

## **NATIONAL QUALITY FORUM**

**Moderator: Sheila Crawford**  
**June 20, 2019**  
**11:52 am CT**

Erin O'Rourke: All right. So, if it's okay with (Alisa) and the rest of the team, I'm going to go ahead and get started in the interest of time, since we want to make sure we leave enough time for the consideration of our candidate measures.

This is Erin O'Rourke. I'm a senior director with NQF and wanted to thank you all for joining us today. Thank you to the members of the committee for taking the time to join us in our closed session. And thank you to the members of the public for your patience while the committee had their closed conversation.

We should now be in open session and we will begin with our agenda for today. The committee will be considering one measure today, that's measure 2539, a maintenance measure up for re-endorsement. Before we get started, I did want to welcome our co-chair Cristie Travis and turn it over to her for a few words of welcome for everyone.

Cristie Travis: Yes. Thank you everybody for being here today. This is our first meeting in this new session for the retaining, readmissions, admissions and readmissions committee. So thank you all for being willing to serve again this time as well as for your work and consideration of the two measures that we'll be

reviewing, one today and one tomorrow. And I do want to welcome the developers as well as the public to our session today. So thank you very much.

Erin O'Rourke: Great. Thank you Cristie. And before I send it over to (Alisa) for disclosures of interests and introduction, I did just want to clarify on the agenda that we have removed the request for reconsideration for measures 3443 and 3445. We are not likely to have quorum on today's or tomorrow's call, and given that we need to have quorum to have the committee vote to officially begin that discussion, we'll be looking for another time where we will have quorum to have that conversation.

So I did want to explain that change. And given that we no longer have that agenda item then we only have two measures. We've gone ahead and canceled the meeting on June 27 to give you all a little bit of time back. So I think without further ado and since we are down to the two meetings, I will turn it over to (Alisa) to go through the disclosure of interest process.

(Alisa Mentali): Thank you so much Erin. And I want to pile on my welcome to everyone and thanks for being on the committee. My name is (Alisa Mentali), I'm the senior vice president for quality measurement at NQF. And when you joined the committee, you received a disclosure of interest form from us and we asked you a number of questions of relevant information as it pertains to the admissions and readmissions committee. And so today we're asking you to orally disclose that relevant information to us.

Just a couple of reminders as we go around the virtual table. You sit on this committee as an individual. You do not represent the interests of anyone who may have nominated you for the committee or your employer. We are interested in both activities as they're relevant to the work in front of you that are paid and those that are unpaid. And perhaps the most important reminder

is just because you disclosed does not mean you have a conflict of interest.  
We go through this process in the interest of openness and transparency.

And so what I will do is start with Cristie. I'll ask Cristie to reintroduce herself, tell us who you're with and let us know if you have any conflicts. And then I will go down the list of committee members as it's presented on the screen in alphabetical order. So, (Christy)?

Cristie Travis: Sure. I'm Cristie Travis and I'm the CEO of the Memphis Business Group on Health and we've worked with employers in the Memphis market. I also serve on the board of the Leapfrog Group, the National Alliance of Healthcare Purchaser Coalitions and as well as the board of NQF. And I also serve as an advisor, employer-advisor to MCQA.

The only disclosure that I'd like to make is that I do hold an equity financial interest valued in excess of \$10,000 in health care-related entities. Thank you.

(Alisa Mentali): Thank you, Cristie. I understand (Katherine Agora) is not with us. So Jo Ann Brooks.

Jo Ann Brooks: Yes, my name is Jo Ann Brooks. I'm recently retired from Indiana University Health in Indianapolis where I was system vice president for safety and quality, presently a healthcare quality consultant. My only disclosures are that I do unbranded presentations for Jansen on readmissions and transitions with care and how to improve those and also speak for Stryker and Stryker Sage, which is a subsidiary of Stryker on hospital-acquired infections.

(Alisa Mentali): Thank you so much. And sounds like you don't have anything to disclose and Helen Chen?

Helen Chen: Good afternoon. This is Helen Chen. I'm the chief medical officer of Hebrew Senior Life, which is an integrated senior healthcare company based in Boston. We provide care across the continuum, including many venues that are affected by readmission measures. I'm also on the board of directors for the Beth Israel Deaconess care organization, which is the Medicare and Medicaid ACO. And like Cristie, I have equity positions in healthcare companies exceeding \$10,000.

(Alisa Mentali): Thank you and Helen, just for the record you have nothing to disclose. Correct?

Helen Chen: Right, exactly.

(Alisa Mentali): Thank you. Susan Craft I understand is not with us.

Susan Craft: I'm here.

(Alisa Mentali): Oh, you are? Thank you.

Susan Craft: I am. Hi, this is Sue Craft. I'm the system vice president for case management and post-acute care at Henry Ford Health System. And I have nothing to disclose.

(Alisa Mentali): Thank you so much. Wes?

(Wes): Yes, I offered my disclosures, as of 2019 (unintelligible).

(Alisa Mentali): Thank you so much, (Wes). I understand (unintelligible) isn't with us today. (Paula), are you here? Okay. (Larry Glass) I don't think is with us today. Tony, are you here?

Tony Grigonis: Yes, I am. This is Tony Grigonis. I'm vice president for quality and healthcare analytics at Select Medical. We're a national post-acute healthcare provider. And I have nothing to disclose other than owning some substantial stock in the company. Thank you.

(Alisa Mentali): Thank you so much, Tony. I don't think we're expecting (Bruce Hall). Leslie, are you on the call?

Leslie Kelly Hall: Yes, I am. Hi, I'm Leslie Kelly Hall and I'm the founder of Engaging Patient Strategy and a consultant and patient advocate. I sit on the HRQ Serious Illness Taskforce. I'm on the board of directors of Direct Trust and on the Carry Quality Steering Committee. I'm also on the Saint Alphonsus Health System board of directors quality committee, and then nominated to the board of directors and am a consulting executive at Lifewire and I have nothing to disclose.

(Alisa Mentali): Thank you so much Leslie. And I don't think Paul is joining us today. (Karen), I think we heard you earlier.

(Karen): I am here. Hi, this is Karen (unintelligible). I am a cardiologist at Barnes-Jewish Hospital in St Louis, Missouri and a health policy researcher here and in the Center for Health Economics and Policy at the Institute for Public Health here. I previously did contract work with Health and Human Services with the office of the assistant secretary for planning and evaluation. But nothing related to - I had no direct contact with CMS around this measure and have not done any work on this measure, so I have nothing, nothing to disclose.

(Alisa Mentali): Thank you so much, (Karen). (Keith)?

(Keith Lind): Yes, (Keith Lind), senior policy advisor, (unintelligible) public policy institute. I have nothing to disclose.

