NATIONAL QUALITY FORUM

June 17, 2019

Missy Danforth: Hi, this is Missy Danforth.

Benita Kornegay Henry: Good morning, Missy. Thank you for all that have already joined. We are assembling here in the conference room. And I just want to remind everyone while we are logging in, to make sure that committee members are logged in to (poll everywhere), as well as Century Link so that you can view the presentation. And we'd like to remind you to please mute your lines and your computers when you're not speaking. Thank you and we'll be ready to start in just a few.

Sure. So, to the standing committee members, I sent an email freshly this morning around 7:30 with the link to login to the Web Plus one if you choose to. The meeting materials, as well as the link for the poll everywhere. So, if you want to go ahead and login just to make sure you don't have any technical issues, you can go ahead and do so now.

Missy Danforth: This is Missy…

Man: Do we have to take the test? Do we have to take the test?

Benita Kornegay Henry: Yes, we will have a test.

Man: I see it. I already took it.

Benita Kornegay Henry: Just as a quick (pulse) check. Is everyone logged in? Is anyone having any issues logging in?

Woman: No, I'm on the Slide and it's just loading (quiz).

Ed: Everything seems to be working.

Benita Kornegay Henry: Okay, perfect. Yes. For those in the room, the login is Guest and the Password is nqfguest. I'll put that up on the screen. Yes, it's up on the screen now. No. Okay. Okay, we'll get you some help, some assistance.

And for those who are having issues or want to make sure that you're logged into poll everywhere, as long as you're able to see the test vote, that should be live, then you'll know that you are in the right place. So, I'll grab someone to help you get logged into the Internet.

Yes, yes, I believe so. Jesse when they log into poll everywhere, should they be seeing a test question? No worries. Okay. So. To view the Web Platform, everyone should be connected to Century Link and that will allow you to view the Slides that we're actually going to go through in the center monitors of the room.

Now to do poll everywhere, we'll need that link to vote. And so, in poll everywhere, if you're logged into the right place, you will see the test vote and that will take you - it should take you directly in there. We do have someone from our IT Department who's going to come in and assist those who are having technical issues in the room. But I believe we're going to go ahead and get started so that we can begin our agenda and not run out of time. Okay? Thank you.

Okay. Good morning everyone, to the Patient Safety in Person Meeting for the spring 2019 cycle. We are so happy to see a lot of faces in the room. I am

going to go ahead and just pass it to your cochairs, Ed and Iona to say their hellos and welcome.

Iona Thraen: Hey Ed.

Ed Septimus: Iona, why don't you go first, Iona.

Iona Thraen: Knowing what your - about your travel experience.

Ed Septimus: We'll do that at the break. We want to keep going very quickly. I'll welcome everybody. (Ted), I'm sorry I'm not there with you, but my flight from Houston got canceled after considerable delays because of weather. We've got a great group of measures to go over. We have three measures from the CDC, as all of you can see. We have some nursing measures. We have some opioid related measures. Hypoglycemia. So, we really have a great diversity of measures.

One thing I will show you on the agenda. Before we do the CAUTI - and many of your will remember that there were some concerns from our spine folks about the measure as it relates to them. We are going to have a short five-or-ten-minute public comment section for them at 10:00. And then we're going to take a break and then we're going to consider the CAUTI measures at 10:30.

A little bit slightly out-of-line, but we felt it was an important enough subject that we do the public comment for CAUTI before we have the discussion for CAUTI. So, we really look forward to a very productive day and congratulations to Iona, who not only is a great cochair, but she has a new position that she may want to tell the committee about.

Iona Thraen. Thanks Ed. Welcome everybody. I have left the Department of Health - Utah Department of Health after 22-years and have joined the University of Utah Hospital and Health Systems as the New Patient Safety Director over the hospital and clinics. So, I get an opportunity to apply everything that I've been learning over the last umpteen years in that environment. And I'm pretty much overwhelmed. I've been there a whole two weeks and I'm trying to keep my mouth shut. So, with that, we'll just say welcome to everybody. Glad to see everybody today.

Andrew: Yes, thanks - from us at NQF, as well. Really great to see everybody in person. Thanks for being able to make it out and thanks to the folks on the phone for joining us. For those in the room, hopefully you've been able to find the rest rooms and get on the Internet. Sounds like we're all set with that.

Just to quickly introduce ourselves. I'm Andrew, Senior Director. We have Nicolette, Jesse Pines here. And (Jiro) and (Dezmira). I don't know if you guys want to introduce yourself. We can just kind of go on. We've got a pretty full agenda, so I won't take up too much time. Oh, and Elisa Munthali, our Senior Vice President. And she's actually going to go through our disclosures. We'll combine that with the introductions. So, I'll just turn it over. Again, a packed agenda, so we'll get into it.

Elisa Manthali: Good morning and welcome everyone. On behalf of NQF, my name is Elisa Manthali and I'm the Senior Vice President for Quality Measurement. I've been here for about 10 years at NQF and this (Patient) Safety Committee is probably one of our first standing committees and so we really appreciate all of the time and commitment you put into the work here.

And so, as (Andrew) mentioned, we're going to combine introductions with our Disclosures of Interest. And when you were named to the committee, you

probably remembered a pretty length Disclosure of Interest Packet that we asked you to fill out. We don't want you to tell us everything you put on that form, but only information that's relevant to the work that's in front of you for the measures that you're reviewing.

Just a couple of reminders, as we go through. You are on this committee as an individual. You do not represent the interest of anyone who may have nominated you for the committee or your employer. And I think what's most important is just because you disclose does not mean that you have a conflict of interest. We go through this process in the interest of transparency and openness.

And the final reminder is we're interested in, not just those activities as they're related to the work that you'd be doing today that are paid, but also those that are unpaid. So, what we will do is start with, I think, Iona, in the room and then Ed. And then we'll go around the table clockwise to my left. And then I know we have a few other committee members that are on the phone and I'll call on you. So, Iona, if you can let us know who you're with again. Let us know if you have anything to disclose.

Iona Thraen: Iona Thraen. Patient Safety Director for the University of Utah Health and Clinics. And I have no conflicts of interest today.

Elisa Manthali: Thank you very much. Ed.

Ed Septimus: Good morning. I am the Department of Population Medicine Harvard Medical School and the Department of Internal Medicine at Texas A&M College of Medicine. So, I have to say howdy to everybody. I have no conflicts.

Elisa Manthali: Thank you Ed. Jason.

Jason Adelman: Good morning. I'm the Chief Patient Safety Officer at (unintelligible) and Columbia Medical University Medical Center and I have no conflicts.

Elisa Manthali: Thank you.

Steve Lawless: I'm Dr. Steve Lawless. I'm the Chief Clinical Officer for the Nemours Pediatric Healthcare System and I have no conflicts.

Elisa Manthali: Thank you, Steve.

Theresa Edelstein: Good morning. Theresa Edelstein, Vice President Post-Acute Care Policy at the New Jersey Hospital Association. I have nothing to disclose.

Elisa Manthali: Thank you.

Pat Quigley: I'm Pat Quigley, good morning. I'm a Nurse Consultant, former Associate Chief of Nursing Research at the Campus VA, the Patient Safety Center, Nurse Scientist. And I have nothing to disclose and no conflict of interest.

Elisa Manthali: Thank you.

Lillee Gelinas: Good morning everyone. I'm Lillee Gelinas. I'm Senior Fellow and Nurse Executive at the University of North Texas Health Science Center in Fort Worth. I made it, although there was a five-hour delay. So, I feel Ed and Charlotte's pain. I have no conflict of interest. I do want to disclose that I was the original cochair to the NQF Nursing Sensitive Measures Committee in 2004; however, I am not a Measure Developer and did not influence any of the backgrounds in those particular measures. Thank you.

(YonLing Geum) Good morning, I'm (YonLing Geum) with the Washington Advocate for Patient Safety and Patient Advocate. And I have no conflict of interest to disclose.

Elisa Manthali: Thank you.

Tracy Wang: Hi, good morning. I'm Tracy Wang, Clinical Programs Director and Clinical Strategy for Anthem. And I have no disclosures.

John James: Good morning. I'm John James, retired from NASA, where I was Chief Toxicologist. I have no conflicts of interest.

Elisa Manthali: Thank you.

David Stockwell: Good morning. I'm David Stockwell - excuse me. I'm a Pediatric Intensivist by background. I practiced at Johns Hopkins. I'm also the Chief Medical Officer of Pascal Metrics, a patient safety organization. That organization helps to collect data on the E-measures that are being disclosed today. Although I did not participate in that, I feel like directing (video) is a step away from those measures.

Elisa Manthali: Thank you.

Lisa McGiffert: I'm Lisa McGiffert and I am a Patient Safety Activist with the Patient Safety Action Network, National Coalition. And I'm retired from Consumer Reports Safe Patient Project and I have nothing to disclose.

Curtis Collins: Hi, good morning. I'm Curtis Collins. I'm a Clinical Pharmacist in Infectious Diseases at St. Joseph Mercy Health System in the Ann Arbor, Michigan area. I have nothing to disclose.

Elisa Manthali: Thank you.

Chris Cook: Good morning. I'm Chris Cook. I'm head of the U.S. Medical Affairs for bioMerieux an In Vitro Diagnostics Company and I have nothing to disclose.

Elisa Manthali: Thank you.

Laura Ardizzone: My name is Laura Ardizzone. I'm the Director of Nurse Anesthesia Services at Memorial Sloan Kettering Cancer Center. I have nothing to disclose.

Elisa Manthali: Thank you.

Kendall Webb: I'm Kendall Webb. I'm the CMIO at University of Florida, Jacksonville. I have nothing to disclose.

Elisa Manthali: Thank you. So, on the phone, Charlotte Alexander, are you with us?

Charlotte Alexander: I am. This is Charlotte Alexander with Memorial Hermann. I'm the Medical Director in the Physician Organization and I have nothing to disclose.

Elisa Manthali: Thanks Charlotte. Missy?

Ed: My travel partner.

Missy Danforth: Missy Danforth. Vice President for Healthcare Ratings at the Leapfrog Group. And I have nothing to disclose.

Elisa Manthali: Thank you. And Leslie?

Leslie Schultz: Good morning, this is Leslie Schultz. I'm the Director of the Premier Safety Institute and I have nothing to disclose.

Elisa Manthali: Thank you very much. And I think I caught everyone on the line, but if not, if you can please let us know if you're with us and let us know your name and who you're with and if you have anything to disclose.

Don Yealy: Hi, it's Don Yealy. I'm Chair of Emergency Medicine at the University of Pittsburgh and UPMC, and Senior Medical Director. And I have no conflicts related to this work.

Elisa Manthali: Thank you very much. And before I turn the meeting over to my colleagues, I just wanted to remind you, if at any time, you realize you have a conflict, we want you to speak up. You can do so in real time. Or you can contact any one of us on the NQF Staff or your cochairs.

And likewise, if you believe that one of your colleagues is acting in a biased manner, we want you to speak up. So, thank you.

(Jiro): Okay. This is (Jiro) from NQF. So, I just wanted to recognize our expert reviewers for this project who have been participating via phone. I just wanted them to - to welcome them. I don't know if any of them are on. If you are, feel free to announce yourself.

Okay. And again, they do not vote on the measures today. However, they are always a part of our project and comments. So - all right, so the next portion of our agenda is a bit of an overview of the evaluation process. I think most

of you are experts at this by now, so I am going to go through this very quickly.

So, next Slide please. Some ground rules, since this is an In-Person meeting. As you all know by now, committee members were assigned as Lead Discussants and Discussants, and should have reviewed their measures beforehand at this point.

And then please base your evaluation and recommendations on the Measure Evaluation Criteria and Guidance. Please remain engaged in discussions without distractions. Also, it's very important to maintain quorum, so please stay in attendance of the meeting at all times, except for the scheduled breaks. If you do need to step away, just let us know via the Chat, for those who are online. Just to let us know that you had to step away for a second. But again, if possible, just stay online.

Please keep your comments concise and precise. And also, what's really helpful, especially for those who are calling in and listening, if you can just please announce your name before you make any comments throughout today. That is very helpful and also when we're looking at the transcripts, it helps us as well. So.

And again, finally, just please let's avoid dominating a discussion and always allow contribution, which I know all of you do very well. So, I'm not worried about that.

Next Slide, okay. All right. And then, again, this is just something that you know, as your role, it's to evaluate against each measure criteria. Make recommendations regarding endorsement to NQF and overseeing the portfolio of patient safety measures as a standing committee member.

All right. So, the process for measure discussion and voting, which again, this is a refresher for all of you. But what you can expect is, once we discuss a measure, there will be a brief introduction by the measure developer, about two to three minutes. There is a lead discussant assigned for every measure. So, they will begin the committee's discussion for each criterion, briefly explaining the information on the criterion provided by the developer.

Providing a summary of the premeeting evaluation comments, whether it be by the public or by your fellow committee members, emphasizing any areas of concerns or differences of opinion is very important. And then noting, if you need to, the preliminary ratings provided by the NQF Staff.

Developers will be In Person and online today. So, they have the opportunity to respond to any questions at the discretion of the committee. And then finally, the full committee will discuss and then vote on the criterion and then move onto the next criterion and discuss and vote again. All right.

Voting very briefly, will take place after the discussion of each criterion. And then those are your criterions which you are very familiar with at this point. There's the importance to measure and report, which discusses evidence in gap. We do not have any composite measures today, so we will not be voting on anything related to composites.

Importance is a must pass. The next criterion is Scientific Acceptability of the Measure of Properties, which is also on a must pass criterion. So, there will be voting on Reliability and Validity. Again, there are no composites so, we will not be addressing that. And then move onto Feasibility and then Use, which is also a must pass for maintenance measures. And then wrap it up with Usability and then a vote on Overall Endorsement.

Next Slide please. And then these Slides are just friendly reminders. Again, we go over this on our orientation meetings that we have every few months. But again, it's just laying out for you in a table format, you know, the emphasis for the criterion's new measures versus maintenance measures. We do have a mix of them today about 50/50, so we will see both of those.

But you can see right here, you know, for our Maintenance Measures, there is a higher emphasis on Performance Gap because they have been around. So, we should be able to see a little bit more of that.

Next Slide. Again, just some highlights on some of the criterions for new measures and maintenance measures, you know, again, with scientific acceptability that is looked at for both. Next Slide. All right. And again, I think the only thing I would point out in this last Slide is for use. There is an increased emphasis for Use for a Maintenance Measure.

All right. So, what we want to do today throughout the day, since we have so many measures, our goal is, ideally, that we will stay with quorum all day long. That is always a challenge, as you know, so we're crossing our fingers. But quorum will be 66% of the committee. If we do not have 66% of the committee voting and present, you know, we will continue discussing the measures, but voting would happen afterwards, if at some point we do lose quorum. Just so that you all know.

So, a passed or a recommended vote would be greater than 60% yes votes of the quorum. A consensus not reached would be a 40-60% yes vote of the quorum. And then a do not pass, not recommended would be less than 40% yes votes in the quorum.

For consensus not reached measures, they do move forward to the public and NQF member comment and the committee will revote at, most likely, the post comment meeting. So, it does not fail right there.

So, next Slide. Okay, so does anyone have any questions at this point, on the process, or voting, or quorum? Lillee?

Lillee Gelinas: What's the raw number in terms of the quorum? I understand 66%, but what's the committee membership number and then what's the number for quorum?

(Jiro): Very good question. Yes, so we have 23 committee members active on this cycle. So, our calculation is, for a majority of the measures, we would need 16 committee members voting. We do have a measure where there is - a couple of measures where there is a conflict of interest by a committee member. So, that would be a number of 15 to reach quorum.

Lillee Gelinas: Thank you.

(Jiro): Any other questions?

Man: Do we have quorum?

(Jiro): At this point, yes. And we will also make sure that nobody has any technical issues with the platform, so. All right. So, I am going to pass it to my colleague, (Dezmira) to go over voting very quickly with you guys.

(Dezmira): Thanks (Jiro). All right. Good morning everyone. So, just very briefly, you've been through this before. But just as a little refresher, I will go through reading each vote. And so, in order for committee members to vote, you have to be logged into poll everywhere.

And so, just as a test to make sure that everyone is actually logged into poll everywhere, we are going to go ahead and do a test vote. And so, I see that a lot of you have already logged into the system, which is awesome. So, what I'm going to do is clear these results and we'll test it just as if we were actually going to vote during the meeting.

So, I will read the voting question and I will read you your options. And I will unlock so that you can actually access the vote, and enter your vote, okay? So, for the yes

Iona Thraen: Poll everywhere is not (unintelligible).

(Dezmira): It's not.

Iona Thraen: So, (unintelligible) to change it (unintelligible).

(Dezmira): In your email it might have been.

Iona Thraen: So, I can just use an old email to get (in).

(Dezmira): Yes. If you use your old email, it should work.

Ed: Listen, whoever was speaking, you need to put your mic on.

(Dezmira): Thanks Ed. We're trying to get (assist) in the room situated, sorry. So, if there's a change in your job and your email has changed, then you might have an issue with logging in. But we're good to go now. So, I'm going to read the voting questions and your options and then you may actually enter your vote and I will read what the answers - what the results will be. Okay?

So, we'll say voting is now open. This is a test vote. Option A is yes and Option B is no. So, you may enter your votes for our test vote. Option A is yes and Option B is no. So, we'll make your question, do you have access to poll everywhere? Option A is yes and Option B is no.

So, it looks like, so far, we have 19 results here.

Iona Thraen: I'm still not (getting in).

(Dezmira): Okay. And again, I say we're looking for 20, so that's good to know. So, we look like we're doing pretty accurate now. Or pretty accurately calculating. And so, we will get Iona up and running. We'll have IT come in and assist her. But everyone else seems to be fine with that? All right.

I will actually read your results. We have 89% voted yes and 11% voted no. So, after that, I will lock the votes and we will move to the next question. So, does anyone else have any questions? Yes.

Charlotte Alexander: This is Charlotte. I have a question.

(Dezmira): Hi Charlotte.

Charlotte Alexander: So, when I - hi, how are you? If I go to my poll everywhere app it doesn't recognize me. If I go to the link through the email, I think you're seeing my vote. Did you get everyone's vote in this last time?

(Dezmira): Yes. We're looking for 20 votes and we have 19 votes counted now. But we know we're missing one in the room, so we should be good to go.

Charlotte Alexander: Okay. Good, thank you.

(Dezmira): Oh, you're welcome. Okay. Well if no one else has any questions, we will move forward.

(Jiro): Okay, this is (Jiro) again from NQF. So, this is just a couple of Slides, the measures we will be looking for - looking through today. I'm not going to read them, but you can see we have 11 measures for committee review. So, this is a very active cycle that we had this go around. So, and then if you also see, we did have a number of these measures reviewed by our Scientific Methods Panel for the Scientific Acceptability Criterion.

Next Slide. Okay. And just a few more measures. Next Slide. Okay. And then there were a couple of measures, and I think we mentioned this on a previous committee web meeting, but we did have a few measures that did not pass the Scientific Methods Panel Review for Scientific Acceptability, so they are not going to be reviewed today.

Okay. Well I am going to go ahead and pass it to your cochairs to get the discussion started. I believe Ed, I'm going to hand it off to you.

Ed: Yes, thanks so much folks. Again, I wish I could be with you. So, the first measure is going to be Measure 2726 from the American Society of Anesthesiologists. This is a Maintenance Measure for measuring of CVC related bloodstream infections. The Lead Discussant will be Charlotte. Charlotte will take three to five minutes to go over the measure. Then we'll open it up for discussion. Do we have the measure developer on the line?

Toni Kaye: Hi. Good morning, this is Toni Kaye from the American Society of Anesthesiologists. And I do want to check that our clinician has been able to join. Dr. Berry were you able to dial in?

Arnold Berry: Yes, I'm on the call.

Toni Kaye: Thank you.

Arnold Berry: Can you hear me?

Toni Kay: Yes.

Ed: Yes. Okay, Charlotte. Why don't you take us through this?

Charlotte Alexander: Absolutely. Can you hear me?

Ed: Yes.

Charlotte Alexander: So, this measure is a description of the percentage of patients who undergo CVC insertions for whom all elements of maximal sterile barrier technique, hand hygiene, skin preparation, and if ultrasound is used, sterile ultrasound techniques are followed. The level of analysis is the clinician, which can be group practice or individual.

It's a maintenance measure. It's also a process measure. Their original evidence showed 23 studies of high quality and consistency to support the efficacy of interventions in preventing infection. There was an update to the CVC Guidelines in 2017 recommending the use of chlorhexidine impregnated dressings.

There are two pre-imposed observation studies. One on nursing and one on residents, which showed that simulation training of sterile technique during either insertion or care of the catheters decreased the use of related infections. There ae no patient reported outcomes and evidence continues to support it. Do you want me to keep going or do you want me to stop, at this point?

Ed: Why don't you keep going and finish it. Well I'll tell you what, why don't we - let me ask you this Charlotte. One of the discussions we had three years ago was, what is the percent compliance with the measure? And whether there has been a change since the last review?

Charlotte Alexander: There has. So, that the decile six and above are all at 100%. So, there's been a significant improvement in compliance since we last reviewed it. There is still a standard deviation of about 15.75%. So, the average performance in 2016 was 93% and in 2018 was 97%.

Ed: So, I think the question as we look at the importance to the measure, is I think there's - if I understood you Charlotte - there certainly is evidence for following this bundle. But the question is, is there still a gap or has it topped out? Would that be a fair summary of that Charlotte?

Charlotte Alexander: I think that's a fair question to ask.

Ed: Okay. So, I know that (Richard), Leslie, Kendall, and Curtis were also assign this measure, but I think before we go to the importance to the measure, which as everybody knows, is a must pass - why don't we have some discussion from the committee? So, Iona, you're going to have to see who's in the room.

Iona Thraen: Thanks Ed. Any comments, so far? Go ahead, Lisa.

Lisa McGiffert: Is this being publicly reported anywhere?

Iona Thraen: I can't remember.

Toni Kaye: So, this is used in a Public Accountability Program, in the MIPS Program which was the successor to PQRS. I don't believe it's in Physician Compare - it's not been accepted by Physician Compare, at this point, in terms of true public reporting to the patient. But it is used in Accountability Programs and Registries.

Iona Thraen: Other questions or comments?

Leslie Schultz: This is Leslie. Just a clarifying question and this only pertains to the operators who are anesthesiologists, be they MDs or CRNAs, correct?

Toni Kaye: This measure can be used by anyone who inserts a Central Venous Catheter. So, for when - it's in our registry because our members are typically anesthesiologists, the data coming from NACOR reflects that. But in the larger MIPS Program, it's anyone who insert a Central Venous Catheter.

Iona Thraen: And would you like to introduce yourself?

Toni Kaye: Oh, sure. Hi. I'm Toni Kaye. I'm the Senior Quality Program Manager with the ASA. And so, I'm here to represent our - to measure and answer any questions that you have. I'm also joined by Matt Popovich.

Matt Popovich: Matt Popovich, Director of Quality and Regulatory Affairs for the ASA.

Iona Thraen: Thank you. Any other comments from the committee members?

Ed: Anybody on the phone?

Iona Thraen: Yes, Tracy has one, hold on.

Tracy Wang: It's Tracy. I was just wondering what is the goal for the measure? (Unintelligible) is pretty high, so it seems like the gap is pretty small for improvement. Is it ever possible to get 100%?

Iona Thraen: Everybody hear that question? She wants to know what the goal is for the measure? The performance gap seems to be pretty small and developer would like to respond.

Toni Thraen: The - part of that is what the committee, I guess, was going to decide on the gap. A couple of things I would point out. This measure does have a medical reason exception, which allows you to remove patients where use of all of those precautions is medically not appropriate, say, in an urgent case where it might cause a delay.

So, it could theoretically, performance could be 100% with that medical exception. Another consideration is that, especially in the MIPS Program, providers do select their own measures. So, there is that aspect of self-selecting the measures that you choose to report.

So, uptake of this measure has gone up. Over time, we find more people reporting it. But that is another consideration.

Ed: Any other comments?

Iona Thraen: Stephen?

Steve Lawless: Yes, hi. Steve Lawless. The question - I may have missed this. Have we seen or do you know the drop in within 48-hours or 72-hours of insertion of infections now? Central line infections versus later on?

Toni Kaye: That one, I can't speak to. We don't collect a lot of the outcome, the actual infection data. Although my CVC colleagues, I suspect, might be able to help.

Matt Popovich: I think the evidence is - because only the evidence is only - data is actually getting so low now, that it's more on a maintenance later on. But just (unintelligible), this is essentially already in place.

Iona Thraen: Lisa?

Lisa McGiffert: It probably would be good to hear - I'm trying to remember about CRBSI rates. They dropped significantly. When was this first…?

Toni Kaye: This was first endorsed by NQS back in 2015.

Lisa McGiffert: Okay. So, I guess it dropped before that. But I know there were a lot of programs to try to institute these practices and there was a drop, but I don't - I don't believe there's continued to be a significant drop each year.

Ed: Well, we'll talk about that when we come up to the CRBSI Measure, Lisa. So, I…

Woman: So, I think - I have a question, do we - does NQF have current criteria that - related to how (it felt) - when we're talking about maintenance, I guess a measure has stabilized out or topped out, how long should we be allowing that to occur before we declare that we've reached that point of stability? I mean

so, if the billing endorsed in 2015, we're talking about a three year - well almost 3.5-year process. Is that a long enough time to say that something is being maintained? Have we had any conversations about that?

Matt Popovich: We don't have any, sort of established guidelines around that or any real thresholds where say something's above a certain percentage of performance, it's, you know, officially topped out. All those things, I think, are within the committee's purview to sort of make a judgment call based on your expertise and experience.

Iona Thraen: Go ahead (YonLing).

(YonLing Geum): I just have a question (any of) the developer's rationale, you quoted in 2002 a survey that found only 28% of ICU were written policies require all five components, maximum (unintelligible) area and very similarly, in 2005, a survey shows physicians - shows only 28% will use all that. I wonder, do you have any update on the statistics and how much we're looking at now, that how much percentage of them using those (MSV)?

Toni Kaye: So, those were the surveys that we cited. Those were for when we first - when we first got those endorsed, because we didn't have the historical performance data to rely on. So, I would say that in lieu that now we have - that the measure's been in use, we would look to the performance data on the measure. But it's not a direct comparison, you know survey data to the performance that's reported to CMS, if that makes sense? But we don't have updated survey information to compare.

(YonLing Geum): It would be interesting to know how much (unintelligible) the measures and then how much percentage actually, you know, physicians (in the practice have been improved).

Iona Thraen: Chris?

Ed: Any other comments out there Iona?

Iona Thraen: Yes, Chris?

Chris Cook: So, one thing that's really nice is that we actually have an outcome measure that is associated with the CRBSI rate piece out of it. So, in many of these, that we're going to be talking about today, we have process measures to where there is no outcome you can actually measure.

Has there been correlation to (UC) alignment with the facilities that are reporting as doing well? With those having low rates, do we see places where they are, maybe in a lower decile? But then actually have a higher rate of CRBSI?

Toni Kaye: So, we've done a little bit of that correlation, but only at the national level showing - comparing the rates of the NHS and the CRBSI measure to the time period when this measure has been implemented and that we included that later in our testing from, I believe, 2013 through 2016 and we did find that it does appear that as performance on this measure has increased, the CRBSIs have continued to drop.

There was, in the middle of that, a certain change in the surveillance protocol for the CRBSI measure, which threw a little bit of a winkle in being able to statistically correlate them. But in their sort of narrative analysis, the CVC mentioned that they attribute a lot of that to improved insertion practices for central venous catheters.

So, we've done it at a national level, but we haven't been able to break it down into specific facilities or providers to get more granular.

Ed: So, this is Ed. We're trying to keep things moving, if it's okay. I think the question on this measure as I introduced and, please, if other people need to still comment, please do. The question is not so much on evidence. The question is whether or not there is still a gap. And that, I think, is what we need to decide as a committee.

Charlotte Alexander: So, Ed, this is Charlotte. I do have a question, because there may be a potential gap. They do have an age and gender breakdown. But the performance scores are not done by those patient characteristics. I'm wondering if there is an opportunity to understand some disparity?

Toni Kaye: That could be something we could potentially look at. We don't have the data available today, but that could be something that we can explore with continued use and collection of this measure.

Iona Thraen: Pat?

Pat Quigley: Thank you madam chair. This is Pat Quigley (unintelligible). And my response is in question of whether or not we have achieved the level of maintenance? And when this was endorsed in 2015 and as it progressed, the actual average rate of performance is really high. And even in 2018 and it's even higher at 97.08%. And my question as it would relate to the standard deviation then.

The standard deviation hasn't changed. And maybe when the standard deviation becomes less, then that would become an indicator of maintenance.

So, that isn't my response. Because there's little gap, but the standard deviations remain the same.

Iona Thraen: Thank you. So highly variable. Good point. Thank you. Any other comments?

Arnold Berry: Yes, can I jump in. This is Arnold Berry from the ASA, the clinician.

Iona Thraen: Sure.

Arnold Berry: So, I think it's important to understand, especially when you're talking about CRBSI rates, that the insertion done in this manner, with the full barrier precautions, is critical to the future of that line. And so, without this being done, what happens later becomes less important.

Or it still is important, but it - this is critical to the central line being placed in a sterile manner. And without this, you know, you're getting started in a bad way. So, it's also important to understand that the anesthesiologist or the other individual who places the line, has no control as to what happens to the line after they leave their care.

So, that individuals are responsible for changing the dressings in a specific way and make injections into the line and that may or may not be done appropriately. So, the system downstream is important as well. But without the appropriate placement of the line, those things become secondary.

Also, that leads to the idea that infection rate, as an outcome, is hard to correlate with this insertion because, especially if the line remains in for longer periods of time, there are more opportunities by others, not those who

placed the line, to contaminate the line. So, I think that becomes important in understanding the significance of this measure.

Iona Thraen: Any other comments?

Ed: Do we have any comments Iona? I would agree with that. It depends upon the studies you read and how long the line remains in. But maintenance of the line is also fairly critical as you pointed out. And so, it's more than just the insertion, but the insertion is important as well. We do better with insertion then we do on maintenance I might add.

So, if there's no other comments Iona, out there or on the phone, why don't we go to the voting then? So, let's go.

(Dezmira): Okay, I'm going to key up voting. I'm going to now open. I'm going to activate the vote so that you can read the first vote for the importance to measure and report, which were voting on the evidence. And this is a Measure 2726.

Is there anyone who cannot visualize the vote? Okay. I will open up the screens in the room. All right. We are now voting on the Evidence of Measure 2726, okay. I'll read your options. Option A is High. Option B is Moderate. Option C is Low and Option D is Insufficient. We are now voting. Voting is now open for the Evidence of Measure 2726. Option A is high. Option B is Moderate. Option C is Low and Option D is Insufficient.

We're looking for two more votes. Perfect. Voting is now closed for the Evidence of Measure 2726 and our results are as follows: Just once again. I see your votes are in. I'm just trying to pull up your results for the vote. Give me one second. All right. Thank you for your patience.

We have four individuals that voted for High. We have 16 individuals that voted Moderately. Zero individuals voted for Low and Zero individual voted for insufficient. So, this measure passes Evidence for Measure 2726.

Ed: Okay. Let's go to vote on the gap.

(Dezmira): Okay. Voting is now open for the Performance Gap of Measure 2726. Option A is High. Option B is Moderate. Option C is Low and Option D is Insufficient. You may now enter your votes for the Performance Gap of Measure 2726. Option A is High. Option B Moderate. Option C Low and Option D Insufficient.

Looking for one more vote. Okay. Is there anyone who has abstained from voting?

Man: (Unintelligible), I'm so sorry.

(Dezmira): Okay. No worries. It's okay. Okay. All right. All right. Voting is now closed for the Performance Gap of Measure 2726. One individual voted High. Twelve individuals voted Moderate. Seven individuals voted Low and 0 individuals voted Insufficient.

Ed: So, that was passed by my counts.

Iona Thraen: Mm-hm.

Matt Popovich: Can we get the percentages on it.

Dezmira): I'm going to show your percentages. I'll pull them up right now. All right. So, that's 5% for High, 60% for Moderate, 35% for Low, and 0% for Insufficient. Okay.

Ed: Okay. Excellent. So that means we'll go on to the Scientific (Set), Acceptability of the Measure, which is also a must pass. So, I'll turn it back to Charlotte.

Charlotte Alexander: Okay. So, we talked about the gap. Let me talk about the liability. The Numerator Statement, this is patients for whom Central Venous Catheter was inserted with all elements of maximal, sterile barrier technique, hand hygiene, skin preparation, if ultrasound is use, sterile ultrasound techniques followed. Maximal Barrier is defined as including cap, mask, sterile gowns, sterile gloves, sterile full body drape, and sterile ultrasound gel and probe covers if ultrasound is used.

The denominator statement, is all patients, regardless of age, who undergo a Central Venous Catheter insertion. There are no exclusions, but there is an exception, which is defined by 630S-1P for the Numerator. And its documentation of medical reason for not following all elements including a risk to the patient, that herein states septic technique would cause a delay in CVC insertion.

Data source is register data, reliability testing. There have been no changes in the reliability testing since 2015. This goal is consistently greater than .9. Empirical comparison of PQRS performance to CRBSI (unintelligible) for the same period, seem to be going in the same direction.

But the data sample was too small for a correlation analysis. The committee had comments on that. One was that it's unclear how many total lines are

placed. And the Capture is only self-reported. They cannot claim credit for all change in CRBSI (unintelligible) improvement. And there's a question about reliable data from a registry that is self-reported.

For validity, during the 2015 review, there was concern voiced about potential harm to infants with the recommended skin prep. There are now differences between deciles with decile 6 and above being at 100. And so, probably more meaningful differences between upper and lower deciles.

From the committee, it's valid only for only NBCRNA who place central lines and report to the registry. (How) representative of all central lines placed is this population? The way it is constructed, they claim no missing data. There is some concern with self-selection bias. Is it topping out? They would like to see sufficient sample size to calculate a correlation coefficient.

So, feasibility.

Iona Thraen: Charlotte, wait a minute.

Ed: Hold on Charlotte. Just for liability and validity, if we have to vote on that, those are must passes. So…

Charlotte Alexander: Okay.

Ed: Okay, are there any comments on reliability or validity from the committee?

Iona Thraen: This is Iona. I want to go back to the question of your sampling methodology. Are you sampling charts or are you actually observing participants? What's the methodology for that?

Ed: Do you want the developer to answer that Iona?

Iona Thraen: I'm sorry, what?

Ed: Do you want the developer to answer that?

Iona Thraen: Yes, yes.

Ed: Okay. Please developer.

Toni Kaye: So, this is a self-reported measure throughout a station from the individual practices and so I believe that they primarily do that through reviewing. They have staff review their charts and report to the registry.

Iona Thraen: So, it's a chart review, not an observation.

Toni Kaye: That's my understanding probably.

Iona Thraen: Okay. Any questions from the committee members? Any concerns? All right, Ed.

Ed: If not, let's go on and vote on the Reliability and Validity then. So, go to your voting prompt.

(Dezmira): Okay, thanks Ed. We will open voting now for the Reliability of Measure 2726. Option A is High. Option B is Moderate. Option C is Low and Option D is Insufficient. So, we are now voting on the Reliability of Measure 2726. Option A, High. Option B, Moderate. Option C, Low and Option D, Insufficient. Looking for one more vote. Perfect.

Voting is now closed for the Reliability of Measure 2726. Two individuals voted High. Fourteen individuals voted Moderate. Four individuals voted Low and 0 individuals voted Insufficient. For the percentages, we have 10% voted High, 70% voted Moderate, 20% voted Low, and 0% voted Insufficient. Okay.

Ed: So, that was excellent. Why don't we go onto Validity?

(Dezmira): Yes, we are now voting on the Validity of Measure 2726. And if you give me one second, I will read your results for you.

Ed: We've got to vote first.

(Dezmira): Yes, sorry I will read your Options, thanks Ed. Okay, here we are. We're now voting. Voting is open for the Validity of Measure 2726. Option A is High. Option B is Moderate. Option C, Low and Option D, Insufficient. You may enter your vote for the Validity of Measure 2726. Option A, High. Option B, Moderate, Option C, Low and Option D, Insufficient. We're looking for one more vote. Perfect.

All right, voting is now closed. For the Validity of Measure 2726, one individual voted High. Seventeen individuals voted Moderate. Two individuals voted Low and 0 individuals voted Insufficient. So, for the Validity of Measure 2726, this Measure passes this criterion.

Ed: Thank you. Okay. Charlotte back to you on Feasibility.

Charlotte Alexander: Okay. So, this uses Registry data generated during provision of care in defined fields. CPT codes are used to capture the process. There is some

proprietary coding included in specifications for convenience and the people need to obtain licenses for that.

From the committee, all elements are not routinely collected. Is compliance all or none? If one element is missing, does that give it a 0? How much training or coaching is required? And account managers work with users to address difficulties in capturing surgical billing data and I'm wondering how much of a barrier that is?

Usability.

Iona Thraen: Hold on.

Ed: Charlotte, hold on a minute. So, on the questions that Charlotte raised on Feasibility, I'll turn it to the developers.

Toni Kaye: Sure, so this is a measure that it originally, when it first was rolled out, was reported via claims, it's moved into registry for some time now. I think that, because it had the benefit of being in use and pretty wide use for a while, those may have been barriers early in the implementation of this measure, but we don't hear really a lot of concerns or feedback from our members as they - even as more have opted to report this measure to our Registry. We do have a lot of back-and-froth with the data, the data collectors with our users and we have not really heard that this presents a significant barrier in terms of data collection. They seem to have just built it into their workflow.

Ed: Okay, any questions then from the (unintelligible)?

Iona Thraen: I have a question about whether they just have to do one, or all of the implements?

Toni Kaye: Sure. So, this is an all or none. You're attesting that you did all and that was deliberate, just with the thought that failure to do one, sort of negates the rest. It's important that the entire bundle be implemented in accordance of the guidelines. So, this is all or none.

Iona Thraen: Any questions from the committee members? None here.

Ed: Okay, so let's vote on Feasibility.

