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NATIONAL QUALITY FORUM

Moderator: Perinatal Committee
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OPERATOR: This is Conference #: 66719888

Reva Winkler: Good afternoon, everyone. Thank you for joining us. This is Reva Winkler at NQF. I'm joined with my project team members, Suzanne Theberge, Nadine Allen and Kaitlynn Robinson-Ector. And thank you for joining us for this last workgroup call for Perinatal Committee prior to our in-person meeting on May 2nd and 3rd.

Just a couple of housekeeping things to make the call run a little more smoothly. For all committee members, please do use the call-in number so you're able to speak. Unfortunately, we're not able to communicate verbally via the webcast. If you are looking at the webcast, please turn off the volume there, so otherwise, we hear you twice. And please don't put us on hold so that we hear your whole music as wonderful as it might be.

So, we do want to get started today. We have a fairly ambitious agenda with seven measures to talk about. Let's just check and see, do we have all of our workgroup members? Do we have Jennifer Bailit? Is Jen with us now? Amy Bell?

Amy Bell: This is Amy. I'm here.

Reva Winkler: Thank you. Tracy Flanagan? OK. Nancy Lowe?

Nancy Lowe: Yes, I'm here.

Reva Winkler: Great. Hi, Nancy. Jennifer Moore?

Jennifer Moore: Good afternoon. This is Jennifer Moore.

Reva Winkler: Great. And Sheila Owens-Collins? OK. Carol Sakala?

Carol Sakala: Yes, hello.

Reva Winkler: Hi, Carol. Do we have any other committee members who've joined us?

Gregory Goyert: Greg Goyert, Henry Ford Health System.

(Diana): (Diana as well).

Reva Winkler: OK, Greg. (Diana), I hear – I heard you, great. Anybody else?

Female: OK.

Reva Winkler: OK. So we're very pleased to have some of the other committee members joined in on this workgroup call to listen and participate in the conversation.

Did either Jennifer Bailit, Tracy Flanagan or Sheila Owens-Collins join us yet?

Tracy Flanagan: I'm in, Tracy Flanagan.

Reva Winkler: Great. Hi, Tracy.

Jennifer or Sheila? OK. Hopefully, they're going to be able to join us. But again, I do want to go ahead and get started.

The purpose of this workgroup call is to provide a bit of an opportunity for the committee members to become comfortable with looking at the measures against the evaluation criteria that you're going to be using. We want you –

sort of a dress rehearsal, if you will, without the dress maybe, but a rehearsal nonetheless.

And the measure developers are with us as well to answer any questions that you might have. At the end of the – just before we close, there will be an opportunity for public comment. Otherwise, we're going to try and focus to be able to get through all seven of these measures.

Four of the measures are measures that have been endorsed by NQF and are undergoing our maintenance of endorsement review. As we've talked about in our orientation call, we do look at maintenance measures a little bit differently than new measures, presumably those measures have already been evaluated. And so we are looking for changes in the evidence, changes in the testing but there, perhaps, hasn't been much.

And the committee is certainly asked whether they would just accept the previous evaluation. However, for the maintenance measures, we are particularly interested in on how the measure is currently being used, what current performance levels are, what the lessons have been learned, what the impact of the measure is. And so, we will want to be spending time focused on that.

For the three new measures, we will be looking at all of the criteria because this is the first time they've been evaluated.

So, with that, let's go ahead and get started with our first measure, which is measure 470. It is the incidence of episiotomy and it's the percentage of vaginal deliveries excluding those coded with shoulder dystocia during which an episiotomy is performed.

This is a measure that's currently endorsed and is up for a maintenance review. And as you can see on the measure worksheet, the developer has added some additional up coding for ICD-10 in the document. But, by and large, there has been very little – there's been no new evidence for this measure.

So, our discussants for this, I believe are Nancy Lowe and Jennifer Bailit. Has Jennifer joined us?

Jennifer Bailit: I'm on the phone.

Reva Winkler: Excellent. Welcome, Jennifer.

So, Nancy or Jennifer, would you like to just make some – give us your brief thoughts on the evidence for this measure?

Nancy Lowe: Sure. I – this is Nancy. And I did a quick search of the literature and, you know, the developer suggested that the evidence had not changed and although there are few recent studies, individual studies, the last Cochrane review is 2009. So that has not changed.

I believe that the gap remains and has been documented. And appreciate that opportunity. I think its evidence from the data and the evidence that the disparity is basically by – it's an institutional disparity rather than a socioeconomic disparity or racial disparity.

So, I believe that that evidence is standing and is fine. I have no concerns about it.

Reva Winkler: Thank you, Nancy. Jennifer, anything to add?

Jennifer Bailit: No, I think the evidence stands as solid and no changes either way. So, I think it's a worthwhile measure.

Reva Winkler: OK. Nancy touched a bit on the opportunity for improvement and disparities. Was there anything you wanted to add to that?

Nancy Lowe: The only thing I would add is I honestly believe this is one that would profit from, I hope, locally provider level data, institutional data. It's important because, certainly, institutional culture affects this as well as the composition

of the medical staff and the particular perceptive on episiotomy. But, yes, I didn't have anything else to add in terms of disparity.

Reva Winkler: Great.

Jennifer Bailit: So this is Jennifer. I'm just trying to make sure I understood you correctly. I mean, I guess my concern would be about doing an individual level for public reporting it's that the – there's not enough power to look at statistical significance, in which case, we can really, I think, only responsibly look at hospital level data. At the same time, the hospitals, given individual data, can do something about the hospital level data. But I wouldn't publish individual data.

Nancy Lowe: No, and I agree, Jennifer, that's what I meant to suggest, is that internal Q.I. processes would hopefully be looking at individual level data.

Jennifer Bailit: Great, it sounds like we're exactly on the same page here.

Nancy Lowe: Yes.

(Crosstalk)

Reva Winkler: Any comments from anybody else on the workgroup or committee?

Tracy Flanagan: This is Tracy from Kaiser. You know, it's interesting on this measure, I just want to underline that we in fact did that. And it was amazing how quickly people came into line.

Nancy Lowe: Good for you.

Gregory Goyert: We have the same experience at Henry Ford.

Reva Winkler: Super. OK. Then let's move on down to the scientific acceptability of the measure, reliability begins with specifications. The developer reports that there really have not been any changes to the specs except for the updating to

the ICD-10 codes. And then, the reliability testing was done at the data element for validity and so it counts for both.

So, anybody have any comments around the reliability and validity of this measure?

Nancy Lowe: No, I believe it's very straightforward and easily captured data.

Jennifer Bailit: Agreed, and I think it hasn't changed much of the ICD-10. You know, it is as good as it always has been.

Reva Winkler: OK. Considering potential threats to validity around exclusions and, you know, meaningful differences in the measure, any thoughts on those various …

Nancy Lowe: The appropriate exclusion is made which is shoulder dystocia, which is the appropriate, I think, pretty much agreed upon clinical indication for episiotomy.

Reva Winkler: Great.

OK. Any other comments or thoughts from the other members of the workgroup or committee?

OK.

Amy Bell: This is Amy Bell.

(Crosstalk)

Reva Winkler: Yes, sure.

Amy Bell: I would just ask a question about this being maybe an outcome measure and not a process measure. Is the thought, was it being a process measure that it could lead to additional perinatal injury?

Jennifer Bailit: Right, the thought is at least typically that certain fourth degree is the outcome and episiotomy is the process that leads to that outcome.

Amy Bell: Got you, OK. Because – and I think, you know, and I completely get that and I understand that and I can support that. I was – I also kind of think that perinatal injury, you know, during an episiotomy is perinatal injury as well. And that in itself can be an outcome.

Reva Winkler: All right. This has been an interesting conversation we've had in some of the other workgroups. And perhaps, we might think of this as potentially an intermediate outcome where the third and fourth – or the larger perinatal injuries subsequent to an episiotomy is the main outcome but this might be something that's in an intermediate step. And it's been an interesting conversation that we may want to continue discussing at our in-person meeting.

Amy Bell: Right. You know, and it's not as severe as the third and fourth degree, but it is more severe than delivering (inaudible), you know, just for perinatal trauma, I think this could definitely cause it directly.

Reva Winkler: OK.

Amy Bell: Thank you.

Reva Winkler: Sure. Any other comments on scientific acceptability?

Then we'll go down to feasibility. Feasibility primarily lies with the data source and the burden of collecting and reporting data.

Nancy or Jennifer, thoughts there.

Jennifer Bailit: You know, this is all from an administrative data that's being collected at every hospital that's doing deliveries and billing for them at least. So, I think this is very feasible and fairly, I want to say, inexpensive but relatively money conscious in terms of collection.

Nancy Lowe: Agreed. And I have no further comments about that. I think this is probably …

Reva Winkler: OK.

Nancy Lowe: … one of the straightforward measures.

Reva Winkler: OK. Any thoughts from anyone else?

OK. Then we move down to the last criteria, which is usability and use, which is something we do want to focus on for all of the measures undergoing maintenance review. How is this measure currently being used? How widespread is it's used? What has been its impact?

Thoughts on that, Nancy and Jennifer.

Nancy Lowe: I think the adoption of the measure has definitely helped continue to bring the issue to the forefront. And that it's important that it continue to be an endorsed measure. And is being used in quality assurance programs, both locally and nationally.

Jennifer Bailit: I have nothing to add, perfectly said.

Reva Winkler: OK. Anything from anybody else?

Carol Sakala: So this is Carol. And specifically, it is being reported in the Leapfrog survey, and I think it's reporting in across 130 hospitals and it's on the Cal quality compare website as well for hospitals in California.

Female: Reva.

Reva Winkler: Yes.

Female: I have a minor question and this is more about how this goes on overtime. It talks about that the steward of this measure is Christiana Health Care System. So once an organization submits the measure, did they do this re-review document that came in? Did they send the information in again to NQF?

Reva Winkler: Yes. The measure information on your worksheet that's basically in the blue type comes through our data system submitted from the developer. The …

Female: OK.

