NATIONAL QUALITY FORUM

Moderator: Reva Winkler
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2:00 p.m. ET

Operator: Welcome to the conference. Please note today's call is being recorded. Please stand by.

Female: Hello, good afternoon all and welcome to the first of four (conference) call. Before we get started I just want to (inaudible). Can you mute that line.

Male: Yes. Just a (inaudible) on the call, we can hear speaking, if you could mute your line that would be great move. And that way, we'll avoid some of the background noise. Thank you.

Wunmi Isijola: Thank you. And just before we get started, I wanted to just give an introduction of those on the NQF staff side that's participating in the call today. My name is Wunmi Isijola Project Manager here. We have Andrew Lyzenga, he's the Senior Project Manager. We have Melinda Murphy, our Senior Director; and Amaru Sanchez our Project Analyst.

I also wanted to get a sense of who from our committee members are on the call today. If you can just please state your.

Larissa Temple: Larissa Temple.

Wunmi Isijola: Hi, Larissa, thanks for joining.

Larry Moss: Larry Moss.

Elizabeth Erekson: Liz Erekson.

Wunmi Isijola: Larry Moss and Erekson, thank you all. Is there anyone else from the call?

Lee Fleisher: Lee Fleisher.

Wunmi Isijola: Hi, Lee thanks for joining. Do we have …

Female: (Inaudible).

Wunmi Isijola: Thank you.

(Jill Bretson): This is (Jill Bretson) with AUGS.

Wunmi Isijola: Thank you, (Jill).

Colleen Hughes: This is Colleen Hughes here with AUGS.

Wunmi Isijola: Thank you, Colleen.

Samantha Pulliam: This is Samantha Pulliam with AUGS.

Wunmi Isijola: Thank you, Samantha.

Collette Pitzen: Hi, this is Collette Pitzen from Minnesota Committee Measurement. I'm not on this workgroup, but I'm calling in for listening.

Wunmi Isijola: Well, thank you for participating. We appreciate that.

Collete Pitzen: Thanks.

Wunmi Isijola: Is there anyone else?

(Sage Clayton): This is (Sage Clayton), I'm with American (Irvine) Society. And I'm not on this work group, but I'm calling in for listening recording the measures we've put forward.

Wunmi Isijola: Great, thank you. Is there anyone else from our committee side who is on the call?

Amber Slichta: Hi this is Amber Slichta with the Health Foundation for Western and Central New York.

Wunmi Isijola: Thank you, Amber. Is Dr. Saigal or Dr. Cima on the call? Dr. Grover?

Frederick Grover: Hello.

Wunmi Isijola: Hello.

Frederick Grover: This is Fred Grover.

Wunmi Isijola: Hi, Dr. Grover thanks for joining.

William Gunnar: (Bill Gunnar).

Wunmi Isijola: Thank you, Dr. Gunnar.

Richard Dutton: This is Richard Dutton from the AQI.

Wunmi Isijola: Great. Thank you, Richard. Is there anyone else?

(Barry): (Barry) (Inaudible).

Wunmi Isijola: Thank you, (Barry). Did I miss anyone else? OK. Do we have Dr. Cima at all or Dr. Saigal or Dr. Levy? OK. Well, with that being said, we'll move forward.

Andrew Lyzenga: And so, this is Andrew Lyzenga, I just wanted to take a quick moment to outline the goal to the call, what we'd like accomplish here. We got a good number of measures to review during these couple of hours. So, we'll need to move fairly quickly.

And so, in the interest of time, what we'd like to do is try to focus our discussion on issues that you've noticed in your review of the measures that you think maybe of concern, things that you maybe find problematic or would like to have some clarification from the developers on or that you think warrant some further discussion from the committee. Things that you think

are looked pretty good and, you know, are not really in need of a lot of conversation or debate.

We'll probably try to skip over during this call and just try to focus our discussion again on those areas of concern that you see and that you think will warrant some additional discussion from the committee on this call and in the in-person meeting.

We do – We'll have a script for each of the lead discussants to use at the in-person meeting and that will kind of walk you through each of the evaluation criteria in detail. But today, I think we're going to get that and just again focus on those areas of concern that you've seen in your reviews. Although if you could try to the extent that you can, you know, keep your comments grounded in the criteria and if you can, you know, walk at a high level through each of the criteria during your report out on the message.

So, we will go ahead and just jump in for each of the measures we're going to ask the primary discussant identified on the agenda to just give a brief overview. Again talk about any areas of concern you found in the measure or anything you think would need some further discussion. And then we'll open that up to the committee for conversation about it. And we do have the developers for each of the measures I believe on line – around the line have representatives of the developers.

So, if you have questions please feel free to ask the developers questions and let them know if there's anything that you would like further application on or explanation of – for the in-person meeting so they could – can be prepared for that as well.

So, with that let' go ahead and jump into our reviews. First on agenda we have measure in number 264 this is Prophylactic Intravenous Antibiotic Timing. And our primary discussant for this is Dr. Grover. Do you want to give us just a quick overview or any thoughts you have on the measure Dr. Grover.

Frederick Grover: Yes, I'll be glad to. Well, this is the rate of Ambulatory Surgery Center patients who received I.V. antibiotics ordered for surgical site infection as – for prophylaxis on time. And the object is, as it clearly stated is to improve the rate of the timely administration of the antibiotics and hopefully in that process decrease the risk of subsequent surgical site infection.

And the numerator is the number of Ambulatory Surgical Center admissions with a pre-op order for prophylactic I.V. administration obviously and the denominator is those admissions that have a pre-op order. So, it's really looking in to the time and the decision about whether prophylactic antibiotics are obviously to be made then by the physician in charge or the surgeon or procedural list in charge.

The, you know, I think it's a pretty straightforward protocol they make a good case I think for obviously there's a very, very high number of patients undergoing surgical – care at surgical centers infection and pre-operative infection is very costly. And it doesn't occur in a lot of people but enough people to present (costly) and to create a very high morbidity associated with it.

There's some question I know that we're supposed to answer about whether something is choppy now and that is a major issue which is particularly one and I dealt with that myself and my experience over the years of being involved to some measures that have gone through in NQF and they have had this in place and there's a high compliance with this for example close – well, a mean rate of 96 percent and a median rate of 100 percent.

So, I think one thing for the committee to discuss is whether this measure – it'd be interesting to determine the opinion of the developer too. Is it tapped out, are there other measures that they could replace it with perhaps, it would be a measure considered for reserved status or is it such an important problem that we're worry – that we would be worried about if it wasn't to continue to be listed as a measure, approved as a measure for current use, will there be a (reservism) with people tend to back off and not be as compliant.

So, the reason the timing of the antibiotic is so important is there are multiple papers and guidelines that show the importance of having a blood level at the time you're making incision or start an instrumentation or a procedure. I didn't see much about any disparity review I may have missed that.

I would assume that's probably partly minimal since this is virtually every patient who has order in place is measuring there the time of the infusion. And the time generally accepted and advocated here is the infusion to be initiated within one hour prior to make that – and surgical incision or beginning the procedure if it's an endoscopy or something of that sort and that it say (inaudible), and perhaps in two hours beforehand. And there are several exceptions which make sense or exclusions I should say to this, but that obviously is people who don't have an order.

