NATIONAL QUALITY FORUM

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MEASURE DEVELOPER WORKSHOP 2016

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WEDNESDAY
MAY 4, 2016

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The Workshop met at the National Quality Forum, 9th Floor Conference Room, 1030 15th Street, N.W., Washington, D.C., at 9:00 a.m., Wunmi Isijola, Moderator, presiding.

PRESENT:
KELLY ANDERSON, The Lewin Group
AMY BENNETT, JD, American Academy of Neurology*
ALICIA BLAKEY, MS, American College of Radiology
KYLE CAMPBELL, PharmD, MS, Health Services Advisory Group, Inc.
PRIYA CHATTERJEE, MSPH, The Lewin Group
CINDY CULLEN, MBA, Mathematica Policy Research
LINDA DAILY, Livanta LLC
MARSIDA DOMI, MPH, American Healthcare Association
TRICIA ELLIOTT, MBA, The Joint Commission
JEFFREY GEPPERT, JD, Battelle Memorial Institute
SHARON HIBAY, RN, DNP, Livanta LLC
WANDA JOHNSON, RN, MS, Oklahoma Foundation for Medical Quality
MEGAN KEENAN, MPH, Health Services Advisory Group
BRIGIT KYEI-BAFFOUR, MBA, The Lewin Group
LAUREN LEMIEUX, American College of Obstetricians and Gynecologists
KATHY LESH, PhD, Battelle Memorial Institute
COLLEEN McKIERNAN, MSPH, The Lewin Group
SUZANNE POPE, MBA, American Urological Association

MATTHEW POPOVICH, PhD, American Society of Anesthesiologists
MELANIE SHAHRIARY, American Heart Association
SAM SIMON, PhD, Mathematica Policy Research
ZACH SMITH, MBA, American College of Radiology
KATHERINE SOBEL, National Committee for Quality Assurance
NAILA WAHID, The Lewin Group
ANN WATT, MBA, The Joint Commission

NQF STAFF:
HELEN BURSTIN, MD, MPH, Chief Scientific Officer
JASON GOLDWATER, MA, MPA, Senior Director
KIM IBARRA, Project Manager
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MARCIA WILSON, PhD, MBA, Senior Vice President
REVA WINKLER, MD, PhD, Senior Director

ALSO PRESENT:
KRISTEN BUTTERFIELD, MPH, Pharmacy Quality Alliance
KAREN DORSEY, MD, PhD, Yale YNHH Center for Outcomes Research and Evaluation (CORE)

*** Present via teleconference**

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Adjourn

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

8:56 a.m.

MS. MUNTHALI: Good morning, everyone. My name is Elisa Munthali. I'm Vice President for Quality Measurement at the National Quality Forum.

We'd like to welcome you to this Measure Developer Workshop. We have a number of measure developer partners that are here in the room at NQF, but many others that are also joining us virtually.

We just wanted to thank you so much for your participation, not just today but throughout everything that we do. We can't do our work around measure endorsement, measure selection or measurement science without you. Your input is very valuable to us, and so we just wanted to collectively say thank you.

So I'm going to turn it over to Wunmi Isijola who's our Administrative Director, who's going to go over the meeting objectives, a few housekeeping notes, and go over introductions.

Thank you, again.

MS. ISIJOLA: Thank you, Elisa.

Good morning, everyone.

So this is day one. I'll be your MC for the next two days. But again just to echo what Elisa mentioned, we want to thank you again for just working with NQF. A lot of the work that we do is largely a part of what you do and how you interact with us.

Over the next two days, we'll have a series of discussion items. It's meant to be interactive, asking for your feedback in a lot of the work that we do, commentary, and any questions you may have, because this is for you. I know this is something that we've done in the past, so we really value your input in the work that we do here.

Before we get started, I just want to introduce our maintenance team. So as many of you know, we have a portfolio of over 600-plus measures that you partially take part in, but we can't do without our maintenance team. So I'm

actually part of that team: Wunmi Isijola, Jean-Luc Tilly, many of you know Reva Winkler in the back, Sarah Sampsel, and obviously Elisa Munthali. I also want to pay tribute to Helen Burstin, our Chief Scientific Officer.

So today, I just want to go over just some of the objectives that we'll be talking about today. We'll take a look at our strategic plan. Helen will go over what we've been doing over the past couple of months of really looking at the work that we're doing and how we can revamp some of the objectives that we have internally as an organization.

We'll also be looking about the work around our measure incubator. I know two years or so ago, we mentioned that we were piloting this, and now it's actually live and real. So we'll go over just some of the work that we're doing there.

Also, something that we've been diving into, our tool-based measurement, understanding and discussing some of the challenges there.

Another item is just a refresher on our eMeasurement. Many of you have been involved in that work and many of you are beginning to get into that work, so we're just going to provide a refresher, but also an introduction to those who may not be as familiar with how we look at eMeasurement within NQF.

And lastly, something that we've really been diving into as of late is our measurement science work. We have a ton of projects in that area, and it's really starting to ramp up. So we'll have some of our staff to go and review some of the work that we're doing there and kind of where we're landing there.

And ultimately, throughout the day we'll ask for comments, questions. There are mics at the tables, so if you do have a comment -- not interject, but please raise your hand and please participate.

We also have those who are on the phone. Please provide your comments in the chat box and we'll call on you. Throughout the day,

we'll also have an opportunity for a public commenting session. So we want to make sure that those on the phone, although you're not here, you're able to participate virtually as well.

And before we get into it, I actually want to know who's in the room. So I know we have table numbers. We want to just ask everyone to introduce yourselves very briefly and tell us what organization you're from.

So Maureen, at Table 1?

I'm going to skip Table 2 because that's all staff.

Table 3?

MEMBER DOMI: There we go.

This is Marsida Domi with American Healthcare Association.

MEMBER ALMENDINGER: I'm Katherine Almendinger. I'm also with the American Healthcare Association.

MEMBER KEENAN: Megan Keenan with Health Services Advisory Group.

MEMBER CAMPBELL: Kyle Campbell,

Health Services Advisory Group.

MS. PHILLIPS: Ann Phillips, NQF.

MEMBER JOHNSON: Wanda Johnson, OFMQ.

MS. ISIJOLA: Great. Thanks. Table 4?

MEMBER LEMIEUX: Lauren Lemieux, American College of Obstetricians and Gynecologists.

MEMBER LESH: Kathy Lesh, Battelle Memorial Institute.

MEMBER GEPPERT: Jeffrey Geppert, Battelle Memorial Institute.

MS. JOHNSON: Karen Johnson, NQF.

MS. ISIJOLA: Great. Table 5? Oh, I'm sorry.

MEMBER DORSEY: Karen Dorsey, Yale CORE.

MS. ISIJOLA: Thanks. Table 5?

MEMBER SMITH: Zach Smith, American College of Radiology.

MEMBER BLAKEY: Alicia Blakey, American College of Radiology.

MEMBER POPOVICH: Matt Popovich, American Society of Anesthesiologists.

MS. SAMPSEL: And I'm Sarah Sampsel with NQF.

MS. ISIJOLA: Table 6?

MEMBER DAILY: Linda Daily. I'm with Livanta.

MEMBER HIBAY: Sharon Hibay, Livanta.

MEMBER MILLER: Amy Miller, American College of Rheumatology.

MEMBER SHAHRIARY: Melanie Shahriary, American Heart Association.

MS. ISIJOLA: Table 7?

MEMBER POPE: Suzanne Pope, American Urological Association.

MEMBER McKIERNAN: Colleen McKiernan, the Lewin Group.

MEMBER ANDERSON: Kelly Anderson, the Lewin Group.

MEMBER KYEI-BAFFOUR: Brigit Kyei-Baffour, the Lewin Group.

MEMBER BERNS: Samantha Berns, the

Lewin Group.

MEMBER WAHID: Naila Wahid from the Lewin Group.

MEMBER CHATTERJEE: And Priya Chatterjee from the Lewin Group.

MS. ISIJOLA: Great. The Lewin table. Thanks. Table 8?

MEMBER ELLIOTT: Tricia Elliott, the Joint Commission.

MEMBER WATT: Ann Watt, Joint Commission.

MEMBER SOBEL: Kat Sobel, the National Committee for Quality Assurance.

MEMBER SIMON: Sam Simon, Mathematica Policy Research.

MEMBER CULLEN: Cindy Cullen, Mathematica.

MS. ISIJOLA: Great. Thanks. And I do have some NQF staff on this side. And Reva, and then Jason Goldwater.

MR. GOLDWATER: And Jason Goldwater, NQF.

MS. ISIJOLA: Great.

I know we have a bunch of people on the line. Just to ensure that we capture them, I'm actually going to read the participants who are on the phone who may or may not have joined yet.

Janna Barry from NCQA, Amy Bennett from AAN, we have Noni Bodkin from CMS, Yvette Bodrick from the Lewin Group. We have Michael Cima from Healthcare Management Solutions, Christina Compher from Healthcare Management Solutions, Del Conyers from National PACE Association, Amy Cowell and Lauren Cricchi from the Lewin Group. We also have Madison Davidson from the Lewin Group, Hiral Dudhwala, Quality Insights of Pennsylvania, Nancy Dunton from the University of Kansas Medical Center School of Nursing, Woody Eisenberg from Pharmacy Quality Alliance.

We have Alexis Estomin from the Lewin Group, Angela Flanagan from Lantana, Sana Gokak from ACC, Zuhal Heidari from IMPAQ International,

Christina Hielsberg from American Society of Anesthesiologists.

We also have Karla Lopez de Nava from the Lewin Group, Jane Lucas from WVMI & Quality Insights, Vy Luong from the Lewin Group, Lisa McGonigal from Kidney Care Quality Alliance, Erica McNamara from American College of Surgeons, Kaden Milkovich, Arbor Research Collaborative for Health, Naureen Mullani, the Lewin Group, Marilyn Parenzan, the Joint Commission, Lynne Perrine, Lantana, Jackie Ryan, American Academy of Orthopaedic Surgeons, Sharmila Sandhu, AOTA, Lucille Schacht, National Association of State of State Mental Health Program, Carl Scheffey, National Hospice and Palliative Care Organization, Kathleen Shoemaker, American Heart Association, Donna Slosburg from Ambulatory Surgery Center Quality Collaboration, Carol Spence, National Hospice and Palliative Care Organization, Monica Weir, Intellicure, Inc., Jenna Williams-Bader from NCQA, and Elizabeth Denton from ACC.

So again, thank you everyone for those who are in the room as well as those who are joining us virtually. Again, this is meant to be interactive. Questions, comments, feedback warranted throughout the next two days.

And with that being said, I will turn it over to Helen Burstin.

DR. BURSTIN: Thank you, Wunmi. It's a pleasure to have you all here today.

It is actually interesting. I've been reflecting on the numbers of years now that we've done this meeting. And the very first year, it was all in the room because it was actually easier to travel, I think, not as many restrictions, especially for those covered by Feds. And interesting how there are twice and many people online as there are in the room.

So anyway, we're delighted to have you, however you're here, virtually or in person. And we hope it will be a good couple days.

So, the first thing I want to do is actually give you a little bit of some insights

into the release of our recent strategic plan. This just came out. Some of you who were at our national meeting heard some of this. So I'll just be really brief.

I mainly want to talk about it today to give you a sense of how you can work with us to really do some of this work. It is not anything we would do alone. All of these are quite collaborative activities, and we really are going to need your insights for that.

Before I do that, I do want to -- Kathleen Gillen, quickly just said her name in the back there. I just want to introduce Kathleen again in the back in yellow. Kathleen is our new Senior Vice President of our new department. So we've already got Quality Measurement, which Iliaci and Marcia lead.

And Kathleen is the Senior Vice President of our new department called Quality Innovation. And it's where our incubator will be housed, where the National Quality Partners will be housed, and any of this other sort of

different kind of work that doesn't quite fit into the measurement world, and obviously lots of collaboration between the departments. But we're really thrilled to have Kathleen join us and I'm glad she could be with us this morning.

So back to the strategic plan. This is just our very high-level view of what sort of the current state is around measure development and measure use.

So it's a pretty linear process. There's a process you guys go through of developing measures, measures then flow into us. We're more of the passive taker of measures as they come forward to us, both in terms of endorsement as well as the selection piece around MAP. And then magically somehow measures are implemented. We don't know very much about that piece of it and actually from our experience dealing with many of you at maintenance, many of you don't actually have a whole lot of information about the implementation of your measures or the performance of your measures in

the wild, as we say.

So part of what we're really trying to think about is how we drive a future state that's much more oriented towards really being about collaboration, and I'll show that in a moment.

But really this being a cycle of how we think about what the most important measures and gaps and accelerate the development of those needed measures, how there's a clear piece of this that isn't just about endorsing and selecting but frankly reducing measures because it's hard to bring in new measures when people feel very overwhelmed by measures they don't feel add value. And it's probably the number one thing we hear, and I'm sure you guys do as well, of why do I still have to do those measures that really don't feel like they help me take care of patients better?

The idea of trying to prioritize and drive that implementation of those prioritized measures, and really importantly that last box in this picture, we don't have any way of having

good feedback on this. We don't know that sort of what happens to the measures piece.

So we'd like to have as part of our role here thinking about how we facilitate feedback of what works and also what doesn't, both in terms of measurement, how measures are used, performance of measures to really ultimately think about how we drive measurement that matters to improve quality, safety and affordability as really being our focus going forward.

So certainly the piece of this that relates to endorsement and selection is still there, but I think that will evolve and change as this changes. And really, as we think about it, it's about how can we help provide leadership here, prioritize and most importantly, particularly with you guys in this room, this is about collaboration.

Nothing in that cycle is something NQF can go off in a corner and do by itself, nor should it, but instead, we really do see this as

being something we do with all of you. How do we expand your influence, our influence, to try to make this happen at the same time building on really a growing foundation of making sure at the same time we advance the measurement science? And that we don't try to re-adjudicate at our tables these sort of sticky issues like attribution and variation and risk adjustment but actually come up with some principles that we can all agree to and work upon.

So one of the very first things you'll see coming out in the next few months is we will be focusing on a prioritization exercise to come up with a set of criteria of how we would prioritize the most important measures, we've got a whole scheme how to get through this -- as well as prioritize the most important gaps. And some of that logically feeds into the work of the incubator but also into your work as well. So lots more on that to follow.

I'm going to stop there before we turn -- the incubator is such a logical continuation

of this that we're going to roll right into the incubator. But I want to stop and see first of all if any NQF staff or Iliaci would like to add anything, or anything questions from the room, or actually online. You guys are welcome to speak as well.

(No audible response.)

DR. BURSTIN: All right. Well, we'll have lots more time to socialize this with you. It was really just a chance for us to give you a high profile, sort of a very high level view of this.

But it will very much drive our work in the next one to three years. We didn't do a vision that would go out ten and 20 years. I think our field is so dynamic at the moment, it's hard enough to figure out what's going to happen in six months much less five or ten years. But we recognize we needed to change and make this critical pivot. So much more on this to follow.

I think with that, we're going to flow into the incubator. We're going to tag team this

and Jason will go first, and I'll come back up.

MR. GOLDWATER: No vests. It's the spring. I retire the sweater vest in April which my wife is greatly appreciative of.

So it's great to see all of you. Some faces I haven't seen in a while and I'm really happy that all of you have significant experience in measure development because that means I can reduce my normal spiel by about ten minutes, which I'm sure everyone is tremendously grateful of.

So what I want to talk about is the measure incubator, which I know a lot of you have heard about and some of you may have actually sat in on some of the discussions that we've had.

The incubator was launched just about a year and a half ago. In fact, I think it was made official the day after I started. So my first day at NQF was fill out all the necessary paperwork, as you all know, which you have to do on your first day, and my second day was, your entire calendar is filled, and this is all you're

going to be doing. And for the most part, this is pretty much all I've been doing since I have been here.

What we're going to talk about -- and we're probably going to try to limit the presentation to about 20 to 25 minutes because I think we're anticipating there may be quite a few questions and some points of clarification we'd like to give.

So we're going to talk about the need for the incubator, why this project was initiated, what the incubator actually is, current status after it was launched last year, and then we'll open it up and try to take your questions.

So why was there a need for an incubator? So I've given this presentation, as has Helen, many, many, many times. And so I generally start off this way -- which is again, all of you have been in this area for a long time. So if you can remember back in the -- I don't know, mid-90s, and I realize that there are

some people that can't think back that far, and that's fine. But in the mid-90s, we were all trying to solve the conundrum of how we actually measure an outcome.

And now we flash forward to 2016, and I can't exactly say that we've completely solved the problem, but we have certainly become much more adept at creating measures to look at outcomes in a variety of ways. And as a result, there are well over 2,000-plus measures in existence, 600 of which or more are actually NQF-endorsed.

So you would think logically, with all of those measures, that every clinical area and concept has been covered. And of course, all of you know, that's not the case, and there are still plenty of areas that need measurement.

And the current measurement process, again as all of you know, and it's so delightful that all of you know this already, is somewhat lengthy and takes time and can be expensive. On average, although we have no hard data to support

this, it generally takes anywhere from two to three years to develop a measure and can be upwards of half a million dollars for a single measure. And that assumes that through the course of the measure's application partnership and CMS that they actually agree that the measure needs to be created and fund a project as such.

So that is why the measure incubator was developed. It was really to look at unfulfilled measurement needs -- looking at major measurement gaps across healthcare and understanding that even in the environment that we live in where there are so many measures and so many CDP projects that they're not consistently achieving measures that matter -- outcomes, resource use, and in particular, patient-centered. And we've noticed since the incubator was launched that there's been a tremendous amount of emphasis on patient reported outcome measures.

Of course, measurement complexity has intensified and has grown. There are

methodological challenges, such as SDS risk adjustment, which I'm sure Sharon can't wait to talk about, informatics challenges which is how the information gets from an EHR or a registry or an EMR into a system in which it could be adequately and accurately reported, there are clinical challenges, and then there's patient-centered challenges.

If you want patient-reported outcome measures, you actually have to have patient data. And how to get that patient data has always been to some extent a challenge even though the opportunities for getting patient data now are probably greater than they've ever been.

And that equals major barriers to measurement innovation. It's expensive. Half a million dollars is a lot of money for one measure. It's time-consuming, as all of you know. Two to three years for a measure, and a lot of that is in the testing phase.

And it's difficult to access appropriate test beds for innovative measures,

particularly when it comes to eMeasures, because the current policy of NQF is what? This is a pop quiz. You will have to leave if you don't know the answer.

No, Ann, you can't -- all right, I'll answer this one.

All right, so the current policy is that if you want to submit an eMeasure to NQF, that it has to be tested in at least more than one EHR system or two. So it has to be tested in at least two. And you would think oh, that's not a problem at all. That is difficult. It's difficult to find sites with different EHR systems and to be able to get enough data to be able to adequately report on the reliability, the validity, and particularly, the feasibility of the measure.

Some examples of priority measure gaps -- and this is not a comprehensive list at all. This is just a sample of them, such as adverse drug events, Alzheimer's disease, behavioral health, diagnostic accuracy, palliative and end-

of-life care, patient-centered care planning, and particularly patient-centered reported pain and symptom management, as Matthew is aware because of conversations we've had before.

So the NQF measure incubator, what is it? It is not a thing. I can't tell you -- I've done this speech a number of times and people are actually well, where is it? It's not a physical entity. There's not a locked room in this building where we open it up and oh, there's an incubator in there.

You do, right? There's a retinal scan you have to view before you actually enter my office. Right, Helen.

All right, so how do we actually use it? It's a process, a process in which we have actually brought together numerous different entities and stakeholders to help accelerate the development of these measures.

NQF -- and I have to say this every time I do this presentation and you all know it's coming, we don't develop the measures. Let me

say that again. We do not develop the measures. But what we do is we are a matchmaker, a yenta of sorts, for those who speak Yiddish. We bring together the right entities to help develop that measure.

We bring together somebody that has a concept. How do the projects come to the incubator? Somebody comes with a topic. It could be just a broad topic, acute pain management. It could be measures that they've actually already developed. It could be concepts that they need to bring into measurement. Or it could be fully developed measures that they just need to be tested and they can't find the appropriate test beds to do so.

And those measures could be eMeasures, they could be outcome measures, they could be patient-reported outcome measures, or they could be across cost efficiency and value.

So we find that topic, that entity that wants to develop a measure. We MAP up to the appropriate developer, that developer that

has the expertise, the interest and the knowledge to develop the measure accurately.

Then where it gets interesting is right here, because as I just told you, and most of you already know this, that the measure development right now takes so long and is so costly because of the data that is needed.

So what we've done is we've contracted -- well, not contracted, but we have somewhat of stable data partners that have significant data assets that could be used to test the measure. Optum Labs at the moment is our biggest data partner. They have the entire United Health Data Warehouse. In addition, they've also acquired Anceta, and so they have the whole electronic data warehouse which is data from roughly about a dozen EHRs.

So you have the topic. You develop the measure, assuming the measure isn't developed already, and then we map up the appropriate assets to test the measure within this environment within this process -- again, not a

physical thing but within the process itself.

And then with the appropriate level of funding to do all of this, we then eventually move to a measure that matters, that ultimately improves patient care and outcomes.

The measure incubator is an environment for innovative measure development. Our process here, what we try to do, number one, is to facilitate. Bring together those people with ideas with measures of the resources they have to see those concepts turn into measures without going through the more elongated process that we currently use.

We have continuous access to robust data through a number of data partners and we believe the rapid acceleration of leveraging data at the point of development will create a more efficient and effective process for development that will take far less time than it currently does.

What are some of the project types that can come into the incubator? And I talked

about this briefly. Measures that need specification testing. Somebody has an idea. We want to do a measure on multiple chronic conditions. Okay? What are you thinking about? I don't know. But I just want to do one on multiple chronic conditions. Okay. So we take the idea, refine the topic, try to build it into a measure.