Reva Winkler: … section on the worksheet, that's the preliminary analysis, is steps done by NQF staff. But the …

Female: Yes.

Reva Winkler: … other stuff – but the majority of it, it's sorted in the blueprint and all of that, that's from the developer.

Female: So once the developer – once a measure is adopted, the developer is forever the developer.

Reva Winkler: Well, they are the owner of the measure and there have certainly been instances where measures have been taken over by others by mutual agreement. And so, the measure steward owner can change but by and large, most of them stay the same.

Female: OK, thank you.

Reva Winkler: OK. Any other questions? All right, let's move onto the next measure, which is measure 476, which is PC-03 antenatal steroids. This measure …

Tracy Flanagan: Can I interrupt just for a second? This is Tracy Flanagan.

Reva Winkler: Sure.

Tracy Flanagan: For reasons beyond my control, I'm going to have to bow out a half an hour early so I just want to let you know that.

Reva Winkler: OK. All right, Tracy.

Tracy Flanagan: And I don't – I think we'll get through this pretty – you know, all of these things pretty quickly, but I just want to let you know.

Reva Winkler: Thank you very much.

OK. So, anything else? All right, so 476, antenatal steroids. Measure assesses patients at risk of preterm delivery between 24 and less than 34 weeks gestation receiving antenatal steroids prior to delivering preterm newborns. This is part of the Joint Commission's five measure set. So, this again is an endorsed measure undergoing its maintenance review.

And our discussants for this measure are Amy Bell and Carol Sakala.

So, Amy and Carol, what are your thoughts on evidence. Is anything changed? Is there anything new since its last review?

Amy Bell: This is Amy. I don't think anything else is new. The one change I would make here is, the top of page three where it says in January 2014, the measure became mandatory for all hospitals with greater than 1,100 births.

I believe that actually has some additional more recent data that in January 2016, the measure became mandatory for all hospitals with greater than 300 births.

Reva Winkler: Right.

Amy Bell: We may want to just add that in there.

Reva Winkler: OK.

Carol Sakala: So this is Carol. And I – there's a lot of references in here to the 2010 or 2012 Cochrane review. I was only able to find the 2006, so I don't know, that might need some tidying up if that is indeed correct. I do want to report that there is a 2015 non-Cochrane review showing that most neurodevelopmental outcomes are also (gathered) with a single course of steroids. So, I think that's new evidence that affirms and supports the previous conclusion.

Reva Winkler: OK. Anything from anybody else on the workgroup, or the committee?

OK. So do you want to go down and look at the data on current performance?

Amy Bell: Sure, that'd be great.

Reva Winkler: Thoughts from Carol or Amy.

Carol Sakala: Sure. So, they now are reporting – this is a Joint Commission on 11 – hospitals with 1,100 or more births from 2011 and the average was – let's see, do I have the average? The – yes, 82 percent, which is quite good. It's – that is up from 54 percent in 2011.

But, we always want to look at the variation as well and the 10th percentile was 38 percent and the 90th percentile was 100 percent fidelity to the measure. So, they're the study trend of improvement.

But, you know, some ways to go as well. And they say that as far as disparities go, not all hospitals are reporting on the major racial ethnic grouping so they were not able to look at the data in that way.

Reva Winkler: OK. Thoughts from anyone else? OK.

Amy Bell: This is Amy. And in California, there were some disparities that they found, you know, in that state with Hispanics and younger mothers. They were less likely to actually receive the steroids.

Reva Winkler: OK. Comments from anyone else? OK.

Jennifer Bailit: So Reva …

Reva Winkler: So we can move …

Jennifer Bailit: … Jennifer Bailit, let me just add. Some of these kinds of administrative data coding have been shown to be different in poor and also hospitals of more

minority. So to the extent that they're actually getting less or the coding intensity is different, that may be part of it.

Reva Winkler: OK. Anything else? All right. So then, we can go down to scientific acceptability and we're talking about anything to do with the specifications and the reliability or validity testing.

Amy or Carol, your thoughts on scientific acceptability for this measure.

Carol Sakala: Well, they didn't do reliability testing for the measure as a whole, but for the question of steroids administered, there was a 99 percent rate of inter-rater reliability, that's hard to improve upon.

They have – they reference previous and continuing face validity for measure users and this applies to the whole spec. They have a website to get real time feedback from measure users that they continuously use to provide clarification or refinement if needed. They've switched to ICD-10 codes and described what appears to be a careful process for doing that.

There is a change that I think would be helpful for us to have clarified from the developer. From steroids administered to steroids initiated, my guess is that this is just a more accurate description of what they're capturing. But, they do say that all of the studies are about administering the – having administered the full single course and I don't – that doesn't look right to me when I look at the review.

So, I – there is a question about whether this change in the language at least is also a change in specifications and has any practical implication for the results.

Reva Winkler: I think the last …

(Crosstalk)

Gregory Goyert: This is Greg Goyert. The developers in the details down below specified that they included this change for the patient that came in fast at 30 weeks, got the

first dose and delivered before the second dose would have been possible. So, to address that specific patient subset.

Carol Sakala: So, I think my question is, is that a more accurate description of what has been happening all along, or are they actually expecting people to collect and report this measure in a different way at this point in time, because I think that goes on all the time.

Reva Winkler: Yes. Do we have somebody from the Joint Commission to …

(Crosstalk)

Reva Winkler: … question.

Elliott Main: Yes, working with the Joint Commission, this is Elliott Main. And the reason for that change in specification was data that was collected showing that if you got the first dose, the only reason you did not get the second dose was that you delivered too quickly. And so it was in response to hospitals asking for a reduction in data collection burden as it was easy to identify the first dose given. And it was harder to come through and then find the second dose with certainty.

So – and so we did do a comparison showing with a very, very high degree of accuracy that if you got the first dose, the only reason you didn't get the second dose was if you delivered very, very quickly. So, was there a reduction in data collection burden that led to the change specification?

Amy Bell: This is Amy Bell. I would add one suggestion maybe if we can maybe, at some point, look at (coming) of that first dose, because I think there is opportunity to improve the efficiency related to when we actually do give that first dose.

Elliott Main: I think that's the next generation of quality improvement with this whole area, because it's been given too early or too late literally, so.

Amy Bell: Right.

Elliott Main: But first thing first, we want to be certain to close the gap of giving the (inaudible) at all and I think that's where we're at at the moment.

Amy Bell: That makes sense.

Carol Sakala: Right. There was also a change that it – it used to be 24 through 31 weeks and now it's through 33 weeks based, I believe, on a recommendation from ACOG.

Elliott Main: New ACOG guidelines came out and we wanted to harmonize at the ACOG guidelines.

Carol Sakala: Great. And then they added another exclusion which seemed appropriate and able to determine the gestational age as this is correlated with not having received prenatal care. But as I look through the exclusions across this whole set and the number of cases that they're actually kicking out, I think a question for the next round at the Joint Commission is whether some, many or most of the exclusions might be able to omitted because I don't think this is materially impacting the results, and could reduce the burden of collection.

Reva Winkler: All right. Anything …

Gregory Goyert: I will tell you that the – at the hospital level, it makes a huge difference when you're presenting your results for – to administration governance and things like that. And you get dinged on this measure because you don't know what the gestational age is and so that's – and the similar exclusion applied to elective deliveries as well. So I think that's a good revision.

Carol Sakala: What I'm referring to is not whether there's a good rationale for it, but whether it is – in calculating the measure, it materially impacts results, because many of the reported cases that were excluded were 0 percent. I'm not sure about this particular one, but it looks like it doesn't. Even though it's a valid consideration, it might not be actually important to the overall process here.

Reva Winkler: All right. Can we move onto any comments about the testing of this measure?

Carol or Amy?

Carol Sakala: So, I guess I would raise a question that we discussed in a previous workgroup that the priority for validity testing in my mind would be to see whether we're accurately measuring the concept of the measure itself and with a little less focus on correlations across the Joint Commission measure set.

So, that was – seemed to be a little less to the point in my view.

Jennifer Bailit: This is Jennifer Bailit. I want to echo that we've shown in different papers that measures of quality don't necessarily correlate across different outcomes. And so they don't necessarily have to be aligned.

Amy Bell: This is Amy. And I would agree with that statement as well.

Reva Winkler: OK.

Carol Sakala: And they reported that the Joint Commission does run 17 quality tests on the data that it received from its vendor and that they assess the vendors themselves to do certain quality test. So, I don't think we have details on a lot of those. But it sounds pretty impressive.

Reva Winkler: OK. Anything else from anyone on testing?

All right. So, the couple areas of potential threats to validity, we mentioned, Carol, exclusions and the overall frequency of exclusions. I think this might be what you were just referring to. And then, the measure is not risk adjusted, but whether the measure can identify meaningful differences.

Any thoughts from anyone on any of the potential threats to validity?

Carol Sakala: I believe that it does identify meaningful differences. And it's also, you know, effective and moving that needle.

Jennifer Bailit: This is Jennifer Bailit. I guess my only concern about threats to validity is a little bit different in which that, if the data shows that – if people adopt the antenatal steroids above 34 weeks and they do it unevenly, that could potentially affect the measure.

Now, the data below 34 weeks is probably still fine, but I'm a little concerned about what happens when the country starts moving up from there.

Reva Winkler: Did somebody have their – we get a lot of background.

Could somebody put themselves on mute? Excellent. Thank you.

Jennifer, were you talking about the change in the gestational age from 32 to 34 weeks from – based on the change in the ACOG guidelines?

Elliott Main: I'm at the airport. So was there a question for me?

Jennifer Bailit: So – and – I was in and out, but I think we're still talking about the antenatal steroids.

Reva Winkler: Yes.

Jennifer Bailit: Yes. So, there's new data out presented at SMFM this year showing that there may be some point in doing this at even older gestational ages. And the question is, what does that do to the validity of this measure if we're doing it up until 37 weeks.