We aren't checking in, you know, we aren't checking in to the appropriateness of the order enough and that's not what this is – not a lot of experience it seems to be small, it seems – whether it has been tested I think adequately. So, we'll develop the important measure.

There are some competing measures, but they, in a way they're competing with different people like there's the CMS SCIP measure which is for inpatient surgery and all the surgery. And so, it doesn't appear that that's covered at SCIP measure and maybe you all can reflect in on this with more experience. This isn't competing with that in this setting in the Ambulatory Surgery Center

So, I think those are the highlights of it. I don't how brief, certainly not more in detail in that or not.

Andrew Lyzenga: No, I think that's great, just a high level sort of summary and again highlighting any particular concerns you have I know that you mentioned the issue of it being tapped out and maybe we could have some discussion around that or – but we can just open it up to the rest of the workgroup at this point. Are there any other thoughts or comments or questions from the other workgroup members on this measure?

Barbara Levy: Hi, this is Barbara Levy, I just joined, I'm sorry. I tried to – this is really, really difficult with me on the load. And I'm doing the best I can and I'm sorry.

Andrew Lyzenga: OK, thank you for calling in.

Larry Moss: Hi this is Larry Moss, I just had a couple of comments. Nice review Fred, just a couple of points maybe for group discussion is that which respect to the evidence, there's, you know, a large body of compelling evidence about the relationship between the timing of the antibiotics in surgical site infections that almost everything presented is in the inpatient population with major surgery.

So, I – yes, I mean the science makes sense, but there's inherently a lower rate of SSI in the ambulatory population and then it might be worth asking whether there's a large enough effect size to be able to measure it accurately which kind of relates to the second point as Fred brought up, you know, if the mean and median is 100 percent compliance there's not a whole lot of gap and there's not a whole lot of room for improvement in this population.

Frederick Grover: Well, actually the mean was 96 percent, but it's still pretty, pretty good.

Male: And it is (inaudible).

Frederick Grover: It was a 100 percent

Chris Saigal: Can you guys hear me? This is Chris Saigal.

Andrew Lyzenga: Yes. We can hear you.

Chris Saigal: Yes. I would agree with that and I think this has been tapped out. I mean, realistically because having people ever report those for the purpose of the performance improvement I think the (banks of that) will be low if you're already at 96 percent.

Wunmi Isijola: OK

Andrew Lyzenga: OK.

Melinda Murphy: Andrew, this is Melinda, there are couple of things if I may that Dr. Grover mentioned that I wanted to just also call out. And he said there are multiple measures and over the course of the consideration of the measure in this group, you'll be looking at nine prophylactic antibiotic measures. Four of them within that indication, a couple of them looking at timing, a couple of them looking at discontinuation, one looking at a combination of both the indications and the timing forth.

So just as you're looking at the measures across them and thinking about what measures to move forward and what the populations are that they're looking at know that you got nine measures to consider as you're looking across those.

Another thing that Dr. Grover mentioned that he didn't really see disparities information and the developer pointed out that this requires collection of patient leveled data or individual populations of patients and in (0.10) whenever the Steering Committee looked at this particular measure, they also pointed that out and asked that there be some more bound to identify disparity. And at that time the developer had looked at starting to red (streak) now. If the group agrees the tapped out without having that disparity information the point is (moot), that was something that was requested back in 2010 as well.

Frederick Grover: OK.

Andrew Lyzenga: And I believe we should have the developers on the line. I don't know if they would like to comment on that.

(Dale Brexler): So, this is (Dale Brexler) in Oklahoma the – I don't in front of me have disparities data. I know in the documents we submitted we actually did provide the breakdown for the population by race. So certainly the measure can calculated by race, age, gender, you know, whatever disparities we want to look at and we actually can calculate that I just don't have those numbers in front of me.

You know, I think you heard that they are already different in the microbial prophylaxis performance measures that will be considered and this measure is

the mirrored measure for SCIP infection one in the hospital setting part of the reason that we have two separate measures as you know, CMS has different federal laws and rule-making process for inpatient and outpatient performance metrics in the way that the denominators get identified or different from the inpatient to the outpatient setting, So, it requires us to have measures that overlap substantially, but have some differences in defining the denominator population.

I think performance rates are high in this metric. They're high because I think most surgeons who operate in the ambulatory setting also have experienced with the inpatient setting in that performance measures been in place starting back – all the way back to 2002, 2003. So, it's becoming an essential standard I don't think any of us know what happens when you retire a measure there's not good data on what happens.

Lee Fleisher: (Tom), this is Lee Fleisher, and I was involved with the SCIP measures, as far as how long – this is I assumed we're discussing (tapping) this measure for – if it's out there. And for how long and – will we have this an over-arching for the NQF staff discussion of when they tapped out measure should be retired?

Andrew Lyzenga: So, that is a decision for the committee whether you would like to put the – endorse the measure with reserved status. That's an option, you know, their option is just to remove endorsements. If you do look to endorse the measure with reserved status or remove endorsement one thing to think about is are the unattended consequences that I believe Dr. Grover alluded to potentially removing the incentive that has led to this measure, you know, having very high levels of performance. So, that is something to consider, but it's up to the committee's discretion in terms of whether they like to endorse the measure with reserve status or not.

Frederick Grover: And when you do endorse is saying the decision was – if it's made to endorse with reserve status what does that mean? Does that mean you can put it back into effect at any time or you come before this group again you don't need to re-endorse, but just to question of whether to reinstate it or what is that involve or mean.

Andrew Lyzenga: Actually I think measures that have reserve status will still be reviewed in the usual cycle every three years, will still be the same kind of maintenance review and presumably at the time of that maintenance review, you can, you know, re-evaluate whether it shouldn't be – keep its reserved status or, you know, lose endorsement or move back into a regular endorsement status depending on what has happened on those intervening three years.

Richard Dutton: Hi, this is Rick Dutton, can I weigh in quickly on that?

Andrew Lyzenga: Sure.

Richard Dutton: Three disclaimers first. I am a member of this committee but not specifically this workgroup. I am a steward for the next measure, I represent the FASA, who is the steward for the next measure which is very similar. It has three – I was part of this workgroup the last time we discussed it in 2010. All that said, although performance on this measure is close to 100 percent when it's reported, I would point out that there is still a very large gap in who reports it.

Our look at the Medicare data shows that about half of eligible industry (virologists) actually report this measure although it's half of the cases where an antibiotic should have been given. There's a report of whether it was given or not. So there's still a huge gap at reporting this. And I read this (including) numbers about 40 percent of all that data is (similar) submission. I don't know if they now have that in the outpatient perspective …

Andrew Lyzenga: Yes, that's a good point, so, for the hospital outpatient departments we think the reporting is fairly high because it's high to the hospital outpatient quality reporting program and their financial incentives harbor in other settings like Ambulatory Surgery Centers, I actually don't know what the gap is in terms of actual reporting in the metric.

Frederick Grover: Yes, that's a – well, you know, as we discussed it too, I can remember, I mean, in my area which happens to be cardiothoracic surgery most things, most patients received local (active) antibiotics because there's been – it's in the guidelines for – because it's evidence-based but the timing of it was an issue until some of these measures would put into effect quite frankly and it is – it's

an easy thing to slip up on particularly if somebody is going some (length) which needs to be started well ahead of time.