(Alisa Mentali): Thanks (Keith). I don't think (Paulette) is with us. Carol Raphael?

Carol Raphael: Yes. I am a senior advisor at Manatt Health. I also have chairs, the technical expert panel for CMS on home and community-based services, managed long term care and the dual eligible, and have been a member of the MIPS Technical Expert Panel on Inpatient Measures. And I also chair the Longterm Quality Alliance, but I have no conflicts to disclose.

(Alisa Mentali): Thank you, Carol. I don't think (Matt) will be joining us. (Paula) are you on the phone? Oh, sorry. Pamela.

Pamela Roberts: Yes, I'm Pamela Roberts, I'm the executive director for physical medicine and rehabilitation at Cedars-Sinai and I have nothing to disclose.

(Alisa Mentali): Thank you very much. I don't think (Derek Robinson) was expected to join and Tom Smith.

Tom Smith: Hi everybody, Tom Smith. I'm a psychiatrist on the faculty of the Columbia University Department of Psychiatry where I do behavioral health services research. I also serve as the chief medical officer for the New York State Office of Mental Health. In that capacity, I'm co-director of the office's Behavioral Health Performance Measurement Center. We develop performance measures for use in the state's Medicaid program.

I also sit on a couple of technical expert panels, one for the Narrative Psychiatric Association Measurement Development Program that's funded by CMS and another - also the CMS Physician Compare Quality Measurement

Panel. But none of that work I think is related to the measure we're developing today. So I don't think I have any conflicts.

(Alisa Mentali): Thank you so much Tom. And before I turn the meeting over to my colleagues, I understand from some web chat were receiving that there's some background noise. I think we've been able to quiet that down. So just a reminder to everyone, if you're not speaking to put your phone on mute, so thank you to whomever did that.

And so before I do turn it over, just wanted to remind you that at any time if you remember that you have a conflict, we want you to speak up. You can do so in real time or you can send a message via chat to anyone on the NQF team or to Cristie. Likewise, if you believe that any one of your colleagues is acting in a biased manner, we want you to speak up. So thank you very much. And I think with that I turn it over to Erin.

Erin O'Rourke: Great, thank you (Alisa). So, just to confirm my math, it looks like we do not have quorum today. So we will not be taking any formal votes. So we'll have our discussion and we'll follow up with you for voting offline. So no need to worry about casting your vote at the moment.

So for this cycle we do have two measures for your review. The first is measure 2539. This is a maintenance measure. The facility seven-day risk-standardized hospital visit rate after outpatient colonoscopy, and measures numbers 3495, the hospital-wide 30-day all-cause unplanned readmission rates for the merit-based incentive payment system, eligible clinicians and clinician group.

So today we'll be focused on 2539 and we'll come back tomorrow to discuss 3495. Next slide.

Both of these measures were reviewed by NQF scientific methods panel. As a reminder, this panel consists of individuals with (unintelligible) expertise and it was established to ensure that we are doing a higher level evaluation of the scientific acceptability of complex measures, and to serve as a resource to the standing committee in your review.

For the summary of the findings of the SMP's review, they were - consent was not reached on the reliability of 2539 and that measure did pass validity. Both 3495, the methods panel was satisfied with the reliability and validity of the measure. We will go into greater detail when we come to the scientific acceptability portion of that - of both measures.

One key factor, I did want to remind you, is that the scientific methods panel is not really able to discuss issues related to (unintelligible) risk adjustment as part of their review. And it is not a factor that they can use to not pass a measure on for standing committee review. So that may be something you would like to keep in mind as we discuss the measures further.

I also do want to remind everyone that (Karen Maddox) and (Larry Glance) are members of the Scientific Methods Panel and will be abstaining from voting on scientific accessibility as they reviewed the measures as part of the methods panel process. And I should see, (Karen) was there anything I missed on the methods panel that as an SMP member you'd want to highlight?

(Karen): I don't think so. Certainly there's - as we go through the measures there will be places where you see in the - some common themes come across the writeups. But I think in general the goal of that panel is really just to try to add some consistency to how the specific methods of the submitted measures are evaluated and take a little bit of that burden off the standing committees so



that more effort can be given to really some of the content discussions and some of the stuff that the standing committees are more well suited to do. So, at least in my opinion thus far it's been a nice sort of division of labor and I think good on both sides.

(Keith Lind): This is (Keith). I have a question.

Erin O'Rourke: Sure.

(Keith Lind): I don't understand why a scientific panel member who reviewed this should be disqualified from voting with the standing committee just because they reviewed it as part of the scientific panel. It's not like that's double counting. And certainly in the case of the SCS adjustment where they weren't permitted to consider it, I guess I don't understand what the rationale is from, I mean, I don't see a conflict of interest if that's the issue. And I, if it is, I'd certainly like to understand better why.

Erin O'Rourke: Sure. So I can, start with a little bit about our thinking and, and (Alisa) if you're still here, she might've had to go back upstairs. The logic from the NQF of not having scientific methods panel members who also sit on standing committees vote, or to ask them to abstain from voting on scientific accessibility was that they essentially already got to vote as part of the scientific method process. And in the current process measures that don't have the scientific method panel, do not go to the full committee for review.

So I think our logic was since the SMP members already got a vote on these, the scientific extensibility of these measures, we don't ask - we ask them to abstain from voting as part of the committee. But I think it's good feedback if you don't see the conflict of interest and wouldn't feel like this is double counting, I think we were trying to make sure that no one voice was stronger

than others when we set out the process and that it's balanced, for how many times the person gets to weigh in.

(Keith Lind): Thanks for the explanation. I - you might want to test out that assumption by some, by checking with some outside people who think about, you know, ethics or conflicts or stuff like that. It doesn't necessarily - let me put it this way, I certainly would not have a perception of bias if they got to vote as part of the standing committee just because they voted as part of the scientific review. But I don't know, other people may have other frameworks for analyzing that, but I just thought it was worth raising that.

Erin O'Rourke: Thank you, that's good feedback.

(Keith Lind): Thanks.

(Wes): From a - this is (Wes) real quick. From a parliamentary point of view, it probably is not in order. I'm thinking about a lot of organizations that most of this - participants as professionals. If you're part of a steering committee that provides a report to the full body, their participation in the steering committee doesn't prevent them from voting on the outputs from the steering committee in the general session.

So, I think this looks like something which is probably a matter of being too aggressive in our attempt to be - to level the playing field. I'm speaking in favor of letting folks who participated in supporting committees and groups still have a voice in the vote on the standing committee.

Erin O'Rourke: Great. Thank you. That's a helpful metaphor. personally, I don't have the power to change the process for today so we'll have to continue to ask Larry and (Karen) to abstain from the voting, but we will definitely bring this

feedback to (Alisa) and to (Karen Doston) who staff the message panel.  
Perhaps this is a policy that needs to be reexamined and doesn't have precedent in other, similar fields.