Now, the technical pieces of this measure will still work, right, so it'll still be good under 34 weeks. I just wonder what it means if we start to go to 37 and we do that unevenly.

I don't think it affects exactly this measure, but to the extent that the coding is messy or the measure really becomes anybody less than 37 weeks and do people calculate it correctly or incorrectly as the variation on the recommendation is changed, would that affect validity? Perhaps it's a bit speculative, but I do think it's in the offing.

Elliott Main: This is Elliott again. We did not change the specifications of this measure to increase it beyond 34 weeks because, first of all, ACOG has not recommended that yet. And I think it's probably going to be only in certain select cases over 34 weeks, so we're hoping every single case so we anticipate that the greatest benefits are still going to be remaining for those under 34 weeks.

So, for the foreseeable future, I don't think we would change the specifications for the reasons you said, as well as the reasons I was describing.

Reva Winkler: OK.

Jennifer Bailit: So, Elliott, I think that makes sense. I just think that, you know, five years from now, probably we're going to have to look at this again a little differently as the nation evolved.

Elliott Main: Sure. But, you know, we review the measures every three years so we have plenty of time.

Jennifer Bailit: Fair enough.

Reva Winkler: OK. Anything else before we move onto feasibility?

OK. Amy and Carol, any comments on feasibility?

(Crosstalk)

Amy Bell: I'm sorry. I think this is fairly, you know, easy to collect, hospitals, I think, are used to doing it at this point. I don't see any issues with the feasibility part.

Carol Sakala: It is manually extracted by vendors. And it's – they say that it's in the queue to be converted to an eMeasure as resources are available, so that doesn't sound like it's imminent to be – to go for that. But there might be more news on that that differs from that suspicion.

Nancy Lowe: This is Nancy. I also think that in terms of feasibility, the change to – that the series was initiated actually helps feasibility at the hospital level.

Reva Winkler: OK.

Carol Sakala: Agree, because it lowers the burden. That's a good comment.

Amy Bell: Yes, I agree with that, too.

Reva Winkler: OK. Anything else from anyone on feasibility?

OK, let's move to usability and use, where we're looking at how the measure is currently being used and what the impact and any potential unexpected findings are.

Carol Sakala: So it's publicly reported in quality check which is a bit of a challenge to find and use, but it's there. And use for improvement in programs internal to the Joint Commission.

And I would also add, which wasn't in their documentation that is included in the Medicaid, adult core set as their population level measure.

Reva Winkler: OK. Amy, anything?

Amy Bell: I don't have anything else to add to that.

Reva Winkler: Anything from anyone else?

OK. Any other comments or questions before we move onto the next measure?

OK. This is measure 476. I'm sorry, that was the last one, 469, sorry. This is PC-01 elective delivery, also part of the Joint Commission set.

This measure assesses patients with elective vaginal deliveries or elective cesarean births at greater than or equal to 37 and less than 39 weeks of gestation completed.

So – and our discussants for this are Tracy, Sheila and Jennifer Bailit again. So, either one of you want to start off. It's a maintenance measure. So, what do we know about the evidence or any changes to the evidence?

Tracy Flanagan: This is Tracy. You know, I think there's been really no additional evidence. I think that there's pretty good support that, you know, that delivering early is not a good thing. And I don't think there's much new in that. But I can stand corrected from anybody else.

Sheila Owens-Collins: I totally agree with that. This is Sheila. And I think that, you know, with time, we're seeing improvement in quality overtime and the expected reductions and all of the outcome measures continue to improve. And so, I don't see – I agree that there aren't any major changes needed.

Jennifer Bailit: The only thing I would say is – this is Jennifer Bailit, is to tweak it a little bit which is I think there is new evidence to show that implementation of this measure is safe, i.e. that still birth rates do not appear to have gone up with the implementation of this measure, so if anything, it's stronger support for the measure.

Sheila Owens-Collins: You said the birth rate?

Jennifer Bailit: I'm sorry, still birth rate has not gone up …

Sheila Owens-Collins: Right, right, right. I agree, yes. And that was a big controversy and concern. I agree with that.

Reva Winkler: OK. Then, we move down and look at the current performance data that's been provided from the Joint Commission.

Ladies, what are your thoughts on that?

Tracy Flanagan: I'll start, and then we can just kind of round robin on this. This is Tracy.

As you can see which is up on the screen, it's been a – there's been steady decrease. And you know, I think that's, as one would expect, from 13 down to 3 percent. I think that the range has become more narrow. I know we're going to talk about this a little bit later but I am concerned about going to zero or saying that zero is good, because there's always exceptions to the rule. But, there's been steady improvement and there's still a variation.

Sheila Owens-Collins: I agree. I have concern about going to zero and I don't think that's reasonable. And I'm encouraged that more hospitals are going to be reporting, I think it's starting in 2016. And so I think to the extent that we can get as close to 95 percent or 100 percent of facilities that deliver babies or, yes, deliver babies, the better we'll be and the better measurements will have.

Reva Winkler: All right. Thoughts – comments from anybody else? Any …

(Crosstalk)

Nancy Lowe: This is Nancy. And I think this is an interesting issue about a zero (realist) or even desirable.

And I just want to provide a perspective from out here in the Wild West, where people may live at considerable distance from hospitals and if the weather report is bad and the woman is (multip) with a history of delivery at 39 and two or 39 and four spontaneously. Both the woman and the provider get pretty anxious about leaving her from, you know, a long ways away.

And I just know that that's a really practical issue that sometimes we missed in some of these measures about those kinds of historical pieces both from the woman in the geographic situations. Like, you know, up where I live, we had 43 inches of snow over this last weekend, so …

Sheila Owens-Collins: That's a good point. I thought I read that there was some stratification according to (rurality). I have to practice saying that word, according to the geographic factors, was there?

There was some discussion later either in terms of (inaudible) discussion or the classification discussion on, you know, some of the disadvantage of being rural.

Reva Winkler: All right. Yes.

Elliott Main: First of all, the Joint Commission …

(Crosstalk)

Reva Winkler: There is a reference. Yes.

Elliott Main: Yes. No one in the measure development side has stated a goal and certainly the Joint Commission, we do not feel it should be zero.

Other agencies, unfortunately, have come out and tried because of the success of many hospitals have tried to push it down further and further. The tension here is between adding more and more and more exclusions which requires more and more chart review versus accepting a 3 percent or 4 percent rate.

We're very happy with the 3 percent or 4 percent rate in the tradeoff of adding more exclusions that require chart review.

The second point is that this measure is now required for the last two years to be reported by every hospitals in the United States to Medicare. Interestingly enough, this is on the Medicare Inpatient Quality Reporting System that the only out – so if you're a critical access hospital or a children's hospital, which obviously (United) delivered many babies. So it is widespreadly used not only by the Joint Commission, but by CMS and Medicare.

Reva Winkler: OK. Comments from anyone else on current performance or disparity?

Tracy Flanagan: I just want to add a comment that, you know, I oversee a system of about 40,000 deliveries a year and I review every single fallout, and the fallouts are not just about transportation, they're about odd medical conditions, there's weird stuff. I can't even think of the examples.

So, I just want to reiterate, again, it shouldn't be zero. There's always going to be some, you know, good reason to do something that isn't – that would cause a fallout on this.

Reva Winkler: OK. All right. Any other comments before we move down to scientific acceptability, the specifications and the testing for reliability and validity?

Diana Jolles: This is Diana Jolles. I just like to plant a seed about retiring the measure in the sense – I don't know what people's feelings are regarding the variation in performance.

I know that we've just gotten to this point. And so retirement of this measure at this endorsement period is probably unrealistic or unwise, but at a certain point, this measure will have lived its course.

We never should have been doing elective inductions before 39 weeks at the rate it was occurring. Once you achieve the performance level, we start diluting our quality movement when we continue to maintain measures that have achieved their goal.

Tracy Flanagan: I agree with your point, but I think it's going to take a couple more years.

Nancy Lowe: Yes. So, I agree. I think that's ultimately the goal, but it becomes the moot issue. But, I think it's premature to do that or …

Sheila Owens-Collins: Yes, you know, it also interesting to look at this, you know, compare this measure with the C-section rate because, you know, I mean, I think it's well known that this measure has, you know, has very well done what it's supposed to do. However, the C-section rate has not budged in a way that we have wanted to at least where we're (at) been.

And so, that's just kind of curious because one of the things that this measure is supposed to do as an outcome is to reduce the C-section rate.

Female: You know, this is …

Jennifer Moore: You know, and this is Jennifer. I would caution – I caution this group to assume that we have met the expectations of this measure on building off of the last comment that we haven't reduced cesarean section rates. But when we also look at other outcomes that should correlate with this one such as NICU admissions, we're also not seeing a downward trend.

And so the question becomes, and I'll save my comments for the reliability section about whether or not this measure is actually capturing what it's intended to do.

If you look at some of the term, many of them are subjective. An early term elective, non-medically indicative that have a lot of variation in terms of its documentation and it's – I think that we need to be cautious.

Jennifer Bailit: I think – this is Jennifer Bailit. I think the other piece here is that the connection between induction during delivery is perhaps a little weaker than we thought. Those trials are ongoing right now.

And the evidence is, I think, at least in the past (inaudible) strong, the link was good and (nullips) and certainly wasn't in (multips) which are the majority of deliveries. I'm not really surprised that the C-section rate hasn't moved.

Nancy Lowe: You know, I – this is Nancy Lowe again. I think there is an interesting system issue in this when we're thinking of these two measures of the elective delivery measure and the cesarean measure.

In talking to many nurses, many institutions have instituted a hard stop on the elective inductions that when the office calls, the provider calls to schedule, the series of questions are asked and the nurse is empowered to say, "No, we will not schedule that induction," versus a cesarean which the medical provider is the one who primarily makes that decision.

And I don't think there's this much empowerment necessarily in many systems yet to question that decision. So it's a team issue from my perspective.

Reva Winkler: All right.