So, it'd bee interested to hear everybody how this goes. I do have some angst about pulling out some measures that they're relatively successful and/or actually some of them very successful in getting compliance about what will happen because it's kind of a pain in the neck, you know, to capture weight of the exact timing, I mean it takes some effort to do that and have people remember them to order the antibiotics at an appropriate time and make sure they're delivered.

Barbara Levy: This is Barbara Levy, so one of the issues that with the institutions are being measured on a more robust outcome with the surgical site infection. And so if their seeing measures on that outcome and this is an intermediate process, I'm not sure that they won't continue to do this internally.

Male: That's a good point. And this is – I agree with that 100 percent that's a great point and it's base, I mean this is part of the process for so many places now that even if you stop measuring it, no one's going to stop giving antibiotics before surgery and when you measure something, the response from their institution, I think just take that burden and put it as a some more effective to move the (inaudible) forward. So I recommend, you know, sunsetting this thing.

(Dale Brexler): So this is (Dale), I'd like to make this one comment in response to that and so I completely agree that in the inpatient setting there are actually is robust surveillance required both by CMS and other programs through the national healthcare safety network. I think there's very, very limited reporting of surgical infections or surgical outcomes in ambulatory settings.

Frederick Grover: Yes, and what worries me is what you said to about the lack of reporting period. Do you have a measure for that? Or is there?

(Dale Brexler): There is one about anesthesiology administration. Yes, so I am – we could get the number that the number of hospital outpatient department, that's all under that hospital outpatient department, you know, the hospital patient quality

reporting system majority passed the lab patient facilities do report this measure. I can't tell you though what the percentages of non-hospital outpatient departments, so ASCs or other, I don't know.

Barbara Levy: Right, (to my earlier) point, we don't even know that this measure is a valid measure in that setting.

Frederick Grover: Yes.

(Dale Brexler): I mean, there's actually pretty good data that antimicrobial prophylaxis in almost every single operation, low infection rate or high infection rate that it's been studied has resulted in lower infection rate. It is true that then you have to weigh the cost and benefits of prophylaxis to the actual risk of infection. But pretty good data that almost with every operation that's ever been studied if you do antimicrobial prophylaxis you will reduce your surgical infection rate.

Barbara Levy: Right, but we have a small list of procedures for which antibiotics prophylaxis is not recommended because the risk benefit profile doesn't make any sense.

(Dale Brexler): That's true and that's why the denominator of the performance measure is limited to a very restricted group of operations.

Barbara Levy: Yes, I'm just saying that the data were all generated from inpatient, settings and …

(Dale Brexler): Exactly.

Barbara Levy: … we don't know what…

(Dale Brexler): What, you know, I mean, basically we just don't know what's happening in that ASC settings, there's no evidence for or against it sounds like in terms of the nature – the magnitude of the problem and there's I think theoretical evidence that it's a less of an issue because the patients are healthier. And so I just feel like it's a way to demonstrate the problem there. I like the idea of looking at an outcome measure in this area as opposed to a process measure given that the process already is already faked in through a lot of places.

Andrew Lyzenga: So, see, I'm going to actually – the culture in the inpatient, the in-person meeting, I'm just wondering from the staff perspective, we spent 30 minutes on this first measure …

Male: Yes.

Andrew Lyzenga: … I think we've outlined the real questions. But this would take a – I brought it up as action that should occur at a lot of these measures.

Female: Right. So I think what the staff will do is capture the discussion identify what are they key points that you've brought forward in this workgroup meeting in order to bring those forward at the in-person meeting and in the process of doing that it sounds like there are couple of things that you may want a little additional information for at that meeting from the developers.

So Andrew, I would say we'll just put that information together, verify with the workgroup the information that they want carried forward and what they want – desire to have available at that time prior to the in-person is fair?

Andrew Lyzenga: Yes, that's sounds good.

Female: How's that sounds?

Frederick Grover: Yes, I think in just the kind of procedurally since I'm new to this committee this year do we bring things up now and then the final decision on these will be made at our face-to-face meeting in Washington, is that the way it works?

Andrew Lyzenga: Yes, that's correct. We won't be making any – doing any reading for the measures or voting on the measures at this point. Well, that will all happen at the in-person meeting.

Frederick Grover: Yes, I think for my stand point a good case, you know, if there's any more information you can help us with the as a committee in regard to the topic now, the issue also the issue of what percentage is your penetration rate of getting this data submitted to you. And if you have – if there's any data that you could get to us or how the surgical infection rate made to compare and surgical centers as compared to in-patient hospital facilities. I think that could

result out and there was a little bit and there are two that we mentioned to about the – any disparities and the issues with disparity.

Am I believe in (anything) out? This is – These are all voluntary measures, I assume. I mean the SCIPs aren't but these are – this one is, is that correct?

Andrew Lyzenga: Well, you could say SCIP is voluntary, it's officially voluntary it's just there are – for both the hospital outpatient and inpatient programs if you don't report them you forfeit part of your market basket update.

Frederick Grover: Yes, OK, yes. What about this one doesn't carry a financial penalty is that correct?

Andrew Lyzenga: There is a market basket update for hospital outpatient facilities also.

Frederick Grover: OK

Barbara Levy: So, this is Barbara and I apologize to all of you. But, I only have about five more minutes and then I need to run is it OK, if I give you a really broad overview of my thoughts on the cystoscopy and the measures that I was suppose to look out.

Andrew Lyzenga: That's good.

Male: It's good for me.

Andrew Lyzenga: Yes. We can actually just …

Barbara Levy: So, I did weigh in on the website .

Andrew Lyzenga: Yes. So, we'll – yes, we have your comments on the website – from the website. If the workgroup doesn't object we could actually just jump to that measure right now, sort of out of order and return to the rest of the agenda after Barbara leaves us. Does that sound good to everyone.

Male: Please do.

Female: Sure.

Andrew Lyzenga: All right. So, let's …

Female: I agree.

Andrew Lyzenga: Yes. So, go ahead and give us to your thoughts on that Barbara.

Barbara Levy: OK. So …

Andrew Lyzenga: And just sorry, just …

Barbara Levy: … where I can find it.

Andrew Lyzenga: Yes. So, just to clarify we are talking of now about measure 2063 Performing Cystoscopy at the Time of Hysterectomy for Pelvic Organ Prolapse to Detect Lower Urinary Tract Injury.

Barbara Levy: Right. And so, my broad view is that the evidence is insufficient. I'm not convinced and I realized that in 2010, where workgroups decided to separate this measure from the measure of using cystoscopy at the time (with) urinary incontinence feature. But I'm not at all convinced that this need to be two separate measures or that pelvic organ prolapse should be excluded from the other measure. I think that's an important thing for us to look at in terms of, you know, it's the liability, validity, I think it's a reliable and valid measure I think there's good evidence to support it.

Obviously not an outcome measure like collecting outcomes in this particular area would take us many, many years to do. And I don't think that that's receivable, it's something that we can import from electronic medical records for that difficulty and I think we have guidelines from the American College of OB-GYN to support it.

