Page 1

NATIONAL QUALITY FORUM

Moderator: Dr. Reva Winkler November 17, 2011

2:00 pm CT

Operator: Good day everyone and welcome to the Perinatal and Reproductive Healthcare Work Group 4

conference call. Please note today's call is being recorded.

I would now like to turn the conference over to Dr. Reva Winkler. Please go ahead.

Dr. Reva Winkler: Good afternoon everybody. This is Reva Winkler and along with Suzanne Theberge

and Gene Cunningham here at NQF.

Thank you all very much for joining us. This is the Fourth Work Group call for this Perinatal

Project. The first three Work Groups have met and we've had some very productive conference

calls to go over some preliminary reviews of these measures so thank you all for joining us and to

the Work Group members thank you all very much for your reviews and submitting your ratings

because this will provide a starting point for our discussions today.

Essentially the goal of these conference calls are to help the Steering Committee members

become more familiar with NQF evaluation criteria, to do a first task review of the measures

before us, to identify any particular questions or clarifications. The measure developers are

joining us so they're available to respond to any of your questions.

Confirmation # 4679691 Page 2

And hopefully by doing this first task review we'll be able to identify the areas of question and

concern and focus our discussion of the in-person meeting in a very - be more efficient so that we

can complete the agenda.

So again thank you all very much for the work that you're doing in preparation for this meeting.

So now I'd like to introduce or have the Work Group members introduce themselves and so I'll

just go down the list.

Is Jennifer Bailit with us? Okay it doesn't sound like Jennifer is.

Charles Denk, why don't you go ahead and just introduce yourself and just give a brief, you know,

background of where you're from and what you do.

Charles Denk: Sure. Charles Denk, I am Social Epidemiologist, Sociologist by training. I work at the New

Jersey Department of Health and Senior Services in a unit dedicated to epidemiology of maternal

and child health issues. I look at a lot of hospital records, discharge files and vital statistics files

and do quality of care assessments and needs assessments on the community level and, you

know, all kinds of things like that.

And I'm loving this project and I'm also finding myself a little challenged because I always think of

these things as, you know, what can I do at the state level in terms of reporting by hospitals.

And I've had to rethink that a couple times when I thought, you know, sometimes these are for

internal use and they don't have a larger agenda than that.

So I'm happy to be here.

Page 3

Dr. Reva Winkler: Great, thanks.

Kim Gregory.

Kim Gregory: Hi. I'm Kim Gregory. And I'm a MSN Health Service Researcher. Done some work looking

at both quality indicators and quality indicator improvement or monitoring. And I'm the Vice Chair

of Women's Healthcare Quality and Performance Improvement at Cedars.

Dr. Reva Winkler: Great. Thank you, welcome.

Bill Grobman.

Dr. Bill Grobman: I'm Bill Grobman. I'm at Northwestern Chicago. Like Kim I'm a Health Services

Researcher, Chairman of the Patient Safety Committee at Northwestern and also a long-standing

interest in quality metrics and as mentioned patient safety.

Dr. Reva Winkler: Super. Thanks very much.

Mary Leslie. I guess Mary's not with us yet.

Nancy Lowe.

Nancy Lowe: Hi. I'm a Professor and Chair of the Division of Women and Children and Family Health at

the College of Nursing at the University of Colorado and the Anschutz Medical Campus. I'm a

nurse midwife and I also serve as editor of the Journal of Obstetric Gynecologic and Neonatal

Nursing that we affectionately call JOGNN for short.

Dr. Reva Winkler: Great. Welcome. Okay, next is Carol Sakala.

> Confirmation # 4679691 Page 4

Carol Sakala: Hi. I'm Director of Programs at Childbirth Connection. And we've been devoted to

maternity care quality improvement for 93 years.

And we've been long term members of NQF and are very interested in having great measures

come down - come up through the pipeline and then leveraging them for maternity care quality

improvement.

Dr. Reva Winkler: Thanks Carol. Rob Watson.

