NATIONAL QUALITY FORUM

Moderator: Infectious Disease
January 18, 2017
1:00 p.m. ET

OPERATOR: This is Conference #: 92555324.

Operator: Welcome everyone. The webcast is about to begin. Please note today's call is being recorded. Please standby.

Christy Skipper: Good afternoon everyone and welcome to the orientation call for the Infectious Disease Measure Endorsement Project. We just want to thank you for taking out time today to hear more about this project and the work that we'll be doing over the next couple of months. And we also look forward to meeting you at our in-person meeting later on in March.

Before I go any further, I just want to make sure that everyone has both dialed in to hear the audio and you need to also be logged in on your computer to view the slide set for today's orientation.

My name is Christy Skipper and I'm the Project Manager for the Infectious Disease Project. And around the table, I have two of my other colleagues and I'll let them introduce themselves.

Mauricio Menendez: Good afternoon everyone. I'm Mauricio Menendez. I'm the project analyst.

Melissa Mariñelarena: Hi everyone. This is Melissa Mariñelarena. I'm the senior director for this project. I would like to welcome everyone for this work. Those of you that are joining us again from the previous project, welcome back. And those of you that are new to the project, welcome to Infectious Disease and welcome to

NQF. We're excited to get this book started. It seems like we've been kicking it out for a while. So, thank you for being here today. And I'm going to turn it back over to Christy.

Christy Skipper: OK. Thank you, Melissa. So, what we want to do next is just to hear who was on the call. So we're going to do a brief roll call. And as you hear your name, please just say a few words about yourself.

Mauricio Menendez: Woody Eisenberg?

Woody Eisenberg: Hello everyone. This is Woody Eisenberg. I'm the Senior Vice President for Performance Measurement that the Pharmacy Quality Alliance and I am very pleased to be part of this committee.

Mauricio Menendez: Thank you. Adam Thompson?

Adam Thompson: Yes. Hi, guys. Good afternoon everyone. My name is Adam Thompson. I am the Regional Partner Director for the South Jersey AIDS Education and Training Center and serve as a coach with the National Quality Center as well and I am also very excited to be here.

Mauricio Menendez: Emily Aaronson?

Emily Aaronson: Hi there. This is Emily. I am currently a Fellow in Patient Safety and Quality Improvement at Harvard Medical School and clinically attend in the emergency department at Mass General. I'll be staying on as Assistant Chief Quality Officer starting in July with most of my focus over last two years and continuing forward on Sepsis. So, very excited to be a part of the group.

Mauricio Menendez: Amesh Adalja?

Amesh Adalja: Hi, this is Amesh Adalja.. I'm in Infectious Disease Clinical Care and Emergency Medicine Physician at the University of Pittsburgh Medical Center. And I also work at – a think tank called the Center for Health Security where we work on infectious disease, emergencies and antibiotic resistance and the whole part – the whole field of infectious disease policy.

And I also – as is nominated to this from the Infectious Disease Society of America so I'm also sort of representing them as well.

Mauricio Menendez: Esther Babady?

Esther Babady: Hi everyone. My name is Esther Babady. I'm a clinical microbiologist and I serve as the Director of the Microbiology Lab at Memorial Sloan Kettering Cancer Center in New York. And I'm here representing the American Association of Clinical Chemist and really excited about working with you guys.

Mauricio Menendez: Nanette Benbow?

Nanette Benbow: Hi, this is Nanette Benbow, Research Assistant Professor at North Western University. I am affiliated with North Western's NIH-funded center for AIDS research and NIDA-funded center for prevention implementation methodology. Prior to this, I was an Epidemiologist and then Deputy Commissioner at the Chicago Department of Public Health focusing on the areas HIV and STI. Thank you. And I'm looking forward to working with you all.

Mauricio Menendez: Kathleen Brady?

Kathleen Brady: Hi. I am the Medical Director and Medical Epidemiologist for the AIDS Activities Coordinating Office of the Philadelphia Department of Public Health and I provide the clinical oversight for our Ryan White A and Part B programs for the Philadelphia EMA and I am an infectious disease physician.

Mauricio Menendez: Laura Evans?

Laura Evans: Hi. Laura Evans. I'm a pulmonary and critical care medicine trained intensivist at New York University in Bellevue Hospital. My job here, I'm the medical director for critical care so I oversee adult intensive care units here at Bellevue. And have a strong interest in Sepsis performance improvement and very glad to be here.

Mauricio Menendez: Piero Garzaro?

Piero Garzaro: Hi, this is Piero. I'm the infectious disease doctor. I'm also the Chair of the Chief of Infectious Disease for Permanente Medical Group Northern California. We have around 4.5 million patients under our care departments, about 30 infectious disease doctors and then supervise them. And I'm glad to be here. Thank you so much.

Mauricio Menendez: Donald Goldmann?

Donald Goldmann: Yes. It's Don Goldmann and I am at the Institute for Healthcare Improvement where I'm chief medical scientific officer but I have legitimate pedigree as well. I'm an Infectious Disease Specialist at Boston Children's Hospital and Harvard Medical School. And I was for a while at the CDC and the National Nosocomial Infectious Study and involved in a number of committees that try to set standards and guidelines for antimicrobial use.

Mauricio Menendez: Jeffrey Hart?

Jeffrey Hart: Hi, I am actually a member of this committee, I believe as a community representative. I actually worked for Kaiser Permanente and a quality consultant there. But I myself, I'm affected by a couple of infectious disease which we'll be talking about during, I'm sure this meeting and any more and so represent the patient's perspective in this committee.

