studies about how the measure has impacted long-term alcohol use.

With the work that we have done we have looked at studies that have spoken to brief interventions being done in the hospital and during hospitalization being a prime time to approach the patients, and that at that point in time they are more amenable to interventions, and that the impetus is to get that process started during the hospitalization. And studies have shown that patients who have that initiated while they're inpatients have a greater tendency to follow through with treatment in the outpatient

setting.

CO-CHAIR TRAVIS: Thank you very much for that information.

I'm going to go back to Mimi, and then I'm hoping that we'll be ready for a vote.

MEMBER HUIZINGA: Okay. I promise this is the last thing I'm going to say.

So the Cochrane Review actually showed that there was a difference in alcohol use at three and six -- I'm sorry six and nine months, but not at one year. So clearly this -- even -- and that was only in the population of heavy alcohol drinkers.

So I appreciate everyone's comments that this has an impact, but we should understand what the impact is. We're asking for a lot of effort to have some improvement in a small piece of denominator population that's currently defined in the measure. It is not a long-term life changing intervention. According to the evidence it does have impact in a period after the hospitalization for a subset of the

denominator.

CO-CHAIR TRAVIS: Okay. Thank you. And just because we can go through rebuttal and everything back and forth every time, if the Joint Commission person would like to make any statements; and it's okay not to --

(Laughter.)

CO-CHAIR TRAVIS: -- I do want to give you an opportunity to. But if I don't hear, I'll assume you would not like to make a follow-up comment.

While you're thinking, Frank?

MEMBER GHINASSI: This is more of a question. I don't know if I'm looking at the same 127-person study you are. Was it South Africa? No, it wasn't?

So it's a similar thing. It was a randomized trial, three-month follow-up. About 30 of the 127 they looked at showed improvement at 3 months. It was self-report, not -- there's no concurrent evidence on it. And of the 60 people that referred to treatment, only 30 of

them actually went. So it was a positive study and significant, but if you read it a little more closely, the significance is not how it would initially sound.

My second question is a technical one. This is NQF-endorsed, so I have to assume that it met a standard for scientific acceptability.

PARTICIPANT: Yes.

MEMBER GHINASSI: And that acceptability was based on primary care effectiveness or inpatient effectiveness? Because that would be my question. That's all.

MEMBER ENGLER: That was my question, too.

CO-CHAIR TRAVIS: We're looking it up so we can read it to you.

DR. BURSTIN: I recall it was a very, very lengthy discussion about what would be translatable and what was uniquely inpatient-based. We're just looking at the submission again. I don't know if the person; sorry I missed your name, on the phone has any

information to shed while we look this up, specifically on the evidence for the inpatient brief intervention.

(Simultaneous speaking.)

CO-CHAIR TRAVIS: Yes, and she did mention some of that.

DR. BURSTIN: They did actually cite; let's see, three different studies, the first of which had 12 trials, the second of which had 11 trials. And there's also a DoD guideline review that had 1,177 studies. So they did have a pretty significant number. Each of the studies was rated in terms of the quality of the evidence as well. And ultimately we felt this was evidence-based. We're happy to share the specific submission form if you'd like to see it.

CO-CHAIR TRAVIS: Okay. This is going to hopefully be our last comment. Well, we've got -- Mimi, is your card still up?

(No audible response.)

CO-CHAIR TRAVIS: Okay. So, Brock, you get to bring it home.

MEMBER SLABACH: Well, I just wanted to quickly follow up on the data that was suggested on the effectiveness.

How was the structure of the interventions made in those studies? And is it done under such a fashion that it could be replicable in terms of the content of those interventions across 4,000-plus acute care hospitals in the United States? And is each of those going to be the same in terms of the quality? And that's the real question I think that I have a concern about in terms of being able to meet this, the intent of what this is trying to achieve versus what the reality will be.

CO-CHAIR TRAVIS: So I'm going to probably take that as a rhetorical question since I don't think we have anybody here who can answer that, but I really failed to see that Marty's card was up before Brock's, so now, Marty.

MEMBER HATLIE: So the evidence gap for me here is really the cost of the burden that

we hear about from hospitals for investing and addressing this real issue, and I don't have that data. I come from a rural part of the country where I know this is a real issue where families who need an intervention, if they're going to get it anywhere, that they can't do themselves, it's going to be at the hospital.

I think it is a huge issue, and I just want to see hospitals stepping up and doing this. If it's a huge or prohibitive cost burden, I guess that needs to be considered, but I don't know that it is. We're talking about a brief intervention for an important national problem.

CO-CHAIR TRAVIS: Okay. Well, thank you so much, Marty.

I think that for the second time in a row we've kind of had a broad discussion and gotten rather deep into some of this, which I think it's worth. So I thank you all for your thoughtful comments.

I think we will go to the vote and I think we'll just go with the vote that's on the

screen. I have not heard any conditions or refine and resubmit, but we will -- like we did yesterday, we'll just kind of go through all those options.

MS. QUINNONEZ: Okay. We are now voting on the IQR Program measure, Alcohol Use Brief Intervention Provided or Offered and Alcohol Use Brief Intervention. And this is MUC 16-178. Option No. 1, support; Option No. 2, conditional support; Option No. 3, refine and resubmit; and Option No. 4, do not support.

I'll go over those options one more time for those on the phone. Option No. 1, support; Option No. 2, conditional support; Option No. 3, refine and resubmit; and Option No. 4, do not support.

(Voting.)

MS. QUINNONEZ: Thank you, Ann.

(Voting.)

MS. QUINNONEZ: Okay. All votes are in and voting is now closed. For MUC 16-178 Alcohol Use Brief Intervention Provided or

Offered and Alcohol Use Brief Intervention the results read 48 percent voted for support; 0 percent for conditional support; 4 percent voted for refine and resubmit; and 48 percent voted do not support.

CO-CHAIR TRAVIS: Okay. So I'm going to huddle over here --

(Laughter.)

CO-CHAIR TRAVIS: -- and see what we need to do. I'll be back with you in a moment.

(Pause.)

MS. QUINNONEZ: The verdict for MUC 16-178 is do not support.

CO-CHAIR TRAVIS: And the rationale is we didn't have 60 percent or above to go, so it fails. So see, we've now had an experience with that and we know what to do on the next time, if and when that ever happens. But thank you all very much.

Before we leave this consent calendar, it has been brought to my attention that although it was part of the consent calendar that we

accepted, the recommendation for do not support for the Patient Panel Smoking Prevalence, there is a desire that we hear some discussion around that so that there can be an understanding for why we as a group decided to accept the do not support. That would be helpful to CMS for us to -- for them to understand our rationale.

So I can maybe start to see if any of the lead discussants have anything they would like to bring up relative to this particular measure. Oh, yes. Sorry. Thank you, Pierre.

MEMBER YONG: So thank you. I know it wasn't proper. We just wanted to get some feedback about this. This folks who are on the MAP Committee last year may remember we had a similar type measure. There was a very robust discussion about the Tobacco Prevalence measure, which I think got 61 percent also. I think it was last year. It got support and continue development.

And so we wanted to bring back -- this was brought back and to adjust some of the

concerns that were raised and some discussion that was raised last year in that. And so Tiffany McNair from the Innovation Center at CMI is going to talk a little bit about this. But the feedback would be helpful to us.

DR. McNAIR: Thanks so much, Pierre. And thank you all. Thank you to NQF and thank you to the MAP for this opportunity to present today. We really appreciate it.

I just want to start off by saying as a practicing OB/GYN and preventive medicine physician myself I'm especially enthused about the opportunity the outcomes-based measures present, especially the one that we're presenting and proposing to you, to the IQR today really to achieve shared accountability across our healthcare system. This opportunity represents a future state I think in which the people that I and all you in this room serve are able to receive the most effective evidence-based care, one in which disease is not only prevented, but really help us promote it, and that's the framing

that we are trying to achieve.

It's in that vein that we are proposing MUC 16-68, which is the Patient Panel Smoking Prevalence measure to the Hospital IQR.

You can go to the next slide. Thank you. This measure is collected to be a hospital records and captures the percentage of adult hospital patients who are current smokers. And as Pierre said, we at CMS did submit a related geographically defined measure to the IQR last year during the 2015 MUC cycle. That measure was assessing smoking prevalence at the county level among household dwelling adults in the U.S.

After robust discussion, as you said, the measure was supported for continued development. And one key reaction that we did received concerned this issue around accountability in the hospital for the smoking behavior of individuals not directly served in the inpatient setting.

And so we took this feedback to heart in response to that and several other responses

that you all provided to us. We did refine the measure, still with an eye towards outcomes, as you'll see, that's really within the boundaries of the hospital, so the patient panel.

Next slide. I just -- I know that all of you know this already, but at HHS and CMS we really are committed to realizing this healthcare system that delivers better care, practices smarter spending and at least to help their people. And so we are trying to focus more and more on quality as opposed to quantity and value over volume.

Next slide. And do as this framework depicts, which some of you may be familiar with, our reform efforts really are shifting toward altering the payment models and population-based payments. And it's in light of this movement towards a value-oriented outcomes-based system that we believe this is the right opportunity for the measure we're presenting to you today.

Next slide. You may also be asking why smoking? Well, number one, we all know this

is expensive. Smoking is the leading cause of preventable death and disease in the U.S. and costs nearly $170 billion annually in direct medical costs. So tackling this particular problem we believe is ideal in terms of improving health and reducing the cost to the system.

But number two, we know that hospitals can do something about it. There's a really strong evidence base that shows that a coordinated multi-modal community-wide and patient-centered approach improves the success of smoking reduction efforts. And I might add that with eight percent of the population being hospitalized each year, there really are repeat opportunities for hospitals to have an impact beginning with the inpatient stay.

In fact, there's already a growing number of hospitals that are already engaged in the types of efforts that we think that our measure incentivizes. This is everything from using EHR prompts to prompt physicians to ask about smoking; improving combined approaches to

treatment like behavioral and pharmacotherapy therapy interventions, which is consistent with the Joint Commission recommendations; referring patients upon discharge to outpatient smoking cessation treatment, right, and quit lines.

And then of course strengthening those linkages with local primary care providers and other community partners in order to improve coordination of care and care management. This in the end not only helps people to quit, but helps to sustain quitting.

We also know of a number of hospitals across the U.S. that are using community-wide policies like smoke-free campuses, which have all been shown to be effective approaches to promoting and sustaining smoking cessation.

So these approaches we believe not only fall within the scope of the hospitals' sphere of influence, but also ultimately move the needle on the outcome that we care most about, which is reduced smoking.

Next slide. Finally, we would add

that we can actually measure the fruits of our labor in this space, the outcome. Until now really smoking and other tobacco use measures utilized in CMS quality programs have focused primarily on process as opposed to outcomes and often without an orientation towards primary prevention, which is perhaps the biggest cost saver.

And so we recognize that this kind of broader outcomes measure used in conjunction with clinical process measures actually could do two things: One is expand the reach of the process measure, right? So incentivize folks to do even more of that, as well as improve our understanding of the magnitude of the impact of our clinical care services such as cessation counseling on the specific health behavior like smoking.

So just taking together those three elements that I described: cost, the evidence base and the opportunities for measuring our success, we believe that this smoking prevalence

measure, as refined since last year, offers the logical next step in terms of assessing the quality of the care furnished in hospitals.

So last slide. Just want to -- a point of clarification based on the analyses that we received from NQF. Please note that we did perform internal reliability and validity testing on this measure utilizing eligible provider data from the PQRS electronic health record. It was shown to have higher liability and moderate validity including demonstrating an association between provider screening practices and smoking prevalence in the subsequent reporting year.

So we actually found that with an absolute 10 percent increase in screening practices in one reporting year we saw a two percent absolute decrease in smoking prevalence in the subsequent reporting year. And this finding was significant and it's critical.

As previously described, there is a strong evidence base showing that hospitals, similar to individual clinicians, can really

influence the smoking behavior of their patients. So while our initial testing was not performed realizing hospital-based data, we expect comparable results among hospitals given the availability of the similar prevention tools and the repeated opportunities for impact.

The last point that I'll make is that CMS has also proposed a tobacco process measure which is on the slate for later on today, MUC 16-60, to this year's MUC list. And although useful, we believe standing alone it captures just a clinical process rather than an outcome. We would propose that using these two measures in tandem would actually achieve the most comprehensive end. It would encourage hospitals to advance best practices to reduce smoking, but it would also promote the formation of critical partnerships that embrace a more coordinated multi-modal and patient-centered approach to care.

So it's in that spirit of shared accountability and coordination across the system

that we're exploring the potential for smoking prevalence measures, not only in the hospital IQR, but also across several other quality programs including the Medicare Shared Savings Program and MIPS. And we think this is a great opportunity for us to think more about this shared purpose and to encourage accountability across our entire healthcare system.

So I'll stop there. I know that I speak very quickly, but I knew that I didn't have a ton of time. If you have any feedback, we look forward to the discussion. And again, I really do thank you for this opportunity today.

CO-CHAIR TRAVIS: Well, you may be quick, but you're very organized --

(Laughter.)

CO-CHAIR TRAVIS: -- and logical. So thank you for that. We do appreciate the overview.

I am, as I indicated, going to kind of go to our lead discussants to see if they have any comments.

Marsha?

MEMBER MANNING: My comment -- and I didn't have the benefit obviously of last year's discussion. I knew to this workgroup. I am just very focused on data that's very actionable at the patient level, and so I have concerns about a population health metric. While I totally support the need for us to develop interventions at the population level for smoking interventions or smoking cessation interventions, a population level doesn't feel actionable to me at the patient level when somebody's there in the hospital. And so that is why I'm supporting NQF's recommendation.

CO-CHAIR TRAVIS: Thank you, Marsha.

David or Jennifer, any comments?

(No audible response.)

CO-CHAIR TRAVIS: Okay. All right. So I think Jack might have done his card first, so we'll start with Jack.

MEMBER JORDAN: Okay. I actually think this is a measure that is a dangerous

mistake for CMS to make, and that is that I think it carries a very real risk of kind of undermining their credibility. This is something that I can see the cynical physician in the health system just puking on with the how can we be responsible, the fact that our hospital sits in a place where lots of people smoke?

The community around us choosing to smoke or not, the best lever for that is not really a hospital. And I think it almost gives a sense of learned helplessness to the people that are trying to do the right things in hospitals because it's -- the connection between the smoking in your community and what you're doing in the hospital seem so disconnected, or at least so indirect, even if you do have some evidence of this. The perception of it alone I think really will hurt your credibility. So I think that it's very problematic for this kind of a measure to go forward.

I know my own health system did send in comments on this, that it just seems like

something that you have very little control over when you list the hospitals of who's good and bad. If your hospital's in Kentucky, you're going to look bad because lots of people smoke in Kentucky versus Vermont. But then that isn't something you should interpret as a good or bad hospital, though maybe over time that might have sense. But I think that it really would carry a huge burden to the hospitals of feeling a learned helplessness kind of a thing, that they have no control over this.

