National Quality Forum

Moderator: Leslie Vicale
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Leslie Vicale: Good afternoon everyone. This is Leslie Vicale, the project manager for the Cardiovascular Project team here at NQF, and I'd like to welcome you all today for the Second Committee Q&A Call that we are conducting here in (advance) of the Phase III measure endorsement project.

So, I first like to we welcome our esteemed co-chairs, Thom Kottke and Mary George. I also like to welcome the developers who joined the call today and I would like to welcome the public who have also joined the call.

And so – I also like to go ahead and introduce our project staff for the cardiovascular project team. There had been a few update to the project staff. As I said, I'm Leslie Vicale and I'm the project manager and then there's Sharon Hibay, our senior director on the project. We're welcoming Karen Johnson today, who's also a senior director and going to be assisting us with the SDS information later on the call. We are welcoming a new senior director and that's Melissa Marinelarena, I think I got that right this time.

Melissa Marinelarena: Pretty close, thank you.

Leslie Vicale: And we're also welcoming Ashley Ridlon, our managing director and we did want to note that Wunmi Isijola, our former senior project manager is not currently on the cardiovascular team anymore. I know you all have worked with her closely over the past few years, and she's just moving to other

projects, so. And then, we also have Laura Ibragimova, our project analyst and finally we have a new project analyst, Donna Herring joining us.

So before – so before I move any further and take roll of the standing committee, I just wanted to find out if Thom Kottke and Mary George have any opening remarks for the call and for the committee.

Thomas Kottke: No I – this is Thom, I just thank everybody for their participation in the – what's obviously a hard work to review these measures but I appreciate your willingness to help out.

Mary George: And this is Mary and I just echo Tom's comments. Thank you.

Leslie Vicale: Great, thanks so much, Tom and Mary. So, I wanted to go ahead and take roll of the standing committee to find out who we have joining us today. Now before I do that, I would like to remind everyone that the lines are open for the committee and for the developers who joined the line today for the call. So, we hope that you keep it on mute to reduce any background noise.

And if you are speaking later on, please go ahead and state your name just so we do know who's speaking. So, I'll just go ahead and take roll. Mary George, we have you on the line and Thom Kottke, we have you on the line. Sana Al-Khatib?

Sana Al-Khatib: I'm here, hello everyone.

Leslie Vicale: Hi Sana. Carol Allred? Linda Briggs?

Linda Briggs: Hi, I'm here, hello everybody.

Leslie Vicale: Hi Linda. Leslie Cho? Joe Cleveland? Michael Crouch?

Michael Crouch: Here.

Leslie Vicale: Hi Michael.

Michael Crouch: Hi.

Leslie Vicale: Liz DeLong? Ellen Hillegass? Judd Hollander?

Judd Hollander: I'm here.

Leslie Vicale: Thom James? Joel Marrs? Gerard Martin? Kristi Mitchell?

Kristi Mitchell: I'm here.

Leslie Vicale: Hi Kristi. George Philippides? Nicholas Ruggiero?

Nicholas Ruggiero: I'm here.

Leslie Vicale: Hi Nicholas. Jason Spangler? Henry Ting?

Henry Ting: I'm here.

Leslie Vicale: Hi Henry.

Henry Ting: Hi.

Leslie Vicale: And Mladen Vidovich.

Okay, well great. Well thank you so much for joining everyone and I just wanted to quickly run through the agenda that we have for the call today and (inaudible) for the purpose of the call is to provide a brief overview of the Phase III Cardiovascular Project.

Sharon Hibay will be providing the eMeasure Review Guidance. Karen Johnson will be providing the SDS Risk Factor Trial Review information and if there's any time, we're going to go ahead and open the call up for any measure specific questions regarding the Phase III measures that were submitted. So, we also have the developers on the line to answer any questions as well. And then we'll have public and member comment and then I will run through some of the next steps and the timeline and the important dates we have for the cardiovascular project.