Woman: Thank you, Erin.

Erin O'Rourke: So I do want to see if there's any other questions or concerns with the methods panel process before we move on. So hearing none, if we could move on to the next slide, I do just want to give a very brief refresher of the evaluation process and some of the ground rules for today. If we could go one more.

Just a reminder of the role of the Standing Committee, that you're acting as a proxy for NQF's multi-stakeholder membership. And we'll ask you to evaluate each measure up for endorsement against each criterion and ask you to indicate the extent to which you believe the measure meets that criterion, and have a discussion about your potential rationale for the rating.

Again, we won't be taking any votes today. This will be discussion only and then we will vote electronically afterwards. As a reminder of how the process works, you'll make an initial recommendation for endorsement. We will then put that out for public comments to get broader input and take your recommendation to the CSAC for finalization. Next slide.

So a few ground rules. We'd ask that hopefully you've reviewed the measures beforehand. We'd ask you to base your evaluation and recommendations on the measure evaluation criteria and guidance. We'd ask you to remain engaged in today's conversation and if at all possible, attend our conversation at all times. If you do have to step away, we'd asked you to put your line on hold or on mute and not put the call on hold and introduce the background music hold.

We'd ask in the interest of time you keep comments concise and focused, and avoid repeating arguments that have already been made, so that everyone can have a chance to share their opinion and contribute. Next slide.

So I think a few housekeeping items here, I won't belabor them too much. Again, if you could keep your line muted, unless when you're speaking to minimize the background noise. We do have the hand-raising platform, the hand-raising feature on the web platform. If you'd like to, let us know you'd like to speak that way. And if you could announce your name prior to speaking to us so that we know who's making comments. It helps us track the conversation. Next slide.

So our process for measure discussion. We will give the measure developer two to three minutes to introduce their measure. I will then begin our conversation by asking the discussants to provide a summary of their review, share any of the pre-meeting evaluation comments that they think should be highlighted. In particular we ask them to emphasize any areas where they may have concern with the measure or a difference of opinion from some of the submitted comments.

We will allow the developers a chance to respond to questions at the discretion of the committee. And again, we will not be voting on each criteria or sub-criteria as we go through the process. So we'll conclude conversation and then move on to the the next criterion rather than stopping discussion as if - as we would if a measure were to fail one of the must-have criteria. Next slide.

So I just want to check in before we get started, if anyone has any questions. Great. So we can move on two slides ahead. Just a few highlights from the

voting process that I want to make sure people are aware of. The first is our issue around quorum. To have quorum, we need 66% of the committee present. We do not have that on this call. So we do not have the quorum required for voting. As a reminder, to pass or recommend a measure, we're looking for greater than 60% voting yes. So 50% of the forum voting yes.

We consider a consensus not reached if we are in the 40 to 60% range. And if they do not pass or are not recommended, if a measure has less than 40%. Yes votes. And again after this we move to public and member comments. We will ask the public to comment on any measures where we have a consensus not reached, and you would resolve that issue at our post-comment call.

So I think we can move on and if there's no for their process questions, we can begin our review of measure 2539. Next slide.

So again, this is the facility seven-day standardized hospital visit rate after outpatient colonoscopy. The developer is Yale Core and it's stewarded by CMS. It's an outcome measure. The data source is claims. The level of analysis is facility, the care setting, you'll note it as outpatient services. Particularly did want to highlight, there's two rates calculated within the measure. One for ambulatory surgery centers, one for hospital outpatient services.

Again, this is a maintenance measure. It's currently endorsed. I think one key thing that we can get to when we get to the validity conversation, our new maintenance requirements ask that measures - maintenance measures use empirical testing rather than face validity. In this case, the developer notes they didn't have an acceptable measure to perform empirical validity testing against. So you'll see there's face validity only with an explanation from the developer.

This was acceptable to the scientific methods panel, but did want to flag that for the committee. So I think with that, I can turn it over to the team from Yale to present the measure.

Elizabeth Drye: Hi Erin, it's Elizabeth Drye from Yale. Can you hear me okay?

Erin O'Rourke: Hi Elizabeth, yes, I can hear you.

Elizabeth Drye: Hi. Okay. Hi, everyone. I think this committee is pretty familiar with this kind of measure, so we recently reviewed two related matters with the (unintelligible) the seven-day hospital visit. So I was just going to highlight a couple of specific issues related to this measure.

First, as Erin mentioned, it's a measure already in public reporting and public reporting started in 2018. And CMS just transitioned it from a measure that used one year of data to a measure that used three years of data. They finalized that in the 2019 outpatient prospective payment system final rule. So public reporting with three years of data will start in next January, 2020. And the reason I'm highlighting that is I think this is a learning experience for us. But the measure is moving through its endorsement on this - on schedule from NQF perspective but that collided a little bit with this transition. So you'll see data in the application that reflects both one year of data and three years of data.

The measure was submitted as a one year of data measure and I think that's what you're going to be voting on. And that was a bit of a point of confusion in earlier discussions. The key issue coming out of the methods panel was reliability. The measure did actually previously pass on reliability, our methods panel and went back with some other issues and it came out. And we

do present signal-to-noise testing for the measure. Even with one year of data those are in a range that is usually acceptable. So if you have questions about that, I can go into the specifics of the testing.

I also just wanted to mention, as you know, as you see in the results that the measure outcome rate is fairly low. If the reason it's a 16.3 per thousand colonoscopies for HOPDs and 12.5 for AFCs and that's the reason we went to three years, so data which is to basically increase the reliability of a measure score.

You won't see a lot of outliers identified with this measure using that strict criteria of 90, 95% interval estimate, being, in other words, we're 95% confident that the facility has a rate that is higher or lower than average. We're limited in what we can identify with that methodology given the low outcome rates, but we've presented other descriptions of variation of the measure score that we can talk more about if you have questions.

Finally I just add that the measure is not adapted for social risk factors. We did look at social risk factors - this is the endorsement and, you know, and in the earlier development period, there was - we talked about it with our expert panel, engaged in public comment around these issues and we examined them in our testing.

There was a - basically the experts in seeing us kind of waived the results of our testing and also what we know about disparities in this population. We noticed disparities in access to colonoscopy, for sure. But in terms of this outcome we're looking at, hospital visit within seven days, it wasn't known and our look at it using dual eligibility shows that there is a difference. The eligibility patients do have a 1.3 an odds ratio, or higher odds ratio of having a

hospital visit. But that is about in an absolute sense one more colonoscopy, one more hospital visit per thousand colonoscopies.