CO-CHAIR TRAVIS: Mimi?

MEMBER HUIZINGA: I echo Jack's comments, although I probably wouldn't have been quite as colorful.

(Laughter.)

MEMBER HUIZINGA: We are extremely supportive of actionable measures. And you listed a slew of potential actionable measures. And so I guess I don't understand why you would go for a measure that hospitals and the providers within the hospitals have no control over versus

all of the different options that you guys did, that they can do and that do have impact. So we would encourage you to rethink your entire approach to this and move away from a population-based measure.

In addition, there are issues that we would have with this measure. So this is -- shows the value of going through the NQF endorsement process. What is a hospital panel? What if somebody visits from -- is visiting from Kentucky in Florida? Are they part of that panel? Is there going to be a Kentucky panel? There's just a lack of definition and understanding about what you mean here that would benefit through the resolution of the NQF process.

In addition, you have an exclusion criteria for an EP, which is an eligible professional. It looks like you took this measure from PQRS and moved it over. I would not say that you should make that assumption that you could do that. There's a lot of things that go

into attribution and thinking through those. All of these highlight the importance of going through the NQF process, which again you shouldn't do this measure, but if you develop actionable structure measures or clinical process measures, they would still need to go through the NQF process.

CO-CHAIR TRAVIS: Thank you, Mimi.

MEMBER HUIZINGA: We would recommend that. I shouldn't say they need to go. We would recommend that they go through.

(Laughter.)

CO-CHAIR TRAVIS: Thank you.

Sean?

MEMBER MORRISON: I'll be brief and I will say this again; and I was here for the discussion last year, I -- it really distresses me when CMS comes with a measure that has not gone through the NQF endorsement process. I know the law says that you guys can do that, but the NQF endorsement process exists for a reason. I don't represent any organization or stakeholder.

So send it back. That was the recommendation last year. Do the right process work and then bring it back to us, please.

CO-CHAIR TRAVIS: Akin?

MEMBER DEMEHIN: I really echo the comments that have already been made about actionability, about some of the technical aspects of the measure.

I think there's kind of a broader conceptual issue here, too. I think by boiling what is a complex multi-faceted societal problem into a single measure -- I think it almost has the effect of trivializing what is a very important effort, and that is the joint effort to address smoking prevalence.

And hospitals recognize the need to play a role in that activity. Part of what hospitals do, using their community health needs assessment process, is to identify things like smoking rates in their community and develop some interventions that they can work on jointly with the community to affect it.

So I really agree with what's been said. This doesn't seem like a very fruitful path and it could actually end up being really quite a dangerous path if it becomes something that's the basis of public reporting, Star ratings, pay-for-performance, and so forth.

CO-CHAIR TRAVIS: Okay. Any comments from Committee members on the phone?

(No audible response.)

CO-CHAIR TRAVIS: Okay. Yes?

DR. McNAIR: Yes, quite briefly. Thank you very much.

First I will say thank you all for your comments and for your feedback. Definitely appreciate it.

Number one, I will say that an NQF submission package is currently underway, so we appreciate that feedback, and we'll continue to work on all of the suggestions that you've provided.

The other piece I would say again is this emphasis around shared accountability. For

that reason we certainly see hospitals as the only locus of that, and so we are looking for opportunities and ways that we can begin to push forward that type of an agenda, which is I think a very important one to all of our quality programs.

But I would actually argue against the response that said that this is not actionable. At the end of the day you're correct that all of these different best practices are available, but as opposed to having this kind of disparate approach where we focus on the individual screening processes or a specific intervention we're basically saying you have all -- you have this menu, this potpourri of opportunity in order to move the needle on the specific outcome, and they're all available to you. And we are beginning to demonstrate at least that there is a correlation between including all of that in your practice and seeing an effect on the outcome.

The other piece that I would just say is that we have more work to do. We want to

continue to hear your perspectives and we will continue to move forward in this space. We definitely appreciate it.

CO-CHAIR TRAVIS: Well, thank you very much. And I always feel a huge sense of responsibility when we said support continued development and then to be where you are today. So I do appreciate you giving us the opportunity to kind of share with you what people's current thinking is.

And I think we're sitting right now in a place of tension. We know that we need to do population health management, but our structures are not quite there yet and that you don't necessarily -- the whole panel description, you don't necessarily have an assigned group of people that you're responsible for, and it could be randomly different every year. And so to a certain extent I think that -- at least my concern around the accountability issue is that I don't have a defined group of people that I'm accountable for. It changes in the way we're

currently situated. And I think if the delivery system structure changes over time, then I think we could see maybe more comfort with that type of a measure.

So I hope you won't give up on thinking about it because it's a critical issue for us. I just think we're in kind of a -- in that in between stage in some of the tensions here. But I thank you for your continued work, and we will look forward to seeing it through the endorsement process as well. So thank you very much.

You know, guys, we're running about 45 minutes behind, and one of the concerns I have today is that I am sure we all have flights out this afternoon. So as much as I hate to say this, we are not going to take a formal break right now. If you do need to take a personal break, please do so, but make it as quickly as possible. But we're going to move ahead so that we can make up for some of the time. It's been all well worth it, but we do want to be sure that

people get out of here. In fact, I know you'll get out of here. I just hope we're through with our work by the time you get out of here.

So I'm going to turn it over to Ron.

CO-CHAIR WALTERS: Thank you. So we're on Consent Calendar 7 now, which has three measures. I'm going to go through them briefly. MUC 16-165 is the Follow-Up After Hospitalization for Mental Illness. The preliminary analysis was refine and resubmit because the NQF measure 576 was specified and tested at a health plan level, and therefore it required more study about attribution to a facility. Also there were some problems noted with the results in the IPFQR Program and should be resolved prior to implementing the measure in an additional program. So that was a refine and resubmit.

The next measure was 16-262, MUC 16-262, which was the Measurement of the Quality of Informed Consent Documents for Hospital Performed Elective Procedures. That was a refine and resubmit prior to rulemaking basically to see the

reliability and validity. And you heard some testimony about that during the public commenting period. So we'll be interested to see what you do with that.

And then the final one is MUC 16-263, which is Communication about Pain During the Hospital Stay. That was also a refine and resubmit originally. It was pulled and then put back on the agenda. And the discussion -- you heard a lot of discussion about that earlier during the public commenting.

So what I'm going to ask now is specifically about 16-165, which is on the consent calendar as refine and resubmit. Is there anybody who wishes to pull that measure for discussion? Okay. Frank.

And now for the next measure, 16-262, which was the Measurement of the Quality of Informed --

(Off microphone comment.)

CO-CHAIR WALTERS: Yes, the team. I'll put team again. Frank and team.

Two-sixty-two, which is the Measurement of the Quality of Informed Consent. Is there anybody that wishes to pull that from the consent calendar?

(Simultaneous speaking.)

CO-CHAIR WALTERS: Oh, okay. Frank and then team. Yes, okay. Got it.

And finally, 16-263, which is Communication About Pain During the Hospital Stay, which again was refine and resubmit. Who would like to pull that? Okay. Good. Okay. So all three are pulled from the informed consent calendar. Got it.

So let's start at the beginning with Frank's comments. Just a second. I got to make sure I got that right now. One-sixty-five. Yes. Frank's comments about MUC 16-165. Why did you pull it?

MEMBER GHINASSI: I'll make this brief because I know we're trying to move ahead.

So this is again one of these measures where it is impossible to argue with the critical

importance of this. I agree with it completely. I think it's a prime directive of the hospital to try to deliver that person to the next level of care. I'm on board completely.

The challenge is that the ability to make that happen is impacted by a number of variables: How important the hospital takes it, the measures they take in place to do evidence-based treatment to make it happen, how they prioritize it, the people they assign to it to deliver that treatment, all of which is within their span of control. The other difficulty is that although you can throw a perfect spiral, if a person catching that ball doesn't have good hands, then you have a problem.

Now the other piece of this is; and not that I'm a football -- so the other piece of this is that if you're going to move toward a measure like this, we need to take into account the prevalence and availability of access in the individual community within which that hospital is sending that individual.

So a frontier state who's held to a 30-day and 7-day follow-up period is going to be in a very different place than somebody's who's in an environment-rich resources. And even if you call agencies and say do you have access, the reality on the ground is if they say yes to you, that they give an appointment on Tuesday at 3:00, and that's their yes, and there's no flex in that, for many people that's a no.

So I think the problem with this is -- I'm totally in favor of the intent of the message. I think the measure doesn't take into account the full system within which that measure exists. I'm done. Thank you.

CO-CHAIR WALTERS: What is your recommendation?

MEMBER GHINASSI: That if -- at the very least that the measure include -- and I think CMS has the capacity to do this -- that it includes an assessment of that region's access, capacity and standards and that institutions are judged based on that access, not solely on does

it happen?

CO-CHAIR WALTERS: And to pin you down just a little step further, is that a --

MEMBER GHINASSI: Please.

CO-CHAIR WALTERS: -- conditional support or is that a refine and resubmit, or is it a do not support?

MEMBER GHINASSI: I would make it --

CO-CHAIR WALTERS: Yes, I'm sorry. It's already -- well --

(Simultaneous speaking.)

CO-CHAIR WALTERS: Yes, that would be a refine and resubmit.

MEMBER GHINASSI: If it's --

(Simultaneous speaking.)

CO-CHAIR WALTERS: Which way is the recommendation?

MEMBER GHINASSI: Yes, if it added that component, if they built into it the access capacity and they benchmark institutions on that marriage, then I think this has more capacity.

CO-CHAIR WALTERS: So it's an

agreement with the initial assessment, but you'd like to see some additional -- comments on it?

MEMBER GHINASSI: Yes.

CO-CHAIR WALTERS: You've given some comments on it?

Okay. Marty?

MEMBER HATLIE: Well, I am always happy when I see measures like this because of the prime importance that's been identified. I think this gets to one of the priorities that we tailor service to every year, which is person and family engagement, follow-up after hospital to engage patients and families. And patients getting the care they need is a really important thing.

I know there's a philosophical divide here, and I'm on the side that really sees hospital accountability being to community as well, to work with the community to work after someone leaves the hospital to really advance the overall journey across transitions to a safe result. So that's really where I'm coming from,

and for that reason I think this is the appropriate place in the category that it's in.

I like all of the suggested considerations that were made about what CMS should consider as they refine this and resubmit it. Thank you.

CO-CHAIR WALTERS: Do you have a recommendation?

MEMBER HATLIE: I have a recommendation that it stay right where it is.

CO-CHAIR TRAVIS: Which is refine and resubmit?

MEMBER HATLIE: Yes.

CO-CHAIR WALTERS: Okay. Mimi was the other lead discussant. Mimi?

MEMBER HUIZINGA: Sorry. So in this measure we support the idea of having better follow-up after mental health, but we actually are a do not support for this particular measure.

I wouldn't say that we have a difference in philosophy from Marty. We do think that the hospital should be working with their

communities, but as Frank said, this is a matter of access. I mean, yesterday we talked about how we have hospitals who have patients sitting in their ER for days just because they can't find a bed. So those same places struggle with access.

The other issue that we have with this measure is that is difficult for the hospitals to drive action on it. They don't receive this data. So this measure was initially developed for a health plan and makes sense for someone who has that data and maybe can influence access more than hospitals can.

So ACOs, health plans, this type of measure that goes cross-continuum, those are the payment models that are focused on that, and those are the payment models that actually have the tools and resources available to potentially drive change on them.

I like the suggestion that Frank made, and that would certainly make this measure more palatable, but without having the data source to drive improvement efforts we would still be do

not submit.

CO-CHAIR WALTERS: Okay, so we have a do not submit and a refine and resubmit. Akin?

MEMBER DEMEHIN: I echo the concerns that both Frank and Mimi have articulated, and this really is a measure where the -- the core idea behind it is sound. You do want hospitals to take action to connect patients with the next level in the continuum of care. But as Frank pointed out, that continuum of care is often a patchwork in a lot of communities, and so we're kind of on the fence between a refine and resubmit and a do not support.

I just don't know if it is technically feasible to do the kind of -- the kind of adjustment that Frank is talking about around looking at access within communities and trying to account for that in comparing performance, so just not sure if the frame of this -- of this particular measure is quite right to achieve the goal we want to achieve.

CO-CHAIR WALTERS: Before we get to

Brock, I'd like to hear some thoughts, or be thinking about, so, it is a currently endorsed measure in the Inpatient Psychiatric Program, and this is for the Inpatient -- Hospital Inpatient Quality Program. Is that two standards of care or not? Yes, yes.

MEMBER SULLIVAN: This is Ann. Can I just talk to this a bit?

CO-CHAIR WALTERS: Sure.

MEMBER SULLIVAN: I realize --

CO-CHAIR WALTERS: Ann, go ahead.

MEMBER SULLIVAN: Now there are big problems with access, I agree, but we've had this one in the Psychiatric Hospitalization Program for years, and when someone is psychiatrically hospitalized, even in some of the most disadvantaged communities, they are able to arrange for some degree of follow-up, because you have to understand, this is not just a regular psychiatric appointment, this is someone who has been in the hospital, who has been very very ill, and usually -- I mean, maybe in some very poor

rural communities, you may have to defer to the primary care doctor.

But that has not been the experience in the psychiatric hospital situation. We have been able to do this for these seriously ill patients in terms of getting them care, and there is usually some availability as an intensive outpatient or partial because we're not totally bereft of any psychiatric services in these communities, but often, these guys are prioritized, and that's what hospitals kind of have to work at.

The second thing is I think that you should not have two standards of care. These are hospitalizations that happen to occur in a general hospital versus a psychiatric hospital, but if you're not going to get a follow-up within seven -- within 30 days, you're going to get a readmission, so I think it behooves the hospitals to really recognize that most of them are pretty close to getting this kind of already because how could you in good faith discharge people with no

follow-up? I sincerely doubt that that is happening.

This is just a way of keeping track and making sure that those connections are made. You know, there is not always primary care capacity. Sometimes, there is no cardiology capacity. Sometimes, there's other problems with capacity. That doesn't stop us from saying there has to be good care after hospitalization, or having impacted on some of the readmission indicators that have been there.

So I think it is a little bit overstating the facts because these are such high-priority patients, even in New York, which has some of the most rural areas, equal to anyplace else, we manage to find places for these individuals because they're such high priorities.

So I think it is perfectly worth refining and resubmitting. I think that's a good idea just to kind of get it -- make sure that it can work within these facilities, but I do think -- I wouldn't overstate that with very high-

priority people, that there is no way to get access, and that it would be such a burden on the hospital to arrange it.

CO-CHAIR WALTERS: Thank you very much, Ann. Brock, you took your card down?