Measures that only need testing. We've gotten plenty of these. Measures that are fully developed, testing is really becoming a barrier. They need to access those data sources or a defined concept that needs development through testing. You can use the incubator based on your individual needs. There is not -- it has to be this and it has to come out this way, it really depends upon the nature of the project.

Our role here, again, don't develop measures. And what's really important to understand is that NQF does endorse measures, as Helen told you, but the incubator does not serve as a fast track for endorsement. So just because

you put a measure in the incubator doesn't mean it's going to be endorsed. That's important to remember. Endorsement is a separate and independent process away from the incubator.

We are a subject matter expert, we fill prioritized gaps, we provide guidance into the eMeasure input and output formats, and we convene leading experts to help shape the measure with the current and most recent data.

We facilitate the process. Again, we match the appropriate stakeholders, organizations, and people, and we understand and contract with the right data providers to ensure the right data assets are there at the point of development.

And with that -- I got to do all the fun stuff, now Helen gets to do the controversial stuff. Love how this job works. There you go.

DR. BURSTIN: This isn't controversial stuff. I got to finish something up which was -- always makes me happy when you get to check something off your to-do list. Not that you guys

should be double processing, but I've heard this talk a few times. So I get a chance to do that.

So one of the biggest questions that comes up when we've talked about the incubator over the last couple of years is really this issue of conflict of interest. So we've actually worked pretty hard to come up with a clear set of conflict of interest policies. We actually have an incubator advisory council including people like Carolyn Clancy and Jed Weissberg and Mike McGinnis from IOM and Bob Galvin, who's on our Board, and others, just to help us think this issue through.

So as a starting point, we have asked them to focus on three key issues, one of which is conflict of interest policies around funding, project priorities, and as Jason just mentioned, the issue of relation to the rest of the process.

So, funding, really important one, put it up front, and this was one of the very first questions at the incubator design session we had. We will accept funds for general incubator

activities or specific projects. In fact, our design session was generously funded by a pharmaceutical company, AZ. But funders cannot specify project outcomes, they cannot influence discussions for projects that are funds, and really importantly, we tried to set up some clear areas where no funding would be accepted.

And again, this is something we will continue to evolve, but just to put a starter point in the ground of where we are. First, we will not accept funding from a funder who has an exclusive interest in a product or activity relevant to a project. So for example, if there is a drug that Company A makes and they want to come forward and have a measure that says for Condition Y use Drug X, no, we would not do that. Not appropriate. Nor would we ever do any development of a measure that names a specific product.

And as you already heard from Jason, we really view this as a place to do some of the more difficult innovative measures. So frankly,

a good number of those sort of classic process measures we don't necessarily think we would add very much to. And so we won't necessarily go to that place.

Project priorities, again, I gave a little hint towards this. We will prioritize emerging measurement areas where measurement is really needed, like the patient-reported outcomes, the eMeasures, identify national gaps which ties back to the brief introduction I did to our strategic plan. We will prioritize those national gaps in the coming year.

We want as much as possible, although not exclusively, whenever possible to get a measure that can be used by the broadest swath of patient groups, diseases, and settings. There may be some very condition-specific measures and one of the measures being incubated is a PRO-PM for COPD. But in general, we're also going to try to incubate, for example, more general PROs around fatigue or pain or physical functioning.

And again, this is NQF. We are, at

the end of the day, a membership organization, and we will have priority for organizations who are organizational members of NQF to participate.

And very importantly, whatever the project is, we will ensure that the projects will solicit input from the target population. So this PRO-PM being developed by Minnesota Community Measurement through the incubator very clearly has woven in patient input and patients from the get-go for a patient-reported outcome measure.

Lastly, and I think also very importantly, and Jason hinted at this, we want to be very careful about guarding about any potential conflicts of interest between endorsement and incubation. So I'll say it one more time, we will not develop performance measures. We will not serve as a measure developer. We will not serve as a measure steward. That is never our intent.

In all the projects we have going to date, and I'll show you, on none of them is NQF

anywhere near that space. Others take that role. We help facilitate this process.

That being said though, we may provide high-level subject matter expertise, but we'll not engage in measure development. So for example, just yesterday, Jason and I had a call where the developer, some of you may know, who's done a lot of work in ICUs, and the question was how do we convert these measures to eMeasures?

So we had that conversation trying to get a sense of the kind of data he would logically need, where that measure might go, but not anything where -- if he starts developing that measure and we try to get him both resources as well as a data set, we kind of take three steps back. It's like that development has started. That is not our place. We will not play that role.

And lastly, incubator measures have no conferred advantage in the endorsement process. Our COI policy has been extended so that any committee members at a table that involve

incubation of a measure are also recused from discussion of that measure, and lastly, making it very clear, if that ICU measure comes forward, I will recuse myself, and I won't even be in the room, for example. So we will extend that policy as well to any NQF staff who may have participated in any of those very early stages of incubation.

So that being said, a little bit of where we are, so project's underway. One of our first data partners has been Optum Labs, although we are looking at other data partners as well.

And part of the effort in that first year has really been trying to really establish this proof of concept. Do we believe that giving developers data from day one with a concept and allowing you to kind of have this, as they affectionately refer to it, a sandbox of data for you to iteratively look at -- change your measure, change your concept and move it forward, is that going to make a difference? And if so, how?

So these are examples of three projects that were -- actually four projects we're doing right now through the incubator.

University of Maryland, Eleanor Perfetto who many of you know in her role at PQA and now at another group -- the National Health Council. They've been looking at inappropriate prescribing for patients with Alzheimer's and related dementias.

AARP has helped to fund and is participating in the incubator for doing two new measures, one of which is looking at more measures around Alzheimer's. They're particularly interested in caregiver burden, although we haven't yet figured out data sources to do that. But a very interesting new project focused on how you define the population of patients who live at home and are homebound and what their care looks like and what outcomes you would look at for that patient population. That's led by Jeff Leff at Hopkins who's been one of the leaders in that movement.

But again, one of the hardest things, you imagine sitting down and trying to come up with measures like this, how do you even define who's homebound? So they've spent the first few months looking at data from both EHR as claims data longitudinal to really try to get a handle on can you even define the denominator, as you start thinking about what would be the key efforts around the numerator?

Mayo Clinic is kind of doing a bit of a precursor to a measure, which is beginning to understand are there phenotypes of patients with multiple chronic conditions? And they've had some discussions with the folks at Yale who have done some of this work, trying to say, if you put certain constellations of co-morbidities together do you get very different risk than you might just by adding them up or throwing them all in a model? So trying to be thoughtful and understanding of that going forward. Very neat work there.

We're also doing work with

PatientsLikeMe, a group in Cambridge that has a very large patient online platform and something called their Open Research Exchange, which allows us to work closely with patients as they develop tests and move forward PROs. We were actually going to have the folks from PLM come today but they could not so they sent me a quickie update of a couple things I just want to share.

So part of what they're doing is really testing this idea. Much of what we talked about to date has been testing the idea of having data all the way through the process. How does that change things?

What we're really trying to think about in terms of the PLM work is how does having patients all the way through the process, from the initial concept, all the way through testing, data, all the rest of it, how does that change that work?

And we've been doing these exploratory scans they've done with their members, but also just a huge number of stakeholder interviews.

And almost everybody they've interviewed has clearly said that measurement is necessary, particularly for patients, to make that link between cost and quality that they're often being asked to make.

So we've been very much pushing on the idea of PROs. And what they've said is the most commonly noted area that the patients want is the most timely, actionable and interpretable data that patients and clinicians can use to make decisions.

So again, we're hoping this will drive some of the way we'll develop PROs going forward and we're now working with them trying to determine which will be the first set of PRO PMs that we'll test through their open research exchange.

Ben Heywood from PLM has indicated although he couldn't be here today, he'd be happy to talk to any of you who'd just like to get a sense of how PLM could work with you on this.

And lastly, I mentioned the Minnesota

Community Measurement who are now developing and testing a PLO-based performance measure for COPD through the incubator with funding from GSK that we have helped facilitate.

So, we had a great design session and I recognize many of you were in the room for that as well, last month. And the idea was to bring together stakeholders across the perspective. We had developers, implementers, funders, users, supplier and industry, I mean truly a panoply of everybody who is NQF and otherwise, to give us strategic guidance and some initial input on this idea, kick the tires. If the basic approach makes sense, what should we do differently?

And really what came out of this was very strong support that we should continue on this path. We should really try to help facilitate the measure incubation process as best we can.

In fact, they went beyond part of what we had been talking about which was incubating selective measures and trying to meet some of

those gaps but instead thinking of a broader vision of creating this measurement learning collaborative, where we would have developers have a chance, in some ways like this but more formalized, to share lessons learned, not repeat the issues people have done over and over again.

And really importantly, create this pre-competitive space, even at the concept level, before you're kind of out trying to get funding for something, kind of really have a chance among all of you interested in pain, for example, to sit down and talk it through -- have us help facilitate that as well as share those lessons learned in development and testing, and as Jason mentioned, strong interest in this matchmaking role for us. In fact, it became quite amusing of the names for this.

But the idea that we would create a portal or a platform that people could come forward with and say I have an idea, I have data, I have expertise in the following things, and I have funding. So it became sort of the joke, you

know, it was like eHarmony for eMeasures and eMeasure match.com -- oh, I guess we're in org, eMeasure match.org.

But the idea would be, could we create this platform where you could come forward and say I'm the Joint Commission, I have expertise in hospital-based measures, I have growing expertise in eMeasures, and the Joint Commission's national priorities for this year are pain and two other things, and then others could come forward and say we are a funder and we're really interested in pain management. And somebody else could come forward and say, we have longitudinal data that looks at patients across the inpatient to the outpatient experience over two years. Anybody want to use it? And could we start helping to make some of those arrangements?

So now as a last step here, we are now going to be setting up two working groups to keep this process going, to keep this stakeholder engagement and thinking about how we can best facilitate this process and really kind of kick

off this idea of a learning collaborative.

So there are two groups. I think many of you got this note. If you didn't, feel free to still let us know today. We're going to be setting up a partnerships and collaboration group and a data and testing group.

I think that's all. That's the email address for the incubator, and happy to take some questions. Please, Ann?

MEMBER WATT: Helen, do you see the -- I realize that the incubator is completely separate from the consensus development process, but do you see the gaps that are identified by those standing committees feeding into the incubator?

DR. BURSTIN: Absolutely. And actually part of the process of this initial stage of work for the strategic planning is actually gathering up all -- we actually now have an Excel spreadsheet, it's quite long as you might imagine, of all the gaps identified through MAP as well as all the standing committees.

And as we develop their prioritization criteria, we'll prioritize the gaps and the measures. And those would be a natural feed in. Absolutely, Ann. Yes.

MEMBER POPOVICH: This is Matt with the ASA.

Just two questions on kind of the structure of the examples that you gave, with entities that are part of the incubator right now.

In those examples, who kind of leads the process and who's the project manager? Who takes the lead, because if you have a flat, horizontal structure, you know, who's responsible for what? So is there a project manager or a project lead on those items, and who supplies that?

And then the second part is if these concepts are spending a lot of money, how does the contracting process work between the different entities as in those examples and NQF's role on that?

DR. BURSTIN: Yes. I'll let Jason answer this.

Well, at least the project manager in part there has been a sort of joint project management. There are elements of it NQF helps to manage the process flow, but then once the development is happening, obviously the developer takes the lead.

MR. GOLDWATER: Right. So for the PatientsLikeMe project, for example, so if Helen is the subject matter expert on this, and I'm managing the project along with a representative from PLM, and we both facilitate that together and Ann Phillips, who's right there, is the staff that's been assigned to work on that project.

Contracting, so Nicole, do you want to talk about the contracting? This is our Chief Operating Officer.

MS. SILVERMAN: Hi, I'm the person that gets to do all the contracting.

So I think each situation would be a little different, but what we are doing is

typically contracting with each party. So we would contract with the measure developer, and we might contract with the funder, and we would contract with the data entity. But if the measure developer was bringing some of that, obviously we would just contract with the measure developer.

So it's going to be flexible as we see what the best structure is that will not impede the process.

DR. BURSTIN: Thanks. Other questions?

MEMBER SIMON: So I had a similar question to what Ann asked, sort of -- maybe the flip of that.

I was wondering if -- sorry, I'm Sam Simon from Mathematica. Is there a formal linkage between measures that have been discussed by the MAP and the incubator staff? In other words, if I come to the incubator and I want to develop a measure and it's already maybe been discussed by the MAP, is there sort of that

feedback loop that says well, wait a minute, this has already been discussed, or is that more incumbent upon the measure developer to do that work?

DR. BURSTIN: It's a really good question, Sam.

I think you're all going to bring up issues we haven't really thought through fully yet, but I think the idea would be we would bring whatever to the table we can and I'm really glad to see Reva standing up because she's clearly got a much better answer.

Go ahead, Reva.

(No audible response.)

DR. WINKLER: Okay, oh, it's green here. Okay. They're usually red.

Tomorrow we're going to have a session on what we've doing over the last year to integrate the CDP process and the MAP process.

The whole incubator addition is something still to be considered because we are generally assuming that the measures that are

coming to the MAP are at least fairly close to finished being developed.

And probably the incubator has some role, yet to be determined, but we certainly have developed communication pathways between the MAP and the CDP to provide avenues to bring measures into one or the other, and we see it as circular and very much interactive. But we'll be talking about that tomorrow.

DR. BURSTIN: And just to add to what Reva just said, I think it's a really good point, there are measures as you guys know who live in -- you live in the MUC, right? You live in the Measures Under Consideration world.

We have seen a tremendous increase in the number of measures that are truly concepts that are on the MUC list that are at very different stages of development. So some of those that come in at a conceptual level that have a thumbs up like continued development, that would be a measure that's got some broad support out there.

So again, if there is an opportunity, that's a prioritized measure and we can think of some resources to make that happen.

Particularly, I think, what we often hear from developers is especially for some of the newer innovative measures the rate limiting step is getting good test beds.

So it may be if a measure has made it up to that point and it's gotten some support, and there's clearly a need to use it, and you just can't get the test beds and we can help facilitate just getting the test beds and moving that forward, we'd be happy to participate again at any point during the path.

It doesn't have to be a brand new de novo concept that comes to the incubator. You guys have lots of ideas about measures you've been working on and what we repeatedly hear is how difficult it is, particularly for PROs and other kinds of measures, to get viable test beds. So we will be working.

Also Jason and I have had lots of

conversations with the folks at the National Test Bed Collaborative and trying to think about how we kind of bring those streams together to make it as easy for all of you to find test beds as possible.

MS. ISIJOLA: Amy Bennett has a question.

DR. BURSTIN: I'm sorry. Let me take the one from the phone. Okay.

MS. ISIJOLA: Amy?

MEMBER BENNETT: Hello. We were wondering how stakeholders are invited to participate in projects, and if during the process if funders are responsible for identifying the appropriate parties involved in the project, what role does NQF have in stating there's a potential conflict that the right individuals were not invited onto the project?

DR. BURSTIN: That's a great question, Amy.

So I think the idea would be that's why we're trying to create this open portal so

that we in fact get everybody's information up front.

This first year of it has been somewhat -- you know, here's a project that comes forward, here's some interest in a particular line of work. We, for example, knew Minnesota Community Measurement had done a lot of PROs, and I knew they were interested in COPD so we literally put the two of them together and that seemed to work.

But we don't want it to just be something where it's those of us internally thinking of somebody at Point A who could work with somebody at Point B. We'd prefer to know who's out there and put that together.

The developers -- I mean, I'm sorry, the funders would not identify the rest of those players. We really see that as part of NQF's due diligence to put that together. They may have suggestions, but it certainly would not be the driving force.

I'm sorry. Sherry, go ahead.

MEMBER HIBAY: So is there going to be, in this open portal, in the vein of transparency, is there going to be an opportunity for you to be sharing whatever the spreadsheet is that you have of ideas? I mean this week we all hopefully have taken a look through the quality measurement plan that's out there and tried to understand what opportunities are out there.

Just the whole process, what are the funding opportunities? What are the concepts that are there?

I do recognize that there certainly is a proprietary nature to some of this information as well, so I'm not sure if all of it is shared that's in the incubator, or if pieces of some of the measure work is done behind a screen or not.

So is there some sort of mechanism that you're going to have that people can look up information at all varying different levels?

DR. BURSTIN: Yes and again, some of that is to be built. We don't have the resources yet to do some of that work. We would like to

have that portal.

But again, we're being fully transparent. There's not a single measure we're talking about looking at that is not open. I think the only things we haven't yet talked about are literally where we're in early stages of discussion with funders who often don't want to have the fact that they are considering funding something out in the public domain until it's happened.

Other than that, I think once the deals are done, we will post everything and again, once we have the ability to have the portal in place, we might hopefully have that chance for you to share that.

Anybody -- I don't know if Kyle or Katherine or Nicole has anything to add, but feel free.

Katherine -- so they can't hear you. Only because it's a webinar so they can't hear you unless you're loud enough.

MEMBER ALMENDINGER: Yes, I

understand.

I was just sharing, Helen is spot on there. We are still in that early build phase but this is the type of forum where these types of questions are all being brought in-house for us to include as we build out the process.

But again, the transparency is going to be critical there so I would hope that as we get further along in the process, we'll be able to release more information. It's just very early still.

DR. BURSTIN: Yes and I think that transparency we have and everything else NQF does will extend to the incubator. We don't see this as something that would go behind a wall.

Any other questions online?

No audible response.)

DR. BURSTIN: Okay. Any other questions in the room?

(No audible response.)

DR. BURSTIN: All right. Are we good?

All right, back to Wunmi. Thanks,

everybody.

And we'll be here if you guys want to have some quick sidebars of ideas or thoughts or things you don't want to say necessarily to the whole group. Please share feedback, share ideas, also share what you think you might want to do. What have been your pain points as we've been looking for data partners? What kinds of data do you need? Things like that.

And we'll probably -- I think one of the things that's being developed is sort of a questionnaire of the kind of data people need to help guide us towards appropriate test beds.

But it is remarkable from that -- just lastly from that design session we had, how many groups at the end of it said I am willing to put forward my data. And they'd never been asked. So, you know, a health information exchange said I commit to putting forward my data. Some other groups said I commit to putting forward my data.

So again, I think some of this is, can we just be helpful by pulling the strands in?

Anyway, your support obviously is something we're going to need to make this real. So thanks.

MS. ISIJOLA: Thank you.

I see that we're kind of a bit ahead of schedule so we'll take about a 15 minute break, and we'll come back and we'll start with the tool-based performance measurement.

(Whereupon, the above-entitled matter went off the record at 9:54 a.m. and resumed at 10:12 a.m.)

MS. ISIJOLA: Okay, everyone we're going to ahead and get started again. So if you can take your seats. There will be plenty more opportunities for networking engagement, especially during lunch.

So, and just housekeeping items. We do have a recording happening and a transcription so when you are commenting could you please state your name so that we have that on record. That would be great.

And with that being said I know we're

ahead of schedule, but I'm going to turn it over to Sarah and we'll talk about tool-based performance measurement. Sarah?

MS. SAMPSEL: Well, thank you. And I was just asked to extend this, but good God. I don't think anybody wants this much of an extension.

So, what I do want to encourage is any questions, comments, et cetera.

This is an example of something not totally dissimilar to the incubator in that we're working through it. We're trying to figure out how do we apply some of the NQF standards and criteria when we're talking about tool-based performance measurement. And I will define that as we get on.

Just anecdotally, I was at NCQA for about six years developing HEDIS measures and focused on things like behavioral health, musculoskeletal child health, obesity, et cetera.

And I always made sure that I was never working on CAHPS health outcome survey or

anything having to do with patient-reported outcome because those were the tough measures.

So you know, years go by, I'm at NQF and it's all come back to haunt me. And it's kind of a joke now. They're difficult. Just give them to Sarah. Now it's really kind of hurting me to some degree, painful, but I've also learned a lot from it.

So our goal here today is to kind of share some of our experiences with tool-based measures such as CAHPS health outcomes survey, the FIM, the CARE tool, et cetera, bring it all together to explain their similarities, but then talk about how do the criteria work with those types of measurement because we are experiencing some challenges not only internally in interpreting criteria, but then in externally explaining, gosh, what did you guys just do.

So, I just want to get some misconceptions out on the table as well, and then allow an opportunity for discussion, questions, answers, et cetera.

So, I really talked about this a little bit, but I do want to describe nuances in measure submission requirements when the data source is a survey, assessment, or tool.

And I do want to bring that back to that is what we're talking about as the data source.

This was really kind of an interesting conversation and I don't want to embarrass you, Helen, but I might.

We were in Helen's office a couple of months ago discussing all of this in preparation for the CSAC and we just couldn't get Helen to understand the kind of data that we were getting in and why it was confusing us so much.

And so finally we said --

DR. BURSTIN: I just had complete clarity, that was --

MS. SAMPSEL: It was her moment of clarity of, Helen, the survey, the CAHPS, whatever, the question on CAHPS is our data element. That's the interpretation here.

And so when you think about it at that granularity and you walk through the NQF algorithms it opens some doors to questions. So that's what we're trying to clarify here.

That is what we're trying to do is promote clarity of interpretation of the evaluation criteria for tool-based measures, not just PRO-PMS but beyond PRO-PMS.

We recognize we have some updates that need to be made to the NQF criteria where we pull out specifically -- and if your measure is a PRO-PM we expect the following. It should actually be true for all tool-based measures.

And then identify opportunities to promote education and understanding of the NQF requirements.

As I said in the very beginning we're working on this. This is where we would really love to hear from some of you on what are those education opportunities and how do we explain this so that you all understand it and we get out of our heads.

So, why are we having this discussion? Because there are a lot more measures derived from surveys and assessment tools that are being submitted.

Measures derived from CAHPS have been around for quite awhile. I think those started in 2007-2008.

But since that time I've had entire projects of 25 to 28 measures all PRO-PM based, or all instrument-based, whether they're clinician-assessed or otherwise such as the CARE tool which CMS has been working on, the FIM.