Mauricio Menendez: Michael Lane?

Michael Lane: Hi. This is Mike Lane. I'm an Infectious Disease Physician at Barnes-Jewish Hospital in Saint Louis in Washington University School of Medicine. Then most of my time, I'm working for a BJC HealthCare where I serve as medical lead of our patient safety and quality improvement efforts.

Mauricio Menendez: Jeffery Lewis?

Jeffery Lewis: Hello. My name is Jeff. I am a Medical Case Manager here at El Rio Community Health Center's Infectious Disease Clinic. And I also chair the agency's committee that monitors compliance with class standard agency wide. Thank you.

Mauricio Menendez: Melinda Neuhauser?

Melinda Neuhauser: Yes. Hi. My name is Melinda Neuhauser. I'm an infectious disease pharmacist and representative for the Society of Infectious Pharmacists or SIDP and currently work for Department of Veterans Affairs and the formulary management or the PBM, Pharmacy Benefits Managements group. Thank you.

Mauricio Menendez: Rocco Orlando?

Rocco Orlando: This is Rocco Orlando, the Senior Vice President and Chief Medical Officer for Hartford Health Care in Connecticut. I'm a professor of surgery at the University of Connecticut. My clinical background is in surgery and surgical critical care. And it's a pleasure to be joining the group.

Mauricio Menendez: Jamie Roney?

Jamie Roney: Hi. This is Jamie Roney and I am the Texas Sepsis Coordinator and Research Coordinator for Provident Saint Joseph Health Hospital that are located in the state of Texas. And my research background has been on Sepsis studies.

Mauricio Menendez: Pranavi Sreeramoju?

Pranavi Sreeramoju: Hi. I'm Pranavi Sreeramoju. I'm an infectious disease physician as well. I'm at University of Texas Southwestern Medical Center and also the Chief of Infection Prevention for Parkland Health and Hospital System which is a public safety net hospital for the Dallas area.

So, this – my sponsoring organization is America's Essential Hospitals, the organization that represents safety net hospitals in the country. My work has been in quality and safety improvement related to how to get associated infections and sepsis mortality and I serve (inaudible) as well regional and national quality and healthcare epidemiology committees. And I'm really happy to be here.

Mauricio Menendez: Thank you everyone. I'll turn back it over to Christy to discuss the agenda.

Christy Skipper: OK. Thank you. So, just to cover what we'll be talking about of the next hour. So I'll start out with an overview of the National Quality Forum and talk a little bit about the Consensus Development Process and roles and responsibilities of you as committee members, roles and responsibility of our co-chairs, and then the role that the project team plays on this project.

We'll also jump into a review of NQF portfolio of Infectious Disease Measures and reviews projects, activities and timeline. We'll also briefly touch on our measure evaluation criteria, SDS trial period and share also a little bit about the SharePoint website where we have all of the documents related to this project. And then we'll follow that with a couple of next steps.

So, I guess we'll start out with a little bit – NQF. We were established in 1999 and are non-profit, non-partisan, membership-based organization. We bring together public and private sector stakeholders to reach consensus on healthcare performance measurement with an overall goals to make care better, safer and more affordable.

Our mission is to lead national collaboration to improve health and healthcare quality through measurement. And we start as an essential forum and convene our stakeholders, setting a gold standard for measurement and leadership in quality.

OK. So now I'm just going to talk a little bit about our activities in measurement. So, the first one is our Performance Measure Endorsement. This project that – this is part of consensus development process project and I'll talk a little bit more about that on the next slide. But we have over 600 endorsed measures across multiple clinical areas including surgery, neurology, cardiovascular and a couple – and several other areas. And we have 19 (empanelled) standing committees that oversee this portfolio.

We also have the Measure Application Partnership and that was created in response to the Affordable Care Act in 2010. The MAP, as they like to call it,

advises HHS on selecting measures for over 20 federal programs, Medicaid and healthcare exchanges. The MAP provides input to HHS on measures for public reporting, performance-based payment and other programs. And it also strongly encourages alignment across public programs and private programs and also across care settings, populations, and levels of analysis. And then also the work involves about 150 individuals in over 90 organizations.

The next big portion of our work is the National Quality Partnership Action Team and convenes stakeholders around critical healthcare topics such as patient safety, early elective deliveries and other issues.

In another phase, we'd like to call Measurement Science. This is where we convene leaders to reach consensus on complex healthcare, performance measurement topics such as attribution, alignment and sociodemographic status adjustment.

So, here, I'm just going to talk about our Consensus Development Process. So this project is considered a CDP project. You'll hear I say that throughout. And there are seven steps within this project.

So first one is a call for nominations for the Standing Committee. We've done that. We've convened the committee. You all have agreed to volunteer your time over the next couple of months.

After the call or actually during the same time as the call for nominations, we also make a call for candidate standards. So, measures that are already in the portfolio, we reached out to the developer and let them know it's time for the measure to undergo maintenance overview and we also just do a general call for any new measures that are related to the topic areas. And the measure developers are given a time to submit those measures to us.

Then we move in to the candidate consensus standards review. We're currently in this phase of the project. So all of our measures have been submitted and the team is working to complete the preliminary analysis and review the measure submission to ensure that we have all of our documents.

We prepare the measure submission for your review at the in-person meeting coming up in March. And also, I just to note that we do have a couple of other activities between now and the in-person meeting in March where you all will become better acquainted with the measure will – over our measure evaluation criteria and then also we'll have a separate workgroup calls to sort of take a closer look at the measures.