(Dezmira): Okay, we are now voting on the Feasibility of Measure 2726. Option A is High. Option B, Moderate. Option C, Low and Option D, Insufficient. Voting is now open for the Feasibility of Measure 2726. Option A is High, Option B, Moderate, Option C, Low and Option D, Insufficient. Looks like we have all of our votes. So voting is now closed.

For the Feasibility of Measure 2726, we have 2 individuals who voted High and 18 individuals who voted Moderately. Zero individuals voted for Low and 0 individuals voted for Insufficient. So, for the Feasibility of Measure 2726, this measure passes the Feasibility criteria.

Ed: Wow, we're really going great guns. Okay, Charlotte. Use, which is a must pass.

Charlotte Alexander: Okay. Usability. This is currently used in MIPS and for external benchmarking in the Anesthesia Quality Institute and National Anesthesia Clinical Outcomes Registry and has demonstrated improvement over time.

Iona Thraen: Any questions? Go ahead (YonLing).

(YonLing Geum): Yes, just a question about public reporting. Does that mean the public can actually go through the dataset and then look at the performance (amount)?

Toni Kaye: So, when measures are included and MIPS are in (unintelligible) before, it's available for public reporting, but it's ultimately up to CMS to select measures to put in their physician compare, which is where the actual patients could login and see performance scores. So, it's available, but CMS hasn't selected that measure yet to be included on that Web site. So, it's kind of in a little bit of a grey area there in terms of whether patients - but it is in the accountability and it's available in a number of registries and other applications.

(YonLing Geum): Do you think there will be a future plan to do it with the CMS?

Toni Kaye: I think, I know that we work with them a lot on getting measures in and providing the supporting materials and so, I think, that there is the possibility this could be included in future years, as long as it aligns with the priorities for what how they roll off the Web site.

Iona Thraen: Stephen, then Lisa.

Steve Lawless: Yes, hi, Steve Lawless. A question for you on the Exceptions. You mentioned that there's an exception clause that you think had to happen. Well now, are they excluded from the numerator? And then, too, how is that publicly reported in terms of adjusted rate?

Toni Kaye: So, they are - if you use an exception, they are removed from the measure only if performance isn't met. So, the way that exceptions - and this is any measures that have exceptions - are included is that they can help a provider score, but they can't hurt. So, it's to allow for things like clinical judgement.

So, typically when measures are publicly reported, they often will report alongside an exclusive rate, how often a provider might have used the exclusion or how often they used the exception. So, usually those would be reported.

Steve Lawless: Again, I'm just following up just - I got it, but I want to be a bit more specific. If somebody feels they couldn't - I couldn't use the chlorhexidine or whatever, I'll say used everything else4, so I didn't use the all or not, I just couldn't use or wait 10 seconds or 15 seconds - is that part of yes, you were compliant or not?

Toni Kaye: So, if they used the exception then that becomes - they just don't - they get removed from the measure all together. And then we do periodic audits within our registry asking to confirm.

Iona Thraen: Lisa and then Tracy.

Lisa McGiffert: Just real quick, because I think you mentioned that in the reporting program that this is in, the doctors choose which measures that they want to report on. Like they have a group of measures. And do you know how many, who are in the program, choose to report on this?

Toni Kaye: So, we do Medicare makes that data available at sort of two years after the fact. I think the most recent estimate I saw, which has been from the year 2017, was somewhere in the ballpark of around (47) or so users of this measure. I would have to double check, but I think that's roughly the ballpark.

Lisa McGiffert: Just one more. Who has access to the registry information?

Toni Kaye: In terms of being able to go in and see benchmarks for example, so then that's available to people who sign up to our registry participants. And this is speaking only for AQI and NACOR the registry. There are other registries who have adopted this measure, but for our registry it's available to the practices who have signed up to report data with us. They can see local and national benchmarks.

Tracy Wang: It's Tracy Wang. I'm (unintelligible) to Lisa, I was wondering, I think you said 50,000 providers reported in 2017. Do you have sense of what percentage of the providers are those among everybody who needs to report?

Toni Kaye: I would have to go back and look. They do - CMS usually makes available the percentage of votes who are eligible for the measure who actually reported. I do believe it was reasonably high. I want to say it was north of 75%, but I would have to double check the experience report to make sure on that.

Iona Thraen: Lisa did you ask (unintelligible)?

Ed: Iona, I have a question for NQF staff. The definition of public reporting?

Iona Thraen: NQF Staff.

Elisa Munthali: So, Ed, this is Elisa. So, we do have - this question comes up quite a bit and Ed knows this because we just talked about it at the consensus standard - the Approval Committee, and he's on the committee. We don't - we're not prescriptive about what public reporting looks like, but transparency, we will say, is probably the highest-level of public reporting, if that helps.

In the Criteria, if you can pull it up, (Dezmira), we do have - okay, if you go down a little bit, is it right there? It talks about public reporting and transparency and I'm sorry, I can't see it. I don't have my glasses.

Woman: So, Use - by the extent in which audiences, consumers, purchasers, provider, and policy makers, User could use performance results. Or in this instance, this is an association proposed measure. And so, it's the provider community that's using the measure to look at their own performance.

Elisa Munthali: And one thing I would add is, that in the (unintelligible) the benchmarks so overall nationally, those are publicly available to anyone. So, if you want to know an individual provider score, that's sort of at the whim of physical compare, but you can (national) benchmarks on this measure matter if publicly available.

Iona Thraen: David? Sorry David, could you use your mic please?

David Stockwell: Yes, sorry about that. So, my question is about the Opt outs. How many of the opportunities that are available within the registry, how many times are physicians opting out because of some sort of emergency? Do you all have a sense of that?

Elisa Munthali: It's been a while since we've looked at that. I don't have the data in front. That's something I think that we could look at. But I don't remember the last time we looked at it that it was very - of significant portion. But I don't want to give a ballpark beyond that without actually looking at numbers. But I don't recall it being very high. I remember it not being significant if that…

Iona Thraen She's saying small. Any other questions or concerns? Anybody on the phone? Ed back to you.

Ed: Okay, well - so I think the next vote and I'm sorry, (the only thing I'll say) is about Use and Usability, is that correct?

Iona Thraen: Yes, that's correct.

Ed: Let's go. I don't know if Charlotte has anything else to say about Usability. But I think that we pretty much covered it.

(Dezmira): Okay, we're going to vote on Use and Usability separately. So, our first vote will be on the Use of Measure 2726. Option A is Pass and Option B is No Pass. Voting is open for the Use of Measure 2726. Option A is Pass and Option B is No Pass. Looking for one more vote. Perfect. Voting is now closed for the Use of Measure 2726.

And 19 individuals voted Pass and 1 individual voted No Pass. So, for the Use of Measure 2726, this Measure Passes the criteria. So, we'll move onto the Usability of Measure 2726. Voting is now open for the Usability of Measure 2726. Option A is High, Option B, Moderate, Option C, Low, and Option D, Insufficient. You may enter your votes for the Usability of Measure 2726. Option A, High, Option B, Moderate, Option C, Low, and Option D, Insufficient. Looking for two more votes. Perfect. Voting is now closed for the Usability of Measure 2726.

One individual voted High, 17 individuals voted Moderate, 2 individuals voted Low, and 0 individuals voted Insufficient. So, for the Usability of Measure 2726, this measure passes this criterion.

Ed: Okay, so I think the next question, I believe, is overall suitability for Endorsement, correct?

(Dezmira): Yes, that's correct.

Ed: Okay, so, I'll just quickly see if anybody else has any last-minute comments. And if not, we can go right directly to (state) overall suitability for endorsement.

Iona Thraen: So, this is Iona. This will come up in three years for another round of maintenance and I'd like to make notes to the developers regarding some of the questions that have been asked in the next round of review that we be able to see data that is associated with the outcome of infections and just so that we can see some - it may not be correlated, but at least trended?

Secondly this is an association related measure and there is no real public access to the data. I would like to see some comments in the next review process of what the organization has done to make this more transparent to the public. And I had a third one, but I can't remember what it was. Is there any other thoughts? Lisa's got a card up, go ahead Lisa.

Lisa McGiffert: Yes. I would echo your comments for sure. And I think Public Reporting means Public - the People. So, when we say that something is public, we report it, it should be available to anyone - anyone who wants to see it. And also, on, you know, my concern about this measure is process measure, it looks pretty high in compliance, widespread adoption. We have outcome measures that are, you know, really tell us what the results are.

And so, I really would like to see us focus more on process - on outcome measures in the future and now.

Iona Thraen: (YonLing)?

(YonLing Geum): I think, you know, when a voting accountability transparency, I feel there is some differences between accountability and transparency. What I would like to see in the future, a little (separate) a little bit as far as the developer would discuss about it. Especially transparency and to really laid out the layer of a transparency to which Stakeholders this data is transparent.

That would be better to help us understand what exactly the transparency (unintelligible).

Iona Thraen: And I think you have to follow that up with the accountability side, which is some of the questions that were asked in terms of percentage of opt out. There was another question that was related to accountability over on that side of the room. You guys can pick it up.

Steve Lawless: Well, I think if we're listing things that could be improved with the application or the re-endorsement, one of them would be, of lines placed across the United States every year, how many are actually in the registry? Because my sense is, that most anesthesiologists are not the folks that are placing central lines every single day. And so that's one of my big worries about this measure.

You can't argue with the Science. We should do it, right? There's no question. But is it relevant beyond just the registry use that's happening today?

Iona Thraen: I'm going to support that. I've had all of two weeks on the job and one of the issues at our Institution is the fact that we're a teaching institution for medical students are doing this and the variability is pretty high when observed, as opposed to self-reported.

And so, you know, we're looking at this issue because of that, whether or not nursing needs to have a standard protocol that then teaches the medical students versus the variability of the surgeons versus the variability of the anesthesiologist, et cetera, et cetera.

So, I think self-report is a problem for this registry. Steve?

Steve Lawless: Yes, one is a please consider. And then the other is an (end frame Q-op). But please consider is, we've talked about the maintenance piece. And I think looking at developing maintenance bundles, because that's really all over the place, especially with the MBIs, the mucosal barrier infections, which was the change in '16 that created the furor in terms of infections going up.

The (end frame Q-op) is at what point do we declare something a Standard of Care, nationally? And so, the idea would be is if you have something that's so good, it's so there, no more measuring value - it's a Standard of Care. The side effect is, if you don't do it, you're violating Standard of Care, so therefore, it's a liability.

Ed: Yes, let me also point out that there was a slight change in definition of (proprietaries), also, besides the mucosal barrier, just to be clear. Now, let me ask NQF Staff, for measures that we consider potentially maybe topped out - isn't there a category we put these measures into?

Man: There is. In fact, there is a - what we call - reserve status and it's specifically for measures that have been topped out in terms of performance, but still meet each of the other criteria very strongly. I think the conditions are that a measure has to fail on the Performance Gap question and then receive high ratings on Evidence, Scientific Acceptability, and maybe the others as well.

Because this one actually passed on the Performance Gap, so this is not eligible for Reserve Status (and passed on down) on Performance Gap, we could have considered that. But that is an option for measures, you know, that have sort of topped out in Performance and put in Reserve Status.

Ed: Yes. I just wanted to point to that. And the second thing, I know, Lisa, knows this very well - that self-reporting of hand hygiene rates, are also extremely different from observed rates. And I think that's pretty common throughout the patient safety arena and is a challenge for certain measures. Are there any respondents?

Iona Thraen: This is Iona. I just want to reinforce this idea that this is an associations' measure. And I'd like to say that - to the developers - that they bring back to their association these issues. That like to have anesthesiologist drive the change that we're asking for, so that they're not surprised three years from now if we don't pass it. Because we said, hey guys, we need to push this further down the road and make it a more robust measure if we're going to continue to review it.

Ed: That's providing, Iona, if it passes. So, we haven't voted yet?

Charlotte Alexander: So, Ed, this is Charlotte. The other thing I'd like them to do if they can, is look at the disparity date and see if they can report out more meaningfully on that?

Iona Thraen: Thanks Charlotte.

Ed: Thanks Charlotte, that's obviously a very important issue for NQF. I think, unless there's any burning other questions, I think we're ready to vote on whether or not the overall suitability for Endorsement…

Iona Thraen: Ed, just a minute. Ed, the measure developer has a comment and Tracy has a question.

Ed: Sorry, just trying to keep it moving.

Toni Kaye: Sorry, I'll be brief. I wanted to thank everyone for their comments and I think, certainly, you know, improving efforts and transparency, and making sure that we can correlate with the outcome measure as data becomes available.

One thing I did want to comment on around the percentages of lines that wind up in our registry. While the ASA registry is probably the largest sample of data for this measure, we aren't the only one who has implemented this measure. So, there are, when you're in the MIPS Program, the measure needs to be freely available for anyone to report.

So, in terms of coverage - and that's why when we can, we use CMS's data, rather than just our registry. Because it's a larger, more representative sample. So, I did just want to make it clear that our registry isn't the only home for this measure, and it's not the full source of truth. So, we do have a little bit of a (wire), but certainly all the comments are well taken. So, thank you.

Iona Thraen: Tracy?

Tracy Wang: Yes, so I have a question following the reserve status. So, once a measure becomes reserve status, does it - does the public stops reporting on this and does it, you know, does accountability stop there?

Man: No. You know, it could potentially have an impact on decisions that CMS makes in terms of, you know, using it in Public Reporting Programs, but in

itself, the reserve designation doesn't have any, sort of, immediate implications for, you know, being removed from programs or anything. It's just, sort of, a signal that the committee would send, you know, giving it that designation that it may or may not be used in public reporting or accountability programs.

Iona Thraen: Okay, Ed, I think we're ready.

Ed: Let's go. This is a yes or no question, buys.

(Dezmira): All right, thanks Ed. We are now voting on the overall suitability for endorsement of Measure 2726. Voting is now open. Option A is Yes, and Option B is No. For the overall suitability for Endorsement of Measure 2726, Option A is Yes, and Option B is No. We're looking for just two more votes. and one - perfect. Voting is now closed.

For the overall suitability for Endorsement of Measure 2726, 18 individuals voted Yes and 2 individuals voted No. So, for the overall suitability for Endorsement of Measure 2726, this measure passes the criterion.

Ed: I want to thank first of all, Charlotte for leading an excellent discussion. The Measure Developers for their input. I think Iona and others have given you, I think, some excellent suggestions for bringing this forth in three years again. And I hope that you found this to be a very constructive process.

So, with that, I'm going to go onto the next Measure to keep us moving, which is 0139, which I believe is CLABSI. The CVC is the Measure Developer. So, the first thing I'll ask is whether or not CVC is on the line?

(Cathy): Yes, we are.

Ed: Who is yes? I mean, who is on the line?

(Cathy Bribson): Hi, this is Cathy Bribson and I am just walking down the hall to get Dan Pollock, as well. Hold on a second.

Ed: Well you tell Dan to get to work.

(Jackie Bribson): I'll let you tell him that.

Ed: So, in this particular discussion, I believe, Laura is the Lead Discussant to discuss that. Is that correct Laura?

Laura Ardizzone: That's correct.

Ed: (Very good I did my homework) waiting for the plane.

Laura Ardizzone: Okay, so I'll get started.

Ed: Well why don't we start it on this first - which is importance to the measure, which will be Evidence and Gap.

Laura Ardizzone: Okay, did you want me to do a brief introduction or go right to the Evidence?

Ed: I'm sorry, I should have done that. I'm sorry, I apologize. This is a Maintenance Measure. It's an Outcome Measure reported as a standard infection ratio. So, you can embellish that - because this is a measure…

Laura Ardizzone: That sounds fine. The original was in 2009. This is a re-endorsement from 2015. It's from the CVC. The level of analysis is at the facility. It's a

Standard Infection Ratio and Adjusted Ranking Metric of Healthcare Associated Central Line Associated Bloodstream Infections are calculated among patients in a bedded inpatient care location, that includes acute care general hospitals, long-term acute care hospitals, rehab hospitals, oncology hospitals, and behavioral health hospitals.

There have been some updates to the evidence. The developer identified a number of prevention activities that can reduce CLABSI and introduced a guideline that was written in 2011. The Guideline for Prevention of Intravascular Catheter Related Infections.

You know, I don't think this lends itself to anymore discussion. I think the evidence provided is updated. It's the same and provides stronger evidence than what was presented in 2015. Unless somebody else wants to say anything.

Ed: Well the other thing you might want to comment is - are there still any gaps?

Laura Ardizzone: Oh, I thought gaps was second question. Sure, they…

Ed: (Actually) I think the sequence is both together, but you can do it either way you want, Laura. I don't want to…

Laura Ardizzone: Okay. No problem. It appears that there's still a gap in the reported data and they talked about…

Ed: And saving a lot of time - oh, go ahead, keep going. I'm sorry.

Laura Ardizzone: It also does show that there is some disparity data that they do report among hospitalized patients that specific patient populations have a significantly

higher rate of health associated infections then White, non-Hispanic patients. Some of the comments from the committee was that there's a clear link. No need for repeat discussion. And that Performance Gap is - there's a moderate gap and there's a demonstrated gap that still exists.

Iona Thraen: And questions - Lisa and then John.

Lisa McGiffert: I just wanted to talk about the disparity gap, because I think it's interesting that this has one and I want to be sure that that information is not used to make adjustments to the measure in the future, so that it would diminish the fact that these populations have higher rates. I mean, they just meant - usually when we talk about disparities, we often talk about adjusting for those disparities.

And I have great concerns for us, even - I mean it's good to know this, but even considering adjustments for disparities for patient safety measures - I'm really concerned about it. So, I want to be - I just hope that this would not be used - that in three years we won't see that CVC has made an adjustment to hospitals that have high Asian and Hispanic patients by giving them some kind of a walk on their infections because they have these populations that have been shown to have higher rates.

Iona Thraen: CVC, would you like to respond to that?

Dan Pollock: So, this is Dan Pollock at CVC NHSM. Looking at our Measure Submission form, because we don't recall the information that was described a moment ago about these differentials. We agree completely that CLABSI has remained an issue of concern of - a patient safety issue of concern. We've made progress with more work to go.

But to our recollection, we have not certainly produced analytic results that would indicate a difference in the subpopulations described. Nor are we aware of any external literature. So, we're a little bit puzzled by that. But for now, that's what we'd like to say.

Iona Thraen: So, this is a question for NQF. So, we're looking at the disparity section here, in which it says, Asians and Hispanic patients have significantly higher rates of (AGIs) then White, or non-Hispanic patients. Does anybody know where that's coming from?

Lisa McGiffert: They quoted an article from Infection Control and Hospital Epidemiology Racial and Ethnic disparities and Healthcare Associated Infections in the United States.

Iona Thraen: So, it's a global statement, not specific to CLABSI? Is that correct?

Lisa McGiffert: I think so, yes.

Iona Thraen: Okay. Does that - Dan does that make sense to you then.

Dan Pollock: Yes, that's very helpful. Yes.

Lisa McGiffert: Okay.

Iona Thraen: Yes, it's a global statement. Okay. John, go ahead.

John James: Yes, so, then my issue is directly associated with that. I kind of read this and said, so what. It's (AGI), not specific to CLABSI. So, I don't see where this statement has any relevance to our deliberations.

Iona Thraen: Okay, so I guess we're just making the point that this particular statement, which is a global statement, is not particularly relevant to this particular measure as a global statement.

Lisa McGiffert: Sure, I think it's just a larger statement, not specifically related to CLABSI as the CLABSIs are one type of (AGI).

Iona Thraen: Okay. And then just to follow up briefly, Dan, this question on adjustment from the CVC's perspective as it relates to health disparities, is there any conversation associated with that kind of idea?

Dan Pollock: Yes. I mean, we've certainly been very cognizant and supportive of the - when appropriate - adjusting for disparities. But bear in mind that simply showing that an infection outside of the hospital, such as MRSA, may have a pattern that reflects the disparity in the community, doesn't mean that within the hospital that same infection type would similarly demonstrate a pattern of disparity.

So, I think, in some of the conversations going back several years, regarding should these disparities be taken into account in our NHS and Risk Adjustment, we're not supportive of the idea of this simply because there's evidence of a disparity for a particular type of infection in the community. That evidence should be brought over into the healthcare environment.

I think, as the previous commentator observed, we are talking about healthcare associated infections. And to our knowledge there really is very scanty evidence that would move us in a direction of wanting to take these social factors into account.

Iona Thraen: Lisa.

Ed: Let me jump in - let me just jump in for a moment, because now that Dan's on the line, I realize that we didn't give the CVC an opportunity to introduce themselves. And piggyback on top of that, Dan may also want to comment - although there has been some continued reductions to 2017, 2018 in terms of Gap. He may want to put that in perspective about what some of the HHS Goal was for 2020.

Dan Pollock: Thank you Ed. So, I'm joined here by - I'm Dan Pollock. I'm Surveillance Branch Chief at CVC's Division of Healthcare Quality Promotion. Our branch has lead responsibilities for NHSM. I'm joined here by (Cathy Ellen Britson) who is the NHSM Protocol Validation Team Lead and others on the phone as well.

So, we have made progress, with respect to CLABSI (SIR) and we are on track to achieve HHS department level goals; however, we really believe it's very important - we adhere to the position that it's very important to continue to monitor CLABSIs and we have made progress, we think, in part, because of that monitoring. So, we're on board with continuing to track CLABSIs as a significant patient safety concern.

Iona Thraen: What is your goal?

Ed: Okay, go ahead Iona.

Iona Thraen: The question was, what's the goal? Do you have a…

Dan Pollock: It's for reduction in the (SIR) and we're going to have to - I don't - we're pulling it up right now - it's a quantitative measure of the CLABSI experience

and standardized infection ration, and I just don't have it memorized, but we're going to try to pull up the form that has that information on it.

Ed: Yes, I think Dan, during our discussion several years ago, I think we wanted another 50% reduction on CLABSI. But I don't remember what the baseline year was. I'm going to assume it was 2015.

Dan Pollock: Yes, I believe you're right. We'll just - we'll pull it up and try to confirm over the next couple of minutes.

Ed: Yes.

Iona Thraen: All right, David?

Ed: And while you're looking at that, to be respectful for the people who are on the phone, we have hands up by (Don), Missy, and Charlotte. So, as soon as CVC responds, I think we should wait for the folks on the phone to have a chance to speak. So, as soon as CVC is finished, we'll go to you Don.

Dan Pollock: Why don't you go ahead and bring Don into the conversation while we do this search here.

Ed: Thanks, thanks. Okay, Don?

Don Yealy: Okay, thanks very much Ed. I think my issue was already handled previously, so I put the hand down. I'm sorry.

Ed: Oh, I was so happy to see your hand up. Okay, Missy.

Missy Danforth: Hi. Thanks. Hi, Dan, Missy Danforth from the Leapfrog. One question I have about Gaps is, I know that from our perspective, one of the most common complaints we hear about these - both CLABSI and the CAUTI infection measures are some small rural hospitals or small community hospitals that, for different reasons, usually small sample size can't have the standardized infection ratio calculated.

And I think, what it does for us, is it raises some concerns about (adoption) performance between the rural hospitals and the larger hospitals that have a standardized infection ratio calculated on a regular basis, contracting trend performance, and do quality improvement around it, which most hospitals in the country are.

Is there anything that you're doing for these smaller hospitals that can't regularly have as they're calculated (unintelligible) drops and performance or to give them any meaningful feedback about areas where they can improve?

Dan Pollock: So, good question. Dan Pollock again, at CVC. Of course, the small facilities that do have infections can look at their numerator data and respond to those infections. That is, of course, an approach that uses the facilities own data alone, really, for comparison and tracking purposes.

We are building into NHSM, the capacity to produce what we call our adjusted ranking metric that will take into account volume of exposure and enable many, many more facilities that have too few central line days currently to calculate an (SIR) to receive an (SIR). And that's under development for release in the NHSM Application in December of this year.

So, many of the hospitals with smaller bed sizes and a smaller volume of exposure, which is to say, fewer central line days, that gets in the way of our

producing a reliable (SIR), will have a reliability adjusted (SIR), which we call our adjusted ranking metric. And that should, I think, address for many of those facilities, the issue that you've just cast a spotlight on. We understand this.

Missy Danforth: And that's going to be December 2019?

Dan Pollock: Correct.

Missy Danforth: Wonderful, thank you.

Dan Pollock: Yes. And, Ed, you were correct. The target we do have is a 50% reduction in CLABSIs by 2020. And we are tracking that and we are on track to achieve that goal.

Ed: Okay, committee, I want you to hear that, that I was correct on one item today.

Iona Thraen: All right. Do we have anybody else on the phone?

Ed: Well Iona, we have to - Charlotte was the next one and then we'll go to the room.

Iona Thraen: Okay.

Charlotte Alexander: My question was answered, thank you Ed.

Ed: Okay. Iona, take it away.

Iona Thraen: All right. We have David and then we have Pat and then Steve.

David Stockwell: Thank you. David Stockwell. I - at the risk of going down a hypothetical rabbit hole, I want to endorse the statement that Lisa made about, hopefully, avoiding any future risk adjustment based on disparity data. There is evidence in pediatric safety outcomes that there are disparities in who has safety outcomes, poor outcomes, safety wise.

There's also in pediatrics now, evidence to suggest that minorities are under voluntarily reported. Meaning that they don't have voluntary vet reports as frequently as White patient's do in a pediatric hospital. So, my hope would be that the CVC would agree that our goal would be to improve performance in those areas to get rid of the disparity, rather than risk adjust those disparities away.

Iona Thraen: Pat?

Pat Quigley: Thank you Madam Chair. Pat Quigley. I have two questions, if I may. And the first question is, on the screen, this reports below 2017 CLABSI. (Is this CAUTI? These are CAUTI measures? Below, under National CLABSI measures, CLABSI (unintelligible).

Dan Pollock: I think that's just a typo.

Pat Quigley: Oh, so that's okay.

Iona Thraen: So, where's the typo?

Woman: I'm just making sure this is correct?

Man: Yes, there's a typo in there.

Iona Thraen: So, there is a typo under the development provides special standards, infection rates for CAUTI - that's supposed to be CLABSI? Has everybody got that? All right. (Forget that).

Pat Quigley: Thank you. And my second question is, four years ago when we discussed this measure to Dr. Pollock, there was quite a bit of robust discussion about spinal cord injury patients remaining in this database and in this measure…

Ed: That's CAUTI. That's coming up next.

Pat Quigley: Oh, excuse me. Okay. So, sorry.

Ed: Yes. So, we're going to have a short public comment before the break and then we're going to go into CAUTI. So, hold that question.

Pat Quigley: Excuse me, thank you for that correction.

Iona Thraen: All right. Steve?

Steve Lawless: Yes. To the developer. This is Steve Lawless. There's a trend that bundles are working. So central lines are going out sooner. People are pulling them out less. Is there any evidence of utilization ratios decreasing? Or that, in order to keep a line for a period of time, you actually have sicker patients.

So, from a CVC perspective, is there any way of measuring, or you guys have looked at, essentially the low hanging fruit is gone and now with levels off a little bit because only those who really need a line are in the line. Or the sicker and most vulnerable like for the (NBIs) and that kind of stuff.

Iona Thraen: CVC?

Dan Pollock: Yes, so we certainly do analytic work looking at different denominator options. Device days is of course, the option that we're using both for CLABSI and CAUTI. Our analysis of the patient day's information, which we do have, does not substantiate that it offers any improvement over the device days.

There are, in fact, there's no evidence of shift in direction of the summary statistics over time at the facility level. So, in other words, whether you use the device days or the patient days, facilities that are moving from one (SIR) level to another over time, it makes no difference if you're using patient days.

That said, in theoretical terms, device days are, of course, the count of the patients who are on a device. Patient days, includes patients who are not on a device, as well as those who are on a device. And in terms of assessing the frequency of an adverse event, we adhere to the concept of making every effort to have the group that's exposed to the risk, albeit a group that we're using in the denominator, not including individual patients whose risk exposure is nil because they don't have a device.

Steve Lawless: Okay, that's good. But that's just not what I'm asking. And I can make it a bit clearer. If you have a lot of central lines that people have in and they didn't really need them, but now somebody's saying, do you need this line we want to get it out? So, you've gone from 10 days to 5 days because you don't need them.

Dan Pollock: Right.

Steve Lawless: Is the denominator, somehow, are you seeing a trend at all, that because of a lot of the low hanging fruits around (unintelligible) people needing it, that the infection rate itself has either leveled off or may be increasing as a result of that.

So, for example, oncology patients, more go into PICC lines than Broviacs because people are saying no, I need this for six months, not a year. It's easier to take it out. But that's a higher rate of infection because of the nature of the line.

Dan Pollock: We have looked at that, particularly with respect to CAUTI and we do know that there have been reductions in device utilization on the urinary catheter front. I don't know, off the top of my head, what our analytic work has shown with respect to CLABSI. But we can certainly follow up.

Iona Thraen: Anybody else? John?

John James: At the risk of confusing this maybe a little more. Something stuck in my head and I kind of need an answer to it. So, it seems to me that the numerator (unintelligible) for this measure assumes a linear relationship between the number of days that the patient has the line and the instance of infection. Regardless of the total number of days - in other words, the assumption is it's a linear relationship - and I wonder if there's really data on that.

It seems to me for this measure and for CAUTI as well, that the risk per day is going to go up as the line is in longer. So, is that, in fact, true? Or is it really a linear relationship as the measure seems to assume?

Dan Pollock: So, I think it's a very astute observation and we do have some data that would suggest as your comment points out, that risk does (unintelligible) over an

episode of care. To move in the direction of actually adding that, or using that in our measure, would require some additional data collection and we're a little bit hesitant to ask for that because it remains a very labor intensive process in many institutions to capture information about insertion dates and other information that might be pertinent to move in the direction that you're describing.

Ed: Any other hands?

Iona Thraen: (Oh Pat is your - any other comments)? I think Donald - Donald has a question?

Don Yealy: Yes, I think - I don't think for this go-round that a catheter frequency information is critical for us to assess vis a vis the measure now, but I do strongly think moving forward, we have to see the overall frequency information. So, I would just add on to the developer, this will come back up around again assuming it makes it through here. And that will be helpful, because there'll be a changing nature of this.

Dan Pollock: No, we hear you and we agree. We think that there are, you know, a variety of different ways that we may want to move forward on the CLABSI front. We're looking closely at a time between events. Metric is another way of looking at CLABSIs because as we do make progress, as they do fortunately become rarer and the time between events may be a useful way to take that rarity into account.

Ed: And not pertinent, necessarily to this discussion, but I know that CVC has certainly looked at peripheral IVs and now we see a number of facilities trying to shift to mid-lines, which is not considered a (gentle) line for the purposes of reporting.

Dan Pollock: Yes, thank you Ed.

Ed: Yes, any other comments on the evidence of the Gap?

Iona Thraen: I think we're good to go on this side Ed.

Ed: All right then. So, let's go ahead and vote on that then.

(Dezmira): Okay. Thanks, Ed. We are opening the vote for the Importance of Measure and Report Section. We're going to vote on the Evidence of Measure 0139. Option A, is Pass and Option B, is Do Not Pass. So, all votes are unlocked and you may enter your votes for the Evidence of Measure 0139. Option A, is Pass and Option B, No Pass - Do Not Pass. Looking for one more vote. Perfect. Voting is now closed for the Evidence of 0139.

Twenty individuals voted for Pass and 0 individuals voted for Do Not Pass. So, for the Evidence of Measure 0139, this measure passes this criterion.

Ed: Okay. So, let's go to Gap.

(Dezmira): Okay. If there are no other comments, we will open voting for the Performance Gap of Measure 0139. Option A, is High. Option B, Moderate. Option C, Low and Option D, Insufficient. For the Performance Gap of Measure 0139, Option A, High, Option B, Moderate, Option C, Low, and Option D, Insufficient. Looking for two more votes. Perfect. Voting is now closed for the Performance Gap of Measure 0139.

Five individuals voted High, 15 individuals voted Moderate, 0 individuals voted Low, and 0 individuals voted Insufficient. So, for the Performance Gap of Measure 0139, this measure passes this criterion.

Ed: Excellent. So, Laura, why don't you take us (through down the) Scientific Acceptability on Reliability and Validity?

Laura Ardizzone: Sure. This was reviewed by the Scientific Method Panel. The Numerator is the total number of observed healthcare associated CLABSI among patient's vetted inpatient care locations. I described what those locations were previously. The Denominator is the total number of predicted healthcare associated CLABSI among patients in those vetted healthcare locations.

Calculated using the facilities number of central line data, with the following risk factors: So, in acute care hospitals at CVC locations, facility bed size, med school affiliation facility type, birth weight category, only if there's a NICU present. In a critical access hospital, no significant risk factors. They're just doing a calculation based on (inter step) model only. In inpatient rehab facilities, it's the proportion of admissions with stroke, proportion of admissions in other nonspecific diagnostic categories. And in long-term acute care hospitals, it's the CVC location type, the facility bed size, the average length of stay, proportion of admissions on a ventilator, and the proportion of admissions on hemodialysis.

There are some exclusions. Patients who are not assigned to an inpatient bed or excluded from the denominator counts, including outpatient clinics, patient in 24-OBS unit, emergency department visits, and inpatient rehab locations and inpatient psychiatric locations that have their own CMS Certification Number are excluded.

It did go to the Method's Panel, which both approved it Moderate for Reliability and Mostly Moderate for Validity. There was one person who voted it Low. For Reliability it was - testing was performed at the data element level and for Validity testing was performed also at the data element level.

Our committee's pre-evaluation, there were no concerns with Reliability overall really, or testing. And there was no concerns about threats to Validity or there were no comments or no concerns on exclusions or threats to Validity.

Ed: Okay, any questions either on the phone or Iona in the room?

Iona Thraen: None here.

Ed: Okay, well, I don't want to ruin our luck, but why don't we go on and vote?

Man: And just as a point of process, because this was reviewed by the Method's Panel, we can actually elect not to vote on this one. In some previous committees that I've been working with, we've just sort of done an informal check with the committee. And I don't know if this is okay with you Ed, we've sort of said does anybody want to vote? And if there's at least one person who does, we've gone ahead and done it. And if not, we can just accept the Method Panel's ratings. I don't know if that works for you.

Ed: My guess is because people seem to be comfortable with what was just presented, I'm guessing that people would vote Yes on the next two questions. But I don't want to be presumptuous. Is it okay with everyone if we just accept that and move onto - to Feasibility?

Iona Thraen: Any objections to moving on? No, go ahead.

Ed: All right. So, Laura, you want to talk about Feasibility then?

Laura Ardizzone: Yes. I think Feasibility is next. So, it is noted that these - the CLABSI and Central Line days, the Numerator and Denominator have to be collected by trained staff in a hospital, so there is some burden on them. Some of the data can be mined from electronic sources and they hope to be using that in the future and moving towards that. But it's not complete at this time.

From our committee review, there were no concerns. It is Feasible. It can be extracted. It is labor intensive, but it's a known entity. And their comments were (that raised) positive that they're trying to move it towards something different in the future.

Iona Thraen: Any comments or questions? Lisa?

Lisa McGiffert: Well I - just more commentary. I think that it is really important for hospitals to actually document where the central lines are. And this measure has required them to do that. And from the very beginning there has been this burden issue. And I think it's a necessary burden in order to protect the patient. So, I would just make that comment about the burden.

Just a note again, there's - we seem to have this CAUTI CLABSI issue. There's a typo in this again.

Iona Thraen: Another typo.

Lisa McGiffert: Yes.

Iona Thraen: Okay.

Lisa McGiffert: They're so interrelated that (unintelligible).

Iona Thraen: Okay. Jason?

Jason Adelman: I guess this comment is a follow up to Steve's comment earlier. As we've had this measure around for a while and the hospitals are getting better at it. And we've gotten rid of, as he said, the little hanging fruit. And I've heard at, you know, amongst other hospitals, that people are starting to take strategies like, for this particular measure, maybe don't draw as many blood cultures. Or don't draw them -- and for the CAUTI measure, be very careful about when doing urine cultures.

And, at some point in the future, we may have to start looking at - like we may be pushing Quality of Care in the other direction to avoid a publicly reported measure. And so, we'll start having some measures about, you know, the appropriateness of blood cultures for patients with central lines and fevers or urine cultures with patients with catheters.

So, I don't think we're there yet, but I just hear very concerning like, conversations, about how to avoid a hospital acquired infection. Not with the intent of actually avoiding the infection, but more avoiding getting (the trigger from the measure).

I just want to put that out there. It doesn't change how I feel about voting right now, but I feel like we're moving in that direction.

Ed: Well Jason, I think there's always the temptation of people trying to game the system. I already mentioned about people putting in more mid-lines because they're not considered a central line.

The other thing, which is a separate discussion altogether Jason, is that there is a lot of discussion about diagnostic stewardship as to when is it appropriate to send the urine. And some, but not quite the same, about blood culture stewardship as well.

And I'm sure as everybody on the phone, I know the CVC I think will affirm this, that drawing blood cultures from lines has an increasing rate of contamination and other unintended consequences. Although occasionally it's necessary.

So, I think, Jason, you know, your comment, I think, is correct in terms of gaming the system. But on the other hand, there is some real discussion and some movement in a positive way, around a diagnostic stewardship about sending appropriate specimens. So, I'll let the CVC maybe weigh in on that, as well.

Dan Pollock: Well, we appreciate both the comment Ed and your thoughtful replay to it and agree. We are very concerned always about the possibility of unintended consequences. We do get anecdotal reports of clinical and administrative leadership providing guidance that looks an awful lot like guidance to avoid certain practices that we would consider to be Standard of Care, but that are being recommended in order to precisely avoid having to report an infection.

Now that's very dispiriting and discouraging, but we think the measures are still very important to track. We think it underscores the importance of

stewardship activities. It does diagnostic stewardship activities and certainly urinary cultures are part of that,

Also, C-difficile testing is another area that we're very concerned about. And we may over time, on the CVC side, want to propose measures related to stewardship activities, diagnostic stewardship activities to help move the field forward and foster a more judicious use of tests and appropriate use of tests than we have right now.

Ed: Thank you Dan. Are there any other comments regarding Feasibility?