Anything else on the testing for reliability and validity?

Jennifer, I think you wanted to say more on validity.

Jennifer Moore: Yes. And in terms of reliability and the validity of the measure, having come from HHS, we're engaged in the (coin) efforts and there's a lot of discussion with various hospitals and initiatives in health departments and state officials expecting concern about how we capture early elective or elective inductions and cesarean sections.

Some of these groups have gone into their medical records and did a check of the induction of labor as an example verifying that it was medical or elective, and in hospitals that do have really strict hard stop and there's robust initiative to address this issue. Sometimes they were finding that an indication like hypertension for the induction. When they went further into the chart, they could not find a documentation of elevated blood pressure.

And so there's been a lot of discussion about whether or not we capture the overall rate such as induction of labor or C-section as opposed to focusing specifically on early elective or just elective, because if elective decreases, the overall rate will decrease.

We don't have an answer to those, but it's definitely something that we continually grapple with and are trying to figure out.

And so, I'm not saying that we'll have a solution as part of this discussion, but I throw that out there because there is a lot of conversation around that. And again, we don't know the solution to that, but it is a challenge.

Reva Winkler: Comments from anyone else? Any other thoughts on the scientific acceptability of this measure?

Tracy Flanagan: I want to add a comment, and I don't know where it goes, this is Tracy talking, about parauterine surgery. I've reviewed a couple charts in the last two years

on people doing repeat C-sections before 39 weeks when at the last C-section, there was a large window of gap in a low transverse uterine incision. And it made me wonder – yes, she's had parauterine surgery because she's a C-section.

The concern was her going into labor sort of like what the intent of a parauterine surgery diagnosis is, but I wasn't sure even really how to weigh in on that. And I'd love some comment or clarification, or any other person's comment on that.

Amy Bell: Hi. This is Amy.

Tracy Flanagan: Because that particular person would not have a parauterine surgery code.

Amy Bell: This is Amy. My interpretation of that is, I think from reading the Joint Commission guidelines when you're abstracting those cases. If the patient has had a parauterine window, they are excluded from that measure altogether.

Tracy Flanagan: Oh, maybe I should go back then.

Elliott Main: Yes. Tracy that was one of the changes made in the most recent set of guidelines when the Joint Commission was removed current or prior windows for that reason. That's the chart review measure, though, which makes it harder in – but that is covered obviously …

(Crosstalk)

Tracy Flanagan: OK, I missed it then, sorry. I'm sorry, I didn't …

Elliott Main: … C-sections, yes.

The other point about whether this has been effective, clearly, there is some gaining of coding as there is for every measure, where diagnosis may not be as strongly supported.

I think the best evidence for effective (inaudible) though is that multiple states have reported a significant decline in the number of 37 to 38 weekers born overall. Moving this back to where we – we're in the distribution of the births about 20 years ago, and recently, the National Center for Health Statistics has also reported that for the United States as a whole.

So that's actually probably the strongest evidence (inaudible). You know, we're doing a whole lot better in baby which is probably somewhat better, but it's – there are clearly fewer 37 and 38 weekers being born in the United States overall.

Reva Winkler: OK. All righty. I think we need to move on a little bit.

Any further discussion on validity, and then any comments on feasibility and use and usability as we've sort of addressed a lot of these issues, but anything further here?

OK. It's not sounding like it.

Jennifer Moore: Can I ask a clarifying question for Elliott?

Elliott, on page one of this – I don't know if you have the same document, but one of the denominator exclusions with UTD, I was not part of this committee when this measure was originally brought forward, but can you give me a little bit of background and an understanding why that is an exclusion criteria?

Elliott Main: (Celeste), why don't you explain UTD, I think that's part of the process of all the Joint Commission metrics definitions.

Jennifer Moore: OK.

(Celeste): Hi, yes. This is (Celeste), and I think you're referring to unable to determine gestational age and that is something that we …

Jennifer Moore: Oh, OK.

(Celeste): … vetted towards internal measures because of the fact that we kept repeatedly that they had not received prenatal care.

Jennifer Moore: Oh, OK. And so we don't want to capture that population who isn't receiving prenatal care.

(Celeste): The rationale being that they don't have an exact or estimated gestational age. Many times they were saying, "We think that she might be 37 to 39 weeks." And we only allow for a single numeric value so they weren't able to put an answer down and they would basically (fail them).

Jennifer Moore: That's really helpful. Thank you.

Elliott Main: That is a very small number.

Jennifer Moore: Thank you.

Reva Winkler: OK. Any comments from the workgroup on feasibility or usability and use?

OK. The next measure is actually the eMeasure version of this same measure, 2829. We do – NQF considers eMeasure versions to be distinct and separate measures, but related.

And so, what we are seeing in the submission is essentially the same information for evidence and gap. In terms of the scientific acceptability for eMeasures, our eMeasure technical review team goes through the HQMS, which is in the three-standard way of specifying an eMeasure. Some of you may call them eCQM. And look to see that the value sets are in the Value Set Authority Center at the National Library of Medicine, and some of the other technical aspects of – that are important for eMeasures.

eMeasures are becoming more and more common, but they're still very much in their infancy compared to the more traditional chart-based registry or claims-based measures.

And so, testing of these measures has been challenging. And so we do allow testing in a simulated data set, which is the information that is provided to you from the developer for the eMeasure.

One question we asked about the other eMeasure from workgroup three was, how much are these – how often are these measures being submitted to the Joint Commission as eMeasures?

And we added the information to your – to the folders on these measures, but they were so nice to provide us some information on this particular measure. It was in single digit for submitting to Joint Commission last year, but this year, anticipated for 2016 about 60 different health care organizations are planning to submit the actual eMeasure for this particular measure. So we're starting to see more use and hopefully enough data that more empirical testing of those measures will be possible.

Does anybody have any questions about the eMeasure version of this measure?

Tracy Flanagan: I'm just going to make a comment on behalf of Kaiser. You know, we've long had the goal of doing what we call electronic upload, which is I think you're the end version of an eMeasure because it really reduces the burden on quality folks and reporting. And we worked really hard to try to do that.

And so, I'm pretty sure we're going to be part of that organization. I think we started doing that middle of the third quarter of last year. And for my health plan in a large health care delivery system, it's a huge advantage to be able to do this.

Reva Winkler: Comments or questions from anybody else on the workgroup or the committee? Is there anything anybody wanted to talk about the eMeasure version of this – of the early elective delivery measure?

Tracy Flanagan: One more comment, you know, obviously, Epic and electronic medical record may exist far easier because of ability to call out gestational age in certain

things that in the past would have taken chart review. But, hospitals that are non-electronic medical record are going to have a real hard time with this, and probably won't put themselves into the pool for that.

Reva Winkler: All right.

Amy Bell: And this is Amy Bell, and I'm not sure if this is something that our team is wanting to do at some point or this is a topic for another day or another committee that this fall about actually setting goals for this initiative having a, you know, a target for PC-01, a target for PC-02.

You know, we just don't have that right now. And I think that's hard to know if, you know, we know we're headed in the right direction, it's just when do we know that we actually arrive or do we ever arrive at what we need to be doing.

Reva Winkler: Yes.

Tracy Flanagan: Are you asking for defined goal?

Reva Winkler: Yes.

Amy Bell: Yes. I mean, I think it would be nice at some point to have define goals that can be agreed upon, you know, from various entities about, you know, nationally, where do we want to be.

Reva Winkler: Amy, this is Reva.

(Crosstalk)

Amy Bell: … 4 percent or 2 percent …

Reva Winkler: Yes.

Amy Bell: … or, you know, we're just getting conflicting kind of target to shoot for.

Reva Winkler: Yes. Amy, in general, NQF has not really focusing on doing any target or benchmark settings. Typically, what we tend to see that is from sort – some of the programs that the measures are used in might do that. And so – but I do think that it's certainly a conversation we can have, and thinking about how the best might – the best way to go about that might be.

Any other thoughts on the measure before we move onto our next measure?

Tracy Flanagan: The non-controversial measure, right?

Reva Winkler: Yes, OK. What can I tell you?

All right. Here we go. Measure 471, cesarean birth, this is another one of the – as we define from the Joint Commission. The measure assesses the number of nulliparous women at a – with a term, singleton baby in a vertex position delivered by cesarean birth.

OK. And our discussants for this are Carol Sakala and Jennifer Moore. And I'm sure we've got everybody else wanting to join in as well.

So, Carol and Jennifer, why don't you start out and we'll try and go through this in the usual order starting with evidence and then opportunity for improvement.

Carol Sakala: Great. So I'd be happy to begin. This is classified as an outcome measure. I think it could be considered an intermediate outcome measure. Right now, it's a paper measure at the facility and also national population level, and I'm not sure if you said, Reva, but it was first passed in 2008 and then renewed in 2012.

I think when it was passed there, we weren't talking so much about systematic reviews. They referenced increased likelihood of hemorrhage, uterine infection and increased cost.

I think it's fair to say that there are indeed quite a few systematic reviews showing that outside of clearly supportive indication, cesarean is associated

with greater likelihood of various kinds of harms, and also that there are ways to change practice that reduce the likelihood of cesarean. So, if anything, I think that the evidence in support of this measure is getting stronger overtime, and could definitely be considered to be high in quantity, quality and consistency.

Reva Winkler: OK. Any other comments from anybody?

Nancy Lowe: I have a – this is Nancy Lowe. I have just a language question. And that is, I've always struggled with this measure, why it's just called cesarean birth rather than nulliparous cesarean birth.

You know, the very name to me is confusing and it's currently the problem with this – with the Healthy People 2020 objectives. You know, that they don't specify nulliparous births just low risk women, when baby had (down) term. And I know it would sure help me if this said nulliparous cesarean birth.

Female: Yes, I would agree with that, too.

Amy Bell: And just to echo, this is Amy. You know, the Healthy People 2020, it does specify women with no prior cesarean delivery. But that, you know, when you're talking about managing, you know, multiparous patients compared to how you manage nulliparous patients, it's very, very different.