We currently have CoreQ which comes out of AHCA and looking at those measures and how they are interpreted into performance measures.

And I think you'll see more as the incubator work, and Jason continues to work with bringing folks together in that matchmaker role some new novel measurement.

And so we did an off-cycle project on patient activation where the PAM is actually the instrument or the tool, so it's the PROM or the

patient-reported outcome, but that's not the performance measure.

We also have some measures coming through on shared decision-making and informed consent which are really kind of on that edge of how do we look at these a little bit differently.

So, continuing on why are we having this discussion. Because we're learning all of this. Because these challenges have created themselves and introduced themselves into their projects we want to hear from you. We want to share with you kind of the way we're going up front versus on the back end to see if we can get ahead of this a little bit.

We feel that greater understanding should promote consistency within NQF as well so that if a PRO-PM goes to person- and family-centered care it's going to be treated the same if it goes to any other standing committee.

And again that comes from clarity, understanding and education.

And then again these measures are

being reviewed across projects. For a little while up until I would say just a few months ago people would say oh, it's a PRO-PM, it has to go to person- and family-centered care.

No, it really doesn't. There are some condition-specific PRO-PMs so let's spread the wealth here and allow other committees to look at these as well.

So, as Helen's talked a little bit about, Jason has talked a little bit about, we're at this point in measurement where there's tons of measures. The low-hanging fruit is gone. And to really get to this sweet spot of outcomes measures, cost measures, but really value to patients we have to hear from patients.

Whether it's patients like me, whether it's the Minnesota community measurement measures, but what is it that's of value to patients and then where does that data come from.

Well, I would hope it comes from patients. So that's really where we're moving toward I think overall in the measurement

industry.

And then therefore the NQF criteria need to move along as well.

So, some examples of tool-based performance measurement. I've already mentioned -- and these are examples of measures that have come through person- and family-centered care over the past couple of years.

And I think the kind of story here, the lesson here is an apple's not an apple's not an apple when it comes to tool-based performance measures, that we're really looking at a lot of different opportunities here.

So gains in patient activation scores, that is a PRO-PM. It's a patient-reported outcome on where are you. Are you activated as a patient. Have you been working on a team with your provider or your provider team to actually show a change in your education level which in result shows increased knowledge and then better management of your own care.

Average change in functional status.

And we have a full litany of functional status measures right now. In fact, I think we approved 28 of them.

And these are clinician-assessed. So, this tool, whether it's using the FIM or the CARE tool, and in this case these are Minnesota community-based measurement tools, it may be the Oswestry Pain Index. It may be something else. But they're clinician-assessed. But the rules are the same when you're looking at a tool-based measure, whether it's patient-reported or clinician-reported.

So, as new measures are developed to assess patient outcomes and drive towards person- and family-centered care we really see this trend continuing.

I have not read the new CMS development plan. I apologize that I didn't stay up last night to do that, but maybe tomorrow.

This is just really important and really in looking at and hearing our colleagues from CMS present, et al, over the past frankly

year and most recently presented at the National Kidney Foundation over the weekend this is what they're talking about. How do we get to patient-centered measures. So we really do have to understand kind of your needs for this, but then NQF needs as well.

Really just kind of -- this comes out of a PRO report that NQF released in 2012, examples of types of patient-reported outcomes, health-related quality of life. There are a couple of health-related quality of life measures in COPD, some in ESRD.

Symptom management. So, talked earlier, and Jason identified the fact that there are gaps in pain management, and reports of pain, and pain follow-up. Pain is a symptom.

Function. We're seeing lots and lots of function measures. Whether you're in a health system or otherwise.

I was at the Cleveland Clinic over the summer and basically they were talking about how do they get a handle on assessing function and

change in function.

And that is what we're talking about here is not only doing the functional assessment, but then figuring out what is the change, has there been improvement, or are there tweaks that need to be made to a treatment plan.

Satisfaction with care or symptoms. That really goes back to CAHPS, but we're seeing more and more surveys, whether it's a nursing home survey that is not CAHPS or other opportunities to really find out what matters to the patient in part of their care.

I think what we're hearing some in the industry about as well is how do we hurry up that process a little bit in that you don't get CAHPS results till a year after a patient has been discharged.

How do we know what's going on right now?

And I do think we're going to be seeing more of those over time.

But not only that, and I think I

should mention here is when we're talking about patient-reported outcomes we're also talking about families and caregivers.

Some of these surveys do need to go there, especially when we're talking about hospice, or we're talking about patients who can't report for cognitive issues. All of that comes into the same bailiwick of being a source of data or information.

Just kind of a couple of other examples. And these are classic examples.

I know when folks come to us and say I need an example of how to fill out your forms because I have a PRO-PM we tend to use this example a lot in the measures related to the PHQ-9 because they were some of the first and at the forefront where what Minnesota Community Measurement originally did was have a simple process measure - percentage of patients who have completed a PHQ-9.

So you have that uptake. You have people using the tool, or the assessment item, or

the survey, whatever, but then you transfer that.

So the patient-reported outcome is symptom. The measure or the tool is the PHQ-9. And then we have PRO-PMs based on this.

So, the percentage of patients with diagnosis of major depression or dysthymia, initial PHQ-9 score and a follow-up score in looking for change over time.

We're seeing more and more and more of these measures.

And that's what we're pushing people too. When people come to us with another process measure about just filling out a tool we actually ask them have you thought about getting to the PRO-PM. Have you thought about getting to your outcomes measure.

A lot of them have thought about it. They don't know how to do it. Great person to send to Jason. Just drumming up business for you, Jason.

Another example is the kidney disease quality of life instrument, or the KDQOL-36,

which is measuring things such as general health status, burden of kidney disease, some symptoms.

It also has -- it actually has integrated into it the SF-36.

We have some potential options for performance measures. But right now the endorsed measure is percentage of dialysis facility patients who have a completed KDQOL-36.

Coming through endorsement right now. We're pushing them. They're going to have a conversation with the standing committee to talk about how do we transfer this to an outcome measure. How do we help get you there. What do we need to get you there.

And just another example is the CAHPS In-Center Hemodialysis Survey. Just different thoughts and examples of different types of measurement when we're talking about PRO-PMs.

The CAHPS In-Center Hemodialysis Survey, very similar to the other CAHPS surveys. So similar constructs.

But when it was brought into NQF we

started recognizing, okay, people think we're endorsing the survey. We're not endorsing the survey. We're endorsing the measures derived from the survey. So that's what we have to talk about when applying the criteria.

If you haven't seen it, kind of a great example of a report, and this was again released in 2012, is NQF released a report on patient-reported outcomes.

Got a bunch of really smart people in a room talking about what does this mean for criteria, what does NQF want to look at, how you translate, what makes not only a good PRO, what makes a good tool or instrument, and then how do you turn that into a measure and what are those criteria.

So this is available on the NQF website. I suggest you go out and look at it. Helen?

DR. BURSTIN: The book is actually on Amazon. It's been made into a monograph by David Cella.

MS. SAMPSEL: And you can find it on Amazon for $15. I'm not sure if that's an advertisement for NQF or Amazon at this point, but David Cella is a very smart man, so.

And I don't expect you to read this, but frankly for some of us who are in this world this is almost our bible in kind of talking about what is a PRO, how do you translate that into an instrument.

And I'll get to this in a few minutes, but we're really expecting some scientific acceptability and integrity of the tool before you ever get to the PRO-PM.

And that's what's really important to us.

So before a PRO-PM comes to NQF we're really hoping you make it through steps 1 through 6 and are able to prove that you have a reliable, valid instrument to turn it into the actual performance measurement.

Because again, that PROM is your data element.

So, understanding the challenges. These next few slides were presented to the CSAC I guess a month and a half ago or so trying to get their feedback on this and make sure that we're going in the right direction.

So this is kind of a testing ground. We did the CSAC first. You all now have an opportunity to react to this as well.

So, as I just described probably in way too much detail is we've started to experience some challenges.

But in listening to the industry, in listening to questions that come up, things that come through public comment we recognize that there's still this perception that NQF endorses the CAHPS surveys, or we endorse the FIM, or we endorse the CARE tool.

We do not endorse tools or surveys. While there might have been some questionable things that happened a number of years ago that makes it look like that, there may even be some things out on the web that says this is an NQF-

endorsed survey.

That was never the intent. We endorse measures. So just, Jason, anytime he talks, we do not develop measures. We also do not endorse tools.

So, that's my thing that I say over and over and over.

What we're seeing though more and more as these tool-based measures are coming forward, as the PRO-PMs come forward, when developers are filling out their measurement information form, filling out their little forms in OPUS, they're still setting up the description to make it look like we're endorsing a survey.

You're going to start seeing some pushback from us on that to say, you know, we'd really like you to consider phrasing this a little bit differently so that it becomes clearer when somebody pulls this up in the quality positioning system that we are endorsing a measure and not the tool.

I think where some of this confusion

has come about as well is, so, if you come to us with -- so the CAHPS nursing home measures. I think it's 11 measures. It's all one data element, one data set, all of the items off the CAHPS nursing home survey.

We allow you to submit one submission form for that, but that's because you have the same level of analysis, all of your denominator is technically the same, realize there are some skip patterns involved in there.

But really, why would you fill out 18 forms for the same survey-based measure?

That does sometimes require a little bit of back and forth between staff and the developers. There may be some reasons that you may not want to do that if your evidence differs for one section of your survey compared to another and you don't think that one section of the survey is going to make it through.

Or as an example we have a measure coming through that has nine CAHPS-related type measures on it.

One of the survey items that reports in to a measure, reliability is 0.18. Can we really endorse the entire set of measures if you have one piece of it at 0.18? I can tell you my standing committee is going to say no.

We don't want the entire survey-based set of measures to fail. We want to help you. At the same time we want you to think about how you submit those.

And that is an appropriate back and forth between the CDP team that you're working with.

So, again, a satisfaction survey is not endorsed by NQF. CAHPS is not endorsed by NQF.

It doesn't matter what anybody else's website says. This is an NQF-endorsed survey. We don't endorse surveys.

I will tell you though the CSAC fully kind of embraced this and so it really is something that we might want to think about.

So, I'm going to pause there just for

a minute and see if anybody has any reactions to the NQF does not endorse surveys.

MEMBER POPOVICH: So, this is Matt with the ASA.

I guess what I'm -- in the process of the endorsement, or in the endorsement process is it kind of like a joint measure steward developer who comes forward? Have you ever had an experience where the product designer of the survey and the measure developer are in the room asking for endorsement in the process?

Is it ever brought forward in a joint manner?

MS. SAMPSEL: The survey or the measure?

MEMBER POPOVICH: So, let's say that somebody develops a measure using a product, right? A specific product. A specific survey.

Is that a joint measure steward, joint developer process? And even though you may not be endorsing a product, I think of the NQF incubator, that is a product as part of the

measure.

And so I just wanted to know what the dichotomy was between, say, using a survey product and then bringing a measure forward.

DR. BURSTIN: It's actually a really good question, Matt.

So, we've not seen to date, for example, the developer of a tool come forward with the developer of the measure based on that tool jointly for endorsement.

That being said we do have endorsed measures that include tools that are named and out there.

So for example, the depression measures include the PHQ-9. Minnesota Community Measurement does not hold the copyright on the PHQ-9, but that other group has given them permission to use it.

We've seen lots of other examples. You guys have used HSCUS. Minnesota has used -- these names are crazy -- HSCUS, Oswestry.

So, I guess one of the key questions

over time is will there be an example where one of those tool developers themselves rather than measure developers like yourselves who would want to embrace that tool inside your measure.

It gets complicated. But we have not seen that so far. If anybody has any thoughts.

MEMBER HIBAY: This is Sharon Hibay with Livanta. In a previous life when I worked as a CMS contractor we developed the measure for depression screening and follow-up.

And we had language in there that the tool itself had to be standardized and validated.

So, I'm feeling like there's a fine line here. We know we don't endorse the tool, you don't endorse the PROM, but is there some sort of criteria?

I was just trying to look at the criteria as well online. There is a nuance there to understand what is the level by which the tool is either standardized validated, or you're looking at the data itself to make sure that the information or the results from the testing of

your tool, not of your measure, of your tool, make it acceptable to be able to get it to that next phase so you can move into measure development. There is a nuance there.

DR. BURSTIN: Yes. And actually, the NQF pathway from PRO/PROM to PRO-PM makes that exquisitely clear, that steps 1 through 6 don't even have anything to do with the measure yet. They're about asking audiences is this an important outcome to you. Then testing the tool and seeing if it's useful.

So way before you get to the measure -- and I think that one of the questions that came up and the reason we had this back and forth argument for so long was in some ways are we holding PRO-based PMs to a higher standard. Because in some ways you have to have testing of both the tool and the measure. So is that a higher bar.

There was never any intent that we would make it harder for PRO-PMs to come forward. But at the same time you want to have assurance

that whatever performance measure you're doing is built on a foundation of a reliable and valid tool.

So this is why we'd really like your thoughts on this.

I'll also mention I'm going to the ICHOM meetings in London in a couple of weeks, the International Collaboration on Health Outcomes Measurement.

So, for years they have been saying this is all the measures across all these different topic areas.

And I kept on saying well, those are really tools. Those are not measures in a performance measure sense of the world.

So we're actually going to have one of the first discussions they've had at ICHOM about PROMs for accountability because not exactly something they've made that leap to think about.

And then how would you use that to assess the performance of different providers.

So I would just love your thoughts.

I mean, is this too high a bar? Any thoughts about how we could be helpful here?

But it is hard to imagine you could have a measure based on a tool when the tool itself has not been judged to be reliable and valid.

MS. SAMPSEL: Well, and I think, Sharon, that's a really good question too.

But what we're seeing on our submission forms is actually an over preponderance wealth of data on the tool and very little data on the performance measurement.

And so there's not been any problem in establishing the reliability and the validity of the tool, but when it comes to the performance measure which is what we're endorsing, correct, then there's not always the testing of the measure.

So that's kind of one of the things that we want to clarify as well. And we'd be looking for feedback on how do we do that.

Because as Helen said if you go

through stages 6 through 4 we have to assume by the time we get to step 7 and 8 and we have a PRO-PM coming to us that it is based off a reliable and valid tool.

But it does seem to be extremely nuanced in how to interpret that into the criteria so you all know what to put in the forms as well.

Any other questions or comments?

MEMBER CAMPBELL: Hi, Kyle Campbell from Health Services Advisory Group.

I have a question that relates back sort of to this topic related to the incubator as well.

So, we've been looking at developing PROM-PMs for CMS. And one of the barriers I think that we're encountering is the proprietary nature of some of the tools that are indeed valid.

So, the question would be does the incubator sort of have that in your radar about how can we bring these proprietary tools and then

get more broader use of them in some sort of licensing fashion or something like that.

Because in general for CMS measure development we've kind of stayed away from things that are proprietary in nature that somebody would have to pay to use.

DR. BURSTIN: It's a great question and it's something that's already come up as Jason knows and others.

So, we have allowed a corridor within NQF and in fact the PAM, the measure that Sarah just mentioned, the patient activation measure, is a proprietary measure.

There was a fee structure associated with use of the measure that went forward as part of the endorsement process. It gets assessed under feasibility. But it is now a measure that's adopted with an understanding there is an associated fee.

So buyer beware, right. You can choose to use this. The evidence and the performance of the measure is great. But then

you need to know that there's an associated fee.

Now that being said, ideally you would prefer to have tools embedded in these measures that are freely available. We know that's not always possible. So ideally that's our preference.

But the other way to think about this, and it raises another issue which Sarah didn't talk about which some of the folks in the room like NCQA and Minnesota Community Measurement are aware of is that there's also a move now to start thinking about PRO-PMs that are somewhat agnostic of the tool.

So could you in fact say that what you're really interested in is the percent improvement in depression using a standardized tool, or the percent improvement in function after hip and knee surgery if you have evidence of some relationship between what are the set of standardized tools that are appropriate.

And more importantly, do you have evidence of comparability.

So as an example, we've already mentioned David Cella at PROMIS. David has been doing this work on something called the PROsetta Stone -- another great name, by the way. They seem to love these great names at PROMIS.

But the idea would be can you line up the different tools you can potentially use to both screen and manage depression and see how comparable they are.

So David now has a crosswalk between, for example, the PHQ-9, the PROMIS 10, the BAC and two others to say if you score here on this one, and you score -- you know, sorry for those on the phone -- if you score high on one and moderate on another, but in fact those scores are comparable, then at the end of the day do we let those in the world using measures simply use whatever they've used.

It's been really hard to get people to change what already may be in your institution. You could have been an organization that for years has only ever done PROMIS. Or you may have

only for years been an organization who's always used the PHQ-9.

Do we want to force people to change what their clinicians are comfortable with just for the sake of a measure? Or can we actually think more about this idea of over time do we get to performance measures more agnostic of tool, assuming there's an undergirding that tells you the following tools are comparable and here's the crosswalk. So percent improvement on one can be judged as percent improvement on another.

It's a big leap, but it's one I think we're going to have to collectively think about how to make going forward.

MEMBER CAMPBELL: Yes, I think that would be -- in my experience I think that's going to be a big opportunity for the science. Because a lot of those studies don't exist, but if they could be done they would definitely facilitate the measurement.

Because I agree that it would be better not to change clinical work flow, or work

flow in general in an organization. So, something for the measurement science box maybe.

DR. BURSTIN: Absolutely. And it also comes up on the risk adjustment space.

Many of you know about the total cost of care measure we endorsed from Health Partners a few years back.

Well, they use the measure with one particular risk adjuster. But now there's the folks at NRHI, Elizabeth Mitchell's group has a grant from the Robert Wood Johnson Foundation to look at five different communities, many of which are using different risk adjusters.

Again, can we move to the point where you just really want to know what's your total cost of care risk adjusted in a way that's comparable.

So I agree, it's going to be a leap for all of us, but I would encourage you to help us think through really what you would need to potentially make that leap to make it easier in some ways.

It would be less about here's a list of all potential reliable and valid tools that have a crosswalk, and can you really focus on what you think is most important, which is percent improvement in X. Or percent stability in Y.

And actually, just one other thought on this before I turn it back over to Sarah.

The other big issue that keeps coming up is the issue Sarah raised about process measure for a PROM versus an outcome measure.

And we know there's a pretty big leap between the two of those. But when we did our PRO-PM work a few years back one of the key findings of that group was please just don't endorse process measures that said did you do an annual assessment of X along the lines of the ESRD one.

Interestingly for those of us who have been around for awhile that measure of doing an annual assessment of quality of life for patients on dialysis came out of the patients on that

committee.

They insisted that if you just keep looking at our dry weight, and our phosphorus, and our magnesium you will miss the forest for the trees which is that most of us feel like crap 90 percent of the time and we want our dialysis providers to know that.

So they were content at that time with the idea that at least putting that score in front of the dialysis providers on an annual basis was a start.

But that's probably five years ago. I'm not sure they'd say the same thing. But I also don't know that we have enough -- back to your point, Kyle -- of the science to say that you would expect 10 percent improvement for a dialysis patient. Or do you actually just prevent a reduction in quality of life over time. It's not easy being on dialysis.

So, how do we wrap our heads around what's between a process measure and an outcome that says percent improvement?

Because for many conditions, particularly patients with multiple chronic conditions, we're not going to find the old medical outcome study that says expect 10 point improvement in Y.

So we'd love your thoughts on that because I think you're going to keep getting pushback from committees saying a process measure on PROM is not enough.

But we've got to figure out what that middle ground is.

Is it for example, and I think ACC did this just last year or something, where it was yes, you did the assessment of I think it was heart failure functioning and symptoms, but you not only said you did it. It wasn't a checkbox, but that score was in the record and there was evidence of what you did based on that score.

So, I think us wrapping our head collectively around around what's clinically meaningful about how you would use that score even if you can't demonstrate an improvement, or

perhaps ideally improvement but maybe somebody doesn't get worse.

There's been a lot of interest in the incubator as Jason knows around multiple sclerosis. Really difficult condition. We have no measures of any kind. I know AAN has some they've been working on. There are no endorsed measures in MS and a great deal of interest from the patient community of wanting MS function measures.

How would you assess the performance of the providers for a disease that's generally quite debilitating over time? So we'd love your thoughts about that as well to give you some more questions.

MS. SAMPSEL: Any other questions? And I'll just add on Helen's example is during the person- and family-centered care phase 2 which was all functional status measures CMS actually put forward a suite of not only their functional status outcome measures, change in functional status, but also they did do process

measures.

But it was not just the percentage of patients that were assessed for functional status at intake, but then that there was a care plan documented as well.

And one that was important to the committee although they really still didn't like the process measure, but CMS was able to come back to the group and say but this is what we heard from the patients. This is what we heard from consumers that they want to see on IRF Compare, or Hospital Compare, or whatever. That's what they want to see.

They don't understand this change in functional status part of it.

So I think that's part of the translation as well is as we're moving towards making data more meaningful and measure results more meaningful to patients how do we translate these patient-reported outcomes so that if we're getting the data from them they mean something to them.

And so, I think we've talked a little bit about this already. But basically unless a new policy and criteria are developed to change the stance, the endorsement of tool-based measures does not equal endorsement of tools.

We will continue to provide technical assistance. Typically we would absolutely love for developers, and Reva will talk about this a little bit more tomorrow, but earlier in the measure submission process.

It's kind of painful for staff where on the submission date you receive a submission, a full submission, and realize that this developer really could have benefitted from a little bit of back and forth on helping us tell you what we're looking for.

And especially with the PRO-PMs and tool-based measures we're here to help you. We can help you understand what we're looking for and what we know the committees will be looking for.

That always doesn't come across in the

guidebook and the criteria, but with experience with these committees, what we're learning from the committees is that technical assistance is invaluable.

I will tell you in our current phase of person- and family-centered care I had three tool-based measures submitted a month before to give them preliminary assistance.