During the in-person meeting, you all make your recommendation as to whether the measures meet NQF criteria for endorsement. And then all of your recommendations then go out for public and member comment. So, we post a report of the committee's deliberations and our NQF members as well as anyone interested in the topic area can submit comments related to whether or not they agree with your recommendations and we then compile those comments and share those back with you as the committee.

The next step is the NQF Member Voting. So the measure recommendations along with input from public and member comment are sent out to our members for voting, and then that comes the – after voting closes, we move into the Consensus Standard Approval Committee, where measures are ratified and endorse. The final step is the appeals period. It's a 30-day process. If anyone would like to appeal a measure recommended then there is also time for that.

So, I just like to get into a little more detail about the MAP. And I sort of covered – I may have covered this some already. But we want to make sure that are work is correlated with the work that the MAP does. So, in the past, it's been a little followed but we we're working together to put or combine the work and make sure input that – input from the MAP is provided to the CDP project process and also the input from the CDP is provided back to the MAP.

So, I just want to show you a quick diagram of how information close between all of the different sectors. So, you can see that at the top is the NQF endorsement evaluation. Again, that's where we are right now. And your evaluation will be summarized and provided to MAP committee. CMS provide the list of the measures under consideration for the MAP for review and at any measures on the MUC list are currently endorse measures or our

measures that came forward but did not receive endorsement, that feedback is provided to the MAP as they make their final decision.

On the opposite side, though, if the measures received in the MUC list are not currently endorsed, the MAP can recommend the measure for conditional support pending NQF endorsement. And so that information NQF will take will reach out to developers to encourage them to apply to the appropriate CDP project. And we'll take that feedback once the committee is informed and sent it to our evaluation of the endorsement of the measure.

So, in the end, it's like a big circle and it's important that we all work together to make sure that the best measures …

(Off-Mic)

Christy Skipper: Before I go, any further, I just want to see if there any questions at this point. OK.

Jeffrey Hart: Hi, this is Jeffrey. I just want if – everybody could put themselves on mute to make sure there's no distractions.

Christy Skipper: Yes, thank you for that reminder. And I believe you can press star six from your phone to mute your line. Thank you. OK.

So, now, I just want to talk a little bit of the role of the Standing Committee. You all act as a proxy for the NQF membership and you are sitting as an individual and not as member of your organization. But we do value your expertise and all the opinions and expertise that you bring to the table.

Every Standing Committee members serve a two-year or a three-year term. And during that time, you are working with NQF to achieve the goals of the project. You also evaluate the measures against our evaluation criteria, respond to comments submitted during the commenting period and respond to any request from the CSAC, the Consensus Standard Approval Committee.

As far as measures evaluation duties, each committee member will be reviewing all measures submitted to this project against each criterion and you

indicate the extent to which criterion is met and rationale for the rating. We'll talk a little bit more about the criterion in more detail on another call next month.

But you also make recommendations to the NQF membership for measure endorsement. And just overall – this is your portfolio of measures. You'll be helping us promote alignment and harmonization and identifying gaps within the infectious disease portfolio and measures.

So, in addition to serving as Standing Committee members, the Standing Committee co-chair help facilitate committee meeting, work with NQF staff to achieve goals of the project and assist NQF and anticipating questions and identify any information that maybe useful to the work of the Standing Committee. The co-chairs also help keep the Standing Committee on track and also represent the Standing Committee at CSAC meetings.

So, in advance of the major meetings within this project, we do meet separately or talk separately with our co-chair just to help them prepare and lead and anticipate any questions at our meeting.

So, what is the role of the NQF staff? So, we work with the committee to achieve the goals of the project and ensure adherence to the CDP process. So, we organize all staff committee meetings and conference calls. And we guide you through the steps of the CDP process and advise on NQF policy and procedures.

We also review the measures submissions and prepare materials for Standing Committee review and we draft and edit the report for Standing Committee review. And we also ensure communication among all participants including the Standing Committee and measure developers, and facilitate necessary communication and collaboration between different NQF projects and external stakeholders.

And then also we respond to NQF member or public queries about the project. We maintain documentation of project activities both on the SharePoint site which we'll talk about a little bit later. And then also present that information

on our NQF website. We also work with measure developers to provide necessary information and communication for the Standing Committee in order that you are able to evaluate the measures for endorsement. And then also we publish the final project report.

I'll stop right there just to get there are any questions again.

OK, next one.

So, now I would talk a little bit about the Infections Disease Portfolio of Measures. So, in this project will evaluate measures related to infection disease. It used for accountability and public reporting. We'll address the topic areas of HIV/AIDS and Sepsis and Septic Shock.

And as I mentioned earlier, we do make a general call for measures to find new measures that could be submitted for possible endorsement. And we currently have 12 endorsement measures in the infectious disease project. And all of these measures undergo periodic evaluation.

So this slide just gives a listing of all the measures that who are due for maintenance in the space of the project. And they're – you see related to HIV, hepatitis, and sepsis and septic shock, and also upper respiratory infection and acute bronchitis. But over the call – during this call for measures, we learned that some measures would – were being differed or were requested to be withdrawn by the developer.

So, on this slide, you can see that the first two measures 0058, 0069. These were requested for deferral by – at the developers request because the developers stated that they needed to update the evidence for these measures. And they also – were thinking about expanding other measures specifications. So a deferral would grant it for them first two measures listed there.