And in that rate, you know, the 23.9, that's not really a rate we can necessarily use for PC-02 because we're comparing completely different population.

Nancy Lowe: Absolutely.

Reva Winkler: All right. Other comments on the data provided by the Joint Commission for performance on this measure?

Jennifer Moore: This is Jennifer. I have a historical question, again, I wasn't involved in this committee when this measure originally came. But how was the gestational

age established. It says denominator exclusions gestational age less than 37 weeks.

Elliott Main: There are two ways in establishing gestational age that are in the specifications. One is using (basically) good data when you're doing this set of population level, and using the (chart) obstetric estimate on the birth certificate and the other is from direct chart, chart abstraction or electronic medical record established – of (best) obstetric gestational age. We're certainly not wanting to use the (last) period gestational age.

Jennifer Moore: Thanks, Elliot. I guess my question, and maybe I didn't articulate it well was, how was 37 weeks identified as the threshold as opposed to 36 or 34 weeks for this particular measure.

Elliott Main: It was meant to be termed, the original name for this measure was nulliparous term, singleton vertex, which is a …

Jennifer Moore: OK.

Elliott Main: … mouthful, and which is why it's been shortened by – in, unfortunately, Healthy Person 2020, actually did a typo on this one, with the specs from 2010, but that's a whole another story.

So it's meant to be termed as many more medical complications in preterm pregnancies, and the idea was to avoid those.

Jennifer Moore: Great, thank you.

Female: Elliot, could you just please clarify the typo, the implications of that, is this indeed the same measure or still different?

Elliott Main: It should be the same and with ACOG, we're working with now Healthy Person 2030 to get that corrected. When you go back to the older records, they probably did came up with a measure for 2020, they took NTSV C-section from 2010 and looked at the national rates. And then, wanting to improve a 10 percent from (NQC), which they probably came up with 23.9.

If you look at term, singleton vertex without a prior C-section, the benchmark rate would be about 12 percent, nowhere near the 29 – 23.9 percent what they have here.

And the National Center for Health Statistics does report this year over year, and never reports within the Healthy Person 2020, if you were to use that original – or their current definition.

Basically, when they transferred it from 2010 to 2020, they forgot – they left out the word first birth of, you know, et cetera.

Reva Winkler: OK. Any comment on current performance?

Jennifer Moore: Just one question I have (related) under the disparity section just seeking clarification on what patient type referred to. So, if they thought there is literature that indicates factors associated with greater odds of cesarean section, African American race, marital status, patient type, insurance type and age older than 35 years. I'm just curious what patient type means.

Reva Winkler: Elliot or (Celeste), are you able to help us out…

Elliott Main: Yes.

Reva Winkler: … here.

Elliott Main: I'm unclear what you're referring to. There are racial disparities, there are differences (inaudible) patient population but the biggest one is African American, though it should be noted that 20 years ago, African American women had lower rates on this measure. And now they have higher rate, so it's kind of flips up in the 20-year period, and for reasons that aren't well understood.

Tracy Flanagan: I don't know where we want to talk about the risk adjustment, but I'd like to make some comments at some point.

(Crosstalk)

Jennifer Moore: Yes.

Reva Winkler: Yes. We're coming down – it sounds like we're ready to leave and move onto scientific acceptability. So, this is where we want to talk about the specifications of testing for reliability and validity, and certainly risk adjustment would apply to both the specifications and potential treats to validity. So, that's where we are now.

Tracy Flanagan: Well, I'll start. I'm going to just dive in on this one. I actually really like the idea that we have this measure because I think it's one of the few C-section rate measures that clinicians have been able to get around – you know, get behind and look at and not argue about whether – I mean, we still argue but can really get behind in a theoretical way.

My own personal concern about this, and it's not because there's a whole lot published on this, I'm aware of Elliott's article, is that it still isn't risk adjusted enough. And you know, I really worry about immutable factors, factors that can't – you can't change, it seems to impact C-section rates. There's age, there's race, BMI, you can argue that that's not really immutable during the pregnancy. And what we found internally is hypertension and diabetes. Those are the three – those are the five big ones and it was huge.

Now, I'm well aware of Elliot's ability to look through this, the CMDC database and see that age and BMI were inversely related. But, that doesn't really speak to a particular hospital who may have a disproportionate diverse population or disproportionately heavy population that isn't young.

So, I guess the question is, it enough risk adjusted. I – but I guess the other comment I want to make is, I personally, in having watched this measure in my own organization for a long time, understand that you can't do everything.

If we do accept that we're not going to risk adjust it more, then I think we have to be very careful about the numbers below which we are striving for or setting a goal. So, I'll stop there and let other people weigh in.

Diana Jolles: This Diana Jolles. I'd like to comment on that.

I appreciate the points, and I think that hopefully we'll live to see the day where those issues become important as this measure develops and evolves. At this point, I feel like the measure is performing very well to identify extreme variations at the hospital level, at the provider level, at the practice level.

As a matter of fact, there's research that supports that hospitals with some of the highest patient acuity with the highest risk status then came from the lowest NTSV. So I don't think that those fears have been demonstrated in research. And I believe that as, you know, just – that there isn't inherent risk control being set in the standardized (inaudible) here in childbearing women. When you're talking about population rates of diabetes, hypertension, some of the hospitals that have far above what (inaudible) show that preexistent hypertension and diabetes rates continue to maintain the lowest NTSV.

So I don't believe that the fear is realizing itself and that until we can get these variations much more controlled and much more limited, then we can move on to developing more compact risks modifiers. But at this point, I think it's fair to say that the variations are unwarranted and then that it's affecting the majority of childbearing women in the United States nationwide.

Tracy Flanagan: Let me just make one short comment in relation to that. I completely agree with you that, you know, that the extreme variation is really where we're at. But then it becomes very disturbing when purchaser collective start to say, "Well, we're not going to pay you below a certain number," which is what's happening. And that number is 23.9.

So, you know, if our average is 25. I mean, I don't know what the right number is and that kind of language starts to get very disturbing to a lot of folks.

So anyway, I know that we don't set a target in this committee. But, the more that we make it right, I think the more people will get behind it and that more will know what the right number is.

Amy Bell: This is Amy. I was – I'm sorry.

Female: Go ahead, Amy.

Amy Bell: I made some comments on my survey about this particular issue. But, really, if we can really look at those cases that are contraindicated for vaginal delivery and add that to the measure, I think that would be a great sort of next step. So, your previous HIV positive mom, previous myomectomy, ones that we don't want to deliver vaginally, if we could exclude those like the breeches have been excluded, I think that would be a good next step to move forward with.

Reva Winkler: Thoughts from anyone else?

Tracy Flanagan: Breeches are already excluded, but, yes, previa, I think that – I'd actually agree, that's pretty easy coding wise, too.

Female: The only thing is …

Amy Bell: Right, and then …

Female: … so rare and a (inaudible).

Tracy Flanagan: Right, and it might be evenly distributed. I'm not aware of anyway that it would be not evenly distributed across hospitals, where that you think age and race and possibly BMI because of geographic differences in eating and culture are going to be different geographically by hospital.

Jennifer Moore: And also overtime, you know going back to Elliott's point, the variation that's occurred overtime for African American. And we also see that in white, so risk adjusting for race or ethnicity may not be a reliable approach, too.

Reva Winkler: OK. All righty, I'm looking at time and I don't want to cut this up too short. But, Elliott, go ahead …

Elliott Main: I can make a couple responses …

Reva Winkler: Yes, go ahead.

Elliott Main: … to that.

We did look at previas, for example, and there are many fewer that are nulliparous at term, most people noted earlier. But we had the ability to drill down and look at the cases that are nulliparous previa – that were nulliparous (previas). And have the case that has a previa code at term in (nullips) were delivered vaginally. Which means that the coding was most likely there because there was a previa voted on ultrasound earlier in pregnancy.

So there are real coding issues with previa, that term in the setting, and ended up being a tiny proportion of women who had a C-section. But even of those, a fairly number had labor, which again, you know, were delivered for CPD, which again, made the diagnoses of previa somewhat suspect.

We also had big variation, it was mentioned, there was big variation in terms of the medical diagnoses in terms of the rates of high-risk centers having below NTSV rates, where some of the hospitals in California has the highest rates of advanced maternal age having very low NTSV rates and vice versa with a high rates of obesity also.

So some of these diagnoses aren't real, they're associated – some of them were self-fulfilling prophecies because of the care that we give. It used to be, for example, that we tried super hard not to do a section on the obese woman. Then we would go to great lengths to avoid it because of the surgical complications.

Now, what you hear on labor and delivery is, well, we should do the section now because we don't want to have to do a (cross) section on her later. And that philosophy has led to increasing rates of C-section for obese women, where it may or may not be medically indicated.

So it's a – risk adjustment is pretty tricky business. I think you have to be real sure that it's a strong indication like breech and that it's coded well. You know, for example, in California, there was only six women that were coded HIV in the whole state on the delivery records. Six women, part of it is because the state laws would vary from state to state what gets coded. But you really have to look at those sorts of things before you add them in to risk adjustment package.

Reva Winkler: OK. All right. Folks, I'm keeping an eye on the clock and we do have two new measures we want to be able to get through.

Are there anymore major issues about this particular measure that you want to get out before we move onto the next one?

Carol Sakala: So this is Carol. And I would just like to ask the Joint Commission about their plan for republic reporting which is mentioned in here. With the pressure to align behind a specific measure right now as we have already alluded to, I think that there is a lot of confusion between total cesarean, primary cesarean, this NTSV measure. And in order to get everybody behind and understand what's going on, I think that we need to coalesce a little more around this measure, and I agree with what was stated that is a fair measure and I want to go for.

So, with public reporting of this measure, I think that would be very helpful for educating women and also for giving women a chance to choose a relatively fair measure to decide where they might give birth.

Female: I agree, Carol. Well stated.