Rob Watson: Good afternoon. I'm Rob Watson. And I'm a Practicing OB-GYN physician and Medical

Director of a Women's Hospital and co-Chairman of Women's Health Service Line for the Baylor

Health Care System in Dallas-Fort Worth.

Dr. Reva Winkler: Great. Welcome Rob.

And Kate Chenok, Kate how are you doing?

Kate Chenok: Hi. Hi, I'm Kate Chenok. I am a Director at the Pacific Business Group on Health and

wearing that hat I am on the Steering Group for the California Maternal Data Center which is a

new registry, being run out of Stanford and formed by the CMQCC.

I also have been involved in founding and I currently run an Orthopedic Joint (Replacement)

Registry in California for hip and knee replacements.

And I'm very interested in this issue. And have a particular interest in patient reported outcome

measures which I know we're not discussing today but that's a favorite subject of mine.

Page 5

Dr. Reva Winkler: Great, thank you Kate and welcome to everybody.

So we have six measures today to discuss. And all six of them - somebody put us on hold. Yes, thank you. We've got six measures to discuss today. All of these measures were previously endorsed by NQF three years ago and they're - well 2008 Perinatal Projects so these measures

are undergoing maintenance review.

Whether a measure undergoing maintenance review or a newly submitted measure all the

measures are evaluated against the same standard measure criteria.

So what has worked very well in the other Work Groups and I propose we do today is we'll go

through the measures one by one. I'll ask the person who was assigned as the lead discussant to

kind of start the conversation. We'll use the ratings that were circulated to you from the

preliminary reviews as sort of a starting point as we go through each of the criteria, each of the

four main criteria.

And we really want to focus in on the areas where the Work Group members and we've got - had

a good response of at least six Work Group members. So we can see where there's a high

degree of agreement or where there might be areas of disagreement that would merit further

conversation.

So with that we'll start with the first measure which is 469, elective delivery prior to 39 weeks.

This measure was originally endorsed three years ago and had been - the original steward was

HCA. But the Joint Commission has selected it as one of the measures that implement in their

new core set and they've taken over the stewardship of this measure.

And we do have the developers with us if you do have any questions.

So I believe the discussant is Kim Gregory.

Kim Gregory: Right. And could I - well yes, and when I open the measures, first of all I did send mine in but I obviously sent them late and I apologize for that.

But how do I find, like when I open up your Excel I see birth trauma. I don't see this one.

Dr. Reva Winkler: You can go to the column that says measure and you can sort it.

Kim Gregory: Oh, okay.

Dr. Reva Winkler: At the very top you see that drop down? Deselect everything and then select the measure you want.

Kim Gregory: I see. All right, well I can't do that and talk at the same time so I'll figure it out...

Dr. Reva Winkler: Okay, all right.

Kim Gregory: ...later. All right, so if I'm not mistaken I should - want to explain the measure and then go through sort of the ranking or do you want to just discuss where there's differences?

Dr. Reva Winkler: Well I think we can talk briefly about it, about anything in general in the subtopic.

But for, you know, importance we want to particularly focus in on opportunity for improvement and evidence particularly for the process measures evidence of relationship to outcomes.

> Confirmation # 4679691 Page 7

So if you don't have your spreadsheet open Kim I can tell you that in general all of the six ratings

that came in ranked this high on impact and high on opportunity for improvement. There was a

mixture of mediums to highs for the quantity, quality and consistency of the evidence.

There seems to be a general sense for this measure of support for this criteria.

Kim Gregory: Okay.

Dr. Reva Winkler: Were there any specific issues you'd like to raise?

Kim Gregory: Yes. I think that in general I would agree with that. In fact where I - my comments come

with - let's see, I think that its high impact, high burden and that there's significant opportunity for

improvement.

One disclaim or discussion point I thought is the - on page 3 they talk about the optimal rate is

3%, I mean is zero percent. And I know that there's the HCA data that actually got it down to

2.5%.

And I just sort of wanted to raise the notion that because of some absolute coding issues I don't

think we could ever get to zero percent because there would always be clinically appropriate

conditions that are in the numerator that we couldn't get out because codes don't exist for them.