And now looking at the Phase III measures that were submitted for this project, you'll see here we have a total of 24 measures under review. Now

that includes 13 maintenance and 10 new measures but that also includes the one ad hoc measure that – you may remember last Monday, we had the other webinar to review measure 0018, the measure that is under ad hoc review.

The rest of the measures include nine composite measures, two are multi-component and seven any or non-measures. Eleven outcomes measure, three intermediate clinical outcomes, ten process measures, four eMeasures and then of course the sociodemographic status trial. And as a reminder, really any measure can – can be involved in sociodemographic status trial but notably the outcome measures are very important for that.

So you'll see here the subtopics included – there are eight measures that are coronary artery disease, acute myocardial infarction, six for heart failure measures, four within the (current) implantable-cardioverter device with their pacemakers, two percutaneous coronary intervention, carotid artery stenting, two hypertension, one cardiac imaging and one statin use.

And then very quickly, we did want to note our wonderful measure developers that are joining us today that have submitted these measures. And you'll notice a number of these developers have been involved in measurement development for quite some time and we welcome the new measure developers to the (list) this year. We're really excited to work with everyone that we had relationships with as well as the new folks.

And so this is just the high-level review. As you'll see here, we have the 24 measures that are under review. And again, you can refer back to these slides but we'll have some time hopefully left over, so you can go ahead and ask some questions about these measures.

And so without further adieu, I'm going to go ahead and turn the call over now to Sharon Hibay, our senior director, who's going to provide the eMeasure Review Guidance. Thanks Sharon.

Sharon Hibay: Thank you Leslie and welcome everyone. Happy – a very nice day, Monday, the last two weeks in August. It's a beautiful day here in D.C. I hope it's lovely where you where as well but I'll start off our discussion today to provide you with a little bit of background, talk about the eMeasures in HIT

space where we – where we were, what we wanted to do, where we are, where we think we're going kind of a (training) and how it's applicable to the work we do with reviewing measures.

So, we're all pretty familiar that in 2009, the HITECH Act was enacted to promote the adoption and meaningful use of HIT by ONC and CMS and the EHR Incentive Program or meaningful use, so MU. The idea was to gain some experience with the development and use of eMeasures and vast majority of eMeasures that we started off with were measures that were respecified by – from Claims and Registry Measures from.

We are now a number of years away from that and we have met up with some – some great successes but also with some challenges and some constraints that we'll talk a little bit about those. The development implementation of testing eMeasure is quite protracted. We are still building the structure, tools, measures and measurement and innovation simultaneously, we're kind of building it as we go.

The testing of eMeasures continues to be hindered by limited use of eMeasures by limited patient data and also performance is being reported still largely by attestation which means we're not getting patient level data. We're getting performance – performance data. Okay?

The industry continues to seek innovation eMeasures using the unique capabilities of EHR data capture and interoperability that demonstrates health outcomes. And those health outcomes would be especially related to the National Quality Strategy or the three-part aim of better quality, help your communities and reduce healthcare cost.

Talk a little bit about eMeasures specifications. So eMeasures maybe (de nuevo) or new or they maybe respecified as we said from existing Claims and Registry Measure versions. And in meaningful use one, Phase I and meaningful use two, we saw mostly again the respecified of measure versions. NQF considers respecified eMeasures as separate measures from their related non-eMeasure versions with different measure numbers.

A little caveat here though, that these eMeasures that are use in (several) programs, meaningful use PQRS,etc. They used the same measure number for the eMeasure and for the non-eMeasure. Emeasure and non-eMeasure versions will be evaluated separately by the standing committee.

NQF, excuse me, eMeasure team have provided a technical review of all measure specifications and you'll see the information related to that review embedded throughout the preliminary analysis for each one of these measures that you are reviewing. There are four of them for this project again.

Now unto the next slide, talking a little bit about defining an eMeasure and evaluating eMeasures. So NQF defines an eMeasure as a measure specified in the accepted standard Health Quality Measure Format, HQMF, you may heard of, using the quality data model (again) and the value set (inaudible) through National Library of Medicine, VSAC or Value Set Authority Center.