Iona Thraen: Nothing here.

Ed: There's nothing in the room, then let's go to vote.

(Dezmira): Okay. Thank you. We are now going to vote on the Feasibility of Measure 0139. Voting is now open. Option A is High. Option B is Moderate. Option C is Low and Option D, Insufficient. We are now voting on the Feasibility of Measure 0139. Option A, High, Option B, Moderate, Option C, Low, and Option D, Insufficient. We have all votes and voting is now closed.

One individual voted High, 19 individuals voted Moderate, 0 individuals voted Low and 0 individuals voted Insufficient. So, for the Feasibility of Measure 0139, this measure passes this criterion.

Ed: Okay, Laura. So, let's go on and, I think this is obviously a measure that is in use for Public Reporting. Let's talk about Usability and Use.

Laura Ardizzone: Sure. So, it is Publicly Reported and currently used in three accountability programs. The Hospital Inpatient Quality Reporting Program, the Hospital

Value Based Purchasing, and Hospital Acquired Condition Reduction Program. There were no comments on pre-committee for Usability or Accountability and Use.

Ed: Any comments from the peanut gallery here? Anything in the room Iona?

Iona Thraen: None.

Ed: I don't see any online. So, let's go on and vote on these two issues.

(Dezmira): Okay. Thanks Ed. We're voting on the Use of Measure 0139. Voting is now unlocked. Option A is Pass. Option B is No Pass. For the Use of Measure 0139, Option A is Pass and Option B, No Pass. Looking for one more vote. Perfect. We have all votes and voting is now closed.

For the Use of Measure 0139, 20 individuals voted Pass and 0 individuals voted No Pass. So, this measure, 0139 passes the criterion for Use.

Ed: Okay. I think, the Usability?

(Dezmira): Yes. Okay. Voting is now open for the Usability of Measure 0139. Option A is High. Option B is Moderate. Option C is Low and Option D Insufficient. For the Usability of Measure 0139, Option A is High. Option B, Moderate. Option C, Low, and Option D, Insufficient. Looking for just two more votes. Perfect. Voting is now closed.

For the Usability of Measure 0139, we have 7 individuals who voted High, 13 individuals who voted Moderate, 0 individuals who voted Low, and 0 individuals who voted Insufficient. So, for the Usability of Measure 0139, this measure passes the Usability criterion.

Ed: Right. Okay. So, then the last vote on this particular measure is the Overall Suitability for Endorsement. So, are there any final comments before we vote on this?

Iona Thraen: None here. It looks like Laura did a great job.

Ed: Yes, Laura. Laura, thank you. So, let's go ahead and vote on this.

(Dezmira): Okay, we are voting on the Overall Suitability for Endorsement of Measure 0139. Option A is Yes. Option B is No. For the Overall Suitability for Endorsement of Measure 0139, Option A is Yes and Option B is No. Looking for one more vote. Okay. All votes are in.

For the Overall Suitability for Endorsement of Measure 0139, 20 individuals voted Yes and 0 individuals voted No. So, for the Overall Suitability for Endorsement of Measure 0139, this measure passes this criterion.

Iona Thraen: Ed, you're six minutes over.

Ed: I - you know, I was just going to say that. Come on. So, as I mentioned, thank you very much Laura and thank you for our Measure Developer. We're going to take 10 minutes now before the break and we'll then take the 10 minutes for public comment on the next measure. And then we're going to take a break.

So, are the Public Comment folks there? Matt and the other…

Iona Thraen: They're coming. They're coming to the table.

Ed: Okay, so we're going to, we can keep this to 10 minutes and then we're going to take a 15-minute break.

Iona Thraen: Let me just say, we're switching now. This is the CAUTI measure that they're addressing.

Ed: That's right. That's right.

Matt Davis: Okay, thank you. I really appreciate being invited here and getting a chance to speak. I always appreciate that about this. I have always appreciated the openness of the National Quality Forum. And I can certainly understand the cause for concern about things like, not letting people with…

Iona Thraen: Can you identify yourself?

Matt Davis: Oh, yes. I'm sorry. My name is Matt Davis. I am a Spinal Cord Injury Specialist Physician. I'm here representing the American Spinal Injury Association and I'm an employee of McGovern Medical School UT, Houston.

So, and yes, I agree, we shouldn't take decisions like this lightly about specialties in populations. There are a lot of folks that are going to come forward and raise concerns. And, you know, we can't just let everybody off the hook, of course.

There need to be criteria. And a lot of these criteria are things that we're talking about today. And if you set forward these criteria to a group of spinal cord injury specialists, just to the spinal cord population said, is this measure valid? Is there a gap to close? Is this reliable and feasible? I think the answers you would see are a whole lot different for somebody who must either chose between a Foley or intermittent catheterization, than they would

be for somebody who is a choice between a Foley and emptying the bladder normally.

There's really no credible data, that there is a markedly higher rate of UTI with Foley catheterization. So, we're not measuring UTIs with imminent catheterization at this measure. So, we're leaving so much data on the table, it's really hard to draw conclusions about quality of care.

So, what is the validity? Is there a gap to close? If it is, it's probably pretty small. And in the meantime, we're adding this whole other layer of complexity. We're having a financial incentive for a group of healthcare providers to take on a measure that they're not - they don't know, what they don't know.

It's hard to - you know, if you go to infection control flow at your local hospital and say, are spinal cord patients having problems with autonomic dysreflexia when you pull out their Foleys? Or if you can't define what autonomic dysreflexia really is, how can you say well no, we're not taking that, right? So if you're, you know, I think one of the things we've heard is, well if this was a problem we'd know about it by now. Well who are you asking? Because (unintelligible) experts are saying yes, this is a problem. We are seeing it.

And these are dangers that historically have led to catastrophic outcomes. I've seen a couple patients with subarachnoid hemorrhage, we've had a patient who (had a) cardiac arrest form hyperkalemia whose (unintelligible) 7.9 form renal failure. And so we can help the patients who come to rehab in time for us to drain their bladder appropriately we have no idea what happens to that 30 or 40% of people who never go to a rehab hospital.

We know that 40% of these patients died from renal failure back in the 1940s. So I had a whole bunch of handouts. You know, we've gotten a lot of comments. But I also have some handouts that were not memos posting online. I was going to leave them laying out back there.

Man: And they're in the documents that were measured 138 if you want to look on SharePoint as well.

Woman: And (Matt) would you help us understand what's your request? What is it that you're wanting to see?

(Matt): I would like to see removal of the financial incentive that drives acute care hospitals to remove Foleys in spinal cord patients. And I would also like the implication that Foleys in (unintelligible) patients is bad care. It's actually very patient-centric care for a substantial portion of our patients. So an exclusion would be one way to accomplish that.

Benita Kornegay Henry: Okay, so excluding that specific population from this particular measure is what you're asking for.

(Matt): That would be the simplest way. I'm open to other options.

Benita Kornegay Henry: Is your association, you saw earlier with the, for example the Anesthesia Association Group having supposed, have a measure that they're sponsoring. Is your association at all looking at a measure that's relevant to that population around this issue?

(Matt): So we have an international dataset that actually Dr. (Getts) helped developed. He's in the corner over there as well. I think you wanted to -

((Crosstalk))

Benita Kornegay Henry: Come on up.

Dr. (Lance Getts): So, you know, that is - that can serve as the framework to an alternative quality measure. I think it's our professional societies are so small that I think funding to these measures ultimately would real challenging.

Benita Kornegay Henry: In terms of testing - doing the science of it.

Dr. (Lance Getts): Correct. So this is, there are about 300,000 spinal cord patients in the entire country.

Benita Kornegay Henry: Three hundred thousand.

Dr. (Lance Getts): We get some perspective on that. There are about 800 spinal cord injury specialists positions in the county, probably less than that.

Benita Kornegay Henry: Okay. So the question - so what they're advocating for just for everybody's understanding is the CAUTI measure currently does not exclude spinal cord injuries. We had this discussion I think a while back, three years ago. And someone, I think it was you Lisa that you said that in the conversation last night, you thought that CDC was going to do something around this issue. CDC, are you still on the line?

Man: Yes, we are.

Benita Kornegay Henry: Could you comment on what's the status related to spinal cord injuries and this particular measure and what work or nonwork that has taken place regarding this?

Dr. (Lance Getts): Sure, well we have certainly heard from Dr. Davis and colleagues for a number of years now about the concerns that they're expressing again today. And our understanding and I think Dr. Davis reiterated it in his comments, is that the concern is what's happening in acute care hospitals. And while, you know, there are undoubtedly dramatic instances and anecdotal evidence of very bad outcomes related to urinary bladder management in the acute spinal cord injury patient. If that's indeed the concern, then we should move toward a measure that addresses a gap in care in the acute care hospitals for those patients. And we have said that over and over again.

Benita Kornegay Henry: Okay, so I just want to ask - so you, in the data collection process that you currently have in place, are you at all able to look at infection rates as it relates to that particular diagnostic state.

Dr. (Lance Getts): We don't capture individual patient diagnoses. We do have some ecological information about the distribution of patients by location type and hospitals as a result of our annual survey. But there's no one-to-one connection with the events themselves. And to introduce data capture by individual disease conditions adds an enormous level of complexity given the current state of recordkeeping both paper and electronic.

So we're -

Benita Kornegay Henry: So I'm just going to reframe this one minute and then we've got several cards up here for questions. So it strikes me that this issue of spinal cord injured patients is very similar to the issue of patient disparities. And that the original conceptualization of these measures were, have been at the institutional level as opposed to the patient level, patient population level. And so I think CDC needs to really think about in the future how do we move

beyond an institutional perspective to a patient populations. And then with that I'll start with Lisa, Laura and (unintelligible).

Man: Before we continue, this was supposed to be a 10-minute segment on public comment. We're going to get into these other individual things when we discuss the measure itself after the break. So I would suggest unless (Matt) and his colleague have something else they would like to present, because we heard this very nicely today and gave us handouts. I would suggest, unless there's disagreement in the room that we take our break and then come back and discuss the measures and integrate the public comment in the discussion of the measure if that's okay with everyone.

Benita Kornegay Henry: And we've got three cards up. We'll go back to the measure.

Man: But wait a minute, this was supposed to be 10-minute segment on public comment we're taking out of order.

Benita Kornegay Henry: I'm going back to measure.

Man: I'm suggesting that we take our break and we come back and discuss the measure and we can discuss the other issues at the same time. I'm just making a suggestion. If the folks in the room would rather continue the discussion, that's fine. But that was the intent of putting them first.

Benita Kornegay Henry: They have questions to the measurer. So what we'll go back to the measurer, starting there.

Man: Wait a minute, we haven't discussed the measure yet.

Benita Kornegay Henry: The public comment, excuse me.

Man: Okay.

Benita Kornegay Henry: I'm using the wrong words.

Man: We set up 10 minutes for public comment and to talk to measure, but if there's a specific issues, go ahead and continue.

Benita Kornegay Henry: Go ahead.

Dr. (Lance Getts): I'll just be way of bio introduce myself. (Lance Getts), I am a member of ASIA, representing ASIA also on the board of directors in Academy of Spinal Cord Injury Professionals. I'm not representing today. Associate professor of DCU Health and staff physician of the McGuire VA Spinal Cord Injury Center. So I've been in the VA system for 23 years. I was also a reviewer for the consortiums for spinal cord medicine, clinical practice guideline on management neurogenic bladder for adults with SCI. Actually a preferred term at this point is neurogenic lower urinary tract dysfunction.

So concur with what Dr. Davis has said. And in the VA, we, you know, our management is a very individualized and it's very complex. In chronic SCI, we find also that many of our folks are using either indwelling urethral or suprapubic catheters. So we actually just published another paper in neuro-urology in urodynamics. I think it was this March and looked at our database as of 2009 and at that time in the - among those 833 people in that database and among the people using chronic - using catheterization, it was about 50/50 using indwelling catheters versus intermittent catherization. So our patients are choosing that as a long term management method for a variety reasons.

So and we see complications like autonomic dysreflexia both in acute and chronic people with spinal cord injury. So I would also concur with Dr. Davis that the data on CAUTI specifically in SCI which is obviously a very tiny proportion of all the CAUTI's out there because we're such a small population. Is inconsistent CAUTI, there's high risk of CAUTI regardless what type of catheter you're using, long term. And so this - the increase is incremental in some studies and nonexistent in other studies. So it's just well or substantiated that CAUTI is dramatically different in indwelling versus intermittent catherization.

Man: I guess the last thing, and this will be very brief is it's really hard to come to the decision without a lot of back and forth discussion. I understand the, you know, this is public comment. And I want to respect that. We'll be sitting in - back here during the discussions but you can always postpone if we can't come to a decision today, we can postpone a decision. Or we can provide you guys, not we, you guys can provide a conditional endorsement. We don't think the CAUTI measure is a bad measure that you should be failed. And we want all of these concerns you guys are raising to be addressed. There are answers to the concerns you guys have and have data that's available.

Benita Kornegay Henry: So we have three cars up, four cards up for questions to the public comment. (Yang Ling) and then Pat and Laura and Jason.

(Yang Ling): Thank you. I just have a question for Dr. Davis. This measure has been in place since 2005. Do you have any data to show, posed to both of you, any data to show how that would be this measure has been unfairly - has unfavored consequences to that population. Do you have any data to show?

Matt Davis: So we have data that could be very easily brushed off as low quality data. If someone was not wanting to believe kind of the reports of people that are in it.

The reason that it's hard to collect data on this that people who are most likely to inadvertently participate in such a practice that cause these problems, are also unable to recognize that oh, this adverse event happened because I removed the Foley. And so these things don't make it into the medical record very well.

And so that makes the data mining extremely difficulty retrospectively. And a prospective study on this sort of thing would be grossly unethical.

Woman: Thank you Madam Chair. My question to our public presenters, is your specific request to CDC to us is to have this population excluded from the measure as you did four years ago?

Matt Davis: That's the simplest solution and yes, I would be very happy with that solution. If the committee wants to look at other options, I think there could be another options - the other option at least come to my mind all, all have shortcomings that would also have to be addressed. It would be a lot more complex.

Benita Kornegay Henry: Laura?

Laura Ardizzone: Thank you for your powerful stories. I did - when I was reading the measure and the comments, I couldn't understand. Sounds like there was meeting between you and the CDC. Can you tell us - make that a little bit more robust and flesh that out? Like what couldn't happen during that? Because it was hard to read between the lines.

Man: Yes, well boy, how do I say this? We - I think there was kind of a fundamental disagreement between both sides as to just how much of a problem this really is. And I think there's - so we have this anecdotal stories. And it's true. You know, I mean, you know, we did - do not have really good

data and we probably never will. We see practices that we know historically were very dangerous and we can't follow these patients after they discharge home. So that's just kind of out there.

This is not just an issue with the acute care hospitals. The other kind of site it really was not discussed very well so far as, you know, as a spinal cord specialist hospital when I leave the Foley in, I am more like to be panelized. And yet frequently I am following clinical practice guidelines from my society because that's the patient centered thing to do.

And so I guess this is where we look at risk versus benefits. I mean you know at the risks through there that are measurable, the benefit of switching from Foley to intermittent catheterization is minimal best.

So I didn't really answer your question, did I?

Woman: So the question again, was you guys had offline meetings in between these past couple of years and I couldn’t understand kind of that happened. I guess it's - you couldn't - fundamentally you couldn't agree. They couldn't change the measure, okay.

Man: I couldn't find the common ground. You know, educational initiative, you know, was kind of framed as a possibility. We have a pretty decent amount of literature showing that we have a hard time educating people who see low volume of spinal card patients. I mean we just - we fail. We have failed for decades on that.

Woman: Jason?

Jason Adelman: So I'm the Chief Patient Safety Officer at Columbia Medical Center. We have a spine hospital. And my thoughts are that the patients you're talking about, I think, if I understand your major concern is that there's legitimate reasons why you should keep tab visit. And people that general idea of being that people have catheters in longer will have more infections and so that your population has more CAUTIs and you and hospitals that service these patients are being penalized for what is otherwise good care.

And I'm understand that point. I think there are other things that can cause CAUTIs besides how long a catheter us in meaning are they - catheters put in under sterile conditions. Is the Foley kept to gravity below the bed? Or is it too high? And so perhaps suggestion is not to exclude these patients which might not be servicing this patient population (unintelligible) because now we're not looking at infections, but stratifying.

And so for example what if I'm just putting this out there, what if the CDC had a non-spinal cord patient CAUTI measure and a spinal cord one. And so the SAR could be one for both of them. And so but there still might be variability in your patient population based on not how long a catheter is in, but on the other important aspects of taking care of inserting taking care of the catheter. So just what are your thoughts of that?

Man: So if we removed spinal cord patients from the current CAUTI measure and put them in a separate quality measure that was at least a beginning separated from any sort of financial incentives. I think that would be a very good solution. And we could use something like the international patient dataset which is well (unintelligible).

The - your question about insertion catheter sterile insertion and maintenance, we actually have a pretty good amount of data on that. So putting a catheter

in under OR sterile conditions is no better than basic hygiene, it turns out. So a lot of these catheter maintenance bundles when you look at the individual elements of which portions of the maintenance bundle actually result in reduced CAUTIs, it is the elements of the bundle that result in early removal of the catheter.

Everybody, if you leave the catheter in for 30 days, everybody's going to be colonized no matter how careful you are and certain of the catheter.

((Crosstalk))

Man: Everybody will be colonized eventually using intermittent catherization as well.

Man: Okay, (Don) you really had a comment online.

(Don): No, but I actually think that mine have more to do with the developer. I apologize that came in and we need to allow the public comments to be completed and then get back with our work.

Jason Adelman: If I can just - my point was that if you would agree that there is - there's the potential for variability of the quality of inserting and maintaining catheters and preventing CAUTIs for the spinal surgeons and nurses and all the providers around the country. And so having a measure that looks at CAUTIs might catch that variability and performance. And allow us to drive improving. The SAR or infection rates may be different, but it's hard for me to imagine that every surgeon, every nurse does everything perfectly everywhere. So I get your point that like my hospital, Columbia, we do a lot more spinal surgeries than other hospitals. And we may be unfairly penalized because of it. But I don't want to not look at the infections of those patients

because I want to make sure that all the providers involved are still providing good care. So if you parse it. And we don't, you know, weigh in on what goes into different pay for performance programs.

I'm just saying if you're questioning the living reliability the measure based on the proportion of patients that have your type of patients, if we can stratify instead of eliminate, then we can still protect those patients but not unfairly penalize hospitals that do more spinal surgery cases.

Benita Kornegay Henry: So again conceptually, the challenge is that the current measures that CDC has proposed are institutionally based, so they're looked at from units, from types of hospitals as opposed to patient populations and so what (Dan) has said earlier rightly or wrongly to collect patient-specific information which would include diagnoses currently in the system, they're not set up to be able to do that. And therefore the aggregation is that the unit or the institutional level and not at the patient population level.

And I would argue that's where we need to go is towards the patient perspective as opposed to just an institutional perspective. But that's developmental future. Pat and then we're going to close it off.

Pat Quigley: Thank you so much…

((Crosstalk))

Pat Quigley: … those comments. But I would just point out that in terms of inclusion, in this measure, the inclusion for inpatient rehabilitation facilities is population specific.

Benita Kornegay Henry: Is it really?

Pat Quigley: It is.

Benita Kornegay Henry: I'm looking at it.

Pat Quigley: Yes, ma'am. It is traumatic and nontraumatic spinal cord dysfunction and the proportion of admissions with strokes.

Benita Kornegay Henry: So it is population.

Pat Quigley: It is population-specific in terms of its inclusion criteria. The other settings of care are not population specific.

Benita Kornegay Henry: So (Dan) in that definition then you're getting stroke and trauma-based patients. Is that correct in as not distinguishable in the database?

Pat Quigley: In rehab facilities.

(Dan): So if I could, this I (Dan). We capture the type of facility that's reporting the event and the denominator data. So we have inpatient rehabilitation facilities as a category. And we have a separate CAUTI predictive model for IRFs, for inpatient rehabilitation facilities, (unintelligible) from the acute care general hospital. And as I mentioned earlier, while don't capture individual diagnoses, we can with our survey understand the proportion of admissions with traumatic and nontraumatic spinal cord dysfunction (unintelligible) and IRF and that happens to be a predictor of CAUTI in that particular facility level characteristic is included in our predictive model.

A form of stratification, we're stratifying by facility type. And we are taking spinal cord dysfunction into account in our predictive model. Is it perfect? No.

Is it patient oriented? I would say yes, it patient- oriented. The fact is that we are concerned about the type of patient in an institution we have the capacity to capture some of that. Would we want to have individual patient diagnoses? Absolutely. We would love to be able to move to that level of detail. We can talk further about what some of the issues are there.

Benita Kornegay Henry: Any other comments? Lisa and then we'll close it.

Lisa McGiffert: I just want to be sure I understand what the patients are experiencing. So if one has a spinal cord injury and they're in the hospital and I have a catheter, I'm assuming we're talking about patient who come into the hospital and their already disabled. But also that there are people who come in from trauma and then they with a spinal cord injury, correct? And do they - is it typical? I just don't know that a person with a spinal cord injury would stay in the hospital for long periods of time. Or would they typically be transferred to a different kind of hospital? And thus the denominator is definitely a component of the score of that hospital. That make sense?

Man: Yes. So typically, one with a severe spinal cord injury would be admitted for about 14 days to the acute care hospital, longer if it was severe trauma. Then at that point ideally they would go to an inpatient rehab facility that has experience dealing with neurogenic bladder. However, at our local Level I Trauma Center about 30 %, we actually have numbers, about 30% of spinal cord patience don't go to inpatient rehab. So they'll go to a skilled nursing facility or (LPAC) or sometimes home. And so they never get that training on here's how to safely manage your bladder.

So if they have their Foley pulled at the other hospital and said bullies are bad and nobody was there to teach them will actually Foley may be the best way

to prevent (unintelligible) which is a light life-threatening condition and renal failure. Then they don't - where do they get that training from?

Woman: (Unintelligible).

((Crosstalk))

Benita Kornegay Henry: We're done.

Ed: Okay, so we're going to take a 15-minute break. We'll cut it short by five minutes. That was a great discussion. And we'll come back and discuss the CAUTI measure itself. Thank you very much to the public comments.

Man: Thank you.

Woman: Thank you.

(Lucy): This is (Lucy). I'm going to stay on the line and not hang up, so I don't miss it when you guys come back. I'll just leave myself on mute.

Ed: (Lucy), we would miss you if you did that.

((Crosstalk))

Ed: As we're coming back from break, I want to make sure that (Don) is back on the line.

(Don): I am.

Ed: Good, because I'll just discuss it for an interesting measure.

(Don): Interesting is an interesting way to word it.

Ed: But I know that you're up to the task. So I've got four more minutes and then we'll start back again if that's okay with everyone.

Woman: For everyone in the room, we have a four-minute warning. We have four minutes left with our break.

((Crosstalk))

Ed: Is the CDC still on the line?

Woman: Yes, we are.

Ed: Excellent.

((Crosstalk))

Ed: Okay, we're coming up to one minute, excuse me. As you're all gathering we've had two other CDC maintenance measures to discuss before lunch. You're all away of the quality measure which we'll take up in just a few seconds. And then the star measure and then we'll have public comment and then break for lunch. So that's the plan of the second half of this morning.

Benita Kornegay Henry: Thanks Ed, I will assemble everyone. If everyone in the room could please make your way back to your seat or make your way to the table, we'll begin our next measure discussion.

Ed: Can’t be there.

((Crosstalk))

Benita Kornegay Henry: Okay Ed, you're on.

Ed: Okay, thank you very much for a great start. We're going to go back to 138 which is the CAUTI measure which is maintenance measure. And (Don Really) is going to be our discussant. So (Don) take it away as we look through the first part of this measure which is the importance of the measure loading on evidence and gap.

(Don): Thanks very much. And I apologize for not being able to join everybody in DC. I do think I probably have one of the better excuses and that I became a grandfather twice inside of eight days including yesterday. So I chose to not leave under those circumstances. I have two grandsons now. Heretofore I had none. So and then also (Mike) who was there presenting from the public commentary, good to hear your voice. I lived in (Coppers Cove), Texas for four years and I bet you're one of the few people aside from Ed who knows where that is. So -

(Mike): Yes, it's a big state.

(Don): Yes, but it's not that far from Austin.

(Mike): No, it's not.

(Don): So as you mentioned, measure 0138 deals with catheter associated urinary tract infection and it's a maintenance measure. And a brief description of it is that it's an infection ratio and looks at healthcare associated, we call it urinary tract infection, but it's actually growth of bacteria in the urine which isn't

necessary infectious. And it uses essentially people who are vetted at a variety of different types of settings. I think it's actually one of the strengths and that it not includes general hospitals. It also includes long term acute care facilities, rehabilitation hospitals, and other types of hospitals. It does not focus on Level 2 or Level 3, neonatal intensive care unit patients.

So that's not technically an exclusion, but it's not part of the target population. And the idea is that there is much we can do to refocus the deployment of indwelling catheters particularly those that are there for an extended period of time that will improve patient outcomes. And not only improve outcomes but avoid costs.

And so the numerator is the number of healthcare associated urinary tract positive cultures called infection among patients embedded locations. And the denominator is the prediction of such. And there are some modifiers of the denominator statement. One of the questions I'll have for the developer is and it's pursuant to other ones. It does say proportionate of admissions with traumatic and nontraumatic spinal cord dysfunction. So obviously there is some of that information available. My guess it's just not at the patient level.

There are a few denominator exclusions. It's essentially four catheters that do not truly dwell inside the body for more than a very short interval. The only except to that is the (unintelligible) tubes are excluded. Don't really understand that one, but this has been in place for a period of time. It is an outcome measure and it has been evaluated already again. And we have lots of information.

Any questions about the basics of the measure?

Iona Thraen: This is Iona. Is the data that was submitted because we have these different types of institutional care related to long term care, rehab care which you could assume have a higher percentage of long term use of catheters. Was there any submitted that indicated disparities across different types of institutions?

(Dan): I think most of the opportunities lies in the differences in either patients and/or locations. I'll let the developer answer that. In that there's an upward tend we're already getting into some of the evidence data. If you look at it, they're looks to be year-over-year improvement through the use of this measure. In other words, fewer and fewer of the associated infections by - and you would say we it the (unintelligible) soon? But to my look, it looked like some of the persistent opportunity was in that hetero (unintelligible) area. I hope the developer might be able to comment on that.

((Crosstalk))

Ed: You mention that, I again, sort of, may have been an oversight on my part. I assume that developers were the same as for the (Clavsy) measure. But if not, if you might introduce yourself if you're new to this particular measure. I apologize for not asking that before.

(Dan Pollok): So Ed and (Don) and Iona and other. (Don Pollok) here at CDC. It's the same group of us as before the break who were talking about (Clavsy) with you. And we got into some of the issues that have been brought up since the break before it. We do have separate predictive models by type of facility. So as we said earlier, the acute care hospitals, the general hospitals have their own CAUTI predictive model. The inpatient rehabilitation facilities have their own predictive model. And we have those separate models because there are

differences. You can call them disparities. They're differences by facility type.

There are also differences within facility types as we were talking about earlier when the proportion of patients with spinal cord dysfunction is relative high within an inpatient rehabilitation facility. That's an independent predictor of CAUTI and we incorporate that in our predictive model. And it is location based. And what am I missing in terms of the questions that have been posed?

Benita Kornegay Henry: That helps. I'll hold the rest the questions until we get into a later state.

(Kathy): This is (Kathy). I'd like to make on small correction to the information. And that is that the measure does not include solely positive urine cultures. There's has to be the infections, what we believe to clinically be infections because there's a required symptoms. So they have to be symptomatic. Or if they're not symptomatic, they also have to be bacteremia with the same organism. So there is no asymptomatic that your urea as a part of the definition.

(Dan): Right, I didn't want to dwell since this is a maintenance measure that the symptoms doesn't - there's a lot of debate about whether the symptom actually has to correlate to the culture positivity. In other words, someone with a longstanding indwelling Foley catheter who grows an organism and has a fever may not actually really have. Yet that would automatically trigger it. That's a conversation that existed when this measure first came up. And we'll not likely solve today. I didn't mean to suggest that it was only the culture. But it's largely driven by the culture.

Benita Kornegay Henry: David?

David Stockwell: I think the enthusiasm around these discussions represents that this measure has obviously been effective. So that's great. One of the things that if it would be more appropriate to wait for me to discuss this in validity. That's fine. But one of the exclusions that I don't see any evidence for, and it has nothing to do with spinal cord injuries. Is the neonatal ICU exclusion. As a pediatric (unintelligible) as a pediatrician, I do not understand that exclusion. I did not see any evidence for rationale behind that exclusion. I'd love to hear more about why those patients are excluded. And just what - why is that there? That doesn't make a lot of sense to me.

(Dan Pollok): Good question, if can respond right now. (Dan Pollok) at CDC again. Based on our interactions with neonatologists, the frequency with which urinary indwelling urinary catheters use is in neonate is such which is a state quite low. And to really make it nonproductive to use this measure in the neonatal unit population.

Ed: I would suggest at that, with the success of this measure, I would suggest that maybe an area you'd like to revisit. Catheters are used in the neonatal ICU. They can cause infections. And so therefore I would hate for them to be getting a pass in an area where they perhaps should not need to (unintelligible).

: We'll certain follow up with our neonatologists with whom we're doing quite a bit of work on some other measures. So appreciate the guidance. Thank you.

Ed : Yes, that's an interesting comment. (Dan) knows full well we've been working with them with the upcoming saw measure where they're certainly not included yet. But there's been a lot of work done because they're too complex population to study because a lot of variables that you have to take into consideration.

Man: You know, and then Ed if I could just briefly add that in addition to the work that he would describe on antimicrobial use, we're also, intending to submit to NQF, a measured proposal on late onset sepsis and meningitis in the neonates So stay tuned for that one.

Man: Look forward to it. (Don), why don't get in proceed with the evidence and the gap?

(Don): Keep moving. Okay it looks like you'll see them on your summary data there if you look at the standardized inspection rate. It really looks year. Progress, which suggests that the measure has benefit as applied currently. And yet as we already have talked about, I don't think it's hit a level in which we have to wonder whether it needs ongoing utility. In other words, I don't think a whole opportunities been extinguished although we'll begin to hit areas where the opportunity is more on the fringes rather than in the, you know, the meaty part of (unintelligible). And so I think there is both evidence of effect and ongoing opportunity.

Woman: So, this is for the developer. The gaps that are identified in the document here. Across all institutions are specific to acute institutions and you have performance gaps specific to the institutional type that we can look at.

(Don): We certainly can produce the performance gap data for institutional types. But what we have right now is really the overall findings. I'm confident that we've done analytic work at the facility level. I just don't have it at hand right now.

Woman: Okay, and then under the disparities comment, I just want to make sure that we're clear. It's been (unintelligible) agree with that disparities comment? The patients hospitalized as acute cardiovascular disease, mowing in major

surgery, Asian and Hispanic patients have significant higher rates. Is that just a global comment? Or is that specific to this particular measure?

(Don): That's a global comment.

Woman: So that's still global. Okay.

(Don): Yes, HIA is across the board.

Woman: In general, okay.

(Don): Our literature, we're trying to be as inclusive in our responses as we possibly can recognizing that this particular study is really across all HIA categories.

Woman: So you've got your reported data. Have you don't any kind of disparity analysis on the data that you have currently? And can you speak to what the disparities might look like?

(Don): Yes, we have race and ethnicity as optional fields in NHSN. And unfortunately the data are very incomplete and spotty. So we actually are not using the race and technicity data for analytic purposes.

Woman: What's the rationale for making it optional?

(Don): Simply because it - there's so much variation in how race and ethnicity data are captured from institution to institution. And are preference would be to bank on any data that we have at least some degree of confidence can be consistently ascertained. It's possible to link some of our numerator data which is at the patient level. With other data sets that could provide

sociodemographic characteristics. That's certainly an avenue that we have considered pursuing. But it's not one that we've done to date.

In large part because again, when you go back to what the larger literature indicates, that once you're in the healthcare facility. And we're talking about healthcare associated infections, the extent to which disparities that might have an impact, demonstrable and significant impact outside the four walls though lessens if not goes away entirely.

((Crosstalk)

Ed: (Charlotte) has her hand up.

Man: Go ahead.

(Charlotte): I want to just speak to the disparities. And I would urge you to consider putting that down as a required field. We recognize that we are not identifying disparities consistently. But unless someone like the national organization requires it for reporting, it doesn't then put the pressure on the facilities to bring their capture of data up to speed. And so we have an opportunity to really drive some improved reporting on disparities. And so I would strongly consider you to consider that or ask you to consider that.

Man: Thanks you, we certainly with (unintelligible) the guidance.

Benita Kornegay Henry: We have Pat and then -

Man: (Unintelligible).

Benita Kornegay Henry: Wait a minute, Ed. We have Pat and Lisa.

Pat Quigley: Thank you. This is Pat's voice and my question to the developer, Dr. (Pollok) is the issue surrounding president on emission. How the under - issue is surrounding misunderstands or press it on emission we're accounted for and how that's been excluded from hospital acquired CAUTIs?

(Kathy): This is (Kathy). I think I can answer that. Prior to 2016, the NHSN protocol just stated that unless an infection was considered to be present or incubating in the mission, it would be considered in HAI. But it didn't provide any other objective timeframe. Recognize that was being interpreted in different ways by different facilities. And so we really tried to make it more objective. And that was when we moved to the two calendar day requirement that if the date of the event occurred on either of the first two calendar days of admission, it would be considered present on admission.

Anything after that, so on Day 3 or later would be considered healthcare associated infection. So we've made that much more objective than it was in - prior to 2016.

Man: Yes, if I can step in. That may be a good discussion under a liability and validity, but I think what we're trying to get past here is to vote on the evidence and the gap first. If I can kind of refocus on that please.

Benita Kornegay Henry: Okay so before (Ying Ling) and (Tracy) have their cards up.

(Ying Ling): I just wanted to comment on the disparities issue. I think (Charlotte)'s comment was, you know, if one major agency would require it, it might change everything. But this fundamental problem that Dan mentioned is that people in these facilities use different techniques to identify someone's race and ethnicity. And it's not consistent and that has been, you know, a major

problem ever since I've been working on these issues which is several decades. And it's going to take a more if you really want to capture that information, you have to nationally create a standardized way to do that so everybody's doing the same thing. Because that just isn't happening and hasn't happened forever.

Benita Kornegay Henry: (Ying Ling), excuse me. Thank you.

Tracy Wang: I just - I have a question for CDC is about under the denominators statement, no exclusion, no statement, and you mentioned previously that you have a different model for different type of facility like long term acute hospital, acute critical (unintelligible) or inpatient rehab facilities, could you help me understand a little bit more. You have a model and you have a different calculations, how do you use this data to help you to get your results?

Man: Well if I understand the question, we use our incidents data that are reported for a given calendar year, 2015 in this particular case to assess what the predictors are of the outcome of concern. And because the facility type is a predictor, we separate the facilities and develop models by facility type using the available characteristics that we have. That enables us then to produce benchmarks by facility type. And the facilities then can compare their performance to like facilities with the understanding that there are differences even among like facilities and to the extent possible, we take those differences into account. And the predictive component of the standardized infection ratio.

That enables the facilities to have benchmarks. It enables the data to be used by facility category for public reporting purposes. And our experience helps to drive change because the data are that much more relevant than they would otherwise be.

Tracy Wang: So in other words, there's a risk, almost like a risk adjustment based on your model. And for the different type of facilities. So they now all penalized in the same way. Is that - am I understanding correctly?

Man: Well in terms of how CMS uses the results in the various programs, the various paper performance programs. That's really more of a CMS determination than a CDC determination. We provide the summary measures, facility level summary measures and their different categories of CMS programs and they ultimately make the decisions about how the data fit into an overall score. And hence how the data figure into incentives of penalties.

Tracy Wang: Could I - one more question. So there's some concerns about because the public reporting and the financial incentive involved with this measure, and there are some observations that some facility would pull out the Foley early than necessary, therefore it's not in the best interest about that patient population. In your perspective, are you concerned about that at all?

Man: We are always concerned about unintended consequences particularly those that could be detrimental to patient care when we were first hearing about some of these unintended consequences, we worked with CMS to issue a communique. I believe it was eventually published in 2016 and that provided 2015 or 2016 or '17. That basically reiterated the importance of avoiding exactly the practice that you're describing because it has an implication for deviating from a standard of care which is in violation of Medicare's own payment practices.

So we take it very seriously. We have concerns about a number of the measures with respect to unintended consequences of these sorts. And we use every opportunity that we can when we hear about these concerns and

oftentimes we will hear about them from individual infection prevention in hospitals. We do whatever we can to support the response internally to those concerns as well as raising its profile though the communications that we do with CMS.

Tracy Wang: Thank you.

Ed: I hate to do this, but I'm still going to try to get us to focus back not on the scientific measured properties, but on the evidence and the gap. That's what must pass before we go to scientific acceptability. So we've gotten a little off tract and so if I can plead with you, let's do the evidence and the gap. (Don) do you have any other thing you want to say about evidence and gap?

(Don): No, I agree with you completely. I think we're ready to act on that.

Benita Kornegay Henry: We have questions here. Tracy.

Tracy Wang: Yes, -

Ed: Is it about - wait a minute. Is it about evidence and gap?

Tracy Wang: Yes, it's on disparity, yes.

Ed: Okay, fine. That's fine.

Tracy Wang: I have a comment. As an insurer, you know, collection of race and ethnicity data is voluntary. But we do have a way to assess disparity. We do some imputation methodology based on the members and last name. And also the code is the Rand methodology that is pretty widely used. And so I would

recommend that the developer look into using the Rand methodology on imputing race and ethnicity data to provide a disparity analysis.

Benita Kornegay Henry: So there on the CDC, did you see that recommendation?

Man: We did. We appreciate that.

Benita Kornegay Henry: Okay, I have a second recommendation. This is Iona. For the next review cycle, if you're measure is capable of looking across institutional types, and this is related to performance gap, Ed that we see data across those types as opposed to the global performance measure. We look at it from the point of view of your capacity to segment across those institutional types. So that we would get a better sense of what's going at the rehab level, at the acute care level, at the long term care level, et cetera.