Their submission on the submission deadline was clean. We didn't have to go back and do the back and forth with them. So it behooves all of us.

It's kind of, we'll continue to do, and as an example we do have another measure in this process that's a CAHPS-like measure where once again the entire measure description that will show up in the quality positioning system is about the survey.

We really want to see that -- in our search features, et cetera, you're able to pick up that it's from a survey. But the ability to focus on the measures because that's what we're

endorsing.

And so you may hear from us a little bit more to say have you thought about phrasing it like this. We're not going to force you to do that, but again, it's something that helps us when we get to committee so they understand when they're reviewing the measure.

Helen actually mentioned this. So, understanding the challenge.

The other big challenge that we've been recognizing is that there is this interpretation that there's a higher standard for the PRO-PMs.

That's something that we're also trying to even out a little bit. So, how do we get those nuances.

In the NQF criteria right now when you get to reliability and validity testing it says we want to see both data element validity testing, so testing of the survey to answer your question, Sharon.

But then it also says we're looking

for testing of the performance measure.

I can't tell you, I would say 90 percent of our submissions leave out the testing of the measure.

Well, you know, we're getting smarter and smarter committees and they're like well, where's the testing of the measure? How do I know distribution by facility? How do I know distribution by clinician?

And then we have to go back to you. And you can either totally not pass, or your measure is in that consensus not reached limit. And then there's a lot of scurrying to get us the testing we need during the public comment period.

So again, pay some attention to we're looking for -- we're endorsing measures. We want data on the measures.

This would be another area whether you want to do it now or in the future, feel free to contact me directly.

If you have ideas on how we can clarify that in criteria we're open to that. We

can make it a conversation on a measure developer workshop, one of our calls with the measure developer advisory group.

How do we clarify what we're really looking for, not to put more burden on you all. And remember I've been a developer, I know how to fill out these forms. I didn't enjoy it at NCQA so I know kind of the chairs that you're in.

And I did just say that publicly, didn't I.

(Laughter)

MS. SAMPSEL: Sorry about that. So, there is no higher standard for PRO-PMs. What we're really trying to push is we're looking for data on the performance measure.

So the PROM, it is patient data or clinician data since a lot of functional assessments are provided and that assessment is done by the clinician.

And so while the testing of the tool and reporting on reliability and validity is certainly helpful in assisting establishing

scientific acceptability, step 1 through 6 on our PRO development cycle and interpretation of criteria.

And it does provide important information to our standing committees. Our standing committees love this, especially Sherrie Kaplan. Put Sherrie Kaplan on a committee. She loves this stuff.

But we do require reliability and validity testing of the performance measure.

At this time when a measure comes to one of our committees and it doesn't have the performance measure testing you're getting that back before it goes to committee. That's part of your measure.

So, really again what we're doing now, promoting clarification, asking you all for ideas. Your questions help us in understanding where we might still not be being clear in some of our messaging.

It's great that we're educating all of you but our staff need to know because we have to

educate our committees. And we have to make sure the committees are up to date so that every PRO-PM, every tool-based measure doesn't have to come to the person- and family-centered care committee.

I'm trying to banish that idea as soon as we can.

And then I think it's really important for us, and that would be another area of feedback that we'd love to receive is what are your thoughts. What are our opportunities to ensure that our standing committees are being consistent?

There's staff consistency, but we also need standing committee consistency.

And if one of these measures comes to person- and family-centered care, and they're familiar with it, and they may be a little bit harder on it, well, we should expect that of every committee actually, to make sure that we have the right level of all of the NQF criteria to meet endorsement.

Any additional questions, comments, feedback? Because we really would love to get your feedback on this.

MEMBER GEPPERT: Can you just comment on patient burden and where that fits into the criteria?

MS. SAMPSEL: Yes. So right now under -- it's under importance and priority.

I mean, I would say it fits in a couple of ways.

So first of all, under importance and priority, and this is one of the questions that's not a must-pass question unless something comes to person- and family-centered care where they pay critical attention to where was the patient involved in this process.

And I've seen some developers be pretty much drilled on why wasn't -- you're calling this a person- and family-centered care measure, or a PRO-PM. Patients should be involved in your development process.

So there is a question. It is a

consideration. And where it would be voted on though, where I think it would be overall endorsement of the measure and that feedback would come out in our reports.

Yes, and then it also comes up in feasibility. But I do think in the development process is where we're seeing some of that data as well is when do patients want to answer the questions.

But then on the tool that does come up in feasibility. And a little bit harder in -- especially when you're looking at facility-based PRO-PMs in establishing what the burden is or burden isn't, and where the data is coming from.

But it is one of the considerations of feasibility and how long the tool is. Kind of how do you, especially since we're seeing some of these newer PRO-PMs and consumer experience surveys coming out that might be home-based, what is the burden on getting that information back as well.

So it's a consideration. We want the

committee to think about it. And you still have the low/moderate/high ranking, and that could come out as a low ranking because it is not facilitated to the patient.

MEMBER GEPPERT: I think just like we've heard from providers about the burden of the growing number of measures we're likely to hear the same thing from patients about the growing number of patient-reported outcomes that are being requested of them.

In terms of measure testing one could think of a criteria, does this measure collect the minimum necessary data for a given level of scientific acceptability for the measure itself. That could be part of the criteria for the measure, or at least establishing what that is.

MS. SAMPSEL: Right. Yes, that's interesting.

MEMBER HIBAY: Sarah, this is again Sharon Hibay from Livanta.

I find the concept of shared decision-making really intriguing. So, besides the fact

of whether or not there's a tool it seems the concept, if I just sit with it for a minute, the concept of shared decision-making might have a little bit more process, be process-oriented, slightly structurally oriented with or without a tool.

Is there thoughts about that? Especially with Helen's insightful comment about comparability of tools.

So with or without a tool or tools that describe shared decision-making, that was one of the first things that you -- on one of the very first slides that you talked about.

I find that idea really very intriguing. I'd like to hear a little bit more about that.

MS. SAMPSEL: Yes, so a couple of things.

One, we have a project funded by the Moore Foundation to look at certification of shared decision aides. We have an expert panel put together that will meet in June to talk about

establishing those criteria for how do you assess kind of the process or the structure that shared decision aides are happening in a kind of evidence-focused mannerism.

And we're mirroring a lot and learning a lot from the State of Washington who's already doing this.

And in fact, there's a project page, it's called Decision Aides Project. And so the Washington group will be giving an overview of their project and we'll be talking more about our project on a webinar I believe it's May 18. So, there's that.

The measures that were up here actually two of our expert panel members for the decision aides project have submitted two measures for person- and family-centered care stage 3.

One of them is kind of that process measure where what they do is they give a numerical score of 1.5 or zero to four questions that they've deemed critical to proving shared

decision-making has happened.

It's for certain conditions. We're looking at preference-sensitive conditions. And this comes out of Healthwise.

But basically you could score anywhere from a 4 saying yes, shared decision-making happened so that proves the process happened.

The other one has to do with a threshold of greater than 60 patients report that they understand the process through, again, standardized assessment tools created by the University of Massachusetts assessing that shared decision-making and informed consent has happened for knee and joint replacement surgery.

So we're learning more about it. We think it's really exciting. And so we have the decision aides project. And then we're starting to see measures coming through person- and family-centered care.

And I think we're going to be learning more about measurement in that area as well.

Matt, I think I saw your hand.

MEMBER POPOVICH: Matt with ASA. What's your vision for how these measures will be used in kind of the private sector such as like consumer reports or health grades?

I mean, one of the questions at the very beginning that Dr. Burstin noted was we don't know how these measures are going to be used.

Does NQF or anybody feel how patient-reported outcomes may be displayed on a public facing front? Especially outside of just payers, but also consumer advocacy organizations.

DR. BURSTIN: Another good question. I don't have a clear answer for you.

I think it's too early to know. But I think given the interest we've seen so far I would suspect the first ones we will see moving forward will be very condition or procedure specific measures of improved function when there's a clear benchmark. When, for example, you know for example hip and knee proportion improvement.

I don't know whether measures like the depression measure will move forward. And again, some of these will be pretty difficult I think to do at the individual clinician level. So perhaps they'd be more at the large group level.

And I'd be curious, those of you in the room who have been doing this, Yale and NCQA and others, any thoughts or I don't know if Minnesota is in the room or only on the phone, but thoughts about how you think that may move forward.

It's clearly where patients are most interested. At the end of the day if you want to get your knee done you'd kind of like to know who got better as opposed to -- I mean, even just the CMS bundled payments for orthopedics is fascinating right now.

So they have to do where the required elements are the complications measure that we've endorsed that looks at complications after total knee or hip replacement as well as the surgeon CAHPS I believe is the other one.

And then it says voluntary use of a patient-reported outcome tool. So again, I think it's early, but the degree of interest out there in using these tools is part of the reason why we think it's so important we get this right that we really make sure the science undergirding this makes sense, that the performance measure itself is reliable and valid, not just the tool underlying it.

And that's where I think this discussion at ICHOM will be very, very interesting because I think there's been a great deal of excitement of saying look, here are the tools you should use for this condition.

But how that actually gets translated into using it for accountability, public reporting, payment I think is still the next leap. And we really want to make sure we get that right.

So, your thoughts, ideas are very, very welcome. I don't know if anybody from NCQA or Yale or anybody wants to share their thoughts.

I know NCQA has even struggled with things like how does goal-setting fit into this. You can't just look at what performance is if you actually need to also consider what somebody's goals are depending on where they begin.

MS. SAMPSEL: So, I want to pause and ask the operator to open the phone line up for questioning for anybody on the phone.

OPERATOR: At this time if you would like to make a comment or ask a question please press * then the number 1. Okay, and at this time there are no questions from the phone line.

MS. SAMPSEL: Any additional?

MEMBER BUTTERFIELD: I'll just say from Yale's perspective, and I'll start with a caveat that I'm not the Yale expert on the hip and knee measures.

But from our perspective I think the measure that you mentioned in the bundle payment program is a good example of an instance where there's some tools that have a good deal of evidence or support, validation behind them.

And our focus is much more on what quality of measure can we derive from the data that's captured in those tools.

And a good example of an instance in which there's been an incredible amount of engagement with orthopedists, with experts in the field, with patients as well to try to get at some of these issues about what concepts, what constructs within the tools are the most important to measure.

But again, thinking about national benchmarks as a way to compare performance across providers is still an area of mystery. It's not something that's addressed in the literature that uses these tools or develops these tools.

And so the interesting thing about the bundle payment program is it's an opportunity to do some real learning with data on a national level about building the measure, and testing the measure, and assessing the measure. So, more to come.

MEMBER MCBRIDE: Good morning.

Tilithia, American Academy of Dermatology.

So, this concept of patient-reported outcomes we're grappling with right now. And I'd be really interested in hearing more about what is going to be valued more when we bring measures forward for endorsement, for consideration. Whether the patient could use the information or the provider?

So I say that because in looking at validated tools our doctors are saying, okay, I want to make sure I get the information. I want the survey or the information to be administered in a time so I can get it back when the patient returns that I can use the information to inform how we deal with anxiety.

And especially with specialties where it's not life-threatening, but life-debilitating. So issues around ITCH, or a person who's had non-melanoma skin cancer and they've had surgery on their face. How are they dealing with quality of life issues? How is it affecting their ability to go out? How comfortable do they feel pre- or

post-surgery? Things of that nature.

So I guess I'm just wondering -- Helen mentioned the patients want to see certain data. But I think our docs are thinking I want to see the data so that I can help be better in disseminating care.

And then the second question. In developing these types of measures we are relying on information where tools are validated. But you don't see information with respect to percentage of improvement. So you're not able to get to an outcome that they feel comfortable with putting out for public consumption and possibly using for accountability purposes.

So, you know, is there consideration for where the evidence is for a particular disease or condition and saying for this condition it was best to start with a process measure. And what should that look like. Assessment, documented, care plan, referral, things of that nature.

MS. SAMPSEL: So, I'll start and then

I'll let Helen finish.

So, for your second question, Tilithia, the patient activation measure again is a really good example of that where what Insignia and Judy Hibbard originally brought forward to us was more of a we want our pool endorsed.

And we really pushed them and said we're looking for outcomes. And they said well, we have tons of outcomes on use of the PAM globally. But being able to set a bar of saying X percent improvement is really scary for us.

But then they went back and looked at the data, and actually the data answered the question for them, enabled to set that threshold.

Do I think that's probably going to be a constant monitoring and maybe a little bit of during the maintenance of the measure where they may need to figure that out.

But they also made it specific to certain conditions. So, in these conditions our data show that a score of this is success.

So, I mean that's one way to do it.

And I think that we're seeing kind of more and more of that is letting the data tell us.

You'll also see in the shared decision-making measures which are again PRO-PMs where it's the data that said for these certain conditions this is kind of the score that we would assume. And those are preference-sensitive conditions.

Back to your first question. You know, kind of to me in interpreting the criteria and then I'll let Helen speak, that's our -- for us trying to understand the use and usability of the measure, and what level of measurement it's going to be.

And so both for the staff and for our committees those are the things that they're kind of instructed to think about is how is this measure being used and is that information going to be useful.

If you bring me a measure that says this is a patient-reported outcome measure, but it's also for use in whatever compare, or

wherever patients are getting data then we're going to be looking for that data. What does that mean to the patient?

We're seeing very few measures at this point that the committees are approving that the data has to be useful to the provider as well.

So, I think it's a balance, but really understanding that use.

DR. BURSTIN: I'm not sure if you were here when I presented some of the early findings from the work we're doing with Patients Like Me where they've been interviewing stakeholders and patients.

One of the things we've heard, clearly everybody agrees that whatever the tool is it should be useful to patients and clinicians, and it should be useful because it's meaningful and actionable.

And actually a really important one that's come out of this Patients Like Me work is patients have to be able -- it has to be interpretable. There has to be something that

they can kind of wrap their heads around.

So I think it's a challenge. I do think you're absolutely right. You may have a very valid score on ITCH, but if you don't know what the percent improvement is to be expected with given therapies it's hard to then set a measure that has a threshold.

So again, I think this is a logical pathway. And it may be that some of this is just beginning internally before we even think about publicly reporting the scores on some of these.

Just getting some experience. Getting them out there. Getting patients to respond. Getting clinicians to give feedback I think are really important initial measures.

And over time you might be able to actually partner with people like David Cella and others at PROMIS who are always developing new tools who may have more data than you realize on the tool itself that they may be able to work with you on.

So, I think those are all really,

really good questions.

I would also point out to Sarah's point though, there may be opportunities to use some of these shared decision-making models for things like non-melanoma skin cancer where a decision to use Mohs or not, et cetera. It's really about a preference-sensitive condition or procedure. And that might be a nice example where a shared decision-making measure could be something you could do while you're continuing to work through the other issues.

But I'm glad to hear people are interested in wanting to think this through. I know shared decision-making is a big deal in urology as well and other fields.

So, this is all new. I think we're all collectively learning. So, we welcome your insights as you go down that pathway.

Karen, Jay, anything you want to add to the methods side? You get to review all these guys. Okay. Sarah captured it? Okay.

MS. SAMPSEL: Well, thank you all and

again feel free to contact me. I put up my email address to make that easy. But it's just ssampsel@qualityforum.org.

And we really are always looking for feedback here. But then again I know some of you are on our measure developer advisory panel and that's one of the ways that we'll be seeking more input from you all.

So, thank you and I think we're now going to the exciting topic of eMeasures. So, Ann.

MS. PHILLIPS: Hey everybody. We're going to talk about electronic clinical quality measures. And we abbreviate that to eCQM. It will probably make the presentation go a little more quickly if I don't have to say electronic clinical quality measure at every opportunity. Go ahead and go to my next slide, please.

I'm going to make sure that we have the same understanding of what an eCQM is. It's a standardized performance measure. It extracts and reports quality data from an EHR by

incorporating the following standards: HQMF to compute and report data on performance measures, the QDM which defines the relationships between patients and clinical concepts, and value sets that define the clinical concepts.

To respond to challenges in electronic measure development NQF has created four paths for submission of eCQMs: de novo and that's a newly developed eCQM that's not based on an existing measure, legacy measures, and that's a respecified eCQM based on a chart-abstracted measure that's been previously endorsed by NQF and is used in a federal program.

Those are reviewed concurrently with a chart-abstracted measure by committee.

We have respecified eCQMs and that's a chart-abstracted measure not based on a previously endorsed measure.

And we also have the trial approval which is a path to implementation, not endorsement, for newly developed measures that cannot meet the NQF testing requirements and are

not used in accountability programs.

The goal for submission for de novo measures is endorsement. And the requirements for reliability and validity are testing in EHR systems for more than one distinct system.

And we've said that in a couple of different places. And what we mean by more than one distinct system is two.

And examples would be Epic and Cerner. Testing in Epic and Cerner.

But you could also have testing in the Epic ambulatory system and the Epic inpatient system. We will count that as two distinct EHR systems.

Also a feasibility assessment that describes and evaluates the data elements and measure logic to demonstrate the measure can be implemented in a real world setting.

The challenges for de novo measures are there's an additional development time. And this is associated with eCQMs. Measure development is a long process and when you get

into eCQM development it also makes the process even longer.

And the reason this happens is evolving electronic standards. There's a lack of clarity around duplicative, overlapping, or poorly defined value sets.

Ongoing refinements of the QDM which defines those relationships between patients and clinical concepts.

The development and implementation of EHRs, and adaptation and integration of work flow for providers, and interfaced systems. All of these things add to development time.

And lastly, testing challenges. As we've said in a couple of different points today there are a lack of testing environments and real world data to test on. And all of these things make de novo measure development a challenge.

The goal for submission for legacy measures is also endorsement. And these are unique because the respecified eCQM and chart-abstracted NQF measure are submitted together and

reviewed sequentially by the committee.

Bonnie is the minimum requirement for submission to establish reliability, validity and feasibility for legacy measures.

And how do we get to legacy measures? Well, CMS programs are moving away from chart-abstracted measures and into eCQMs for reporting.

Many of the measures in these programs are NQF-endorsed chart-abstracted measures. NQF policy is that a chart-abstracted respecified into an eCQM is a new measure.

Testing data is limited on these newly respecified measures. And Bonnie is a compromise that allows measure developers to meet the minimum testing requirement for NQF submission.

And these three statements are directly from the 2015 measure evaluation criteria and guidance for evaluating measures for endorsement and apply to the evaluation of legacy measures.

And we've mentioned the first statement in a couple of slides. An eCQM is not

automatically endorsed even if there's a chart-abstracted version of the measure.

ECQMs should be submitted separately from chart-abstracted measures.

And results from testing from a simulated or test data set can be used to demonstrate the measure logic performs as expected.

And these are all from the 2015 evaluation criteria and guidance.

Let's talk about Bonnie testing because that's really where we're getting a lot of simulated results from.

Bonnie testing can be used to meet this requirement for simulated data set. Bonnie test results are the minimum, and I'm going to emphasize minimum requirement for submission of legacy measures and approval for trial use.

Bonnie testing summaries should describe patient details, measurement details, how each patient fits into the measurement population, the measurement logic, and any risk

adjustment.

So when we look at a Bonnie summary it's got to look like measure testing. You want to specify enough patients in your Bonnie testing that we can try to mock up a real patient population.

If you just give a single patient for everything you've verified that the measure logic works, but you haven't really captured what's going on with a patient population. And we rely on Bonnie for that.

There's ways that Bonnie testing can be leveraged to better support measure submissions to support reliability and validity, and that's that simulated test bed of patients that really looks at like a real world test bed.

We want to also see better submission to support feasibility. So, attempt to describe how the measure would be implemented in an EHR in your feasibility summaries, how the test bed of patients would replicate actual patient data, and how the measure would be collected in an EHR.

And if you supplement the simulated data with real world data from an EHR, even if it's not complete it makes more sense to the committees who are looking at these measure submissions.

So we understand that getting measure testing information from EHRs is difficult, but if you can present feasibility from both Bonnie and an EHR it gives the committees a little more information about the measure does function, you've established that with Bonnie, but that the data can be collected in a real world setting.

And this is really important because our committees are becoming more sophisticated and they're less satisfied with Bonnie testing.

So we're faced with two challenges regarding legacy measures.

And the first is satisfying the NQF criteria for importance to measure and report, specifically, performance gap.

As legacy eCQMs are reviewed with a chart-abstracted measure if neither version is

able to demonstrate an opportunity for improvement neither measure can satisfy the importance to measure and report criteria.

The second concern is in 2015 we began accepting simulated testing from Bonnie results as that minimum requirement for legacy submission.

And standing committees reviewing these measures are not generally satisfied with simulated data without some accompanying real world data.

And this is a relatively new development. This is something we're seeing recently.

So, the goal for submission of respecified electronic clinical quality measures is endorsement.

And while a respecified eCQM is based on a chart-abstracted measure, that chart-abstracted measure has no history of NQF endorsement. So, a respecified measure must meet the submission requirements for any de novo

measure. Testing in more than one EHR and a feasibility assessment addressing the data elements and measure logic.

So, the background on respecified measures.

Not every measure in a federal program that was originally specified as a chart-abstracted measure has been NQF-endorsed. But they are being respecified for use in NQF programs.

So we have a respecified path for submission. And these measures have to meet the same requirements as a de novo measure for submission.

And MACRA may lead to more respecification of existing chart-abstracted measures.

So, respecified measure challenges are that measures are unique. They've been in the field in their manually abstracted form for some time.

The same challenges in respecification

as development of the de novo measure - testing and testing environments.

Development is time-consuming and there's limited data.

The goal for submission for measures for trial approval is implementation of measures that have the potential for benefit and quality improvement, but cannot yet satisfy NQF's testing requirements for submission.

The program requirements -- it's got to be a new measure. It can't be specified for use in an accountability program.

It must be ready for implementation in a real world setting.

And these measures are reviewed against the NQF criteria with the exception of scientific accountability.

Trial approval designation expires three years if not submitted for endorsement with testing data.