Andrew Lyzenga: Thanks, Barbara. And just to give a quick note. I should have mentioned this before that this measure number 2063 as well as 2038, and 2052, these are all measures that went through importance to review previously as part of what we were recalling at that point a two-stage CDP process. That process is now defunct and we're no longer going to be doing it. But, we still have this few measures that went through that process.

And so, what happen with those is that their importance – these measures were already evaluated against the importance criteria. So, there will be no need to do that again. And we'll really be evaluating them against the remaining criteria of scientific acceptability, feasibility and use and usability. So, with that said, are there any other comments or questions from the rest of the workgroup? And this is a …

Larissa Temple: This is Larissa and I was the secondary reviewer and Barbara, it'd be helpful maybe I miss some issues when I read the measure. It struck me that the cystoscopy information would not be housed in CPT codes because it's bundled with the procedure. And so, they talked about a separate database that was in the development process.

Barbara Levy: No, it's not going to move into this codes, it is bundled into the (FUI) code.

Larissa Temple: OK, let me – OK.

Barbara Levy: But, you're right. And that – if you're just using administrative claims it's may or may not be paid depending upon whether there's a diagnostic reason to do the cysto. So, that's a covered decision not a bundling decision. But, it's true that using only administrative claims will be problematic.

Larissa Temple: Yes.

Barbara Levy: That this would have to be pulled out at the EMR.

Larissa Temple: Right, so, that's – you're right. It struck me that the CPT codes would not be able to be pulled from the administrative data. And there was discussion about that pelvic floor disorder registry. And I think at the main meeting it would be interesting to hear the development of that and the acceptability of that to the field.

The other issue that I've found was – and again I'm getting this some of these measures confused there was discussion with the reliability when they looked at four hospitals – this is actually for the developer, when they looked at the – they looked at four hospitals and one person – one hospital used CPT codes in a wrong way. And I think that it was very important, if the developer could

give us a little bit of information because it just speaks to how reliable it would be to get the denominator with administrative data.

Samantha Pulliam: I'm not sure this is a perfect time for me to answer that. But Samantha Pulliam with the American Urogynecologic Society, one of our developers.

Female: Yes.

Samantha Pulliam: And I was part of the study that looked at this four hospital group.

Female: Sure.

Samantha Pulliam: What we found was that one of the four hospitals and this is sort of bouncing back to their work ahead to completely misuse the codes. So, there is nothing correct or appropriate about their code use and basically instead of continuing to work with it we bounce it back to them for future correction. And something that I think it's not really pertinent except that we sort of uncovered something that they need to address.

Larissa Temple: And you would say that's a one hospital area as opposed as something that's …

(Dale Brexler): Absolutely.

Larissa Temple: All right. That was just a concern that it was not being used – done and systemically properly, OK.

(Dale Brexler): Right.

Larissa Temple: So, those are my only additional identification of the cysto piece to this. And I agree with everything Barbara said.

Frederick Grover: Can I ask you this on these two ones from the American Urogynecologic, well one's American Urologic and one's American Urogynecologic, they are pretty similar it's just the procedures that are different is that right or am I oversimplifying that?

Samantha Pulliam: This is Samantha Pulliam, again I think the issue really was that the denominators might be very different. The one is the group of patients who had hysterectomy possibly not (slings) and the other might be group of patient that have (slings) and possibly not hysterectomies.

Barbara Levy: But, in the end what we want to know is the people are using cystoscopy to …

Frederick Grover: Right.

Barbara Levy: … correctly identify urinary tract injury. And I really felt that they she could be combined (into) the measure.

Frederick Grover: Yes. Because, you could – I don't know, I mean, I'm just bringing this up and no one could say that. The main thing is does cystoscopy trying to accomplish the same thing but in different procedures. And could you combine although it is two different societies here, but I wonder if they could get together and combine them into one. Well, up to certain (inaudible). Just tell me if I'm crazy or, you know, I'm just asking a question.

(Dale Brexler): I think it wasn't – these were intended to be combined those public comments that happen to have after they were endorsed last time and they got them split because of that?

Female: Right. That's correct.

Female: That's what I can't …

Female: Yes. That's correct that is what happened.

Frederick Grover: I missed that what was that?

Andrew Lyzenga: The previous committee that did the importance review initially recommended that this few add measures be combine in the public comment period there was some push back on that idea and upon reconsideration the committee sort of backed off at recommendation. But it's still something that you can consider as this workgroup and committee whether that's occurred.

Frederick Grover: I didn't know that.

Female: Right.

Samantha Pulliam: Great. I certainly want. This is Samantha Pulliam again one of the other concerns with that the gap for one and a gap for the other were sort of different. And that you might just combining this sort of artificially elevator depressed the compliance rate for one or the other of the practices. Sort of hiding on compliance because we thought perhaps that there was a higher – smaller gap for (sling) cystoscopies and a higher gap for hysterectomy cystoscopies.

Frederick Grover: Yes, well you'd have to stratify.

Samantha Pulliam: Yes.

Larry Moss: That's a question about their performance gap, this is Larry Moss, is a non-content expert here. The measure says that their reports an 88 percent performance gap and the site of study that says 12 percent of graduating rather than from the field use cystoscopy. That's a – If the evidence is so clear that there is benefit why is there such a large gap, you know? Are there a body of folks out there who believe that the evidence isn't so clear?

Barbara Levy: I think that's correct. I think that there's a guidelines from the American College of OB-GYN says that this should be performed when the urinary tract is at risk and so I think that the issue is that definition of when the urinary tract is at risk and then (who can't). And because of the (class) of measure it's a little bit complex but the data would support doing this as a risk of injury is 0.5 percent or greater.

And there are couple of studies showing that level of risk but one could argue that and other people maybe highly experienced people hence the risk of injury might be 0.1 percent or 0.01 percent. And so the individual judgment have come in in that area and whether people expect the fact that in fact that everyone of this procedures the urinary tract is at risk.

Male: Right.

Larry Moss: Was there any risk that asking the 88 percent of folks who don't do cystoscopy to do it as a measure that it may not be done effectively since they are this large group of gynecologists who don't do it and assumedly aren't that proficient in it?

Barbara Levy: Absolutely. Yes. Go ahead, Larissa.

Larissa Temple: Go ahead, Barbara, because we may actually have different answers.

Barbara Levy: Well, you know, I think that's actually a key point. And it depends on what sort of injury we're looking for. So it's pelvic organ prolapse surgery we're looking for – in general, we're looking for obstructed ureter, and that's a little bit easier to ascertain than if you're putting in a sling and you're looking for a little bit of mesh in the corner of the bladder that maybe more difficult to ascertain. So I think the data are a little bit different. I think it's relatively straightforward to determine whether this (inaudible) coming out or not.

Andrew Lyzenga: Are there any issues that you'd like to flag for the developer to take a look at and bring back additional information to the in-person meeting?

Barbara Levy: I'm just trying to think s. I don't really think so, I mean I think some of these data is relatively old and it's not as simple as it might be now. If there – I don't think there's anything in addition, there's certainly not additional literature that I know of that would be useful.

Frederick Grover: OK. This is, I mean, there a lot of studies listed but it's interesting to me that the guideline – the specialty guideline didn't mandate or didn't sound that strong recommending to that. Were there be a way that you could strength them in the case on this by maybe taking some – quoting some of this – some of the papers that you have listed in your bibliography that might make a stronger case?