MEMBER SLABACH: Well I was going to put it back up as soon as she finished.

I -- I would like to reiterate that one of the most difficult problems in rural areas around the country, maybe New York probably is an exception, is referrals to mental health follow-up, and if this is going to be a measure, as Frank said, that is going to point out the access issues and not be a penalty for the hospital in terms of doing what it is supposed to do, then I would be in favor of it. In other words, it is indicating that we need to invest more resources in mental health and we need to have better networks of care, you know, in rural and more underserved communities.

But if this is going to be, say I'm holding the hospital responsible for the fact

that the patient didn't follow up to a mental health provider following the discharge, then I find this to be somewhat offensive to 2,000 hospitals in the United States who are doing their best to try to make this happen, so -- .

CO-CHAIR WALTERS: You are which side of the fence?

MEMBER SLABACH: Oh, I do not support --

CO-CHAIR WALTERS: Okay.

MEMBER SLABACH: -- unless -- unless the things that Frank talked about earlier were introduced into it.

CO-CHAIR TRAVIS: I just -- this is Cristie. I have just a clarifying question, in that this -- the way this measure looks is that you were actually treated for selected mental illness diagnoses, and then whether or not you have the follow-up afterwards, so that your hospitalization included, or was for, treatment of mental illness.

And I think the other piece that -- I

wanted to be sure I was reading it right, but the other piece I was trying to understand -- and I really don't mean to introduce a competition here, and I really apologize -- but the Inpatient Psychiatric Facility Program, does it include psychiatric units in general acute care hospitals, or is it -- and it does, doesn't it? Okay. So it's not just freestanding psychiatric hospitals.

DR. YONG: No, the facilities included in the program include both freestanding psychiatric facilities as well as psychiatric facilities embedded in general acute care hospitals.

CO-CHAIR TRAVIS: Okay. So the reason that I wanted to confirm my understanding is, you know, I am trying -- I am not saying there wouldn't be some people who were admitted to a hospital for mental illness that didn't have a psychiatric unit, because I assume that could happen, but that is who this really ends up applying to that it doesn't already apply to.

In other words, if a general acute care hospital has a designated psychiatric unit, assume they're participating in your program under that, so they're already reporting it for that. So this would be patients outside of that unit?

DR. YONG: Right.

CO-CHAIR TRAVIS: I mean, I am trying to figure out how these two things work together. Maybe I should just say it that way.

DR. YONG: So we do know that -- but there are also patients who have -- are hospitalized for mental illnesses that aren't hospitalized for the psychiatric ones, and so that I think would be the population that would additionally be captured.

CO-CHAIR TRAVIS: That's -- that's what I'm trying to -- so the only reason I bring this up is that it -- it is not all -- I mean, some people are already having to report on this, even from general acute care hospitals if they have a designated psychiatric, so we're talking

about expanding that in that those patients then that fall outside that psychiatric unit, or are in a hospital that doesn't have a psychiatric unit, are the ones we're talking about.

But the other piece is, I mean, these people were in the hospital for mental health issues, not that they were in for a cardiac issue and needed follow-up care.

CO-CHAIR WALTERS: Lee.

MEMBER FLEISHER: So I am sort of torn because I actually -- at my own hospital, until the measures existed for readmission and for appointments, we didn't have people who were actually dedicated and going out and asking the patient, when can you actually get to an appointment? So that having something like this would drive the right thing.

It's NCQA, so it is not Yale CORE, and I'm just thinking if you can't do what Frank suggested, some sort of SES look in this population would tell us a lot as a surrogate for -- because I don't know the data that would exist

to look -- do you have it, where, I mean, to --

MEMBER GHINASSI: I mean, there's a variety of studies on this, and I can send you data. But the --

MEMBER FLEISHER: No, I am talking about -- I am not talking about the -- what -- what exists in easily accessible data because it is CSAC --

MEMBER GHINASSI: Oh, that would be -- that would be from -- my hope would have been that there would be a way for them to assess the availability and access within a community before you judge one part of the system.

MEMBER FLEISHER: Right, but I am not sure that that data exists in an easy way, so as a first pass, if -- it would be great to see if regions that had different SES sort of by -- had different rates of this to start, and even getting better some of those regions would be an important different way of looking at it because I think improvement might be a -- a different way of scoring better over time than just rates

looking between individual hospitals.

CO-CHAIR WALTERS: Andrea?

MEMBER BENIN: I just wanted to -- I think Cristie your question was helpful to me for understanding this because frankly, my understanding is that if you can't have a CON for a psych bed, you cannot admit someone with a principal diagnosis of a psych problem to -- to anywhere. And so if you are being admitted to a regular bed, that means you have to have some other diagnosis, so it is overdose, whatever that is, it's suicide attempt that has an injury remaining, so that, your principal diagnosis actually is a medical diagnosis. It has to be or else you cannot go forward. I mean, you couldn't have a patient there.

I mean, Pierre or Ann Marie might understand this better than I do, but so I am not actually sure then if that is the group that we're trying to capture who those patients are at this point because you have to be in a psych -- unless it is psych facilities with -- with sets

of CON -- you know, with beds within hospitals that are not freestanding psych hospitals, but not -- it can't -- it's not just like every hospital admitting patients who have a mental illness. That is -- there just is a principal diagnosis, just --

CO-CHAIR TRAVIS: Right.

MEMBER BENIN: -- I am trying to make sure I am super clear on your --

CO-CHAIR TRAVIS: And I don't know, yes, I mean that was kind of my -- and that was trying to be sure we were clear. Now I will say that CON is not in every state, but I don't understand the -- there could be licensure requirements. You know, I -- but that is -- that is kind of what I was trying to say.

These people are not in a psychiatric unit, I mean, because if they were in a psychiatric unit, they would already be reporting this information through the other measure of psychiatric hospitals that we talked about earlier, because even units within general acute

care hospitals are covered under that other program.

CO-CHAIR WALTERS: Let me not put words in your mouth, but you're saying do not support because it's not needed and not necessary?

MEMBER BENIN: I mean, I was fine with the revise and resubmit, let people think about it some more.

CO-CHAIR WALTERS: Okay.

MEMBER BENIN: I mean, if it needs more --

CO-CHAIR WALTERS: Okay.

MEMBER BENIN: -- thinking or figuring out, I am not --

CO-CHAIR WALTERS: I got you.

MEMBER BENIN: -- I don't have any sort of stake in this.

CO-CHAIR WALTERS: Mimi?

MEMBER HUIZINGA: So I had a question for clarification, and then a point to make, but my question first: so if we look at QPS, the NQF

measure that is currently being used in the inpatient psych program, it says the level of analysis is health plan or integrated delivery system, so were there any modifications made? I mean, it seems like it's kind of like an off-label use to use it just in a psychiatric facility and not at the health plan level, where it is endorsed, so did it go through a modification process in order -- it didn't.

But it says endorsed here. I don't know --

MS. MARINELARENA: It's endorsed at the health plan or IDS level.

MEMBER HUIZINGA: Okay. It is -- do you know if in their maintenance, they will -- are there any plans to resubmit it to --

MS. MARINELARENA: I do believe it is going through maintenance now in our Behavioral Health Project, I believe. I can check right now. If you read the preliminary analysis, that was one of the -- that's the refine and resubmit to specify it, test it at the inpatient hospital

level.

CO-CHAIR WALTERS: Wei? And then I think we'll try to see if everybody has enough information --

MS. MARINELARENA: But let me -- let me --

CO-CHAIR WALTERS: -- to vote.

MS. MARINELARENA: -- confirm that it's going to be --

CO-CHAIR WALTERS: For the inpatient --

MS. MARINELARENA: That -- right, yes.

MEMBER HUIZINGA: And so then my point was, you know, going along with kind of what Frank says, how this might be modified to be more appealing to hospitals or useable by hospitals, so I as a primary care provider, I would spend many hours on the phone trying to get appointments for patients. I would get them, and then they wouldn't go for various reasons that were all outside of my control, so could there be a way that in order, if you can't measure access

or adjust for it, that this measure could try to be more structural or process to assess intent to get scheduled or actually scheduling the measure, not -- those are the things that the hospital can gather data on and can develop programs for and act upon. Whether or not a patient actually goes is a little bit separate.

CO-CHAIR WALTERS: So I have heard a lot of discussion that basically is around refine and resubmit, or do not support, for the Inpatient Quality Reporting Program. I think we're ready for a vote?

(Pause.)

CO-CHAIR WALTERS: So what we're talking about up here is from a practical purpose, even though we can't stop you from voting for option 2, the options we -- the options in reality are number 1, number 3, and number 4. That's what the discussion hung around.

MS. QUINNONEZ: Okay. Voting is now open for Follow-up After Hospitalization for

Mental Illness. This is MUC16-165 of the IQR program. Option number 1, support. Option number 2, conditional support. Option number 3, refine and resubmit. And option number 4, do not support.

I will read those options one more time. Option number 1, support. Option number 2, conditional support. Option number 3, refine and resubmit. And option number 4, do not support.

Thank you, Marisa. Thank you, Ann. Okay. Voting is now closed.

(Pause.)

MS. QUINNONEZ: Okay. We're going to ask you to vote one more time.

(Laughter.)

MS. QUINNONEZ: Oh, here we are, okay. We actually have our totals now. Thank you.

All right. For the -- I will read the results for the IQR Measure 16-165. 0 percent support, 0 percent conditional support, 72 percent for refine and resubmit, and 28 percent

for do not support. This stands at a refine and resubmit.

CO-CHAIR WALTERS: And as we said yesterday, even though that was the preliminary analysis recommendation, I think input by the comments given to CMS would be very helpful.

Now proceeding on with MUC16-262 -- I am going according to the agenda list -- which is the measure The Quality of Informed Consent Documents for Hospital-Performed Elective Procedures, and again, the preliminary analysis was refine and resubmit, and basically, the whole right side of the room said they recommended pulling it.

So would you put your cards up? Not the whole side, just half of it or so.

(Laughter.)

CO-CHAIR WALTERS: Mimi?

MEMBER HUIZINGA: Thank you. So we don't support this for several reasons. Informed consent is a process covered in other mechanisms, namely the Conditions of Participation, and the

Joint Commission of course has standards. There is a high level of effort required for this measure.

There is some ambiguity. I realize that we heard a little bit about reliability and validity testing, but we would argue that there is still a great deal of training and development that would need to happen in order to achieve those numbers, and further testing would be needed, but we don't recommend that either because we think that CMS should just stop here with this.

And if you were ever going to consider a measure like this, it should definitely go through the NQF process so that it could be assessed for the reliability and validity as needed. And most importantly, we feel that informed consent is not an outcome. It's a structural measure, and the way that the points are structured in this measure, if you read what you get points for, it really is just a yes or no, did they write a different language? It

doesn't say anything about was the language used actually understood by the patient in the intent that it needed to be so that the patient was really receiving an informed consent process.

So informed consent can't be judged by a chart review. It is really -- or the quality of it, I would argue, is judged by what the patient understands. So we think, just in summary, CMS has other mechanisms in place to check off structural measure yes or no for informed consent. The measure doesn't really address an outcome, nor does it do much to drive the quality of informed consent, as there is some -- a lot of variation that could be allowed within the language as it is structured, and we think that if you wanted to understand this better, it really should be based on both the patient, their preferences, and what they understand to be the procedure that they are undergoing and the risks that are associated with it.

CO-CHAIR WALTERS: Marty, you were

there to lead discussion?

MEMBER HATLIE: So I was delighted to see this on the MUC list --

(Laughter.)

MEMBER HATLIE: -- because it really does address a problem, and that is I see the informed consent process as one of the main ways in which we can reach shared decision-making, the costs of shared decision-making, and it has become a check-the-box kind of thing in hospitals, or -- at best. At worst, a risk management strategy that has almost no shared decision-making content anymore.

It is a priority because shared decision-making is a content. It is a priority not only for NQF, but in the CMS quality strategy now.

I do think also I was impressed by the analysis and the way in which hospitals who used this seemed to find -- to get information that they would find useful in improving their -- their informed consent processes. It just seemed

like the testing was surprisingly creative and interesting in pointing out ways in which things can be done better, which I -- I do think hospitals need.

I am sympathetic, I mean, to the burden issue here. I think this could be one that does take additional training, but I think it is needed because this is just such a broken process throughout the healthcare system, so for all those reasons, I -- I want to just support where it is, continue to look at it in the refinement and resubmit category, but I also want to compliment CMS for actually taking this step, CMS and NQF.

It's kind of a next step. It was positioned nicely in the decision guide as a next step in really looking at this key, key process and taking it to the next level. Thank you.

CO-CHAIR WALTERS: Lee?

MEMBER FLEISHER: So I am -- I am glad the lawyer was supportive because -- correct, it's the lawyer? -- because in fact the people

who have caused this to occur in my hospital are actually the lawyers all around malpractice suits.

To put this in perspective, the underlying issue is that is this a conceptual model according to which informed consent happens, or is this the legal document at the end of that conceptual model that leads to the support when you end up in court whether or not informed consent happened?

So my concern, and I did actually comment privately, which they -- I didn't see your responses, so I have to be accurate, that were supposedly put up on the web, to some of these concerns that a lot of the elements -- reliability is great, but if it doesn't -- if the reliability is whether or not you time it and date it, which are requirements by Joint Commission, et cetera, and whether or not it is legible, which are requirements by our lawyers, that is different than whether or not the patient actually understood everything.

So while I commend them for taking a first step, I think along the continuum of what is shared decision-making and where we get to, starting with a legal document is the wrong place. And again, I would say what you have done is created a great structure for every hospital in this country to think about how to defend their process because when you look at this, what happens is patients do not read it. So while highly educated patients read it, and while sort of the people who need it potentially the least read it, it -- it won't get to the achieved goal.

So getting back to I think it's Allen who previously said utility of a measure, I think this does not rise to a utility. Put in the Joint Commission participation, let your legal team say how great a job Yale did at defending what the process occurred.

CO-CHAIR WALTERS: So I interpret that as a do not support?

MEMBER FLEISHER: Do not support. And lastly, I really do believe I agree with Mimi

entirely. This needs to go through the NQF process where it is truly vetted and by the appropriate panel gets to CSAC, and then we'll see what happens there too.

CO-CHAIR WALTERS: I -- I am just -- I am just thinking a second. So with that last sentence you made, which is what the initial recommendation was, refine and resubmit, and everybody agrees it should go through the process, so is this measure as you read it refinable --

MEMBER FLEISHER: No, I --

CO-CHAIR WALTERS: -- and --

MEMBER FLEISHER: -- I actually -- I would be -- I would be curious what happens in the process, but I do not support this measure.

CO-CHAIR WALTERS: Got you.

MEMBER FLEISHER: I do not believe it achieves the goals of improving the care of our patients.