And some background on trial approval. NQF piloted this program in 2014 in the

Musculoskeletal Project.

The committee was open to approval as a way to facilitate implementation, to generate more testing data for future endorsement.

In April 2015 the program was approved by CSAC. And candidate measures are approved through the multi-stakeholder consensus development process.

Trial use designation does expire three years after approval if the measure is not submitted for endorsement.

And challenges in the approval for our trial use program. Well, is simulated data, the minimum requirement for the program, sufficient to indicate the measure can be implemented in a real world setting?

NQF still has questions if approval for trial use encourages implementation the same way that endorsement does.

And communications that approval for trial use is not just an alternative pathway for endorsement is a challenge. So there's

perception of what the program means and how it can improve measurement.

The goal of the program is to encourage the development of needed innovative measures and facilitate implementation.

So, this is an overview of the required materials for eCQM submission.

Every eCQM submission requires four artifacts which include the simple and eMeasure HQMF in XML, the HTML human readable file, value set spreadsheet, the feasibility score card, a testing for endorsement for approval, and a summary of Bonnie testing for legacy and trial approval if that's what's being submitted.

And this is a summary of testing requirements. And we're actually going to be updating the measure developer dashboard in a couple of days to include some of this information because it puts it together in a nice chart where you can compare the different submission requirements.

The last part of this presentation

will discuss the feasibility assessment for all eCQMs.

There will be no major changes in the feasibility assessment. I need to say that first. No major changes.

We're still asking measure developers to demonstrate that the measure logic can be executed, score feasibility for all data elements, explain low scores, and have a plan to address low feasibility scores.

What we are asking for a little more detail about is who performed the assessment. Was it the measure developer? Was it an independent testing organization?

When and where did assessment take place? What kind of environment? And when was the feasibility assessment performed?

We'd also like to know a little bit more about EHRs that testing takes place in. We'd like to know which EHR, what version of EHR.

This is really helpful. Nearly all EHRs are ONC certified for testing. There really

wouldn't be any reason to test in a non-ONC certified EHR.

But this helps us gather more information about implementation.

It's extremely helpful for standing committees reviewing feasibility assessments for eCQMs to have an understanding of the role each data element has in the measure.

And since interoperable systems such as labs and imaging systems are informing quality measures, we've received feedback from the field that data elements should be identified, evaluated as well.

So if there are data elements that are in your EHR that come from a lab information system that you've used for testing we would really like to know which those data elements are, and if there are any issues in bringing those data elements in from the lab information or imaging system into the EHR.

And then we've got the future of eCQMs. Really, what is the future? And I think

MACRA is going to have a significant potential impact in changing quality measurement.

I think we're going to see -- and we've discussed this all today -- movement towards more patient-reported outcome measures and alignment measures of similar type and topic through reduction and harmonization.

I also think there will be a lot more emphasis on usability in the measure development process. And stay tuned for more.

Does anybody have any questions about the eCQM submission process?

MEMBER ANDERSON: Hi, this is Kelly from the Lewin Group.

My question is how the trial endorsement interacts with the incubator. If the only missing piece there is testing data is the measure able to go into the incubator after receiving trial endorsement?

MS. PHILLIPS: First, trial approval, not endorsement.

The path to implementation that can

lead to endorsement when you bring back your test results.

And I will say that trial approval, trial approval was before the incubator and we see more measures submitted for trial approval because it's an active program at this time.

I think the incubator -- measures are further along in trial approval. They've already been tested.

DR. BURSTIN: A measure that's otherwise fully specified and just needs testing and has been approved for trial use could be very natural candidates for the incubator.

I don't know if Jason wants to add anything. So that would be fine.

MR. GOLDWATER: So, it's possible. But the point of the trial use program or trial approval program is that you're unable to find data to adequately test the measure to meet NQF requirements.

So, if you're submitting for trial use you're basically asking the standing committee to

approve your acceptance into that program which the measure then gets put into the field so it can collect data. So essentially it's being tested in the field.

If you were going to shift to the incubator you wouldn't be doing that. So, you would actually be incubating a measure with data assets at the beginning which would take away the field testing.

But if you're going to go into the trial approval program you're basically testing in the field.

So it's possible that you could move it into the incubator if you're unable to find any testing sites whatsoever.

But if you're actually going to go into trial approval they're really mutually exclusive at this point.

MS. PHILLIPS: Are there any other questions about the submission of eCQMs?

MR. TILLY: We have just one question from the line.

I guess, could you explain in a little bit more detail what -- and maybe back up a couple of steps. Just what the data element feasibility score card is and how that fits into the overall submission process.

MS. PHILLIPS: All right, let's go back to the data element feasibility slides which are like three back.

So what a data element feasibility score card does is it defines all the data elements, their action in the measure, where their role is in the measure logic, and how easy they are to reproduce.

And this gives us a real window into testing in a real world environment.

You can inform a data feasibility score card with simulated test data with Bonnie. That's going to tell us the measure logic is functional. That's not going to really indicate whether all of the data elements were found in the EHR.

And really that data feasibility score

card is a link between measure implementation and measure specification.

We can see that that measure is functional in a real world environment. Does that answer the question?

MR. TILLY: Hopefully it does. We'll find out if there's another question.

So, Mike Saca asks can you talk about how the planned NQF value set review process will play into revisions to the feasibility criteria.

MS. PHILLIPS: Well first of all, again, the feasibility criteria really hasn't changed. We're using the original guidance from the feasibility assessment.

All we've done is clarified some information. A lot of the guidance were suggestions. And now we're looking for specific answers.

So, this is to Mike and everybody else. Again, we want to identify the EHR the testing took place in. We want to know when and where, what kind of environment.

And for data elements that come, for example, from a laboratory information system or from a picture archiving system that go directly into the EHR that populate the measure we want to identify which data elements those are.

Also, if there's an issue with collecting data elements at the time of testing we would really appreciate understanding more about that in the feasibility score card.

And this is really in response to how committees have responded to the feasibility score card.

So if you go through our very complex feasibility assessment report from 2013 you'll see all these things in there. And we're just making it a little less complex to get to the answers.

MR. GOLDWATER: Let me just add about the value set review. And I'm sure Kathy's smiling because I just talked about this yesterday.

So, we finished our value set

harmonization project back in January which Ann was an integral part of along with Katie Streeter who is not here.

And one of the conclusions that came from that project over the last 18 months was there had to be a way of reviewing value sets as part of the NQF CDP process.

So, how do we then incorporate that into the review without it being so complex that a standing committee who is probably not as well versed in value sets as you all are would actually be able to understand to make an informed decision about whether to recommend for endorsement.

So, the value set review which at this point we don't know when that's going to start. We're anticipating maybe sometime over the summer. That what we're really going to do is as measures come in and we look at the feasibility assessment it's really to make sure that the value sets are complete, that the value set intent has been filled out, that the value set

aligns with the measure intent, that the value set is specified and that the value set is published.

I was asked yesterday during the call does this mean NQF is going to review every data element within every value set to determine its appropriateness. And the answer is oh God no, we're not doing that.

And the reason we're not doing that is because, one, as Ann can tell you, with some measures those value sets go two, three hundred, four hundred elements deep.

We don't have the resources or the time to be examining every conceivable element.

We do have the time, however, to make sure that the value set has been filled out appropriately which was in our analysis one of the things that we noticed was significantly missing.

And we also noticed that there were a lot of value sets being used that were not published.

So it's really to make sure that the value sets are complete, that the value sets are published, that it's using the most current terminology.

If we see that you're using an expired value set we would want to know why. If we see that you're using a value set that you've created when there's another value set that's very similar we would want to know why, and why you would choose the value set you're creating, and how it's distinct from the value set that's published.

That doesn't mean that we would reject the measure and that we wouldn't move it forward, or that we would put that into the PA, it just means we would ask questions to get clarification before the measure actually went onto the standing committee so that could be incorporated into their review.

It is I would call a basic review, a higher-level review. We are hoping that as the work continues with value sets that we would

actually be making changes to the VSAC that would automate this process a little bit. So that would make it easier for developers that if you're developing a value set you would already automatically see the value sets that are similar.

And as that value set's being created you would be prompted to fill out that information which would make the review very, very easy and very quick.

MEMBER WATT: Hi, Ann Watt from the Joint Commission.

Did I understand you correctly, Ann, that a measure that is in a federal program is not eligible for trial use if it has an associated chart-abstracted measure, for example?

MS. PHILLIPS: That is correct. Measures in the approval for trial use program are newly developed measures, not specified for use in federal programs.

MEMBER WATT: So, where do they go? Would that kind of a measure -- would it be

considered a legacy measure? Would it be considered a respecified measure? It's not a de novo measure.

MS. PHILLIPS: Well, it's kind of a flavor of de novo measure because it's a newly developed measure in the approval for trial use program.

MEMBER WATT: Okay. I'm talking about a measure that has an associated chart-abstracted measure that is in a federal program.

MS. PHILLIPS: So you'd be talking about a respecified measure?

MEMBER WATT: Okay.

MS. PHILLIPS: Okay, there are two different kinds of respecified measures. There's a legacy measure that's associated with a chart-abstracted measure that's NQF-endorsed, and there are respecified measures that are not associated with an NQF-endorsed chart-abstracted measure.

They're still developed from a chart-abstracted measure. That's a respecified measure, and that's going to -- the same

requirements as a de novo measure.

And it's confusing. We'll go back to that slide because I think now that we've been through this we can see them all together.

So what you're talking about, Ann, is a respecified measure. It's a chart-abstracted measure. The chart-abstracted is a respecified eCQM from a chart-abstracted measure that has never been through NQF endorsement. Does that clarify that?

MEMBER WATT: Yes, thank you. Actually, I do have a specific measure in mind and I think it's a legacy eCQM because it is NQF-endorsed.

But the requirements are basically the same for those too, is that not correct?

MS. PHILLIPS: Respecified measures are the same submission requirements as de novo measures.

MEMBER WATT: But a legacy is not.

MS. PHILLIPS: No.

MEMBER WATT: Okay.

MS. PHILLIPS: Basically with a legacy measure it's reviewed with a chart-abstracted measure.

We see most of the respecified eCQMs in the legacy submission category. They come in with a maintenance measure.

And the eCQM is brand new, it's never been endorsed, but it's accompanying the legacy measure which is here for maintenance.

Respecified measures can show up at any time. I think the reason we are seeing more respecified measures is CMS programs are moving to eCQMs from chart-abstracted measures. So it may be the equivalent of a chart-abstracted measure that's been around for quite some time, but they're not all NQF-endorsed.

There's a question behind you.

MEMBER BERNS: Hi, this is Samantha from Lewin.

Kind of as a follow-up to that, if there's a chart-abstracted measure that is no longer endorsed but was previously that's being

converted to an eCQM would that also be respecified?

MS. PHILLIPS: It's got to have no history of NQF endorsement.

MEMBER BERNS: So that would be considered legacy?

MS. PHILLIPS: That would be a de novo measure.

MEMBER BERNS: De novo, okay.

MS. PHILLIPS: If the corresponding chart-abstracted measure no longer has NQF endorsement and you're just submitting the eCQM that's a brand new, that's a de novo measure submission.

MEMBER BERNS: Okay. Are you interested in any of the history of the chart-abstracted measure if there's data for that?

MS. PHILLIPS: Absolutely. If it informs the eCQM.

MEMBER BERNS: Okay, thank you.

MR. TILLY: And we have another question on the line.

So, I guess the question is about the exact definition of what goes into trial use or not.

There's an example about a composite behavioral health measure that was approved for trial use, but that actually had been proposed for I think meaningful use and developed under a SAMHSA/NIDA grant.

MS. PHILLIPS: That was early in the program during the pilot phase. And before it became an official program. So I think we were a little more flexible about requirements.

I'm familiar with the measure. And right now that would not be accepted in approval for trial use. But that was during the pilot phase of the program.

MS. ISIJOLA: Mike, did that answer your question? Operator, can you open the lines, please?

OPERATOR: To ask a question please press *1. And there are no questions from the phone lines.

MS. PHILLIPS: Okay. All right. And I think we're getting pretty close to lunch time. Nope, more questions? Okay.

MEMBER CULLEN: What percentage of measures that are coming in are eMeasures for endorsement? What type of training are the committees receiving? And what type of questions are they asking about eMeasures?

MS. PHILLIPS: Right now I can't tell you how many. I can tell you it's more.

I was looking at data for the year. So far in this batch of measure submissions I've reviewed at least a dozen eCQMs. That's a lot. We really do need to give you guys actual percentages because I think this is really descriptive of where the instrument is going.

And can you go ahead and repeat the rest of your question?

MEMBER CULLEN: What types of training and then what types of questions are the committees asking.

MS. PHILLIPS: We start in committee

orientation explaining what an eCQM is. Very, very basic. We want them to understand it's the difference between a manually abstracted or chart-abstracted measure and an automatically calculated measure.

When you have chart-abstracted measures you've got inter-rater reliability on one side. That's kind of the negative. Because eCQMs are always going to report the same data out of an EHR.

But you've also got an interpretation through chart-abstracted measure that you don't quite get in terms of flexibility with an eCQM.

If the measure is not correctly populated for whatever you're looking for there's no other way to research the data where chart-abstracted measures, you can always look a little deeper into the patient's chart.

So, we give the committee some training during the orientation. And then dependent on the type of measures that are being reviewed in the project we will go into all of

these different measures. That's really important.

If the standing committee is not reviewing any legacy measures they really don't need to know about legacy measures.

And the committees are becoming a lot more sophisticated at the review of measures. Initially, when I first started -- would accept the measure submissions. Now they're starting to ask questions, especially about simulated data. Because a lot of the measures in use for the legacy program have been in use for awhile.

So, I would say committees are becoming more sophisticated and we are answering a lot more questions about measure development, construction and testing.

MR. GOLDWATER: So, Cindy, I can add onto that.

Like Ann said, we do training at the beginning of every CDP meeting. And a lot of it is like this, only it's obviously a little bit more abbreviated because of time.

But to just generally talk about the pathways of eCQMs. And then to spend, as Ann said, spend time on those that we've noticed have come into that particular project.

Because again, if there are no legacy measures we don't spend a lot of time talking about that.

The two I guess categories of questions we're seeing the most of are feasibility. There's a lot of questions on that. Will the eCQM actually work in an EHR. How is it going to interrupt work flow. Is this something that could be collected in the course of work. How is this information going to come out of the EHR.

That becomes a big question if the measure is presented as reliant on unstructured data which very few are at this moment, but there have been a couple, and those have been questions, how would you get that data into the EHR.

And then as Ann put out we've gotten

several questions about Bonnie testing which we expected to get.

There's a lot of members on the standing committee that don't understand the tool. So we have to sort of walk them through what the tool is and what the tool is not, and how it is used at a very minimum level to show the measure logic is functioning correctly, and how it can be used again minimally for feasibility for legacy measures.

And that has led to questions about how synthetic data can be used. We've pointed out how that assessment could be done and evaluated in the best way that we are able to do. And the measures are either voted up or they're voted down. But traditionally those have been the questions that we see the most when it comes to eCQM.

MS. PHILLIPS: And one other additional thing. Beyond the committee orientation we have workgroup calls.

And I have been called into more than

one workgroup call to answer questions about eCQMs.

DR. BURSTIN: I think we've also heard from some committee members, and again, we do try to emphasize these are our requirements.

I think on the ground, particularly for clinicians or providers on the front line, the idea that these measures would work is something they really do question when they've got an idealized sort of evaluation.

And frankly, as somebody who sees patients on Monday mornings I never see my meaningful use stuff. It's done in the background. It just kind of goes off in this magic.

But if I have to actually enter all these data you can easily see how the concerns about feasibility in something that's not -- more than an idealized assessment is what they're going to want.

So I think it's clearly where we need to go. I think Bonnie testing was considered a

good first step on that path, but it was never considered really the ultimate way that I think providers and end users using those measures would feel comfortable that what we're seeing there is truly reliability and validity.

And I think the other issue we're increasingly seeing is what do we know, or really what don't we know about the comparability of the same measure using different specifications.

This comes up all the time. And I previously had an example of some Joint Commission measures that came forward that the measure is topped out on the paper record.

What do we know or understand about how its performance might be in an electronic record?

So I think these are smart groups, people who are just thinking about it, and logically there's going to be a set of questions that will follow above and beyond our base requirements.

And I think those over time will

logically evolve as you guys evolve and we think about how to do the testing better.

But your thoughts there also would be very welcome. This is definitely a new area I think for all of us.

MS. PHILLIPS: Did you have a question?

I would say a year ago we didn't see these four paths for eCQM submissions. I think NQF is trying to stay on top of all the different ways that eCQMs come to us for endorsement or in the case of a trial approval for approval.

And we're trying to be flexible, but we're also trying to really be rigorous and make sure these measures can be implemented in healthcare organizations for performance measurement.

All right. I think I've got everybody's questions. Okay, thank you.

MS. ISIJOLA: Okay, so I think we're going to go ahead and break for lunch. I know we're a bit above schedule, but we'll break for

lunch.

This is an opportunity for you guys to network amongst each other. Some of you have seen each other yesterday, or haven't seen each other in years.

So we'll come back at about 1:10 and we'll start off our session on new measurement frontiers. Thank you.

(Whereupon, the above-entitled matter went off the record at 11:47 a.m. and resumed at 1:10 p.m.)

MS. ISIJOLA: I know we're a bit ahead of schedule but we're going to start off our next presentation.

A lot of the things that we're doing now has really dived into measurement science. So, we do have a host of projects that really focus in on some of the projects within the measurement science landscape.

I know NQF is always known for endorsement of maintenance, but we wanted to showcase some of the work that we're doing across

the spectrum.

And one of the projects is variation in measure specification. So with that being said, Debjani?

DR. MUKHERJEE: Hello, good afternoon, everybody. So my name is Debjani and I'm a senior director here at NQF.

And the project I'm going to talk about is variation in measure specifications.

And I just want to say Jeff Geppert is on our expert panel and he's here today so, Jeff, if you want to chime in at any point feel free.

So, what is variation? I'm just going to start with that before going into the slides because when we talk about measure variation we're talking about a change, a variation. A variation in a measure. So in their specification.

But when you talk about that you have to have a reference standard from which you're varying. So just keep that in mind.

And also, the other thing to think

about is not all variation is bad. A lot of variation comes out of innovation and changes in clinical evidence. So, we're talking about variation that's probably not beneficial and should be mitigated, but not talking about trying to inhibit variation that's actually beneficial.

So, our project objectives is to sort of understand where variation is happening, why it's happening and how to work through variation, mitigate it, and when we're incapable of doing so to be transparent about it.

And also to create a taxonomy, a framework to classify and assess measure variation.

So, what do we mean by variation? As I said it's a modification. It's a tweaking. It's creating a measure that's very similar to an existing measure, almost like a me-too drug.

So, what we want to prevent is having too many measures that are very similar to each other. So when you're going to compare data you can't really compare because there are slight

differences, and the slight differences create a bigger delta in the differences in the data you're collecting.

So, the first thing we did is define variation. What do we mean by variation? And our official definition is any deviation from a fixed reference point.

And note a fixed reference point. And by reference point we mean a standard set of measure specification.

And this reference point for the purpose of this project is a standardized set such as NQF-endorsed measures, HEDIS measures, et cetera. A commonly known reference point.

So then the next thing we did was talk about what will be the focus of this variation.

There are measures that are used for internal quality improvement, and then there are measures used for accountability.

The expert panel had a discussion about this and then we decided that when you have internal quality improvement efforts the whole

process is a closed system. It's internal.

So, the focus of this project is external accountability. And by accountability we mean the use of measures for public reporting, for payment and other decision-making efforts.

And we're also doing this because of NQF's traditional focus on accountability.

So, what are the types of variation that we see? One is a formal modification of existing specifications. And it's usually used to accommodate user and/or provider preferences.

So changing the definition is something we see commonly. So changing the definition of a primary care provider with the intent of more accurately capturing data, but at the same time that is variation.

The second is variation arising from incomplete or ambiguous measure specifications or a lack of operational guidance.

So for example, a transition record. What does it mean? And sort of the interpretation of that by different providers and

data submitters can cause variation.

And finally, implementation challenges. That could be data challenges and/or resource challenges.

So, taking a chart review-based measure and then implementing it in a less granular registry and losing some of the nuances that may be available in more detailed chart notes.

So, what we did is create a table. And I know the font is rather small, but I'll go through each of them. And think about the different types of variation we're seeing and examples of them when we're looking at measure specification elements.

So, the first is numerator, changes in the numerator, which changes the measure focus.

And some examples are differences in definitions, how things are being defined, differences in coding, and/or documentation of clinical concepts such as an encounter and adherence, or even how you're defining your

providers.

The other is the denominator, change in the denominator or the target population. And changes there are differences in definitions again, coding, documentation of clinical concepts.

And because of the prevalence of changes in definitions a lot of the work is focusing on defining terms, creating a language, a common set of language and words that we can use to talk about variation.

So, for denominator it would be measures intended for adults being changed to be applied to the pediatric population.

Then exclusions. Exclusions from the denominator and changing the target population.

So, differences in acceptable exclusions. Specific medical conditions versus unspecified medical reasons.

The other big one is risk adjustment. And risk adjustment includes not only risk models, but also sociodemographic factors, and

also differences in how modeling is done and how the risk adjustment strategy is laid out such as logistic versus hierarchical modeling, and things like that that sort of change the way the data is being collected and/or being analyzed at the end.

Data source or collection instrument. So, taking administrative claims versus registry reporting versus chart review.

Also, care setting. So, taking something that's meant for the hospital setting and applying it to an outpatient clinic.

And then finally, level of analysis. So, taking a measure that's intended for health plan performance and applying it to the clinician level.

And also, for all of these if there are any additions, suggestions, please feel free to speak up, raise your hand. Any feedback at this point is much appreciated.