Barbara Levy: Well actually I think a lot of a literature that's listed is for hysterectomy in general and it's related laparoscopic hysterectomy and it's not specifically directed to hysterectomy for pelvic organ prolapse and that's one of the problem is that most of the literature is about where does hysterectomy

(lobotic) and laparoscopic (inaudible) not specifically for the this pelvic organ prolapse.

Frederick Grover: If there are any data that can provide an example where, you know, a large population in this policy was instituted and a lower injury rate was demonstrated that it would be really helpful to quote that.

Samantha Pulliam: Yes. The other thing I felt and I'm a pelvic surgeon but not a GYN surgeon was, you know, I think that's when I read – I only reviewed the – for the pelvic prolapse cystoscopy, but you know what I think is very helpful to hear the differences in the type injuries you see with cystoscopy between the two measures because I think that also pushes to keep them separate and I think that commenting that if you see the injuries are very easy fix in the operating room where as if you don't, I think that that would be helpful to be explicit to non-content experts in the type of injury I thought would be helpful.

Frederick Grover: I think there could be a little more detail.

Melinda Murphy: It's Melinda. I have a question for the group. So as you discuss this it seems pretty clear about when you would be looking to have the cysto done but that does not seem to be a part of the measure is that important to you about when the cysto is done?

Samantha Pulliam: Well, I think it has to be done intra-operatively when the patient still is still asleep.

(Crosstalk)

Frederick Grover: At the end of the case right?

Samantha Pulliam: Yes, it has to be done at the end.

Melinda Murphy: And so, is it OK to assume that is what this means without it being specific to that?

Barbara Levy: Yes. I think so.

Samantha Pulliam: I think it does, performing at the time of hysterectomy during the surgery, as a surgeon it made sense but it maybe …

Barbara Levy: Right.

Samantha Pulliam: … it needs some more …

Barbara Levy: (Inaudible) could make sense. We know we're not performing diagnostic cystoscopy for bladder lesions. We're looking for injury, was always to be done at the end of the case.

Male: Great.

Female: Right. And in some cases it talked about malignancies and those kinds of things which will be present before so that lead me to ask a question if the time …

Barbara Levy: OK. And I think that was an irrelevant comment that probably doesn't even belong. It's purporting to show the good for this but that's a diagnostic cystoscopy and those are incidental findings unrelated to the measure.

Samantha Pulliam: I agree that was a – I though that was some – that to the measure developers, I agree that that should be in the stress contents one as a rationale for doing it after procedure.

Barbara Levy: All right. So I'm going to have to sign off. I really apologize to everyone and I will be on the other calls but I can't now.

Andrew Lyzenga: Yes. Thanks Barbara.

Male: That's OK.

Andrew Lyzenga: Any other comments or questions on this measure?

Well, hearing none let's switch gears again and jump back up to measure 269. This is Peri-operative Care Timing of Prophylactic Antibiotics Administering Physician and we have Dr. Moss as the lead discussant. Are you still on Dr. Moss?

Larry Moss: I am.

Andrew Lyzenga: Great, you want to give just a – some thoughts talk if you noticed anything of concern or that is worth discussing on this measure?

Larry Moss: Sure. I'm happy to. So back to issue of peri-operative antibiotics which – so I'll try to be brief since we've discussed this a bit.

This is measure is submitted by the American society of Anesthesiologist and it's specifically refers to patients undergoing in aesthetic and the administering physician for the peri-operative antibiotics which is the anesthesiologist. The numerator and denominator is similar to their first measure that we talked about numerator being patient for whom antibiotics have been ordered and denominator being – I'm sorry numerator being antibiotic given to in which case it's been ordered and the denominator being all cases in which they've been ordered.

Couple of comments with respect to the evidence, you know, it's obviously we discussed it's widely accepted that there's a relationship between giving the antibiotics on time and reducing surgical site infections. Probably worth pointing out that there are recent data which I didn't see quoted in the measure which have shown that in hospitals with high compliance with this measure in SCIP program have not necessary been those with the lowest surgical site infection rates. So the relationship between the two variables is not as ironclad as might be assumed then the evidence in a controlled scientific study on a small population is pretty compelling but it hasn't really been all that clearly demonstrated at the population level to something that we're keeping in mind.

Comment related to the performance gap so the data provided are from NACOR which is the National Anesthesia Clinical Outcomes Registry which reports a very large volume of patients and as was pointed out by one of the other panelist there's a less than 50 percent compliance rate which reporting in the non-Medicare population it goes up to about 50 percent in the Medicare population. So there is a gap there but in terms of the actual performance, the

rates tend to be at the high 90's and they provide three years of data. And there's been really little of change over the past three years which kind of gets back to what Dr. Grover pointed out that this measure may have potentially be have – maybe tapped out.

And I guess I'd put up there for discussion at the in-person meeting, you know, in this whole field of surgical site infections it maybe time to be thinking about outcome measures and we may have passed the point were these individual process measures are of the same value they were when they first started.

With respect to disparities there are some minor variances in race and socioeconomic status but they are not of at least to me they didn't seem to be of substance. I would raise the issue of why children are excluded from the measure I'm a little bit biased because I take care of children. But, it's the measure list in passed eight they list child – children health as a specific target as a measure yet exclude children. So, I think its worth probably works in discussion.

With respect to the other issues the priority is pretty clearly established in the – their reliability is I think been already discussed with respect to the other measures. So, probably doesn't need additional discussion here. I think in the interest of time I'll just stop here and open it up for discussion.

Andrew Lyzenga: Great. Thank you. Any other comments or questions from the rest of the workgroup? Probably going to have a lot of the similar issues we had on 264 with this one and most likely the next one as well. So, we can kind of …

Richard Dutton: Oh, this is …

Andrew Lyzenga: Yes, go ahead.

Richard Dutton: This is Rick the developer. The kids thing there's probably no reason it can't apply to kids. In terms of rolling this into bundles or collaborating with the other similar measures we are happy to do that as we stated this is crosscutting to the last one we discussed which was outpatient specific, ours is both inpatient and outpatient but physician specific.

And in terms of disparities, we did find in our national registry data that there was a disparity difference of about between 94 and 98 percent from the lowest socioeconomic to a higher socioeconomic status. And we don't know if that's really yet or not, we just found that as we were doing the preparation for this. But I think it's an interesting observation. Otherwise, thank you very much for understanding what the focus on for the face-to-face meeting.

Andrew Lyzenga: Great. Thank you. Any other comments or questions from the workgroup?

Melinda Murphy: And Andrew, it's Melinda.

Andrew Lyzenga: Yes.

Melinda Murphy: I would just like to note the act the face-to-face meeting there will be that discussion of related in competing measures and this one will follow in a group of measures that that discussion will catch on.

Andrew Lyzenga: Thanks, Melinda. Well, as there are no other comments or questions, let's go ahead and moved on to the next measure. This one is 527 Prophylactic Antibiotic Received within One Hour Prior to Surgical Incision. I don't know if we've Dr. Cima on the call. Dr. Cima are you there? Well, if not maybe we could get a few comments from, you, Dr. Grover and just from rest of the workgroup if you have any thoughts

Frederick Grover: I'll exactly be brief here because we are – we've got over saturated with this peri-operative or peri-operative antibiotic measures, but this is the SCIP measure from CMS and it's basically the prophylactic antibiotic received within one hour or two hours and if it's (inaudible). And this is to – as I understand it all inpatients, right? And it's also related to who it is ordered by I believe.