But looking at the data, including data showing that facilities with the most dual-eligible patients don't really do worse on the measure as their proportion of patients get worse. Looking at the differences across facilities, it didn't, it didn't look like this was burdening facilities in particular - that in other words not adjusting would burden facilities in the measure score who have more dual eligible patients.

And, as you know, and as we talked about with this committee recently, (unintelligible) has looked at that, we had the tradeoffs and there are questions about adjusting because it could potentially mask a disparity in the outcome of care and the quality of the care provided.

So the decision CMS went with is not to risk-adjust the work in this area. We're actually doing more work on colonoscopy with (unintelligible), looking at this in greater depth, which hopefully we will be able to share with you in the future. But at this stage, that is their policy choice and the way to measure its structure. So, I'm going to stop there and I'm really here to answer your questions and I really appreciate your consideration of the measure. Thanks.

Cristie Travis: Okay, thank you, Elizabeth. This is Cristie. Erin, I just want to be sure I've got the process right. Should we hear from Tony and Keith about their overall thoughts on the measure or do we do that by criteria, for each criteria?

Erin O'Rourke: Let's go through each criterion separately. So if we could ask Tony and Keith to start with importance of the measure, first pass any comments on the evidence might make it a little bit clearer.



Cristie Travis: Okay, thank you. Tony, would you like to go first and share with us your thoughts on the evidence?

Tony Grigonis: Sure, thank you. I think the evidence is that there is enough of a performance disparity among facilities, although as was just mentioned there's - it's a relatively small rate, low rate and the differences between the percentiles are pretty close. The median rate was 12.5 for surgical centers and 16.3 for hospital outpatient departments. So I think it's clear that the separation of those two different sites is also appropriate.

My only concern had to do with what was also said - I think Elizabeth hit on all the major points - is that if you're trying to make this a usable metric in terms of rating facilities, the fact that the 95% clinical center doesn't really work in that I think only one facility was able to be noted as better than average in each case. And I'm not sure if that is more sort of when we get to the usability part of the discussion and that may actually be beyond what we are tasked to try to determine.

But, as a usable metric and going any further from what's presented here, I think that that does raise some questions.

Cristie Travis: Thank you. Tony. Any thoughts on evidence, (Keith)?

(Keith Lind): I would agree with what Tony said basically, and just add that in the end, I think it's under usability, that they point out that the hospitalization rate has declined over the last year or so, which suggests that there's room for improvement. I mean if the outpatient facilities are looking at the data or whether they are using this data or not, they're able to influence the hospitalization rates.

So even though it's currently low, and it's a fairly narrow spread in terms of the range, it seems like it's still an important measure and unless there's some other measure that we're not at this point considering that would do a better job, I would certainly give it - pass on this.

Cristie Travis: Thank you, (Keith). So I'll open it up to the committee. Are there any comments or questions from the other committee members around evidence?

Leslie Kelly Hall: Hi, this is Leslie Kelly Hall. I just - I have a comment and I think it's on all maintenance measures in general about what our expectations are for when there is a - is there still a gap? Is the evidence or the validity moderate. I wonder if in general are scoring needs to be better defined and criteria for scoring for maintenance agreements, or maintenance measures. When we're doing the job well, then the gap gets closed. But there also might be a compelling reason to continue to review and measure. So I just throw that out as a consideration as we get the measurements more mature in the industry.

Cristie Travis: Thank you, Leslie. Any other comments around evidence? There is another aspect that kind of follows on, and it's a performance gap, is the disparities, and how this plays out relative to disparities. Does anybody have any comments based upon the information we were provided? It does say that the developer found higher observed hospital visit rates across quintiles for the dual eligible patients and did give us that information. So any questions or comments around disparities?

Tony Grigonis: Well, this is Tony. I think one of the issues always seems to come down to whether or not including the disparity or dual eligibility in this case in the risk adjustment doesn't affect the C statistic. And I feel that's almost a statistical or mathematical methodological question as to whether that means that the -

adjusting for social demographic factors is not important. And I think there's recent studies that sort of address that fact, but could involve a whole different level of analysis, which obviously we don't have access to. But I just thought I would bring that up because it seems to be prevalent in many of our discussions.

Cristie Travis: Well, and the nuance here is that during this discussion of gaps, what we're - I'm sorry actually now that I'm (unintelligible) evidence but, I need to be sure. We haven't gotten to gap yet, so I apologize for that, that's my fault. I did kind of introduce it because it is part of the gap and we were talking about that as well, but we will get into more detail Tony in our discussion under scientific acceptability as to whether or not there should be social risk adjustment. So, you know, these two things are definitely related. There do appear, if I'm reading the information correct, there do appear to be some disparities that exist in this area. But I am trying, I apologize, I got ahead. I was looking ahead on my summary.

So, let's go back to gap. I mean to evidence. Any last minutes before we get to gap? Any last comments around that? Okay. And I think we have started the discussion on gap already and we've covered disparities. Are there any other issues relative to gap that we would want to consider?

(Wes): This is (Wes), just a question that I wish I knew the answer to, but in terms of access to these kinds of specialty services, I'd sort of be curious about claims data that looks at colo done as part of an inpatient stay versus these kinds of scheduled procedures in outpatient settings. My thesis would be the folks that have this done electively are probably in more stable, acute and chronic condition than folks that have it done as part of a unscheduled hospital inpatient stay.

I'm asking the question because I think that might skew some of the issues that surround gap as well as the socioeconomics stuff. Because my argument would be, especially for many, many folks that they're less likely to have surveillance-based procedures done as outpatients, and that it's more common in my clinical practice for these things to pop up when they become unstable, in particular as a result of either infection or bleeding, most importantly. So I'm just asking you a question about what the baseline data shows about complications following colo with a variable being whether it's done on an emergency or scheduled basis.

(Elizabeth): I can speak to that a little bit, this is (Elizabeth) for IDL. The challenge with looking at that as we know, the underlying condition of the patient - when the patient is having something original emergent - if you're then looking at the outcomes, it's hard to know if the outcome was related to the procedure or related to their initial condition. This measure just to clarify is just looking at outpatient colonoscopies that are billed as outpatient, whether they're, even if they're at a hospital, I think you know, so we're only capturing the outpatient procedures and we have a lot of ways of verifying that we're doing that.

And the measure's been through a national dry run and so hospitals and AFCs have all seen their patient-level data and they will be continuing to get it. So even if their score isn't high, they're going to see what's happening to their patients. We've isolated in on just the outpatients for the reason that you're talking about. It's just too hard to - I think the outcome it would be hard, but we're not, we wouldn't be able to as easily tease out what's related to quality versus, you know, what's just related to patient's underlying status. So (unintelligible)...