Measures not meeting these criteria are not considered eMeasures. So, other people may say they have an eMeasure but if they don't meet this basic criteria, they're not suitable for evaluations, for endorsement evaluation. Emeasures are expected to meet all the endorsement criteria with some specific applications. Testing for reliability and validity is required from systems with more than one EHR product. And a feasibility assessment is required to assess data elements availability in multiple EHRs.

Talk a little bit about eMeasure pre-testing with Bonnie. So Bonnie is basically – it is a tool that is an add-on to the measure authoring tool that helps us test the measure logic and create pre-test samples. So if we're saying that we have limited patient data to be able to say if the measure is calculating appropriately, able to pull all the numerator, denominator exclusionary information, we can utilize this Bonnie tool. Again, hook up with the measure authoring to those two pieces, provide us with some logic testing and also provide us with the opportunity to develop pre-test sample population.

As far as reliability is concerned, we talked about for the evaluation, we wanted to know if value sets again or registered in the VSAC and we want to know that the measures are pre-tested, the measure logic is pre-tested in

Bonnie. So as far as validity is concerned, we talked about this already, pre-test population samples will be looked at in (validity) inclusion, exclusionary criteria.

And what you will see in the – what you will see in the – in the evaluation information is that we will show you the expected to the actual sample inclusion for reliability to understand whether or not the logic itself as presented by the developer is able to pull the right patients into the numerator, pull the right patient into the denominator, the denominator exceptions, numerator (new) exclusion, all that good stuff. So, that's the tool that Bonnie has helped us with until we can get these measures implemented into the EHR.

Another thing that you're going to see related to the validity in the preliminary analysis has to do with covered data elements, so what covered data elements are. So if you think about all those dates, pieces of your measure, again your initial patient population denominator, denominator exclusions, numerator, denominator exceptions. So, there's a certain level of concepts that are involved.

And you have a patient sample that's going to test these concepts. The covered data elements that this is the percentage that you have of all the covered data elements. So one of the measures might say 85 percent of the data elements are covered.

That means 85 percent of the possible configurations of the initial population denominator, denominator exclusions, etc were covered in your patient sample, in your pre-test population. So, you will also see that in the information in the preliminary analysis.

In addition, what you will see evidence of in relation to eMeasures in the preliminary analysis is the eMeasure feasibility scorecard assessment using a 3-point likert scale, the feasibility of the measure data element is assessed for both current and future use next three to five years. The scorecard must be completed for multiple EHR as we talked about that earlier and we would like the settings to be varied.

Specifically, the eMeasure feasibility scorecard assessment evaluates data availability, is it readily available and structured data. Data accuracy. Is the information contained (and) the data element correct or the data source and record specified? Data standards. Are the data elements coded using nationally accepted terminology standard? Workflow. To what degree is the data element captured during the course of care? How does that impact typical workflow for that user?

Lastly, what I'd like to talk to you about related to eMeasure is the eMeasure approval for trial use. So again, we discussed early – as we discussed earlier, patient level data for testing eMeasure remains somewhat limited due to performance reporting via attestations.

With that in mind, in 2014 NQF implemented the eMeasure approval for trial use pilot with the goal of approving measures, of eMeasure, excuse me for trial use to promote implementation and the ability to conduct more robust reliability and validity testing, taking advantage of the clinical data in the EHR.

In 2015 in April, the VSAC agreed to make this approval for trial use available for all eMeasures submitted to NQF. Approval for trial use, excuse me, is not time limited endorsement and it carries no endorsement label. That's really important to understand, so it's not time limited. We got the – we have no more time limited measures in the NQF portfolio in this measure and eMeasure that would be approved for trial to use is not endorsed for trial use, it's very clearly approved for trial use.

To be approved for trial use, again the measure must meet all the endorsement criteria requirements except for scientific acceptability one more time as they're challenging to do that without patient level data. Okay?

The standing committee will evaluate each criteria submitted for each eMeasure submitted if it's a request for trial use approval except for scientific acceptability, pieces of scientific acceptability. Should the committee recommend the measure for endorsement, they will also vote on whether or not the measure would be recommended for trial use. Okay.