(That raised), it's very much the same, the issues are kind of the same I think. The topic now and issue is a major one area here were 98 percent in 20, 13 was a national rate of compliance with this measure. There is some room for improvement like for the fifth percentile it is 90 percent and the 10th

percentile it's 95, but beginning at the fifth percentile on up it's 100 percent. So, that's an issue here as well as the others.

You did have the race, ethnicity, so forth listed in and they virtually capture this on and almost equally in all of these folks.

So, I think (there is an) issue obviously these are important measures and there's a major tied in infection and a major tied in timely administration and to the effectiveness of the prophylactic antibiotics. But I think those are the main issues.

Andrew Lyzenga: Thanks, Dr. Grover. Any other thoughts or comments from the workgroup? Dr. Moss, I know you had other comments on this measure. I think in the survey I don't know if you wanted to raise any issues, yes.

Larry Moss: I think they've been discussed, thanks.

Wunmi Isijola: OK.

Andrew Lyzenga: Great. Thank you.

All right. Well, is there any other a comment or questions from the workgroup? We can go ahead we'll move on to the next measure.

So, our next measure is number 453 Urinary Catheter Removed On Postoperative Day One Or Postoperative Day Two With Day Of Surgery Being Zero. And Dr. Erekson and I believe we had as primary discussant on this, do you have any initial question?

Elizabeth Erekson: Yes. Hopefully you guys can hear me pretty well, I've had a bad connection. This measure is a process measure obviously not an outcome measure trying to reduce urinary tract infections after surgery by taking the catheter out by postoperative day number two.

It's another one of the SCIP measures proposed by CMS that's been in place for a while and they show that although we are tapping out – continuing have the measure in place or the national average is going up that more people are

complying with this, my question would be is it more people are complying with it or are we just getting better at documenting why we didn't take the catheter out and I'm not a 100 percent clear on that.

Other things when I was looking through the measures, one of the big exclusions and the major reasons why patients don't qualify for this is the actual procedure being a urologic gynecologic (inaudible) procedure. But, they're included in table 510 of the ICD-9 Codes and then excluded in table 516. And I wasn't 100 percent sure why they were included to begin with. And perhaps the measure developers could let – add a little insight on that.

And then in the section 4C.1 they say that there are no unintended consequences of this measure. But we do know that urinary retention can lead to a couple, pretty catastrophic consequences in a very, very few numbers of patients and I'm not sure that that data was presented in the measure.

Andrew Lyzenga: So, does the developer want to respond to that or provide any comments?

(Dale Brexler): So, this is (Dale) again. I'll just – couple of points. So, we actually have looked carefully at the performance measure to see whether or not more catheters are being removed or whether people were just documenting better reasons to leave the catheter in. And we actually have now data over a number of years. And while all of it is true that the number of patients for whom that passed the measure because a documented reason to keep a catheter in has increased that's only gone from about 14 percent to 17 percent over the past three years.

So, most of the cases that are passing now are not passing because somebody's just doing a better job of documenting a reason to keep the catheter in. And the actual performance rate, the actual number of patients where the catheters are removed has gone up substantially. There was another question and I don't recall exactly what the other comment that she made the other question.

Elizabeth Erekson: I think my big question and I just don't maybe understand what you're capturing in the measure. I was reading through table 5.10 which where all of the procedures that fell into the scope of what was included in the measure.

And there were procedures that overlapped with table 5.16 which were all of the procedures that were excluded for the measure. And I was just wondering about that because those specifically are gynecologic, neurologic, and perennial procedures I think.

(Dale Brexler): OK. And Colleen is on the phone she may be able to respond better than me. I know that – I believe table 5.10 defines the denominator for the performance metric and then that additional table just defines cases that get excluded from the measure, 5.10 is used for all of this – for many of the SCIP measures to define in general, denominator populations for SCIP and then there are certain cases like the urogynecologic procedures that are excluded from this particular performance measure.

Frederick Grover: Do you have any – do you know – do you have the breakdown of the exclusion of criteria that patients who would had a physician or best practice person document a reason for not removing the urinary catheter post op? They're breaking that down and they say the top five that are a kind of in that general pile is hard to know what would – I mean, I know at our place if somebody has a epidural catheter in, frequently that leads to even – to fully and a little longer.

(Dale Brexler): Right. All right. So the – for the most part, we can't tell because the case of that particular exclusion is based on document. We don't question the reason the clinician document, so whatever they document, then the hospital can abstract that there was a physician documented reason to leave the catheter in. But as it pointed out that that proportion of cases for which that going up the arrow, to me that proportion is not changed very much over the past three years.

Frederick Grover: Yes. Now that's reassuring. I just kind of say on this that your – you have a little more room. I mean, you still have a very high compliance grade from 50th percentile, I mean when you're 50th percentile but you do have some that are down low that are only 80 percent compliant.

Male: Would the measure be enhanced by asking them to report the reason and you'd learn over time and maybe do something in the future to improve?

Frederick Grover: That's where I was driving at. Thanks for asking again.

(Dale Brexler): Yes. So I guess that comes down to increasing the complexity of the data collection. What we've tried to do is not insert ourselves at the bedside and second guess but – I mean, so Dr. Grover highlighted epidural catheters, we know it's common were reported this is a reason that people leave, right, catheters in even though there is actually little evidence that it's needed in patients with epidural catheters.

So, you know, I can certainly take that back to the technical panel. My concern is that they're going to be a little reluctant to increase the complexity of the data collection.

Male: I guess, I was asking because it seems like that's where the actual margin of benefit might be. And if you learn that that was the reason given in the vast majority of cases that, you know, might lead to more study in a different action in the future.

(Dale Brexler): I actually found my data on – I have several tables that we've been looking at this metric to see, you know, the concern about why cases are passing and the rate of actual catheter removal doubled in the first two years that the measure was placed. So a lot more catheters were being actually taken out.

Larissa Temple: I'm just going to sound really stupid here. It's Larissa here and actually I spent a lot of time try to find, its appendix with all of the – I'm particularly interested in the exclusionary codes. Which in these three documents is it, I can't seem to find it.

Andrew Lyzenga: Sorry, just looking that up right now. It's in the document set on the SharePoint.

Larissa Temple: Yes.

Andrew Lyzenga: If you know how to get there, it's the …

Larissa Temple: Yes, I'm in there.

Andrew Lyzenga: … Excel table. Oh, but there are a number of different sheets in the table in the Excel files were using.

Larissa Temple: No. I may have been looking on the wrong one. OK. I'll go back and look again. Next on spreadsheet.

Andrew Lyzenga: It says developers …

Larissa Temple: OK. I'll find it.

Andrew Lyzenga: Yes. If a developer know is on the line and knows maybe you could clarify where the exclusion codes are.

(Dale Brexler): (Carla), can you answer that?

(Carla): Yes. They're in Table – Appendix A.

Larissa Temple: Yes, I know it. Yes, I'll find – I just hadn't been able to find it yet. So if I can't, I'll bug you again.