Man: So - yes, it's - you know, it's a great example of why for design purposes or for validation purposes if you set the corral in a fashion that's more narrow that

serves the purpose of the measure and perhaps it's sponsors or developers, there's a potential iceberg effect when for the program or for the populations that they serve if you leave out from the denominator the folks that have the highest burden of disease and the highest risk of complications, you know, my question is whether or not it discounts the value of the measure in terms of using it for either looking at outcomes or quality.

(Elizabeth): Yes, I think that the target...

(Leslie Kellyhall): Building a...

(Elizabeth): Oh, sorry. The target population here, you know, is a very large population in the U.S., since this is a recommended prevent - really critical life-saving or prolonging procedure if - because it's an effective way to prevent colorectal cancer. Was that outpatient population only? Like, you're raising a great question, but I -- just to be honest -- we never really went down that path because we were focused on very, very high volume, you know, recommended important procedure that was - really didn't have any outcome measures related to quality.

(Leslie Kellyhall): This is (Leslie Kellyhall). Building on that, too, is the gap in quality then related to the fact that the patient was poorly selected for outpatient versus inpatient or is the gap in quality because as a result of the outpatient there were complications? So I'm not sure how to determine that based upon the measure.

(Elizabeth): So I just want to clarify, our assumption developing this with, you know, a lot of clinical info from gastroenterologists and others. All of these - we - it would be rare that you would admit a patient for a colonoscopy in the - for the kind of procedures that we included here. We - it's just - particularly

(unintelligible) Medicare data, so really admission is you stay in the hospital for two nights. So we really saw that population as a very separate population since it's not a procedure -- maybe an example -- it's a procedure, you know, like a knee replacement which now can be done in the inpatient or outpatient setting. You would really worry about that case reduction. But here we're talking about routine diagnostic or screening colonoscopies. So you would not admit a patient for that normally.

And so we never - you guys are great - but like things that we should have probably more thoroughly pressed. But they - you know, I think that line is -- it's probably from my years as a measure development -- some of these things are cleaner than others. This is one that we didn't worry about. Not because it would never matter, but because it would probably rarely matter that the intended target population would somehow be - you know, we worry that providers would push their patients to inpatient to avoid this measure. This is just not a procedure you admit for unless there's a lot of other things going on. But, you know, there are a lot of clinicians on the phone, so I welcome - my experience, you know, my experience and my knowledge about this isn't infinite. So I might be missing something here.

Tony Grigonis: This is Tony again. I have sort of a research question -- it may or may not be relevant -- but did you get a chance to examine the rates of some of those patients that are in the exclusion category? Like when you're doing research it's often an empirical question about choosing to, you know, eliminate a certain acuity of patients in your model. But it would be I think important to see whether or not there's an empirical evidence for having done that. And on the reverse side, could there be some important information that could be found if some of those patients that were excluded could be examined in more detail?

Woman 1: We did look at that. And I don't - I actually off the top of my head don't know how much of that - the analysis of the excluded population is in the (unintelligible) application. My colleagues, you know, might be able to pull that up while I'm answering your question. But yes, the way that we approach it is we're thinking about a - we usually want to be as inclusive as possible in this population. So we only go to exclusions if we think we can't fairly assess quality if we include the patient group.

So an example here is patients with colonoscopy and a history of diverticulitis or diagnosis of diverticulitis at the time of the procedure. The way we approach thinking about that exclusion is we looked at their rates of the outcomes. We looked at their reasons for return. We consulted with our technological panel and we also had a working group of gastroenterologists.

And we, you know, say, "Do you think we can risk adjust to this and keep them in the group?" And if we really don't think we can, we don't have enough refined clinical information and we're going to bias the measure against people who have - more patients with this - diverticulitis or facilities that treat more patients with diverticulitis, then we end up - our only solution to avoid the bias is to exclude them. But yes, we do look at that and we're happy to share it with the committee if you'd like the results of that kind of analysis.

Tony Grigonis: Thank you.

Cristie Travis: Okay. Well, thank you all for comments on our important measure in report criteria. Let's move on to the discussion for scientific acceptability. And as Erin indicated at the beginning, this has gone to the scientific methods panel. They were not able to reach a consensus on reliability, so we will have a full discussion of reliability. And so we will do that. They did find validity was

moderate and are recommending that. But as Erin pointed out, it was not within their task to think about the social risk adjustment.

So after we do reliability we'll talk a little bit about validity and whether or not we want to accept the scientific method panel's recommendation or go into additional discussion, especially around social risk factors. So I will ask Tony if you would like to give us some of your feedback on reliability. We'll start with reliability.

Tony Grigonis: Sure. Thank you. I think for clarification, the issue of the reliability had a lot to do with what was under evaluation. And I guess from what I heard in the introduction, are we still evaluating the one year or are we able to evaluate their three year - at the three year projections in their data and they also have a three year actual result. And I think that that makes a big difference.

Cristie Travis: Yes, Erin, can you kind of give us from the NQS perspective what we are focused on. Because I think that will drive the rest of the discussion.

Erin O'Rourke: Sure. So if you take a look at your preliminary analysis -- as (Elizabeth) was saying -- there is a little bit of a timing challenge with what was submitted on the initial NQS testing attachments and the measure specifications. And you'll see that specifications note one year and Yale submitted data based on a three year time period. At first they used simulated (unintelligible) testing. Just came up during the scientific method panel call that there was a little bit of confusion about the specifications of the measure and the testing that they submitted.

The measure -- and (Elizabeth), please correct me if I'm getting any of this wrong on the technical aspect -- the measure was originally implemented and developed for a one year time period but CNS has gone -- through the rule



making process -- moved to a three year period. Yale submitted data for both to I think support that it was reliable if he did the one or three year time period. That did cause a little bit of confusion at the scientific methods panel. And I believe through the rule making process the plan is that the measure will be implemented with the three year time period. Yale originally submitted the simulated testing data with - for the three years.

And in the document you have has submitted some supplementary data that was omitted from the original attachment - or the original testing attachment that the scientific method panel did not have that shows the actual data. And I believe the results were very close to each other. So I think -- again -- this is one of the grey areas where to the committee on what you would like to accept and what you believe is reliable. But that is where some of the confusion and why the methods panel struggled with this one to three year issue. Maybe I should see if (Elizabeth) has anything from the developer's perspective or if I misspoke to anything.

(Elizabeth): Erin, that was perfect. That was what happened. The measure was in transition. And it is final (unintelligible) mentioned for January reporting going forward with three years of data. So we apologize for contributing to the confusion. But yes, the measure was submitted in (unintelligible) as a one year measure but then that was prior to DNS moving its policy forward and then it's doing consideration and finalized. So we wanted you to see the full scope of data and then happy to answer questions about it.