Man: Makes sense, appreciate that. Will do.

Benita Kornegay Henry: Okay, Ed.

Ed: Any other discussion on the evidence? So maybe we can go ahead and vote then on evidence and gap.

Benita Kornegay Henry: Okay, thanks Ed. We are now voting on the evidence of the Measure 0138; Option A is pass. Option B is do not pass. Voting is now unlocked, and you can vote on the evidence of Measure 0138. Option A is pass. Option B do not pass. Looking for three more votes.

Woman: Yes, (unintelligible) get back in.

Benita Kornegay Henry: No worries. Okay, looking for almost there.

Woman: (Unintelligible).

Benita Kornegay Henry: Okay, we are going to close the vote now. We have a verbal confirmation for one vote. So it looks like for the evidence of Measure 0138, 20 individual votes to pass, and 0 individuals voted do not pass. So for the evidence of Measure 0138, this measure passes the evidence criterion. And we can move to performance gap.

Ed: Fantastic.

Benita Kornegay Henry: All right.

Ed: Are we moving to the scientific acceptability now or liability (unintelligible)/

Benita Kornegay Henry: No, not just yet.

Man: (Unintelligible).

Benita Kornegay Henry: We need to vote on performance gaps first. I'm keying that slide up, okay. All right, so for the performance gap of Measure 0138, voting is now open. Option A is high. Option B is moderate. Option C is low and Option D insufficient. For the performance gap of Measure 0138 Option A is high. Option B is moderate. Option C is low and Option D insufficient. Okay, just looking or two more votes. Wonderful, voting is now closed. For the performance gap of Measure 0138, 1 individual voted high, 19 individuals voted moderate, 0 individuals voted low and 0 individuals for insufficient. So for the performance gap of Measure 0138, this measure passes this criterion.

Ed: Great, so now guys, we can go to the scientific acceptability. I also will remind that the group and tell me if I'm wrong about this. This past the scientific method panel for reliability and validity. But I suspect that there still may be some questions for the committee.

(Don): Yes, this is (Don) and you are right Ed. This has been to the method panel already and had a positive vote there. On the reliability side, the testing was done at the data element level. And they're described actually, it's a little bit of a challenge to sort through the reliability and validity kind of in an overlapping presentation. It appears that there's a large dataset available to evaluate the measure and the individual criteria.

It looks like the results were driven primarily from ten states which to my read I don't see any reason why I would not expect that to reflect the entire 50 states experiences. Data, the validation is, conducted by trained auditors who review records. All the usual performance metrics, sensitivity, specificity, predictive values, are calculated at the panel before us.

There was some concern about more advanced measure score testing. I don't actually retain that particular belief. I think the actual both reliability and the mechanical side of the validity testing both are adequate. I think our biggest issue is what we have been talking about just prior to the break. And will be likely talking about now is on the validity side are appropriate exclusions considered and particularly those with the spinal cord injury group.

It's clear given what we heard earlier that the total number of people with that particular condition compared to the population who would be risk for urinary tract infection is small, but they also have not only different frequency of urinary issues. But a complication that is really unique to them and that's the

autonomic dysregulation part. And so I think the validity side may be where we have some brisk dialogue now.

Benita Kornegay Henry: We have a question here, David?

David Stockwell: Just want to very briefly because we get into the spinal cord injury topic, just implore the CDC to not rely on the neonatologist view that they don't have CAUTIs and actually if they aren't placing Foley's then they'll have great CAUTIs rates. And again, if - when this comes back up for reinforcement, that that population should really not be excluded. I just can't find any justification anywhere in the literature or just even with any face validity.

Iona Thraen: And this is Iona. I have a question for CDC. So is it - it's my understanding that if a practice goes against current standards. So in the instance of CAUTIs and spinal cord injured patients, if a practitioner decides that keeping a catheter in there is the appropriate methodology for that particular patient. All they have to do is mark that into the chart. Is that correct? And then it's sort of overridden or taken out? That's my understanding but I don't know that's the correct understanding.

Man: Well if I understand your question, yes. I mean a standard of care would be to document that urinary catheter has been inserted and used and to have an explanation for why. That would be fantastic if we had that in a consistent way.

Unfortunately, we don't. But we do what we can in terms of our methodology which does not rely on a statement of indication for the use of a catheter but rather the presence of the catheter in use which is enumerated and used as part of our catheter day denominator (unintelligible).

Iona Thraen: When this is reported - this is being captured at the local level usually manually by an infection control person, and if there's an indication against removing the catheter for whatever reasons. And that indication has been documented in the chart and by the provider, is that then captured and counted anyway?

Man: Again, we don't capture indication or documentation that might suggest there isn't an indication. What we capture is that the presence of a urinary catheter - indwelling urinary catheter.

Iona Thraen: So it's a yes/no, with no modifiers associated with it?

Man: Well it's actually a count. So it's a matter of identifying patients who've got indwelling catheters. And sometimes it's done by simply making rounds in a particular patient care location and enumerating those who've got a catheter in place. In some instances it's available in electronic health record, but we would like for it to be more consistently available in electronic health records.

Benita Kornegay Henry: Lisa.

Lisa McGiffert: So (Dan), I know between endorsements there are often many changes that you make on definitions and how people submit data and that kind of thing. So how difficult would it be to have some kind of check the box or some kind of indication like Iona was talking about and what Jason was talking about where it was clear that there were certain - there was a certain number of patients or patients per unit or I don't know now it would be done. But some kind of indication that would allow you guys to analyze these patient populations a little bit differently. And I don't know if that gets to the problem, but it seems like it would be relatively easy to ask hospitals to give some one more level of detail information on the type of patient it is.

Man: So thank you, Lisa. I think it's a very interesting line of thinking. We'd love t to pick it up. Don't know that we'll necessarily have the opportunity to do a deeper dive into it with our discussion today. But we're glad to follow up and look further into the ideas that you're suggesting.

Lisa McGiffert: And I think need to be consulted with some pother people who know precisely what is the information we need collected and not depend on my interpretation of it.

Man: Understood.

Benita Kornegay Henry: Pat.

Pat Quigley: My question, and I would like more information on terms of validity and reliability on the issue surrounding present on admission and the three day after admission for determining whether or not a CAUTI is actually present. Considering the settings of care that are documented in acute care, the average length of stay for medical/surgical patients is still 72 hours. Critical access hospitals even though their small beds, 26 beds, 30 beds, oftentimes of the patients are admitted are in swing beds. They're admitted from long term care and they stay there. And long term care it's a very different patient population. The long term acute care hospitals as well as or - so we could have a little bit more discussion present on admission, also risk adjusting for the population.

We've talked about diagnoses but even patients are admitted from nursing homes. So if you could help explain that a little bit more that would be helpful. Thank you.

Woman: I'll do my best (Kathy). So yes, so different types of facilities that you mentioned area all stratified differently and have their own rates and FYRs that are calculated. So the (unintelligible) are separate from (Irs) and from the acute care facilities. And I don't know about critical access hospitals, if those are separated from acute care, okay. I'm not on the analysis team, so I do my best here.

As far as the question related to the patients coming from nursing homes, I think I need to understand that question a little bit more. Is the question related to them coming in with a catheter and therefore how would the three-day rule apply?

Pat Quigley: Thank you so much for that question. It's more about being colonized rather than having a Foley catheter already having a low grade urinary tract infection. Thank you.

Ed: Maybe the way to answer that, CDC, is to tell them what it is to emphasize the definition of what you consider a CAUTI now. Maybe that would help the discussion.

Woman: Sure, so you know, the urinary tract infection itself can be healthcare associated versus present on admission. But when we get to the definition for catheter association for the urinary tract infection, the catheter has to be in place for greater than two calendar days on the date of event to be considered associated with the catheter.

So if someone had a catheter put in one day and the next day they are have suprapubic pain and the take the urine culture and it's positive. Then that would not be considered catheter associated because the catheter had not been in place for greater than two calendar days at that point. Is that helpful?

Ed: Yes, and also the changes about the colony count in (Candidoria) that took place a couple years ago also.

Woman: Yes, that was four years ago now. We did in 2015, we did do away with the lower microbial count for the colony forming units in the urine cultures. That really was based on findings form surveys that we had done in conjunction with the American with (APIC) and understanding better that not all facilities would identify lower colony counts in the urine and trying to level the playing field for all of the facilities that were reporting.

So some of the facilities that were actually reporting growth at lower colony counts were being unfairly penalized. And so, you know, we had to reassess that. And you know, back in 2015, the urinary tract infection definition went - underwent a major renovation based on about two years' worth of working group input and discussion about the definition themselves including probably the biggest change which was the removal of yeast from the full - as being a full cause of the urinary tract infection. And that really was to reflect the clinical determination that most cases where yeast is the only organism in the urine, it's not usually a urinary tract infection. It's usually colonization.

Ed: Yes, I thank you for that answer. Of course when the definition changed I think around 2009, 2010, they removed the asymptomatic part and CAUTIs went in again (Dan) and others correct me if I'm wrong. I'm just doing this for historical purposes. CAUTIs used to be the Number 1 cause of HAIs and it dropped to Number 4 when the definition changed indicating that a lot of CAUTIs in the past were really asymmetric bacteria.

Man: I think you're right on Ed, thank you.

Ed: So I just for historical …

Woman: (Unintelligible).

Ed: … perspective. (Charlotte) had a hand up so I want to make sure we're good to the people on the phones. So (Charlotte)?

(Charlotte): Okay, I'm off mute. So I'm just wondering, one of our earlier measures that we discussed had an exclusion where use of the measure might cause patient harm. And when (Matt) was talking about his patient population, there are some patients that can do intermittent catheterization successfully and well. And there are others that can't. And so I'm wondering if this might be a place where an exclusion where it might cause patient harm would be appropriate.

(Dan): So thank you for that. I think it goes back to the question of the extent to which the harm you're describing and that (Matt) has described is occurring. And if we had a compelling evidence and acknowledged that it's difficult to ascertain, but if we're talking about catastrophic outcomes, in high risk patients, and we're still unable to determine beyond anecdotes and beyond very dramatic and painful stories the extent of the problem, I would say from our perspective, we don't want - we're prepared to act but we don't want to act without substantial, credible scientifically sound evidence that there's a reason to act.

You know, we get a lot of inputs about can you exclude this patient group? Take that patient group. And we do our utmost to work it through with the folks who are bringing to our attention these requests. And use wherever we can, the approach of well where are the - where is the evidence here? Where is the magnitude evidence here? Undoubtedly there are tragic episodes and outcomes of mismanagement that have some relationship to what the acute

care practitioners do or do not know about managing bladders in a very high risk patient population.

But if that's the issue, and it's that catastrophic, we should be working to address that issue head on. And bear in mind, the spinal cord injured patient are at high risk for urinary tract infections. We have CDC prevention guidance that includes guidance as to how to prevent in the spinal cord injured patient. There are advances being made in the catheter technology and we don't take a fatalistic approach to say well, they're all going to get urinary tract infections regardless of how they're being managed. That's not acceptable. We want to do our utmost to prevent the infections particularly in high vulnerable patient populations.

Iona Thraen: Dan, this is Iona, have you looked at - have you done any kind of analysis between - so you talked about the different methodologies by institutional type. Have you looked at rates between acute care, rehab, long term care, et cetera to see if there's any significant differences in their overall CAUTI rates.

Man: Yes, we have.

Iona Thraen: What do you see?

Man: Well we find significant differences and that's why we break out by facility type and establish models for each facility type because there are these underlying differences in the patient population.

Iona Thraen: Right, but my question is what - to what extent? Are you talking about there's a two standard deviation difference between a rehab facility versus an acute care facility in terms of infection rates? Or to what extent are the differences?

Man: I can't give you a quantitative statement about that. Don't have that information in front of me. But we certainly can pull it together.

Iona Thraen: Okay, we'd like to see that, I think and then (Steve), you had a question?

(Steve Wallace): Yes, this is (Steve Wallace). A question for you because these are a lot of questions people are asking. I got - understand you're saying how hard it is to collect the data. I would say that probably not for this cycle, the next cycle, I would try to make this an e-measure. The amount of data sources you were asking for you're saying can't be done over - is hard, actually are fairly easy within an electronic record own.

And I think maybe mechanism of collecting the data for this measure are outdated compared to what should be happening. I don't want to put that before us. So you'd actually be able to see. That's one thing, and the other piece is, is there something (unintelligible) like they do with (Nisquip), surgical quality improvement program? Where there's an inter-relater reliability testing that goes on with the person at the facility who actually monitors this. It's a very complex process to (unintelligible) urinary tract infection. It's a couple pages of decision supports.

But do we know there is actually inter-rated reliability that works here?

Ed: You want a campus score?

(Dan): Yes, we would love to be able to have the resources that are available to ASC, (Nisquip) and the ACS (Nisquip) hospital subscribers to do the type of inter-relater reliability evaluation. We don't have those resources. ACS (Nisquip) is a subscription service. We provide the NHSN software without charge to the facilities. Yes, they incur costs, because an infection prevention system staff

are responsible for submitting data. But we don't have the wherewithal frankly that the American College of Surgeons does with their system to support data validation.

Would we like to strengthen data validation, absolutely. WE think it's the Achilles heel in fact of the whole movement to value-based purchasing which depends on credible outcome data. We as a society are moving in that direct and yet, were not investing in data valuation to the extent that it is needed to justify use of the outcome measures for the purposes to which they're being put. We'd be the first to acknowledge that.

Ed: Thank you (Dan). It is a problem throughout the industry. It's certainly a problem with sepsis, in terms of (capa) reliability between different clinicians. (Don) had a question on the phone though.

(Don): Yes, so two things. First and foremost from the developer, one of the answers was about the present on admission. You talked about two-calendar days. So if I'm understanding this correct, a catheter placed at 11:30 at night, if 24-1/2 hours later a fever and a positive culture existed, that would be considered hospital required. Is that correct? Because it would be technically two calendar days even though it was not a particular long period of time.

Woman: That is correct. When we moved to, in 2015, to use of calendar days, there was discussion about the electronic health records. And the fact that auto stamped times are used. And if a late entry is made that would automatically be stamped with thee entry rather than necessarily the assessment of the action. And so it was determined that the calendar may be accurate than the actual time that was associated.

And so that was the rationale for using calendar days versus hours.

((Crosstalk))

Ed: That just helps me understand a little bit more. Thank you very much. And my only other comment is as a clinician and getting some of the feedback about this exclusion concerns particular in the spinal cord injured patients. I run 24 emergency departments and have about a million patient visits that roll up to me in a year. So given the feedback that we got, I actually tried to poll how frequently there were autonomic regulated complications in spinal cord injured patients seen in our emergency departments. For the exact reason that I think (Dan) notes that if it was such, you know, we should - if it's a really big problem, we should know something about it. There should be more than terrible stories and I will tell you, I could not pull it, and I think it's exactly for what (Matt) described. And he and I haven't spoken area before in that I don't think it's well recognized or well documented.

And so I had to use (unintelligible) because Ivory College over the weekend who could easily show me four cases in six months of really bad related events. Yet on initial, not only electronic search, but even a chart review wasn't done by the right person. This would have come up. So I'm retain concern that we have a subgroup that has an acceptably morbid related complication that will flourish as folks are trying to follow the measure. And they try to find some way to address it. I know it's not big unit. Vis-à-vis, the population that are all hospitalized. But it's an unusual and important subgroup. And I say my files keep changed in the past week. I didn't have the concern before.

I don't know if the developer might be able to help us get past this. So thanks (Don). No, you know, I think that what you're pointing out is yes it's a challenge to get at outcome data. But it sounds from what you're describing is

that you actually were able to get to it fairly quickly. And so my question would be if you can do that, how come others can't do that? And let's get to an actual scientific rigorous assessment of the extent to which this problem is occurring and then the more difficult the connective problems, the extent to which it can be attributed to a response to the measure itself to opposed to simply not understanding how to take care of these patients.

(Dan): All good questions, my in turn would be what should we do while we're trying to put together that approach? Because this is a difficult problem. If in fact we think there's a mistargeted group who has harm from it that hasn't been excluded. Does -

Man: Yes.

(Dan): All this will take time. I did it because I happen to know a physiatrist who could tell stories about this. But it wasn't any of the scientific rigor. So I could do it quickly but it's very dirty, no pun intended.

Man: Right and I think before we decide to exclude a vulnerable patient population from any measure, and after all spinal cord injured patients have a higher risk of urinary tract infection then non-spinal cord injured patients. Before we decide we're not going to include them in a measure, I think we want to have really sound evidence to make that decision.

(Kathy): And this is (Kathy), you know, I think for myself, you know, it goes back to education. And I actually was talking with the hospitals that we have, a consultant here, and she and I brainstormed. We said, you know, when mastectomies first started being done and we weren't supposed to be taking blood pressures on the arms of patients that have mastectomies, we could find them. Or we put a bracelet on the patient or somehow indicated that shouldn't

be done. And maybe the same thing needs to be done with these patients that are freshly had trauma and had a Foley put in. Maybe, you know, we need to have some of a flagging system that said do not remove this Foley unless YZ occurs. And I think that there are options that could be explored that might be in the best interest of the patient.

Iona Thraen: This is Iona. We've got two questions here at the table Lisa then David.

Lisa McGiffert: Just a quick question to CDC as to whether and how you are exploring making this and maybe others an e-measure. Have you been looking into that?

Man: With CAUTI per se, because there are clinical dimensions to our definitions, that raises the specter of having to have some type of consistently applicable practice with electronic health records. And as much as the records systems can provide valuable data that are entered in a structured format when we're talking about text expressions, we're still talking about a major effort to get the standards and have them applicable technologically across the various platforms that are in use right now and the way the practitioners are using. I wish we were further along in being able to use the clinical statements and electronic health records. Not the discharge diagnoses about the clinical statements and the records themselves for quality measurement purposes, but we're not. And while there's steps that we can take and we're beginning to look into some of the techniques that could be used to identify cases from tech strings, that's still a whole bunch of work ahead.

Iona Thraen: So does (NH) (unintelligible) currently receive any electronic submissions through the EHR or is it all still pretty manually entered or?

((Crosstalk))

Man: Extensive amount of submissions using electronic health record systems.

Iona Thraen: Okay.

Man: But what we're talking about right now is that a precursor to that. It's not just a matter of reporting the data from a system, that's a relatively easy process to set up and maintain in 2019. The precursor step of identifying cases using clinical statements and electronic records in a consistent way across different platforms and facility types, that's a much higher bar for us to get over.

Iona Thraen: Okay, David.

David Stockwell: Just a quick comment on the spinal cord injury conundrum, it would seem to me there's not a lot of areas of research that administrative data can provide some insight. This seems like it maybe one area that there could be some real identification of morbidities associated with this type of removal of a Foley catheter and a spinal cord injury patient. And there's obviously massive datasets that are amendable to that kind of searching to provide the evidence that we're talking about.

((Crosstalk))

Man: We'd love to see those data.

Ed: Okay, so we're still on reliability and validity, so are there any other comments related specifically to that before we…

((Crosstalk))

Woman: Yes, we have (Ying Ling).

Ed: Good.

(Ying Ling): Yes, thank you. This is a question to CDC. I am still concerned about, you know, those patients that would be harmed when they are necessarily have a longer Foley in them. And because the measure, they may untended consequences. I'm just wondering if the CDC will be open to the idea that since the data had been collected by CDC since 2005 and it would be able to work with, you know, stakeholders to really look at the data to see how, you know, what is the gaps of this problem. And also rather than another idea, rather than exclude the whole population of a spinal cord patient, have a flag like someone discussion. I suggest easily in your collecting your data just put a flag in there justification. Check the boxes saying the patient needs clinically justify needs a longer (unintelligible) cath. Will that be a possible approach?

Man: Well, we'd be glad to explore it. There are a multitude of issues underneath that, that I think we don't really have time to go into today. But we are always open to exploring alternatives or replacements to what we do if they make sense. And or adding to our data collection, again, if it's purposeful and compelling to do so. Absolutely.

Ed: Iona, is there any other hands up?

Iona Thraen: No, I think we need to - oh, wait a minute, Laura.

Laura Ardizzone: Just quickly, I distinctly remember having this discussion three years ago. And it sounds like we're having the same discussion. So can you remind me what our notes were from three years ago then? Does anybody remember? Did we say we wanted them to go back and work with the group again?

Iona Thraen: We haven't gone anywhere.

Man: I think if my recollection is correct, that was the recommendation last time. To go back and work, you know, have some further discussions amongst themselves that appear not to have been productive.

Ed: No, they've had discussions. But that's not true. I'm sure that -

Laura Ardizzone: Discussion, but no resolution or we're going to recommend discussing again.

Ed: (Unintelligible), well they didn't -

Laura Ardizzone: No resolution.

Ed: Unable to reach a consensus that would change the measure. So again, in (unintelligible) correct me, we are voting on reliability and validity as the measure is presented today. We may make again certain recommendations to the measure developer moving forward. But we're voting on this measure of having heard input again from our very nice people from the spine trauma group, but we've not resolved that issue. So that's my understanding. We're voting on the measure as is presented today with potentially a recommendation that CDC go back and look at this again.

Iona Thraen: So have a question. This is Iona. So if the measure meets the reliability/validity standard as we've already talked about as it's currently constructed and in the emerging needs, we say this measure is not adequate to meet some of those needs. How do we grapple with that issue? Is that a usability problem? Is that a performance gap problem? Is that a preconceptual? I can - could a measure go through all these pieces and pass and then at the end when asked to endorse, we say no? We're not endorsing it

because three years ago we had this conversation. We've not gotten - we've not made any progress and so we've got to send you back. What's the NQF's position on that?

Man: It's within your rights, yes, it is your decision. You are as Ed said voting on the measure as specified at this - today. You can make recommendations to the measure and sort of I've, in my experience, I've seen committees sort of make some conditional, you know, basically recommendations for the next time it comes up. If, you know, if you don't do this and this, the next time it comes up, we're voting it down. As sort of, a - that kind of a threat. But, you know, that is contenting on, you know, the committee sort of, following through with that and you know, the developer (unintelligible) as well.

Ed: Okay, and maybe we should go ahead on vote on the rest of the measure and then at the end perhaps we can put some conditions for the next time this issue comes up.

Iona Thraen: Right.

Ed: Or vote it down now based on some people may think there's a deficiency.

Missy Danforth: Hold on. I'm sorry. This is Missy. I'm having a hard time doing the hand raise thing. And I apologize for having -

((Crosstalk))

Missy Danforth: No, that's okay.

Ed: I didn't see your hand Missy. I'm sorry.

Missy Danforth: That's okay. I'm getting a little bit confused with the conversation. So it sounds like that there's been a repeated from last year, you know, last (maintenance cycle), this maintenance cycle request for some kind of an exclusion or different way of handling a certain subset of patients. And then the measure developer has come back and said (unintelligible) between cycles, we looked at this and there's not strong evidence that this should be an exclusion.

And now it sounds like this group is saying well, if the measure developer says that they look at a possible exclusion and found that there's not strong evidence for that exclusion. But we as a standing committee believe that there should be that additional exclusion, then we should consider, I assume voting down the measure of this particular criteria. And I think it's for liability where you have to look at the exclusions. Is that?

I think it's challenging if we ask the measure developer to look at something and we say we did look at it, and there's not strong evidence that this should be excluded. For then this committee to say well we don't agree with you. We think - I mean without, you know, vote on the committee bringing for the necessary. Someone bringing forth the necessary actual evidence that we would hold a measure developer to. I just want to be a little bit careful about what we're trying to say here.

Iona Thraen: This is Iona.

Missy Danforth: (Unintelligible).

Iona Thraen: I'm sorry Missy. I didn't mean to cut you off.

Missy Danforth: No, so I mean I'm just, sort of, trying to follow along what the committee has been talking about for the past, you know, 30 minutes. And that I've heard (Dan) repeatedly say different ways. I understand …

Iona Thraen: I think the problem-

Missy Danforth: … that this position (unintelligible) and anecdotally we understand that there is individual cases, but there's not a strong body of evidence indicating that any group other than those we've currently included should be excluded from the measure.

Iona Thraen: So what I got was that there's sort of standoff right now in the sense that the developers think I don't have quantitative evidence to indicate it's a problem. The advocates are saying we have some quantitative evidence but it's not really strong. We're not in a position to do a full-fledged development effort. And so there has been no resolution. We ask them to quote look at it. I don't think we defined what that means. I don't think we ask for a resolution. I think we just sent them back and said go talk to each other.

One of the things that I feel that we didn't get from the developer in the data is to look at rehab hospitals where there'd be a predominantly high population of this kind of subgroup in those environments. We don't have any idea what that performance gap looks like in those environments versus acute care environment. So I don't feel like the developer has brought forward in relationship to this issue any evidence to refute the anecdotal evidence that this is a problem either.

So I don't think we -

Missy Danforth: But I don't think we're talking about a performance gap issues. I mean I think -

Iona Thraen: Well I don't -

Missy Danforth: What I keep hearing, what I heard during the 10-minute public comment period, it's not that this is an issue with like with performance gap. It's an issue with, I think I'm hearing. Because these measures are used in payment providers may feel compelled to remove catheters before they should be removed.

Iona Thraen: That's correct.

Missy Danforth: Then I guess when we go to - okay, so it's not a performance gap issue. So if any (unintelligible) -

Iona Thraen: The reason why I was using the performance gap piece of this is try to get a sense of the size of the problem. So if the infection rates are minimally different between acute care and rehab care, where we know that in rehab care they're like to be more catheter days, et cetera. I was just trying to get a sense of the size of the problem. That's why I went there.

Missy Danforth: Because the size of the problem would give an indication of how much of this special population of patient is - has an overall hospital wide SIR. Because frankly that can be seen now in the reports that (unintelligible) make available. And I know there's - I think there's a (Don) you on PC and Jason from somebody from (unintelligible). Today you can see by unit what each of your actual predicted numbers of infections are at the unit level. I would think that you would have an overall sense of if a particular like a trauma unit or a (unintelligible) recovery unit is having an oversized impact on your overall SIR. And I want to be careful because I also found this (unintelligible).

And I'll tell you that these are the types of things that the (CSAC) looks at, right? So the measure passed. The measure passed. Then all of a sudden at the end, it didn't pass. Where did it break down? And so if the committee truly feels that its specific criteria that the measure doesn't make, then that's where the voting should take place. So if it's at reliability because it's lacking an exclusion, whether it's evidence or should be one, if it's that use and usability because there's some overwhelming, unintended consequence and so then people aren't - so I'm just kind of putting it up as a caution as we move through the voting.

((Crosstalk))

Ed: (Dan) could I just weigh in?

((Crosstalk))

Ed: I do have summary data from (IRF)s from our just-released progress report. And to the question that Iona is raising, there has been a 15% increase in CAUTI compared to the baseline year of 2015 in inpatient rehabilitation facilities between 2016 and 2017. So among the (unintelligible) 74 (IRF)s in the US with an updated to calculate and SIR, 5% had an SIR significantly higher than 1.15 to value the national average. And there are no significant difference between 2016 and 2017 overall, but among the 374, there was a 15% higher than the national average in a - among those facilities.

((Crosstalk))

Benita Kornegay Henry: So we have Lillee.

Ed: Wait on second. (Dan) in your risk calculation, see if I understand this correctly, you do look at inpatient rehab. You look at the proportion of traumatic and nontraumatic spinal cord dysfunction in your risk calculation, correct?

(Dan): Right.

Ed: And so I just want to make sure people understood that. It may not - it may could be fine-tuned but I don't want it to sound like the CDC didn't take that into account at all.

Woman: And I apprentice that actually. We hadn't heard or seen that. Lillee then (Steve) then Lisa.

Lillee Gelinas: Excuse me, thank you. And it's amazing, you know, we're not in the post (unintelligible) slump here after lunch and look at the level of the discussion here. I guess for the NQF staff I just have a process question. Because we were going to vote on whether or not we were going to accept the recommendations of the scientific panel. And I note that there were only four people on the scientific panel that were present to weigh in on this. And I think about, I mean, there are just a tremendous number of very smart people in the patient safety world sitting around this table. And think about our conundrums. There are only four that weighed in on the liability and validity from the scientific panel standpoint.

I'm not comfortable with that. Just from the standpoint of making sure that everyone weighed into the degree they needed to weigh in. So I don't know what to do about this conundrum when, you know, we only vote for ourselves. But if only four people were present for the scientific panel, what do we do?

So (Andrew) has said earlier if only one person on this committee is not comfortable accepting that, we would vote.

Iona Thraen: Okay. Thank you. Lisa then -

Lisa McGiffert: Okay just real quick. I don't favor exclusion. I think the point is not for the spinal cord injury patients, but I do think that CDC - the thing I want is for us not to kick this can down the road for three years. Because a lot of us aren't going to be here in three years probably.

Woman: On the committee.

Lisa McGiffert: On the committee, yes or otherwise. But I think that, you know, and (Dan) just came up with some information that we didn't have before. So what I would like is for us to - I don't know if it requires a conditional acceptance and we're not going to really accept it or endorse until we see their analysis of what they have now to show us. Whether it be rehab versus acute care or because I believe that they can do more than we've seen.

And so I'm not sure what mechanism we have and frankly if we have to sort of say well, we like this measure. I like this measure. I want this measure to continue. But I don't want this issue to continue. I'd like to get it resolved and I think that there are some things that they could do. And the other option would be for there to be a real concerted effort to try to do the research. Like get a state - give the state a grant to do in their state. What happened? Just like the validity process that they go through on this particular issue. And do a targeted study that we can put our hands around.

Benita Kornegay Henry: (Steve).

(Steve): Yes, there's a lot to what you just said. The - that will throw in there's a 15% increase over the last couple of years. There's an important throw in which actually supports the public comment. A little bit of hey, is there something changing here? So I would like to see that incorporated also. And if there's claims data, there's social security data, there's Medicaid data. There's all this stuff. I think, I know it's hard. Now you're seeing the big impact here. The patient (unintelligible) impact, so I would actually second that. I think there's a lot more data that can be obtained to separate out populations better.

Iona Thraen: So NQF, can we table this measure until we get additional information?

Man: That's an interesting question.

Ed: You want to table the measure?

Iona Thraen: What I wanted - so it sounds like from what CDC has said in pulling up the measure that there's additional information that they could share with us around this issue. So my question is can we table the voting, not the measure, the voting at this stage until we get some additional information to review and pick this up in our phone conversations that we have post.

Ed: Well the CDC, can the CDC give us a verbal report, or they just don't have it available yet?

Man: In what kind of timeframe we would want to know too.

Man: What I read to you earlier is from a report that's publicly available posted at our website that is our HIA progress report for 2017. So that's readily available.

Iona Thraen: So I'm going to go back to the review committee. So the subcommittee that actually reviewed this in depth, what is your recommendation?

(Don): So this is (Don), I'm the lead discussant. I actually think the newer data that we just got actually does offer some concern about harm from the measure. And I don't think tabling it. I think we have to act upon what we have.

((Crosstalk))

Man: The question I have, you know, it sounds like there's some things that can be tweaked and looked into, but if the measure has been effective over the years, is this the - is perfecting the, as Voltaire would say, is perfect the enemy of good?

((Crosstalk))

Man: I'm going to echo (Don)'s suggestion. I think we need to deal with it today and not push it forward. I have a lot of scientific concerns with this as I listen to the different issues from exclusion of neonatal, neonates based on opinion rather than rigorous evidence. So there's a lot of things that trouble me here. And I think we need to send a clear message that I think is coming through to CDC that this need some serious work regardless of what they've got in the parking lot so to speak.

Iona Thraen: Any other comments before we take it to the vote? None here Ed.

Ed: Well let's let the chips fall where they may. Let's vote.

(, : Okay, the hand raising thing definitely isn't working. This is Missy.

Ed: Oh, I’m sorry Missy. I know you were there, but I thought that was from before.

Missy Danforth: No, I don't know. I’m trying to send messages, but I don't know if it's not getting to you in real time. But so I apologize. I just want to understand where we're at with this measure. So where we're at is that we passed it on evidence. And we passed it on gap. And now we're at reliability or validity and we want to go to a vote. And based on some discussion, it sounds like there is some concern, I guess, about reliability. Is that where we're at?

(Andrew): I think just to clarify; I think the exclusion issue would sort of be implicated in validity rather than reliability.

Missy Danforth: Okay.

Man: (Unintelligible).

Missy Danforth: So can you clarify something (Andrew)? Because I think it was Lillee I heard say that there's some concern over only four members of the scientific method panel reviewing the measure. But my understanding is that at most it's like five or six people from the scientific method panel.

Ed: That's correct Missy.

Missy Danforth: Okay, -

((Crosstalk))

Missy Danforth: To make clear for like the other folks in the room who might not be aware that four is not a small number. Like that's the typical number, four to six is the

typical number of people reviewing all of the measures that go to the scientific method panel.

Ed: Yes, I can tell you on (CSAC) that four or five is pretty standard. They don't all review every measure.

(Andrew): All right, I'll note that the method panel has a number of times reiterated that they do see a number of these, of validity issues as being in the standing committees, sort of, scope of you know, authority. They try to look at specifically at the methodological issues whether the testing was done appropriately. Whether it got adequate results. And have recognized the number of times with their clinical issues related to validity that may need to be adjudicated by a standing committee rather than them. Things related to the things such as exclusions or risk adjustment, potential factors that are included are not.

So it's not, you know, way out of bounds for this committee to vote on validity related to concerns that are less about methodology and about clinical considerations potentially.

Benita Kornegay Henry: Jason.

Ed: I suggest we go ahead and vote and see what happens.

Benita Kornegay Henry: We have cards up Ed. So we have Jason and David.

Ed: Oh.

Jason Adelman: Sorry I'm going to introduce one more issue, and I apologize. This is just again from my personal conversations with other patient safety officers. Years

ago the denominator for CAUTIs was determined by and the developer can correct me if have this wrong, was developed in prime nurse managers who at round 10:00 in the morning, you could pick your time, would go around and see which patients on the unit had catheters.

And then a couple of years ago, the CDC introduced the ability to extract that data from the electronic health record which you had to validate against the manual process. And I believe that caused a lot of confusion and unfairness in the system because I think what is going on from conversations is that some hospitals instead of getting the catheter at a point in time, they just scan the EHR and find out, you know, (Jason Newman) had a catheter on these days. And so if I had a - in the old system, if my catheter was removed at 9:00 am, you wouldn't see it that day. But with the new system with scanning it, you do see it. So those that are using electronic methods for finding catheter days have many more catheter days than their denominator. I don't know if you understand what I'm saying.

Woman: I do.

Jason Adelman: It's like a video of the whole day as opposed to a snapshot at a point in time. So any - now you're not really supposed to do that. You're supposed to validate against the manual process, but in conversations I'm having, people aren't doing that. So like if you want to, you know, game the system, use the electronic way of capturing the denominator catheter days and you'll have many more catheter days. Your SAR will be less.

It' just - what I'm saying is, if you do it the right way, you would validate it but what I'm hearing is that people aren't validating. Or they don't understand how to validate it. And so a large portion of hospitals are using the electronic

way and some are using the manual way. And I think that's affecting the denominator and variance that isn't really about outcomes.

(Kathy): So this is (Kathy), if I could respond to that. You know, I - we have heard different things from different vendors related to how they collect the denominator days electronically. Some capture it at point in time. Some capture it as you said across the 24-hour continuum. But you are correct that the protocol does state that facilities have to validate for a period of three continuous months. And not have a difference of more than 5% in either direction between electronically selected data and manually collected data.

And we do get questions about it. So I do know that facilities are doing it. I don't have any more of an objective, you know, figure I think - what I think I hear you also. You know, to me that sounds - it's subjective. It's, you know, it's what you hear and, you know, we also hear that people are doing it. Because we get questions about it.

Benita Kornegay Henry: David.

David Stockwell: So this is a, excuse me, a process question. So I think this is an important measure. I think we could all agree with that. This has led to a lot of change and to a lot of good. I don't want to baby and bathwater this measure. I would like to personally see the neonatal population included in that. So and I have not been convinced to my satisfaction as to whether a recommendation should be made about spinal cord injury. So those are just statements.

My question for perhaps (Andrew), the NQF staff, are what are our options at this point if we conditionalize future endorsement which is the one thing that I think I heard you say earlier. That puts this down to three years from now. But what - are there other options that we have right now because what I

worry about is that if this committee does not endorse this measure that we are sending a really bad message out there to the healthcare world that the United States doesn't care about CAUTIs and I would hate to do that.

(Andrew): Yes, there is the option of, sort of, conditional endorsement. That's really informal condition. Again, sort of, subject to this committee then coming back in three years and, sort of, enforcing their recommendation. We have had in some instances a vote or endorsement deferred, you know, to a little later in the process if there's some additional information that could be useful to the decision making. I don't know (unintelligible) or not. And

Man: I have to ask the CDC, but I'm not sure that they have that readily available. So I'm not sure that's an option either.

(Andrew): Yes, it would have to be fairly quickly. You know, we would need (unintelligible).

Man: Yes, and I don't think they have that. It might be. I don't know. It's conditional, but I still think we just need to go and vote and see what happens.

(Andrew): Yes, and there's voting and let the chips fall where they may (unintelligible).

Benita Kornegay Henry: Okay, you have a comment? All right, we are now going to open up voting for the reliability of Measure 0138. Okay, Option A is moderate. Option B is low. And Option C insufficient. We're now voting on the reliability of Measure 0138; Option A moderate, Option B low, and Option C insufficient. We're looking for two more votes. One okay I'll give us five more seconds to submit your vote. Okay, voting is now closed. For the reliability of Measure 0138; 14 individuals voted moderate, 4 individuals

voted low, and 1 individual voted insufficient. So I will read out the percentages.

Ed: The percentages that looks like it's passed.

Benita Kornegay Henry: Yes, so 74% voted moderate. Twenty-one percent voted low. And 5% voted insufficient. So this Measure 0138 passes the reliability criterion.

Woman: The next one is validity. Because we have to vote for validity.

Benita Kornegay Henry: Yes. Okay, we are now voting on the validity.