As we said this is a multi-phase project. We have two in-person meetings. We have already had our first in-person where we

came up with the examples, the types of variation, the definitions.

And the next phase is to talk about the taxonomy, how we classify as well as mitigate some of this variation.

So, as far as mitigating variation one of the things that the expert panel did was develop a set of guiding principles, a framework for assessing variation.

And some of the elements here are promotion of comparability. So variation should be assessed and mitigated based on its impact on comparability.

Reduction of burden, especially provider burden. If you have five very similar measures that you have to report on it causes and creates reporting burden.

Also, on the other end if you have the data and you want to compare, especially with this movement from volume to value you want to be able to appropriately capture the differences in quality across the spectrum without variation

being an issue in your analysis.

Protecting innovation. No matter how much we want to mitigate variation we always should allow for innovation. Innovation from clinical evidence. Innovation from advances in the field and changes in best practice.

Meeting end user needs. Measures should be able to meet end user needs. And measures should be developed so that they're not varied too much at the implementation phase to meet user needs.

Transparency. So, to be transparent in what is being changed during variation and also almost like an annotation that transparently reports what was changed and why it was changed.

And then specificity. Consistency in implementation. Measures used for accountability should include full detailed specifications so that at the implementation stage users don't have to put a layer of their own understanding and interpretation to be able to implement a measure.

And just to that point, for the focus

of this project we're looking at accountability measures at implementation and further.

We do realize that variation happens in the development ideation level with the number of guidelines out there and which recommendation is chosen to develop the measure.

But the hope is maybe to look at that at a different phase because trying to get at the nuances of variation at each of the stages are slightly different just because of what happens at each stage.

And with that, any questions, any comments, any suggestions, next step? And also, Jeff, anything you would like to add? And we also have Helen.

MEMBER GEPPERT: Just to say that I think a lot of this goes back to what we talked about at the very beginning of the day of trying to create more of this feedback mechanism. Instead of having this linear process where measures are developed and then they're implemented, trying to actually provide feedback

to the developers about how they're being implemented and what issues people are having doing the implementation.

And then have the developer involved in that process and considering what kinds of changes, modifications are really consistent with the original measure intent and which ones might be more problematic.

DR. BURSTIN: I just had a couple of thoughts. And thanks, Jeff. Jeff has been really helpful on this panel.

And there are actually several other developers. NCQA is on the panel and also a couple of other folks. I'm looking around the table.

DR. MUKHERJEE: Wisconsin Collaborative.

DR. BURSTIN: Wisconsin as well, right.

So, part of the idea here has been -- this is an interesting committee and we'll share the roster with you.

I mean, it includes people who use measures every day. I think we had three or four states represented, communities and states who use measures.

We've had developers at the table. We have guideline people at the table. We had EHRs at the table, vendors at the table.

And the idea was really just trying to wrap our head around this. How does variation happen, why does it happen. Is there some variation that's okay, and if so it should be transparent so people know they're comparing apples to apples. And there's just not a lot of transparency there.

So you should know this work was asked for by -- well, we requested it, but HHS and in particular ASPE is really interested in understanding this.

So, Ann Page was actively participating in the panel from ASPE.

So, we would really like your thoughts here. One of the things that was eye-opening for

me was to hear how difficult it was, for example, and Jeff may have had this experience as well, some of the states saying how hard it is to take what we think of as a fully specified measure and then actually try to implement it.

And they just had a whole list of questions. Well, that's really interesting, but how do I make that work with the data systems I have.

So it feels like there's a missing piece between what we do on the measure specification side and how it's implemented that we'd like to work with you to think about how to fill in.

But then also a sense of buyer beware. There are differences here in the way these measures are applied. And you may be actually seeing more measurement noise than you're seeing actual differences in performance.

So, this is early and I think as Debjani mentioned the next phase of this is a whole set of key informants. Some of you may be

among those key informant interviews.

So, it's iterative, it's ongoing. But if you have ideas about things that you struggle with, or as you're putting your measures together and how specifications can be pretty difficult at times to be incredibly precise please share them now or afterwards. I mean, we're happy to take your feedback as we go forward.

You look very post prandial.

MEMBER CULLEN: So, one of the areas that you talked about was a lot of measures that may be very similar used in different settings and things like that.

Has there been any talk or discussion about potential changes in the scientific acceptability of the measures as you move from setting to setting?

I mean, I see that there's a desire to have consistency across, but validity may not be there. That's something that I haven't really seen in any of the documentation that's been coming out from this group.

DR. BURSTIN: I think it's an interesting question. Anybody else have any thoughts on it? I mean, it hasn't really be something I think we've thought a lot about. Jeff, did you want to say something?

MEMBER GEPPERT: I just think part of it is trying to be a little bit more explicit about what that quality construct is so we can better make that determination of scientific acceptability and validity.

So, sometimes it's a little bit less specific than it might otherwise be trying to really articulate what -- the exact providers' behaviors that you're trying to measure with your measure construct.

And I think if there was a little bit more explicitness in that then it would be more obvious when you transfer it to a different setting about what the validity issues could potentially be.

So, I think part of it is on our side, on the measure developer side to be more explicit

about that.

MEMBER LEMIEUX: Yes, and I was just going to add I think we think of validity as being context-specific. But we're kind of the choir here. And I don't know that that is -- people may not understand that you can't just kind of plop a measure into another setting or whatever. It may seem perfectly valid, but it isn't.

But I would say that a lot of people may not understand that.

DR. MUKHERJEE: And just to add, some of the examples we have seen is say one of the Medicaid core set measures, states taking it and tweaking it slightly to be able to implement it and saying oh, it's the same measure.

And that's something we have heard from our federal partners where when you're looking across it's not the same measure. But at the same time you're trying to let them know what is acceptable when you're tweaking and what's not. Thank you.

MS. ISIJOLA: Great. Thank you, Debjani.

So our next presentation, I know many of you have heard about our SDS trial period and kind of where we've been when we started it.

Erin O'Rourke will come and present on where we have been, where we're going, and some of the challenges that we've been facing to date. So, Erin?

MS. O'ROURKE: Thanks, Wunmi. I'm also excited that we'll have some presentations after I give you a bit of an overview of how we got to where we are today with the trial period from some of our developer colleagues in the room.

Karen Dorsey from Yale CORE is going to present on some of the exciting work they're doing.

And Kristen Butterfield will be sharing with us the results of PQA's work on SDS.

So, just to give you a little bit of the high level how we got to where we are. As

Debjani said NQF endorses performance measures that are intended for use in accountability programs such as public reporting and pay-for-performance.

So, in this context the overall performance measure score is used to make a conclusion about a provider's quality in relation to other providers or against some other comparator such as average performance.

Historically SDS adjustment of quality measures has been avoided. And prior to the start of the trial period NQF actually had a prohibition of these factors being included in risk adjustment models.

However, there's a growing body of evidence demonstrating the association between patient sociodemographic status and healthcare outcomes.

Additionally, we've seen a dramatic shift to value-based purchasing with an increased focus on outcomes measurement being used in those programs.

However, generally caring for the sociodemographically disadvantaged populations is associated with poorer performance on current measures. That's just on average. There are some noteworthy exceptions to that general pattern.

Given the higher financial stakes especially for safety net providers we want to ensure that performance measures are really getting that apples to apples comparison between providers.

We want to ensure that the safety net providers aren't being unfairly penalized because of the populations they serve. Doing so could risk creating greater disparities, or take away the additional resources that are needed to help close some of those gaps in care.

So we know there are at least two divergent views on adjusting measures for sociodemographic status.

Interestingly both positions are based on a shared concern about not worsening

disparities in the healthcare system.

Those who oppose adjusting the measures this way feel that providers may deliver worse quality to disadvantaged patients.

Adjustment could make meaningful differences in quality disappear. Worse outcomes might be expected. There would be no expectation to improve.

It implies or sets a different standard for providers serving different populations.

There's also a lack of adequate data to really do these adjustments correctly.

And there's thoughts out there that people prefer rectifying these issues through payment rather than adjusting the measures.

However, those who support SDS adjustment feel it's necessary to really allow for comparative performance.

That a performance score alone, whether it's adjusted for SDS factors or not cannot identify disparities.

They feel hospitals caring for the disadvantaged are already being penalized, and there's no evidence that disparities would be reduced through further negative financial incentives.

And that not putting in these adjustments could create a disincentive to care for the poor and for vulnerable populations.

So, to consider and address these issues NQF convened an expert panel to determine when and if how quality measures should be adjusted for SDS factors.

These recommendations were made through the usual NQF consensus process. The expert panel was composed of multiple stakeholders with a variety of experiences.

And the recommendations were submitted for public comment and then modified in response to the comments received.

Ultimately the results of this work was that NQF would undergo a two-year trial period where performance measures could be

adjusted for SDS factors prior to a permanent change in NQF policy.

As I said before, prior to this trial period NQF had prohibited consideration of these factors in risk adjustment models, preferring stratification based on those variables.

So, during the trial period if SDS adjustment is determined to be appropriate for a given measure NQF will endorse one measure with specifications to compute the SDS adjusted measure as well as the non-SDS adjusted version of the measure. That is, it's clinically adjusted only to allow for stratification.

Each measure must be assessed individually to determine if SDS adjustment is appropriate. Not all outcome measures should be adjusted for SDS factors. For example, something like a central line infection measure should not be adjusted.

There needs to be both a conceptual basis, that is, a logical rationale or theory as well as empirical evidence to support the

adjustment.

And these recommendations apply to any level of analysis, including health plan, facility and individual clinician.

So all measures submitted to NQF for endorsement after April 15 of last year are considered to be part of the trial period.

And the standing committees evaluating them may consider if the measure is appropriately adjusted for SDS factors. So this includes newly submitted measures, measures undergoing maintenance, measures that were conditionally endorsed such as the ones we've seen in the admissions/readmissions and cost and resource use projects that finished up right before the start of this trial period.

This could also be a basis for an ad hoc review.

Just a note, measures undergoing endorsement maintenance review during the trial period are considered fair game for consideration of SDS adjustment.

So this slide just shows you some of the considerations that the standing committees are asked to make when they're reviewing the measures to determine if they're appropriately adjusted.

They're asked if there's a conceptual basis between the SDS factor and the focus of the measure.

They consider if the factor is present at the start of care and if there is variation in the prevalence of that factor across measured entities.

They are asked to consider if the empirical analysis submitted by the developer shows that the SDS factor has a significant and unique effect on the outcome.

And finally, they consider if information on the SDS factor is available and generally accessible for the measured patient population.

So, just to share a little bit about what we've learned so far from the trial period,

to dive in a little bit on the cost and resource use project.

Three measures in this project were endorsed with the condition that they enter the trial period.

Based on the empirical analysis the developers chose not to include SDS variables in the model citing nominal impact of those factors on the risk model performance and the outcome of the measure.

Ultimately the committee voted to continue endorsement of the measure without including these SDS factors in the risk adjustment approach.

However, we have received an appeal of this decision, so there's still ongoing work on these measures.

For the admissions/readmissions work the standing committee is currently in the process of a series of meetings to review 16 measures that were endorsed with the same condition, that they enter the trial period and

be considered for the need for SDS adjustment.

Some very early findings from the standing committee's preliminary review are on my slide here.

The variables currently proposed by the developers may not be sufficiently robust. However, there's a need to consider the current limits to the availability and accessibility of data around these factors.

Any patient characteristic that is present prior to treatment and is a known or suspected confounder of the treatment may be included in the risk adjustment model.

The committee encouraged developers to consider age, gender, some measure of poverty, as well as to test community-level variables when patient-level data were either not available or not robust enough.

The committee noted that geographic proxy data should represent the actual SDS characteristics of the patient as accurately as possible.

For example, they stressed consideration of a nine-digit zip code versus a five-digit zip code.

And finally, the committee urged caution on the use of race as a proxy for patient SDS. This was something the original TEP that developed these recommendations said should not be ever used as a proxy for SDS.

So when we do see measures that have tested race the committee wants developers to be very crystal clear on the conceptual analysis for why they're testing it and what they're really trying to get at by looking at race.

So, overall we've learned quite a bit about the challenges of risk adjusting quality measures for SDS factors.

First, really running up against challenges related to the limited availability of patient-level data. We're finding available proxies such as five-digit zip code may not really be granular enough or otherwise adequate to show the differences.

Standing committees have raised some concerns about the factors selected and analyzed to date.

Developers have noted difficulty in accessing nine-digit zip code or Census block data.

However, the standing committee has noted that five-digit zip code may not be specific enough.

Similarly, dual eligible beneficiary status is readily available, but again, may not be granular enough to show meaningful differences.

And again, we've had the appropriateness of including race as a variable has been questioned.

We've also heard some calls for a more prescriptive approach. Historically NQF has not been prescriptive in its approach to the variables included in risk adjustment models. The measure developer is responsible for selecting the variables included in the model and

for defending the selection of those variables to the standing committees.

This approach applies to both clinical and SDS factors. However, we've been getting some questions about whether we should establish firmer guidelines for what SDS factors should be considered to ensure that we're having a consistent and thorough trial period.

So with that I'm happy to take any questions. And if no questions I can turn it over to Karen Dorsey from Yale CORE to share a little bit about what they've been doing.

MEMBER DORSEY: Thanks. Hi, everyone. So, Erin asked that I share some information about our experience to date with the sociodemographic trial period in our measures that have gone through which I think number about 14 at this point, either have gone through or are in the process of being considered by committees.

I'll say that I oversee this work at CORE, but our director of quality measurement programs, Susannah Bernheim, actually leads the

work. And I am not one of the brilliant analysts who have done a tremendous amount of conceptual work and number-crunching to support all the materials we have submitted. So you guys are stuck with me this afternoon, but I'll walk you through at a high level our experience and then I'm happy to answer questions.

So, today I just want to provide an overview of our approach to using both SES and race variables in the measure testing that we've done so far, to describe the approach to using these variables in our risk models, in our modeling structure, and then to talk about some key findings.

So, to start, our approach to variable selection sought to identify data sources for assessing sociodemographic status that have several characteristics.

And these characteristics are really defined both by the NQF criteria for variables that Erin just went through, and also sort of the inherent nature of our measures which are

national measures that attribute the results at the hospital level.

So, our models have a patient and hospital level, the hierarchical models. And so we use patient-level variables or proxies for patient-level variables in the models for risk adjustment.

Most of the variables in the models are comorbidities that come from inpatient and outpatient claims.

So, this use of socioeconomic status and race variables at the patient level is in keeping with our methodology for risk adjustment.

We also need variables that can be linked to Medicare fee-for-service claims since these are the data that we use to calculate the measures.

They have to be available therefore for everybody over 65 who's a Medicare beneficiary.

And we need to have them now so that we can be responsive to the NQF trial period, and

we can talk about potential work that could be implemented in measures in real time.

And Erin already alluded to some of the limitations that we know in the SDS and information about race and ethnicity in national data sources. And I'll talk about that a little bit more.

So, what data sources are available to us that may have variables that meet all these criteria?

There's Medicare Part D data and specifically data that's used to assess coverage for low-income subsidies in Part D.

This includes information about dual eligibility for Medicare and Medicaid, and also the low-income subsidy.

And I'll just pause here to say that in our analysis of the low-income subsidy what we've found is that generally everyone who qualifies there is included in dual eligible. It's a larger group and dual eligible patients are a subset of people who qualify for the low-

income subsidy.

And they're in fact a lower income subset of that group. And so, I'll talk about this a little more, but selected dual eligibility over low-income subsidy because it gives a little bit more specific information about low-income and low-asset enrollees.

We also use the Medicare enrollment database which has both beneficiary demographic information, so information about race and ethnicity, and also benefit coverage. So it also gives information about dual eligible status.

Just for information this is also where we get our mortality data for the 30-day mortality measures is from the enrollment database.

So, just for a moment I want to talk about the American Community Survey because this provides sort of a nationally representative sample of information about the socioeconomic environment in which people live.

This survey uses a sample that's based

on the Census so it can be applied at units that we consider associated with the Census like zip code as Erin was talking about.

It's recommended that you use five years of combined data to get a representative sample and accurate information.

It currently can be linked easily to the five-digit code, but you need additional software to link it down to the nine-digit level. And in fact, you can only attribute with accuracy the information from the American Community Survey to the Census block group level which is basically the first digit and the last four digits of the nine. And is meant to represent between 600 and 3,000 people with an ideal number of 1,500 people. That's what the block group aims to capture.

So, from these choices we have elected to use Medicare and Medicaid dual eligibility status which as I said is found in the Medicare enrollment database, also in Part D data.

It's an indicator of poverty that's

based both on income and assets which is an advantage. And as I said, it still represents sort of the poorest of the poor if you think about the low-income subsidy as the largest parent group.

We also elected to use the Agency for Healthcare Research and Quality validated SES score. This is based on the seven elements that are found in the American Community Survey data.

And if you guys scroll down you can see that these are elements that characterize the resources in the community in which people live.

And the way that we use these in our models is to look at the Census block group in the lowest quartile of the index and compare it to all others. So, the lowest quartile compared to the three higher quartiles in the distribution of score.

We also very purposefully elected to look at race which we derive from the Medicare enrollment database again.

Unfortunately the race variable in the

Medicare enrollment data is limited in that only the black and white categories have been found and researched to be sensitive and specific. So we can't look at ethnicity, and we can't break out other minority groups using this information.

But we thought it was still very valuable to use, especially given that a lot of the disparities research around minority groups is focused on black patients versus white patients.

I want to say very explicitly that we did not use this as a proxy for SES. Our intent with using race was to have a comparator variable. This is because much of the research around SES and race associated with outcomes overlap. And often the association between race and outcome is stronger than that of SES variables and outcome in the same studies.

And also because many of the pathways by which race is linked to health outcomes can also be applied to SES. And some of the disadvantages of including those variables in

risk models are analogous.

So for all those reasons we wanted to use this as a comparative variable to try to understand what we were seeing when we were examining our results.

So, just a brief review of approach to analysis. Erin touched on this, but we focused on what was requested of us by the NQF committee and by the NQF staff guidance as we were putting measures into endorsement maintenance or initial endorsement.

We were tasked with characterizing the conceptual relationship between these variables and the outcomes. This is true for the payment outcome, the 30-day mortality outcome, and 30-day readmission outcome.

To look at the statistical relationship both by variate and in the context of all the variables that we include in our risk models.

And then to look at the impact on measure results which is ultimately the hospital

performance assessment.

And then we were also asked to look at hospital-level and patient-level contribution. And this is something that we're doing specifically in relationship to the readmission measures, not something that we needed to do with payment and mortality which I'll talk about in a second. And I'll get at this in a couple of slides.

I want to say that even though we looked at AHRQ SES index I'm not going to show you guys results. I'm going to preview that I'm going to disappoint you and not show you results.

And that's because we are really just at the point of getting down to the Census block group level with this variable.

If you guys are interested in seeing how that plays out with a readmission measure stay tuned because there will be public meetings of that committee and they will be reviewing and discussing those results.

So, the conceptual relationship with

the outcome was really informed by our cohort in outcome-specific literature reviews that we produced for each measure.

This was an incredible amount of work that our team did to do literature reviews that were specific to AMI, heart failure, pneumonia, and to each of the outcomes that we've tested so far.

And they include -- the four potential pathways that sort of emerged from this review of the literature include differential health at admission. So, patients who have lower SES indicators may have a greater burden of disease when they present to the hospital.

The use of low-quality hospitals. So, we know patients who have low SES indicators may cluster at certain hospitals that are within their communities perhaps, and that that may be one pathway.

That patients may receive differential care within hospitals. And there's evidence to support this both for patients with low SES

indicators and for black patients compared to white patients.

And that there may be also other influences on outcomes outside of hospital quality. Things like competing economic priorities for patients and accessibility of post-acute care providers in communities, et cetera.

So these were the four large buckets of ways by which these factors are connected to outcomes that we found in the literature.

When we began to look at association with outcomes we did this both for race and SES variables and we found some associations.

I'm just showing you the bivariate association here. And if you go down the rows I'm keeping it simple limiting it to single condition AMI but showing you the results for three different outcomes, AMI payment in that first row, AMI mortality in the second, and AMI readmission in the third.

Again, as promised I'm only showing

you the results for dual eligibility and race. Stay tuned for more information about the AHRQ SES index.

And what you can see is in that third column these are patients with the indicator variable, and in the last column those are the patients without. And so there's a very modestly higher payment associated with dual eligibility and with black race. Very small. This is again just the observed.

A little bit bigger differences that you see, but still pretty modest with a bivariate relationship with each of those variables in AMI mortality.

And then readmission as expected is a little bit greater in the unadjusted observed difference.

Then we move onto actually putting these variables into our multivariate models with all of the rest of the comorbidities.

And I'm showing you here the impact on model performance. We assess that with a quasi R

squared for the payment outcome and with C statistics for the mortality and readmission outcome.

So when you look at those numbers next to the payment outcome they look quite a bit different because they are different statistics. Don't be alarmed.

But what you can see when you look within each measure, so AMI payment you look at those three rows, the current model which only includes comorbidities and demographic information like age and gender for some of our conditions, you can see that then when you add dual eligibility or when you add race the quasi R squared doesn't change.

And similarly for AMI mortality and readmission the C statistics just don't change.

So, these models are equally well discriminating with and without these additional variables.

For impact on hospital results I'm showing you a picture hoping that it's worth a

thousand words.

And these two figures are for the AMI payment measure. The one on the left is for dual eligibility added to the risk adjusted model, and the one on the right is for black race versus white race added to the risk adjustment model.

And what you can see for both is that all of those dots align pretty darn closely along the slope.

And just to give you a sense of the correlation values here, we're talking about 0.99 and until you get to the third decimal place you don't get a deviation from nine. So these are very highly correlated results with and without these variables in the model.

I'm showing you the same for AMI mortality. Here we added the nuance of breaking out the quartiles of performance but with different colors just to show that no matter whether you were a high performer or low performer your dots all line up with again 0.99 correlation here.