Cristie Travis: Erin, this is Cristie Travis. Just kind of a clarification issue for me. The specifications are still -- I assume -- written at a one year. Is there anything -- and maybe this is for (Elizabeth) -- is there anything - I mean, is there a plan to change the specifications for a three year and/or is that just literally

changing the one to a three? Or is there implication elsewhere in the specifications to moving to a three year time period?

Erin O'Rourke: It doesn't change anything else. I have my team on the phone - and (Craig), jump in. But no, it's just the number of years. It allows us to - because there are more cases per facility, we can get - show greater variation and have more reliable estimates. So that's (unintelligible) that direction. And I don't - there isn't any going back. So it - I think that, you know, we couldn't just mid-process from the NTRS staff point of view kind of flip that switch. But going forward, you know, finalizing we're making it will be two years of data. Still going to change like the - we - the risk variables are the risk variables. You know, we estimate them using the data set that we have. We don't see any -- I don't know -- changes in the measure. We use two years of data, we just get better ability to identify quality differences. And report scores. Because we set a minimum sample size for reporting. And so many more facilities come over that score.

Cristie Travis: Thank you. So Erin, to turn these point in question, are we looking at then the three - this as a three year measure?

Erin O'Rourke: I think - and perhaps we can go through and make sure that we work with the Yale team to clean up the specifications. (Elizabeth), correct me if I'm wrong. I think your desire would be to have this endorsed as a three year measure. And we can remove any instance of the one to a three and that was Yale's intention by submitting the three year testing was to move this to a three year measure to align everything with how this is implemented.

(Elizabeth): Yes, I think Cristie Travis that that's the best outcome.

]

(Leslie Kellyhall): Can I - may I ask a question about that? There - is this three year -- this is (Leslie) -- is there material changes in care that would impact this? For instance now that there's some new findings in people's testing and self - patient self-testing that in the past might have required a colonoscopy and today doesn't. Does a three year window accommodate changes in care assumptions?

Erin O'Rourke: That's such a great question. I don't think so, because - so what - that's the uptake of other modalities for colorectal cancer screening with potentially lower the volume of patients in this measure. I think that's more of a reason to be using three years. Going to the phenomenon we were talking about earlier, it might shift - I don't know whether it would shift to lower risk population or high risk populations out or, you know, specific regions like may have shifts and others not or (unintelligible) specific (unintelligible). That's something we can look at over time. But fundamentally I don't think so, because I think the vast majority of, you know, Americans who are eligible and have a recommended colonoscopy are still going to get one. So for now (unintelligible)...

(Leslie Kellyhall): I guess I would just advocate that as we consider one year or three year measures in the past that part of the due diligence includes any sort of rate of change for assumptive - assumptions around the future standards of care.

Erin O'Rourke: The difference here - I don't know. As an outcome measure, we are looking at an outcome that is relevant regardless of how those testing protocols evolve. So if we do have a colonoscopy this is still going to be an important outcome. I don't think it's going to perturb the risk factors that we are, you know - we have to reconsider the risk factors anyway every two years. And we estimate - CMS re-estimates it every year. When they fit the model, they estimate the data coefficients or the odds ratio for the - for each respecter. So if things are

shifting steadily in the - like the - because the population is shifting, that shouldn't be a problem over time. But I do think who is in the measure and who's not will shift over time, but the measure should still work well on the population that's in there across the three years that we're pulling people in. But you're raising the right question and I - we haven't thought about it. We can think more about it. But for an outcome measure, you know, where we're really looking about essentially complications of care I don't think it's an issue. It's not a guidelines based measure.

(Leslie Kellyhall): Thank you.

Cristie Travis: All right, Tony, did you have any other comments that you kind of wanted to make now that we I think are working under the assumption that we're looking at this as a three year measure?

Tony Grigonis: I just would comment that the C statistic for the actual three year reliability test were well within the range of acceptability; .75 for the hospital outpatient divisions and .87 for the ambulatory surgical centers. I did sort of want to bring up a quick point that we may get into when we talk about disparities and that is when you looked at the three year, did you notice any difference in the distribution of sociodemographic patients in the risk adjustment model? And I think you can hold that for the next discussion. But I'd wanted to get that out.

Cristie Travis: Okay, thank you. (Keith), did you have anything in addition to what Tony has pointed out that you would like to draw our attention to?

(Keith Lind): Well, I was looking at the staff summary -- the first 20 pages -- and I - the only thing I saw about three years of data was a calculated measure. I didn't see the - and maybe the staff - I'm so glad we don't have to vote on this at the

moment, because maybe the staff could point me to where the three year statistics are - the actual data - statistics from the actual three years of data are and I could take a look at that after the call. It's just -- for me -- not being a statistician, looking at a measure of - it says its projected based on multiplying one year data to make it three years. Of course the reliability goes up, but to me that was not a very meaningful or credible measure. And I just did not see the actual three year data. So that was a big stumbling block for me.

Man: (Keith), I agree with you, but they did -- and I don't know exactly where it was -- but they did cite the calculated three year reliability from...

(Keith Lind): Well, when it says calculated, that's what I understood to be where they took one year and multiplied it by three.

Man: No, those were different results, actually.

(Keith Lind): Okay, I guess I didn't...

Erin O'Rourke: Well, we presented both. And again, I'm sorry that's - because (unintelligible). But we have the actual data; they were published in CMS' proposed rule about moving to three years of data.

(Keith Lind): I mean, I'm looking at the summary on page seven, and to estimate the median facility reliability for three year performance period, we multiplied the median case count by three. So I'm like, "That doesn't - to me that doesn't really do the job." But if you can point me to where the actual data is - if it's really that close to what the multiplied or whatever you call it -- calculated -- then there's the results using projections from 2017 data were .814 for outpatient and .893. So maybe that's the three year measure? But I thought that was...

Erin O'Rourke: That's the projected. But I can give you the actual. I don't know if it's an end cap summary, but I can get you the inter-application, but it might not be clear. So the actual three year combined data reliability - (unintelligible) reliability was 0.75 and that was for HOPDs. And for (unintelligible) surgery centers, it was 0.87. And again, I apologize (unintelligible)...

((Crosstalk))

Man: Yes, I think that...

(Keith Lind): That's what I said, yes. Yes, that may be what you said. I just didn't find that. And not being like - for me I'm not sure whether the one year data -- what they showed is .59 -- whether that's good enough or not. I was going to defer to the scientific panel. But if the three year data is in a range that other, more sophisticated people deem reliable, then I'm fine with that. I just didn't feel comfortable with just multiplying the one year by three.

((Crosstalk))

(Elizabeth): Yes, it's on page seven.

(Keith Lind): Oh, yes, I see that. I see that.