CO-CHAIR WALTERS: Okay. I just wanted to clarify that. Akin?

MEMBER DEMEHIN: We have a number of significant concerns about this measure, many of which both Mimi and Lee have articulated very well, so I won't rehash them.

But I did want to underscore one particular aspect of this that has us troubled. There absolutely are standards from the Joint Commission and under CMS Conditions of Participation around informed consent, there are often state-level laws that dictate what goes into a -- an informed consent. This to me has a very real risk of just adding to the confusion, and it really is focused more on the piece of paper than it is on sort of the real issue to address here, and that is making the informed consent process meaningful to patients. So we absolutely do not support this measure.

CO-CHAIR WALTERS: Marty, did you have another comment?

MEMBER HATLIE: Yes. I mean, informed consent documents are unreadable because the lawyers have put them together. I mean, we are

talking really about a paradigm here where no one could understand it, or else they are so meaningless. I mean, I have been asked to give informed consent now on a computer screen, you know, that makes me feel like I'm in a department store.

So -- so this is an opportunity actually to get out of that old paradigm that the lawyers are defending because of defense worries. Actually, there would be less litigation, in my belief, if we had better communication at this stage in the process, where people really did understand the risks they were undertaking, and what -- and I totally agree with you though that this needs to go through a thorough vetting process. The NQF process I think would be a great, great step to really bring out all the potential of -- of this opportunity to kind of create a better practice here that might have some influence on the bar, in saying, you know, it's not just about defending the hospital, it's actually about communicating and choosing risks

and making better decisions. So I love the idea of this actually going through the NQF process in a really thorough way.

CO-CHAIR WALTERS: I am trying to avoid rebuttal, rebuttal, rebuttal number two, rebuttal number three, rebuttal number four. Mimi, do you have anything else to add that is different from what has already been said?

MEMBER HUIZINGA: I do, and then this will be the last time I speak on it.

The -- so the first thing is that there is no evidence that implementing this would in any way change what currently exists. It would only -- it would likely, although I don't have evidence, but I feel that if we were to gather a group of hospital lawyers, this would add to what's in an informed consent document, not take away, and it wouldn't do much to improve the clarity or understandability by the patient.

However, if the CMS would like to collect information on that or the measure steward and bring that back for NQF through the

process to evaluate, that would be the appropriate place to handle that, and then we could have actual backing instead of conjecture.

I would say that I think that Lee hinted at this earlier: we are strongly supportive of shared decision-making, but that should happen well before you are ever into a consent document. There should be a long, thought-out process when an initial diagnosis is made, and that conversation or guiding that shared decision-making process should not try to be captured in a document that really exists for more legal purposes than the actual conversation and documentation of how the patient arrived at the decision to proceed with the procedure.

CO-CHAIR WALTERS: Akin, incremental information?

MEMBER DEMEHIN: More sort of on the more constructive side. You know, we've talked about this measure, we talked about the smoking measure, to a certain extent the follow-up for mental illness measure, and I think part of the

struggle we have is we are talking about what can be put into a quality measure versus what is an important improvement area that should be addressed.

To me, something like informed consent could be really, really nice to include in the efforts through the TYO. Maybe it is something that the HIMSS take a look at downstream.

I also think that gives an opportunity to see if there is anything in the context of that improvement where it lends itself to a nice measure that could be used in a national program, but to me, this sort of feels like we're going to boil it down to the measure to solve the overarching problem, and I think it has to be looked at in a much more holistic way.

CO-CHAIR WALTERS: Okay. I am going to open it up for voting. I did -- oh, sorry, yes?

DR. SUTER: Hi, this is Lisa Suter. I directed the measure development. I would like to respond to some of the comments made. I very

much appreciate this opportunity to speak.

The first thing I would like to just clarify is that this is -- definitely goes beyond just having a document or dating a document. I think it is important to recognize that this measure was developed in a very innovative way, with patients involved from the very beginning. They were brought in at every step. They were involved in every step of testing. We have heard positive results from the hospitals that we're working with to test, including premier hospitals that have found it beneficial.

So I think important to recognize that we've heard the hospital perspective. We've heard a legal perspective. But we have not heard the patients' perspective. The patients that were involved in this measure feel it is very valuable.

They also, as well as the patient advocates who commented during public comment and participated on our TEP, acknowledged that it does not go far enough, and we acknowledge that

as well. This is a first step, but it takes us a very long way. Can we all imagine what it might be like as a patient regardless of their socioeconomic status to have a piece of paper that actually describes the procedure that they are having before an elective procedure well before the actual procedure, before they are under anesthesia?

This is the information that this measure conveys. It is a potentially very powerful document. Mimi is right. We do not have data prospectively that indicates that this has changed anyone's life at this point, but we know from deep investment and collaboration with patients organized through the National Partnership for Women and Families working collaboratively with us that this is a meaningful measure to them. They see it as important even in addition to a shared decision-making as a first step, that this is critical information to anyone going forward with an elective procedure.

It is low-burden. We anticipate it

would be a very minimal burden on hospitals. It takes only a few minutes to abstract. We are working -- as you heard earlier, our reliability estimates are exceptionally high. We ought to be able to drive the sample size per hospital down to minimize hospital burden.

So we think that there is a tremendous amount of short-term benefit, right? This is something we could get -- we could get every hospital in America to a point where they could offer information to patients about elective procedures, or every physician, or every outpatient surgical center, to get to a minimum standard, and we hear again and again from patients that this is a minimum standard, but it exceeds what is legally required.

The legal requirements are vague, and they vary from state to state. We do not envision any incompatibility with existing state laws. For example, Louisiana has a lot of requirements for their informed consent documents. Hospitals we have tested from

Louisiana actually rate very well, so they are working to improve, and what the states are doing is in complete alignment with what this measure shows.

I will also acknowledge that in terms of the NQF endorsement, there has not been an NQF call for measures relevant to this measure. We are eager to have it in front of NQF. I think it is important for the MAP to recognize that the process of getting a measure out into use is a several-year process, so when this meeting decides in December of 2016 to revise and resubmit a measure, that is probably a three- to four-year delay for implementation in federal programs because of the -- if we move out next year, putting it in rulemaking, it gets signaled in rulemaking in 2018, and it gets implemented in 2019, we'll for 2020 report it, so that -- I am just recommending caution when you're on the fence about measures to recognize that it is a 12-month delay when you guys make decisions that may -- you may be on the fence about.

So I don't know if I covered all of the concerns, but I really appreciate the opportunity to speak. Thank you.

CO-CHAIR WALTERS: Thank you, Lisa. I am sorry I didn't see your card up before.

Okay. I'm going to call for a vote. I think you've heard all the considerations. The one you did not hear discussed by anybody was option 2, conditional support. Any of the other three options I think were brought up. So let's vote.

MS. QUINNONEZ: Voting is now open for IQR program measure Measure of Quality of Informed Consent Documents for Hospital-Performed Elective Procedures, and this is MUC16-262.

Option number 1, support. Option 2, conditional support. Option 3, refine and resubmit. Option 4, do not support.

I will repeat those one more time for those on the phone. Option 1, support. Option 2, conditional support. Option 3, refine and resubmit. And option 4, do not submit -- do not

support.

(Pause.)

MS. QUINNONEZ: Okay. Thank you, Marisa. Voting is now closed. The results of IQR MUC16-262, 17 percent voted to support, 0 percent conditional support, 46 percent refine and resubmit, and 38 percent do not support. This yields a refine and resubmit.

CO-CHAIR WALTERS: It's refine and resubmit.

Okay. The last measure in Consent Calendar 7, which was pulled, is MUC16-263, Communication About Pain During the Hospital Stay. We will start with Kim, who asked that be pulled.

MEMBER GLASSMAN: Thank you, Ron.

CO-CHAIR WALTERS: About -- I am sorry, you want to do about the measure first? Okay.

DR. YONG: Thanks Ron, I appreciate it. Just wanted to give you some context for this measure as we undertake this discussion. So

folks who have been following the program and the regulations relating to the Hospital Value-Based Purchasing Program may have been aware that in this past year's rule, we did propose and finalize to move the domain relating to the pain component in HCAHPS given -- even though we do acknowledge and do firmly believe that, you know, the pain is a critical component of a patient experience, it does need to be addressed that it may have -- we don't want to confuse the situation given the concerns around opioid overuse, and so that's why we finalized taking it out of the HVBP calculations for HCAHPS.

So as we have done that, we have continued to do work, and I wanted to give Bill Lehrman, who has been working as a steward of this measure, a chance to speak about our continued thinking and evolution of thinking around sort of how do we potentially address pain as part of the HCAHPS survey?

MR. LEHRMAN: Thank you, Pierre. As Pierre mentioned, in the outpatient rule this

year, we propose removing the pain management dimension from the VBP formula, beginning in the fiscal year 2018 program.

This stems from concerns raised by healthcare providers, physicians, et cetera that they believe the current pain management items in the HCAHPS survey and especially their inclusion in the VDP program was encouraging overuse of opioids. This happened to coincide with the opioid epidemic. CMS carefully considered the comments and commentary and decided to remove that measure from the -- the payment program. However, it remained on the survey because we believe that proper patient care should be a routine part of good quality hospital care.

However, we had the opportunity to investigate alternative questions for the HCAHPS survey that tapped into the same dimension about pain. Given the concerns about the current questions, the new items that we tested focused on communication about pain rather than patients' need for pain medication or belief that their

pain was well-controlled or that hospital staff did everything they could.

So the items that we tested and the items that we are putting forward today focus on communication about pain with the patient during the hospital stay. We have tested this earlier this year. We have good empirical support for the three items we would like to propose in the new composite measure, which is 263.

We also tested the cognitive testing with patients, inpatients and emergency department patients, about the new items. We also had a number of interviews, informative interviews with hospital administrators, physicians, and nurses about the content and direction of the current items and the proposed new items.

We feel that these empirical and cognitive informative interviews support the items in the composite that we are -- we have proposed in the MUC list, and with that, I will close.

CO-CHAIR WALTERS: Thank you. Okay, Kim?

MEMBER GLASSMAN: Okay. And I can kill two birds as both a puller and a discussant.

So we would commend CMS for being directionally appropriate in the changes that you are proposing to these questions, and particularly, I am pleased to see more plain language in the HCAHPS survey and would urge you to consider that for other questions, but also feel that this is very premature in testing. We are not aware of any of these data and therefore do not recommend including this at this time.

I would also add that I believe we're discussing questions 1, 2, and 3, which are directionally better than questions 4 and 5, which I believe generated a lot of comment this morning, so as these questions are being considered, we would urge CMS to also not focus so much on pharmacologic measures, but allow a wider range of treatment for people for pain.

CO-CHAIR WALTERS: Pierre is going to

respond to the question about the questions.

DR. YONG: Yes, just to make sure we're all on the same page, but yes. So for the committee's considerations, just HP1, 2, and 3, which are part of MUC16-263, so we're not talking about the other measures.

CO-CHAIR WALTERS: Akin?

MEMBER DEMEHIN: I think Kim covered a lot of the salient points already, so first just want to commend CMS for your willingness to take another look at these questions and really try to improve them in such a way that we are striking that right balance between treating pain, which we absolutely have to do because of the enormous negative consequences it can have, along with the concerns around the spread of the opioid abuse epidemic.

Definitely for us, this falls pretty squarely into the refine and resubmit category. We would strongly urge you to bring this through the NQF endorsement process before it goes into the program to really make sure we get a deeper

look at how this was tested and how this was developed.

I -- I -- we do have some questions too around making sure that there are some questions that target not just use of pain -- pain medications, which I think is fair game to ask, but some of the non-pharmacological interventions as well, so look forward to continuing to work with you on the development of this measure. It is really important to get it right, and we're -- we're glad that you are going down this path.

CO-CHAIR WALTERS: I forgot to ask, what was your recommendation?

MEMBER DEMEHIN: To leave it where it is, refine and resubmit.

CO-CHAIR WALTERS: And Kim?

MEMBER GLASSMAN: I had indicated my recommendation of do not support at this time.

CO-CHAIR WALTERS: Are there any other people who wish to make a comment about this measure for the IQR?

(No audible response.)

CO-CHAIR WALTERS: Okay. I did not hear anything resembling a condition for conditional support, so we'll open it for voting.

MS. QUINNONEZ: We are now voting -- before we vote, we'll have one more response.

CO-CHAIR WALTERS: Yes.

MR. LEHRMAN: Okay. In response to a couple of the comments, we did the testing of the items earlier this year. We tested the new survey items in 50 hospitals from around the country. We had about 16,000 surveys. We have -- we can reveal here a few items that we learned from that testing.

We found that the new items in the three-item composite that Pierre mentioned, that's just the three items, HP1, 2, and 3, in MUC-263, they weren't subject to floor or ceiling effects. They have excellent reliability at the hospital level at the recommended sample size, which is 300 completes per hospital per year.

They are not redundant with any of the

current items in the survey. They were related in a predictable manner with the standard patient mix characteristics that we use when we adjust the HCAHPS scores with public reporting. They are predictive of hospital rating and recommend. A lot of hospitals want to know that. They do not -- they do not vary systematically by survey mode -- that is, telephone, mail, IBR, or mixed mode -- or by patient race, ethnicity, or by hospital characteristics, after we adjust for patient mix. And they have a higher internal consistency as composite, a Kronbeck offer of 0.81.

So we were encouraged by the empirical results. That was part of our decision to put these three items in particular into the new composite to replace the current items. We probably will go through the NQF. Timing was such that the MUC list came first.

Oh, and of course, I should indicate that quite deliberately, the new items do not mention medication. They ask if the hospital

staff talked to the patient about treating their pain. We do not limit what "treat" might mean, and we know from cognitive interviews that patients interpret "treat" as medicines and other therapies and methods for relieving pain.

CO-CHAIR WALTERS: Sean?

MEMBER MORRISON: I'm sorry, Ron, I just can't let this one go by. I think you guys really need to look not at the research in the past five years but the research what was done 20 to 25 years ago that looked at these line of questioning and demonstrated that there actually wasn't a link between patient experience and outcomes and all it did was generate nurses talking to patients about their pain but there was no change in the experience. There was no change in outcome. And there actually wasn't a change in practice. And I think that has been forgotten because those data were done almost three decades ago.

So, please take a look at that before you -- I would strongly encourage you to look at

those data before you bring it through endorsement.

CO-CHAIR WALTERS: Kim.

MEMBER GLASSMAN: Just a clarifying question, then. Because it is included in the materials, are HP-4 and HP-5 off the table? Okay.

MEMBER DEMEHIN: So, I know we are not discussing them here, but are they undergoing any further development or kind of where do you see it going?

DR. YONG: So, I will say what the committee will vote on is HP-1, 2, and 3.