I'm not going to show you the correlation figures for readmission, but it's not because I'm hiding anything. They look exactly like this. It's just because we had a lot of competing priorities this week with respect to SDS analysis.

So, in a nutshell for the payment and mortality measures for both of these types of variables, the race variables and the SES variables we really only found a modest association with the outcomes when we include our other risk adjusters.

The addition of these variables had really a negligible, like no impact on model performance. And hospital performance is incredibly similar with and without these variables in the risk models.

I want to just give you a brief preview of some of the information that we've added with the readmission measures that we didn't do with the AMI payment and mortality measures.

This gets back to the hospital-level and patient-level effects I alluded to at the beginning of the talk.

For the readmission measures we were asked to do this additional analysis to try to understand to what degree is the association between, for example, dual eligible status and readmission related to the hospital, the characteristics of the hospital that a patient goes to, and to what degree is it due to that patient coming in as a dual eligible patient for an example.

So, to get at this we perform what's called a decomposition analysis using some standard methodology that's been developed for other purposes to assess the independent effects of these variables at the patient and hospital level.

So essentially we kind of break the coefficient if you will into two pieces and attribute those pieces to the hospital and to the patient separately.

And basically it gives us a simultaneous estimate of the independent effects of any average patient receiving care at a hospital that has a high proportion of patients with low SES indicators, or a high proportion of black patients in the case of the race variable, or a patient having low SES indicators, or a black patient walking into and receiving care at an average hospital. So it's those two different things being compared.

And what we found is that both the hospital-level and the patient-level effects are associated with readmission. And I'm showing you the information for AMI although it's similar for all of our readmission measures for which we've done this analysis so far.

And in the table you can see the coefficients for the patient-level portion of the variable and the hospital-level portion of the variable and the P values in that final column.

Unfortunately you can't look at these coefficients and compare them directly. It's

tempting to do so, but we can't because these are measured on different scales for a patient. They either are dual eligible or are not. They either are black or not. But for hospitals the proportion of patients that they have in these categories is a continuous variable. So those scales make it impossible for us to directly quantitatively compare these.

But it's important to understand that both contribute in a statistically significant way.

So, one of the things that we're working on, and that you all can see if you're following the work of the admissions and readmissions committee over the next six weeks or so, we're working on quantifying and directly comparing the hospital and patient-level contributions using a prediction analysis. It's actually pretty neat so please tune in if you are interested in that.

And then we are also going to be presenting the AHRQ SES data that is defined down

to the Census block group, again aimed at a local population of about 1,500 for each block group.

And our analysts have done some brilliant and innovative work adjusting for median income for differences in cost of living and different geographic areas which we think is really important when you're using a national sample.

Because if you compare New York and Mississippi then it will look like New York doesn't have any low-income areas. So we've done some really innovative adjustment work. And so you all will be able to see that in some of the discussions that are upcoming.

So these were our conclusions. I've said all of this. I'll sort of jump over the first two bullets, but say that the work that has gone into this has really been tremendous. More than we probably could have anticipated at the beginning of the year.

It probably doubled the work that we need to do for measures that go through regular

endorsement maintenance, if not maybe a little bit more than doubled. So it was an incredible undertaking for all of us, and especially our analysts.

And I think that we would concur with a lot of what many stakeholders have brought up which is that all of the work around disparities is greatly limited by the data and variables that are available to compare groups across the nation.

And we are as eager as anybody to have a richer data source to look at social and economic disadvantage, and how it impacts health disparities.

So I'll stop there. Questions now?

MS. O'ROURKE: Yes, any questions for Karen?

If not, I'd like to ask Kristen Butterfield from PQA to come up and tell you a bit about the work they've been doing around SDS adjustment.

MEMBER BUTTERFIELD: Thank you, Erin.

So, I'm just going to talk a little bit about what the Pharmacy Quality Alliance has been doing around kind of our efforts to address sociodemographic risk adjustment.

I want to tell you a little bit about PQA. We are a non-profit organization established about 10 years ago.

We're a member organization, so we currently have about 160 members. And really our mission is to develop medication use performance measures. And these are for health plans, PBMs, drug plans, providers, pharmacists and pharmacies.

So we have a couple of measures that are being used in national programs. Five of our measures are being used in the Medicare Advantage and Part D contract Star ratings program.

And three of those measures are medication adherence measures. We call them the proportion of days covered measures.

And it's looking at basically three

different measures of medication adherence to hypertension medications, diabetes medications and statins.

We also have a high-risk medication in the elderly measure being used in that program. And our statin use in persons with diabetes measure will be used next year for that program.

Our medication adherence measures are also used in the health insurance marketplace quality rating system.

So, we've been closely following along with NQF and their panels and their recommendations for starting to look at SDS risk adjustment.

So about a month or so before the trial period began by NQF PQA decided to kind of really start looking at our measures and to convene a panel to determine what measures do we currently have that would be appropriate for SDS risk adjustment and what kind of methodology would we be using.

Our initial panel was made up of four

or five people who were just kind of interested in the topic and wanted to discuss it.

And then we opened it up to additional members to create a more diverse panel. And we had an application process. And we currently have 17 members that represent academia, health plans, pharmaceutical industry, PBMs and health tech companies. So this is what we're considering our expert panel.

The panel has decided to focus on the three medication adherence measures that are currently being used in the Star ratings program.

Most of our measures are process measures, but the medication adherence measures are more like intermediate outcome measures that would be more appropriate for risk adjustment.

Also, the fact that they're being used in a national program. We thought that that was important to start taking a look at that.

So, we have our -- lovingly referred to as our RAAP, which is our Risk Adjustment Advisory Panel.

And this is a panel that meets telephonically. We meet once a month.

And this panel is really charged with, as the measures are being developed by PQA to really look at any kind of risk adjustment including clinical and SDS risk adjustment for any endorsed measures or any measures that are under development.

They're tasked with identifying the variables that would be used for risk adjustment based on conceptual or empirical evidence. And then also developing, reviewing analytic plans and also looking at the results of any testing that's been happening.

Ultimately the panel is charged with, after reviewing all the conceptual evidence, the empirical evidence, to make some recommendations to PQA regarding SDS risk adjustment of our measures.

So we had some initial testing done. PQA, our three medication adherence measures basically use Part D administrative claims data.

So pharmacy claims.

And PQA does not own its own data so we look to our members to do our measure testing for us. And we did have a PQA member who was interested in doing some initial testing.

And we decided to focus on, kind of based on the literature and based on some other empirical evidence we decided to focus on these indicators, variables to include in our models.

We looked at age, gender, race, ethnicity, low-income subsidy status which again is if a person is having a subsidy for their medication which might be an indicator of socioeconomic status. We also looked at dual eligibility, disability status, number of unique medications which is kind of a measure of disease burden.

And then these other variables. Households that own their own home, population below poverty level, education level. These were those community characteristics. So again, these variables that were found at the five-digit or

nine-digit zip code level.

We also looked at language and if the patient resided in a primary care shortage area.

I just want to tell you a little bit about what we did with this analysis. It was a two-step process where we ran a regression model to look at -- to determine if any of these variables were significantly associated with medication adherence.

And then after we did that we then risk adjusted the measure scores and kind of looked at how the scores changed after risk adjustment.

The data that was used was a database that had 44 Medicare Advantage Part D plans. And we ranked them based on their score, adjusted versus unadjusted.

So the initial testing found that there was just very great consistency across the three medication adherence measures for what was significantly associated with adherence.

We find that disability and age,

race/ethnicity, dual eligibility status, number of meds and then those community-level characteristics were significant predictors of adherence. And this was for all three of the adherence measures.

We also found that income and education which again get to those community-level characteristics, not the patient-level characteristic, we found that those were significant predictors even after controlling for dual eligibility status and disability status.

This is just kind of the results of this initial analysis where basically here we have the unadjusted rate on the bottom and then the risk adjusted rate on the left.

And each triangle there represents a contract. Again, there were 44 contracts in this analysis and each contract had a score after risk adjustment.

The closer that the triangle is to being on the line means the less that the performance score changed after risk adjustment.

So, what we're kind of seeing here is that these plans kind of at the top. So they're ranked 1 to 44 with 1 being the best score and 44 being the worst.

So, the plans at the top that were kind of the worst performers unadjusted tended to stay poor performers after risk adjustment.

And the plans at the bottom that originally were kind of the higher performers tended to stay high performers after risk adjustment.

And it was really these plans in the middle that changed, the kind of two quartiles in the middle that really had a variation after risk adjustment.

You can see for B, plan B up there, that it was originally ranked 29 and then it dropped to 37 after risk adjustment. So it was risk adjusted to look like they had a poor performance.

And a plan like plan A started off as a lower performer, and then after risk adjustment

was ranked higher at 18.

So again, that was some initial analysis that we did. And our risk adjustment advisory group right now is kind of taking the findings from that and we're wanting to apply that to a larger population.

So again, that was just 44 contracts, 44 Part D contracts, and it was the Medicare Advantage contracts.

We know that there's a lot of people enrolled in stand-alone prescription drug plans and that was not included in this analysis. And that makes up almost -- over 70 percent of people who are enrolled in Part D. So we want to get those additional data sources to be able to look at that.

This availability of the five-digit code versus the nine-digit code is definitely an issue as we've heard, the data availability.

The initial testing that we did, our PQA member actually did have access to nine-digit level zip code information. So that data that

you just saw was used at the nine-digit level zip code which is I think about eight households.

So although it's not a patient-level indicator, it's very close, versus a five-digit level zip code which again could be hundreds and hundreds of homes.

The problem is that one PQA member who had access to the data, that's great. But not everyone does. And so it may not be available to everyone.

And so we're talking about what that means. Is there an easy way to get access to that data. Our risk adjustment advisory group is working through those issues of where do we get this data.

We're also -- the group is also discussing including some measures of disease burden and potentially some cost or some copay for medication information, knowing that that might also affect the outcomes.

Again, we're looking at risk adjusting using other populations. So right now we are

working on getting some other PQA members who have access to data to do some of this testing as well.

When we originally did our regression we did not look at within-contract differences. So we were just looking at the overall differences for the sociodemographic characteristics kind of between contracts. And again, our measure is at the contract level.

So we want to start to do this analysis looking at our people who are low-income subsidy status, our dual eligible within the same contract. Are they receiving care that's different than those who are not within the same contract. So kind of controlling for that contract level. So that's the next round of analysis that we'll be doing.

And then the other thing that our ongoing work is also looking at other measures of PQA that might be impacted by SDS variables. So, discussing some of our other measures that have already been endorsed, or that are currently

under development. So we can kind of look at that as we move through our development process.

And just to let you know we have not been through the SDS trial period. Our medication adherence measures I think come up for maintenance review I think in 2017. So this is kind of pre-work that we're doing to prepare, knowing that this trial has been happening.

Any questions?

MEMBER CAMPBELL: Kristen, it's Kyle from HSAG.

In your case you don't have I guess a starting point of a clinical model for risk adjustment. You sort of started with the SDS, right? And then are working back the other way. Right?

MEMBER BUTTERFIELD: Right. So, our three medication adherence measures are not clinically risk-adjusted. So we're just starting to look at SDS.

And then as we're talking through these on our panel we're thinking what else might

also be associated with these outcomes that could affect that. So, exactly.

MEMBER CAMPBELL: And is that part of your plan when you say you're going to look at disease burden? You're going to sort of build a model, like a regular clinical model, and then compare running SDS with and without that?

MEMBER BUTTERFIELD: Right, exactly.

MEMBER CAMPBELL: Okay, thanks.

MEMBER POPOVICH: Hey, this is Matt with ASA.

Does PQA have any measures related to patient satisfaction, communication with the pharmacist, understanding if they feel that their concerns are being addressed?

I mean, when you think of adherence to a medicine is it just they're refilling the prescriptions? Or is it that they're splitting pills, or that I'm not taking this pill because it doesn't make me feel well? What are the intangibles that you see that might influence SDS or other sorts of things beyond sort of education

or income where that communication between the patient and the pharmacist would probably be higher than others?

MEMBER BUTTERFIELD: Yes, I think that we -- there's evidence, there's literature out there that shows that those issues can affect medication adherence.

The measure specified only uses pharmacy claims so we don't have any kind of data source to assess what's impacting the medication adherence.

We do not have any measure that relies on any kind of survey data or any of those. So again, I think it gets to that. We can't include every single thing in a model because we just don't have the data to be able to do that.

So in the end when we finally look at -- after these measures are risk-adjusted and what the change is will they even be adequate knowing that we're not necessarily capturing everything. So that's again the ongoing work of what our panel is doing.

MEMBER WATT: Ann Watt from the Joint Commission.

Can you tell us a little bit about the composition of your RAAP panel?

MEMBER BUTTERFIELD: Sure.

MEMBER WATT: What kind of people are on there is what I'm asking.

MEMBER BUTTERFIELD: Yes, we have people from academia who are well versed in the adherence literature and medication adherence.

We have some representatives from health plans who work within the Star ratings program at their particular health plan. I'm trying to think off the top of my head who else.

We have some data technology companies who have access to data and have been looking at some of these topics as well.

So, it's a panel I'd say that's very representative of our PQA membership.

Any other questions? All right, thank you.

MS. O'ROURKE: So, I think with that

I just wanted to see if anyone else would like to share a little bit more about their work they're doing.

We have a couple of questions here to spur discussion if anyone else would like to discuss their experience including SDS factors in risk adjustment models. What variables you've had available to test.

And from the developers' perspective, if you have any thoughts about how race should be handled as a potential variable. So I just open it up for conversation.

MEMBER GEPPERT: So, I've seen a couple of state models that are sort of of interest.

States have some advantages in that they might have a little bit more information about people than might be available in some of these federal data sets. They usually have like a street address and even a name which helps with the creation of a master patient index, or the assignment of a Census block group.

So I think that's something to look into about some of these state data sources and whether that data might be useful in evaluating some of these models.

And then I know there are some states that have sort of gone the total hierarchical route where they just assign everyone to a Census block group and then just try to adjust for everything associated with that Census block group and not even try to be so specific about which socioeconomic or sociodemographic variables that are included.

And that's sort of another approach that people have taken and are trying to evaluate what the impact of that is.

It's even like, Karen, you sort of had your four pathways. I'm just sort of curious about how much discussion there really has been about those pathways.

Is it just a matter of sort of showing that there's literature associated with those pathways? Or is there really a lot of discussion

about which pathways are potentially most relevant?

I mean, some of those you'd want to hold any hospital accountable for and other ones, you know, you wouldn't. So it might matter which pathway you're talking about.

MEMBER DORSEY: So, to be totally truthful some of that analysis and examination of pathways is responsive to what we needed to do for NQF.

Although I'll say that there are many members of my team who have a particular interest in this, who have published in this area, who have had a longstanding interest in thinking about these things.

In terms of trying to compare the pathways and figure out which is more important for what, that's tough.

I think there's not a lot of research to stand on.

I think that the decomposition analysis is one attempt to begin to get at that

to try to understand what pieces might be more important, although that limits it to sort of what level of the model are you attributing to. It doesn't really get quite as granular as I think your question is aiming.

So for example, hospital-level effects are about how hospitals perform that happen to have a high concentration of dual eligible patients, for example.

But discriminatory care within a hospital? That travels at the patient level. We can't tease that out.

And so modeling also gives you limited answers about the importance of those pathways.

One thing that we're particularly interested in is trying to incorporate the patient voice in trying to understand which pathways are more important.

I think that's important for how we interpret these kind of data, but also how we think about measurement aimed at reducing disparities moving forward.

So, that's one way to think about it. But I think it's really challenging.

DR. BURSTIN: I'll also mention on the state side we've been trying to collect some of these examples of where there actually has been some state innovation.

There's been a lot of work done in Missouri, for example. And they have a slightly different model. We'd be happy to share that white paper if people would like to see it, the way they've been approaching SDS adjustment.

The other group we've been talking with recently is actually the State of Vermont. Craig Jones who some of you may know who leads the Vermont Blueprint for Health, very, very thoughtful guy. Actually I was just at the Medicaid directors meeting with him last week and was pulling up these slides.

They've actually found that Medicaid expenditures on special services, meaning the services that go beyond the usual medical care, but as a clinician these make sense to me.

Transportation services. The kinds of things that probably go along with vulnerability truly are having a huge effect.

And they adjust their clinician-level variables for this Medicaid expenditures for special services.

So we'd love your ideas. And I think the states are often a laboratory because they have these kind of data that, for example, are obviously more difficult to get at a national level. But there might be some great examples that could bubble up if you have any other thoughts.

MEMBER CAMPBELL: You alluded to incorporating the patient voice in it, or the difficulties of teasing out a patient experience within certain hospitals.

Can you kind of expand upon that and how you see perhaps that going in the future in several years? Or how you might even contemplate modeling that?

MEMBER DORSEY: So, I'll try not to

get out of my depth in answering your question.

I think for now we're asking a narrow question which is what do patients identify as some of the key mechanisms by which these things may be related.

You all may be familiar with the National Academy of Medicine having just come out with a conceptual model around these things.

But I don't know of a really patient-driven or patient-centered conceptual model around these things. And I think that's a really important missing voice as we start to think about how we structure. Because these things tend to drive how we structure research and measure development around these areas.

So that's where we're starting, with a more narrow question.

I think it can get broad really quickly. I think it's important when you're thinking about how you collect data, what data people rely on. These are questions that we're not asking, but I think are really important to

include the patient voice in.

Ultimately we develop measures in partnership for CMS. So ultimately our clients are people. And I think a lot of developers feel similarly.

And so we want to make sure that we're moving and including that perspective in everything that we're doing.

MEMBER HIBAY: Karen, are you going to be listing on the NQF website just all the variables that people are using from their different measures? I think that would be very helpful.

We may understand the data sets or the data elements that we've explored, but just having some sort of a resource to tap into the types of measures, the types of organizations, or the level of analysis, or is this a state measure, a national measure, provider, payer, blah blah blah.

So I think that could be helpful to allow us as measure developers to continue to

explore opportunities to research this topic.

MS. O'ROURKE: We are collecting all the variables that various developers are looking at. We're still in the process of that, but that's part of our evaluation plan, to collect this information and report it back out.

We're working through our disparities standing committee to report back out and get their input on a lot of these topics.

So we just had a webinar at the end of April to give them an update of the results to date. And we'll be updating them every quarter about what we're finding, what's going on, what different developers have been doing, what variables are available for testing. And we will be compiling that and making it publicly available as we go further through the trial.

I did want to be sensitive that we have quite a few folks on the phone. Operator, could you open lines and see if anyone on the phone has a question?

OPERATOR: At this time to make a

public comment you can press *1. There are no comments at this time.

MS. O'ROURKE: Great, thank you. I didn't want to cut off conversation in the room. Any other thoughts before we move on?

MS. ISIJOLA: Thanks, Erin. So we're ahead of schedule still, but we'll break for break. We'll be back in about 20 minutes. Thanks, everyone.

(Whereupon, the above-entitled matter went off the record at 2:22 p.m. and resumed at 2:47 p.m.)

MS. ISIJOLA: Thank you, everyone, for your patience. I think we're going to go ahead and get started. Okay, so our last and final presentation will be on one of our measurement science projects, attribution.

We'll have an interaction -- interactive session at the end, but also I wanted to make note, we do have a happy hour that will be at Claudia's Steakhouse, which is literally right next door to this building, so following

this developer workshop, we encourage you or invite you to join us for happy hour downstairs.

And with that being said, Kim.

MS. IBARRA: Thanks. Thanks, Wunmi.

Hi, everyone. My name is Kim Ibarra. I'm a project manager here at NQF, and I'm managing the attribution project. I have a lot of stuff to manage, so let me put this down.

So I wanted to start by talking a little bit about what this project is about, some of the background, and the policy context, then really open up a discussion to get your perspectives as measure developers on some of the challenges that you face in your work in terms of incorporating attribution rules into measures and just perspectives to inform an environmental scan that we're -- we undertaking.

Starting off with some background and policy context for this work. In the past few years, we've seen landmark legislation that has expanded value-based purchasing across the healthcare continuum, so the Affordable Care Act

created pay-for-performance programs, particularly in hospital settings, IMPACT Act expanded this to post-acute care and long-term care settings, and MACRA is creating the new quality payment program which encompasses the Merit-based Incentive Payment System, or MIPS, and incentivizes advanced alternative payment models or APMs.

As the U.S. healthcare system increasingly shifts towards paying for value and towards care provider and shared accountability models, being able to accurately identify who is accountable for a patient's care and a patient's outcome becomes really critical.

HHS has adopted a four-category framework for healthcare payment where category one, on the left-hand side, is fee-for-service with no link to quality and value. Category two is fee-for-service with a link to quality and value, so we might see things in here like pay for reporting, rewards for performance, or rewards and penalties for performance.

Category three is where we get into alternative payment models, and category three is alternative payment models with built on fee-for-service architecture. And in this category, we would see things like APMs with upside gainsharing or upside gainsharing and downside risks. And, then the fourth category is population-based payment either for comprehensive care or condition-specific care.

Moving from left to right from category one to category four involves two shifts. The first shift is increasing accountability for care and total -- increasing accountability for quality, excuse me, and total cost of care. And the second shift is this greater focus on population health management as opposed to payment for volume of care and the number of services that are provided.

After the ACA was implemented, an estimated 20 percent of Medicare reimbursements had actually shifted to where it's category three and four linking provider reimbursements directly

to the health and well-being of patients.

And, so in January 2015, HHS announced new goals for value-based purchasing and for APMs and Medicare. The first goal by the end of 2016, HHS is aiming for 30 percent of Medicare payments tied to quality or value through APM, so categories three and four.

Also, by the end of 2016, the goal is 85 percent of Medicare fee-for-service payments tied to quality or value, and that would be categories two to four. And, then by the end of 2018, on the far right, 50 percent of Medicare payments would be -- they're aiming to tie that to quality or value. And 90 percent of all Medicare fee-for-service payments tied to quality or value by the end of 2018.