Cristie Travis: Is the (unintelligible) 2539ta\_4committee. Now, I will have to say there were lots of documents floating out here. And I think it - to me it was too confusing as to which ones we should be focused on for today. I kind of did some comparisons and figured out this one was the one I felt most comfortable with. But that's something, Erin, I can kind of share some, you know, sometime offline with you about. But...

Erin O'Rourke: Yes, thank you. I...

(Keith Lind): Yes, I see that now, Cristie Travis. I just didn't understand that that was actual data. Because the sentence preceding that says the signal to (unintelligible) reliability for three years were calculated, not projected. Period. And then it goes, based on data from 2011 to 2014. And I, you know, that just flew past me. So sorry for that.

Cristie Travis: That's okay. I found it confusing.

Erin O'Rourke: This is Erin. I do want to apologize for the confusion. And the actual data based on three years should be in your preliminary analysis. And unfortunately that's the only part of - place where it is in the NQS materials. We asked the developers to submit the testing attachment back in January. And then when this issue came up with the message panel about the confusion of the time period and -- to (Keith's) point -- about the actual versus projected data, that kind of introduced some of the confusion.

So we shared the actual data that Yale shared with us that was in the role that (Elizabeth) was referencing. But that is not anywhere else in the NQS testing attachment. So I do apologize for some of the confusion around the different reliability testing results.

(Keith Lind): Well, thanks for that. I think that addresses my main concern on reliability measure.

Cristie Travis: Well, thank you, (Keith). Are there any comments from others on the committee around reliability? Okay. Well, let's move to validity. And Tony, I'll ask you to maybe share any comments that you would like to around the validity.

Tony Grigonis: Sure. As was noted before, there are no similar competing measures to sort of address validity. And so they continued to rely on the face validity testing that they had as a result of the tech panel. And the only issue that seems to raise -- at least, from my perspective -- the way they report the results from the tech panel is somewhat high. Validity has to do with how the tech members responded to the question about. And that is they included all the responses, somewhat, moderate, or strongly in agreement with a statement that the rates can be used to distinguish between better and worse quality facilities.

And it's just -- in my opinion -- the inclusion of somewhat is questionable, but it would be nice to see where the portion of responses were for each of those response - specific responses. When we're looking at surveys it's easy to just lump everything together and say 12 of the 14 members responded positively. So there are two issues; one is there are no other available external validation metrics to use. And the issue concerning is the tech panel response considered strong enough to continue the validity - moderate level of validity.

Cristie Travis: (Elizabeth), is there - is there a way for us to know those - the percentage that were moderate plus strong without the somewhat in there?

(Elizabeth): We tried to (work with those) a while ago and we weren't able - but we can look again and see if we can find that breakdown documented somewhere. It was six options. So somewhat, moderately, strongly agreed or somewhat, moderately, strongly disagree. So - but we can look for them again. But we weren't able to put our hands on them. I have my staff on the phone. We are happy to share them. We can look again. But I apologize. We - going forward we'll make sure we have the specific responses.



Cristie Travis: Okay, thank you. Tony, any other comments around validity?

Tony Grigonis: Do we bring up the dual eligible status risk adjustment here?

Cristie Travis: Yes.

Tony Grigonis: Okay. Well, I think that's still on the table. As you said earlier, there was an effect of dual eligibility, but it did not add to the -- let's say -- the test of the reliability of the model. And my question was did that change in the three year analysis? But as far as the differences in hospital visit rates between dual eligible and non-dual eligible, it's 2 to 3%. It looks like. So it's a relatively small proportion. I was just curious if there was an effect after the three year testing.

Cristie Travis: (Elizabeth), any feedback on that?

(Elizabeth): Yes. (Craig), do you know the answer to that?

(Craig): I mean, we're doing a lot of work on this now and I can say that the results are relatively consistent. But unfortunately I think because of the work being done under contract with CMS under the impact (unintelligible) you can't share these (unintelligible) results.

(Elizabeth): We can check with CMS after this call and see what we can share with you.

Cristie Travis: Okay. (Keith) (unintelligible)...

Man: (Unintelligible) issue, isn't it? That could affect the model.

Erin O'Rourke: Yes, we're not worried about the model. But we're doing a lot of - the impact deck -- as you know -- is, you know, specifically addresses sort of the risk factors and quality measurements. So we're doing - we just happen to be doing a lot of work on this measure right now under that. But as with other work under contract with CMS, we can't share it without their permission. It hasn't been - it's not even done. We're wrapping up in the next couple weeks. But it just - according to the committee. We can check with them and see if we can share - we're not in any way worried about it affecting the model. It's just the - you know, if you want to see the results, we'll share them.

(Craig): Right. And, you know, I'll just say with other measures that - I mean, the results we see are very consistent in terms of whether or not including dual eligibility into the model affects the final measure scores. We generally always see extremely high correlations around .99. And so I would find it very difficult to believe that three years of data would change that result to a meaningful degree.

Tony Grigonis: Thank you.

Erin O'Rourke: And I just want to - I'm sorry. I just want to add that, you know, the - I would say that - I agree. I'm sympathetic with the point made earlier that that isn't really the defining result in terms of deciding whether to include a risk adjustor in the model - a special risk factor as a risk adjustor in the model or not. I think over time we have a much richer consideration of these factors and how to illuminate the affect that they're having or not and what the trade-offs are in terms of potentially masking disparities versus, you know, decreasing the risk of unintended consequences or the concern that provider is going to have that caring for a specific economic patients would hurt their measure score.

We try to now put the data out across a number of different kinds of tests and again it's DMS' decision about what to do. But I would say that's one of the factors not really important in their decision making at this point. They're really looking at a richer range of data.

Cristie Travis: (Keith), any thoughts around validity?

(Keith Lind): Yes, so I guess it would be helpful if developers could address why at least a couple of the reviewers suggested that an external measure was available in the seven day hospital visits after general surgery procedures performed at an ASC - why that wouldn't have been a good candidate for empirical testing. Since it's under the NQS guidelines, my understanding is the maintenance measure is supposed to demonstrate empirical validity.

Erin O'Rourke: Are you saying why did we not compare the hospital ratings on that measure to the ratings on the colonoscopy measure?

(Keith Lind): Right. A couple of reviewers suggested that that would be an appropriate measure. There may be others that I don't know if. That just jumped out at me since NQS does say maintenance measures are supposed to be empirically tested.

(Elizabeth): I actually - I cannot remember why we didn't look at that. From my team, is there a - and that would not be hard to do. But I expect there - we have to sort of (unintelligible) say, "What would you do with the results and what correlation would be reassuring?" And I think one of the things we're struggling with in the - those kinds of comparisons about some measures is we're not sure what we would - we could run the - we could easily run the correlation. So what would we be looking for that would make us think, "Okay, yes, these are, you know, both valid?"