Andrew Lyzenga: Yes. Any other comments or …

Amy Moyer: Hi this is …

Andrew Lyzenga: Go ahead. Go ahead.

Amy Moyer: Hi. This is Amy Moyer. I guess my question on this one especially in light of the discussion we just had around the prophylactic I.V. antibiotics is we have an outcome measure around urinary tract infection in catheter associated. And it appears they cover a very broad population as opposed to the surgical site infection where with endorsed measures we're still looking at very narrow areas. But I guess my question is why from accountability and public reporting perspective, we would be looking at this process measure when we have the outcome measure.

(Dale Brexler): Well, at least up until – so I don't know. I'm lost a little bit of track but the NHSN measure that's required for CMS has been limited to ICU patients only

for urinary tract infections. I know they're planning to expand populations, I don't think we've done so yet.

Andrew Lyzenga: I believe the latest version of the measure – and actually it's undergoing review right now through the Safety Committee, but that version of the measure does expand beyond the ICU. So I think the next version of the endorsed measure which should be endorsed, I don't know, late this summer will be expanded beyond the ICU. And actually my understanding was that it may have done that previously as well. I'll take a look to see. But I think it may actually apply beyond the ICU at this point already.

Female: So, the summary of the measure and the NQF say indicates that it – this ICU, FDAs, and other inpatient locations. It looks like it excludes nursery. But I'm not working at the actual specifications.

Andrew Lyzenga: Yes. That sounds correct to me that it's – yes, basically all inpatient locations excluding nursery, NICU.

Frederick Grover: Yes. You know, I just want to – this kind of interesting, for some reason I feel a little bit differently about some of those others and maybe that's because it – it always drives me nuts when I'm making rounds and I see people still with their Foley catheters in and maybe they can't get around and, of course, by at least and there's a reason for it but sometimes it's just that a patient isn't really getting out of bed much and, you know, that requires effort to get people out of bed when they help and – or at least up to the side of the bed. And I kind of have this feeling that there's still a lot of work to be doing on this but that's – I realized very subjective. Good point. And …

Larissa Temple: Can I – I'd actually like echo that. When I'm looking at table 5.15, and I'm looking at the perennial procedures that are typically done by, you know, anal procedures. There are several one here that I don't see as being an indication not have a Foley removed. So I guess I'd like the developers to send us – I don't know how you came – how did you picked those specific ones but there are several of those that I'd like to just remove. For instance, hemorrhoid, actually a patient should not have a Foley catheter for two days.

(Dale Brexler): Certainly, we can go back and look at that exclusion list.

Larissa Temple: Yes. I think, for the perennial procedures, there are several I think that should be removed.

Amber Slichta: Hi. And this is Amber Slichta and as the first thing to me is advocating for the consumer. You know, I think it would be very important to go back and look at this because as a consumer or a patient perspective, you know, the last time you have to have a Foley catheter in the more comfortable you are and certainly if it's being less than in a worst case scenario for the convenience of the hospital's best. You know, that's not a solid reason to leave something in.

Larry Moss: Larry Moss, just one question for the developer. Could you explain the rationale for excluding patients less than 18 years of age?

(Dale Brexler): No, other than that's been typically the performance metric for all of the CMS performance measures, the age group of 18 or over. But …

Larry Moss: Yes, I guess I'm going to push on that and see – maybe open it up for discussion at our meeting.

(Dale Brexler): Then that's certainly something we can take back and discuss with the committee.

Andrew Lyzenga: OK. Thank you.

Female: Yes.

Andrew Lyzenga: Any other comments or questions on this measure from the workgroup? All right, well let's go ahead and move to measure 2038, Performing Vaginal Apical Suspension at the Time of Hysterectomy to Address Pelvic or Organ Prolapse. And Larissa, I think you're the lead discussant on this one. You want to give a – any thoughts that you have on the measure?

Larissa Temple: Yes, I thought some, you know, this is one of those that came to the two-part process. So, the importance of evidence we won't discuss. The only thing comment I'd make to the reviewers is that I think it's important to that there's a comment about potentially the untoward effect of the (PACSI) and that somebody's procedures I'm told have the potential of causing some pretty

brisk bleeding and I think they'll be interesting – it would be important just to note what the percentage of that possible complication is with the (PACSI) are licensed that important piece to make sure that there's no untoward consequences.

The reliability, acceptability, you answered that question earlier in terms of those capturing with CPT codes. I thought it was fairly extensive and made sense and what I liked about this measure was you could use administrative data and they went to uncheck the reliability and validity with (hand short) which I thought that I was the strongest of this three measures I thought.

In terms of feasibility I think because it's all generate electronically, I think it's feasible, there is no real comment on public reporting. There were some differences both in terms of surgical volume and surgical volume showing that there is a gap that could be improved so I thought this was a reasonable measure.

Andrew Lyzenga: Great. Thank you. Any other comments or question from the workgroup? Maybe a quick, fast question, we notice that the testing had only evaluated critical data elements for the numerator and not the denominator. Does the developer have any clarification about that? Why that was the case?

Female: What was the question?

Andrew Lyzenga: Well, the question is, it appears that the measures would that – that only that critical data elements or the numerator were tested for reliability and not the critical denominator data, is that – are we misunderstanding that?

Female: I suspected that something that just wasn't specifically included if it's not there the critical data elements for the numerator are discussed I think in terms being affirmed by the chart review, but certainly for the denominator they were as well.

Female: I actually thought I read something where it said that they looked at the denominator and looked at the number of patients that would be – that were incorrectly coded and they noted like two or three patients with cancer and

one and that to me looks like a little bit of work on the denominator or somewhere on the document right?

Female: Yes.

Andrew Lyzenga: All right. Thank you. Any other questions or comments from the workgroup? All right, well we can move on – oh yes, go a head, go ahead.

Frederick Grover: I saw a one strong point here is a third – roughly one-third undergoing hysterectomy for prolapse only one-third together, I get the colpopexy perform so there is – assuming then your evidence is really strong that is a – does decrease the risk of recurrence and re-operation and so forth. There's a lot of room for improvement obviously, so.

Andrew Lyzenga: Thanks, Dr. Grover. Go ahead. Is there another comment?

All right, well hearing none, we can move on to our last measure which is 2052, Reduction of Complications Through The use Of Cystoscopy during Surgery for Stress Urinary Incontinence. Our primary discussant for this was Dr. Saigal. I don't know if Dr. Saigal is on the line?

Chris Saigal: Yes, I'm still here.

Andrew Lyzenga: Sorry, great. So you would like to …

Chris Saigal: Yes, I can be brief this is very similar to previous discussed measure regarding cystoscopy and prolapse, but it's for cystoscopy in time of a sling surgery and it already passed a process that looks good previously by NQF where the importance of measure report –separately from the rest of the criteria. And it passed the importance to measure and report is specified using CPT codes and as a previous discussant mentioned the CPT codes are bundled for the purposes of billing.

So it's hard to use this in terms of looking at that payment data, but the developers looked at an EMR reporting feasibility event that it was a very feasible in five sites that they studied and I think the question that is – it's a process of care measure with reasonable evidence that it’s (committed) the

five problems effectively and it's recommended according by guidelines for all the different in relevance of special societies.