Female: Okay.

Sharon Hibay: Okay, keep going down. Okay, okay. So a little technical difficulty here, goes back the (other way), I'm sorry. One more.

Female: Here?

Sharon Hibay: One more, okay, yes, all right, very good. The measure (inaudible).

Oh my goodness, okay, we got it. I think it's there. Can you (check) that, like little loop, I'm sorry. Okay, so far as the measures for Phase III, I said that there were four of them and you will see three of them submitted to us by our friends the (AMPCPI) and run by one of our new measure developers, the National Minority Quality Forum.

So, the criteria for approval for trial use one more time will include – and I'll kind of go over this a little bit more detail. Again, they must meet all the criteria for importance to the measure and reports. Clinical evidence and opportunity for improvement and performance (gaps). The eMeasure must have a completed eMeasure feasibility assessment.

Results from testing with a simulated or test datasets that demonstrate the QDM and HQF for use appropriately in the measure logic has performed as expected. That is our Bonnie sample population I talked about earlier and again while the trial measures are not intended for accountability purposes, there should be a plan for future use and discussion of how this roll for accountability and for improvement.

You will also be talking the measure (inaudible) will be talking about related and competing measures which are identified and how plan for (harmonization) or justification for developed – developed competing measure should the measure be deemed to be competing. Okay, next slide.

And for those people who might be interested for all of the four measures that are submitted on the – on the SharePoint, the committee site for the SharePoint, each one of those measures will come with a couple of different pieces of information. Mostly for each measure will be zipped files. That's

outputted by the measure authoring tool and inside that measure authoring tool are a number of attachments.

One of the attachments, here this is the HQMS and what I'm showing you here is that header information. This is more of that narrative, human narrative that at the top that provides again the numerator, denominator subscription. It provides information about copyrights, certainly the number of the measure, diversion of the eMeasure, obviously the title of the measure.

It will provide some guidance. Sometimes the information in the – for calculating the measure or implementing the measure, you know, the developers might want to add a little more guidance, so that information could be there as well. So, this is the HQMS header information. Again, it's more narrative in nature. Let's go to the next slide. One more please, very good.

So, this is the same document if you would just scroll down, this is the HQMS logic. This is what I essentially called the and, (but), or, nor's. So you know, include this population and (inaudible) in the (MDM) but don't include that one, so you get or, or not or you will see unions, all of that. It's a – it's a – it's not always intuitive for everyone to be reading this. So you know, the NQF eMeasure team provides the technical review for you. Okay, next slide.

And again, we're still on the HQMS, so the top part is the header and then you have the logic and then the bottom part really speaks to the value sets. So, the measure that we have here and (these are) an ENT measure, the cataract measure. Just go (ahead), quite a few value set as you can see. Individual value sets will be listed as well as groupings of value set.

Now you also see an Excel spreadsheet that's outputted by the measure authoring tool. Again, we strongly recommend that all value sets are registered in Value Set Authority Center or VSAC and if they're not, then we (have four) plans for how they are going to be entered in to the VSAC, so this is an example of an Excel. Is there anything else?

Okay – okay and so there are other – there's other attachments as well inside the zipped file, some of them could be the XML which is the coding and now again I said the spreadsheet is there and also the HQMS. You will also see a

document that says the eMeasure feasibility scorecard, that's another document that you will see as far as eMeasure information for review.

Are there any questions related to eMeasures?

Okay.

Mary George: This is Mary George. I have one question. If submitted for trial approval, it has – it is require to submit to Bonnie testing results?

Sharon Hibay: So if – if the measure is submitted for trial approval, it is strongly recommended to include the Bonnie results. Bonnie results are required if the measure is being submitted and the measure is currently being utilized in a federal program. It's strongly recommend that it would be submitted for measure for approval for trial use.

Mary George: Thank you.

Sharon Hibay: You're welcome Mary.