The next two measures 0405, 0409 were also differed as the developer is speaking a new measure steward to take over the measures. So, those – those who are – if they're currently endorsed but they will not be undergoing review within the space of the project.

These measures were withdrawn from consideration at the request of the developer. So, the first five of those hepatitis measures were the developer requested removal of endorsement to align with the change in endorsement status from CMS, and also due to the advancement to the advances and hepatitis treatment.

The last two there 0404 and 0408 were also retired due to relevance in the treatment in motoring of HIV.

So, these are the measures that – the maintenance measures that aren't being submitted or were submitted to the project. So the sepsis and septic shock measure and then also the four measures related to HIV/AIDS. We're also expecting sepsis mortality outcome measure. And we will let you know when that measure comes in. So, we'll be reviewing all the measures shown on this slide and then also – on the next slide, you'll see we received three e-measures. So, these are the electronic versions of the HIV measures you saw on the previous slide.

And so all told, in this project, we will be reviewing up to nine measures and you're making recommend it – you'll be making recommendations for endorsement for these nine measures.

Next slide.

So just a couple updates on our activities and timelines. So following this call, we'll have our measure evaluation Q&A call on February 7th where we – we'll walk through as preliminary analysis forum and give you more information on the measure evaluation criteria. Following that we'll have two workgroup calls. The first on February 28 and the next on March 1st. On this call, we'll be able discuss and answer any questions that you all have about the measures being submitted to the project.

And on these calls, we also have the measure developers participate so that you can ask questions directly of them. You'll notice that initially we had four workgroup call scheduled but we've scaled it back to two and these are the

two calls and we'll assigning you individually to one of these calls, but you're welcome to participate and both of them.

Our next or our first face-to-face meeting is in March 14th. Again, we scaled it back to a one day meeting, so we will see you in March. Following that in-person meeting, we'll have our post-meeting conference call just to wrap up anything that we weren't able to resolves during the in-person meeting. And then in June, we'll have it post-draft report comment call.

So, after that first in-person meeting, we write a report of the committee's recommendations, post it for commenting, and then we bring you to the committee back to respond to any comments that were received during that time.

And again, I will just see if there are any questions about anything we talked about. So far, the measures submitted, anything regarding the timeline or questions about your role on the committee.

Donald Goldmann: Hi, this is Don Goldmann. Can you go back to the slide of existing measures?

So, are – just looking at this quickly, are immunizations somebody else's responsibility like pneumococcal immunization for the population?

Melissa Mariñelarena: Hi, Don, this is Melissa. Yes, immunization falls in the health and well-being portfolio. So those were just reviewed and I believe just looked up by CSAC. So pneumococcal – I'm not even sure there's pneumococcal measure anymore but the influenza was looked at in the several different settings.

So, even though – we'll have measures that may be infectious disease related but sometimes it'll fall in different portfolios. What we'll do at the meeting is provide an overview of the portfolio. I like to use a – like a patient episodic care. We'll see if it's relevant here to identify gaps but we'll also pull in all related measures to infectious disease that may not necessarily be in this portfolio to give you an – a broad look of infectious disease related measures.

Donald Goldmann: OK. And just to be cleared in terms of really big bucket. There are no antibiotic resistance measures on this list that would be important at the CDC and at the HHS antibiotic resistance initiated level or are they somewhere also?

Melissa Mariñelarena: I have to look and see if we have any. I know that there's a new one that was endorsed about year and a half ago, but that was more – I think it's like antibiotics stewardship measure. But we'll have to look to see if there's any other one, antibiotic resistance, and any other feedback that you have as well that you would like to consider would be great that maybe we might have. Like I said, we might have another portfolio or it maybe a gap.

Donald Goldmann: And this – you know, I don't want to hug the microphone. I'm sure other people have things to say. But, just for my information, if the Joint Commission comes out with national standard as they just have for antibiotic stewardship. Does that stand on its own or does the Joint Commission ask – become sponsor for a measure, how would that work?

Melissa Mariñelarena: It depends on if they develop the measure then it comes through to us. I know we have an antibiotic stewardship. We just did a big project on it that came out about a year ago and then I think the guide book came out.

Donald Goldmann: Right.

Melissa Mariñelarena: That was under the national quality partnership work. I'm not – the only measure that I'm aware of is that one from CDC because I know it came through MAP last year. And Woody I know you're on MAP this year but I can't remember if you're on it last year.

Male: No, it wasn't.

Melissa Mariñelarena: Yes, I know it's fairly new last year and we're trying to collect data. We can – I can give you the information on it and I think it came through Patient Safety. There are some measures on Patient Safety but we can – like I think if you take a look at all measure in all other portfolios, I also like to look back at what previous committee identified as gap so that we're not listing the gaps – the same gaps over and over again.

Donald Goldmann: That would be great. Yes, that would be great because for some of us it's all like hard to figure out. Having the broad view would be really helpful.

Melissa Mariñelarena: Right, we'll get all of that prepared for you in time for the meeting. Like Christy mentioned, you know, it's the Standing Committee you will be overlooking this portfolio so we ask you take ownership of it but we like to do all this background work for you so that you can help us identify gaps moving forward since this is the first standing committee that we have for infectious disease.

Donald Goldmann: Great.

Melissa Mariñelarena: Thank you.

Piero Garzaro: This is Piero. The similar question regarding hospital acquired infections. Is that in the project further to things to come or thing that were discussed already? I'm thinking, for example, catheter-associated UTI that all hospitals have a big problem with. What is the definition of that? Is this something that will be valid at some point or (inaudible)?