And I'd say that the, you know, the issue that if you're going to decide around – is mainly around harmonization between this measure and the prolapse measure and again, they're previously recommended to be harmonized but I believe in the public comment section the (division went through first).

Andrew Lyzenga: Great. Thank you. Any other comments or questions and thoughts from the workgroup on this measure?

Female: I think I still, you know, I think the comment I had with 2063 is relevant for this one as well. And I think that when the developer – when we talked at the meeting it seems that the cystoscopy is going to be best extracted from the – this pelvic floor registry and I think that's just understanding the feasibility of that and the endorsed for that would be helpful to understand how effective this measure will be.

Andrew Lyzenga: Did the developer catch that? Great. And what we'll look back with other developers and review our notes from the transcript and make sure we're getting – asking you specifically for any information that the committee's requesting by the time at the in-person meeting.

Female: OK.

Andrew Lyzenga: Any other thoughts or comments, questions on this measure?

Melinda Murphy: Andrew, it's Melinda and the Steering Committee meeting that looked at importance of the measure …

Andrew Lyzenga: Yes.

Melinda Murphy: … that is one of the notifications there was that concomitant surgery should not be excluded and maybe I have an old submission that it appears that it remains excluded and this is one of the things that this was approved by the CSAC with an amendment that the recommendations to the developer be

addressed, so am I perhaps looking at a no submission or it is concomitant prolapse that (are still) excluded.

Andrew Lyzenga: Thanks, Melinda. Does the developer have any response to that?

Female: It still is excluded at this point because that's – it was based on our guidelines excluded that.

Melinda Murphy: OK. So I think everybody will be just have to be prepared to have that discussion at the Steering Committee because that was one of the recommendations that was approved on CSAC.

Frederick Grover: What was the basis of that recommendation do you recall?

Melinda Murphy: I wouldn't recall because I was not involved at that Steering Committee activity and we we're going to ask that go back and ask some questions about some of these. So there may be some additional clarification also available for the Steering Committee but at present everyone should just expect that will made to be discuss.

Frederick Grover: OK.

Melinda Murphy: And if would can get it, Dr. Grover, we'll get it out to everyone.

Frederick Grover: Thank you.

Andrew Lyzenga: We'll try to pull that information from the previous committee review and provide that to you an example to the in-person meeting.

Frederick Grover: Great.

Andrew Lyzenga: All right, any additional thoughts or questions on this measure or any other measure?

Frederick Grover: I don't think so from my standpoint.

Andrew Lyzenga: All right. All right. Great. Efficient call. Well, we can move on to couple other agenda items. We have – actually, maybe right now we can open – we

could open it up for public comment to see if there's anybody on the line who would like to provide a comment.

Operator, could you open the line and request public comment.

Female: Probably doesn't matter.

Operator: At this time, if you would like to make a public comment, please press star then the number one on your telephone keypad.

And there are no public comments at this time.

Andrew Lyzenga: All right. Great. So I'll just – in that case, say a few words just to prepare for the in-person meeting, talk a little bit about the role of the discussion leader. That'll be a very similar to what we've done on this call today except maybe a little bit more sort of regimented in our approach to each measure.

As I mentioned at the beginning of the call, we actually have a script that we've drafted up for the lead discussants, so you can just kind of take a look at that. We'll provide that to you very shortly. And that will kind of walk each lead discussants through the questions they should be asking of the committee sort of summarize the information briefly that has been provided in the Measure Information Form.

We will do that for each of the criteria we'll have sort of a – well, at first, I should say that will allow the developers to give a short summary and give any thoughts that they have on their measures upfront. Then we'll have the lead discussants walk through the measure about for – by each criteria. And after we discuss each criterion, we'll hold a vote on that criterion. So we'll discuss the importance, we'll hold a vote on importance, then we'll discuss scientific acceptability and hold the vote on scientific acceptability and the sub-criterion and so on.

So that is sort of basically the process that we'll have for the – in the in-person meeting. Are there any questions or clarifications on that?

Frederick Grover: No. And you highly encourage us to be on the other three conference calls before that, right?

Andrew Lyzenga: If you would like. It's not necessary certainly but it can be helpful just to hear what the other workgroups are saying. We'll also summarize those workgroup discussions and provide the summaries to you just to give you some high level notes on the general issues that were raised or concerns that were raised. And we'll give that to you if you're not on the workgroup call. But certainly if you have the time and interest, you should to call in to each one of the workgroup calls. I'm sure it would be enlightening and useful in advance to the in-person meeting.

Frederick Grover: And we'll be given the, honestly that well, we can pull up the protocols and review on. Now, on those, would you expect us to fill out the survey ahead of time or just be familiar with the protocols and have them at hand?

Andrew Lyzenga: No. I don't think we'll have you do any survey beforehand. We did the surveys prior to the workgroup calls. And we'll probably – we'll carry that information forward to the in-person meeting. All that information will actually be sort of included in some measure worksheet that we'll have available.

So you'll have the pre-workgroup comments. I don't think we're going to ask you to provide any additional input before the in-person meeting. So, certainly we would, yes, ask you to consult the algorithms while you're reviewing the measures and to keep them in mind as you're evaluating the measures at the meeting. We'll probably try to sort of call them out explicitly at that time and ask you to walk through the algorithms for each step. So it would be great if you could be as familiar with those as possible.

Frederick Grover: OK. Good. Thank you.

Wunmi Isijola: And just to add to that as well, like Andrew mentioned, all that information from the pre-workgroup surveys as well as the workgroup summaries that we're talking about today. That'll all be included in each measure worksheet because as a committee member we do expect you to have reviewed all of the measures, prior to the in-person meeting. So that'll help in terms as kind of a

reference of some of the discussion points and some other feedbacks from your fellow committee members.

Melinda, do you have anything to add?

Melinda Murphy: No, thank you.

Wunmi Isijola: OK. And …

Male: One question, we have nothing to do until the next meeting, right? Basically, to the in-person meeting we're done with our assignments?

Andrew Lyzenga: Well, we do. We do still want you to review all the remaining measures. We have – I know it's a heavy lift. So, to this point, we ask you to review the measures that are in this workgroup to – in the workgroup …

Male: Oh, I see.

Andrew Lyzenga: … to which you've been assigned but we would like you to review each of the measures that is in this project, the ones in this workgroup as well as the others before the in-person meeting.

Male: But no written comments?

Andrew Lyzenga: No written comments, but yes …

Male: OK.

Andrew Lyzenga: … we would ask you to take a look. Thank you.

Male: Oh, thanks.

Wunmi Isijola: And just for those who are on the call today, we really appreciate everyone who has joined us even those who have spoken and as well as those who just participated including our developers. But just in terms of our timeline, our next workgroup call is on May 8th at the same time from 2:00 to 4:00 p.m. We have a host of measures I guess being presented, but if you can definitely

take a look at that. And as we've done previously, we will be uploading the survey responses for the next call prior to the May 8th call.

So those who are on the call today and have designated measures, we ask that you complete your surveys by May 6th. And as always, if you have any questions or need technical assistance, please feel free to reach out for any one us then we'll definitely be happy to help. And if there aren't any other questions, we will convene the call and we look forward to speaking with you then.

Male: Great.

Wunmi Isijola: Thank you.

Female: Thank you.

Andrew Lyzenga: Thanks, everybody.

Female: Thank you.

END