Man: Yes, I'm still here but I'm listening. I know deep in the weeds I know.

Benita Kornegay Henry: Okay, we're now going to open up the vote for 0138 for validity. Option A is moderate. Option B is low and Option C insufficient. We're now voting on the validity of Measure 0138. Option A is moderate. Option B low, an d Option C insufficient. Looking for one more vote. Okay, voting is now closed.

Ed: Great.

Benita Kornegay Henry: For the validity of Measure 0138; 10 individuals voted moderate, 8 individuals voted low and 2 individuals voted insufficient. And so I'll read the percentages for you. Fifty percent of individuals voted moderate. Forty percent voted low and 10% voted insufficient.

Ed: So that's - if I get that percentage, that means it's - we didn’t make it quite. We didn't reject it, but it fits into that category consensus not reached, correct?

Man: Right, that falls into our so-called (unintelligible), consensus not reached.

Ed: We'll still go on and vote on the rest of it, right?

Man: Correct, and then we'll revisit this. We'll put it out - our recommendation out for comment. They will receive public comment on that. And then we'll revisit. We'll have a chance to revote after the public comment period. If we still get a consensus not reached determination, then I believe we'll go to the (CSAC) for sort of more of an adjudication of that.

Ed: You mean I have to discuss this again? Oh.

Woman: Could I just say something? You know, I really wanted this to, like many of you, I really wanted this measure to pass because it's an important measure to protect the patient. But I really don't want to come back to discuss this again. Out of - personally I'd rather to post for a month and have some data to give us more confidence to vote rather than throw the darts. Then we may scrap this measure. I'm just (unintelligible).

Benita Kornegay Henry: David did you have a comment? So what NQF staff is saying because we're split, this is the gray area. This is going to have more conversation and I think what we're saying to the developers is we'd like to have that conversation informed with whatever data they might have. So if they could submit additional information related to the rates that you're seeing in the rehab environment or in the skilled nursing environment, if there's some data out there that we have not looked at specifically, it would be helpful to us in our deliberations.

Curtis Collins: Yes, this is Curtis. On the opposite side of that, I would like to see more data if the CDC has to present data for something that they say is not there. I would

like to see the public or the, you know, the groups that come here present their data as well. If we're going to do a deep dive into that, I think that's very important because, you know, frankly what I'm hearing is there is no data outside of anecdotal data. So I'd like to see that as well.

Ed: CDC, do you want to respond to that?

(Dan): Yes, I have to admit I'm a little bit confused because I think there are two issues here that are being conflated. We can easily provide data about what's going on with respect to CAUTI and inpatient rehabilitation facilities. And we actually my colleagues reminded me the report that I quoted from, there's a URL within the measure proposal to that report. We can go beyond what's in that report and provide data on what's happening in (IRF)s with respect to CAUTI.

But I think that let's not conflate that with this lingering anecdotal concern about the spinal cord injured patients and the, you know, purported up unintended consequence premature catheter removal or avoidance of catheter insertion. You know, we - again, we have implored the advocates to provide data that would substantiate these claims we have not seen that. And this goes back five years.

Iona Thraen: So (Dan), this is Iona, just quickly, how do you explain the increase in CAUTI's in rehabs? What's your thoughts about that?

(Dan): Well typically it means that there are prevention opportunities that are being missed. And that's important for us to continue to focus our attention on.

Iona Thraen: So I guess is there any kind of initiative or activity or awareness or push going on in CDC specifically related to rehab? I mean we want to celebrate the

successes that you've had in the acute care world. But is the rehab world sort of being overlooked at this point. You know, this is the first time we've, sort of, heard that it's on the increase in the rehab world.

(Dan): Well let me be clear about it. The increase is above the national average in a small proportion of the (IRF) facilities. Overall, there has not been an increase, but in approximately 5% of the (IRF)s there has been a significant higher than expected CAUTI FIR. Overall, (IRF)s are working about the average, but there is this minority that is above average.

Iona Thraen: And all of that information you just quoted is related to the URL link in the documents that we were - need to drill down into to understand that. Is that correct?

(Dan): Correct.

Woman: It would be (Dan), it would be really helpful if - I don't know if the specific link that specific data is what you put in the document. Is it? Or is it just the link to the report? Because the report has a lot of information.

(Dan): So yes, but it's relatively easy to search on (IRF)s within the report. It's a couple of T strokes.

Woman: In the atlas?

(Dan): No, it's in the progress report, the 2017 progress report. So it's called the HAI progress report. If you were to search on HAI progress report until you see 2017, you'd get the report. And then you can search on facility type and get to the national data for (IRF)s.

Woman: Okay, I'm looking at a spreadsheet that has about 10 or 15 tabs.

(Dan): Well that's not the place I'm looking at.

Woman: Okay.

(Dan): I'm looking at the summary statistics. So we can send you the URL that will get you here.

Man: Yes, we can follow up with you and maybe at the staff level and send out a link, the relevant link to the (unintelligible).

(Dan): And just to be clear simply because here's no significant change in a CAUTI SIR over a period of time doesn't mean that there isn't a problem. There remains a problem in (IRF)s.

Benita Kornegay Henry: And I agree with you in the sense that you're showing improvement and successes in the acute care world. And this is a continuum of care issue specific to this population. But if you're not seeing the same kind of direction in these other entities, then we have a problem. You know, whatever that problem might be, we don't know yet.

(Dan): Exactly.

Benita Kornegay Henry: So we're going to move forward and vote on feasibility.

Woman: Did you want to discuss feasibility first or?

Woman: (Unintelligible).

Ed: Yes, (Don) do you have anything to add on feasibility?

(Don): Yes, so it looks like the data are collected using a standardized approach and that trained staff are able to assemble both the numerator and the denominator. Looks like while it may not currently routinely generated during delivery or electronically, this is we've already heard some comment about it. This look very feasible and well oiled. I don't have any concerns on the feasibility side.

Woman: Okay, if there are no other questions or comments, we can move forward toward the vote for visibility. So voting is now open for the feasibility of Measure 0138. Option A is high, Option B moderate, Option C and Option D insufficient. Looking for one more vote for the feasibility of Measure 0138. Option A high, Option B moderate, Option C low and Option D insufficient. Thank you for your votes. And voting is now closed. For the feasibility of Measure 0138, two individuals votes high, 18 individuals voted moderate, 0 individuals voted low and 0 individuals voted insufficient. So for the feasibility of Measure 0138, this measure passes this criterion.

Ed: Okay, time to discuss usability. So this is a publicly reported measure. I'm not sure how many in the lay public actually choose to access it. It also used in a variety of accountability program including value-based purchasing. So I think that it made the usability and use criteria very nicely. And it's very well presented.

Woman: Okay, if there are no comments or questions on use, will move to a vote. What we're now voting on the use of Measure your 138. Option A is pass. Option B is no pass. For the use, excuse me of Measure 0138, Option A is pass and Option B is no pass. I'm looking for two more votes. Perfect. Although the random voting is closed, for the use of Measure 0138, 29 individuals voted for pass and 0 individuals voted for no pass.

We'll move forward to the vote for usability. So right now voting on the usability of Measure 0138. Option A is high, Option B moderate, Option C low and Option D insufficient. You may now submit your votes for the usability of Measure 0138. Option A high, Option B moderate, Option C low and Option D insufficient. Looking for one more vote. Okay, thank you. Voting is now closed. For the usability of Measure 0138, 0 individuals voted high, 18 individuals voted moderate, 0 individuals voted low and 2 individuals voted insufficient. So for the usability of Measure 138, this measure passes this criterion.

We will not vote on the overall suitability for endorsement of this measure.

Benita Kornegay Henry: So I'm thinking it's 12:30. I think - when are we breaking for lunch, now?

((Crosstalk))

Man: On the last vote?

Benita Kornegay Henry: No, because it didn’t pass the validity. To be discussed, continued.

Man: So we'll defer the overall vote.

Ed: I see what you're saying, yes, then I would agree with that. I think we ought to have lunch and then have the SAR after lunch.

(Dan): Yes, again for our colleagues at CDC, can you join us again in about a half an hour? Is that possible?

(Dan): Unfortunately, I'm going to have to be traveling this afternoon to Dallas. I thought, you know, my schedule would be enough that I could accommodate this. It's going to be very hard for me to get on that call.

Benita Kornegay Henry: Is there somebody else that can represent you as the developer?

(Dan): Not here today, no.

Benita Kornegay Henry: I'm wondering if we should postpone it. I think we'll have to postpone it then until we do it on the phone call.

Ed: Yes, this is going to require you on this (Dan). We do have a - what is our call setup for if we don't get to all the measures? What day was that?

Man: Hello. I'm sorry. I was in an N2F call all morning. It's still going on.

Ed: Do we have the -

((Crosstalk))

(Hiro): Hi Ed. This is (Hiro) from NQF. We have a web meeting scheduled for next Monday, June 24 from 1 to 3. So anything that we do not get through today we have those two hours.

Man: Yes so (unintelligible) the first response is let's divert everybody away. And mine was let's be careful with that.

Ed: So (Dan), are you available from 1 to 3?

Man: There's always magical thinking. Yes, everything I might occasionally need. We should say no to all the patients.

Ed: (Dan), are you still there?

(Dan): I am, Ed. I think there's some traffic on the call, but I am available on the 24th.

Man: They would say they choose to use it a lot. I'm not sure.

Ed: So that Monday you're available.

(Dan): Absolutely.

Ed: All right, so why don't we postpone the SAR discussion until that Monday and then go for lunch and come back in 30 minutes? How does that sound?

Missy Danforth: Great. This is Missy. I'll call back in 30 minutes.

(Dan): Thank you.

Benita Kornegay Henry: Okay, folks I think we're going to get started. And I think the consensus is that the CAUTI measure gets further discussion. Hopefully with some new data or some additional information The next one, the, hold on, the 2720 which is the antimicrobial use measure I think is going to be postponed because CDC cannot be on the line to discuss it tonight, today.

So we are moving into the afternoon agenda and starting with 3498E, hospital harm, specifically pressure ulcer, pressure injury. And that's a CMS impact international measure and if the developers are either on the line or here in the

room, would you introduce yourself? Come on up. Yes, please. And while they're getting situated, who of the committee do we have online currently? (Unintelligible) are you there? Missy are you there?

Missy Danforth: I am.

Benita Kornegay Henry: And (Don) are you there?

Woman: And I think (Charlotte Alexander)'s online.

Benita Kornegay Henry: And (Charlotte).

(Charlotte Alexander): I am.

(Leslie): (Leslie)'s here.

Benita Kornegay Henry: (Don) or Ed? We just have Missy and (Charlotte)?

Ed: What did you say?

Benita Kornegay Henry: Are you there?

Ed: I'm here. I'm sorry. I'm here. I'm listening.

Benita Kornegay Henry: All right, and what about (Don)? What?

Man: (Unintelligible)

Benita Kornegay Henry: Okay, so we're going to email (Don). So we'll go ahead and get started. The lead discussant here is (Teresa). So why don't you go ahead and gets started?

(Teresa): Sure.

Woman: Do you want to do an internal developer first of the measure.

(Teresa): That's fine. Whichever works, whichever is the right.

Woman: Developers, introduce yourselves.

(Jacqueline Saki): Good afternoon, thank you for having us. I'm (Jacqueline Saki) from UC Davis. I'm part of the team from (Impact International). And we have a large group in the back as well.

(Bill Thin): Hi everyone. My names is (Bill Thin) from (Impact International).

Benita Kornegay Henry: Okay. You want to give a brief introduction to your measure?

Man: We can do (unintelligible).

Benita Kornegay Henry: Okay, and is anybody on the phone from CMS for this measure? No. And then (Teresa) will introduce the measure. We'll get it right sooner or later. Go ahead, (Teresa).

(Teresa): Okay. And anybody else that was involved in the review of the measure if you want to time and at any point please feel free. The new electronic clinical quality measure that assesses the proportion of inpatient admissions for patients ages 18 years and older. We developed a new Stage 2, 3, 4 for

(unintelligible) injury, deep pressure injury, or an unstageable pressure injury during a hospital stay. It's a facility level outcome measure. There is no risk adjustment methodology associated with the measure. And that's in general, that's the description of the measure.

The developer stated that (unintelligible) will fill a gap in measurement and provide incentive for hospital quality improvement. And although there are several pressure injury measures currently in use, there are currently no electronic health record based measures intended for use in acute care hospitals. And in addition, the intent of the measure is to incentivize greater achievement in reducing harm and enhance hospital performance on patient safety outcomes.

Benita Kornegay Henry: Okay, so developers would you like to make any introductory comments?

(Jacqueline Saki): Sure we especially want to thank, because we have three measures in front of the committee today for consideration. So we thank you for your time. This is the first of three. It is the hospital harm pressure injury measure. And as stated, we do believe this (unintelligible) in the current measurements that are out there because there is no electronically specified measure. And there's also not a measure that addresses the gamut of pressure injuries to in Stage I. So this measure will accept Stage 2, 3, 4 and stageable as well as tissue pressure injuries that are newly acquired in the acute inpatient setting and not documented within the first 24 hours.

That's the definition of new acquitted; no exclusion, no risk adjustments. And we believe it helps to fill a gap because not only will it incentivize hospitals to (unintelligible) their outcomes, but it will also incentivize better documentation, right? Can't really measure what is it documented. And you

can't really improve what you don't measure. So somewhat of the premise behind this measure.

Benita Kornegay Henry: So you said in the introduction or actually (Teresa) talked about it being that there's other measures that are out there and this is a different one because it's an electronic data pool. Is that, in your assessment, are the variables that you're pulling or the data elements that you're pulling, how are they different than what's currently out there in terms of data collection?

(Jacqueline Saki): We appreciate the question. If I'm understanding you correctly, yes there are other measures out there. There are a couple of other (unintelligible) but there's four different patient populations for the long-term care facilities, inpatient rehab facilities. In addition there are some measures that are not (unintelligible) endorsed at this point. You're probably familiar with (GSI 3) which is a component of (TSI 90) and that is the claims based measure. And it does have some exclusions, and it also will include State 3, State 4 and unstageable pressure injuries.

And then some in the room might be familiar with the (unintelligible) prevalence (unintelligible) from (MDA 2I) and/or (unintelligible) and that is a different methodology as well because it's a point in time prevalent (unintelligible) to quarter and those databases are now part of their proprietary membership.

Benita Kornegay Henry: All right, (Teresa) do you want to talk about the important, I think is the evidence to start?

(Teresa): Sure, so based on the model that was presented by the developers, there is at least one evidence-based action a provider can take to affect change. It includes best practices such as frequently positioning, proper skin care and

specialized cushions or beds. In general, the comment on this criterion stated that the developer provided appropriate evidence from (Arc) published data. However, there is no systematic literature review, or any evidence results are not graded.

Benita Kornegay Henry: Any questions or comments about the importance of the measure? Anybody on the one have any questions? Lisa.

Lisa McGiffert: I just want to make sure I understand the numerator. Any stage of pressure ulcer, right? Or pressure injury.

Woman: (Unintelligible).

Lisa McGiffert: Two and higher. Pardon? Stage 2 and higher.

(Jacqueline Saki): Two and higher, yes.

Lisa McGiffert: Okay. So not distinguishing between two and four or anything like that, correct? Thank you.

Benita Kornegay Henry: (Unintelligible).

Woman: So (unintelligible) everybody is taking care of me. Even though you say there are no denominator exclusions, it excludes a pressure ulcer Stage 1. But what happens for people who come with a Stage 1 pressure ulcer? Are they excluded or are they (unintelligible)?

(Jacqueline Saki): Thank you for the question, and yes. Those who come in with a Stage 1 pressure injury, that's not captured. So it would be more correct to say that

Stage 1 would be excluded whether be present on admission or whether it be newly acquired during the admission. Does that clarify a question?

Woman: So would that patient be excluded for later if they have the same one? So I work in the ED. A lot of times they come in and they've been down for however amount of time. And they have a Stage 1 ulcer wherever. That is going to progress, right? So because they have been done. So they come in with a Stage 1, do they get excluded for the later calculations of Stage 2, Stage 3, Stage 4?

(Jacqueline Saki): I believe what you're asking is with regard to worsening pressure injuries and that was initially part of this measure. But in testing it was determined to not be feasible to rely if you capture that worsening status, so that patient would be excluded if they were to later develop a worse than Stage 1, a worsening to one of the other stages.

Woman: Thank you.

Benita Kornegay Henry: Other questions? (Don) are you back on the line? All right, so do we need to take a vote?

Woman: All right, we are actually going to open the vote for Measure 3498E. We're voting on the evidence of the measure. Option A is pass. Option B is no pass. We're now voting on the evidence of Measure 3498E. Option A is pass and Option B is do not pass. Votes are coming in. Looking for one more vote. Okay, so we will actually close voting now. For the evidence of Measure 3498E, 19 individual voted pass. And 0 individuals voted to not pass. So for the evidence of measured 3498E, this measure passes the evidence criterion.

Benita Kornegay Henry: Okay, performance gap.

(Teresa): Okay. How this measure was tested with three test sites that included 24 hospitals and to state located in the Midwest, West and Northeast. The hospitals vary in size by bed, by EHR system, by teaching status and location. The measure performance was stratified to disparities by age, race, ethnicity and payer source. These results are derived from a relatively small dataset that is not generalizable to the entire population. And the datasets include some characteristics that are unknown in the EHR.

Comments on the performance gap overall pointed to agreements that this measure shows an opportunity for improvement. There are other pressure injury measures (unintelligible) stated, but none that are EHR based. One question that was raised is whether documentation deficiencies affected the results of the beta test.

Benita Kornegay Henry: Any questions (unintelligible)? I have a question NQF. So this is basically an e-measure. Does it go through an e-measure review as well?

Man: It goes, indeed. Excuse me. We have a team that does the review of the sort of clinical logic or measure logic and gives it a feasibility score. So that's really what they're evaluating is the feasibility section. So once we get to that, we may have some folks on the phone who can speak a little bit to the scorecard they use and what (unintelligible) to be interpreted. But that really only comes into play at the feasibility question. At least in terms of that specimen.

Benita Kornegay Henry: So is - are they reviewing it after we've endorsed or (unintelligible) before?

Man: Beforehand, yes, there should be some information.

Benita Kornegay Henry: It's in there, all okay. All right, cool, thank you. Any other questions or comments or concerns? Pat.

Pat Quigley: Thank you so much. I just wondered if we could have a little bit more information in terms of the testing, the beta site testing. And the test hospital for the group of one, Hospital Site 1, there was only one hospital for the test site. For Number 3, there was only two hospitals but for Test Site 2, there was 21 hospitals. I don't know if that makes any difference in terms of what you found or how this works. So could you just explain how that was decided?

(Jacqueline Saki): So that's correct. There were three beta sites and they were divided among EHR vendors. So this measure was tested in three electronic health record vendors. That was according to the number of sites that you mentioned. One for hospital Site 1. The first DHR, 22 for the second and 2 for the third. There was a - because of the three difference electronic health records as you might expect, there was a little bit of difference noted in the documentation specification to Data Site 1 and you can discuss in more detail if you'd like to now. Perhaps when we get to feasibility, did I answer your question or were you looking for something difference?

Woman: Well the sample sizes were different, so different for the three difference. That's EMRs, I guess and (Serner) or Epic or (Meditec). Is that kind of what you're (unintelligible)?

(Jacqueline Saki): That is correct. I can name the EHR venders if you would like. But yes, there were three different vendors across the country that were included in the data testing.

Woman: Okay, thank you. So I guess the extraction would be the same irrespective of the vendor?

(Jacqueline Saki): Correct, the methods were the same regardless of the vendor or the beta site.

Woman: What were the three vendors?

(Jacqueline Saki): Sure, for Beta Site 1, it was (Meditec). For Beta Site 2, (Serner) and for Beta Site 3 (Epic).

Woman: So basically you got them all.

Benita Kornegay Henry: Go ahead (Steve).

(Steve): The e-measure, so going off the extraction query, was the query written and then the hospital had to adjust to it? Or the EMR systems or was - what was the elements of the query that picked it up? Because these are nursing assessment. This is all about nursing assessment.

(Jacqueline Saki): Correct, the data are gathered during the assessment process and then documented in the electronic health record. And then the comparison of what was collected electronically was made to a manual chart extraction. We can talk about that when we get to validity if you would like.

(Steve): So the query essentially was (unintelligible). You built a query for each of the systems. Or you built the dataset.

(Jacqueline Saki): The dataset was built and testing, yes, for each of the three systems.

(Steve): Okay, got you.

Benita Kornegay Henry: Other questions? Pat?

Woman: (Unintelligible).

Benita Kornegay Henry: Anybody on the phone?

Ed: No questions.

Benita Kornegay Henry: All right, shall we vote? Oh, wait a minute, we got one. Go ahead (Ying Ling).

(Ying Ling): I just have a question about is this (unintelligible)? I don't know about the gender disparity. We've not talked about disparity yet.

Man: (Unintelligible).

(Ying Ling): Okay, I just have question that the gender, when look at woman and man, male and female and it seems like the man has higher rate than woman. I'm just wondering what is the explanation.

Ed: We're the weaker sex.

Woman: He said it.

Ed: I just want to make sure everyone's still awake there.

(Jacqueline Saki): So you're correct, in the data set there were just over 164.000 patients and in the instance in male patients, the pressure injury was slightly higher than in female. Don't quote me exactly, but I believe about just over one point, .08% in males and perhaps closer to 0.5% in females. But again, don't quote me. We

did notice in this particular dataset, there was a higher percentage of pressure injuries captured in the male gender.

Woman: We don't know why.

Woman: I was asking why.

(Jacqueline Saki): That's not their job. And also there's Medicare patients that have a higher rate than any other group.

Benita Kornegay Henry: Well Medicare is your older patients, so that would make sense.

Woman: Okay.

Benita Kornegay Henry: Other questions before we vote? Okay, should we vote?

Woman: I have a question.

Benita Kornegay Henry: Sorry (unintelligible).

Woman: If it's feasibility, if it's wrong you can strike me down. What about the groups how are at (All Script) that's not been testing?

(Jacqueline Saki): The (All Script)'s group was not tested in this beta testing. You are correct.

Ed: (Unintelligible) standards testing at least two differing EHRs.

(Jacqueline Saki): Three.

Ed: No, I'm asking. The (unintelligible) is at least two, right?

Man: I believe, yes, at least two.

Ed: Right, so this one has three.

(Jacqueline Saki): Correct.

Ed: Okay. So that certainly meets our minimum standards.

Benita Kornegay Henry: Should we try to vote again? Let's vote.

Woman: Okay, we are going to open voting for the performance gap of Measure 3498E. Option A is high. Option B is moderate. Option C low and Option D insufficient. We are voting on the performance gap of Measure 3498E. Option A is high, Option B moderate, Option C low and Option D insufficient. Looking for just two more votes. Perfect, the voting is now closed for the performance gap of Measure 3498E. One individual voted high. Seventeen individuals voted moderate. Zero individuals voted low and one individual voted insufficient. So for the performance gap of Measure 3498E, this measure passes the performance gap criterion.

Benita Kornegay Henry: All right, reliability (Teresa).

(Teresa): Okay, this measure was evaluated by the scientific methods panel. The measure passed for reliability. Reliability was assessed at the measure score level. The signal to noise ratio yielded a median reliability score of 0.969. There was some concern among the reviewers about the extent to which in the absence of risk adjustment, the variation between providers represents true variation and quality versus variation due to differences in patient case mix between providers.

Benita Kornegay Henry: So this is an example where they've approved it. Do you want to accept their approval or vote on it? Any comments.

Woman: Accept.

Benita Kornegay Henry: I have one accept. Anybody not want to -

Woman: Accept.

Ed: I'm fine with accepting.

Missy Danforth: Oh sorry, I said accept, sorry.

(Don): This is (Don). I thought we would vote on it.

Woman: There you go.

Benita Kornegay Henry: We had one that said vote. So we will vote on it then. And (Don) is now back.

(Don): I was here. I was just muted, sorry, from your end.

Benita Kornegay Henry: All right. So we'll vote on the reliability. Is there any comments before we take the vote? All right, go ahead and vote.

Woman: Okay, we're now voting on the reliability of Measure 3498E. Option A is high. Option B moderate, Option C low, and Option D insufficient. You may submit your votes for the reliability of Measure 3498E. Option A high, Option B moderate, Option C low, and Option D insufficient. All votes are in and

voting is now closed. For the reliability of Measure 3498E, two individuals voted high, 16 individuals voted moderate, zero individuals voted low and one individual voted insufficient. So for the reliability of Measure 3498E, this measure passes the reliability criterion.

Just as a reminder, David has recused himself from these next measures. So he will not be voting. So that's why the numbers are down to 19. Thanks.

Benita Kornegay Henry: Thank you. Validity.

(Teresa): Okay, validity testing included both score level and data element testing. Positive predictive values were calculated for each critical data element. The developer reported that all but one data element had a match rate of 86% or higher with most over 91.3% indicating valid and accurate data elements were extracted from the EHR.

There was some concern among reviewers about weak validity results in one of the tested datasets. Reviewers suggested that inconsistent use of structured fields in EHRs raises concerns about data quality and documentation practices. The developers shared that hospitals were using structure fields but not documenting in them.

One panel member was concerned that there could be miscategorization based on documentation or the lack there of. That impacts a hospital's performance. The developer replied that problematic documentation is part of the quality signal. And facilities should be responsible for proper documentation.

A panel member responded that one cannot tell if the problem is pressure injury or documentation issue. Some of the reviewers disagreed with the decision not to risk adjust and/or stratify reported results. Reviewers

contended that there are clear differences in patient population served among hospitals and suggested risk adjustment or stratification should be considered.

Benita Kornegay Henry: So you did the data - this is to the developers. You did a data element testing. Do you collect any disparity data in this measure?

(Jacqueline Saki): The only supplemental data that were collected as part of testing were specific to gender, race and ethnicity, and primary payer. So not specifically disparity set that you might be referring to.

Woman: (Unintelligible).

(Jacqueline Saki): That's correct; race and ethnicity were collected as supplemental data points.

Woman: And do you have any sense of how that data looked? This is actually related to an earlier conversation about collecting race and ethnicity data. What did you see? Do you know?

(Jacqueline Saki): Sure, and I can pull the table if you'd like me to cite specifics. So we did notice that specific to ethnicity, there was a slightly higher incident of pressure injury among non-Hispanic ethnicity and then among race slightly higher among black or African American race. But again this is a dataset of only 164,000 patients across those three data sites.

Benita Kornegay Henry: Any questions about, where we at, validity? Validity, yes. Anybody on the phone have any questions about validity?

Ed: No.

(Don): No.

Benita Kornegay Henry: All right, let's vote. No, we didn't.

Woman: Okay, we are going to now vote on the validity of Measure 3498E. Option A is high. Option B is moderate. Option C is low, and Option D insufficient. You may submit your votes for validity of Measure 3498E. Option A high, Option B moderate, Option C low, Option D insufficient. Just looking for one more vote.

Man: Scientific acceptability or validity?

Woman: Validity.

Woman: Validity. Okay, all votes are in. For the validity of Measure 3498E, zero individuals voted high. Seventeen individuals voted moderate. Two individuals voted low and zero individuals voted insufficient. So for the validity of Measure 3498E, this measure passes the validity criterion.

Benita Kornegay Henry: Feasibility.

(Teresa): Feasibility assessment across 24 hospitals with three different EHR vendors showed that most data elements used to calculated the measure were reliably available in a structured format within the EHR. Captured as part of the course of care and coded using national accepted terminology. However, during testing by NQF, this was not validated, and several data elements demonstrated problems with feasibility.

Benita Kornegay Henry: Would the developers comment on what problems they ran into with feasibility?

(Jacqueline Saki): Certainly, in beta Dataset 1 there was a - the facility did not actually have a structure data field for pressure injury at the time of testing. They had a more general (unintelligible) narrative field. And that led to the decrease in the ability to capture data specific to pressure injury. However, they recognized during testing that this was a limitation of their system and have since made adjustment. So there does now exist a structured field in that beta dataset.

Benita Kornegay Henry: Any questions? (Steve).

(Steve): Was there integrated reliability done on this? And if it's still even when you're just checking off the boxes, you have this. You have this. You have this. Was there independent integrated reliability even with that in terms of yes, this is a (unintelligible) first. This is deep red and that kind of stuff. I mean was there any variation?

(Jacqueline Saki): There was not. That was not part of the testing specifications for this measure.

Benita Kornegay Henry: Go ahead, Laura.

Laura Ardizzone: So I guess this is one of the first e-measures that we've seen with review by the technical committee. And tis a little concerning to me. This statement there that they couldn't replicate what the developers had seen. Are there any - you have any comments from the NQF technical committee? Or do you know what they were saying that they can't validate some of the data elements. This is not my world. So.

((Crosstalk))

Man: Is the same, you know, is that (Chris?).

(Chris): Yes, his this is (Chris) (unintelligible). I work on the (unintelligible) technical review. And for me clarify what we found. What we do is we go through the assessment and the submitted assessment. And we looked at certain things to ensure that the measure is feasibly from the standpoint of using the e-measure standards in a way that this can be used by other sites who are also implementing those standards.

And the things that we found that - those are concerns that were mentioned earlier that we found were in the feasibility assessment, there were a few data elements that were not - that were bound to have some issues which were the ones that I believe the developers spoke to earlier. The kind of issues were related to when they were assessing their sites, they did not necessarily find that - they mentioned concerns that those feasibility assessment surface that some of those elements weren't a no brainer in terms of the unstructured data.

So those are the ones that (unintelligible), developer (unintelligible) just speak to kind of let you know what they found when they were trying to implement those data elements.

Woman: So it's resolved or no? Because the developer stated that there was just the beginning. They didn't have structured notes. They worked with the teams. And they - you found it was fixed or.

Benita Kornegay Henry: It would be resolved if the institution when to a structured data capture mechanism. And that instance that did after the fact, but you could have EHRs where it's not structure data. And if it's not structured data then you would have a feasibility program.

Woman: Okay, thank you.

Benita Kornegay Henry: Is that accurate? Okay. (Unintelligible), excuse me (Kendall).

(Kendall): So the group that did got to the structure data, I hate to ask. Do you know with EHR that was?

Woman: (Unintelligible).

(Jacqueline Saki): So certainly since you're asking this is Beta Test Site 1, and that was the (Meditec) system. So it was the single hospital.

Woman: So being in a technological field, Epic, one of the things I noted and actually I talked to Laura about was Epic's got what 55% of the market share. And yet we looked at two hospitals from Epic. Epic is a customizable product. (Serner) is an out of the box product, right? So Year '21 (Serner) sites are great, but there's 21 of them. But basically (Serner) is that (Serener is) and you can't really customize it.

Epic on the other hand you can customize. And whether this is a discreet dataset in Epic or not, is going to very variable. Even if it is, how they are collecting is going to be variable. And Epic having the, you know, lion share of the market, added to that, would make me relatively concerned about the feasibility of this. So I just wanted to mention that. Because every instance is different. Even my instance at US Jacks, is different than the instance at US (Gavesaw). We're an enterprise system, but we have differences between us. And the way we store data is different between each one. So that could represent especially if you're looking at a smaller hospital, Epic is changing Epic is not cheap.

And so getting it changed in light of all the business changes that have to, you know, come every day is not cheat, you know. May create a prioritization problem. So I have personally would have a lot of concern about the situation.

Benita Kornegay Henry: (Unintelligible).

Missy Danforth: Thank you. Just a question for the measure developers, because I think maybe this is one of the first e-measures the committee without in general. But when the measure gets rolled out into ECQM, is there an implementation guide that goes out, a way to make sure that everyone regardless of what HR they're using has the same information about what the minimum requirements are going to be to be able to capture the data. But what goes out with the measure from an electronic or technical support standpoint?

Benita Kornegay Henry: Are you addressing that to the developers or NQF?

Missy Danforth: The developers.

Benita Kornegay Henry: Hold on. They're having a conversation. And I'm so sorry, but I can only hear one conversation at a time. And I hate to have to ask, but do you mind please repeating the crux of the question?

Missy Danforth: Oh, I'm wondering.

Benita Kornegay Henry: Go ahead Missy.

Missy Danforth: Yes, like what kind of like is it like a manual? Does a technical manual go out with the measure so all of the hospitals can assess what the minimum requirements are to do the data collection? There's obviously a lot of documentation with the measure, but I don't actually see the list of the required standard data elements are like examples of the capture or anything like that. How do hospitals know what the minimum requirements are?

(Jacqueline Saki): You raise an excellent question. We actually have an ECQM nursing expert online. And if I could differ that the physically to her because her expertise and experience outweighs mine in this field. Ms. (Shana West).

(Shana West): Hi, are you able to hear me?

Benita Kornegay Henry: We can hear you well.

Missy Danforth: Yes.

(Shana West): Okay, perfect. Thank you. So the, what happens with the measures in their put out, they are made available, the specifications are available. They are also values that that are made available that specifically identify the types of information that a hospital would be looking at when they're implementing this measure. Additionally, if this is moved into a CMS program, they do have logic implementation guide us as well as the guidance that's available in the header information for each of the quality measures that are made available to them. So it kind of helps to standardize them and help with interpretation of the measure specifications and how they are to implement them consistently across different hospital.

Missy Danforth: Okay, I guess that's, kind of, an important distinction. And that's what I was trying to clarify. That was very helpful. I think this is an incredibly important measure. I think one of the biggest enhancements to this measure that hasn't been brought up is actually the fact that captures all patients. And all of the claims based pressure also measures, only capture Medicare fee-for-service patients. So I think this bill a huge gap. But I do have a lot of concerns about the feasibility issues because of the issues that the scientific panel brought up that the NQF electronic measure team brought up that actually my colleagues from Jackson health just brought up.

So what I'm hearing is that it so that your job to develop the measure and the data elements that will going to the measure. But the CMS's job or whoever's doing the implementation, their job to actually develop like the implementation manual.

(Jacqueline Saki): So, it's not really CMS's job proper. The developers have a direct hand in that. So CMS kind of leads that effort, but the developers that are creating all the measures (unintelligible) program actually have direct involvement in that by (unintelligible) put out. And also just to address the feasibility concern, it wasn't that the fields were unavailable because the fields were available. The challenge was ensuring that the documentation was being placed in those rather than in free text fields or elsewhere.

So if you look at the feasibility scorecard, a lot of the pieces that were addressed there were there were some challenges noted. The providers that did the feasibility assessment did indicate that it was an important measure while would cause a little bit of burden in order to modify some of those workflows, but that there was benefit in doing so. As you can see by some of the facilities actually implementing the changes, post testing.

Iona Thraen: So this is Iona. Is your target for the rollout going to be the vendors or the hospitals?

(Jacqueline Saki): When the measures are placed out there for use in program specifically vendors to go ahead and implement those measures to make it easier for providers to then report on those. So it's kind of twofold. The vendors help implement them in the system, but the providers have to be aware and have to be directly involved in that process as well and ensuring that when the vendors pointing to a certain data field, that the pointing to the correct data

field. And then working with the actual providers that are doing that documentation; the nurses, the physicians, that they are documenting (unintelligible) locations so that the data can accurately (unintelligible).

Benita Kornegay Henry: Tracy.

Tracy Wang: Hi, so since we're going to be reviewing a few e-measures, my question was what is the adoption of, I guess, EHRs of hospitals across the nation? And also how much of the data capture a structured? And if it's not structured, do we then apply national language processing to (unintelligible) keywords so that you can capture with analyzing data?

Benita Kornegay Henry: The adoption of EHRs in hospitals is pretty close to 100% because of the incentive programs that have taken place over the last five to six years. In terms of using natural language processing to capture text data, I don't know the answer to that. Measure developer, want to comment on that?

(Jacqueline Saki): So this measure was not built to test or to draw from NLP. It's extremely, as you know in the room, it's extremely resource intensive. There would be quite a bit of validation and burden involved in that. So this was developed to strictly pull from discrete data fields.

Benita Kornegay Henry: Other questions? Anybody on the phone? Are we ready to vote?

Man: Just to make sure that the committee has the right information. I guess for, back to Laura's question, based on the measure testing here it sounds like the issue with not being able to capture the structured data for those were fixed in subsequent iterations. Is that right?

(Jacqueline Saki): So that description was applicable beta Dataset 1 and I may not have been clear enough in my description for that. I apologize. And I believe Ms. (West) also spoke to this. But the data (unintelligible) are collected as part of the normal assessment that takes place when the patient presents to the facility and they are collected within the amount of time that is within this measure specification. What we did find variability for was the use of the structured fields. So the data were collected but often was in a narrative form and then later put into a structured data field, if that helps.

Benita Kornegay Henry: So from nursing notes to a structured data capture mechanism, whatever might be there.

(Jacqueline Saki): Correct, from the narrative portion of the nursing notes. But the structured fields within the nursing flow sheet do this across the electronic health records mentors specific to this measure.

Benita Kornegay Henry: Okay, other questions? Let's vote.

Woman: Okay, before we go on our next vote, I would just like to remind everyone, if you're not using your microphone, if you would cut it off please. That way we won't get any feedback. Thank you.

All right, no worries. Thank you. We're going to open voting up for the feasibility of Measure 3498E. Option A is high, Option B moderate, Option C low and Option D insufficient. We're voting on the feasibility of Measure 3498E, Option A is high, Option B moderate, Option C low, and Option D insufficient. Looking for one more vote. Thank you. All votes are in and voting is closed. For the feasibility of measure 3498E, zero individuals voted high. Thirteen individuals voted moderate. Five individuals voted low. And one individual voted insufficient. So I will give you the percentages. Zero

percent voted high. Sixty-eight percent voted moderate. Twenty-six percent, sorry that was two-six, 26% voted low and 5% voted insufficient. So for the feasibility of Measure 3498E, this measure passes the criterion.

Benita Kornegay Henry: Usability and use.

(Teresa): Since this is a new measure, it is not used for public reporting or any current accountability programs. But it is under consideration for use in accountability programs. In December, this measure was presented to the MAP, the measures application partnership and they - the MAP is recommended implementation in an accountability program pending feedback received during the process.

Benita Kornegay Henry: Any questions? So if you look at the voting, it says that it used in accountability within three years, public reporting within six years. Or if it's new, a credible plan. Shall we vote?