Judd Hollander: Hi, this is Judd Hollander I have a question. I'm looking at measure 70 and you know and some of the validity testing, you know, obviously this is all new to me but they're doing agreement between 134 patients. And the reliability testing in the Bonnie output is 55 patients, you know, every other measure we're seeing is tens of thousands, if not hundreds of thousands of patients. These numbers just seems small. Are those acceptable numbers, is that what we expect to be seeing in this eMeasure?

Sharon Hibay: So, what I would say to you is, Judd, you have to remember this is a pre-test sample. So, these are individual patients that the developer has created to test the measure itself, to test the components of the measure. We would not consider this testing, we consider it pre-testing as an ability to say is this measure implementable, is it correct, all of those things.

So for validity itself, you want to know that it's able to capture the actual to the expected number. If this was not pre-testing, 55 would be a low number, I agree, but I think what you heard very clearly is one of the very strong

constraints we have related to eMeasure is capturing patient level data. Again, most of them are via attestations, so.

Judd Hollander: Right and so then what sort of an acceptable number for simple agreement on a small sample set. So, this one is in the low 80s in a 134 patients, I didn't calculate the confidence interval, it wasn't given to me but I imagine it drops into the upper 60s. You know, is this stuff we're sort of okay with or where should we be looking to hit?

Karen Johnson: So, this is Karen let me take a shot at answering your question and the caveat is I haven't looked specifically at this measure. So just in general when you're thinking about sample sizes and samples they are using in testing you're hoping that the developer was able to get a reasonably representative sample of the kinds of patients and providers that would be actually used in the measure.

So with that said, so in some ways that kind of negates at having a need for having an actual number you must have 200 patients or 2000 or something like that. But that said, in terms of what kind of agreement, it's almost the same kind of thing. It's really hard for us to put an actual number on. You must have an (x-percent) agreement.

But what we do suggest is that in some cases if you are doing the plain agreement, the problem with plain agreement, is that people can agree on things just by accident. So there are other statistics that can be used that kind of take that into account. So, I'm not sure if this measure did this or not. This is (Bonnie's) staff so perhaps not. But in lieu of that there is also other what we call categorization that it had been used in literature to give the flavor of what level of agreement those numbers reflect.

So, there are – depending on the categorization used, a 65 percent agreement may be considered fair or poor or slight – I'm not quite sure what categorization they used. But hopefully there was some sort of categorization that was used to help guide you in interpreting that number.

Sharon Hibay: And this is Sharon, just to be clear about what you're reading in the submission itself, so you are correct there are 55 pre-test patients in the

sample, OK? And the agreement between the expected, excuse me, the actual to expected is 100 percent agreement for this measure and the 82 percent are those covered data elements. So 82 percent of all the possible data elements can – were covered in the sample population. So of the 82 percent of the elements that were tested, there was 100 percent agreement.

Male: OK, yes.

Sharon Hibay: The actually…

Male: I have to say without that explanation that wouldn't have been clear to me from this reading this.

Sharon Hibay: OK. Is there – are there any other e-measured questions that we have? OK, I turn it over now to (Karen Johnson), gracias.

Karen Johnson: OK, thank you. I think SDS trial is going to be a much easier thing to think about than e-measures which I just find them mysterious. So, many of you have probably heard that NQF is in the middle of what we're calling our SDS trial period and just to give you a little bit of background on.

In late 2013, NQF convened a panel to consider whether and so how Socio-Demographic Status variables should be included in risk adjustment approaches for performance measures. And the expert panel put out the report right out a year ago, August 5th, 2014 and they basically did recommend potential use of SDS variables and risk adjustment approaches.

Now this was not without quite a bit of controversy, you know, even had been controversy we would not have meet to create an expert panel to talk about it in the first place, right? So, there are two main perspectives on this. One perspective is that adjusting for SDS factors or Socio Demographic Factors. I'm going to say SDS just because it's a lot easier to say.

But some folks are concerned that if you do that in your risk adjustment approach that you'll actually mask disparities and that's something we don't want to do. So, that line of thought would make you not want to adjust and then the other way of thinking about it is that SDS factors can actually be

confounding factors and may actually misrepresent if they are not taken into account. The actual performance measure score may actually misrepresent what's going on in terms of quality.