The domain - the cohort is completely different. There's no overlap in the cohort. So you would be saying it's a similar outcome. I would expect there would be some relationship because probably the facility or hospitals have (unintelligible) hospital because it's a hospital based measure have similar approaches to discharge planning and, you know, follow up care and what consultations patients have available to them in the hours and days following the procedure and in their pre-procedure and post-procedure instructions (unintelligible) all those things that might (unintelligible).

So I think there could be some correlations. And we can run it. I don't know what the magic number would be, but I - my team can jump in if they think I'm wrong here. But that would be easy for us to run if you wanted to see it.

(Keith Lind): I don't know if there's a magic number, but it just seems like the way you're describing it there's no - it would be difficult to find a circumstance under which an external - another external measure could be trusted against. I mean, it seems like we're - if you look at, you know, hospital visits after outpatient surgery, there ought to be - the rankings ought to be similar, you know, for ASCs - for colonoscopy and general surgery. Yes, the cohort, the patient cohorts may be much different. But if there's a facility affect, you'd think there would be some relation - I mean, if the rankings get totally inverted or have no relationship, then okay, maybe it's not a good testing - measure to test against. But I would think there'd be some way to try to get a sense.

(Elizabeth): (Unintelligible)...

(George): Hi, this is (George) from Yale. If I could just chime in a little bit, because I was part of some of these discussion about how to approach this. So for ASCs, ASCs specialize and so one of the issues is you would -- at least with

ASCs -- have difficulty in the overlap. So you would have a group of ASCs that specialize in gastroenterology and then the general surgery measure is much broader and would also, you know, look at probably a different group of specialties in terms of the ASC. So the overlap in facilities is probably difficult for that and you wouldn't necessarily see a specific - facility specific affect there, at least for ASCs.

And for HOPDs -- while they're not typically single specialty -- we believe they're unlikely to share the same procedural suites or providers that are captured by the measure. And so again, we felt it was not a really reasonable approach.

And actually we resubmitted the measure back to the scientific methods panel with this argument, because in the prior submission the scientific methods panel, you know, did not vote the measure - pass the measure on validity for this reason. But when we resubmitted our argument here to explain why we did - approached it this way, the scientific methods panel accepted it as, you know, a reasonable - a reasonable approach to why we didn't do it this way.

So we wanted to first -- as (Elizabeth) was saying -- hypothesize why we would or not see a relationship before doing these kind of analysis. And so that's our - that was our approach.

(Keith Lind): Thanks, that's helpful. I appreciate having that additional information. I would just mention on the duals, I guess, I'm not as convinced as Tony that the - I mean, at least one of the -- maybe more -- of the viewers said the duals affect the significant and consistent across facilities that suggest that - has something to do with the risk profile of the patient, not simply bad care. So if you're not going to adjust for dual status because it's too crude or might be confounding, I mean, that reviewer suggested using other markers such as

frailty, functionality, or behavioral difference problems. It just seems like if you don't - if there's consistent differences based on dual status and you don't want to use that, maybe there are other things that explain it. But probably want to explore that. I don't know. Maybe you could address that.

(Elizabeth): Well, I'm not sure at this stage, I guess, I get (unintelligible) staff - Erin. How, you know, - as I mention, we're actively working on some of those explorations as part of our follow on work. But at this point I'm not sure that - I don't know, how do you suggest we proceed, Erin? Because we submitted the analysis that we, you know, were able to do at the time. And I don't - I just - I'm not sure if - what do you think makes the most sense, Erin? To be both responsive to the committee and then, you know, just acknowledging where we are in the process.

Erin O'Rourke: Sure, that's a great question. And I think at this point the committee should look at what was submitted and determine whether you think the lack of adjustment for dual status is a threat to the validity of this measure. And if the measure is not adequately adjusted, you know, we'd ask that you evaluate what's in front of you. And the dual question is certainly fair and certainly something that's in the scope of what the committee's allowed to look at. I think at this point we probably can't go back and ask for additional analysis. I think we'd have to just direct you to what you have and ask you to use your expertise and your judgement to make a call on whether you agree or not if this is a valid measure.

(Keith Lind): Okay, thanks.

(Craig): This is (Craig) (unintelligible). Yes, I just want to mention something about the respond that we do have. The current model does adjust for psychiatric disorders and drug and alcohol abuse and dependence. And just in general our approach to social risk adjustment is to first push for the clinical factors that

are most important for the outcomes. And that helps, you know, attenuate a lot of the arguments that (unintelligible) patients are sticker. And so we begin with generally a list of tentative variables that are in the range of 50 to 60 tentative variables. And in this particular case we ended up with 15 risk adjustors in the model. And of which included at least one more frailty related variable and - as well as psychiatric disorders and drug and alcohol abuse and dependence variables that are in the model.

Cristie Travis: So I know that we're running over. Erin, should we - what is your guidance? I know we probably would like to have - there may be other committee members that would like to discuss this dual eligible and validity criteria. What are your thoughts about what we should do? I don't know if people can stay on the line for a little bit longer or...?

Erin O'Rourke: Sure. I was wondering -- since we're already seven past and we do have the call tomorrow -- would it make sense if maybe we finish up validity tomorrow so that in case anyone had a hard stop, they can be part of the conversation and, you know, that we're not putting on - putting anyone out by running over? So we could finish up any maybe remaining thoughts on the social risk issues or validity and then we can briefly do feasibility use and usability on 2539 tomorrow and then transition to 3495. But perhaps if there's any comments from anyone who can't join us tomorrow, we should let them make them now so that we've got them on the record.

Cristie Travis: That's a good idea. So is there anybody on the line today that will not be on the call tomorrow that would like to either ask a question or make a comment about validity? Okay. Well, then I support moving forward with (Erin's) recommendation that we'll finish up validity and then to feasibility and use and usability tomorrow on this measure and then move on to our next measure. I'm going to thank the developers for being here and answering our

questions. And all of the committee members for your active participation.  
And any other comments, Erin, before we close for today?

Erin O'Rourke: Sure. And this might be going back a bit. If you just want to check in, I think (Wes) might have been having trouble making an earlier comment that he made through the chat box. So I just wanted to see if he wanted to stake that on the record or if he's okay with having submitted it through the chat.

(Wes): No, that just (unintelligible) trying to be a good citizen (unintelligible) word count I'd do it as a chat comment and I'll leave it as it is.

Erin O'Rourke: Great, thank you. Did just want to direct everyone if you want to scroll through the chats and read (Wes)'s comments. But otherwise, I think we will see everyone virtually tomorrow to continue this conversation and to discussion 3495.

Cristie Travis: All right, thank you everybody. Bye.

Group: Thank you.

(Leslie Kellyhall): Bye.

END