Woman: Okay, voting is now open for the use of Measure 3498E. Option A is pass and Option B is no pass. For the use of Measure 3498E, Option A is pass and Option B, no pass.

Ed: Yes, and this is a new measure, correct?

Benita Kornegay Henry: Correct.

Ed: Okay, just want to make sure that's correct. Got it, thanks.

Woman: Okay, all votes are in and voting is now closed. For the use of Measure 3498E, 19 individuals voted pass. Zero individuals voted no pass. So this measure passes the use criterion.

And we will move to usability of Measure 3489E. Voting is now open. Option A is high. Option B is moderate. Options C is low and Option D insufficient. We're voting on the usability of Measure 3498E. Option A high, Option B moderate, Option C low, An Option D insufficient. Looking for two more votes. One more, perfect, all votes are in. And voting is closed. For the usability of Measure 3498E, three individuals voted high. Fifteen individuals voted moderate. One individual voted low and zero individuals voted insufficient. For the usability of Measure 3498E, this measure passes the criterion.

Benita Kornegay Henry: So vote for pass or no pass?

Woman: Yes, if there are no more comments, we'll move for the overall suitability for endorsement of Measure 3498E. Option A is yes. Option B is no. We're voting on the overall suitability for endorsement of Measure 3498E. Option A yes, Option B no. Looking for two more votes, one. Thank you. Voting is now closed. For the overall suitability for endorsement of Measure 3498E, 19 individuals voted yes, and 9 individuals voted no. So this measure passes the criterion.

Ed: I don't - I'm just jealous. You got all the easy measures.

Benita Kornegay Henry: I know. We stacked it that way. All right, next one is 3501E, hospital harm opioid related adverse events. And Jason is the lead. Go ahead Jason. You want to introduce it?

Jason Adelman: All right, this is another new measure, outcome measure from CMS. Another hospital harm due to opioid related adverse events. The general aim of this measure is to use Naloxone which is a reversing agent for narcotics as a marker for unintended overdoses of narcotic use. The way the measure is

designed is the numerator if they are looking for the number of inpatient admissions during which Naloxone is administered as a proxy for the administration of excessive amounts of opioid medications.

They - in the numerator, they actually say they exclude patients in the OR. And to address patients who come in with heroin overdoses and other issues, in the first 24 hours of the hospitalization, there must be an opioid administered in the hospital and then Naloxone given. That's only for the first 24 hours. That's the numerator statement.

The denominator is all patients 18 years or older, that are start their encounter in the ED and have a hospital admission during the measurement period. I can keep going or I can pause for the developers.

Benita Kornegay Henry: Let the developers speak.

(Kendall Hall): Sure, hi. My name is (Kendall Hall). I'm actually another (Kendall) from (Impact International). So yes, everything to what has been said, but I just want to draw attention that despite the clinical importance and the work that has been done previously on this, there is currently no Foley specified EHR based outcome, ECQM, in a quality reporting measure - quality reporting program that captures this type of event. And it will help to provide us more information about what is going on in the field.

Woman: I have a question and it kind of relates David to your expertise. Is there a reason why it's 18 and over? And is it relevant?

(Kendall Hall): I think that we're trying to capture all adults. And I don't have a good explanation for why only 18 and over.

Man: I think it, excuse me. I think it could apply to the pediatric population. I don't know if it was tested in that population.

(Kendall Hall): It was not. It was tested in the adult population.

Man: It would seem to be relevant in that population as well.

Benita Kornegay Henry: All right, Jason you want to continue with evidence?

(Don): Can I ask one question? I'm sorry, I had the hand up. It's (Don).

Benita Kornegay Henry: Go.

(Don): So, it says in the first 24 hours of hospitalization, and opioid must be documented prior to Naloxone. Are you including the emergency department with that? Because they are not technically hospitalized at that point.

(Kendall Hall): No, it is throughout their whole - there hospitalization started in the emergency department, that 24-hour clock starts at the arrival. So it would capture. It would exclude patients who are coming in from a community acquired, so to speak, overdose.

(Don): Okay, so the (EV-con), the clock starts in the in the emergency department.

(Kendall Hall): Correct.

(Don): And how about field opioids? A big chunk of the patients we see will have received an opioid just prior to arrival.

(Kendall Hall): Well again, it's the 24-hour limit. It would not -

(Don): Not by EMS providers. So that it wouldn't be on any (unintelligible).

(Kendall Hall): That's correct. That would not be - this is an inpatient hospital harm measure.

(Don): But my concern would be, and I don't know how bit the volume is, is that someone who got an opioid in the field and got a reversal agent, would be miscategorized or not categorized the way you want. There is a potential for that.

And then Number 2, just the delivery of Naloxone becomes evidence of the opioid harm. Tell me what kind of data you had to make that strong connection, because a lot of Naloxone is given on empiric basis for any type of change in sensorium and doesn't produce an outcome one way or the other. It's kind of, you know, ABC Naloxone kind of thing. And so how do you know that this is a good surrogate for opioid harm?

(Kendall Hall): So we know it's a good surrogate. It's been shown through (Arc) as well as through IHI trigger tools to be useful as an indicator of opioid overuse or over sedation because of opioids. Back to the first question, I think that if you get an opioid in the field, and then you come to the emergency department and need to be reversed, if you see that Naloxone there's going to need to be in that hospital a proof that there or an indication that an opioid was given in the inpatient setting, right? So that - I see what you're saying.

So if it was given and there again, if there was none give, you're not going to be picked up by that numerator until after that 24 hour period.

(Don): Right, so there's a small but tangible miss classification thing. I guess I'm still stuck on the, you know, Naloxone is given empirically for a lot of things and

doesn't actually relate to an opioid. And I'm just wondering more about the data behind that link.

(Kendall Hall): So during the testing period, when the adjudicators went into look at what the EHR was pulling out and what the chart abstraction looked like, one of the questions that they were asked was whether or not this truly represented an event related to an opioid or overdose as opposed to something like you're speaking to like as a differential diagnosis type tool. And there were few cases where it was not related to a true harm.

Benita Kornegay Henry: (Steve) and also (Charlotte) and then (Kendall).

(Steve): Are you considering an epidural administration of a narcotic?

(Kendall Hall): Correct, any route, correct.

(Steve): Okay.

Benita Kornegay Henry: (Charlotte)?

(Charlotte): Get myself off of mute. So you excluded the operating room. Does that include (Pacu)?

(Kendall Hall): This doesn't not include the (Pacu). It is within the OR as consideration of part of an anesthesia plan. And anything that occurs outside of that OR would, including the (Pacu) would be considered to be an event.

(Charlotte): Because our anesthesiologist will give narcotics in the operating room, no way to - looking at respirations and things like that, maybe monitor that. But then

they get to the (Pacu) and they may need to be reversed. And so you're including that as a harm event.

(Kendall Hall): Correct. One could say that the patient shouldn't' be in the (Pacu) with that level of sedation and analgesia and then require Narcan or Naloxone.

Benita Kornegay Henry: (Kendall).

(Don): This is (Don). One more question. There's no acceptance.

Benita Kornegay Henry: Hold on. (Kendall) first, then you.

(Kendall): Well he can actually answer my question as well. So I'm trying to figure out, you know, being an ED doc, we do empirically sometimes give narcotics in the ED. But that would not have been preceded with any sort of an opioid. So I'm trying to figure what sort of empiric narcotic I mean Narcan would be dosed other than say an RRT or rapid response type situation. But even then, if no narcotic had been given, prior to the Naloxone, then it would count in this study.

So I was hoping (Don) you could comment on that.

(Don): Yes, I think there is a problem for counting - misclassification either direction, probably it might be on the underside for that particular reason. It's also comment that we attribute an effect of Naloxone that doesn’t really exist. I mean just having practiced long enough.

My other question is, we use opioids commonly as part of a procedural event. And many physicians titrate the opioid analgesic to the peak of the procedure. And then just automatically reverse once the nociception is gone. In other

words, I put in a shoulder back on Friday. At the peak of it, the person was well treated. But as soon as the painful stimulus is gone, the concern would be there's an inappropriate opioid amount. Neither of which is a bad thing. So my question is, do you have any carve outs for opioids used as part of procedural analgesic? Because some people just routinely give the reversal agent and it's not really sign of harm. It's sign of you successfully treated the underlying condition.

(Kendall Hall): Well I respectfully disagree. I think that the literature and looking at, you know, some of the guidance that comes around on - out on moderate sedation by the American Society of Anesthesiologists back in 2018 indicates that should not be a routine part of a moderate sedation plan. And that actually the first things that you should do are increase the physical stimulus provide additional oxygen, positive pressure ventilation. And then if all those things don't work, then you go to the Naloxone so that you don't kind of go over kill and cause the patient undue pain.

So I think that - we feel very confident that this should, you know, if it's happening during procedural sedation, that that truly is an event.

(Don): So I'll just counter with you that outside of the ASA, many other organizations did not accept those ASA guidelines specifically because they're written from one vantage point. And this is one of them. It's nothing pronounced ahead of time is another one. So I just because in the OR that doesn't happen, procedures happen a lot of other different places. I'm a little less confident in that declarative approach.

Benita Kornegay Henry: Other question (John)?

(John): This might require some speculation. Is it possible that this measure, if it were implemented, would cause a reluctance for a patient to get Narcan when they should for an opioid - say a marginal overdose? And rather than pull the trigger with Naloxone, just kind of wait it out and end up harming the patient.

(Kendall Hall): I mean I think that is a potential with any time we put into place a patient safety measure, there's always unintended consequence that we might anticipate. I think with that the first thing you would want to do - I know I had a discussion with anesthesiologist about this would be to, again, the physical symptoms increased physical stimulus, give them the additional oxygen. If that patient was re-intubated, ultimately that patient is getting treated, correct? You would agree to that.

I think that if that patient doesn't get treated with anything, whether it's Naloxone or any kind of intubation or airway support, I see then we're heading into an unethical territory. And it's hard for me to believe that a measure would stop people from treating patients at all. And again, yes, I'll stop there.

Benita Kornegay Henry: Other questions or concerns? Shall we vote on the evidence? Oh Jason, sorry.

Jason Adelman: Sorry, are we doing just evidence now? I was going to talk about the gap. Okay.

Woman: (Unintelligible).

Benita Kornegay Henry: All right, we'll vote on the evidence.

Woman: Okay, we're now voting on the evidence of Measure 3501E. Voting is now open. Option A is pass. Option B is no pass. Let me share the screen. Okay, so for the evidence of Measure 3501E, Option A is pass. Option B is no pass. You may submit your votes. Looking for two more votes, one more vote. Okay, all votes are in. Voting is now closed for the evidence of Measure 3501E. Eighteen individuals voted pass and one individual voted do not pass. So for the evidence of Measure 3501E, this measure passes the evidence criterion.

Benita Kornegay Henry: Okay Jason performance.

Jason Adelman: Right, so the developers believe that there is a performance gap and that's based on the fact that they found significant variability in the hospitals that they evaluated the measure in was two systems, five hospitals. And they saw a range from .16% of patients to .52% of patients, so a wide range. Here's where I feel like the measure itself is fundamentally flawed. And that is that I don't understand why the denominator is all patients and not all patients that receive narcotics. I would think, you know, the last measure anybody can get a pressure ulcer, but you can only have an overdose of narcotics if you've got a narcotic. Can only get a CAUTI if you've got a catheter.

And so because it's all patients, then it introduces this real variability of how hospitals use narcotics. So if you have more sickle cell patients, you may use it more. Then you have more Narcan use, but the denominator is all patients. Or if you have more operations then you have more pain afterwards. It just seems like such a simple thing that it should just be Narcan overall (unintelligible) real patients. So the developers address that.

(Kendall Hall): Sure, I think that there were a couple reasons. One is that the percent of patients that are receiving as you alluded to that are receiving opioids during a

hospital stay varies considerably. Or I should say who have them ordered can range anywhere from the literature says 5 to what like 73% which is a huge variability. By having a denominator that brought that take that into consideration. I think it's also one of the things that is of concern would be to identify all patients that have received that opioid any time during this day would be quite burdensome for all the hospitals to put that into place from a ECQM perspective. So that was the other reason and the (TEP) overall agreed with this approach to use all patients.

Jason Adelman: I don't understand either explanation. So for the first one, because there's a lot of variability is exactly why I think you should. So for example if two hospitals gave 100 patients narcotics, and in both, ten got Narcan, then their reversal rate would be exactly the same. However, if one had 1,000 admissions and the other had 10,000 admissions, according to this measure, it would like 1% versus .1%. So the variability has nothing to do with performance. It has to do with the percentage of patients that get narcotics.

So it very much affects. And then the second, you know, we're already looking for patients who got narcotics to exclude people that in the first 24 hours. It doesn't seem like it's, in fact, the defense of the feasibility is this is very straightforward data. It's just looking at people who have administrations for narcotics and so it doesn't seem technically whatever the (TEP) committee said very difficult to just see during this admission was there a narcotic given, yes or no.

Benita Kornegay Henry: Other questions or concerns.

Man: (Unintelligible) answer responsive on Jason's comment. So I mean the (unintelligible) retained the measure's denominator to the subset of the population. That just ties back to the (unintelligible) decision about not to risk

adjustment because I mean like a (unintelligible) standpoint or you can't find like (unintelligible) evidence from the causal inference literature, no subset in that population to a small population is basically helping us to avoid that condition on positive or self-selection bias. Just based on the example you used.

So one example, one Hospital A and Hospital B, they may say (unintelligible) different patients while Hospital A have a lot of patients going in that need opioid to begin with comparing to Hospital B who does not. So drawing the populations I think will help us clearly relieve that selection bias.

Jason Adelman: I don't think that's selection bias or risk adjustment like you're not risk adjusting for comorbidities. We're simply saying if you didn't get a narcotic, you can't have an overdose. Just like if you didn't have a urinary Cath, you can't get a CAUTI. We don't - just this morning we spent, looked at both the (unintelligible) measure and they were both restricted to people who got urinary catheters and got central lines. That wasn't risk adjustment. That simply the opportunity for an error. So you can't have an overdose if you didn't get a narcotic. That's not risk adjustment. That's just normalization for hospitals.

Woman: (Unintelligible).

Man: I think another perspective is to make sure then the measure captures a broader set of the population because we think the patient can be at risk of developing (unintelligible) harm while being in the hospital.

Jason Adelman: That the patient could be at risk for developing on overdose of a narcotic if they never actually received the narcotic? I don't understand.

Benita Kornegay Henry: Go ahead.

Man: I'd like to support Jason because I had that same thought when I was reading through and reviewing it. And it's interesting because when you look at it and think the numbers, you're oh, it's only .16% to .52%. It makes it look like oh, this isn't really a problem. There's not a real justification there. But when you multiply and what I did out of that comment to 6,000 hospitals that are in the US all of a sudden now you're talking about hundreds of thousands of patients a year when in reality it's then becomes when you're comparing one hospital to the next and oh, well you're .17 and I'm .18 it looks like there's nothing there. When in reality, there could be a larger difference.

So I think that by decreasing the denominator, you actually see a larger difference between the groups and hospitals in that variation. Because variation was about 300%. If you're talking about .16 to .5, that's over 300% variation. But yet it looks so small when you're putting it in the entire population.

((Crosstalk))

Woman: Oh, I'm sorry. Was that about the topped out performance? Well I guess since this is an outcome measure, and topping out, I think there was enough variability in the signal, the median signal to noise ratio is what, .98. And that the variability between hospitals and the standard deviation was such that I think there's still room to move the needle to improve. Also this is again, I work with the partnership for patients in the 4,000 and handful of hospitals around that. And there really is no standardized way to measure Narcan across the hospitals right now, these types of events.

And I think this will help us understand how big of a problem is it at this time as we move forward. And I also just have a philosophical question. Is, you know, can you top out an outcome measure for patient safety? Is that a possibility? You know, now far is it good enough? Is it when we start seeing no variability? And then we have to keep the pressure on. I think that was something that was discussed earlier. Like how do you know when to stop keeping your foot on the gas pedal and to back off and what are the inherent risks with that?

Benita Kornegay Henry: This is a new measure, right?

Woman: Correct.

Benita Kornegay Henry: So I think topping out is not a relevant discussion at this point because we don't really know.

Woman: Right, we don't know.

Benita Kornegay Henry: So I think the critical issue is the denominator. Is that correct?

Woman: And may I respond to that? Also speaking with the other measure developers on this, one of the things that was found to be difficult with some places in the hospital do not record Narcan, or I'm sorry, the opioid used within the EHR. The method that was used to determine these was found to have a positive predictive value 94-97% for the numerator. So feeling comfortable that we are measuring what we say we're measuring but we are not able to provide a denominator that only includes every patient that received an opioid. Because of that issue with it not being recorded consistently across outside of like procedural areas where it might not be that opioid given might not be in the.

Benita Kornegay Henry: Yes, not recording the use of opioids in hospitals sounds pretty outrageous.

Woman: In the EHR.

Benita Kornegay Henry: Not in the EHR?

Woman: (Unintelligible).

Woman: In a procedure note, correct, as opposed to.

Benita Kornegay Henry: It's not in the (MAR)?

Woman: Yes, maybe it's written.

Woman: Procedure note, correct. So it wasn't - it would be extraordinarily difficult to then create for those hospitals and EHR to create those fields in order to capture that. But during the testing, they found that it was able - that the positive predictive value was high. Sensitivity specificity also very high.

Benita Kornegay Henry: (Steve).

(Steve): I would tell you that I would have a big problem with a hospital if you couldn't - if somebody's not documenting a narcotic. There's so many things involved in that whole thing. I think just be careful how you're saying it. Because I cannot imagine it's not in the (MAR). It's not controlled so much with everything, with diversion, everything else going on. So I - it - there's a bigger problem that can't.

Woman: It's documented somewhere but the ability for the ECQM to pick it up (unintelligible). If you're still on the line, if you could correct me if I'm wrong, that is -

Benita Kornegay Henry: So you're saying it's not a structured data element all the time.

Woman: Correct.

Benita Kornegay Henry: Is a narrative of some sort potentially. Go ahead Jason and then oh also who is that? (Don) on the phone.

Jason Adelman: I would just say that, you know, later we're going to get to the feasibility and then the feasibility is described as, you know, Naloxone is just straightforward EHR data of administrating drugs. You can't cut both ways. Either measure documented and we can see them or they're not. But Naloxone is just another drug just like a narcotic. So it's either feasible we can get the med data, or we can't. It's hard for me to reconcile those two things.

Benita Kornegay Henry: (Don).

Ed: This is Ed. Is the question documenting whether patients admit they've been on opioids when they come to the hospital?

Benita Kornegay Henry: She was referencing the procedural component of the use of narcotics in where the documentation would be in a text-based note as opposed to a discrete field.

Ed: I know that. But does this include patients coming into the hospital?

Benita Kornegay Henry: Who have had an opioid use outside the hospital? Is that what you're asking?

Man: The way it address that Ed is you have to within the first 24 hours have gotten a narcotic order in the EHR which again you have to be able to document that. And that's how it addresses if somebody comes in with a heroin overdose and they get Naloxone, they're excluded. Because there needs to be some documentation of some hospital order done.

Ed: So that's what I thought. So I was thinking to myself it would be unusual not to have that documented that they got an opioid. Am I just not seeing this right?

Benita Kornegay Henry: We're raising that question. (Don) and then Lillee.

(Don): I'm not sure if my concern is best here or perhaps in a different part of the conversation. But someone else brought it up too. I'm still struggling with the idea that the use of Naloxone is in itself evidence of harm. Naloxone is devoid of side effects. It's - we let anybody give it. Police can give it. You can get it at your own pharmacy. Because short of reversing somebody with having cardiopulmonary bypass or exceptionally large doses, you can give it on almost anybody. And nothing happens if you're wrong. It's just safe.

And we do it empirically for a lot of people who 12 or 18 hours earlier who might have gotten one whiff of an opioid because it's safe and easy and quick and once in a while you get lucky. But most times you don't. I am struggling that we will either discourage that which it's hard for me to see that's a smart idea. Or will include that in as a harm event when in fact I'm not sure it's that at all. I mean I think there's a fundamental problem here that maybe a lot of the clinical insight and expertise came from those who practice in one

particular setting. You know, the anesthesia world where those kind of concerns we're talking about really just, it's not part of the daily practice.

But everywhere else it is. And that's where this measure is going to come from. And I just struggle with it. I'm not sure what we're doing is good or helpful.

Benita Kornegay Henry: Lillee.

Lillee Gelinas: One of my comments was there too. I was really struggling how this is an indication of harm when we look at so many other measures of omission of commission or in the process of care where we know harm may occur. But just giving Naloxone, I'm having a hard time with how that's the proxy. And would like to see more discussion or evidence related to that. Because I'm struggling with that gap.

Secondly, a lot of us that are or have operated in large systems, outpatient departments, ambulatory, have a very broad definition and we have to be very careful of our definition. And so when I look at some of this and the measure developer could probably help me on this, when we think about consolidated electronic health records across systems that include ambulatory meaning surgi-centers, primary care offices, urgent care centers, a number of are entities, that data rolls into the system electronic health record. And is there the potential that there are a lot of the outpatient use of Naloxone that could mistakenly be clustered into what might be the inpatient dataset.

The reason I say that is we see a lot in the DSW area, a lot of the outpatient not inpatient use of Naloxone because of what's happening in community from a public health standpoint. So I would just - if you'd comment for me just a bit on the how clean the data is the way you tested it to truly indicate

that it was inpatient and not muddied with any of those outpatient areas that are also part of large system reporting. Am I making myself clear on that one?

(Kendall Hall): Yes, absolutely. So I just want to call on (Shana West) again, our ECQM to talk about how determined that it was an inpatient admission during which the Naloxone was given. (Shana), are you there?

Woman: (Unintelligible).

((Crosstalk))

(Shana Hall): Like the phone and then placed my headpiece with me. So basically when we look through - when the testing was done, the record was looked at and looked at the (MAR) and looking at the date/time stamps for locations and all of that. So that's kind of how it was determined. The measure logic itself looks at the first 24 hours of the patient's arrival. So whether that's the ED, the an observation or an inpatient hospital admission. So looking at the date/time stamp through all of those to compare to see whether or not the patient was actually in the hospital at the time of an administration in order to pull them into that, excuse me, subpopulation.

Benita Kornegay Henry: So do you have any sense of the percentage of times that the opioid was not available in a discreet data field that you would have, you know, end up with no information on that particular issue?

(Shana Hall): I think that I'd have to look at the documentation. I don’t know off hand the percentile for that.

Benita Kornegay Henry: Do you think it was a small amount of large amount?

(Shana Hall): I think it would be a small amount. Typically you would find that more so in records where perhaps the hospital systems aren't fully - the HR systems aren't fully implemented to include all areas unless they're in a process of rolling out or transitioning over where you might have challenges retrieving that data.

Benita Kornegay Henry: Okay. Other questions or concerns? Yes Jason.

Jason Adelman: I just want to summarize by the question of the evidence behind is Naloxone a good measure for medication error. It was used, in fact, in one of the studies as part of IHI trigger tools and they used the work trigger instead of measure because Naloxone is an indicator to a manual chart review to see if there's an error or not. Where a measure is we're just relying that Naloxone equals error. And I actually think that's a validation question which we'll get to when we discuss validation.

But when it comes to the performance gap, I'm still focusing on that because that's what we're about to vote on. I think that the fact that the denominator in my view is just simply wrong. Meaning like it shouldn't hard to have the denominator be all patients that got narcotics then I just feel like that when we vote that we have insufficient evidence because I think it's a fundamental flaw of the measure. I just want to say that.

Benita Kornegay Henry: So for the pharmacists in the room, so what I remember back in the day about the discussion of that as a trigger was that there were a lot of false positives associated with using Naloxone as a trigger. And so what I remember from our pharmacy advisor group is they actually dismissed it as a tool. So I don't know is that still the case today or do you have any sense of that?

Man: Are you referring to our recent review by a pharmacy group? You said the pharmacy group dismissed it. I'm not aware of that.

Benita Kornegay Henry: No, this conversation was like five years ago when I chased, (unintelligible) first came out with that as a trigger. And our pharmacy team locally in Utah did analysis and they determined that it wasn't that useful as a trigger. I don't know if that's changed. I've got all data in my head.

Man: Yes, you know, so as far as the numerator, I don't necessarily have concerns or issues with it. There is valid. No measure is perfect. I think the denominator like Jason said is a little more concerning. But, you know, I don't know if I share those same concerns that the Utah group did.

Man: To me, sorry, as far as the numerator, I think what we're talking about is Naloxone is given in the ED for heroin addicts who come in with an overdose. And then there are - I'm a safety officer. I chair all the RCA's at Columbia. When a (PGUI-1) inadvertently gives an overdose of a narcotic, and then it's reversed, that's really what we're looking for.

Then there's the procedural anesthesiologist in a very controlled environment who the patient is not waking up fast enough and they give a little bit of Naloxone and a lot of people have debated now will is that an error not? An argument is made that some say it is an error. And others have said it's not. And how the Window is, is that 30%? Or 10%, it's not very clear. The research isn't very clear. The information the developers made is not so clear again, I think that has to do with validity so I can talk more about it when we get to that. But as I said, I'm still concerned about for this vote.

Benita Kornegay Henry: So I think - go ahead Lisa.

Lisa McGiffert: I have probably just a really basic question. Because it - here's what I'm hearing from my lay person point of view is that Naloxone is given to everybody, not everybody. But it's used very commonly used for anything that could be a possible need for it. And that - I'm just wondering is there a problem with overuse of Naloxone? Which is not what this is measuring. But when I hear this discussion I'm kind of thinking wait a minute. Why is this being given so freely? And is that an issue? And I don't even know if it's related to this measure. But that's where my head went.

(Don): So this is (Don). Since I work in the world where this happens the most. It is virtually devoid of side effects. I mean if you haven't taken an opioid, you'd never know anything about it. It is the closest thing to risk free that one can have in clinical medicine. It just doesn't happen.

So the cost used to be an issue. That's really not quite the issue that we once thought before. And it's so devoid of badness we allow anybody to use it at home now. You don't even have to have a prescription anymore in many states. You can just go to the pharmacy if you're worried that you'll find your son or your daughter with an opioid overdose. You can do it. And if you're wrong, it's no big deal.

Benita Kornegay Henry: I'm seeing some eyebrows raised, but I'll go ahead with (Kendall).

(Kendall): So I guess one point Jason can you clarify what you would like the denominator to say? Or is there nothing that could fix that denominator to you?

Jason Adelman: No, I think it should be all patients that had a narcotic order in the hospital and administration, thank you. Meaning like that's the opportunity for an error. If you administer the drug and there's an opportunity for error. But if you never

got it, it's the same as CAUTI and (unintelligible). If you never had a catheter, you can't have a CAUTI. And so -

(Kendall): Okay, and then my second is really just a comment that the one place you're - not that I think this should be included in this, but I think a follow on potentially to this is going to be you're going to see inpatient populations like mine. I'm in the hood. I work in the ED. I have a huge sickle cell population. We know when we put an IV in that population in order to control their pain. They have real disease. We can't not control their pain.

But we know when we put an IV in that patient that a decent percent of them are going to go downstairs and shoot up with that. And it's going to cause a need for Narcan that we didn't actually cause. The VA had a similar problem. And so, you know, this is going to hurt your inner city hospitals in a way because we have a different patient population then you see in the community. And there's no really way to risk stratify that.

But I think that's what you're going to see when the data comes out.

Benita Kornegay Henry: (Kendall) just for clarification, that would be seen if there was not an order for - if the population denominator is the broad population versus if the denominator is for those with an order for opioids.

(Kendall): It doesn’t matter because I'm giving them opioids, right? So I'm giving them opioids. They don't think it's enough. So they do downstairs and administer their own anyway. Then they're overdosed but that's not really my fault. But we have to give them Narcan and I'm going to get dinged for it.

Benita Kornegay Henry: Okay, any other Lisa are you done? Lisa? Hello Lisa, are you done? All right, thank you. Go (Ying Ling).

(Ying Ling): Just a question, even when you change the denominator for just patient who are given opioid, but if the time window is second - after 24 hours, the hospitalization, right. So is there any chance for patients to get overdosed during that period? Then you have to require Naloxone? It does.

(Shana West): So sorry. This is (Shana). So if we were to change the denominator to require that an opioid be administered prior to Narcan use, then you'd also have to shift other parts of the measure logic such as the 24 hour window which is you'd have that in there as well. But then you would also have to look at adding the logic elsewhere in order to support looking at it. So you would still capture all of those patients that have received the Narcan. And I'm sorry, received an opioid and then received the Narcan later. And just kind of - just offer to clarify some of the discussion earlier.

The use of that Naloxone is not to harm. With that 24-hour window, it just triggered that look back in order to ensure that the hospital staff did actually administer a narcotic. And we do recognize that we'll have those challenges such as was stated just prior to know about patients that are administered, self-administering their own narcotic. That would pose a challenge as well. But we need to make sure that we are at least doing - that hospitals are putting things in place in order to try, you know, to the extent possible to minimize these instances and particularly these instances that may be caused by overdose - over administration in the hospital setting itself by staff.

Benita Kornegay Henry: Okay, any other comments. I think we need to vote. (Unintelligible) are you done? Okay. Anybody else? All right, shall we vote?

Woman: Yes, we are now voting on the performance gap of Measure 3501E. Option A is high. Option B moderate, Option C low and Option D insufficient. You

may submit your votes for the performance gap of Measure 3501E. Option A high, Option B moderate, Option C low and Option D insufficient. Just looking for all votes are in. Voting is now closed. And for the performance gap of Measure 3501E, 1 individual voted high. Five individuals voted moderate. Four individuals voted low. And nine individuals voted insufficient. I will show you the percentages just to make it clear. Five percent voted high. Twenty-six percent voted moderate. Twenty-one percent voted low and 47% voted insufficient. So for the performance gap of Measure 3501E, this measure does not pass this criterion.

Benita Kornegay Henry: This is a must pass criterion, so do we stop at this point? Okay, we'll stop at this point on this measure. Thank you to the developers.

So we'll do the next one which is hypoglycemia. If you need to step out and run to the restroom, feel free. Please come back. The e-measure 3503 hospital harm severe hypoglycemia. CMS and (Impact International) measure and (Teresa) is again the lead.

I'm sorry. It got changed. I'm looking at the wrong one, yes. Hold on. Sorry (Steve) go ahead.

(Steve): (Unintelligible) a lot of the discussion we just had over the last two measures, if you look at all the gaps that people have mentioned actually this is interesting and I think addresses a lot of them. So this is a e-measure like we said. It's an outcome. And it's a ECQM. So what it is, is a measure of hypoglycemia which does cause clinical symptomatology. So there is a clinical syndrome or a clinical condition here with low blood sugar. And the numerator is patients who developed severe hypoglycemia defined as 40 milligrams per dekaliter and it's kind of important why that number was chosen, I think, even though it was not in the methodology.

For those patients who had a low sugar within 24 hours of receiving an antihyperglycemic medication. So it's patients admitted in the hospital. I think it's admitted for other reasons and the emergency room and changeover from observation status onward who while in the hospital received an antihyperglycemic agent like insulin or other agents to lower your sugar down that went too far literally were the implications of that.

If you had one episode or multiple episodes, it's counted as one event of patients who have experienced this or not. That's what the measure is. So the measure relies on a query that says yes, I have documentation of an antihyperglycemic agent. And I have a laboratory documentation of a low sugar. That's where the connection of EE occur.

Woman: (Unintelligible).

(Steve): So the linking of your laboratory system and your medication - and your MAR system, your medication administration system. So conceivably it's independent of a person at the bedside saying I'm doing this.

Benita Kornegay Henry: Measure developers anything you want to say?

Woman: Thank you for that introduction. Yes, spot on. This is also if we could just mention it is the - there is currently not fully specified ECQM in a CMS accountability program that looks to this hospital harm if you're hypoglycemia. So it would fill that gap.

(Steve): Yes, the only piece of the - reason of the 40 and again in terms of the measurement itself, there's to ways of measuring sugars in a hospital patient. One is blood goes to the lab. Lab measures it (unintelligible). The other is an

increased common use of something called Nistat which is a bedside finger stick. Something you can do that way. And the Nistat has a lower limit of 40. So if it's 40 or less and Nistat, if you can't go lower than that. It just tells you it's there.

So I just didn't - couldn't tell whether a Nistat and a Nistat is not sometimes as well documented in the same location in the laboratory, usually in the nursing notes versus the laboratory is in the laboratory section. So if the developers can clarify is that Nistat or lab or both?

Woman: Thank you for the question. And yes, thank you for allowing us to clarify or elaborate on that. This measure does look to test (unintelligible) sent off to the laboratory. And also looks to those point of care tests that are done at the bedside whether they be a Nistat or another point of care device.

Man: So that's the measure.

Benita Kornegay Henry: Which, what you're saying (Steve) is that it may not show up in a discreet field. It's probably in some sort of note. Is that correct?

Woman: In testing it does show up in a discreet field, yes.

(Steve): That's what I say, there has to be a dependency on - it shows up in a discreet field. If it does, then it works fine. It's just making sure that - that's just an added area of complexity we can go into feasibility discussion on that.

Benita Kornegay Henry: All right, evidence?

(Steve): So there is good evidence actually that the - there's an incident around 2.3 to 5% of hospitalized patients who hit the criteria of this who have a

antihyperglycemic agent who have this occur. So there's an instance of this and about anywhere about 1-1/2% of 1.9% of ICU patients and 1/2% of non-ICU patients had this happen.

I think that's a little bit higher of an incident reversing the logic of what we just had. This is an instance of patients who are very selective who either had insulin or some kind of an agent. This is that percentage. So if you look at a global hospitalization, how many patients actually get insulin or anything, that's a lot lower. And so this is - we need to be careful. This is 2.5 or 5% of patients who receive this agent. That's probably closer to the order of 1/2 to 1% of hospitalized patients, if that.

Woman: So (unintelligible) staff, this is another question about age limits. So do we have - does NQF have a policy that anything that's under the age of 18 is deemed pediatric and is treated separately? Is that?

Man: No, we don't have. We really only treat those measures separately in the sense that we have kind of bring some pediatric expertise onto our committee that otherwise they're, you know, treated the same as any other measure for purposes of evaluation.

Man: In fact there would be, again, no reason not to include pediatrics in this. I mean more than likely it's a new onset diabetic, so (unintelligible) is brittle. And so again, the developers, there's no reason not to. In fact it may actually be good because there's some evidence in some ICUs. It's purposeful to use antihyperglycemic agent because there is some evidence - there is some push out there to keep sugars low in critically (unintelligible) patients. And so it may be insulin. It may not be insulin going forward. So it's - it would be a good population study.

Ed: Yes, this is Ed. I think the pendulum swung a little bit back towards a more moderate stance on strip glycemic control which is - should have reduced their instance of hypoglycemia in the ICU.

Benita Kornegay Henry: You had a question?

(Don): So this is (Don). I have the same view that, you know, 15 years ago, we were trying to achieve (unintelligible) control thinking that was manna from the heavens. And in fact we found out that when we did it really well, people did worse. And it's probably from these episodes of detected or undetected hypoglycemia.

So just so that I'm certain about this, this measure does not care how the glucose is measured, whether it's plasma, whole blood, capillary blood glucose. You don't care how it - how someone accesses it. Is that correct?

Woman: That is correct. The measure has (unintelligible) to the source of the lab test or if that be a lab or a point of care at the bedside.

(Don): And the reason you picked 40 is not because of those issues, but you wanted real hypoglycemia. You didn't want things on the fringes where we would have a long conversation about whether this was important or not. I gather that's the real reason behind it, not calibration and lower limits on the differing devices.

Woman: Correct, severe hypoglycemia that threshold so to speak was defined as 40 for measure testing. That's fairly consistent with what we see in the empirical literature for severe hypoglycemia and the ill effects associated with that.

(Don): Okay, thanks.

Benita Kornegay Henry: Do we want to vote on the evidence if there's no other questions?

Woman: We are now voting on the evidence of Measure 3503E. Option A is pass. Option B is do not pass. For the evidence of Measure 3503E, Option A is pass. Option B do not pass.

Okay. Voting is now closed. For the evidence of Measure 3503e, 18 individuals voted Pass; 0 individuals voted do not pass. So, Measure 3503e passes the evidence criterion.

Iona Thraen: Okay. Performance Gap.

(Steve): So, actually there is a, there looks like there was a performance gap. There's anywhere between a 2-to-5% incidence, depending on the hospital in the subcategory of patients that were looked upon.

A couple of things: one of the criticisms was it was only two test sites or four hospitals - six hospitals, one time, and two other hospitals the next time they went. So, there's a little bit of a limitation of testing that was done. I don't know - with the number of EMRs, there is a requirement of testing, there was enough of a limited number there even though this represented still about 15,000 patients, per se.

So, that was that low there. In terms of disparity, kind of a tier, also. There was a Black or African American rate that was higher than everyone else. Everything else was a wide range - relatively wide range, but not really a particular difference in scores, or in incidence.

Iona Thraen: So, how many EMRs were tested with this?

Woman: This measure was tested at two beta sites for two different Electronic Health Record platforms.

Iona Thraen: Which ones?

Woman: Cerner and Epic.

Iona Thraen: Questions? Concerns? Shall we vote? Go ahead, (Lilly).

Woman: It was really just an intra-staff question, when you see just two data sites, or is the n so small, or is there a minimum number that NQF requires?

(Steve): It's really just more than one, or you know, two sites that we…

((Crosstalk))

Woman: Okay. So, two is sufficient?

((Steve): Yes, that's sufficient.

Woman: Okay, thank you.

Iona Thraen: Shall we vote?

Woman: Yes.

(Yen Ling): Thank you. Iona. Just looking at the performance gap, there are two test site. You look at a performance rate for Hospital Number 1 and Performance Rate Number 2, then you're taking into account 95% confidence interval, they're

actually interlaid. So, it's not well separated, it seems like. Did I read it correctly? Between those two test sites? If you look at a 95% of the interval, the differences are really not…

(Steve): Right. There's no difference. The only group there was a difference was an African American, but you can argue that both the different groups they were looking at, that ran, and that's even marginally different, but that's just a random statistical significance.