CO-CHAIR WALTERS: Presumably, what the appropriate Steering Committee would hear along with the data presented, if that is the choice.

Okay, let's open it up for voting.

MS. QUINNONEZ: Voting is now open for IQR Program, communication about pain during the hospital stay. This is MUC16-263, the questions HP-1, HP-2, and HP-3.

Option 1 is support; Option 2, conditional support; Option 3, refine and resubmit; and Option 4, do not support. You may cast your vote.

I will read those one more time.

Option 1, support; Option 2, conditional support; Option 3, refine and resubmit; and Option 4, do not support.

Okay, voting is now closed. We will give the software a second.

(Simultaneous speaking.)

CO-CHAIR WALTERS: While I have an opportunity, let me kind of give a layout of what we are thinking here, at least some people.

Since we just got done talking about this measure, that is a preview of all previous measures. We are going to have vote again, aren't we? Oh, go ahead.

MS. QUINNONEZ: Yes, we are going to have to vote again. One second.

CO-CHAIR WALTERS: Okay, let's do that first.

MS. QUINNONEZ: Give me one second and I will queue.

CO-CHAIR WALTERS: Ready? One second.

MS. QUINNONEZ: Voting is now again open for MUC16-263, questions 1, 2, and 3.

Option 1, support; Option 2, conditional support; Option 3, refine and resubmit; and Option 4, do not support.

Thank you. Voting is closed. It was successful. The voting results read 17 percent voted for support, zero percent voted for conditional support, 67 percent voted for refine and resubmit, and 17 percent voted for do not support.

So, this will move forward with refine and resubmit.

CO-CHAIR WALTERS: Okay, here is what we were just talking about. And opportunity opened up this morning because, against, we didn't have anything in the Consent Calendar for value-based purchasing but it cleared. And it is exactly the same measure that we just got done

talking about. So, we are going to go over briefly the rules of a value-based purchasing program. Probably there won't have to be a great deal of discussion about the details of the measures we just got done talking about. It will be mostly about whether it is appropriate for the value-based purchasing program.

And then, for you hypoglycemic people, we are going to take a little bit more than just go get your food but a moderately brief break for lunch and then head into Consent Calendar 8 and 9. So, that is kind of how things are laying out for one o'clock on.

And we are going to go to the overview and then the opportunity for public comment and then talk about this measure.

MS. MCQUESTON: Thank you. So the Value-Based Purchasing Program. Medicare bases a portion of hospital reimbursements on performance through this program. Medicare began withholding one percent of its regular hospital reimbursements from all hospitals paid under its

Inpatient Prospective Payment System to fund a pool of the value-based payment incentive payments.

The amount withheld from reimbursements increases over time. For 2016 it was 1.75 percent and for 2017 and for future fiscal years, it will be 2.0 percent.

Hospitals are scored based on their performance on each measure within the program, relative to other hospitals, as well as on how their performance on each measure has improved over time. The higher of these scores on each measure is used in determining incentive payments.

This is an overview of the current measures in the program and those proposed for rule. And we are currently considering one measure on the MUC List.

Current measure needs include adverse stroke events, cancer, behavioral health, care transitions, palliative and end of life care, as well as medication reconciliation.

This is an overview of the first part of the current measures in the set. The program includes seven safety measures, four measures related to clinical care measures around readmissions, and then there is the one measure related to efficiency and cost reduction, as well as the HCAHPS measure within the domain of person and community engagement.

Value-Based Purchasing also has five measures for mortality, soon to be six, as CABG was more recently or actually now six. And then two measures related to payment associated with episodes of care.

And now we will move to public comment on this measure.

CO-CHAIR WALTERS: Operator, can you open up the lines for any public comment?

OPERATOR: Thank you. At this time, if you have a comment, please press star then the number 1 on your telephone keypad. We will pause for just a moment.

And there are no public comments at

this time.

CO-CHAIR WALTERS: Are there any public comments in the room?

Okay, there weren't any lead discussants assigned to this because it didn't exist until this morning. Oh, okay, thank you.

I might also just add that as far as I remember, a measure had to be on IQR for a year before being placed into the Value-Based Purchasing Program.

So, Lee -- well, he didn't know. Oh, Kim. You probably just acquired this, then.

MEMBER GLASSMAN: No, we were prepared and then it went away and it came back. So, obviously, because this isn't leading the fit test for what would be included in Value-Based Purchasing, we would not recommend it for inclusion.

CO-CHAIR WALTERS: Jack? Oh, I'm looking at the wrong one. Sorry. Akin. I am looking at my agenda. Akin.

MEMBER DEMEHIN: So, I think I am a

little confused about sort of how to address this particular measure in the context of VBP. I think it is way too early, frankly, to talk about whether it is a fit for VBP. And even a recommendation of refine and resubmit feels like well, if we don't even know if it is working in the IQR yet, it is very hard for us to get a sense of whether it is ready for VBP or not. So, I think we would probably lean towards do not support for now.

CO-CHAIR WALTERS: Could I ask the measure steward what their thinking was of putting this on VBP at this point in time?

DR. YONG: It is just for the committee's consideration as for potential inclusion in HVBP, just like I mean in this circle, we have done that. We put measures that we have potentially put in for IQR and for HVBP, either substantive changes or new measures for the committee at the same time.

CO-CHAIR WALTERS: So, Akin, I think I interpret yours as do not support. And Kim, I

am moderately sure I interpret yours as do not support.

Is there any other discussion about this measure for the Value-based Purchasing Program? Ready for a vote.

MS. QUINNONEZ: Voting is now open for the Value-Based Purchasing Program. Communication about pain during the hospital stay. This is MUC16-263, questions 1, 2, and 3.

Option 1 is support; Option 2, conditional support; Option 3, refine and resubmit; and Option 4, do not support.

Option 1, support; Option 2, conditional support; Option 3, refine and resubmit; and Option 4, do not support.

Okay, voting is now closed. The results read 5 percent voted support, zero percent voted conditional support, 19 percent voted refine and resubmit, and 76 percent voted do not support. This is a do not support recommendation.

CO-CHAIR WALTERS: Thank you very much

for your time.

Now, the race to the counter, right? How long?

CO-CHAIR TRAVIS: How far behind are we?

CO-CHAIR WALTERS: We probably have a good hour and a half yet for Consent Calendar 8 and 9.

Fifteen minutes, 1:10-ish. Thank you.

(Whereupon, the above-entitled matter went off the record at 12:55 p.m. and resumed at 1:15 p.m.)

CO-CHAIR TRAVIS: Okay, I think it is time for us to get started. Just as a reminder, we are still in the Hospital Inpatient Quality Reporting Program but we are now on Consent Calendar 8.

Okay, if we could ask the people in the back of the room to recognize that we are about ready to get started and need to hear each other, I would appreciate that. Is that a polite way of asking you all to -- thank you.

All right, I really appreciate it. Now, we are in Consent Calendar 8 and you see the measures that we are going to address in this Consent Calendar. And several of them, in fact, all four of them in this Consent Calendar, deal with nutrition and malnutrition.

We do have an update that we want to share with you before we get into whether or not any of these get pulled. And so I am going to turn it over to Melissa.

MS. MARINELARENA: Thank you, Cristie.

So, these nutrition measures were or are in the health and well-being project that is undergoing now. They were three of them being the number one, the MUC16-372, MUC16-294, MUC16-296 were all consensus not reached during the in-person meeting. MUC16-344 was not recommended by the Standing Committee during the in-person meeting.

On Tuesday, during the post-comment call, the Standing Committee met again to vote on the consensus not reached, the -- I think it was

validity and evidence on some of them.

We are in the process of finalizing those results and we do not have them yet. It should be finalized probably next week or so. And that is an up or down. They will either pass -- if they do pass and they are recommended by the standing committee, then they will go forward to member vote. If they do not pass, then they will not be recommended and they will not go on to member vote.

So, the way they stand right now, three out of the four are still consensus not reached but one has not been recommended. And you see that in the preliminary analysis, based on what the recommendations are. So, the ones that are with conditions is that they would be NQF-endorsed.

CO-CHAIR TRAVIS: Okay, so we have one update but still more news to come on these measures because the results of the standing committee and then the CSAC review, we don't know that as of today. So, we won't have that much

added information but it is helpful to know that they are moving through the process.

So, we have already had public comment on our IQR program. So, we won't be doing that at the moment. So, we can move right into these particular measures. And I will read for you what the recommendation is for each measure and then see if anybody wants to pull it off the Consent Calendar or leave it on the Consent Calendar.

The first one is nutrition care plan for patients identified as malnourished after a completed nutritional assessment, which is MUC16-372. It is currently sitting with a recommendation for condition support or rulemaking, which is based on it continuing to go through the NQF process and to pass and be endorsed.

So, is there anyone that wants to pull this measure for discussion and vote?

Okay, Karen.

The second measure is completion of a

malnutrition screening within 24 hours of admission. It currently sits on the Consent Calendar as conditional support for rulemaking or, essentially, the same condition, which is that it goes through the NQF process all the way through and receives endorsement.

Would anyone like to pull this measure for discussion? Okay, Karen and Lee.

The third measure is completion of a nutrition assessment for patients identified as at-risk for malnutrition within 24 hours of a malnutrition screening. This is conditional support for rulemaking for the same reasons to complete the NQF process and be endorsed. Pulling that one? Okay.

I feel like I am almost at an auction. People are raising their hands back and forth.

And then the fourth one is appropriate documentation of a malnutrition diagnosis. This currently sits as a do not support. The rationale was that it did not meet the evidence requirement for the NQF standing committee. Does

anyone wish to pull this measure for discussion?

Okay. So, we have a Consent Calendar that includes in item. It is MUC16-344 appropriate documentation of a malnutrition diagnosis. The recommendation moving forward would be to do not support. Are there any comments that we would like to hear about this measure? Lee.

MEMBER FLEISHER: More of a comment to Pierre. I have been thinking a lot about this measure because it may get to frailty and this may be the missing measure that we need to help risk-adjust, rather than SES. So, I don't know where in the future you want to think about this. This is actually the reason I pulled the other measure but Yale Corp. keeps saying if we want to do it clinically, I think this is -- could be the missing clinical factor.

CO-CHAIR TRAVIS: Thank you for that input, Lee. Anyone else?

Okay, are there any objections to the Consent Calendar which just has this one measure

on it? Okay, seeing none, the Consent Calendar moves forward.

Okay, let's go to MUC16-372, nutrition care plan for patients identified as malnourished, after a completed nutrition assessment.

Karen, you pulled the measure. If you would to tell us your rationale for pulling it and then we will have a broader discussion.

MEMBER SHEHADE: Thanks. So, initially, on 372 I wanted to get some clarification around what had come from that meeting.

So, initially, it was to really get a sense of what had happened in the meeting on December 6th, to get a sense of where the Committee was headed, you know what kinds of -- I think they were looking for evidence for that one. So, what additional evidence were they looking for?

CO-CHAIR TRAVIS: It's validity. This one is validity.

MEMBER SHEHADE: Okay.

CO-CHAIR TRAVIS: So, there were some testing questions.

MEMBER SHEHADE: And in looking at some of these nutrition measures, and it is hard to think about them all as single measures because it is really about the patient, when they come in, for doing an appropriate screening for that patient, doing an appropriate assessment for the patient and then doing something about it.

And as a clinician who, as I mentioned yesterday, and who has cared for lots of Medicare beneficiaries over the years, when they come in to an inpatient setting, this was something that was key to the initial admitting process, an assessment for that patient.

And when I read that only 30-something percent had actually been completed, there is clearly a gap in the work that needs to take place to help identify patients for the appropriate care and especially in a frail elderly population where wound care is critical,

infections, good nutrition is just paramount.

And it became, from a clinical standpoint as a PA, I was the house officer that never left for 11 years and admitted over 500 patients, this was something that we did automatically. And calling nutrition in, you know the dieticians in to come and help us come up with an appropriate plan was really just good, clinical care and it shouldn't be variable across the country. It is something that should take place and be really a standard. It should be an expectation of any Medicare beneficiary that good nutrition is just fundamental to what we are doing.

So, I am hopeful that whatever it is that is needed from the committee to look at this -- and clearly, we want to go through the appropriate process and make sure that everything has good evidence behind it, but clearly, to make sure that all those patients receive that same level of good screening assessments and a care plan identified for them.

CO-CHAIR TRAVIS: Thank you, Karen.

We have some other lead discussants. We have Brock, Andrea, and Wei. And feel free, somewhat like Karen did, if you want to discuss these measures, all of these measures at the same time, I think that is fine. We will vote on them separately but feel free, if your comments are much like hers.

So, any comments from Brock? Anything to add?

MEMBER SLABACH: And I'm not sure. Were some pulled for further discussion?

CO-CHAIR TRAVIS: Yes, we have got the completion of the screening, completion of the assessment, and the care plan all pulled for discussion.

MEMBER SLABACH: Okay. It is our position that we are in agreement with the recommendations from NQF on staff and the Consent Calendar was appropriate.

CO-CHAIR TRAVIS: Thank you. Wei or Andrea?

MEMBER YING: I just have -- so, it would be great if physicians working in hospital can comment so that completion of -- sorry.

I was just going to say it would be great if the physicians working in hospital can comment on it so completion of a screening within 24 hours of admission, I kind of feel like it is a given, right, as part of, as Karen mentioned, as part of the admission process. I don't mean screening. I mean this is a more formal way of documenting it but as part of the intake process, the height and the weight and the routine blood work that usually has been done in a timely fashion, from that a pretty good sense of where a patient is at in terms of nutrition status already presents. So, this is more a formal way of documenting it.

My question is adopting this measure will change the clinical practice but does it add any value to the existing process? So, that is a comment on that.

And then on nutrition plan for patient

identified as malnutrition, I looked at specs and it actually has five or six pretty long lists of the elements that has to be hit in order to be considered completed.

We talked about the burden for the hospitals. Is this an eMeasure so it can be pulled automatically from the system?

MS. MARINELARENA: Yes, it is an eMeasure and it is being proposed for IQR and the --

MEMBER YING: Okay, so this eMeasure. So, my question is more about the screening. Does it add value?

CO-CHAIR TRAVIS: Thank you, Wei. Andrea?

MEMBER BENIN: You know I think that obviously this is a critically important topic and a really important topic to address. These metrics make sense. I think the one concern that I had was really around the idea of having three or four malnutrition metrics in sort of the balance of the portfolio. And so if one were to

pair them down for this purpose, which one would be to choose -- you know it just seemed like a disproportionate number of metrics on malnutrition in the portfolio. And maybe it is that important. You know I don't have a good sense of that. And certainly in pediatrics, it is important to deal with this for everybody's nutrition but it is different when you get into geriatrics. So, I recognize that.