Elliott Main: (Celeste), you want to take that?

Ann Watt: This is Ann Watt at the Joint Commission. Thanks for the comment, which I'm not – I'm sure you're not surprised we've heard before.

We are committed to publicly reporting our measure results. Because this is an outcome measure, we're still in the process of finalizing our policy with regard to publishing those outcome results because of the issues associated with expected versus actual and those kinds of things, and we just want to make sure that we're doing it right. But we hear what you're saying and thank you.

Reva Winkler: OK. Anything else from this measure before we move onto the next?

Which is not taking us too far away form the subjects of cesarean section. This is a new measure called the birth risk cesarean birth measure brought – submitted by a Birthrisk.com or Birthrisk, LLC.

Sorry, coming up slowly on my computer.

OK. And this – so this is a measure of the – fact that obstetrical care providers labor management strategies have on their laboring patients risk per cesarean birth. The target population is limited to women who attempt labor with a singleton vertex pregnancy without a history of prior cesarean birth and give birth between 37 and 42 weeks of gestation.

So, this measure, Jennifer Moore, Nancy Lowe and Tracy Flanagan, shall we go ahead and talk about this measure like we have the others? Starting with evidence and then opportunity for improvement.

Nancy Lowe: I think – if I hear – actually the question – this is Nancy, the question that you're asking us, Reva.

I struggled with the basic definition of this measure, because indeed, it talks about obstetrical care providers labor management strategies. So, the way I read it, it's meant to be at the provider level and it doesn't measure labor management strategies, and it mixes nulliparous women and multiparous

women together, which I think is problematic. And this – in the rationale, if their labor management strategies or better or worse than average, it doesn't measure labor management strategies.

So, I must admit that I was confused from the outset, and then for more substantive scientific reasons that come up later. But I really struggled with the very first page, where we were going and what this really was about.

And then there's a discrepancy between the definition, term which is seven to 42 weeks on page one and then over on the next page, which is page three for me under reliability, it's 36 weeks and four days and 42 weeks and three days. So, those were just a few of my thoughts right out of the gate on this one.

Reva Winkler: Thank you. Anybody else?

Tracy, I know you have to leave, but do you have any thoughts before you have to leave us?

Maybe she already did.

All right. Jennifer, any thoughts from you?

Jennifer Moore: On the initial piece, or are we diving in?

Reva Winkler: Well, you know, however, I'm – because of time, if there are things you think are particularly pertinent to dive into, let's go.

Jennifer Moore: OK. So I agree with the last comments and I also had challenges reviewing this particular one, recognizing the discrepancies and the mismatch between the intention of the measure and what they're claiming it will measure.

But I think the biggest piece in terms of the other components was the use of birth certificate data which we know is one of the most least reliable sources of birth information. So that was of concerning to me also, and made it difficult to review this measure.

Reva Winkler: Comments from anyone else?

Are there any questions you would want …

Gregory Goyert: This is Greg Goyert from Henry Ford. So, based on the overall review of this, I don't see why the – under 1A would be – the evidence would be rated as a pass.

Reva Winkler: Oh. Good point, Greg. I think …

(Off-Mic)

Reva Winkler: … you raised a good point. Thank you for bringing that up.

How would you rate it?

Gregory Goyert: No pass.

Reva Winkler: OK. How about on a high moderate or low scale?

Nancy Lowe: This is …

Gregory Goyert: Moderate on a good day, low on most days.

Reva Winkler: OK.

Nancy Lowe: That's what I felt, too. This is Nancy.

Reva Winkler: And that's on the evidence. OK.

All right. Do we want to move down to other aspects of the measure? Again, I'm keeping my eye on time. What aspects of the measure, Jennifer or Nancy, do you want to talk about?

Jennifer Moore: This is Jennifer. I feel like Nancy summed it up just from the first page.

There's a disconnect. And I'm still trying to figure out all of the pieces because it's not – yes. And the reliability testing and – I mean, there's no published data on the use of birth certificate data, the disconnect, but we've said all those things. I have nothing additional to add.

Reva Winkler: Anybody else on the committee or the workgroup? Do you have any …

Nancy Lowe: The other thing that came through for me in – you know, I kept feeling like I'm just not getting this. And I felt like I needed a whole day to really go through all this information, track it down and make sure that I understood it, and I just couldn't get there.

And I was concerned when I got to the validity testing that the developer talks about Cronbach's alpha in a – under validity. Cronbach's alpha has absolutely nothing to do with validity. Nothing. And so there's …

Jennifer Moore: Yes.

Nancy Lowe: … once there's a misused of statistics, I get very disturbed fundamentally. And I know that you – there was a comment from NQF that you were going to have your statistical advisors review the data to provide an interpretation of the (Inaudible) results. I didn't get that either. And that we would have that by our in-person meeting. But, you know, I got lost there and, you know, I work with statistics a lot. And I had great difficulty following what was going on here.

Jennifer Bailit: This is Jennifer Bailit. I had similar statistical concerns. The values of predictive ability that they quote just are not true. And anybody who's looked at predicting C-section before and there have been multiple publications, and it makes me concern about how they did their predictions.

Reva Winkler: Are there any questions?

(Crosstalk)

Gregory Goyert: Yes, but seeing those taking it together that the rating in terms of the validity would not be moderate, but would be low. And that reliability going back to using birth certificate data would be not moderate, but low as well.

Jennifer Moore: Yes, I would agree.

Nancy Lowe: Agreed.

Reva Winkler: That's fine. Are there any specific questions around the technical details that you would want to ask the developer about?

OK. Is there anything more around the scientific acceptability? And we move onto feasibility. Anything there that – comments from feasibility.

Nancy Lowe: Well, it certainly not from a feasibility standpoint. This is Nancy. It's not the type of measure that the individual institution could do and it's a commercial fee-for-service measure. So, from my standpoint, I think that the feasibility is low in terms of a – even a system-wide adoption.

Jennifer Moore: Yes, I agree.

Gregory Goyert: Agreed.

Reva Winkler: OK. Any comments on use and usability?

Jennifer Moore: I'm not sure how you use it if you don't understand it.

Reva Winkler: OK.

(Off-Mic)

Reva Winkler: OK. There seems to be some questions about, you know, understanding the measure. What is it – is there anything we can do to help committee members? We've got, you know, 10 days before the meeting. Is there anything we can do to help your understanding?

Gregory Goyert: I'm not sure that it's a lack of understanding. I think it's a more an assessment of the value of the measure.

(San Roman): Reva, can I add anything as the developer?

Reva Winkler: Sure. The developer is Dr. (San Roman). Please.

(San Roman): Thank you for your comments and taking the time to review the measure. And it is a somewhat complex measure and I do apologize about the discrepancy in the gestational age that you're finding. There was a correction made to the measure that didn't make the April 11th cutoff that corrected those errors.

The reason for those is that the national birth certificate gestational age uses 37 to 42 weeks without days. And the original data for the development of the measure came from New York State, and New York State have used days. So, we could use – and we did analyze data from 36 weeks, four days to 42 weeks, three days, but I do apologize for that discrepancy.

It is appropriate to mix parities the way I have done it. The way I've done it is a little bit different than what you used to seeing and, unfortunately, when I spoke with Reva, the same thing happens. Everybody thinks this is somehow predicting C-section rates. And that's not at all what the measure had done.

The measure is much more in kin to a logistic regression modeling, where you take the risk factors, in logistic regression modeling, you would take the risk factors in a fixed data set. You'd create an equation and then you would create a predictability of the expected rate of C-section for each individual patient in the target. And then once you have the predictability for each patient, you create effective C-section rate for that target. And then you compare that to the actual rate.

Logistic regression, the equation is based on prior outcomes. The equation looks at the data set and assigns the value to each risk factor. What my program does is it actually looks back over the actual deliveries and finds 100

women and gives you a cohort, 100 women with those same risk factors and it uses the percentage of those 100 women to determine what the predictability for that patient is.

So in essence, what I'm doing is giving you an inherent risk for each patient who goes into labor.

The reason the measure talks about assessing the labor management strategies is isn't that what we talk about when we talk about a cesarean birth measure, we're not talking about a rate, you know, C – primary C-section rates are rate.

The measure is, we want to measure how good or how bad that these doctors are taking care of these patients and that's really what the measure is supposed to tell us.

So, my thinking is that you can't really measure that on patient who don't labor, because if you have a placenta previa or a breech, I think those doctors get a pass. And that's why those are the exclusions in this measure.

If you want to actually measure what happens on labor and delivery and, you know, who's tired and who's going to do a section because they're tired, and who's going to stay the night and make sure the patient delivers vaginally, you actually have to include the risk factors for each of those patients.

And I heard many risk factors that you'll brought up, hypertension, diabetes, race, age and BMI. And part of the problem with that is those are great risk factors, but is diabetes truly the risk factor or is it the patient's age, height, weight, BMI and the size of her baby.

And basically, I look at labor as a physical process. It's a woman who comes in to kind of like she's running a marathon, it's a physical process and the obstetrician decides what to do. The obstetrician decides if this woman is going to have an epidural or she should walk, or is she should be admitted. Those are the labor management strategies that I referred to.

That's what this measure is going to measure. It's going to measure how good or how bad your obstetrician, is it managing patients, but you need to adjust for the inherent risk of the woman who come in to give birth. It's not fair to judge the outcome of 18-year-old patients versus the outcome of 35-year-old patients who labor. And that's what this measure intends to do.

I think it would be who's the committee members to take 30 minutes of their time and go to my website and look at the information for health care professional's page, and there's a 33-minute PowerPoint presentation that goes soup to nuts that when you finish watching that presentation, you will understand where I'm coming from. And where I'm coming from is a very different viewpoint. It's not the typical viewpoint that you've been looking at. And it's something that I would appreciate if the committee members could take 30 minutes of their time and look at that presentation. Thank you.

(Crosstalk)

Reva Winkler: Thank you. All right, any other questions because I'm looking at time here, folks?