So, that line of thinking says that adjusting for SDS factors is necessary otherwise you might make incorrect inferences about quality of care that's provided and that's particularly concerning when you're comparing providers. So, as I said the panel did recommend going forward to include SDS factors and in risk adjustment approaches. And what the board of NQF suggested is rather than lift the prohibition – and let me backup and say that prior to this panel and their work NQF actually explicitly said don't use SDS factors and risk adjustment approaches. It was prohibited.

So, what the NQF board did is basically instituted a 2-year trial period where that prohibition is lifted. So, for two years, we're going to have measures come through just like they always have but this time instead of being told you cannot include SDS factors, we're going to say you can and I'll get into more detail about that (ton) that I was just talking about.

A couple of the major things to take away from today's work is to realize that each measure has to be assessed individually to determine if SDS adjustment is appropriate. So, the panel did not say every measure needs to be SDS adjusted. Again, you have to look at each measure individually and that's really no different than what you're doing. Anyway, you're looking at each measure individually to see how they do or do not lineup with the criteria for endorsement.

The other major thing is that there must be a conceptual basis and empirical evidence to support the inclusion at SDS factors and risk adjustment approaches. So, those are the two kinds of things that we have added if you will to your workload and that is to think about the exceptional basis and empirical evidence. And one thing that I'll mention here and you'll see it I think again and again as you think about the measures that are brought for (QNTB) III is that efforts to implement SDS adjustment really can be constraint by data limitations and the data collection burden.

So in a way not to different them what Sharon was about in terms of e-measures, data availability can really make a big difference as to whether SDS adjustment is appropriate or even possible.

So, to the next slide, please. Thank you. This slide really just tells you that one of the main things to keep in mind is that basically all measures coming forward to NQF are part of the trial. So, we're not distinguishing certain measures are and other measures aren't. But basically there are different pathways if you will to be considered.

All new measures and measures undergoing routine maintenance are considered in the trial but also if you have an ADHOC request for a measure that could be one way to have a committee to think about SDS adjustment. And there's also some earlier projects that are – that kind of like measure (inaudible) if will.

And they were ongoing at the time that the SDS expert panel was doing it to work. So, basically they received conditional endorsement and now they are going back through again and the committees for readmission and custom resources were actually thinking about SDS adjustment for them.

Next slide please. So, what's that mean for you on the CV committee? As I think or hope I said before, you will continue to evaluate the measures as a whole. So, we're adding a little bit extra but we're trying to not make this like a huge big thing; this is just a little bit of extra stuff that we want you to think about. But you'll still be thinking about all the other criteria, important gap reliability, validity, et cetera.

Risk adjustment particularly SDS factors and inclusion and risk adjustment is going to be considered primarily under the validity criteria. So, as part of validity for certain kinds of measures that are risk adjusted, you think about the appropriateness of the risk adjustment model. So, when you're thinking about the appropriateness of that model, you think about the clinical factors that are in there just like you always did. Now the little extra piece is just thinking about potential SDS factors that may or may not have been included in those models.

As Sharon had mentioned and I'm sure you've seen by now we did do the preliminary analysis and the measures in the project and we've identified areas that we want you to think about in terms of SDS adjustment. So, hopefully there's (PA) we call them PAC-Preliminary Analysis would be helpful to you.

So, the main questions that you'll be thinking about as you go through this part of the evaluation for some of the measures is – or the conceptual relationship between the SDS factor and the measure focus. So, measure focus is the NQF jargon that means what the measures about, OK? And the SDS factor here just recall that there may be one SDS factors or there maybe 10 that the developer is thinking about and looking for literature about. So, there can be lots of different conceptual relationships between lots of different SDS factors.

What are the patient level SDS variables that were available and analyzed during development? So, there's really two pieces here and this is – this is where it's bifurcated. There's the conceptual piece and there's the empirical piece. So, before you get into the empirical results we first have to find out what was even available.