The idea that the screenings seem to me actually to be the most critical because I think that starts to trigger things. And I think that we do find that when these screenings, you know, you deliberate and you do whatever it is, you start doing these screenings, it does start the process going. So, that one seemed to me to be the most critical but I think perhaps those would be questions if this committee is going to meet again, the committee that is reviewing it is going to meet again.

Maybe there would be a way for that committee to also sort of prioritize how to think

about these things and that may help some of us decide. Because if we vote these all forward as conditional and then the committee approved, there may be an option to have a little bit of additional help with how to prioritize the metrics. So, I think having the experts weigh in on what that looks like would be valuable because this does seem to be critically important. And the one, to me, that seemed probably starter important was the screening. The other two seemed to me not to stand alone however. So, I think it did not seem to me that if you have 372 or 296 without 294, that that didn't actually seem to make sense. So, if you were going to go with one, it seemed like 294 was the one that had it.

So, it just seemed like there could be a little bit -- there needed a little more thought in that. So, if we say conditional support, I might add the condition of with other, I don't know exactly how to frame it, but with a little bit more recommendation from the committee

that is working on this about how to think about it. But it was a little bit concerning that the committee, themselves, initially didn't even approve it. And that gave me a little pause, without understanding the nuances there.

CO-CHAIR TRAVIS: Thank you. Is there any additional kind of information that you can give us maybe from the meetings that have already occurred? Because then you are still out kind of finalizing the committee recommendations.

MS. MUNTHALI: So, with regards to the screening, the committee had a lot of concern because the screening wasn't linked to evidence and it was so hard to see the proximity was quite distal.

And then the other issue with screening was that all patients 18 and over were to be screened. So, patients at-risk was not stratified or there was no risk adjustment. So, the committee was really concerned about burden for inpatients and hospitals.

Essentially, those are the largest

issues with the measure.

CO-CHAIR TRAVIS: That's helpful. And is there anything to add about any of the other two measures, too, at least from the MUC meeting?

MS. MUNTHALI: I have to pull it up. With the care assessment, I think we -- the care plan, the issue was around exclusions. They were not specified and that was the validity issue.

And then if I can refresh my memory, there is a third one.

CO-CHAIR TRAVIS: Issue of a nutrition assessment for those at risk after screening.

MS. MUNTHALI: And that was also evidence. And Angel, who is part of the developer team is there as well. And correct me, if I am wrong, but it was also around evidence and just linking process to help him.

CO-CHAIR TRAVIS: Thank you. I think that will help our thinking as we move forward.

Okay, I will start with Lindsey.

MEMBER WISHAM: Quick question in regards to the 1:34:38 or eCQMs. It does seem

that the specifications, one leads into the other. So, I didn't know if they were tested. When they were field tested, were they tested as a package? So, in essence, one of the measures will produce a data element that then feeds into the denominator of the next measure.

So, I think the best thing to consider is that do they get approved as a package or not at all? So, if you move one from the continuum do you then not use the prior data elements?

MR. VALLADARES: Yes, so the four measures were tested together. I'm sorry, Angel Valladares. I am with Avalere Health, who worked with the Academy of Nutrition and Dietetics who developed the four malnutrition eCQMs.

So, the four eCQMs were all tested in a cohort together with the same hospitals. However, as you indicated, yes, sort of if you look at them in order, so they are technically supposed to go along the nutrition care process, which is screening, assessment, care plan, recommended and documented, and then a diagnosis

by the provider. The data elements are generated from the predecessor measure.

So, for instance, if you really want to accurately identify the denominator of patients who should be assessed based on the risk level from the screening that was identified. You need to really identify that patient population in the first cohort, which is the patients that were screened for malnutrition risk.

So, if you don't have that cohort accurately identified, then what occurs is you may have a misleading denominator population in the assessment because the appropriate rates of documentation are not happening, which is what we are finding in terms of the gap for this, which is their measure set.

CO-CHAIR TRAVIS: Very good question. I was wondering about that, myself.

Akin.

MEMBER DEMEHIN: So, this set of measures definitely gives us a little bit of

pause, especially since there are two of the three are ones where the evidence doesn't appear to be particularly strong and it sounds like that is why it is landing in the consensus not reached at this point.

And if there are questions about validity in terms of whether it is actually measuring what we think it is measuring, I don't know. And I also have to say that the fact that it is an eMeasure, I do think that something like this makes sense as an eMeasure but I don't necessarily think that this being an eMeasure in and of itself obviates the potential burden that this could entail. And in particular, I am curious about whether this measure is supported by all of the -- or would be supported by all of the EHR vendors.

I think it would be hard to lend this too much support without an understanding of kind of where they are in that process. And some of the evidence and validity issues, that gives us some pause, too.

CO-CHAIR TRAVIS: Is your card still up, Lindsey?

Andrea.

MEMBER BENIN: I would just say that having heard some of this other discussion a little bit more about what the committee was thinking, perhaps this needs to go into a refine and resubmit category. Maybe it needs a little bit more work than I understood it to need for all three of them.

I mean if I had to choose one, I would probably choose the screening one but maybe there is a little bit more work to go into those.

CO-CHAIR TRAVIS: Thank you, Andrea.

I guess my question is how did the committee really look at these? Did they look at them as related? Did they look at them as -- I mean they are not a composite. So, how did the committee kind of look at the cascading effect, if you will, of this set of measures?

MS. MUNTHALI: It was a topic of discussion and I think there were some

recommendations for the developer prior to submitting to think about them as a composite because they did recognize that they were related and that, as it was mentioned before, this screening proceeds, particularly for the first two measures. I think the other measure on the evaluation plan, the assessment plan, is not a screening measure. And that is something the developer wanted to point out. But for the others, you have to set your base population and then build on that.

So, that was a recommendation by staff, prior to submission and then the Committee, when they first looked at the measures.

CO-CHAIR TRAVIS: Okay, Sean.

MEMBER MORRISON: Yes, quickly Cristie. So, if that is the case, that there was a recommendation on a composite measure, what I would -- and it has not gone through endorsement process, what I would like to recommend or suggest is it goes back as a revise and resubmit

with that comment.

Because if it goes through and is endorsed by NQF -- I'm sorry -- and we put that as a conditional support, then it goes through four specific measures and we never see it again. What I would like to see is it go through the evidence process and then for us to evaluate as whether those four items are appropriate for this program.

CO-CHAIR TRAVIS: And so that is refine and resubmit from your perspective. Okay.

Are there any other comments? Would you like to make one? Sure.

MR. VALLADARES: So, I have a few comments that I can make on some of the concerns that were addressed by the committee members. I think one of the important things I can start with sort of high or low. We will talk about sort of the feasibility of the measures and validity to adjust Akin's question that was around the EHR vendors.

So, we did conduct feasibility

assessments with three of the largest EHR vendors in the country, Epic, Cerner, and Allscripts. We received very high scores on our feasibilities assessments for all of the data elements on all four of the eCQMs. They indicated to us, in general, that at this time most of their recent platforms have the capabilities to capture these data elements. However, it is up to the discretion of the hospital implementing that particular platform to, obviously, decide if they want to incorporate that data element in the structured manner that is required for the collection of an electronic measure. So, I just wanted to share that.

Then with validity to be clear as well, we did test the measure. So, this is the nutrition care plan measure. So, we did test that measure with -- well, we tested all four measures because they were tested together as a package for specific exclusions. When we worked with our technical expert panel, we were not able to show with our data we were able to collect

that there was a valid reason to include the exclusions that we tested on, with the exception of the length of stay under 24 hours because don't want to, obviously, penalize a hospital for a process if there wasn't even enough time to complete that process or location.

However, there were three what we were calling experimental exclusions which were discharged to Hospice, discharged palliative care as well and then also, left against medical advice, which those were the three major exclusions. So, that is something that we are continuing to test as we move forward with these measures. We are testing these in other hospitals.

So, the other comment around the evidence, that is something that I do want to bring to the committee's attention because I think this is helpful with the discussion and will also help with your recommendations to us as to how we can move forward with these measures.

So, the evidence really sits more on,

of course, as we know whatever process is most linked directly to patient outcomes and improvement in patient outcomes. And that is really when the intervention, the nutrition invention gets implemented. We know that when a specific nutrition intervention, there are several. ONS is one. There is different parenteral enteral nutritions, supports as dietary, supports and modifications to the diet. Those, there is strong evidence to link that patient impact. And that is why the third measure of the nutrition and care plan did pass evidence.

However, the first two measures, which are further back in the process, as we know, they are a little more distal to the process but the guidelines internationally, there is international consensus from the United States, Europe, other countries, that before you can reach intervention, you need to properly identify and assess the patient for physical indicators for malnutrition. So, a lot of these studies

that we cited in our evidence submission showcase the use of the proper screening and assessment tools for studies that looked at really what type of interventions were implemented for patients.

So, I think that is where a lot of our -- the challenge for us has been is really being able to hone in on the direct causal linkage of a screening to the outcome of the patient. We have a lot of evidence to showcase that. If you identify the patient and intervene on them early, you can improve outcomes. And we also have a lot of evidence to showcase that assessments are a great tool to identify risk factors for patients and there is independent associations with increased length of stay, increased readmission, mortality, several other clinical indicators that are very important, obviously, for Medicare patients.

So, those are a few of the items that I wanted to mention.

And the last thing -- and I do apologize for going I am sure overtime, is the

composite. So, that is another discussion that we did have, as Elisa mentioned, at NQF.

So, one of the challenges that, of course, there is with the development of a composite measure is that you need to test all of the individual components in the field and generate performance evidence for each of the individual composite components.

PARTICIPANT: No, that is not NQF.

MR. VALLADARES: Okay, well, originally, that was our perspective, was we wanted to first implement each of the measures and sort of allow the performance used to be generated and then create the composite but it is not anything that we were held to but that was sort of the approach that we took. Before actually submitting a composite measure, we wanted the four measures to be considered as such.

So, those are the comments. Thank you.

CO-CHAIR TRAVIS: Thank you very much.

Mimi.

MEMBER HUIZINGA: I will be very quick. So, in general, we support these measures. We think that malnutrition has been linked to many conditions and that it is something that hospitals can have direct impact on and make a difference here. And it aligns with maybe the other initiatives that our hospitals are working on to try to prevent complications and reduce readmissions.

So, we are supportive of the three in the conditional support that were recommended by NQF. However, if we had to choose one, I would likely recommend actually a little bit different than what was mentioned before.

I would probably go with the full assessment, instead of just a screening. Care planning often happens with assessments but we find that the breakdown often happens from the screening to full assessment. So, we would, if you are only going to go with one, that is the one that we would like. And if there is going to

further information available from this, we would like to see and provide more information about what validated tools we should use for specific conditions. For example, what should be used in a patient with concerns much like that.

But in general, we think these measures are a very good idea and we are very appreciative if they are e-specified.

CO-CHAIR TRAVIS: Jennifer.

MEMBER EAMES HUFF: I guess I have the question, and I am thinking again of the diagram, Helen, that you showed yesterday about the outcomes and the drivers. I forget the bottom one.

I am not clear what role malnutrition plays against the other drivers we have been talking about in terms of priority. I got this great evidence management, the role it plays in terms of better outcomes, and the patient safety, and better costs but I just want to connect to the conversation that we are trying to -- or not have it so separately in terms of thinking

holistically of how you prioritize about what gets in this program.

So, I guess that is a question for me because where does it stand in the priorities of drivers in terms of whether or not just being sure it be in the program.

And then looking at the specific measures, themselves, it sounds like the if you had to choose one, you would choose. So, I will throw mine in of I would choose the 372, which is the nutrition care plan for malnourished.

And as a part of that, as a part of the dominant, it includes and assessment and it feels a little bit more complete and actionable. It means you know what actions are going to be taking place based on that, their status of malnutrition.

CO-CHAIR TRAVIS: Thank you, Jennifer.

Akin.

MEMBER DEMEHIN: All very helpful points to hear. I mean I am a little caught up in sort of this not necessarily a dichotomy but

when we are talking about malnutrition screening, we are talking about what a patient comes into the hospital with. And then the plan portion of it, the 372 is what you do once you know someone is malnourished.

From what I am hearing, there may be some pretty good evidence around there being downstream impacts on outcomes as the result of having that care plan in place but less certain that there is good evidence around just the act of screening and the act of documentation.

So, it still feels to me that there are enough questions about these measures and how they hang together and how they are packaged that a refine and resubmit sounds a little better to me.

I do think Jennifer raises a really interesting question, too, about so where does this fit in the overall constellation of issues that you would look at. Is this one of the most important things we can do to affect outcomes? And based on that we see here, it is not quite as

clear-cut as one might hope.

CO-CHAIR TRAVIS: Sean.

MEMBER MORRISON: Sorry.

CO-CHAIR TRAVIS: Dan is that you? I can't tell whose card is up. Oh, Lindsey.

MEMBER WISHAM: And just in regards to the comment about if I had to pick one, just based off of Angel's comment, I would strongly suggest not just picking just one, simply because if we pick one or we recommend one, there is going to be a whole host of implementation problems when it comes to actually identifying what data elements or codified data elements, rather, are we able to pull in.

I think there is somewhat of a cat and mouse game already with eCQMs, which is we specify the measure and then vendors and clinicians then figure out how to put it in some sort of a discrete field. So, it looks like -- again, I have not reviewed the exact data elements in this group of measures but it sounds like from the description because they feed into

each other you are, in essence creating your denominators for the next round of measures.

CO-CHAIR TRAVIS: Well, I think we have run the gamut. I think there is general consensus that nutrition and malnutrition is an important topic. However if it is within the whole measure set, I think is something else that would be important for us to kind of feel and be sure that it is one of the drivers.

And then it does appear to me that there are a number of questions about the measures, themselves, and how they hang together. And I'm still trying to get a better feel for what the Standing Committee's recommendations are.

It would seem to me we are going to vote but I have heard a lot about refine and resubmit, some of which is defined by what happens in the endorsement process but not all of which is having to do with the endorsement process. And that is what makes refine and resubmit different than conditional support.

Because if it went through and was endorsed, it would automatically be eligible for the program.

So, as you are thinking about the way you want to vote, just keep that in mind in terms of the difference between conditional support and refine and resubmit. Conditional support is if it goes to the endorsement process. If each of these goes through and they are endorsed, then they would be eligible with our recommendation. Our recommendation would be they are eligible for the program.

If we would like to see how they hang together and see what the ultimate results were, then refine and resubmit what would be what we would need to do.

So, we will go on with the vote.

Oh, I'm sorry. There is a question. David.

And then I realized I was talking about all three measures. We are going to vote on each of these measures separately, right? Okay.

MEMBER ENGLER: So, I just had one comment and it goes to the question of food insecurity. And how close of these metrics point to issue of food insecurity with patients that are being treated?