Somebody had a question?

Nancy Lowe: Well, this is Nancy Lowe again. And Dr. (Roman), I just wanted to respond in a minute. I certainly do agree with you that clinical decision making hopefully in consultation with the woman, in shared decision making not unilateral decision making, has a lot to do with outcomes of birth.

But if I'm following your statistical approach in a logical fashion that you've tried to present, you're still basing the expected rate unobserved occurrences in the past.

So, the question then becomes, how reliable in terms of predicting outcome is that historical data. And in fact, the data set, the way I understood it, does not have these other variables in it that you talked about are so key to outcome which have to do with the labor management strategies.

So, I think there is – I'm struggling with this conceptual idea of a disconnect upon the regression equations upon which you – the data set upon which you based the predictive equations, and therefore, then compare what happens for that individual woman, because that's based on data that's contemporary at the time those women delivered. And so, I would ask you to kind of hear that concern that we have, and I did spend time on your website, quite a bit of time on your website. So, I think I did my due diligence in trying to understand that.

And then the other question that I would ask you is, how could this realistically be used by a system, or on a national level to be a real measure of outcome that organizations could get behind.

Reva Winkler: OK.

(San Roman): OK, let me try …

Reva Winkler: Thank you, Nancy. Yes …

(San Roman): Yes, let me try and take those both questions.

The measure itself doesn't do any predicting whatsoever. The prediction that you're looking at is to validate the measure. So the data they use of this measure does not predict outcome in any way, shape or form.

Basically, it creates an expected, what I like to call, an inherent risk for each woman. And if you look at some of my comparisons, an 18-year-old nulliparous woman who is five foot four at a good BMI who comes in with an average size baby in spontaneous labor has about a 7 percent risk of ending up with a C-section when she comes into labor. Whereas you compare her to a 36-year-old whose five foot two, somewhat heavier and with a larger baby, if she is getting induced, she has a 70 percent risk of ending up with a cesarean birth.

So, if you have one institution that has 18-year-old and you have another institution that has your 36-year-old, you're going to have a huge difference in the outcome of these patients that have nothing to do with the doctors who are taking care of them, because there's no way that if all my patients for that 36-year-old, I won't ever hit the target rate.

However, if I have all 18-year-old, I can do a whole lot of unnecessary cesarean birth and still be well underneath the threshold that's being proposed.

So without taking all those factors into account, they're trying to measure the effects of the doctor on the patient is really not very simple. And we could look at, you know, Healthy People 2020 is promoting a 23.9 percent NTSV cesarean birth rate.

And I just post this very simple question, I mean, we all know that as patients get older, their risk of the NTSV risk goes up. So, if we have this great campaign nationwide to reduce teenage birth to zero, that's going to raise that NTSV rates. And everyone is going to want to know what if the doctor is doing wrong. You know, well, why is that rate going up, because we're not adjusting for the patients who are coming in. It is a two-way – it's patient and a doctor.

Reva Winkler: OK.

(San Roman): So …

Reva Winkler: Thank you. Thank you.

(San Roman): … that hopefully answers the first question. In a hospital system, if you got 20 hospitals …

Reva Winkler: Excuse me, excuse me, we really do need to move on.

(San Roman): All right, sorry …

(Crosstalk)

Reva Winkler: So we'll have a chance to address. Thank you.

We appreciate your responses to the question, but I do want to be sure we have time to talk about the last measure as well.

(San Roman): And absolutely, and there'll be time in May to sit and talk as well.

Reva Winkler: OK. So, for our last measure, 2896, this is another new measure. It's the structural attributes of a facility in which high risk women deliver newborns.

This measure characterizes the facility that is the site of delivery of newborn infants born to high risk women by four key structural characteristics, identified as critical structures by their national expert panel. The four structures are level through your higher NICU services on campus, 24/7 onsite blood banking, 24/7 in-house physician dedicated to labor and delivery, and 24/7 in-house anesthesia. This is a composite measure and it's structured as an all-or-none composite.

So, as I mentioned, this is a new measure. So, our discussants are Amy and Sheila. Ladies, what are your thoughts on this measure?

Sheila Owens-Collins: OK. I'll go first. Number one, I mean, I'm really excited about this measure. I think it's a good measure. And I think it's going to be very feasible and usable because it aligns with the guidelines in the guidelines for perinatal care.

It's also important because despite the – all the technologies and all of the advances that we've made, when I look at this in 2014, because I've worked on a similar project in Texas, the maternal death rate was – we were one in 50 in the world from maternal death rate and went in 28 in the world for infant mortality rate.

And so, I think that, you know, a lot of that will have to do with where we deliver babies so I think it's …

Larry Kleinman: Hello?

Female: Hello.

Larry Kleinman: We just lost the feed for the call.

Reva Winkler: Can you hear me?

Larry Kleinman: I hear you, but I don't hear the speaker, any of the speaker.

Reva Winkler: Yes, that's Sheila. I'm just wondering if it was Sheila who we lost.

Larry Kleinman: OK, that's possible. It just went silent in mid sentence, so.

Reva Winkler: Yes. OK.

Larry Kleinman: And this is Larry.

Reva Winkler: OK. Hi, Dr. Kleinman.

All right, Amy, did you have any thoughts as we you look at the initial evidence and opportunity for improvement for this measure?

Amy Bell: I guess – I struggled with this one, maybe a little bit more than Sheila did. I think just because it's a completely different way of looking at measures than what we typically have been, you know, looking at this – the last couple of hours.

You know, there were studies done in New York and I think it's in references made to California. But my concern is about the spread of this nationally, is this going to be something that we can do. And there are different – you know, there are different patterns noted with disparity. So I think they did cover – they did cover some of that.

Down in reliability, where, you know, one of the questions for the committee, it says, is it appropriate to include delivery complications (inaudible) as markers for high risk.

And my comment to that would be, this may happen with seemingly normal pregnancies. I don't know how we would, (inaudible), I don't know how we would track it, by facility or by state or by nation, is it a – is this a rate we're trying to do for the nation, exactly what is it – how we would report this. I guess I just – it just wasn't as clear to me maybe as it was to some others.

Reva Winkler: Yes. Amy, this is Reva. The level of analysis for this is health plans, integrated delivery systems or populations.

Amy Bell: OK.

Reva Winkler: Thoughts or comments from any of the other workgroup members on the evidence for this measure or the opportunity for improvement for this measure?

Gregory Goyert: I'm not sure that this is a measure of quality, rather just a classification of a perinatal unit. Either you have it or you don't, so I too share the confusion with it.

Jennifer Moore: And I'm – this is Jennifer. I'm concerned how this measure will be used in terms of women's access to birth preferences.

Amy Bell: Right.

Female: Agreed.

Amy Bell: This is Amy. And I think just – this may be more semantics, but I think section 1A was supposed to be, it was required to be completed and I did not see that that was actually completed.

Reva Winkler: What, on the evidence?

Amy Bell: I think it was 1A7 looking through the details, I think – when they follow the specific algorithm, they were supposed to complete it, they had to complete – if I can find that section again.

Gregory Goyert: And this really doesn't address the clinical circumstance, Reva, a catastrophic outcome in here to for low risk patient who just have to go to a level one or level two hospital.

(Crosstalk)

Amy Bell: I'm sorry, this is Amy again. On page 19 at the top, it's checked with clinical practice guideline recommendation, it says complete sections 1A4 and 1A7. I did not see where 1A7 was actually completed.

Reva Winkler: OK.

Sheila Owens-Collins: OK. Hello.

Reva Winkler: There is …

Sheila Owens-Collins: OK, I gave a five-minute opening statement and didn't realize I was disconnected. But …

Reva Winkler: Hi, Sheila, welcome back.

Sheila Owens-Collins: Yes. I was looking forward to this.

I worked on a similar project in Texas, in fact, we looked at guidelines and best practices as well as a committee of experts of neonatologist as well as family practitioners and obstetricians and (inaudible).

And so the goal was to establish levels of care simpler to the neonatal levels of care for hospitals that deliver high risk mom. So, it's very similar to what, I think, this has intended to do.

And I think it's very important and I think it's, you know, it's progressive and I think that's the way it's going to go in the future being on the managed care site.

One of the drivers is – and it wasn't well mentioned in the background information for this measure, was that when I look at the statistics in 2014, the

United States is 50th in the world in terms of maternal death rate and 28th in the world in terms of infant mortality rate – maternal mortality rate and infant mortality rate.

And so, in spite of all of our technology and how much money we spend on our citizens, we still have a very long way to go in those two domains, and I think a lot of that has to do with the access to care and where women are delivered. And you know, making sure that the risk is aligned with the facility. That's the first point.

The other point was that, I think that these structures are well aligned to the guidelines in perinatal care, was outlined there in terms of how the facility should be tiered.

The other – the thing that I would – the only other thing that I would add was – is that, even though it's implied that a level three or higher service should be available, I think that the criteria are geared primarily to the mothers and conditions that they have. But, there are conditions where the mother may have a (harvest) fetus. And that would make her eligible to, you know, to go to one of these facilities as opposed to a condition that she may have.

Female: Sheila, may I ask how you see this measure being used though as an indicator of quality that would be useful to the public?

Sheila Owens-Collins: Well, you know, I can give you a lot of anecdotal evidence as a neonatology, you know, babies that clearly, should not have been at facilities, usually rural facilities, community hospitals that were not equipped to deliver the babies or to take care of the babies that had very poor outcomes.

And so, I think that as an outcome measure, infant mortality rate and maternal mortality rate would – could possibly be correlated to the facilities that deliver care.

Reva Winkler: Is there any evidence of that ...

(Crosstalk)

Female: Yes, I was just going to say (inaudible) that there's not evidence.

Sheila Owens-Collins: OK. So, as I've said, you probably didn't hear me. I had just gotten all of the work that was done in Texas as currently in the legislature now for approval in 2018 and 2019. And this is a plethora of evidence – you know, of articles and (inaudible) that was done.