Melissa Mariñelarena: Those are all I believe under patient safety. We can pull all the information. And I'll have to look to see when the last time they were last reviewed. But we can pull out information so that you have the most recent information. I'm not sure if there was supposed to be like new definition that CDC that supposed to be coming with new definitions for CLABSI or something like that but we can pull all of the information together of the most recent endorsement so that you have it.

Like I said – and it may at some point make sense to move some of those measures over to this committee. I know right now it's in patient safety, like I said some of the topics sort of overlap each other but we'll give you the latest information.

Woody Eisenberg: So Melissa, this is Woody. It sounds like this committee has a great appetite for knowing about all of the infectious disease as antibiotic measures that might be out there in NQF committee land. So, is that something that you

folks can pull together so that we can see that and get the lay of the land and identify gaps?

Melissa Mariñelarena: Absolutely. We could do that.

Woody Eisenberg: Thank you.

Melissa Mariñelarena: So, any other questions? OK, if not we will move on to the very exciting measure evaluation criteria overview. So, I'll make this kind of brief because you will see this over and over again. And so you become very familiar with it. So like Christy mentioned, we have our NQF measure criteria for endorsement and – so NQF endorsement measures for accountability applications.

And we identify accountability as either public reporting, payment program, accreditations, all of the things. We also look for measures for quality improvement. So, we've come up with the standardize evaluation criteria, it has evolved over time. For those of that have been with us before, it's the same – the criteria pretty is pretty much the same, it has not change but it has evolved and we become a little more explicit in our guidance – in our criteria.

So, they maybe look a little different but it really has not change. Like I said, it just become a little bit more explicit than it was in the past.

Next slide.

So our major endorsement criteria and it does have – it looks there is hierarchy. We start off with importance to measure in report. This is most trust criteria. So if reliability and validity which we consider scientific acceptability as a measure.

When you're evaluating the measure, it must pass importance to measure and report and scientific acceptability in order for the measure to be able to go on to the rest of the criteria and then for you to be able to consider it for overall suitability. We also look at feasibility, use and usability. Once the measure has met all that criteria on its own then you look at related or competing measures as well.

So you're looking at importance to measure and report the first thing we're looking at is evidence. We want to see if the measure focus is evidence-based. And then we're looking at opportunity for improvement. So that's your gap in performance gap in measures.

And we'll talk about the difference between something that has change a little bit as the difference between new measure and maintenance measure. And there are specific criteria that it has changed. So there is a little bit of a difference there. And then for composite measures we look for quality construct and rationale.

So for outcome measure, the one thing that we're looking at is a rationale for how the outcome is influenced by the healthcare processes or structures. We have – we may have a sepsis outcome measure. And we have one of out HIV measures, is right now identified as an outcome measures. So the only thing that we ask is for the measure to developer to provide a rationale, time to healthcare – healthcare process to that outcome.

For structure process, intermediate outcome measures, those are little more stringent. We do ask for the quality, quantity, and consistency of the body of evidence. So we're looking for empirical studies and we consider expert opinion as like the lowest level evidence or, you know, and we'll show you the algorithm that we use to identify the level of evidence that we are at.

We also look for a systematic review and grading of the evidence. Often for process measures, we'll get Clinical Practice Guidelines and we like to see this level evidence or the grading of the guidelines which is how we approach evidence of how we grade the evidence.

Next slide.

Just trying to get a screen shot of the algorithm. And you'll have all is this information as well. And we put page number in the slides that you to the page numbers in the Standing Committee guide book. So you know exactly where to go for this. OK. Here you go.

So this is what it looks like and we actually a whole. There's a whole handout. And when this gap does a preliminary analysis, we will actually walk you through when we do our preliminary analysis whether it's an health outcome measure or a process measure. So we start at the top when we talk about, you know, if it's a health outcome measure, as we say, you say yes then we take you to box two, then we ask standing committee, do you agree that the relationship between the measure outcome. And at least one healthcare action is identified by the developer. And all you have to answer is yes or no and then that either passes or does not pass it.

So some majority of our measures are process measures, we'll start off with box number three. And here its cut off that we do have, like I said, it's on page 36 of your book. So we'll start off with looking for a systematic review of the measure of the evidence. If we find that, we move on to the quantity, quality and consistency. And if we have that, then we ask, you know, is it high, moderate, medium. And we'll talk you all through that.

Again, the preliminary analysis that the staff provide is just sort of a springboard for you to start your work. It does not mean that you have to agree with us but it's just somewhere for you to look because sometimes there is a lot of information. And we do provide links for you back into the original submission so you could go back and look at what part of measure developers originally provided. But this is just to – we try to pull out the most relevant information and try to – just synthesize it for you without changing the meaning, just because it's a lot of information and we know that your time is valuable as volunteers.

So here is one of the differences between the new measures and maintenance measures. So for criteria number one, importance to measure and report. For new measures, we require everything. So for evidence, we want the QQC for outcomes. We want you to give us that link between, you know, process and the outcomes.

However, for maintenance measures, there is a decreased emphasis. What we've asked developer is, if the evidence has not changed since their previous submission, they just have to attest to that. Then we'll come to the committee

and will ask you, "Do you agree that the evidence has not change?" If there has been a change in evidence then we just ask them to update the evidence. And then we'll ask the committee, "Do you agree with this update?"