(Shen Ling): Right, yes, yes. Maybe due to small sample size.

(Steve): Yes.

(Shen Ling): Yes, thank you.

Iona Thraen: Okay, any other questions? Let's vote.

Woman: Okay, we're now voting on the Performance Gap of Measure 3503e. You may submit your votes. Option A is High. Option B, Moderate. Option C, Low, and Action D, Insufficient. We're voting on the Performance Gap of Measure 3503e, Option A, High; Option B, Moderate; Option C, Low; and Option D, Insufficient.

All votes are in. Voting is now closed. For the Performance Gap of Measure 3503e, zero individuals voted High; 17 individuals voted Moderate; 1 individual voted Low; and 1 individual voted Insufficient.

So, for the Performance Gap of Measure 3503e, this Measure passes this criterion.

Iona Thraen: Okay, Reliability?

(Steve): Okay. This is not risk-adjusted to the - not risk-adjusted. The Reliability actually was here was high at medium Reliability score 0.89, which was on their scale as relatively high that way. And so, there really was the only concern, again, was the number of hospitals.

And since only two - just a couple of hospitals, I mean, a lot of it depends on your endocrinologist - how tight wound they are and how controlling they are with things. So, that's the only piece, I think, that didn't interfere with how reliable the measure. It's just more about probably what the absolute measure of hypoglycemia rate is.

Iona Thraen: Okay, just a reminder. If you look at the Reliability and Validity both from the Scientific Methods Panel, there were no Lows and no Insufficients. Do we want to accept that, or do you want to vote on it?

We have a motion for acceptance. Is there any disagreement? (Don)?

(Donald): I'm good.

Iona Thraen: Okay. We're moving on. Moving on. So, we're going…

((Crosstalk))

Ed: I notice you didn't ask me.

Iona Thraen: Ed?

Ed: I'm fine.

Woman: Okay. We're moving on to Feasibility.

(Steve): In terms of Feasibility, again, a relatively straightforward query. If - it's funny, just the logic we had on the last measure about how hard it was to do all those things, and now all of a sudden, it's pretty easy to do all of those things, in terms of picking the drug, picking a lab, and linking them together in a timely fashion.

So, I (reject) this as developers, there's a consistent developer in all of this. The guy in the middle there.

Iona Thraen: Yes, the young man. He looked away. He doesn't even love me.

(Steve): How (Patty) can have the logic of problems with one and not the logic of problems with the other. This shows what the (parity) can do. Which is actually pretty straightforward.

Iona Thraen: Okay. Any questions? Shall we vote?

Woman: Okay, we are now voting on the Feasibility of Measure 3503e. Option A, High; Option B, Moderate; Option C, Low; and Option D, Insufficient. We're voting on the Feasibility of Measure 3503e. Option A, High; Option B, Moderate; Option C, Low; and Option D, Insufficient. Looking for one more vote. Thank you. All votes are in, and voting is closed for the Feasibility of Measure 3503e.

Eleven individuals voted High; 8 individuals voted Moderate; zero individuals voted Low; and zero individuals voted Insufficient. So, for the Feasibility of Measure 3503e, this measure passes this criterion.

Iona Thraen: Use and Usability, (Steve).

(Steve): Sure, so now, this is not currently reported. Actually, most of the forms, but there is actually one scenario that it is. And that's in the U.S. News and World Report. So, it actually is a question within that - a variation of this is in a question within that query for Pediatric Hospital - Pediatric Hospitals. We're asked something very similar to this.

So, that's as close as to we're there, but in terms of the evaluation stuff, there was pretty much a path. And it seemed to be very usable.

Iona Thraen: So, what's the plan?

Woman: The plan with this Measure is similar to - actually, exactly the same as what you heard from our pressure injury ECQM. So, it was reviewed by MAP and conditionally supported for rulemaking, and it is in the Fiscal Year 2020 IPPS proposed rule for the CMS hospital IQR program.

Iona Thraen: Any questions? M-A-P?

: So, the MAP Committee did - M-A-P as in Paul. No, is there an M-A-T as in Tom?

(Steve): The Measure Authoring Tool. It's a tool for creating, developing e-measures.

((Crosstalk))

Iona Thraen: So, there the ones developing - okay, got it. I thought it was different. And it says, “The MAT could not support the Measure as specified.” Was that changed?

Yes. It looks like you’ve changed it after the MAT weighed in, and then the MAP actually adopted it. Is that right?

Woman: So, it’s a little confusing, we agree.

Iona Thraen: Yes.

Woman: This is a re-specification of a previously NQF-endorsed measure, and that previously endorsed measure was never implemented because of the M-A-T, the MAT.

So, the re-specification and the testing with this ECQM largely simplified, and we can go through line-by-line, or table, if you’d like to know the exact difference, but largely simplified, that previously endorsed measure while still retaining the quality signal.

And then the MAP, M-A-P, (unintelligible) conditional support for this measure for rulemaking.

Iona Thraen: Other questions? Let’s vote.

Woman: We are now voting on the Use of Measure 3503e. Option A is Pass; Option B, No Pass. Votes are now open. Voting is now open for the use of Measure 3503e. Option A is Pass; Option B, No Pass. Looking for one more vote. Thank you. Voting is closed for the Use of Measure 3503e.

Nineteen individuals voted Pass, and zero individuals voted No Pass, so the Use of Measure 3503e passes this criterion.

Iona Thraen: Okay. We're an hour behind. See we're not so bad. We have - the next two are 3502: Hybrid Hospital-Wide All Condition Risk Standardization.

((Crosstalk))

Woman: All right, before you do that, I want to read this Need for Usability and then vote on Usability and then overall. No? Okay. We're going to do our vote for Usability of Measure 3503e. You may now submit your vote. Option A, High; Option B, Moderate; Option C, Low; and Option D, Insufficient. We are voting on the Usability of Measure 3503e. Option A, High; Option B, Moderate; Option C, Low; and Option D, Insufficient.

All votes are in. Voting is closed. For the Usability of Measure 3503e, 7 individuals voted High; 12 individuals voted Moderate; zero individuals voted Low; and zero individuals voted Insufficient. So, for the Usability of Measure 3503e, this Measure passes this criterion.

And if there are no other comments, we'll move on to vote on the Overall Suitability For Endorsement. Okay.

We are now voting on the overall Suitability for Endorsement of Measure 3503e.

Iona Thraen: For a comment? Did you have a question?

David Stockwell: Yes, I did. I wanted to ask about related or competing measures. I don't know if this is the timeframe for that, but you mentioned that you had another

measure that was endorsed. But this is replacing that. Was that 2362 or -63? Which measure was that? Because it says here that there's no relating or competing measures. All right?

Woman: So, I could look for the exact number. I don't have it straight in my head right now, but yes, it was a previously endorsed NQF measure that was not never implemented. So, this is a re-specification of that measure that largely simplifies the previously-endorsed measure.

Iona Thraen: Was it an e-measure as well?

Woman: It was not an e-measure.

David Stockwell: From an NQF standpoint, from a bookkeeping standpoint, will you guys kind of harmonize or take out that old measure? How does that work? Sorry, is the original measure still endorsed? Is that correct, or was that…

Woman: I misspoke. So, the original is 2363e. It wasn't ECQM. It was endorsed, but never put into any program.

David Stockwell: And so, 2363 is still an endorsed measure at - I do believe.

(Pireau): David, this is (Pireau). I actually believe that was a PMS measure too, and they actually retired it and are not maintaining it. So, there is no competing measure.

David Stockwell: Okay. Thank you.

Woman: If there are no other comments or questions, we will vote on the Overall Suitability for Endorsement of Measure 3503e. Voting is now open. Option A

is Yes, and Option B is No. So, for the Overall Suitability for Endorsement of Measure 3503e, Option A, Yes; Option B, No. Looking for two more votes. One more?

(Leslie): This is (Leslie). I may have logged off of prematurely, so my vote is Yes.

Woman: Thank you, (Leslie). Okay. We will close the voting now. So, for the Overall Suitability for Endorsement of Measure 3503e, 19 individuals voted Yes, and zero individuals voted No.

So, for the Overall Suitability for Endorsement of Measure 3503e, this Measure passes. Thank you.

Iona Thraen: The Option is off. Okay, so, we're an hour and 15 minutes behind now. The request has been that the next two - the 3502 and 3504 - that we addressed those, because we have outside travel people that have come for that, specifically, which will probably push us beyond the capacity to cover the last two, the Skill Mix Of Nursing and Nursing Hours.

We will pick that up in our phone conversation. And we thought we should take a 15-minute break now and come back, and then we'll address those two. Okay?

Are we ready?

Ed: Absolutely.

Iona Thraen: We're still gathering here, Ed.

Pat had to leave. I think (Lilly) is still here, right?

(Millie): (Leslie) had to log off too.

Iona Thraen: (Leslie) logged off? Okay. So, 1, 2, 3, 4, 5, 6, 7, 8, 9, 10.

(Millie): Yes, so we should still have 18, so we're still at quorum.

Iona Thraen: Okay. Sixteen - sixteen's our minimum.

Let's skip all the steps and fly right through.

Missy, are you on board?

Missy Danforth: I am.

Iona Thraen: Why don't you go ahead and start with Introduction?

Missy Danforth: Okay. We are going to start with…

((Crosstalk))

Iona Thraen: Wait. Missy, I screwed up already. We switched the order from 3504 and 3502 to 3504, because 3502 is dependent on 3504. I'm sorry. So, Lisa, start.

Missy Danforth: Okay, so we're going to do the Claims-Based first and then the Hybrid?

Iona Thraen: Yes.

Missy Danforth: Okay, got it.

Lisa McGiffert: And I would say, Missy - this is Lisa - if you want to jump in on anything that you looked at that I talk about, please do.

Iona Thraen: And the developers want to also say something about the two measures together, so maybe we should start with you guys?

Lisa Suter: Sure. Hi, I'm Lisa Suter. I'm a rheumatologist and internist at Yale, and I'm here with my colleague, Dr. (Karen Bursey). And we're two of those team that helped develop these two measures. They're not necessarily dependent upon each other, but they were developed and harmonized together.

And the Claims-Based measure and the hybrid measure are identical except for the addition of validated Electronic Health Record risk variables for the hybrid measure.

So, a lot of the conversation for the Claims-Based measure will be relevant to the Hybrid measure. And we're happy to try and address those at the same time if it is - if it works for the Committee in terms of efficiency or understanding.

Iona Thraen: Okay. Go ahead, Lisa.

Lisa McGiffert: I have a question for the developer to start out with, because he says there's a referral back to doing a similar thing with Readmissions measures and that there was a Hybrid measure after the Final Claims measure.

So, can you talk a little bit about how that works and how it's implemented and used out in the field?

Lisa Suter: So, these are both entirely new measures, so they're not in use right now. They were developed in sequence, starting with the claims-based measure. We used an approach that is similar, but not identical, to CMS's Hospital-Wide Readmission measure, which is in use in programmatic use by CMS.

And that is to divide patients up into what we call specialty divisions in order to classify them, mostly by their service lines, as well as by their presence or absence of significant surgical procedures. And that is in order to better develop risk adjustment models for each of those 15 subdivisions of the overall cohort.

And then the model calculates standardized mortality (risk) ratio for each of those divisions and, and rolls that into the overall risk standardized hospital-wide mortality rate.

Missy Danforth: This is Missy. Can I ask - (Missy again). Can I ask a question related to that?

So, in my reading of this 3502, which is the Hybrid Hospital-Wide for Standardized Mortality Measure, my understanding is that the goal is actually to only have this measure go into use - not the claims-based. Can you talk about why your (C handle) is meant for both?

Woman: And I was just going to address the question about the hybrid measure. So, the idea of sort of hybridizing what was originally specified in claims data only is to use clinical information that physicians and other clinicians have at their fingertips at the time of care in the risk model, right? And this is sort of responsive to stakeholders who, some of whom have a distaste for depending on claims-only to assess risk in the patient-level risk models.

And so, both for the Hybrid Hospital-Wide Readmission measure and this measure, which essentially uses an identical set of risk variables, the addition of the EHR data - that's basically a set of laboratory test results and vital signs that are captured on most patients who end up hospitalized - most adults who end up hospitalized.

Those are added to the claims data to enhance risk adjustment. And so, the Hybrid And Hospitalized Readmission measure recently just completed a voluntary reporting period in the IQR program, and its implementation has been included in this year's proposed rule for IQR. So, it may be familiar to some.

And as I said, this hybrid version of the Hospital-Wide Mortality measure essentially uses identical set of clinical data elements to enhance the claims risk adjustment.

And the reason that we're putting forward both is because we, you know, you can imagine instances in which one or the other would be adopted - depending on the program, depending on the setting. And so, and both are independently valid - and have been validated, I should say, in our testing.

So, we're putting them both together. We certainly - I do not anticipate that CMS would use them both in the same program at the same time. But that's not to say that they're not both good measures for use in different settings.

((Crosstalk))

Missy Danforth: I don't know if you want to start?

Lisa McGiffert: Okay. So, we'll start with 3504, which is a hospital measure. It is Hospital Level 30-Day Hospital-Wide Risk Standardized Mortality Rate. And that's defined as death from any cause within 30 days after the Index admission date.

It only includes Medicare fee-for-service patients, and it is for ages 65 to 94. It - let's see. The numerator is mortality, 30-day all-cause mortality. The denominator is inpatient admissions for a wide variety of conditions. There are some denominator exclusions, but they're pretty minimal, which I like.

They exclude patients with inconsistent or unknown vital status from claims data or other unreliable claims data, discharge against medical advice. And then they have a list of what I would categorize as serious trauma, kinds of patients that they don't include spinal cord injury, skull and face fractures, intercranial injury, crushing injury, and open wounds of the head and neck and trunk burns.

And then they also - and there were some questions about this. They have excluded patients with a principle discharge diagnosis with a CCS and - oh dear, don't ask me what that stands for. But basically, a code that has fewer than 100 admissions within the measurement year. And my understanding is that's across all the hospitals; not in each individual hospital. So, those would be rare conditions are excluded.

And - should I keep going? That's basically the description, and I can go on to…

Iona Thraen: Any questions before we go into the criteria?

Lisa McGiffert: Well, the other thing is that it's not being used in public reporting, which I was kind of surprised.

(Donald): It's a new measure, isn't it?

Woman: It is being used?

Iona Thraen: No.

(Donald): It's a new measure.

Lisa McGiffert: 3504 is not a new measure, is it?

Woman: They're both new measures.

Lisa McGiffert: Oh.

(Donald): It says it's new. So, it could be…

((Crosstalk))

Lisa McGiffert: Why did I…

Woman: It's the Hospital-Wide Readmission Measures are in use, but the Hospital Mortality Measure is a new measure.

Lisa McGiffert: Okay. I'm - the current mortality measure - it's Lisa - are, like, condition-specific.

Missy Danforth: Okay.

((Crosstalk))

Iona Thraen: (Don) has a question.

(Donald): Yes, is the 30-day all-cause mortality, is that all location-mortality, also?

Lisa McGiffert: For the death, you mean?

Iona Thraen: Go ahead.

(Donald): Yes.

Lisa Suter: Yes.

(Donald): Okay, and so how do you assess that then?

Lisa Suter: Through Medicare beneficiary data. So, we have the, Medicare has the possibility to identify all deaths in their beneficiary population.

(Donald): And what's the longest lag interval? See, we do a lot of research in this area, and if I was going to do a national death index, it would be an entire year before I could be certain.

Lisa Suter: So, we've looked at this data in the availability of claims, and it's approximately 98% of the data is available within 60-to-90 days, and these measures are reported out usually a year after the data is available. So, there should be more than ample time to identify the mortality cases.

(Donald): Thanks.

Iona Thraen: (John)?

(John): How did you arrive at 94 is the upper limit for age?

Iona Thraen: It's as long as we're going to live, (John).

(John): I don't know. (Rose) has lived for 120 years.

Lisa Suter: We were privileged to have a lot of input from a Technical Expert Panel and a group of patients and caregivers to advise us on some of these decisions to make recommendations for this measure.

There's no perfect answer. We did look at age distribution. And we looked at mortality rates, and there's sort of a leveling of the mortality rate at a quite a high number after 95 or 94. So, that was why we selected it.

Iona Thraen: All right. You want to talk about the evidence?

Lisa McGiffert: Sure. Okay. So, the - this is where I get in trouble. The developer provided a logic model that outlines the relationship between various healthcare processes and interventions.

They certainly identified the medical harm, medical errors as a cause of death - 440,000, thank you, (John James). And so, they identified a number of different things that hospitals can do to reduce mortality, and different strategies they can take on medications, and infections, and communication, rapid response teams - there's a whole laundry list of ways that this that these deaths could be prevented. And yes. Is that enough? I don't know.

((Crosstalk))

Iona Thraen: Any questions? Anybody online have a question? Oh, (Steve)'s got something.

(Steve): How do you decide? It may have been in there. Somebody had multiple admissions, if it's the last hospital, or?

Lisa Suter: You randomly select in order to avoid the obvious bias of choosing the last admission, and that's consistent with CMS's condition and procedure-specific mortality measures that are in use to try and avoid that.

So, you can only die once, but you can be admitted multiple times, so to try to avoid a situation where hospital care could be evaluated across a number of different hospitals that are touching a patient, we randomly select one admission per year for patients to be included in the measure in order to avoid only addressing the care provided at the last hospital in the chain of many hospitalizations.

So, for example, if you're hospitalized and you had a complication at one hospital, you may not capture that mortality, but you capture that patient. And we want to look across all admissions at all hospitals to try and capture all events.

We obviously want, we - in thinking about this, we know that the last admission may - you know, obviously you can't die more than once - but we do not want to bias the measure by looking only at the last hospital to touch the patient.

(Steve): Well, Shirley MacLaine may disagree with you. But the -

((Crosstalk))

Ed: I still don't get it.

Iona Thraen: About dying only once.

Ed: But again, I just don't - so you're randomly selecting hospitals. So, if I'm in the hospital and had, like, had major surgery, whatever - discharged, went to another hospital who just seeming not - and then died, that could be either one of those hospitals.

Lisa Suter: So, just to clarify, we're selecting random hospitalizations for patients that have multiple hospitalizations over a 12-month period. So, if you're talking about a situation where a patient walks into a hospital and is discharged, and five days later gets admitted to a different hospital, and then dies, the first hospitalization is held accountable for that death, just to be clear.

If it's selected as a random - and we don't - it's going to get complicated, but in the event that that initial admission is selected, they are held responsible for that death.

Iona Thraen: (Millie)?

(Millie): I just wanted to clarify that you're using Medicare data, but not death certificate data? We just did a study trying to see the correlation between cause of mortality and what's on the death certificate, and you'd be really shocked what - at least in our state - we…

((Crosstalk))

Lisa Suter: Oh, I went through residency. I wouldn't be shocked at all - as an intern, filling out those death certificate in the middle of the night. This measure doesn't use death certificate at all. It uses beneficiary data to calculate the mortality outcome, and it doesn't distinguish the cause of death.

So, in setting up the measure, we try to only capture patients for whom we think mortality is a signal of hospital care quality. So, patients who are enrolled in hospice and have metastatic cancer - those kinds of patients - or who are admitted in a comatose state.

Those kinds of, at least already address them as exclusions or not included in criteria. But we try to refine the measure cohort to only look at patients who are - for whom 30-day mortality is a reasonable expectation.

Iona Thraen: (Don)?

(Donald): A couple questions. First off, the follow-up on the people who have multiple hospitalizations and not at one site. If the second hospital happened to be randomly chosen, they would get the attribution for the mortality, even if they had, you know, 23 hours of care, and someone else had a month before them. Is that correct? It's all dependent on the random draw.

Lisa Suter: That's correct. But if you're averaging across all selections, across all patients, across all hospitals, you know, we're looking for a challenging quality signal, which is that of hospital-wide mortality. And we think that that's an important signal of quality. There are no perfect measures, as I'm sure you guys are confronted with on a regular basis. And we are trying to develop a measure that is - as much as possible - avoids systematic bias.

(Donald): Right. I understand that.

Lisa Suter: Yes, that's correct.

(Donald): But there are, within the hospital world, there are places that never get higher-acuity folks. And there are places that only send them away. So, this thought that this all comes out in the wash actually isn't really so accurate. And it gets into Question Number 2.

There's an interesting list of care-related or hospital-quality-related activities that can impact on mortality. I think it's fabulous, but do you have a more global sense in this fee-for-service Medicare population of the relative contribution for 30-day mortality of patient factors versus care factors?

And I mean, that's a really big question, but it's just not, it's not clear to me that we'll be attributing something that's fully a hospital-quality issue to this broad of a measure. It's a very simple measure. I like that part of it, but.

Lisa Suter: I think - and to try and get at your first question - there are two issues. First of all, for patients who are admitted to one hospital and transferred to other hospitals in a contiguous chain of admissions, those patients are always attributed back to the original admitting hospital.

So, the hospital that makes the initial decision to admit a patient to their institution is held accountable for the outcome, regardless of how many times they're transferred or moved around.

And then, the second piece of information is that we looked at the rate of hospitalization in the 30-day period from admission to determine how much

of a quality signal we might be losing if we are randomly selecting hospitalizations.

And we select the second hospitalization, and that's the example that (Stephen) and I discussed earlier and that you just raised. And that's not a common occurrence. And so, we think that the better part of valor is to randomly select.

(Donald): Okay.

Lisa Suter: And then you had a second part to your question, which I think was that sort of broader issue of how can we - does hospital-wide mortality actually capture hospital-level signal versus a patient-level signal.

And I'm sure we'll get to this in the Validity conversation, but I think the answer is, you know, if you compare it to other outcomes such as readmission, the answer is absolutely, patient-level factors have a much higher influence on this outcome than they do on readmission. But there still is a hospital-level effect that's evident in the distribution of rates across hospitals.

And I think we also looked for - you know, we can talk about it in under risk adjustment - but we did some decomposition analysis to try and understand the influence of different effects at the hospital versus the patient level, and there is still a hospital-level effect, even after you're correcting for patient level comorbidity and clinical status, depending on the measure.

(Donald): Okay.

Iona Thraen: (Yen Ling)?

(Yen Ling): Yes, I just follow up on your comment. I know this is the year - you have - maybe this is not the right place. I'm talking about risk adjustment. That's not this is the place to talk about it. This is Validity? Okay, I (unintelligible). Sorry.

Iona Thraen: Okay. Other questions? Should we vote?

Woman: Yes. We are now voting on the Evidence of Measure 3504. Option A is Pass; Option B, Do Not Pass. You may enter your votes for Measure 3504. We're voting on Evidence. Option A, Pass; Option B, Do Not Pass.

Looking for two more votes. One. Is there anyone who is unable to submit their vote? Okay. We'll close voting. For the Evidence of Measure 3504, 17 individuals voted Pass; zero individuals voted No Pass. So, this measure passes the Evidence criterion.

Iona Thraen: Performance Measure: Performance Gap.

Lisa McGiffert: There was a performance gap. They looked at the range of the mortality scores over, like, 4600 acute care hospitals, and it ranged from with 4.3 million admissions, it was 3.95% to 8.70%, and so there was quite a range.

And I had a question, because it kind of looked like there was a cluster around the top of the scale, but I may have - that may have been an earlier comment. They did look at disparities. This is where we talk about disparities, right? And the developer might want to go into that. But they, you know, they did some testing. They use enrollment data also, so there is some information there about the patients.

And they looked at the SES AHRQ social risk factor. And, let's see, they looked at another. So, they looked at dual eligibility, and I think they looked at - was it the AHRQ one that has sort of some income level issues? And seems like there was a third one. Was there a third one? No.

And they tested all that and found - my understanding is that you found that there really wasn't much variability at all based on those measures of disparity. And so, they did not adjust based on the disparity. Is that accurate?

Lisa Suter: It's a great summary. I mean, we think about the conceptual model. We look at the empiric data. We dive a little bit into different issues, such as, like, the patient-level effect versus the hospital-level effect.

We bring that together and present it to CMS, the decision-maker, and the decision was not to risk adjust based on the very limited impact that social risk factor risk adjustment, either dual eligibility or this AHRQ SES Index, which as you said, is a composite of a many both patient and community level factors that drills down to about it's the 10-digit - sorry, 9-digit - zip code - almost the census-block level.

Iona Thraen: Questions? Shall we vote?

Woman: We are now voting on the Performance Gap of Measure 3504. Option A, High; Option B, Moderate; Option C, Low; and Option D, Insufficient. You may submit your vote for the Performance Gap of Measure 3504. Option A, High; Option B, Moderate. Option C, Low; and Option D, Insufficient.

All votes are in. And voting is now closed for the Performance Gap of Measure 3504. One individual voted High; 17 individuals voted Moderate;

zero individuals voted Low; and zero individuals voted Insufficient. So, Measure 3504 passes the Performance Gap criterion.

Iona Thraen: Okay, Reliability and Validity.

Lisa McGiffert: They did test for Reliability in detail and found high Reliability - 0.82 and 0.84 across the - I think with all the hospitals, right, in each hospital. They used a split sample approach, where they took a random subset of patients and measured it against using a second random selection, exclusive of the first. Ad I think they even did a third random selection. And so, they - I don't know if there's anything else I need to say about that.

Iona Thraen: So, scientific panels found in favor of Reliability with no Lows and no Insufficient information?

Lisa McGiffert: Yes, this was looked at by the Science Panel, and all of them rated either High or Low - I mean, High or Medium - in Reliability and Validity.

Iona Thraen: You want to say anything about Validity?

Lisa McGiffert: Reliability? Validity. Yes. So, they did find meaningful differences between the hospitals. These scores fell into a kind of tight range, and I guess I used that again previously when I looked at the Performance, but between 3.95 and 8.70%. And let's see if I have anything else.

They looked at empirical Validity and compared this with three other measures that are measures of quality. One was nurse-to-bed ratio; another one was the hospital star rating mortality score; and the other one was overall star rating. So, they looked at that, and the Science Panel found that the Reliability was Moderate or High - I mean, Validity, sorry.

Iona Thraen: Do we have any concerns or questions? Go ahead, (Yen Ling).

(Yen Ling): I have a - I think the most risk adjustment seems reasonable, but I do have one concern at how complications are identified. That, therefore, to contribute to the death - that patient deaths would contribute to it.

And in your description, you have a two-step way; you know, two step. You identify - one is you determine if this potential complication case was associated with a present admission code, you know, a clinic code. Then given that code is present, then you put it into a - calculating the risk model.

Then any potential complication without this present admission code you would put under assumption that you present a complication of care. So, my - if I understand correctly, that means that if you put a risk model, then you wouldn't consider this as not due to the care in the hospital.

My concern, if I understand correctly, my concern is some patients, they die not because a new complication occur in the hospital. It's because - especially for elderly, and some people have a different situation - that because they report quality care or medical error, whatever happens, it (specifies) their own condition. Therefore, they die.

So, that is not a quality issue, but therefore, but not will not be captured in this, you know, two-step approach.

Lisa Suter: Thank you for this question. So, you're correct. We do try to - using an approach that's used across CMS's claims-based measures that we've developed and validated with medical records and clinical input in the past, we try to understand whether or not a code is present on admission, either

through a specific indicator code, or whether it's probable that that represents a complication that occurred during that hospitalization.

And we have an algorithm to do that, and it represents the risk adjustment model captures in-patient claims data from the prior 12 months. And so, if we don't see that code, that's a potential complication of care in the prior 12 months, and it is a clinical likelihood that, for example, a code of pneumonia that you've never had before, that you're not admitted for, we consider that kind of code a complication of care, and we don't risk-adjust for that.

I think the other part of your question is that you're worried about patients who are ill because of care prior to - that they've received prior to the hospital, and they're coming in and they end up dying, but based on quality of care that may have occurred prior to that hospitalization.

So, under those circumstances where patients really are in that extreme state, those patients are excluded from the measures. So, if you're coming in comatose, or coming in with certain, you know, irreversible codes, there are a few of those, those patients are pulled out of the measure.

If you're made hospice in the first two days the period of admission, you are also removed from the measure. Why do we pick two days? We could have picked one; we could have picked three or four. We had a long conversation with patients and caregivers on our Technical Expert Panels, and they were most comfortable with a two-day window, to give hospitals an opportunity to initiate and have those complicated discussions about end-of-life care.

We know that's an imperfect process, but we are recognizing that some patients do come to a hospital at the very end of their life, and we wanted to represent that.

For other groups of patients, like cancer patients, if you are made hospice care at any point during your hospitalization with a diagnosis such as cancer, you are also pulled out of the measure. So, we try to address that, maybe imperfectly, but it was a consideration and the specifications reflect that.

(Yen Ling): Yes, sometimes it's not just end life patients, or a patient that has cancer. Example: like a person that's already have fluid imbalance in the hospital. And you get admitted; you have a cold. Similar reflect that.

And this study, if you gave (unintelligible) improperly, or somehow flow not properly managed in the hospital, the patient depends on your - how your baseline, and the patient, he died of it. Just simply because that. They are fragile. So, you know, that's the type of thing that's not just patient on the hospice or anything.

Lisa Suter: (I will stop). I think it's an unsolvable problem, but I will say the counterargument to that that we heard from our technical experts, mostly, was the issue of rescue and wanting to recognize rescue and an opportunity for hospitals that really do rescue. Maybe in your situation, it may or may not be an appropriate rescue. We can get into that or avoid the moral complications of end-of-life - that complexity.

But you're constantly trying to balance those two issues in defining this measure, and so we use the input from technical experts and patients and caregivers to make these refinements and hope that that, you know, is as representative as possible of the larger patient, caregiver and provider community.

(Yen Ling): (Unintelligible).

Iona Thraen: Are we willing to accept the recommendations of Scientific Review Panel? Shall move on?

(Millie): I think that (Donald) has a question.

Iona Thraen: Yes, sorry.

(Donald): I think we should…

Iona Thraen: Okay. Accept the Panel? All right. Any other questions? We're moving on to Feasibility.

Lisa McGiffert: I have a note here. We skipped of them. I think this is highly Feasible. They're using claims data. They're using codes that are commonly used. They're using enrollment data to identify patients. Other, you know, whether they died or not. I think it's highly Feasible.

(Millie): I guess I just have one question about Feasibility. So, you're using information from the enrollment, Medicare enrollment source of data. How does that play out in terms of, I guess, this is a measure for CMS to use, is that the intent? So, they have access to the enrollment data, so they can - okay, then why don't you answer this. Any questions? Go ahead, (Steve).

(Steve): Yes, go back. I think it's very good as a measure. I have trouble finding - again, here within the randomization. But I'm seeing scenarios of patients, and how do you interpret the data?

So, the idea of with - you've got multitudes in the day, especially if you have multiple hospitalizations where you're going, "Yes, I'll eliminate it if you're

in palliative care." But should you have been in palliative care from the prior hospitalization with something not happening right? How do you foresee interpreting the results? The negative feed results. Make it Feasible; make it rational to do something with it?

Lisa Suter: So, this measure is not implemented yet. But when CMS has implemented its other measures, it presents us a fair amount of detailed data both publicly, and then even more data individually to hospitals.

So, hospitals in CMS's measures, in CMS's programs, get much more. There's a hospital-specific report, which is a file that contains every single patient in the measure, and why they're in the measure, and what happened to them. And, you know, detailed information about their risk variables and how they compare to their state and the nation.

So, each hospital can drill down to the patient-level data, or the division-level data in the, you know, in the 15 divisions of this measure, to try and understand where their mortality rate is coming from, in terms of a performance standpoint. I don't know if I'm answering your question.

(Steve): So, in another way, in looking at it, I'm Hospital X. I'm not randomly selected, this Hospital X. What happens to the patients I've discharged? What percent were - died within 30 days? These deaths still available for people, versus defined, end up with 30-day mortality on a random basis.

Lisa Suter: So, if you're not one of the randomly - and I think, I don't have an exact number, but I do feel like we need to sort of contextualize this conversation about patients getting readmitted. And you know, in the several million patients that are in this measure, on a high five million, you are not losing any

patients, first of all. You're maintaining every single patient in the measure, just by the random selection.

And only a small proportion - and certainly the proportion that's (highest) risk of mortality - are the ones that are being admitted over and over and over again.

If you are a hospital that has a patient that is readmitted during a period of time, you will be captured in the Hospital-Wide Readmission measure, and you will understand that your patients are readmitted to another hospital in a 30-day period.

So, there is that; this is a complementary measure to that existing measure. So, while I may not be able to tell you whether or not your patients are living or dying - if you're not selected, that admission is not selected in this individual measure - you will have an opportunity to capture that as a readmission, right?

If you're Hospital A, and then there's a Hospital B, and the Hospital B gets selected for the mortality measure, Hospital A is in the readmission measure. So, Hospital A, you'll see that that patient readmitted in Hospital B.

I don't know if I'm entirely addressing it, but between these two measures, the concept of patients returning to care and the quality signal that that represents is captured across the two measures.

Iona Thraen: Vote on Feasibility?

Woman: Voting is now open for the Feasibility of Measure 3504. Option A, High; Option B, Moderate; Option C, Low; and Option D, Insufficient. You may

submit your votes for the Feasibility of Measure 3504. Option A, High; Option B, Moderate; Option C, Low; and Option D, Insufficient.

Looking for one more vote. Okay, thank you. Voting is closed for the Feasibility of Measure 3504. Four individuals voted High; 14 individuals voted Moderate; zero individuals voted Low; and zero for Insufficient. So, for the Feasibility of Measure 3504, this measure passes this criterion.

Iona Thraen: Okay, Usability and Use.

Lisa McGiffert: This is not currently in use, as we said before, but there is a specific plan to use it for public reporting by CMS. They've signaled in a proposed rule that they might include it in the Hospital and Patient Quality Reporting Program - and either this one or the hybrid measure that we're going to talk about.

And it's a highly understood measure, I think, for the public. I think that a lot of the measures we deal with are pretty complicated, and this is something people can understand, that there are patients that go in the hospital, and then something happens, and they die from that care. So, I think it's very usable.

Iona Thraen: Any questions? Go ahead, (measure).

Woman: I just wanted one point of clarification that this measure has gone to the MAP for potential use in IQR, and was conditionally supported, but has not been in rulemaking.

Iona Thraen: Okay. Other questions?

Ed: I don't really have a question about Use and Usability, but people don't come in and die from the care. They die with the care. It's a big distinction, and it's

still the part of this measure that I'm the most uncomfortable about. It's not for this particular vote that we're about to have.

Lisa McGiffert: I stand corrected, but I will push back a little bit, because sometimes people do die from the care.

Ed: Yes. And something they die with it, and I'm just not certain…

((Crosstalk))

Iona Thraen: Right.

Ed: …you've gotten the mix right.

Iona Thraen: Shall we vote?

Woman: Voting is now open for the use of Measure 3504. Option A is Pass; Option B is No Pass. We're voting on the Use of Measure 3504. Option A, Pass; Option B, No Pass.

Looking for two more votes. One more. Thank you. Voting is now closed. For the Use of Measure 3504, 18 individuals voted Pass; zero individuals voted No Pass. So, this Measure passes this criteria for Use.

Iona Thraen: This is Iona. I just have one good question. You may not be able to answer this, but I remember back in the day, some of us are old enough to remember when mortality rates were issued about hospitals. How is this measure different from that measure at that time? Do you know?

Lisa Suter: That's a great question. That was a long time ago, and we did try to pull the specifications. But I confess, we don't actually have the exact details.

But lots of things are different. For example, the structure of the measure, the fact that we divided it up into clinical - clinically derived service lines. We allow the risk models to vary across all the different service lines. We divide surgical and non-surgical patients.

We're using ICD-10 data that has 40,000 codes, as opposed to whatever was in use. I think it wasn't even…

Lisa McGiffert: Oh, ICD-1.

((Crosstalk))

Lisa Suter: It wasn't even, yes, it wasn't even ICD-9 back then. I don't know what it was in the '80s or - but, you know, you know, and hospitals now code 25 codes. I mean, all of that data. We're also using 12 months of data prior to hospitalization for risk adjustment, so I guess there are a lot of distinctions that separate this from the old measure. But, absolutely fair question.

Iona Thraen: Go ahead on the vote.

Woman: Okay, we're voting on the Usability of Measure 3504. Option A, High; Option B, Moderate; Option C, Low; and Option D, Insufficient. We're voting for the Usability of Measure 3504. Option A, High; Option B, Moderate; Option C, Low; and Option D, Insufficient.

Looking for one more vote. Thank you. Voting is now closed for the Usability of Measure 3504. One individual voted High; 16 individuals voted Moderate;

zero individuals voted Low; and 1 individual voted Insufficient. So, this measure passes the Usability criterion.

Iona Thraen: Next one.

Woman: Okay. We're voting now for the Overall Suitability for Endorsement of Measure 3504. Option A, Yes; Option B, No. You may submit your votes for the Overall Suitability for Endorsement of Measure 3504. Option A, Yes; Option B, No.

Looking for two more votes. One. Thank you. Voting is now closed for the Overall Suitability for Endorsement of Measure 3504. Seventeen individuals voted Yes; and one individual voted No. So, this measure does pass this criterion.

Iona Thraen: All right. So, let's go back to the - hold on to the right sheet - the 02 - 3502 Hybrid Hospital-Wide.

And Missy, do you want to talk about what the differences are between this and the claims?

Missy Danforth: Yes, so, thanks, Iona. So, just a couple of things. So, first is the developer submitted this basically identical information for a lot of the sections of the measure endorsement form, including Evidence and Gap.

But they did miss some differences that I think it would helpful to review. So, the first is that the hybrid measure, which is what we're covering now, in addition to all of the claims-based risk adjustors, it includes 10 additional clinical risk adjustors that are captured from the Electronic Health Records.

Another major difference is that the hybrid measure was developed and tested using a subset of hospitals. So, because they needed this EHR data for these additional 10 clinical risk adjustors, they used 21 hospitals within the Kaiser Permanente network, and they actually expanded the patient ages to be 50-to-94.

So, where the claims-based measure was Medicare fee-for-service only, 65-to-94, the measure we're talking about now includes some (A) guard data, but only from these 21 Kaiser hospitals and the patient age was 50-to-94.