So in this shift, which we've been talking about all day around rewarding for value as opposed to rewarding for volume, the need for clear attribution models is really critical. The lack of clarity around attribution approaches limits the ability to use meaningful cost and

meaningful outcome measures.

What do we mean by attribution? Attribution can be defined as the methodology used to assign patients or their quality outcomes to organizations or providers. And this is really important because it helps identify that provider-patient relationship that can be used to establish accountability for quality and cost.

We might need to attribute overall quality of care, different parts of a patient's care, episodes of care, health outcomes, individual patients, or even populations to individual clinicians, to groups of providers, or other entities. This starts to get really challenging when there's so many different providers involved in delivering patient care and providers have payments at risk.

Some of the challenges we've heard that have been raised around attribution include, how to align the care delivery model or the payment model with a particular attribution approach, the impact of small numbers of patients

and provider profiles, unreliability, and aligning the attribution approach to what's actually in the control of the accountable entity.

So what we're really looking for and what's needed is measurement approaches that recognize that there are these multiple entities involved in care delivery and that they have individual and also joint responsibility in improving quality.

The attribution project at NQF is aiming to provide greater guidance to the field on attribution. Through a multi-stakeholder committee and commissioned authors will be exploring and cataloging different approaches to attribution ones that are currently in practice, and also those that have been identified in the literature.

We'll be analyzing the strengths and weaknesses of the various approaches, particularly as they're applied in different context in the healthcare system. The project

will involve describing the subset of measures that are particularly affected by attribution issues and describing the models in enough detail to enable further testing at some later stage on CMS data. And, finally, one of the goals is to identify principles and recommendations that can guide how to select and implement attribution models in practice.

We're doing this with 25 committee members and one federal liaison from CMMI. We have representation from measure developers, including NCQA and Yale CORE. We have health services researchers, statisticians, specialists and generalists' physicians, nurses, administrators, suppliers, purchasers, and consumers, so as in everything we do, I'm trying to include all of the different stakeholders to develop recommendations and look at, look at attribution.

We started this work in September 2015 by convening the committee and commissioning the authors who will be conducting an environmental

scan and producing a commissioned paper. Our first led meeting was at the end of March, and this was to review the outline for the environmental scan and the paper.

Currently, we're in the third box over here, which is the authors are conducting the environmental scan and drafting the paper, and this is where we really want your feedback.

The committee will then meet in person in mid-June to review the draft paper and to start to develop principles to guide selection and implementation of attribution approaches. That paper will be published in July 2016 with a 30-day member and public comment period.

The committee will meet again in person at the end of August to review the public comments and to start to develop their recommendations and guidance around how to approach attribution in practice.

A draft report with those recommendations will be published in late September, and we will also have a 30-day public

comment for that report. And the final report is due at the end of December of this year.

So as mentioned, we're currently in the environmental scan phase of this work. And the environmental scan aims to identify current and proposed approaches to attribution through literature review, key informant interviews, and discussions with our stakeholders, like yourselves.

The commissioned paper is going to include criteria that's going to help us assess and evaluate the identified approaches and really have a discussion about the strengths and weaknesses of the different attribution models, and it'll include a discussion about the technical issues around reliability and validity and other implications of using different attribution approaches and different payment and care delivery contexts.

This is the team of authors we're using for the environmental scan and the commissioned paper. They represent health

services, researchers, policy experts. We have a methodologist, a generalist and specialist physician, and a research assistant.

So we wanted to do is to have a discussion with you all about some of the challenges that you face in your roles as measure developers because of attribution, and so at your tables, you will find colored pieces of paper that I handed out right before this.

Green is challenges related to data, and orange is challenges related to measure development and specification, and so we'll take the next 15 minutes to discuss at your tables amongst yourselves the answers to these questions. Think about some of the challenges you faced, how they've been addressed, and then we'll come back together as a group to collect your insights, collect your challenges, and then I will be taking that back to our authors and it'll feed directly into our environmental scan to inform the rest of the work of the committee going forward.

So before we do this breakout, are there any questions about anything I've presented? Yes.

MEMBER GEPPERT: Can you just clarify the goal attribution to whom? Is it a physician, you know? What -- what level are we talking about?

MS. IBARRA: I think that's one of the questions that the committee is exploring and the authors will be exploring, so as a first step, the authors are going to be looking at how has attribution been addressed and practiced in the literature, so who is being attributed to whom, is it at the individual clinician level, is it at -- is it at a more systems level, and then the committee -- some of the early discussions they've had has been around these questions of what is the scope of the attribution that we're looking at and where can they make the most meaningful contribution with a recommendation.

So right now, that is a question they're exploring. I don't have an answer for

you in terms of a project, but we'll probably come up with specific vignettes or vignettes that help to illuminate attribution to whom and answer that question.

Anyone else?

(No audible response.)

MS. IBARRA: Okay. So it's 3:00. We'll take 15 minutes, walk around, discuss amongst yourselves. I know there was great discussion during the break, so hopefully, you can bring that to this discussion, and looking forward to hearing back from you. If you could assign someone or choose someone or have a volunteer for your table to report, to lead the report back, that would be really helpful.

And for those on the phone, you can participate as well by providing your input for the report back session.

(Whereupon, the above-entitled matter went off the record at 3:01 p.m. and resumed at 3:18 p.m.)

MS. IBARRA: Okay, so I think we'll

get started. We did have a question come in from the chat during the, during the breakout, which was, "Will this project address things that are outside of the healthcare provider's control, so, for example, socioeconomic issues?"

And, so this project as part of what the authors are looking at, one of the alternate payment models is the Accountable Health Communities' model, which is starting to link healthcare with things that are in social care and things that, things that address the socioeconomic issues, but it's something that NQF is very sensitive to as providers are being held accountable for factors that might be outside of their immediate control, so we've heard about things like the SDS trial, the disparities' work, risk adjustment.

And it's something that we are looking at in all of our work, and in this project specifically, one of the examples is the alternate -- the Accountable Health Communities' model.

So I hope that that answers the question. Please chat in if you have a follow-up or if you wanted to clarify.

So I walked around the room. There seemed to be some really great discussion on attribution. Wanted to start with table seven because they finished first. And we'll just start -- we won't go through all of the questions at your table, but if you could maybe pick one and tell us a little bit about the conversation you had and what your challenges around this issue are.

MEMBER BERNS: Sure, so to start with question one, we talked a lot about how different data source is, either have different strengths or weaknesses when you're thinking about identifying patients, so I didn't know a lot of us work with Medicare claims' data and it's pretty easy to link patients over years and across providers and facilities using that data, but then it doesn't have the same amount of rich information that you might get from an EHR, but

with EHRs, you certainly have challenges of linking patients across facilities or from a primary care provider to a hospital.

So we talked a lot about how thinking about when you're thinking of attribution thinking about whether or not you need to look at patients longitudinally or not, and then think about data sources based on how long a time span in history you need for the patient.

MS. IBARRA: I saw a lot of nods, so it seems to resonate. Is there anything at the other tables who loved to add, measure development and specification challenges wanted to add around question number one, how to deal with problems of accurately identifying patients for attribution? I think it's table six and three are the orange card tables, or others who did not look at these questions, definitely, please.

MEMBER DAILY: So, I guess, we can expand on this. We talked a lot about challenges with establishing, you know, who should be

attributable to whom. And, so one of the things that I know a lot of measures do is sometimes, you'll build within your specification a minimum number or type of interaction, so maybe you have to have so many visits with the provider to then be attributable to that provider or maybe a certain type of visit to count, to kind of be counted as their patient, which isn't ideal and it's somewhat arbitrary, I think. I don't know that there's any great evidence that this many visits makes a patient your patient, but that's one way, one workaround.

Other approaches, I know sometimes depending on if you're working with a development group, and sometimes if you're setting out to develop measure for a specific purpose, say for a registry for your individual clinicians to report on.

Unfortunately, if they aren't comfortable being held accountable for a specific action, sometimes you have to forego that concept for that particular implementation if you have a

specific purpose in mind or concept. Sometimes if you can't reach consensus on attribution and accountability, it winds up getting rolled up a level that maybe it's just not best as an individual measure, so it winds up being a team-based measure or a facility level measure, etc.

None are ideal ways of really getting at this, but those are some of the things I think that kind of workarounds that are used now.

MS. IBARRA: Other comments?

(No audible response.)

MS. IBARRA: Okay. Well, let's stick with table six, and if you wanted to answer question two, I think you, you touched a little bit on this, but was there anything else specific to question two around handling uncertainty related to how to attribute patients?

MEMBER DAILY: I guess the one thing I'll add is we kind of talked about the notion of team-based care and how do you account for that measurement. You know, there's discussion on, should everyone -- a team is a team, so everyone

kind of has equal responsibility, equal weight for that patient, or do you try to somehow wait, you know, you're 30 percent responsible for this patient because you provide this much care or -- and so, I don't know that there's a great answer to that, but that's one thing we kind of talked about as challenges, especially when you consider this move towards more team-based approaches to care as being more patient-centered, and I think that's a challenging aspect.

MS. IBARRA: Any additional thoughts on how to handle uncertainty? Anyone from the tables that looked at data challenges around handling uncertainty?

(No audible response.)

MS. IBARRA: Okay. Table three, question number three, which is, how do you see attribution issues impacting the reliability and validity of a measure?

MEMBER CAMPBELL: Okay. So maybe first there are just a couple of things we might be able to add to question two. I think for

handling uncertainty, we're all measuring -- I mean, we've -- the developers represented here at the table have measured across all the various settings of care, and so it's very different for each setting.

So, for example, with a plan-based measure that PQA would work on, they would be looking at continuous enrollment requirements. So like if, you know, to ensure accurate attribution, you would want to make certain that the patient was a member of that plan for the majority of the year say for example.

And it's a very similar type of thing, I think, in clinician-based measures where you might be looking at, let's say, the plurality of the care provided if you were really trying to assign accountability. Who had the most E&M visits or, you know, type of visit that would be considered an encounter with the physician?

In terms of the reliability and the validity piece, I think, as you begin to try and attribute down more granular in the healthcare

system, probably the biggest issue is the sample size considerations and your ability to distinguish performance between providers first to go down.

So if we think about signal-to-noise and reliability, we start to lose all that as we attribute down, you know, layers in the healthcare system. Validity was an interesting question. I think a lot of us use face validity to evaluate some measures primarily because there isn't a lot of other measure comparators for conversion or empirical validity testing that are really suitable candidates.

So if you think about validity, you know, I don't know that anyone can answer what does that look like as we sort of go down the system if you had, you know, sort of a plan level measure let's say of hemoglobin A1c and that looked like it showed that at the plan level that it was correlated with high performing plans, but if you went down then to the physician level or the physician group level or the individual

clinician, would that relationship hold true? I don't know. I don't think anyone knows that, but I think those are good questions as we sort of wrestle with this, you know, going forward.

MS. IBARRA: Thank you.

MEMBER CAMPBELL: Yes.

MS. IBARRA: Any reactions, comments? Anyone want to add to some of the challenges around validity and reliability that attribution raises? Yes.

MEMBER ANDERSON: We certainly talked about signal-to-noise testing as well and how attribution can play a pretty large role in the reliability of a measure. I think one of the pieces that we talked about related to that was how if you're attributing patients to the wrong providers or for the wrong encounters, you're just going to see a reduction and reliability overall, and so how that signal-to-noise testing actually can help you to see if you have attribution problems as you're developing measure.

MS. IBARRA: Thanks. Anyone else? Anyone on the phone?

Operator, can you open up the lines to see if anyone from the phone has comments around the challenges attribution creates related to measure development and specification?

OPERATOR: Okay. At this time, if you would like to make a comment, please press star, then the number one.

No. No comments at this time.

MS. IBARRA: Okay, thank you.

All right, so let's move to the second set of challenges. And these are challenges related to data and these would be the green card tables, so let's start with table five.

Question one, what are specific data requirements for attribution? What did your table talk about?

MEMBER POPOVICH: Well, we -- we're actually the table of the non-patient facing specialties of anesthesiology and radiology, so our knowledge of attribution is based upon your

guys' guidance. Within the value-based payment modifier, we have very few members who are attributed to patients, and so, so what we have, it's claims, but it's also, it could be registry data, EHRs if you could.

I mean that's just a starting point, but, you know, going into depth about it, you know, I don't think we have the expertise to answer this fully, so we'll open it up.

MS. IBARRA: Other thoughts from the other tables, the patient facing tables?

MEMBER GEPPERT: If I can read down our list? So in terms of the data requirements, we thought you need, obviously, a way to identify the patient, you need a patient identifier, you need a way to identify the provider, some sort of provider identifier, you need a way to link the two, patient and provider, and then you need to decide what counts as a link.

Is it an encounter, a visit, a phone call, a prescription? You have to have some rules about sort of what matters in terms of a

linkage.

You probably need a period of time to know over what period of time this attribution applies. You might want to know a little bit about the nature of the interaction, whether it sort of fits your idea of attribution and accountability, and then maybe something about the provider type, whether it's a physician, a non-physician, some other type of clinician, non-facing clinician.

MS. IBARRA: Thanks. Any other comments or -- about this? The back.

MEMBER ELLIOTT: Hi. We're table eight. Some of our discussion is similar to what we just heard, but also looking at, you know, that relationship of the patient to the provider, so that linkage that you spoke of, but we kind of went down the road of, are they solely responsible, partially responsible in a consulting capacity?

And, then, also the -- I lost my other train of thought. I think we focused mostly on

that relationship back to the patient and how to do that both either in a hospital setting or a practice, a physician practice.

Also, attributing some data that could be used for attribution could even be in one of our scenarios was a center, you know, attributing back to us in a bundled payment model where you have many people caring for patients, the attribution may need to be at a higher level.

MS. IBARRA: Okay, let's stick at table eight and talk about question number two, which is, how could or should attribution models evolve as we move away from fee-for-service?

MEMBER ELLIOTT: That kind of gets into our bundled conversation and looking at the center or a population. We talked about per member per month, you know, kind of attribution. Hierarchy in terms of the responsibility to the patients, you know, who's all involved -- who's ultimately responsible for the care plan?

I'm not sure -- we kind of went down a couple different paths, how do you actually

attribute that and how do you develop the data models to do that? So some of it could be state and zip code kind of data, you know, kind of back to where they live may be how you attribute to a center.

I think that is it. Am I missing anything that we touched upon?

(No audible response.)

MEMBER ELLIOTT: Okay. We kind of went down that path for a while.

MS. IBARRA: Thanks.

Do the other tables that talked about data challenges have anything to add around how models should or could evolve?

MEMBER POPOVICH: Well, I think that in the different levels working within the rubric or the framework of what MACRA is doing with the patient attribution codes and everything, that's kind of, at least for ASA, trying to develop policy around this of where do our variety of physicians fit within that schematic, or not within the schematic, but the matrix, the matrix,

is something that's challenging for us because of the different variety of physicians that we have, so it needs to be on an individual clinician basis at this point is kind of what we're thinking.

Did you want to add anything?

(No audible response.)

MS. IBARRA: Other thoughts?

MEMBER GEPPERT: As we sort of thought about it from two -- well, first, we started thinking about what other specific data challenges with using the EHRs that, you know, claims data might, might be better suited, so, you know, maybe the availability of identifiers, tax IDs, Social Security Numbers, you know, might potentially be more readily available in the fee-for-service data, then you might be more challenged in getting access to that data depending on the EHR system, and what kind of linkages there are, but then we sort of migrated into more of the, well, thinking more about, well, what's the need for the data when you move

away from fee-for-service to alternative payment models?

We started thinking about more system accountability versus individual provider accountability and where the accountability and the alternative payment model really resides with the system, and then you let the system sort of figure it out how they want to allocate accountability with the individual providers.

MS. IBARRA: Other thoughts? Yes.

MEMBER HIBAY: I have a question just in general. As we talk about the shift from fee-for-service to alternate payment models, not necessarily what additional data elements are required, but more so maybe a representation of performance scores and/or testing when we look at those two different spaces comparatively.

So as we say we want to move from one payment model to a different more team-based payment model, is there an opportunity to share performance and testing or somehow to explore testing from that perspective to understand if

there are meaningful differences in outcomes related to the varying payment models?

So, you know, we do believe these alternate payment models are supposed to be more team-based, and we, you know, finger in the wind, we do believe that they will provide better outcomes to meet the National Quality Strategy, those three happy aims, but do we really know that, and is this an opportunity to say through an attribution exploration whether or not, you know, that they are demonstrating such.

MS. IBARRA: Thanks. And I think that's something as part of the work that the committee will be exploring and deliberating on, we will be looking at different payment models, different care delivery models, how does -- like what does attribution look like in these different kinds of contexts, what are the strengths and weaknesses in these different contexts of applying different kinds of attribution models and roles?

So I think it is something that the

committee and NQF and the authors are going to explore through this work.

And, then let's go to the last question, which is, can you imagine data other than medical claims being used for attribution models? So we started to hear some ways of getting alternative data that we might be able to use for attribution rules.

Is there any other kinds of data that you think could be leveraged as we start to look at these different attribution models? Table four.

MEMBER GEPPERT: So the first thing we thought of was just asking, you know, asking the patient if they have a preference or if they could identify their attributable provider or asking the provider the patients that they -- or feel accountable for.

And, then we talked about some of the other things that have already been discussed using census data or, you know, where you live, or using things like pharmacies or schools or

other kinds of retail, healthcare providers, and then we talked about the Accountable Health Communities.

And, then, finally, we just gave up and said, "We'd just ask Google, you know, what." Google knows everything, but maybe social media might be another data source that could be utilized.

MS. IBARRA: We just wanted to pick up on something that you, your group mentioned, which is asking the patient. And what we heard in some of our early committee discussions is some people on the committee use patient attestation as the default, and for others, it's the gold standard, and for others, it's really the last resort, and so just wondering kind of some of your thoughts on that.

Is that surprising that there's that much variation in how people are -- how people view a patient self-report or patient identification of their provider, accountable provider?

(No audible response.)

MS. IBARRA: Not surprising? Are there -- do you have thoughts on what should be the default or what should be the gold standard?

DR. BURSTIN: I think part of the issue is we don't know what the gold standard is. Hopefully, that's the part we'll be able to figure out is what did we learn from the literature, etc.?

Just as a funny anecdote, I practiced for ten years here in town at a Latino health center, and, you know, I was "la doctora con la pelo muy largo," like that, you know, they went, I was the doctor with the long hair.

You know, so it wasn't, anybody knew who I was, so, again, depending on your patient population, that may not really work. I'm not even sure my mom really knows the names of her doctors, so I think we have to think about ways to make this easier for patients.

Actually, at GW where I practice now, there's little, you know, the name shows up in

every record, so as you're seeing a patient, it says, "PCP Helen Burstin," so you can say to the person, "Is that your doctor?"

So I think there are different ways in this new IC -- this new CPT code approach of having the doctor code your relationship to the patient, which is being tested. All these are exactly the sort of fodder for this kind of work.

MS. IBARRA: Thanks, Helen.

Is there -- are there any comments from the phone?

Operator, could you open up the lines?

OPERATOR: If you'd like to make a comment, please press star, then the number one.

And there are no comments from the phone line.

MS. IBARRA: Okay. Before we wrap up, I -- we will be taking your feedback and compiling it for our authors as they conduct the environmental scan. It'll be shared with the committee as well.

We -- we will be, as I mentioned,

identifying principles and recommendations around attribution, and so just before I end, wanted to hear your feedback on the kinds of recommendations, the kinds of guidance that you think would be most helpful and most meaningful in this space?

(No audible response.)

MS. IBARRA: Now's your chance. Yes, and more chances to come, so if there is nothing today, the contact information for our project is attribution@qualityforum.org. That will go to me, to Erin O'Rourke, who's a senior director on the project, and our project team.

You can follow what's going on about this project on our project page and sign up for project alerts. Please participate in the web meetings and in-person meetings, provide your comments on the draft reports that are going to come out, and certainly feel free to continue to provide your feedback to inform the environmental scan, and let me know if you have any questions or comments.

Thanks.

MS. ISIJOLA: Okay, that was the end, but then again, we thank you all for just coming through with us on this long journey of this day. I think we're about an hour ahead, but just wanted to wrap up.

Today was really informational, just really explaining and showcasing all of the work we've been doing thus far in measurement science space. Tomorrow, we'll be really looking at, and this may really be impactful for you guys, about our submission requirements.

This past year, we've done a lot of revisions and upgrades to our current requirements. We'll be talking about that. Also, something that will be new is our appeals and endorsement process. We've been showcasing that and explaining that in a bit of detail during our monthly webinars, but we'll give a better explanation of that tomorrow.

Also, something that's pretty new is our off-cycle activities. We'll get into that,

and really what that is is really engaging our committees outside of an active projects and what some of that work will look like.

Also, we've been talking about intended use for time. It's been approved by our CSAC. We're going to put that into practice, and Karen Johnson and Helen will talk about that. And we're calling it now, "Endorsement Plus."

And, then Karen Johnson again. She'll talk about assessing validity. I know we talked a little bit about risk adjustment, and she'll be giving some examples and expectations of what that will look like.

And, then, lastly, I know we mentioned it earlier in the morning about our CDP and MAP work really making sure that we're making those connections when we're talking about endorsement, how those measures being included in federal programs, so we'll give an overview of that.

And, as always, more opportunities for networking and engagement. At 4:30, we'll be meeting at happy hour at Claudia's Steakhouse, so

if you are interested in joining us for a drink or so, definitely join us.

Helen, did you want to make any closing remarks?

(No audible response.)

MS. ISIJOLA: But, again, thank you, everyone, who joined us remotely. Please stay tuned for tomorrow. We have a lot of exciting things to talk about. And, again, thank you, everyone, for joining us today.

The meeting is adjourned.

(Whereupon, the above-entitled matter went off the record at 3:43 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

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Date: 05-04-16

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