And because it's a maintenance measure there's a decreased emphasis in evidence because often it doesn't change very frequently. The committee can decide that they don't want to discuss or they don't need to discuss and revote on evidence. Often, a committee will discuss evidence but not necessarily revote on it and just accept the previous vote and let the evidence pass.

However, for gap, for a maintenance measure, there is an increased emphasis for gap because the measure already been endorsed for at least the minimum. We consider at least a minimum of three years because we do typically require maintenance every three years. So, we want data on the performance of the measure. We're looking at trend. So we do require that.

On initial endorsement, there may not be data from the measure as specified. So in order to identify a gap, they – developer can provide us a data from the literature demonstrating that there is a quality issue. But on the maintenance there must be data provided to us. Again, we'd like to see some trend, anything like that. So there – that is required and there is an increased emphasis on this. You must discuss this and vote on it.

Criteria number two, reliability and validity, which sums up scientific acceptability. So the reliability we're looking at the specifications and reliability testing either the data elements or the measure score. And for validity, we're looking again that the specifications are consistent with the evidence and validity testing either of the data elements or measure score.

And then we look at a justification of exclusions if there are exclusions. Risk adjustment if there is – if it's an outcome measure, identification of differences in performance. Rarely, we see comparability of data sources because I haven't seen any measures to date that have more than one data source. We ask for analysis of missing data.

This is just a quick look at reliability and validity. The first picture just shows a measure that would be reliable but not valid so it consistent but wrong. The middle picture would be neither reliable nor valid, it's inconsistent and wrong. And then the last picture is what we're looking for false reliable and valid where a measure is both consistent and correct.

So from measure testing, we're looking for – we prefer empirical analysis to demonstrate reliability and validity of the measure as specified, including the analysis of issues that post threats to validity of conclusion such as exclusions, risk adjustment/stratifications, any of those things. So we prefer – especially for validity, we prefer empirical analysis. We don't often get it. And we'll talk about that in the few slides. But it's – if that's what we prefer, and again, as the measure specified.

If the measure has exclusions, we ask that the measure be test it for exclusions, if its risk adjustment, we ask that you test the risk adjustment. And also if the level of analysis, it should be tested at the level of analysis as well because that is how the measure becomes NQF endorsed.

So for reliability of the measure score, one example, and this is – we don't know always get this but one very common statistical analysis that we get for the measure score is signal-to-noise analysis. But that's not the only acceptable statistical analysis but that is a very common one that will get. We'll also get for reliability we'll get data element inter-rater reliability. And when we get inter-rater reliability, that counts for inter-rater validity as well. You don't have to do both. And so it just depends on which is acceptable for the measure and appropriate for the two and which better demonstrate to reliability and validity for the measure.

And here, this is an example of the reliability algorithm and this like the evidence algorithm, once the staff does the preliminary analysis, we will walk you through it. So we ask, you know, we start of with box one and then box two if there is empirical validity testing. Is it at the patient level of data, if it is, then we go – we consider that validity testing which is fine. And if its not, if it was measure score then we start with box four and we go right now through that. And we'll provide you with the rating.

For ratings of insufficient, if and when you see a rating of insufficient, it is not necessarily bad. It's a rating of low is worst than a rating of insufficient. The rating of insufficient only need that the staff do not have enough information in front of them at the time that they did the preliminary analysis. Often, we will work with the measure developers to get additional information or we ask the Standing Committee to use the testing information that is in front of you in addition to your expertise with these measures and you expertise in the field to determine the rating of a measure. So, insufficient is not a bad rating, it's just we do not have enough information in front us to determine whether it was high, moderate or low.

For validity testing, different types of empirical testing, if it does measure score testing, data element testing. And face validity which is the minimum amount of validity testing that we accept, and the algorithm for validity very similar to the other one that you see.

We will talk you through the algorithm when the staff does the preliminary analysis. We do not expect you to memorize this. That's our job is to be experts. We're not experts in the field in every field. But our expertise is in following the algorithm and knowing the NQF criteria so that is where you rely on us to be able to interpret the criteria.

Some things – some choice to validity that we look at, here is just the list. And we will also provide that information if it's provided to us in the submission form. Got it – yes.

So for criteria number two, again, the difference between new measures and maintenance measures for scientific acceptability, for the measure specification there is no difference. For maintenance measure if the specifications have not changed, they don't have to provide any updates, just say, there have been no changes in the measure specifications, the same for reliability and validity including risk adjustment.

If nothing has change in the measure specifications, we do not require measure developers to update their testing. If the previous testing was

sufficient, they do not have to provide us with new testing. Occasionally, because if a measure hasn't met/look at in awhile, like I said, our criteria has not changed but has evolved and we're little more explicit.

A lot of the times, we'll go back to measure developers and just ask for additional information to meet our criteria today. Then often it's not a problem but it doesn't require additional testing. And that was just to decrease the burden on measure developers because if nothing has changed in the measure, there's no need to retest the measure.

Feasibility, so we looked at – and this is not a must pass criteria. But you're looking to see if the required data is readily available. So you look at clinical data, electronic sources or a data collection strategy that can be implemented if it's a new measure.

For use and usability, we're looking for accountability and transparency, improvement overall to the benefits outweigh to harms, and then we asked what is the measure vetted by those being measured and others.

So for feasibility and usability between new measures and maintenance measures, so feasibility there's no difference. That's the same. Usability, there is an increased emphasis for maintenance measures because we're assuming that the measure have been endorsed and it's been used so we want to know about the use and usability of the measure. They want you to provide us that information.