In addition, because of the limitations, I guess, is the number of data points they're able to capture from these 21 Kaiser hospitals. So, it's my understanding in reviewing the information is that the Reliability and the Validity testing is actually submitted based on the claims-based measure, and not specifically on the hybrid measure.

There's a couple other minor differences but I think those are the really the largest ones. If I got any of that wrong, please correct me. I know the measure developers are on the call, but those are the ones that I thought were important to point out to this Committee.

Iona Thraen: Any comments from the developer?

Woman: I think that was a good summary that we, because this measure only differs from the claims-only measure with respect to the addition of the EHR data elements, by definition, we're limited in terms of the availability of the EHR data in the world, right? It's not like a claims-data set. And so, similar to some of the eCQM discussions you all had before, you noticed that we have a smaller sample of hospitals in which we can test the data.

And so, what that means is that, you know, for the purposes of Validity testing, to have an external source that we can compare the measure score to, you just don't have that for the smaller set of hospitals.

We did assess the (TEP) Validity independently for this measure, so that qualifies it for Moderate Validity, and, you know, we submit that there's really no rational reason why we would think a measure that simply added EHR data elements would be less valid than the claims measure, which we tested extensively.

The other big issue becomes the ability to empirically test for SES, because we're in a set of 21 hospitals that's in a single region and a single location. Anything we found in those small hospitals would not be representative of what we would see in a national test set.

And again, there's no reason to think that disparities would behave differently simply because of the addition of some EHR clinical data elements. It's really only adds an enhancement to the patient level or risk adjustment. Doesn't sort of change the measure in any substantial way. So, if anything, the Validity would be higher, and we don't expect it to affect the disparities in alpha.

So, that's where we lean on the claims measure and based on that rationale.

Missy Danforth: So, I was thinking on this that, because of the evidence in the performance graph, that what they submit is for the last measure is the same for this one. Maybe we can get to the voting for those two, and then if people do have a question, or if there needs to be discussion around some of the differences in Reliability and Validity, we can open it up for discussion there, but it just didn't make sense to discuss the evidence in gaps since it's identical to the last measure.

Iona Thraen: And NQF is suggesting, if you're willing to just roll over the voting from the other two from the last one in those two sections and move on into the science part. Is that acceptable? Okay. So, we'll move on to Reliability and Validity.

Missy Danforth: Yes, so I actually did have one question about Reliability. So, I understood some of the challenges, because you're using the 21-hospital sample from Kaiser and doing some of the additional testing with this measure, which has these 10 clinical points - or these 10 different clinical adjustors - but it actually seemed like there was potentially an opportunity to do the opposite kind of testing.

So, I think one of the biggest limitations of the previous claims-based measure is that it only captured those Medicare fee-for-service-only patients, and what's interesting is that in Kaiser, that's hardly any of their patient population at all, but they're a closed system.

So, it would seem like one thing that you could have done extra is actually looked to see if using Kaiser as an example, your claims-based measure was reliable in terms of actually representing, or being close to representing, an actual all-hospital, all-cause mortality rate.

Lisa Suter: So, the data - running the claims measure in the Kaiser data is running it on all of their patients. So, we were not just running this measure only on Medicare claims data in the Kaiser patients, but all of the Kaiser claims data.

So, we fundamentally did do that. We also looked at the Kaiser data compared to the national data, and just in terms of representativeness. And they're not actually as strikingly healthier as you might anticipate compared to what, I think, Kaiser patients used to be, you know, 20 years ago.

They look a lot more like the U.S. Medicare population. They are younger. But in general, they have similar rates of co-morbidities, and so it seemed like a reasonable test data set.

Woman: And I also failed to clarify in my previous remarks that we did test for liability separately in the hybrid measure and found a high Reliability score of (ICC) 0.78.

(Millie): Yes, so the Scientific Methods Panel reviewed this measure as well. And the Reliability was 2, High; 3, Medium; zero, Low; and zero, Insufficient.

Iona Thraen: And do I have a question?

Woman: So, in the denominator statement, it says that there are additional details provided, and it's just got seven denominator details but there's no (F.7).

Ed: What was that last part? I'm sorry, I didn't hear that.

Woman: So, in F-dot-six - F.6, the denominator statement, there are additional details, it says, there are additional details provided in F.7, denominator details, but there's no F.7. Is there supposed to be?

Lisa Suter: So, I apologize for if there's an error in the form. The denominator for this measure is the same as the denominator for the claims-based measure. It's the same group of patients. We did some minor modifications for testing it in Kaiser. We looked at patients who were as young as 50 years old, but the fundamental - the way it is specified and tested is identical to the denominator in the claims-based measure.

Iona Thraen: Missy, you want to go up to, go to that Validity?

Missy Danforth: Sure. So, the technical, the Scientific Methods Panel also reviewed the measure for Validity, and as a reminder, they looked at the same Validity testing document as the claims-based measure.

So, this one, and is scored - all the Scientific Methods Panel scores measured Moderate.

Lisa Suter: Actually…

((Crosstalk))

Missy Danforth: So, there's actually, there shouldn't…

((Crosstalk))

Lisa Suter: I thought there was one that voted Low. Can we go back to the Validity?

Missy Danforth: Oh, there is one that voted Low. Yes.

Lisa Suter: Yes.

Missy Danforth: I'm sorry.

Iona Thraen: Insufficient.

((Crosstalk))

Missy Danforth: No, Insufficient.

Lisa Suter: Okay.

Missy Danforth: And I believe it was because they didn't actually submit Validity testing for this specific measure, the hybrid measure.

Woman: Yes, and let me just - you know, this hybrid measure gets us into this weird space, and sometimes it's not crystal clearly understood by everyone, but that when you're testing independently Validity of an ECQM, for example, then assessing the Validity of the data element is sufficient, that you don't need to supply measure score Validity testing for it to pass at least as a Moderate level.

So, here, you know, we have measure score Validity on a national sample based on the claims, and we do have data element Validity for the EHR data elements. But we can't test the measure score because it include the EHR data elements, and that meant we used the male population of hospitals. So, it's nuanced because it bridges those two sets of criteria for ECQMs and claims measures.

Iona Thraen: Are you willing to accept - go ahead. Sorry, Missy.

Missy Danforth: The other thing I just wanted to point out; I know, I don't want to get stuck on things that people really don't care about, but the only comment that the Scientific Methods Panel made was there was some concern about the missing lab values. So, one of the things that this measure does, and it got into the (unintelligible) based on all the series of I think eight different lab values. And in instances where the lab values are missing, it absolutely imputes in the low lab values.

So, I do think that, potentially, one thing that we'll want to make sure is when this does get rolled out to a national sample that you reevaluate those missing lab values to really be sure that all of those are missing.

Because they're coming from surgical patients where the lab values might have been collected, like, days prior to admission, and that's why they're missing. Because it did seem like that was one sort of question that couldn't be answered because you were using this Kaiser sample.

Lisa Suter: That's great. That's great to be (back).

Iona Thraen: Okay. Scientific Panel approved this. Are we accepting of the Scientific Panel, or do you want to vote?

((Crosstalk))

(Donald): It's (Don). I think we should vote.

Iona Thraen: You want a vote?

((Crosstalk))

Iona Thraen: (Don), did you want to vote individually on this, or accept the Scientific Panel's approval?

(Donald): Vote individually. I actually wanted to do it last time, too.

Iona Thraen: Oh, okay. Then we'll go ahead and vote.

Woman: Okay. We are voting on the Reliability of Measure 3502. Option A, High; Option B, Moderate; Option C, Low; and Option D, Insufficient. You may submit your vote for the Reliability of Measure 3502. Option A, High; Option B, Moderate; Option C, Low; and Option D, Insufficient.

Looking for one more vote. Thank you. Voting is now closed for the Reliability of Measure 3502. One individual voted High; 15 individuals voted Moderate; 1 individual voted Low; and zero individuals voted Insufficient. So, for the Reliability of Measure 3502, this measure passes this criterion.

We are now voting for the Validity of Measure 3502. Option A, High; Option B, Moderate; Option C, Low; and Option D, Insufficient. Let me clear this screen. Okay, perfect.

Looking for one more vote for the Validity of Measure 3502. Option A, High; Option B, Moderate; Option C, Low; and Option D, Insufficient. All votes are in, and voting is now closed. Zero individuals voted High; 12 individual voted Moderate; 3 individuals voted Low; and 2 individuals voted Insufficient.

So, I will read the percentages for you: zero percent voted High; 71% voted Moderate; 18% voted Low; and 12% voted insufficient. So, for the Validity of Measure 3502, this measure passes this criterion.

Iona Thraen: Feasibility.

(Millie): So, for Feasibility, this measure uses a combination of the same 21 data points from claims, and then these additional 10 clinical data points, which the additional data points are mostly lab results, but also temperature and, I think, systolic blood pressure. These are all standard tested information available in

the EHR. And testing the measure was all additional 10 elements were Available and Feasible.

Iona Thraen: Shall we vote?

Woman: The voting is now open for the Feasibility of Measure 3502. Option A, High; Option B, Moderate; Option C, Low; and Option D, Insufficient. For the Feasibility of Measure 3502, we're looking for one more vote. Option A, High; Option B, Moderate; Option C, Low; and Option D, Insufficient.

((Crosstalk))

(Charlotte Alexander): I'm sorry, this is (Charlotte). I'm trying to get to the voting screen again.

Woman: Okay.

(Charlotte Alexander): I have to switch out every time.

Woman: Were you able to refresh, (Charlotte).

(Charlotte Alexander): I haven't been able to refresh yet. I'm working on that.

Woman: Okay.

(Charlotte Alexander): I've got to find your email again.

Woman: All right. Are you comfortable giving a verbal?

(Charlotte Alexander): I am. I would give Moderate.

Woman: Thank you, (Charlotte). Okay. So, voting is now closed for the Feasibility of Measure 3502. Three individuals voted High; and 14 individuals voted Moderately; zero individuals voted Low; and zero individuals voted Insufficient.

So, for the Feasibility of Measure 3502, this measure passes that criterion.

Iona Thraen: Use and Usability.

(Millie): So, this is a new measure. It's not currently used in any public reporting or payment programs, but as the measure developer described, there is a plan to have the measure included in the future in the inpatient quality reporting program.

Iona Thraen: Any concerns?

Shall we vote?

Woman: Okay, we're voting on the Use of Measure 3502. Option A, Pass; Option B, No Pass. You may submit your vote for the Use of Measure 3502. Option A, Pass; Option B, No Pass.

Looking for two more votes. (Charlotte), were you able to get on? Or would you like to a…

((Crosstalk))

(Charlotte Alexander): I can't get back on. Let me give you a Pass.

Woman: Okay. All right. Thank you. Voting is closed for the Use of Measure 3502. Seventeen individuals voted Pass; zero individuals voted No Pass. So, this measure passes this criterion.

Moving on to the Visibility of Measure 3502. Option A, High; Option B, Moderate; Option C, Low; and Option D, Insufficient. You may submit your votes for the Usability of Measure 3502. Option A, High; Option B, Moderate; Option C, Low; and Option D, Insufficient.

(Charlotte), feel free to give us a verbal, if you would like.

(Charlotte Alexander): Yes, I'm sorry, I can't get on. I would say, Moderate.

Woman: Okay, thank you. Voting is now closed for the Usability of Measure 3502. Zero individuals voted High; 15 individuals votes Moderate; zero individuals voted Low; and 2 individuals voted Insufficient. So, for the Usability of Measure 3502, this measure passes this criterion.

And we'll move to our last vote, for the Overall Suitability for Endorsement of Measure 3502. Option A, Yes; Option B, No. You may submit your votes for the Overall Suitability for Endorsement of Measure 3502. Option A, Yes; and Option B, No.

Looking for two more votes. Okay. (Charlotte). Would you like to submit a verbal?

(Charlotte Alexander): Yes, okay.

Woman: If you're comfortable. Okay, thank you. Voting is now closed for the Overall Suitability for Endorsement of Measure 3502. Sixteen individuals voted Yes; 1 individual voted No. And this measure passes this criterion.

Iona Thraen: And now that we've exhausted ourselves, just a reminder that we will follow up on the Nursing measures, 0204 and 0205, in our phone conversation. Go ahead.

Woman: So, Iona, what's our backup time? Pat has already said she's not available on Monday.

Iona Thraen: Right.

Woman: I will look to move my schedule to be able to be with you, I think, the first 30 minutes will be impossible to move, because it's a Committee I can't, that I'm in charge of. So, I just wanted to make that clear, that Pat definitely has declared she can't be there.

I know that there are others in our subgroup, but I think it's really important for those of us that have been a part of these measures since their inception in 2004, that we be available to all of you to be able to talk about the trajectory and longevity.

I was sharing with (Andrew) and (Jessie): I actually brought the original 2004 NQF Nursing-sensitive measures document that details how these measures were developed to begin with out of a really huge database.

The Military Nursing Outcomes Database, the Army Outcomes Database, a number of very large databases. So…

((Crosstalk))

Woman: I will email you when I know…

((Crosstalk))

Iona Thraen: I'm not sure I understand. So, we know Pat's not there. She's could (ride the air). You don't think you can join us until at the half hour. So, we start at 1:00 my time, Mountain, so you'll be joining at 1:30 hour. So, if we push it to start at that time…

(Millie): We do have the CDC Measure to go over first.

((Crosstalk))

Iona Thraen: Which measure?

(Millie): The CDC Measure that we didn't get to.

Iona Thraen: The one we postponed on?

(Millie): Yes, so we can schedule that…

Iona Thraen: Do you really want to start with that? That was the other question. Do we want to combine that conversation with the Nursing measures? Or just get the Nursing measures done and come back to that conversation?

(Millie): I thought it was a totally different measure; it's in my (Crowbill) storage here. Or (Angela) my (Crowbill) is.

((Crosstalk))

(Millie): Oh, that's actually the one that we missed.

(Don): That's the SAW measure with the…

((Crosstalk))

Woman: All right. I was confusing it with the other one. Okay. Iona, do we know that the ANA staff, the measure developer are going to be available on Monday to do their initial?

Man: We are.

Woman: Okay, great. Thank you. All right. So, we can…

((Crosstalk))

Iona Thraen: Is anybody getting ready to leave, has to leave? Other than being exhausted?

Man: (Unintelligible)

Iona Thraen: No, I'm fine. We can do it.

Woman: Do we want to do it?

((Crosstalk))

(Don): I'm fine with it.

Woman: Which one are we doing?

Iona Thraen: Is (Emily) available, (Greg)?

(Greg): (Emily)'s on the phone.

Iona Thraen: (Emily)'s on the phone, great.

Missy Danforth: I have to - this is Missy. I should drop off in 30 minutes. So, if that's going to mess up our Forum, I just want to let you know.

Iona Thraen: That's fine. Oh, we'll lose our Forum?

Missy Danforth: I don't know if we are. I don't know how many people are left in the room, but I have to drop off in 30 minutes to start another call.

Iona Thraen: So, we also have to have members in public - so why don't go member public comment and postpone it until the telco?

Woman: (Unintelligible).

Woman: Well, we're working on it. We're thinking we will.

All right. So, is there any member or public comment? Answer a question. Anybody? All right. There's no member or public comment. So, now we're back to doing - are we doing the Nursing or the microbial?

(Millie): So, it was CDC is not available today. So, it would be the Nursing.

((Crosstalk))

(Millie): Zero-two-zero-four..

Woman: Zero-two-zero-four, you guys. So, 0204 is the Nursing, so (Lilly), that's you.

(Lilly): Okay. Hello, everyone. And really, I think you can download the original document from 2004. I think it would be well worth your reading, if you have any interest between the direct correlation between Nursing care and clinical outcomes. I was very impressed with the information that we got that's in our Consideration Candidate Measures packet.

So, this is Skill Mix: Registered Nurse, Licensed, Vocational or Practical Nurse, Unlicensed Assistant Personnel and Contract Personnel. The original measure was endorsed by NQF in 2009 and re-endorsed in 2015.

The reason that 2004 version is not cited is the original Skill Mix as well as Nursing Hours for Patient Day, the other measure, were part of a set. And so, if you think about these 15 measures originally endorsed by National Quality Forum, think of them as threads in a fabric and they all came together to impact the outcome of the patients.

And the later years, these were undone because (CLABSE), (TOWDY) were other of the measures in this measure set. So, that's why Skill Mix, as well as the other Measure, which is Nursing Hours for Patient Day, are now separate. But they were once part of a much larger set.

The description of the measure is the percentage of total productive Nursing hours worked by Registered Nurses, including employee and contractor Travelling Nurses with direct patient care responsibilities by hospital unit.

Really important for you to understand that this measure pulls out supervisory personnel, educators, anyone that's basically not touching the patient. This is a structure measure, and I will tell you, being a Nurse Executive for many, many years, and I absolutely agree with the line that says Developer Rationale.

Despite the consistent evidence that better Nurse staffing contributes significantly to improved patient outcomes, there is considerable variation and skill mix across and within different Nursing unit types.

So, when you look at all the additional measure information and the hours - and for those of you that may not know, in some states, LPN is Licensed Practical Nurse; in other states, like the State of Texas and California, it's Licensed Vocational Nurse. It's the same licensure. It's just called something different, and we haven't standardized those terms, believe it or not.

I will tell you that as a part of your packet, if you look at it, there is a large amount of additional evidence that has been submitted to us over the amount of evidence that was considered in 2015, and it's a very impressive evidence set. And I know all, listening to the thunder, there's something prophetic about that. We're talking about Nurse staffing. The largest workforce in the United States. There are over 4 million Registered Nurses in the United States. We're talking about patient outcomes, and there's thunder.

Man: Told you.

(Lilly): Yes. So, I would like for us to go to the questions for the Committee, because I think that the developer provided updated evidence for this measure that were very strong.

But what I would like to hear you talk about is the Evidence. Do you believe that it is updated and directionally the same, compared to our previous NQF review? And do you agree there's no need for a repeat discussion and vote on the question of Evidence? The algorithms are very strong as well.

Iona Thraen: So, the community for this was (Bill) - he's not here - (Steven), (Patricia) - who's not here - and (Yen Ling) - not here as well, right? It's up to you, (Steve). What do you think?

(Steve): I would go right to the (unintelligible).

((Crosstalk))

Iona Thraen: All right. Shall we vote on the Evidence? Let's do it. What's the matter; are you okay?

Woman: Okay. We are now voting on the evidence of Measure 0204. Option A is High; Option B, Moderate; Option C, Low; and Option D, Insufficient. We're voting on the Evidence of Measure 0204. Option A, High; Option B, Moderate; Option C, Low; and Option D, Insufficient.

Looking for one more vote. Thank you. The voting is now closed for the Evidence of Measure 0204. Five individuals voted High; 11 individuals voted Moderate; 1 individual voted Low; and zero individuals voted Insufficient.

Therefore, the Evidence of Measure 0204, this measure passes the criterion.

Iona Thraen: Performance Gap. So, there is a performance gap that is indicated through the data. And I would ask (Emily), if she's on the phone, if she can speak to the

Performance Gap, which demonstrates quality problems that are illustrative to the data and (unintelligible) for improvement.

(Emily): Yes. Can you all hear me? I'm online.

Iona Thraen: Yes.

(Emily): Okay. Yes, so we work across a number of issues to look at the performance gaps, including different kinds of hospital types, hospital sizing, also unit types. So, we see all kinds of gaps in terms of differences across those characteristics of hospitals and units.

And then we also look at different gaps based on - we match to data looking at Medicaid days. So, hospitals with higher percentage of Medicaid days to kind of get at the patient mixes in the hospital. And we definitely see a range in the skill mix provided across hospitals with different Medicaid days. So, there's disparities across a number of categories.

Missy Danforth: So, this is Missy. I have a question, (Emily). So, what would you want to see, ideally, there? So, you have sort of three metrics. You have the RN skill mix, the LPN skill mix and the UAP skill mix. What would you ideally want to see, like, for those us that aren't as familiar with this metric?

(Emily): Well, I don't want to say there's necessarily a benchmark where we say this level is the best; you definitely need 90% Nursing, or RN versus other, because that is going to vary a lot by the setting.

So, the expectation of what you need RN care versus LPN care versus UAP care for is going - is going to be a little bit different, depending on the patient. But one thing that we do see is that, for example, a study done looking at falls.

I'm sure that you can't judge, if you're low on RNs and add LPNs to the mix, you can't, you can't keep that outcome on falls.

So, you definitely need to, the skill mix is really important, and you can't just interchange bodies in terms of the relationship to these outcomes. Though we always encourage higher RN percentages, but there's not really, I would say, an absolute cut off for these.

And we can sort of start to show with the data, you know, where we see things start to trend a little bit differently, and I think we've got a couple papers cited around that. But it all depends on the setting that you're looking at now coming over the end.

So, there's definitely evidence linking skill mix to these outcomes, but there's not an absolute value that it should be at. And we talk about, similarly, with Nurse staffing ratio, which I guess will be the next measure. There's not an absolute number. We just know you need a sufficient amount. But sufficient depends on the context.

Iona Thraen: I think we're at a gap here, and I'm…

((Crosstalk))

(Millie): But for me, yes, for me, then these data were really difficult to illustrate a gap because of all of those points that you just raised. Like, it's difficult to look at those three bullet points and say, like, oh, there's a gap in performance here.

Like, to me, there it just needed to be a lot more context and analysis to really illustrate that there's a gap. Even if, I mean, within NDNQI, it just seemed to be able to do it by various specialty types, at least to some level.

(Emily): I think that in here in this illustration, perhaps, the narrative is not as strong as the evidence base. And I will give you that. Where the gap is, when you read the evidence base, and when you read the supporting documents and scales that were provided, where the gap appears to be were when RNs, for instance, were eliminated and replaced with two unlicensed Assistant personnel, for instance, or replaced with LPNs.

For whatever reason. I know practically and tactically we do it for financial reasons. But then we see the impact on patient outcomes. Falls go up, pressure ulcers go up, patient satisfaction goes down. All of those parameters.

So, I agree with you. I don't think that the narrative here is as strong as it could be. But the gap is very clear because there's such variation in hospital types, bed size, teaching status, academic versus non-academic, rural, urban - there's just so many parameters there that it would be really hard to see that it would be anything but a very large gap.

Iona Thraen: (Steve), you have…

((Crosstalk))

Missy Danforth: But it's hard to - I'm sorry. For me, it's hard to actually interpret this as a gap instead of just a range or a difference because all of these different hospital types that you just named and all these different units are included in these analyses.

I mean, I guess, like, I've seen a lot of different data of reports out of the NDNQI database. And I would expect a little bit more robust analysis for this

gap piece, considering this is a maintenance measure, and there's years of data available for hundreds, if not thousands, of hospitals.

(Emily): Okay.

(Steve): So, one thing to consider is actually when you have RNs, you know, RNs going for advanced degrees. So, the days of electronic record, all the smart pumps, all the technological whatever else is the gap may show better if you say hospitals that have RNs correcting out for people going for their master's or other advanced degrees.

It's a little bit more educated, savvy, with things going on versus a straight RN out of school or a diploma, ends there. So, I think that there is a big cap there. So, that may accentuate for future more of that gap of care.

Iona Thraen: Other comments?

(Millie): Thanks, (Charlotte). (Charlotte Alexander), have a question?

(Charlotte Alexander): I do. I want to follow through on that last ask, because as we're asked to be good stewards of our resources, we're having to make choices as far as what is the thing that we can financially afford, and what do we need for quality. And I need to look to my nurses to say, "Here are some guidelines around care where we know that a certain skill set is needed to manage."

Now, I think in most cases, it you're talking about an ICU, everyone's going to understand that not only do you need an RN, but you're going to need an RN that's at a higher level, that's got a better skill set.

But for other areas on the floors, we really need to have you take advantage of all this data you've gotten and help us really understand what is the appropriate staffing level? I know in the physician world, we're looking at we're not going to have enough physicians, so how do I elevate my nurses, my advanced care practitioners up to where they're working at top of license so that we're providing adequate care.

We aren't going to have enough nurses either. And so, understanding where best to employ our highest skilled people is really going to be critical, and I would hope you could give us guidance on that.

(Emily): And when you've seen one Nursing unit, you've seen one Nursing unit, because of the physicians that practice there and the type of environment it is. So, it is a very complex mix.

I know that it's later in the discussion, but I do think that the Logic Model - it's on Page 18 of your Measure Worksheet - but shows you just how complex this is, and it isn't just one thing that contributes to the performance gap. It's a number of issues that don't make this as concrete as "If this, then that," so to speak.

Iona Thraen: So, what's the definition of performance gap for this measure?

(Emily): Well, that's a good question.

Woman: (Unintelligible)

(Emily): The definition of the performance gap?

Iona Thraen: I see the numbers, but I'm trying to understand what it is, what is it that you're actually measuring, in terms of performance?

(Millie): Iona, I think that's what I was trying to ask too, so thank you.

Iona Thraen: So, you're just counting the number of RNs versus LPNs versus whatever, by units? By types of…

((Crosstalk))

(Emily): By type of unit, by hospital, by bed size, by magnet staff, and then looking at patient outcomes: number of falls, number of pressure ulcers, any other patient outcomes that are measured.

(Steve): And I assume that's controlled by staffing ratios?

(Emily): Correct.

Iona Thraen: Because it seems like…

((Crosstalk))

(Emily): …by the - it's a calculation of hours. So, it's not bodies. It's hours. So, the number of hours of care that are provided by RNs versus LPNs, versus UAPs. Everything in our staffing measures is defined by Nursing chair hours.

So, 0205, which is Nursing Hours per Patient Day, this particular measure is actually the ratio of the RN hours and total Nursing hours that are the numerator for 0205. So, this is the number, to your point, Iona, is the number

of the count of Nursing personnel, and that's the numerator that is used in 0205, which is Nursing hours per patient day.

((Crosstalk))

Iona Thraen: Calculating the ratio - okay. So, this is sort of the means to that end.

(Emily): Right.

Iona Thraen: Because as I look at this, I mean, the ratio, the skill mix of 0.69 to 0.95 doesn't make any sense to me. I don't know what that means. Does that mean 69% of the time it's RN, ranges from 69% to 95% of the time by unit? Well, if you're talking about ICU versus CTU versus skilled nursing, it makes sense to me.

(Emily): Yes.

Iona Thraen: Right?

(Emily): Right.

Iona Thraen: So, I don't know how to interpret this for purposes of understanding what the gap is, is I think the point that we're trying to get to.

(Jessie): So, if I could clarify that, so for the first one, the definition is the percentage of total productive Nursing hours worked by LPN/LVN with direct patient care responsibilities. So, basically, this would be a proportion of the overall Nursing hours where an RN was working that hour.

Iona Thraen: But what I'm saying to you is that it's by unit type?

(Emily): Yes.

(Jessie): Yes.

Iona Thraen: So, the range makes sense, depending on what unit you're talking about.

(Emily): So, it would have been more helpful for us to break that out because we do have it. You know, the average is one RN to every two patients in ICU; and one to every six patients in medical/surgical, but there's so many different types of units.

And to (Jessie)'s point, I want to emphasize what he said: direct patient care is really important in this, because managers and educators and other non-direct caregivers are not in this number. These are actually number of Nurses that are touching a patient in the course of care.

Iona Thraen: So, I think, going back to Missy's point is that performance gap material that you've given us doesn't really address performance gap. It just describes…

(Jessie): It shows us the range and the proportion by unit. So…

((Crosstalk))

Iona Thraen: But it doesn't mean anything.

(Jessie): It's a, yes, it's a structural measure of who's providing care.

(Lilly): It's not an outcome measure.

(Jessie): Yes, it's a structural measure.

Iona Thraen: Is there a goal? Or is that a mix, a skill mix, is there a particular…

(Lilly): No, the goal - there's true, that is their goal. No, it depends on the hospital, and what their budget is, or what their mission is, or whatever their goal is.

Missy Danforth: Right. But I mean, so I administer a lot of structural measures. So, even in a structural measure, it's like a yes/no, or - I mean, I understand this is a structural measure, but what the measure developers provide is a set of quantitative values to show something.

And I think what we're all saying in slightly different ways is it's very difficult to understand what it's showing. And/or how it's showing, or even if it's showing a performance gap, which is the section we're on right now.

(Lilly): So, I think…

((Crosstalk))

Missy Danforth: It's a range of values, but without any context, it doesn't actually look like there's a gap in performance. I guess, from my perspective. I don't…

((Crosstalk))

(Lilly): The lack of total Nursing time and the lack of RN time contributes to poor patient outcomes. So, what we're measuring here is total Nursing time, which is RN/LPN and Aides clustered, and then the total amount of RN time and the lesser of those two indicators, the poorer the patient outcomes.

Ed: And just to support that, just published recently showed that exactly what you said actually has an impact on HAI rates.

Iona Thraen: Mm-hm. So, we have (Steven), we have David, we have Curtis and we have Tracy.

(Steve): Sorry. Page 25 of the document actually has a listing of the outcomes, whether positive or positive-correlated or not. As a structural measure, these are co-factors. So, it's a co-factor, but also has studies that say, "Here, here's a positive or negative correlation to falls and everything else." So, Page 25 and 26 has a list of 20-plus measures that are impacted here, where the performance gaps are.

It doesn't tell you specifically if you're 75% or 25%, what it is. It just, you have to figure if you - that's why it's a structural measure, I guess.

Iona Thraen: Curtis?

Curtis Collins: Yes, So, I'll go. (Lilly), you mentioned "we" a couple of times. You've used that. Were you are measure developer here?

(Lilly): No, I was not. When I say that, I'm talking about from the perspective of a nurse-executive that's had to staff many hospitals, so thank you for that clarification. The measure developer is on the phone.

Iona Thraen: Can they help us understand this, or? David?

David Stockwell: Yes, that's really my question, too, is that I find it interesting that the Committee is advocating for this measure, and we're not hearing from the measure developer. Can you speak to several of these questions?

Woman: Sure. So, yes, we do examine this to the point of the bullet points that are provided where it is a range and it's across unit types. That doesn't give you a lot of information.

There is a lot of information in the documentation, and when you look across a number of unit types that we provide, the range is from the minimum to the maximum across all the quartiles. So, you can see the ranges there, not only across unit types, but across individual unit types. You can see the variation, for example, in critical care.

And so, for that, for example, in the RN skill mix, it ranges from 7% of the hours being provided by RNs to 95 in set percentiles. Or 100% in the maximum case.

So, those differences are there. And I do agree, that doesn't really necessarily tell you what does that unit that has only 7% of RNs, or hours provided by RNs in critical care, what does the outcome on that unit look like. We did not provide that analysis here.

But we feel that the substantial evidence that has been presented in Page 25 where we have the table of evidence of how these skill mix measures relate to outcomes in a number of adverse (events) that occur in hospitals, additionally makes this point, that lower levels of RN skill mix impact outcomes in a real and meaningful way.

So, between the two pieces, that's where we felt find the gap in care. Or at least differences across skill mix, making it against patient outcomes and how that's actually meaningful.

So, we do provide at the unit type, differences. We provide across the number of hospital characteristics and differences in terms of the minimum and maximum balance that we see by hospital types - so, comparing General to Pediatric.

And for example, across bed sizes, teaching status, across metropolitan status, across magnet status, which is a hospital Quality of Nursing designation. We see differences there as well.

So, there's the three bullet points there are in the summary are just a very small piece of the narrative, and the numbers - the ranges across all of these issues and hospital characteristics and unit types, so that there are massive differences in the way the hospitals go about staffing. And hopefully, the table of evidence linking skill mix to outcomes helps sort of fill in the gap a little bit.

Iona Thraen: Tracy?

Tracy Wang: Hi, this is Tracy. So, in terms of reviewing for performance gap, clearly there is a clear linkage between the increase in Nursing staff and better patient outcomes.

So, I guess my question is, is there evidence from the literature that tells us that what is, like, the ideal skill mix, or ideal Nursing skill mix that would lead to the best patient outcomes down the road?

Woman: I think the difficulty there is that it really depends on the outcome that you're looking at. I think a secondary difficulty there is with skill mix, like with Nursing care hours, that mandating any kind of minimum level is in an absolute sense, is not always appropriate.

Because depending on the mix of patient acuities and on a unit, so if you have a wide variety of patient acuity on a unit, the needs of that unit are going to be different. And as (Lilly) said, when you've seen one unit, you've seen one unit.

So, we really start to get pretty cautious about mandating any kind of absolute thresholds. And I think there's lots of evidence out of California when they started implementing their staffing ratios that that didn't always have a positive outcome.

So, there isn't necessary a mandatory or minimum level that we'd want to recommend. We can connect that there is certainly a relationship between these things and that it's important to know who is doing better in terms of RN skill mix versus not.

(Lilly): So, is the evidence around correlation, is not positive. You can't say, "If this number of RNs, then that patient outcome," but it does provide a basis for hospitals to make decisions around staffing based on what the evidence shows. And that's what happens day-in and day-out.

But there is no - to answer your question - there is no ideal staffing number you're trying to reach, such as with medication error, the optimal number zero. It's not the same when it comes to Nurse staffing.

Iona Thraen: Lisa?

Lisa: I'm trying to figure out if the charts on Page 29 and 30 and 31 - I don't understand what they tell us. And it's listed under Performance Gap - 29. It starts on 29.

Woman: Oh, sure, those are the ranges that I was speaking of before. So, this is within the (unintelligible), like, data set. And I'm sorry; the tables are really hard to look at. We've got them in nice tables, I swear, but when we transferred into the NQF submission portal, it takes all the formatting out of it.

So, those are the means and the standard deviations, and then the ranges of what we see in terms of staffing - or skill mix, I'm sorry. So, for example, if you look at that first (kind) of the adult critical care is at 89 - 89% of the hours were provided by RNs.

So, that first section, about a little ways down, there's the LPN skill mix. So, that's the first number there is 0.002. So, less than 0.2% of the hours were provided by LPNs, on average, in critical care units. So, the table kind of proceeds like that. That first section is the unit type groupings. So, that's all of the unit types - units of that type, in an NQI.

And then, slightly below that, then, is you're looking by hospital characteristics. So, that includes the hospital type, bed size, teaching status, locations such as rural or metropolitan, magnet status as well. Does that help answer the question?

Iona Thraen: Okay, any other questions? Do we have a quorum?

(Millie): We just lost our quorum, I think. (Three had to leave).

Iona Thraen: We need 16. I think we're at 16 now, so if everyone participates, we should be okay to vote on this. Why don't we go ahead and vote.

Woman: Yes. So, we will now vote on the Performance Gap of Measure 0205 - 0204, thank you. We're voting now on the Performance Gap of Measure 0204. Option A, High; Option B, Moderate; Option C, Low; and Option D, Insufficient. So, you may enter your vote for the Performance Gap of Measure 0204. Option A, High; Option B, Moderate; Option C, Low; and Option D, Insufficient.

We're at 13 votes now. So, we're looking for 3 more votes. Okay. We are 14. We need 2 more.

Woman: Call on (Charlotte).

Woman: And I think Missy had to log off. She didn't share a vote, but she said she felt it was Insufficient. So.

Iona Thraen: Okay. So, that would leave us at 15, but we're still short one vote for quorum.

Woman: (Unintelligible). The question is do you want to continue the discussion and not vote, and come back to it?

Iona Thraen: The question is we no longer have a quorum. Do you want to continue to discuss this and not vote, or come back to this on the phone?

((Crosstalk))

Woman: Correct.

((Crosstalk))

Woman: Correct. So, what is your pleasure? It's time. We're calling it. We're calling. We're calling it. It's - all right. So, we will follow up on Monday. We will pick up the microbial - antimicrobial measure first, (Lilly), and then when you join us, we'll do the nursing.

(Lilly): So, I was trying to pick up the questions of the Committee, though, so that we're prepared for them, so the ANA staff that are the developers, I don't know if they're still with us, but I did pick up what's the ideal staffing mix. And I did pick up was it the staffing mix by unit? What was the question that you have?

Woman: Yes, by unit. It's the numerator calculator.

Iona Thraen: And I don't know if we can in the PowerPoint, but if we could have the tables that make it really clear to you. For instance, Neonatal ICU and ICU staffing is very similar. It looks like a bunch of spread numbers right now, so I know it's really hard to absorb, especially when we're in decision fatigue right now.

But is there another question? I can make sure we get answered for you.

((Crosstalk))

Iona Thraen: Okay. And what time is the meeting on Monday?

Ed: It's a week from Monday. Isn't that correct?

Iona Thraen: No, I think it's this coming Monday.

Ed: No, I'm sorry, it's a week from today. Forget what I just said.

Iona Thraen: Yes. So, it's 3 o'clock Eastern Time?

Woman: 1 o'clock Eastern Time.

Ed: No, no, no.

((Crosstalk))

Iona Thraen: Because I'm in Eastern Time.

Woman: So, it's from 1:00 to 3:00 on Monday, and if you, since we have to vote, please reach out if you think that you cannot attend, because we do need quorum. So.

Iona Thraen: Well, we do want to thank everyone for joining us today. And thank you.

((Crosstalk))

Woman: It was a lovely time.

Woman: Thank you for sticking around. We have our next steps up on the Web screen. We do have our Web meeting, our post-measure evaluation Web meeting on June 24 from 1:00 to 3:00 Eastern Standard Time, where we will continue the discussion from this measure, and tackle the other two measures that we didn't get to today. And then we will bring everyone up to speed.

So, you can look forward to hearing from your project team. And as always, you can reach us from at PatientSafetyandQualityforum.org, and I'll turn it over to Ed and Iona to close us out.

Iona Thraen: Ed?

Ed: Well, from me again, I am sorry that I am not there personally. You can blame the weather here in Houston. The Committee is just fantastic. I also want to give a big kudos to the NQF staff that helped Iona and I enormously, trying to prepare for these meetings.

Man: Thank you.

Ed: So, big kudos to them. We've said this over and over again, that we couldn't do it without your support.

Iona Thraen: Thanks, Ed. Anybody else have anything else to say? Safe travels.

((Crosstalk))

(Steve): Thanks to Iona and Ed.

Ed: Bye, everybody.

Iona Thraen: Iona.

END