So, let me have a little time to review that and I will make a note to come back to you on that.

Female: OK. All right.

Carol Sakala: So, this is Carol. And I just have a question about a related measure that seems to be stronger in terms of meeting the criteria. Previously, we had endorsed 0477 under 1,500 gram infant not delivered at appropriate level of care. And I don't see it before at this time. So, could we get an update on this data surveillance?

Reva Winkler: Yes. Carol, the measure developer elected not to resubmit it for ongoing endorsement. And I don't know, Elliot, are you still on the line?

Elliott Main: Yes, the reason for that is that it's really best used at a population level and is pretty much being used by State Department of Health currently. So we didn't want to spend the time and your time trying to do it at the hospital level. It doesn't quite make sense at the hospital level. And that may have impact on how you do this measure too whether it's mother is not delivered at the level – appropriate level of care or whether – or what you're going to do with the levels of care.

Jennifer Moore: Yes. I mean, I think that's a really good point, Elliott, because it's more of a provider measure than a hospital measure on quality, and someone shows up at their door. You know, I'm struggling with that.

(Crosstalk)

Larry Kleinman: Can I respond for a moment? This is Larry.

Reva Winkler: Yes. Dr. Kleinman is the developer.

Larry Kleinman: So, a couple of things. One is – God help us, we did not choose this topic, so the reason I say that is CMS and AHRQ assigned us this. From our point of view, it came out of left field but as we did the work, we realized the importance of a measure set, and this is really only one in a set but it's the structural components of availability of high risk care. So it does not make a distinction between good care and bad care.

It characterizes the availability of care not at the level of a hospital because that would be – that that would make no sense in this. It is at the proportion of deliveries at hospitals that meet this characteristic, so that's one thing. So it is a prior – it was a priority for the federal agencies, AHRQ and CMS who assigned it to us.

Secondly – and it seems to be – it fit nicely with the levels of care and where ACOG and others are going.

Secondly, the issue of the – identifying a high risk pregnancy at birth. We felt this was important for a couple of reasons. We do recommend stratifying by how they qualify and that's in the details, that if it's a mother only, it's child only or if it's both. And the reason we say this is because, otherwise, there might be systematic reason to not refer mothers where the babies may have difficult complications or where just the delivery may be difficult, then there's local knowledge that suggest that, even if there is an ICD-9 codes, we can tease out and specify.

So, we didn't want to put the mother and the child in opposition to one another. We wanted to align that and felt that if something bad happens, it means the risk was there whether we could identify it or not.

Therefore, this is not supposed to be 100 percent, this is an index. It should reflect the general availability within a population. Just like not every woman

we identify as high risk will be high risk, nor every woman we don't identify as high risk will not – will be at low risk at the population level with the law of large numbers.

This will stabilize and it will require us to have some actual use in benchmarking to fully understand the nuances of what the measures mean. But nonetheless, it is a high priority, it is for the feds, it is important and it is not simply a measure of what the hospitals have, but rather where the mothers deliver.

To what Jennifer said, I would note that in New York City, we found that fully one-third of the black-white infant mortality difference can be attributable to hospital of birth, and presumably, at least a good selection of that is family sorting to where they want to deliver to their own detriment where there's an asymmetry of knowledge. And I think in the context of an asymmetry of knowledge, it's a more complex issue than simply parents delivering where they want to deliver.

Reva Winkler: Thank you, Dr. Kleinman. I'm sorry that, you know, we're running short on time. We've only got a minute or two.

So, from the committee or workgroup members, any other, you know specific things you want to get out or questions you want to ask at this point in preparation for our in-person meeting?

Thoughts from anyone? Any particular question? Yes.

Jennifer Moore: I have two questions. This is Jennifer. When you mentioned that this was assigned to you by CMS and AHRQ, you serving as a contractor in some capacity, can you clarify that …

Larry Kleinman: No, we were one of seven national sectors of excellence in the Pediatric Quality Measures Program. So we were …

Jennifer Moore: As part of CHIPRA.

Larry Kleinman: As part of CHIPRA. We were classified as an AHRQ-CMS CHIPRA center of excellence.

Jennifer Moore: OK, got it. And then, has there – have you looked at the potential impact of – in rural areas related to this measure?

Larry Kleinman: Well, what we have is a normative expectation that rural measures – or rather rural states or rural populations will have lower levels of access.

We don't know what that range exactly ought to be. We did look in New York State and found that using UICs, Urban Influence Codes, there were differences in availability by rurality, which we expected. And we did find, when we looked at 15 different states using the (Max) data, that states depended to be more rural did tend to have less – this is expressionistic, we didn't do statistical analysis on this. But states that tended to be more rural did tend to have lower levels of availability.

So this is part of our challenge was there opt to be normative differences and how do you establish a quality measure at – where there should be normative differences. And that's why we came up with this idea of a population index.

Jennifer Moore: OK.

Reva Winkler: Thank you.

Jennifer Moore: And then, I'm also curious if ACOG has responded to this measure citing potential concerns that if they're not – if providers are not sending women to the right hospital based on this quality measure, the risk of liability to them and the impact on – I think that that was my last concern that I identified.

Larry Kleinman: Sure. We had an ACOG member on our steering committee, we circulated this information to ACOG. One of the co-chairs of development was designated by ACOG as a representative. She was a co-chair of their national disparities group, (Inaudible). And we did not hear that.

In part, because this is not placed on any individual physician and we very explicitly say in our definition of specifications, this does not reflect the quality of care for any individual, because we recognize the impossibility of using this kind of data to identify any individual. It is at the population level.

Reva Winkler: OK. All right, folks, unfortunately, I think we're at time. And we do have just a couple of things we need to address. As with all of our workgroups, we need to take the opportunity for any public comment.

Operator, would you see if there's anyone who wants to make a public comment?

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

We'll pause for just a moment.

(San Roman): I'd like to make a comment as a member of the public, even though you don't want to hear from me anymore.

Reva Winkler: Do we have anything on the phone and then – OK, go ahead Dr. (San Roman).

(San Roman): Dr. (San Roman), I'll make it very quick and it's not about my measure. It's about the comment that I submitted on measure 471. Is it possible that you could bring that comment and the response from the developer up on the screen?

If we could bring that up and the committee does have it, but I can read you what the Joint Commission has decided. You guys are doing your measure maintenance on a measure that they are making a material change to for their use in reporting. They're removing the risk adjustment as of July 1st. Any hospital with 300 births or more is going to be reporting on an unadjusted NTSV rate.

So if you could go to their response, it will just be below that, the developer response.

Female: Excuse me, sorry, jumping off to another call.

(San Roman): OK. I'm sorry?

Reva Winkler: Thank you.

(San Roman): According to the developer, the recent study show that all the women have lower BMIs and younger women have higher BMIs, and that somehow in a more robust risk adjustment model, age and BMI tend to cancel each other out. Please stop and think about this statement. The statement defies logic.

If our older NTSV patients have lower BMIs and our younger NTSV patients have higher BMIs, and age and BMI cancel each other out, and our older NTSV patients would have the same cesarean birth rate as our younger NTSV patients.

The statement contradicts the last 20 years of research, therefore, it's imperative that we take a closer look at the body of evidence they are using to remove the risk adjustment.

I ask that each of you pull the (Kasara) study and figure out how BMI cancels out age in that study. And I just ask that you look at that, that study is available on my website, it's a publicly available study. And I think you'd be very surprised at what you find in that study.

So, six years ago, I tried to inform the Joint Commission they had a big problem with the direct standardization. They didn't listen to me. Here we are six years later, and they're getting rid of it. And now they're not listening to me again. Please, for that study, take a look at it and we can review it in May. Thank you for you time.

Reva Winkler: Thank you. Thank you. Any other comments? Public comments?

Operator: And there are no public comments.

Reva Winkler: Thank you. And I apologize, thank you everybody for hanging in there.

You will be receiving e-mails from us with further preparatory things for in-person meeting. We will update any information that we received from developers on the SharePoint information for you. You should have received travel and logistics information. So, please don't hesitate to get in touch with us with any questions you have. And we look forward to seeing you at our in-person meeting on May 2nd.

Any other comments from you, Nadine or Suzanne?

Female: Yes, I just had a question that we can talk offline. I just want to make sure that I can follow up and what I need to follow up with for this last measure, the structural …

Reva Winkler: OK.

Female: … attributes. So maybe can …

Reva Winkler: OK.

Female: … you e-mail me or we can talk offline.

Reva Winkler: OK.

Female: OK. Thanks.

Larry Kleinman: We'd welcome helping if we can to clarify anything. This is Larry.

Reva Winkler: Right. From our committee members, anything?

All right, with that, thank you all very much for your time today. And enjoy the rest of your afternoon. Thanks.

Female: Do the same, thanks.

Male: Thank you.

Operator: Ladies and gentlemen, this does conclude today's conference call. You may now disconnect.

Male: OK, I have to hustle because I got to get something ready for 3:15 with (Patty). But that was actually …

Female: That was really good.

Male: Yes, we got to find – you know who she is? You have a list of things, we have the measures here.

(Off-Mic)

Male: OK, we should get them just – that would actually be a good thing for this – for the future if we have others. We don't need it now, not in (inaudible) but …

(Off-Mic)

Male: Yes, but while we're on the phone, you know, Jennifer, I knew who's Jennifer Bailit because I've reviewed this in advance, but she's crossed out.

Female: OK.

Male: She was at metro, we could have taken the call in the same room.

Female: Yes. OK. Was the call for the meeting (inaudible) register you or you want me to register you …

Male: For which meeting, this one?

Female: Yes.

Male: Either, you work it out with (Marie), it doesn't matter. We should see if (Liz) wants to come.

(Off-Mic)

Male: Why don't you tell her when it is and what's happening and that – I just – can tell her – I'll e-mail her tomorrow, but I was thinking if she could come, it could politically be a good thing.

(Off-Mic)

Male: OK?

Female: OK.

END