Some of our criteria does say I believe after we have – we do talk about after how many years after endorsement it should be use in accountability programs. Staff will call that out if a measure is being endorsed then – have not yet been used will ask measure developers to provide a rationale why the measure have not been – have not been used it.

And then the Standing Committee can decide if that's an appropriate rationale, should the measure continue to be endorsed just because they haven't been used. Again, it's not the most trust criteria but that's the discussion that we'll ask the standing committee to have.

And then once we have gone through all of that, we'll look at related and competed measures. I don't believe we have any right now. We do not consider – we do have the new e-measures which we consider legacy measures. But we don't consider the original paper measures and legacy measures, competing measures at this time. So, don't think right now we have to have that conversation, but when we do have competing measures we ask that you pick the best in class, if not – if it's a related measure, we'll ask measure developers to harmonize measures for better alignment or provide a rationale, but that's after a measure stand on its own, meet all the criteria on its own before we have this discussion.

The evaluation process is where I talk about the preliminary analysis and honor next call, the Q&A calls where you'll actually will go through and we'll show you a preliminary analysis, an example of one of the staff has done. And again, it just summarizing the information that is been provided by the measure developer determining where they have met all of the criteria then asking questions, sometimes just for the conversation for the Standing Committee but it does not mean that you have to follow our recommendations. It's just a starting point for you.

And like Christy mentioned earlier, we will be assigning measures to everybody and you'll be lead discussant on the measures that are assigned to you. But then we just ask you to review all of the other measures because everybody will be voting on all of the measures during the meeting.

We have workgroup calls which are the two that we have scheduled. We only do those for new standing committees and that's to help you get familiar with all of these evaluation criteria. So we'll ask you to start working on your preliminary analysis – on your preliminary analysis, you'll submit questions.

The measure developers will also be on the phone and this will be a chance for them to hear any concerns that you have and for you to provide any questions to them or any questions to the staff about the process or the specifications or any issue that may come up, and that we can have them hopefully resolve or have any answers for you and time for the meeting. But you won't be making any recommendations on this call. The

recommendations will be done at the in-person meeting and this is where the entire committee will be voting on all of the measures with the recommendation.

This is new for us. This is first time that I know that I'm going to – with my one of my projects where we do Endorsement Plus. And the staff who identify measures that are – that meet the criteria for Endorsement Plus and this is where they have to have the evidence criteria cannot go through without exception.

So, we have in our evidence criteria. There's a place where it can go through with the exception. That's something we could talk about through later but this has to meet the evidence criteria without exception. There has to be good results on the reliability testing of the measure score so it cannot be reliability testing of the data element

There has to be good results on empirical validity testing of the measure score, again, not data element, validity testing or safe validity. And then it has to be well vetted in the real world by those that are measured and others. And then the committee votes on whether the measure should be recommended for this endorsement plus designation.

I'm going to stop right here to see if anybody has any question so far before I move on to the SDS Trial Period?

Woody Eisenberg: Melissa, this is Woody. You've mentioned that the Committee will be reviewing three electronic clinical quality measures. Are those considered replaced for measures that are already NQF endorsed or are these new measures or competing measures?

Melissa Mariñelarena: So, those are considered legacy measures. It will give you a little bit more information about them later. We have different types of e-measures that we looked at. We have legacy measures which are, basically, re-specified measures of existing measures. However, in order to be a legacy measure, the original measure has to be in the federal program.

So, for a legacy measure, we don't require them to be fully tested. Usually, we can see developer provides us with synthetic testing because they have a hard time getting tested. So this was sort of a bridge for measures that already exist, but they have to be in a federal program. It will give you the specific because you're only going to be reviewing legacy measures in this project. Sometimes, it gets confusing when we have the other types.

Woody Eisenberg: Yes, yes. And …

Melissa Mariñelarena: We also have approval for trial use which is a different program. And then we have the full on e-measures that must meet all the criteria that every other measurements need.

Woody Eisenberg: OK. Thank you.

Melissa Mariñelarena: You're welcome. Any other questions?

Woody Eisenberg: Actually, this is Woody. I have another question. So, what's the importance of having an endorsed plus, you know, other than going to the head of the class or something like that? What is that mean practically?

Melissa Mariñelarena: I'm not sure. That's brand new for us. I know that we just started it. We can get you more information on that. I know they've played around with what it would mean, you know, would it be better to use those payments. But we can't – there was really no science behind all of that.

So, we'll get you more information behind Endorsement Plus. I think it's just – it is more, you know, head of the class because they have – their testing is stronger than the other ones. A lot of the time, you know, we may see a measure that comes back to us with face validity testing over and over and over again. It maybe a great measure but the testing hasn't been updated. So, it's just as, you know, put them in a different category.

Donald Goldmann: Yes, this is Don. I don't know where this came from either or how it ended up being phrased that way. But there was a discussion I was involved in – on the used committee, whatever it was, I can't remember the exact name of it.

And one of the points that we tried to drive home really strongly was the tendency for measures to we put out in the field. They've not really been tested in the field very much. So, they're put into a health system that can't really accommodate them. It's more work, it doesn't really work for them. It's not aligned with whatever they are doing whatever, there are million scenarios.

And I think the idea at least for part of this was, at this thing, actually have been taken out – and has the prototype and tested in the real world of health care or is it just another construct that needs a lot of criteria but it's not going to be easily used by the people providing care.

Woody Eisenberg: Very good. Thank you.

Melissa Mariñelarena: Great. Thank you. Are there any other questions, comments? OK. If not, I will go over the SDS Trial Period briefly.