There is a hunger crisis in America that has wound up on the doorsteps of a number of the hospitals, in particularly in California, who are facing large amounts of food insecurity, especially when their supplies run out at the end of the month. And we know that because we see major spikes, hypoglycemic spikes and ED returns and high amounts of ED utilization at the end of very predictable times.

So, I am wondering, because I don't know the literature on malnutrition in these particular measures, whether or not they are picking up or there are other metrics that they can look at relative to issues of food insecurity, which to your point, are real drivers of negative outcomes, especially in the high rates of ED utilization.

CO-CHAIR TRAVIS: Thank you, a very important thing for us to keep in mind.

We are going to vote on each measure separately. So, the first one we are going to look at it is nutrition care plan for patients identified as malnourished after completed nutrition assessment, which is MUC16-372.

MS. QUINNONEZ: Voting is now open for IQR Program measure MUC16-372. Option 1, support; Option 2, conditional support; Option 3, refine and resubmit; Option 4, do not support.

Option 1, support; Option 2, conditional support; Option 3, refine and resubmit; and Option 4, do not support.

If we have anyone on the phone, if you could submit our votes, please.

Okay, voting is now closed. For MUC measure 16-372, 9 percent voted for support; 43 percent voted for conditional support; 39 percent voted refine and submit; and 9 percent voted do not support.

MS. MARINELARENA: So if it is refine

and resubmit, we need a rationale of the suggested modifications. This is a measure that is fully developed and tested and going through the NQF process.

DR. BURSTIN: One of the opportunities here says opportunities for improvement. And I suspect from the discussion, something along those lines.

CO-CHAIR TRAVIS: Yes, I mean I think that was the main thing was that the opportunities to kind of think about how they hang together and some of those issues that I am sure you recorded well conversation.

Ready?

MS. QUINNONEZ: Voting is now open for IQR measure completion of a malnutrition screening within 24 hours of admission. And this is MUC16-294. Option 1, support; Option 2, conditional support; Option 3, refine and resubmit; and Option 4, do not support.

Option 1, support; Option 2, conditional support; Option 3, refine and

resubmit; and Option 4, do not support.

Okay, all votes are in and voting is now closed. For the recommendation of MUC16-294, 13 percent voted for support, 46 percent voted conditional support, 39 percent voted refine and resubmit, and 4 percent voted do not support.

So, this yields a refine and resubmit.

Voting is now open for IQR program completion of a nutrition assessment for patients identified as at-risk for malnutrition within 24 hours of a malnutrition screening. This is MUC16-296. Option 1, support; Option 2, conditional support; Option 3, refine and resubmit; Option 4, do not support.

Option 1, support; Option 2, conditional support; Option 3, refine and resubmit; and Option 4, do not support.

Voting is now closed. For the recommendation of MUC16-296, 17 percent voted for support, 43 percent voted conditional support, 39 percent voted refine and resubmit, and zero percent voted do not support.

This yields a conditional support recommendation.

CO-CHAIR TRAVIS: Okay, thank you all very much for going through all of that with us.

All right, now we are going to go to Consent Calendar 9. Ron doesn't think I have done enough today so I'm doing two in a row.

So, Consent Calendar 9 is the tobacco use and antipsychotic and an influenza, and a safe use of opioids. So, we will be walking through those and if you will give me just one moment, I'm trying to be sure that I give you all the right information here.

Well, it was done but it was done for a different program. Here I go. We will. We will.

So, here we are. Okay, so the first one is tobacco use screening, which is MUC16-050. It comes to the Consent Calendar with a refine and resubmit. It is currently undergoing field testings. The field testing should demonstrate reliability and validity in the acute care

setting. The eMeasure needs to be submitted to NQF for review and endorsement.

Is there anyone that would like to pull this measure for discussion and vote? Okay.

The second one is use of antipsychotics in older adults in inpatient hospital setting, which is 16-041. It currently sits with a refine and resubmit. This is a newly developed eMeasure. It is fully developed and specified but it is currently undergoing testing. It is one of the reasons it sits here.

The testing results should demonstrate reliability and validity and then the measure should be submitted for NQF endorsement.

Anyone want to pull MUC16-041? Okay, Akin.

The next one is influenza immunization, MUC16-053. Oh, here it is. This is coming with a recommendation of do not support. I'm just going to read what is here but the Health and Well-Being Standing Committee acknowledged the importance of this hospital-

based measure but did not believe narrowing performance gaps were clinically significant in the chart abstracted version of this measure, which is already NQF-endorsed at 16-059. There was no data or evidence provided demonstrating that this eMeasure addresses a performance gap, essentially, in IQR. And Lindsey would like to pull this measure.

And then we have the safe use of opioids -- concurrent prescribing, which we did look at yesterday for a different program. And that is MUC16-167.

I have so many things I am keeping notes on, it is hard for me to find it. But I believe that this was seen in a hospital outpatient quality reporting and I believe it was a do no support in that program. And it comes into this program with a refine and resubmit on the Consent Calendar.

Anybody want to pull it? Lee and Sean. Okay, great. Thank you.

All right. If you all could see my

books and how many different pieces of paper I am trying to -- you would understand why I lose track. Everything gets updated along the way, too.

All right, let's go to our tobacco use screening, which is MUC16-050. And who pulled that one? Nobody. Sorry. Although, is there a comment?

Now, I know where I am. Is there a comment on that particular -- before we go with the Consent Calendar, is there a comment? And I think there is.

MEMBER DEMEHIN: Yes, just didn't pull it but did want to make a comment that, as we look at this kind of screening measure, we know that this is designed as an eMeasure. It makes sense to design it as an eMeasure. We know that some of the requirements around modified Stage 2 and Stage 3 include a requirement around documentation of smoking status. I think it is more kind of the overarching conceptual question of how much value we get from measuring this.

Even if we are capturing in the EHRs and the EHRs required to capture it, it is less clear exactly how much value this will add to the program measure set.

CO-CHAIR TRAVIS: Okay, thank you very much. Are there any objections to the Consent Calendar, which has that one item on it, which is the tobacco use screening?

Okay, hearing none, we will accept the consent calendar.

Now, we will move to those that have been pulled, use of antipsychotics in older adults in inpatient setting. And Akin, I think you pulled this one. Can you give us your rationale and then we will see if we have any comments from our lead discussants?

MEMBER DEMEHIN: Yes, I mean this is one where the staff recommendation around refine and resubmit may actually be the right one here. But as we looked at the denominator exclusions, it made us wonder whether the right groups were included. So, it basically is looking at giving

antipsychotics to anyone other than patients with schizophrenia, Tourette's, bipolar, Huntington's disease at the time of admission.

So, just maybe this is more a question for some of the clinicians in the room. Does that look like the right group? Are there any others that we should include.

And then some more practical questions around where the data come from. It is an EHR measure or it is a claims-based measure? It is an EHR measure. Okay.

So, I mean I guess our overarching question is are there any other diagnoses for which you might be prescribed an antipsychotic for a clinically appropriate reason.

Otherwise, I think refine and resubmit probably is the right category here.

CO-CHAIR TRAVIS: Yes?

MEMBER EISENBERG: PQA has developed an almost identical measure for outpatients. And we came up with exactly the same categories of exclusion that appear in this measure.

When we brought that measure before NQF, the only objections that we received was that there are some people that have seizures that could be excluded but it was felt by the endorsement panel, at that point, that those represented such a small number of patients that that exclusion should not be included.

CO-CHAIR TRAVIS: Thank you, Woody.

Frank.

MEMBER GHINASSI: Just a brief thing. The other one to consider is augmentation with depression and doses. So but many people looked at that.

But I think it is a good measure. I just wanted to make that comment. I think that my biggest concern is that often subclinical doses of antipsychotics in moderate and sufficient dosage to address any of these disorders are given for two things, agitation and sleep. So, I think this is a good measure.

CO-CHAIR TRAVIS: Thank you, Frank.

Woody.

MEMBER EISENBERG: Yes, I would just add that I would support this measure conditionally with an NQF endorsement. I am not sure what needs to be refined.

MEMBER ENGLER: Can you repeat that?

MEMBER EISENBERG: Yes, I don't think this measure needs refinement. I just think it needs NQF endorsement. I would support it conditionally.

MS. MARINELARENA: It's not tested. That's why it ended up in this category.

CO-CHAIR TRAVIS: And it doesn't -- let me be sure I am on the right measure. It has not been submitted for review yet, right?

So, if you look at kind of the way these decision categories cascade, it hasn't even been submitted yet. So, that is why it is in --

MEMBER EISENBERG: Good. I withdraw my comment.

CO-CHAIR TRAVIS: Okay. But it is good for them to know that that is how you feel. Okay, thank you.

Jack?

MEMBER JORDAN: Yes, I think one thing in this, too, as I have been starting to play with these, oftentimes with this, how they define the drug list. That EQM measure is usually in the RxNorm Codes, which aren't entirely stable and they also cause work statements for the people who are trying to maintain these eMeasures. Then, if they can actually be defined by a kind of pharmacy class methodology instead, those are much more stable and easy to build.

So, I think that is just a generic thing in how you are building these medication lists, that they are harder to build and maintain when the lists are defined by RxNorm Codes. There might be five or six thousand codes that you have.

CO-CHAIR TRAVIS: Thank you, Jack.

Lee.

MEMBER FLEISHER: More of a question because there is a lot of concern, questions about the right treatment with delirium

postoperatively. So the question is, there is actually more and more talk about how there will be an ideal agent, certainly not Benadryl, which is the opposite.

So, that is my only concern. When it goes to NQF endorsement, whether or not a diagnosis of delirium during the hospitalization should be considered potential exclusion. So, I still would say refine and resubmit.

CO-CHAIR TRAVIS: Okay, I don't see any more cards. So, I think we are ready to go to a vote on this.

MS. QUINNONEZ: Voting is now open for IQR program measures use of antipsychotic in older adults in inpatient hospital setting. And this is MUC16-041. Option 1, support; Option 2, conditional support; Option 3, refine and resubmit; and Option 4, do not support.

Option 1, support; Option 2, conditional support; Option 3, refine and resubmit; and Option 4, do not support.

Okay, voting is now closed. The

results for measure -- for MUC16-041, 13 percent voted for support, 9 percent voted for conditional support, 78 percent voted for refine and resubmit, zero percent for do not support.

So, this yields a refine and resubmit recommendation.

CO-CHAIR TRAVIS: Thank you. The next measure is MUC16-053, influenza immunization. And Lindsey pulled it.

MEMBER WISHAM: Yes, thank you. So, going back to one of the conversations we had yesterday in regards in an outpatient measure, we ran into the same scenario, where there was a chart-abstracted version of the measure and an eCQM version that was aimed for this. And I know we tried to keep ourselves in line by saying the measure is the measure. That is what we are looking at.

The rationale behind the do not support list is two-fold and I don't disagree with it, which is that the measure is nearing top value rate. It is an 84 percent and even so,

looking at if there was any data performance gap. However, I would like the committee to consider that if this could be a conditional support, based on the fact that if the chart abstracted measure does remain in the program, that the eCQM version of this measure would offer a potential reduction in reporting burden for people that were reporting the measure.

So, just looking at the measure for itself, aside that the performance rate is high right now, if this an option for providers or hospitals to report, it is an option. So, I am asking for folks to consider conditional support based off of that the chart abstracted measure also remains in the program.

CO-CHAIR TRAVIS: Thank you.

Any other thoughts or comments on this influenza measure? Yes.

MEMBER DEMEHIN: So, I guess from our perspective, one of the most important things to consider with these reporting programs is whether we are identifying the right topics for measures

and whether we are really focusing on the most important opportunities to improve.

I certainly appreciate the potential benefits of an eCQM version of this but it seems to me that in terms of looking at it in terms of whether we are going to advance all that much here, it is hard to see.

I think we want to send the message that we want to move quality forward and not just implement measures to demonstrate that EHRs are able to report on measures. I think it needs to be tied to something a little more than that.

So, I guess the thing that I am personally struggling with, so I'm taking the chair hat off, is if the chart abstracted version stays in, I mean this could replace the chart abstraction version, at some point, I am assuming but maybe I shouldn't assume that. Is that the intent that this would replace that, roughly?

Okay. So, we get back into that same dilemma we had yesterday with the measure. So, whether it is better to live with the chart-

abstracted version of it or replace it with the eMeasure, that is my major struggle with it.

Lindsey.

MEMBER WISHAM: Just that I think for consideration that as we look to give opportunity for successful eCQM reporting, this is an opportunity to have a measure that is straightforward and that has been well-tested and well-received, transition over, I guess from the chart-abstracted world into the eCQM.

Again, I don't discount that the performance rate is high. I am not disagreeing with that at all. It is just that I think this should be considered as an opportunity if this measure is meaningful to CMS and it is meaningful to patients as recognizing quality in a facility. I think it should be further considered to remain in the program and ask that it be replaced with the eCQM.

CO-CHAIR TRAVIS: So, I do have a question for the staff, perhaps. I mean this looks like -- and I am just looking at this one

sheet of paper I have, which summarizes it pretty briefly. It looks like it is done through the Health and Well-Being Standing Committee but they didn't believe that narrowing the performance gap was clinically significant.

So, I guess did they not endorse? I'm trying to figure out what they did with it.

MS. MUNTHALI: It was recommended for endorsement with reserved status because of the performance gap. The gap was narrowing. I think it was around 95 percent.

CO-CHAIR TRAVIS: So, I am sorry for this technical question. Was MUC16-053 that version, e-version, it was endorsed for reserved status out the gate?

MS. MUNTHALI: No, we haven't seen that one. We have seen the chart-abstracted one.

CO-CHAIR TRAVIS: Okay. All right, I'm sorry. The way this read, it was difficult for me to --

MS. MARINELARENA: So, here is a little nuance, just to confuse everybody. Okay?

So, the chart-abstracted version is one that has been recommended for reserve status because it is considered topped out by the Standing Committee. That has not been finalized. It still needs to go to member vote, CSAC, be ratified. So, it has to go through the entire process.

However, for the eMeasure, the eCQM that is before us right now, would not qualify to come before us because the chart-abstracted version that this is based on is topped out. So, it would not meet the NQF requirements of there is a quality issue. So, that would -- it would not. It would get voted down. It would not.

So, it would not be -- if you wanted to do a conditional support, it wouldn't be NQF endorsement. I'm not saying you couldn't do it, but that couldn't be a condition.

MEMBER WISHAM: I mean I guess what I was proposing was that the conditional support -- this should be considered if the chart-abstracted measure is intended to remain in the program, which, by looking at our spreadsheets, it is.

So, that was just a suggestion, again, to reduce reporting burden, just looking how applicable it is to the programs.

CO-CHAIR TRAVIS: Ron.

CO-CHAIR WALTERS: That leads to an interesting paradox. So, what I just heard, which I am still trying to think through is that there is no incentive for developing an eCQM version of a measure that is already topped out, regardless of how important it is.