So, what this means that there could be conceptual thinking to link SDS factors with the outcome of interest, but there may not be the data available to actually look at it empirically. So, we asked what are the – what are the data available and then finally going on just the empirical analysis shows that the SDS factor has the significant and unique effect on the out coming question.

So this is basically the same thinking that you would do about the risk model that you would do in the absence of an SDS factor. You'll think about, you know, how good was that model to perform well. And then finally just the reliability and validity testing match the final measure specifications. So what this is getting at is it's really actually a price more to maintenance measures that maybe have been changed in terms of the risk adjustment approach.

So, let's say that a measure had been risk adjusted earlier and came through and was endorsed but there was no SDS factors in the risk adjustment approach and let's say now the developer has decided that there is a good

reason to include an SDS factor in that approach. What this is saying is once those specifications have changed in a very significant way by changing the risk adjustment approach, the testing also needs to change, so that it reflects the most current recommendation.

So, again there is really nothing new here. If the developer had decided to add in an additional exclusion or something like that you would expect some testing to reflect that appropriateness of the exclusion. So, again there is really – it's the same idea that reliability and validity testing should basically match the measure specified.

So, let me go a little bit more in depth in thinking about the conceptual description but basically what we've asked the developers to do is to provide a conceptual rational of the linkages between any SDS factors and the – what's being measured and for the committee to basically think about whether there seems to be a conceptual relationship.

And there's no major – there's no set criteria. Often what we've seen is developers going to the literature and maybe pulling a few or maybe many articles that play in a different literature to either suggest that there is conceptual linkages or maybe that they are not conceptual linkages. So, again, it's – as we go through not just the CV project but other projects going forward to see the kinds of things that the developers bring forward.

Again, just like we discussed with the testing, we don't have actual thresholds and that's were (the things that) we weren't very prescriptive about what the committee must bring to you. We ask you to think about whether the SDS factors are present at start of care or caused by the care being evaluated. I'm not going to that right now, those are pretty simple. I think that will be a pretty simple thing for you to think about but it relates to – those are – those are criteria about confounding which is kind of what we're – that's the statistical concept that we're building on – the idea of confounding.

More in depth to look about, data and variables, basically again you're going to look at what the developer told you about what they had available and what they were able to do with it and one of the main questions to think about is

going back to the conceptual release day presented to you how well did the data that they had available aligned with those.

So, for example – my favorite example because it's so easy is to think about income. So, it could very well be that there is conceptual reason to think that income has something to do with an outcome that you're looking at. But the developer may not have actual income data but they might have something like property level or they may have something like Medicaid status.

So, you have – in those kinds of situations you have to think about how well that aligns with the conceptual idea of income and then also to think about whether the variables that they have are available and generally accessible. In terms of the empirical analysis, as I've already alluded to, was the if they actually have some data so they have first the conceptual rational for inclusion and then if they have the data then they may actually have done from empirical analysis and you would look at the model and basically this is the first rule that this model diagnosed the diagnostics to see how well that model performed and then we're also asking developers to basically one – two sets of data for you.

One were the SDS factors are included in the risk adjustment approach and one where they are not included and actually look to see what the real differences are between the results from doing it one way versus the other and we'll see how that goes. We haven't seen a whole lot of that come through yet I don't think but that's one of the things that we want you to look at.

Go ahead to the next slide, please. As I've already mentioned if SDS factors are included in a –or risk adjustment approach then updated reliability will be included. And finally one more criteria that we are asking – well that's not a criteria that we are asking developers to do is to provide basically the information needed to calculate the measure without the SDS adjustment so that the results can actually be stratified by the SDS variable.

So, that's a little confusing if it comes to it in this project, we will give you more information about what we mean by that but I won't go into it now especially as I'm looking the clock (it seems) that I am running out of time

here. We do have a page up now web page up for the SDS trial period and we've noted it here in your slide deck. You can take a peek there to see a couple of things that we have up.

I think the other thing that I would like to note maybe emphasize is two strong words that, you know, what we really are seeing this as is a learning opportunity where, you know, this is new for developers because we used to prohibit this and it's new for staff and for committees because we haven't seen this kind of thing come through before.