Go to the next slide.

So, we started the SDS Trial Period, it will be two years ago in April. That's when it concludes and that's when NQF declared that there would be no – that the adjustment of measures for sociodemographic factors will no longer be prohibited.

So, we assess every measure individually to determine if SDS adjustment is appropriate. In this, for the trial period, all measures are appropriate for the trial period. More than likely, it only – it only pertains to outcome measures so far.

You can go to the next slide.

So, what we've asked is even for new measures, existing outcome measures, we ask measure developers to, at the minimum, provide us a conceptual rationale for SDS risk adjustments.

If they found that there was a relationship between SDS factors and the measure outcome, then we ask them to do an empirical analysis. If they found that there was a relationship, then we ask them to provide a risk adjustment model with both the SDS factors and a non-SDS risk adjusted model.

So far, we haven't come to any real conclusions. This project doesn't have – as of right now, we don't have any – none of the measures are risk adjusted. So, it doesn't necessarily apply.

However, it does not exclude the committee from having the discussion of whether you think a measure should be SDS risk adjusted. In this conversation maybe – we don't have any readmission measures but, you know, I know that that risk adjustment or SDS is been a topic of frequent conversation recently, especially after the ASPE report came out with the readmission measure.

But, again, nothing prevents the committee from having the conversation about whether a measure should be SDS risk adjusted. Are there any questions on that?

Woody Eisenberg: And Melissa, what about clinical risk adjustment? How is that built in?

Melissa Mariñelarena: That is separate. So, again, as the measures that we've look at so far, they are – none of them are clinically risk adjusted. We assume that the outcome substance measure that we are planning to receive that that will be clinically risk adjusted. Then, if we do receive that measure then we would ask for a minimum, a conceptual rationale for SDS to see if there's a relationship between, you know, SDS factors and (the) sepsis outcomes. But we'll see when we get that information.

For the other ones, again, if the Committee – even though the process measures, we tend to not see much of relationship unless the committee feels that there is a relationship that there is evidence, then we can have that discussion.

Woody Eisenberg: Very good. Thank you.

Melissa Mariñelarena: Thank you. Are there any other question? OK. Now, I'm going to turn it over to Mauricio to do the SharePoint overview.

Mauricio Menendez: Hello everyone. So, I'm just going to do a quick run through of our SharePoint site. This will be where – like documents will be housed for this project. You should have by now received your SharePoint credentials but if you haven't, definitely please let us know immediately and we'll send those – that out to you.

So, this is what you'll be seeing when you access the SharePoint site on the infectious disease project page. We will send the link out to you, your e-mail and there also be a link at the end of this presentation.

But, as you can see, our general documents are here and everything you need to make recommendations will also be here so your CDP developer guidebook, Standing Committee guide book, Standing Committee policy documents are here.

Just a quick note that some of these title slides have plus/minus bars and documents are hidden within the titles, so you may have to go digging for certain documents. There is also a committee roster here and a committee calendar for our upcoming events. And it's pretty self-explanatory.

On the Committee homepage, we will also be putting up the measure worksheet and measure information worksheet forms after the team finishes the preliminary analysis. That will also include evaluation comments when you guys complete those, and public comment develop. We will also include information submitted by the developer. Those are the evidence and testing attachments and additional documents.

Just a reminder to look at the plus and minus signs for different documents within the SharePoint site.

And finally, for upcoming next steps as Melissa and Christy already explained, we have the upcoming measure evaluation Q&A call and the two workgroup calls where you – will be making recommendations and you're definitely more than welcome to attend both calls.

Christy Skipper: Thank you, Mauricio. Before we close out for today, I just want to remind you all that if – we're not reminding you, but ask if you have any assistance that you would like us to also CC on e-mails that we send to you, please send over their contact information and we'll also – and we'll include that in all e-mail correspondents.

The slide just shows contact information for the project. We'll try to – we'll be e-mailing you from infectious disease at qualityforum.org and you can also give us a call as the number shown. And then these two links show you how to access the NQF public web page as well as our SharePoint site.

Following this call, I'll send out our slides and also links to both of these pages just so that you all can have easy access. And I would encourage you to just get familiar with the SharePoint website, play around on it. And just as Mauricio said if you haven't receive your credentials yet, let us know and we'll be sure that those get out to you.

Woody Eisenberg: Well, Melissa, this is Woody. Are there documents that we should be reviewing prior to our next call? And will you notify us about that?

Melissa Mariñelarena: We will send you the measure worksheets that are assigned to you before the next call because we'll ask you to have those done and we'll give you a due date for those. And then there'll be a serve – it will be in form a survey that – and – that you'll submit all of your questions or comments. And then we will compile all of them and then send them back out to you so you can see everybody else's questions and comments. They will send very explicit instructions before that.

So, as of right now, you have some time off that will – we'll be in touch with you. We'll give you a plenty of time to submit that information back to us.

Woody Eisenberg: Very good. Thank you.

Melissa Mariñelarena: Thank you.

Christy Skipper: Are there any other question? All right. At this time, I just want to turn it over to the operator to open us for any public comments.

Operator: OK. This time with your line, to make a public comment, please press star then the number one.

And there are no public comments at this time.

Christy Skipper: All right. Thank you, everyone. We will adjourn at this time. Have a good afternoon.

Woody Eisenberg: Well, thank you. Thank you.

Male: Thank you.

(Crosstalk)

Female: Thank you.

Female: Thank you.

Christy Skipper: Bye-bye.

END