So, the chart-abstracted version would sit there forever in reserve status and we would never have even an eCQM version in reserve status, which you know --

DR. BURSTIN: It's a fair paradox and we have talked about this a lot. We love paradoxes at NQF. It is our specialty.

But in this particular instance, if we know, for example, that a clinical area is topped out, we don't have any presuppositions that if you made it an eMeasure it would be any less topped out, do you? I guess that is one of the

basic principles.

MEMBER WISHAM: We would hope not.

DR. BURSTIN: You hope not but then it might -- but if you think, for now, we think truth for now is what you are abstracting, right? And the eMeasure shows a performance that is not topped out. Your first reaction is is because the eMeasure is not valid because, again, it is circuitous.

MEMBER WISHAM: It does lead to questions about parallel reporting of the measures in chart-abstracted versus eCQM. If there are discrepancies between the two reporting rates, is it that there is incorrect with the eCQM? Maybe not. Is it that there is something in a configured EHR that is not being reported correctly? Could be. So, it raises questions as to it might not have the issue with the eCQM, per se, because this one is you would say relatively ingrained within a clinical process already.

CO-CHAIR TRAVIS: And just because I have already admitted that I am challenged today

with all of the paper in front of me, is this measure in any other program? Okay. Okay, I didn't remember it being.

I guess the question from my perspective would be if it is in a quality reporting program, one of the things we would be looking for would be that it is still high enough up on the radar screen of the providers to want to look good and to do the right thing and to keep immunizations high.

The other piece is for consumer and purchasers for transparency for us to be able to use it. I guess that is the dilemma I come into, and this is my personal opinion, is that if everybody is at the same rates from a selection standpoint, it is not helping me.

I guess I could feel good that my hospital is at that rate and they are not worse than every other hospital but there is, even in that arena, being topped out I think does have implications for the value to the people who would be trying to use the data.

So, if anybody has any thoughts about that to help me with my dilemma, I would appreciate that.

You found some. Thank you. I knew where they would come from, too.

Brock.

MEMBER SLABACH: Yes, really it is my memory. No, I think that this is a real problem because if CMS is going to continue this measure, I would much rather have it an eCQM than in an abstracted form. So, I guess that is why I really would prefer this because that is where we need to go. But then NQF is saying that they are not going to consider that because it is topped out.

So, we are on a hamster wheel and it is --

DR. BURSTIN: You know one possibility is, regardless of the vote, your comment could still go forward. So, whatever you say, again, CMS is here. They are actually listening. So you could, regardless of what you ultimately vote

on include the comment that says if this measure remains in this program, please move forward and at least consider moving towards an eMeasure as an option.

CO-CHAIR TRAVIS: Marty? I did Marty before. I'm sorry. Oh, it was Greg. So sorry.

MEMBER ALEXANDER: I just have a process question, I guess, because I don't understand what happens if we keep this measure or if we let this measure go and we don't endorse it, then how do we know at some point that by not requiring the reporting that the vaccine's rates will drop? And maybe it is doing a good thing by being high. Maybe that is why we want it. I mean do we just stop measuring it because it is -- as output reaches 95 percent, are you dropping all your measures that reach that?

DR. BURSTIN: We do have a requirement that measures show a gap in care or show variation across providers if this is otherwise topped out without variation.

We don't drop it but what Elisa was

saying is it becomes an inactive endorsement with reserve status. And the idea would be these would not be the measures you would go to at first choice but you should do some sort of ongoing surveillance to make sure exactly your point that you are not seeing a decrement in performance.

Obviously, the eMeasure would make that a whole lot easier and that goes back to Lindsey's comment.

CO-CHAIR TRAVIS: Mimi.

MEMBER HUIZINGA: I would just add if we think about what CMS is trying to do on a broad perspective, if you look at the physician measures and the ACO measures in terms of immunization, trying to improve reporting to registries that would help improve the care, I would see having these as an eCQM in addition to reducing potentially the fraction burden as also being supportive of trying to have it submitted to those broader registers.

So, I think if you look across the

whole portfolio, it might make sense to have this measure as an option.

CO-CHAIR TRAVIS: Akin.

MEMBER DEMEHIN: So, I mean I actually do think part of our role as the MAP is to say whether we think something has enough importance to merit its inclusion in a program, regardless of how that measure happens to be reported. And to me, keeping a measure, even if the eCQM version is easier, and I think, frankly, there is a pretty significant switching cost to go into an eCQM that would have to be factored into the conversation as well, but retaining a measure like this, to me, feels a little bit like going back to the future and not really advancing quality forward.

I think looking to include eCQMs in programs, I certainly agree that that is a good goal but really to focus the development efforts around something more fruitful, I think would be great. Like tetanus, for example, to me feels a lot more like a topic that would merit exploring

an eCQM and potentially implementing one in the future, rather than a measure that has been around for years and that has already been topped out.

CO-CHAIR TRAVIS: Okay, Andrea.

MEMBER BENIN: I will just, I guess, just make a couple comments. You know as far as metrics that are potentially even feasibly measured well electronically, this one has potential to be in that category more than many others. I think certainly more than, I'm sorry, the sepsis measures, which are frightening to think of in an electronic format.

So, if we were to want to place value on the typed in metrics that may be more readily measured electronically, this would fall, I think, into that category.

I will also say, and this is at least an opinion, I don't necessarily have fact, but I would assume that if this metric were to be withdrawn from the measure set, that the performance would drop because there is a

substantial -- and I don't know that -- there is a pretty substantial amount of activation energy that goes into getting this done but is not inconsequential. And even some of the hard stops that may have been written into various computer things are so painful that there is a lot of work that is going into getting this done. Maybe not just in pediatrics, I don't know. But it is pretty hard to achieve this and so people have hardwired it in various ways but there is a lot of resource going into that.

So, if we think that this is important, then I think we may need to make a decision that we should keep this metric if we think this is an important enough thing to do. Frankly, immunization is one of the few things we actually do in healthcare, I guess.

But if we don't think that this is important or that because you can easily screen out. Like this measure doesn't mean you get a flu shot. It just means you get screened for a flu shot. So, it is not even that powerful of a

tool. In some ways it is and in some ways it isn't, speaking, again, to the commentary about registries and the other things, which is really where we should be putting our energies in this country but that is a different conversation.

So, I guess I would just make those comments. That depending on how important people consider this, it probably is important to keep it in the measure set and that it is something that could be amenable to being electronic, whether it is the right place to put our resources. And maybe we could put our resources somewhere else because I don't think that the abstraction burden in this bowl full of abstraction burdens is the hardest one either. So, it is a little bit of six of one, half dozen of the other.

CO-CHAIR TRAVIS: Thank you. Greg, you still have yours up.

MEMBER ALEXANDER: I just wanted to say so I work in the long-term care world, like I said, so there is some redundancy. Because then

Nursing Homes Compare, which has over two million patients across the 16,000 nursing homes in the country, they have vaccination reporting there. And those immunization rates are up around 95, 96 percent across the country.

So, that sort of validates these results, I think a little bit, too.

CO-CHAIR TRAVIS: That's helpful. Lindsey.

MEMBER WISHAM: Just one final comment, which is I think if we were to transition this to an eCQM and the performance were to remain as high as they are now, which we would hope would be the case, that because it is already going to be implemented as an eCQM would make it an ideal measure for surveillance. Even if it were just kind of put off to the side and not necessarily used in the program, hopefully by that point, by that time, the capabilities are already built into electronic health records to be reporting with the CDC.

CO-CHAIR TRAVIS: So, Lindsey, taking

what you just said and kind of the earlier conversation you had with us around conditional support, to you mind sharing with us what your thoughts are about your recommendation on where we come down on this measure?

MEMBER WISHAM: So, it is a little bit different how we have been treating conditional support, which is take it to NQF because, as Helen points out, this is not one that would be eligible for that process. I guess the condition I would place on this conditional support that if the chart-abstracted measure were to stay in the program, that, to me, tells me that CMS finds this an important measure and that the eCQM should be a reporting action with the idea that potentially then performance rates are stable, that the chart-abstracted measure could be removed.

So, conditional support and that the chart-abstracted measure is deemed to be important and ultimately in the program.

CO-CHAIR TRAVIS: Okay, I think

everybody heard that clearly. Is there something we are huddling on over here?

MS. LEMONS: Hey, this is Tara Lemons. May I add a comment?

CO-CHAIR TRAVIS: Yes.

MS. LEMONS: Yes, I just wanted to clarify. I think there was a comment about the IMM-2 measure not requiring vaccination but it does require vaccination prior to discharge, if indicated by the screening. So, I just wanted to make that clarification.

CO-CHAIR TRAVIS: Thank you.

All right, well, let's move forward. If people feel comfortable with the way that Lindsey phrased the condition, let's consider that to be the rationale if you decide to vote for conditional support. So, we will vote for all of these measures.

Marisa, do you have a comment?

You want to read it?

MS. MCQUESTON: A brief comment from Marisa Valdes at Baylor Scott & White that they

would support the CMS moving to the eMeasure for several reasons, testing of the validity as a possible replacement of the chart-abstracted measure.

CO-CHAIR TRAVIS: All right, so now we have had an opportunity to hear from everybody. It is important not to forget our people on the phone. So, thank you, Marisa.

Okay, so, let's go to voting.

MS. QUINNONEZ: Voting is now open for IQR program measure influenza immunization, IMM-2 and this is MUC16-053. Option 1, support; Option 2, conditional support; Option 3, refine and resubmit; and Option 4, do not support.

Option 1, support; Option 2, conditional support; Option 3, refine and resubmit; and Option 4, do not support.

Thank you, Marisa. Thank you, Jeff.

Voting is now closed. The results of the influenza immunization, MCU16-053 16 percent voted for support, 68 percent voted conditional support, zero percent voted for refine and

submit, and 16 percent voted for do not support.

This yields a conditional support recommendation.

CO-CHAIR TRAVIS: Okay, thank you all very much.

So, our last item on this Consent Calendar is the safe use of opioids -- concurrent prescribing MUC16-167. And I believe that Lee and Sean pulled this.

Lee.

MEMBER FLEISHER: I do not support; ditto from yesterday.

CO-CHAIR TRAVIS: Sean.

MEMBER MORRISON: Ditto.

CO-CHAIR TRAVIS: All right, Woody.

MEMBER EISENBERG: I would just like to point out the importance, again, of trying to limit as best we can the combination of opioids and benzodiazepines for sure. Real killers.

And if this measure could be refined to just focus on that combination, I would vote for a refine and resubmit.

CO-CHAIR TRAVIS: Okay, thank you, Woody. Greg, do you still have a question? Okay.

That's okay. Jack.

MEMBER JORDAN: I would like to make one suggest or comment to CMS and that would be I think this is something that maybe very ripe to have some selection of in hospitals or QIOs really start to get a little bit of feel for how much of when this is happening it is really problematic and not thoughtful use of the medications and how often it is really thoughtful.

I think we would learn a lot from them. I think some people might pick up some things that might, without having pressure of a public website from CMS, you know ranking hospitals on that, may very well get the end results you are really looking for in kind of an alternative manner.

CO-CHAIR TRAVIS: Thank you, Jack. Any other comments before we vote, having

discussed this issue yesterday?

Okay, I think we are ready.

MS. QUINNONEZ: Voting is now open for IQR Program safe use of opioids -- concurrent prescribing. And this is MUC16-167. Option 1, support; Option 2, conditional support; Option 3, refine and resubmit; and Option 4, do not support.

Option 1, support; Option 2, conditional support; Option 3, refine and resubmit; and Option 4, do not support.

Okay, voting is now closed. The results for MUC16-167, 9 percent voted for support, 4 percent voted for conditional support, 26 percent voted for refine and resubmit, and 61 percent voted for do not support.

This yields a so not support recommendation.

CO-CHAIR TRAVIS: Okay, well, thank you all for that.

Now, we have done a little bit if shuffling about our schedule because we know we

are close to our time that we are going to end today and we know you have flights.

We are going to have a call where we are going to go over the other programs and get feedback. We can do that, we think, over a conference call. So, we will get that scheduled.

But before you pack up, we do have some comments that Pierre would like to make about the Cures Act and I think that would be very helpful to us. So, thank you.

DR. YONG: Great, thanks, Cristie. So, I just wanted to -- we referenced this yesterday. I just wanted to make sure that folks were aware of a provision in the 21st Century Cures Act relating to the hospital readmissions reduction program.

So, this is relating to Section 15002 in the Cures Act, which pertains to adjustment for dual eligibles in the readmissions reduction program. We didn't have any measures for the reduction of readmissions program this year but it has been in prior years, last year, for

example. It has been a hot topic in terms of risk adjustment and what it is really about, SES.

So, I just wanted to make sure you were aware of the legislation that is currently and signed by the President, since he supports the bill.

It requires stratification of the hospitals in the readmission reduction program by status of full eligible dual -- full dual eligibles. So, if folks are familiar with the MedPAC report of I don't know there it was 2013 or 2014 but where they did the analysis looking at what people call right to life hospitals. So, compensate hospitals that have similar proportions of SES patients, in this case, the Cures Act specifically calls out use of dual eligibles. So, that would be the stratification variable that would be used for a calculation of the human adjustments for HRRP.

That is sort of the main provision. The other provisions relating to that, although our program would remain budget neutral, there

are also some provisions in there relating to consideration of exclusions for certain conditions, consideration of use of certain V codes, as well as potential consideration for any recommendations that come forth on this particular topic.

CO-CHAIR TRAVIS: All right, thank you.

Operator, would you see if there are any public comments on the call?

OPERATOR: At this time, if you would like to make a public comment, please press star 1.

And we have no public comments, at this time.

CO-CHAIR TRAVIS: Any public comment in the room?

Okay, well, I am going to turn it over to Kate to talk about what our wrap-up and next steps are.

Sounded like a drum roll for Kate.

MS. MCQUESTON: It must be time for us

to go.

So, we will be in touch regarding scheduling our call to discuss the current measure set shortly.

I just want to thank you again for all of your input into the discussion today and to thank our wonderful co-chairs. Thank you very much, Cristie and Ron.

And please feel free to be in touch with us with any questions in the meantime and we will be back in touch with everyone shortly. Thanks, again.

CO-CHAIR TRAVIS: And thank you to the wonderful staff. We couldn't have done this without you, clearly. So, thank you all very much and thanks to all of you.

(Whereupon, the above-entitled matter went off the record at 2:41 p.m.)

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C E R T I F I C A T E

This is to certify that the foregoing transcript

In the matter of: Measure Applications Partnership Hospital Workgroup In-Person Meeting

Before: NQF

Date: 12-09-16

Place: Washington, DC

was duly recorded and accurately transcribed under my direction; further, that said transcript is a true and accurate record of the proceedings.

Neal R. Gross

Court Reporter