So, we were going to do our best to help everybody developers and committee members and the public and ourselves walk through this but we're not going to have all the answers but we're going to do our best, so I think that's the most – the best that we can promise is that we will just do the best we can as we through this.

And I think we're actually going to learn a lot and we've already had a little bit of experience with this not a lot, you guys and CV seems to be the cutting edge committee here. You guys get to do a lot of things first, so you're not quite the very first folks to do SDS trial kind of work but you're pretty close to the first. So lucky you to see that that we're already seeing some things that we're learning with a few others and I'm sure that we'll learn more as we go through it.

So, let me stop there and see if folks have any question and I know we're running late but we'll see if there's any burning questions right now.

Operator: At this time, if you have a question, please press star one. And there are no questions at this time.

Karen Johnson: So, the committee has no questions about SDS factors. That's great, should be easy then. If you do have questions, let the project team know. We can – we can try to answer those for you before this meeting and as we said in the meeting we'll be helping you walk through this and hopefully we've already got start through the preliminary analysis that we've done.

Leslie Vicale: Thanks, Karen. This is Leslie, Thom and Mary if you would like, we might be able to take one or two questions about the Cardiovascular Phase III Measures if you would like to facilitate that.

Thomas Kottke: Sure, Thom here. Does anybody have any questions about their measures that they'd like us to address? I'm hearing nothing.

Karen Johnson: I know we're tied on time. The folks may feel a little shy and not wanting to go over. So we can again (wait to try to) facilitate questions through email if you have any.

Leslie Vicale: OK. So at this time, what we'll do is that we'll go ahead and open the call up for member and public comment. Operator, can you open the call for public comment?

Operator: Thank you. At this time, if you have a question or comment, please press star then the number one on your telephone keypad. And there are no questions or comments at this time.

Leslie Vicale: Great, thank you very much. So, before we do close out the call, I do have a couple of next steps and timeline information that I like to provide everyone on the call. And so, you'll notice here that fast approaching is our in-person meeting on September 9th and 10th.

And so, to those committee members who registered, thank you very much and if you haven't already registered we definitely encourage you to do so very soon and we wanted to just let everyone know that we're making some minor adjustments to the agenda that we'll be sending out a final agenda very soon.

Right now, we have the post in-person meeting committee call scheduled for September 25th from 2 to 5 pm, please note that we did extend that by one hour. We have quite a few measures to review the in-person one to allow enough time in the post in-person call to review any other measures that may not get reviewed at the in-person meeting.

And then we're in the process of scheduling a second call to discuss any related and competing measures again that we will not have an opportunity to discuss (related competing) component during the in-person meeting. And finally, you'll notice that the (expert the) public and member comment for the draft report.

So I just want to provide you a quick reminder for the committee if you have not already done so please go ahead and place your vote for the measure 0018ADHOC. That survey will be open to you and we provide that vote by (close the business) on Wednesday the 26th. I also want to note that the Phase II Cardiovascular report will be sent to HHS on August 31st and post it to our project page.

You'll receive – committee members and developers, you'll receive an email notification from me and the public will also get notified via that project alert. So, I want to find out if Thom and Mary as our coach chair that you have any closing remarks or anything you wanted to address the committee or anyone else on the call about?

Mary George: This is Mary and I just want to thank the committee members and developers for being on the call today. This was a lot of information to take-in in a short period of time but and also thank to our staff for this review.

Thomas Kottke: I'll just second that.

Leslie Vicale: Certainly. Wonderful. Well thank you and like Mary said we do understand that this is a lot of information today. So, we do thank you all for joining us and again if anyone has any question please feel free to contact the project team and we'd be more than happy to address any of your questions. Thank you very much everyone on behalf of the NQF Project – Cardiovascular Project staff. Thanks for joining and we look forward to seeing you all at the in person meeting.

Mary George: Thank you very much.

Leslie Vicale: Thank you. Bye-bye.

Mary George: Thank you.

Operator: Ladies and gentlemen, that concludes today's conference call. You may now disconnect.

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