So for example, prior classical or a prior myomectomy would be a good reason not, you know,

where you might want to do an elect - I mean a delivery early. But there's no code for that.

And so and there really isn't an opportunity to - even though when you clinically review it and you

say it's appropriate the way as I understand the indicators are you can't really excuse it even

though clinically it was appropriate.

Confirmation # 4679691

Page 8

Dr. Reva Winkler: Okay.

Kim Gregory: And then it also raises the whole issue which is everybody goes back and forth on and

that's the whole fetal lung maturity which would be another way - reason why you might not get to

zero.

But moving onto the evidence, I was pretty much in agreement with how it was interpreted with - I

actually went medium on quantity, medium on quality and high on consistency.

Does anyone wan to comment on that or feel differently?

Dr. Bill Grobman: I'm sorry, this is Bill. I guess the only thing I want to comment on is I wanted to support

what Kim had just said just prior to that which is even though we would all think that there really

should not be an elective delivery prior to 39 weeks, the measure as it presently stands isn't able

to capture all the things that are actually indicated and are not elective but end up coming out

looking like elective.

That's a really important thing that compromises its validity at their bedside for people and gives it

people concern about it and thinks that it's not really representing fact as well. So just I just want

to support what Kim said strongly.

Jennifer Bailit: This is Jennifer. I would agree with that. And I think the other thing to consider is that

there's a new article out, sort of a consensus statement about when it is appropriate to deliver

somebody late preterm and this does not...

Dr. Bill Grobman: Or early term.

NATIONAL QUALITY FORUM Moderator: Dr. Reva Winkler

11-17-11/2:00 pm CT Confirmation # 4679691

Page 9

Jennifer Bailit: ...necessarily match. I'm sorry, early term. The - this does not necessarily match with that

new consensus statement.

And so we just need to maybe make sure that we're not being inconsistent and the classical C-

section is probably the most obvious example of that.

Kim Gregory: So Reva I thought it might be worth sort of talking a little bit on page 5 about the net

benefit, you know, one of the things that the Task Force is perhaps overly scrutinized or criticized

for is looking for harms. And I don't think that that's addressed in any of these indicators. And I

just think we should sort of put that in the back of our mind.

And I know there's a recent paper that we can all criticize and it's an item about the one, you

know, institutional-based study that's on an increase in still births because clearly the evidence

that's documented here has found no increase in still births and/or in fact overall improvement.

But, you know, I do think that as we do move forward with some of these quality indicators we

have to think about the downstream impact of things that are - that we have not yet thought to

measure.

Dr. Reva Winkler: Okay.

Charles Denk: This is Chuck Denk from New Jersey. This has been an issue on our radar screen for

about two years. We've been - the Department of Health has been collaborating with the March of

Dimes and the Hospital Association to try to get hospitals to take responsibility for this. And we've

had a lot of hospitals adopt various kinds of, you know, internal review policies that are, you

know, that are prospective reviews.

NATIONAL QUALITY FORUM Moderator: Dr. Reva Winkler

11-17-11/2:00 pm CT Confirmation # 4679691

Page 10

And, you know, and I want to comment a little bit when the time comes about the actual exclusion

criteria. But I wanted to share the fact that, you know, in New Jersey I did a fairly elaborate study

and found that our rate of deliveries at 37 and 38 weeks had more or less tripled over the last

decade.

And we - and I had used a lot of those - these exclusion criteria to sort of hone in on it at least a

low risk population if not elective and found that at least half of these deliveries overall not just the

increase but half of deliveries don't meet any of these criteria at 38 weeks.

So in New Jersey it's, you know, it's widely acknowledged to be a very serious problem. And

we're making some headway but of course there's also a lot of pushback.

Kim Gregory: You know I would just like to point out the OPQCC did a study looking at when comparing

birth certificate data assessment of elective delivery versus hand collected data and there's an

11-fold over call when you look at administrative data.

So yes, it may be half of the 38 weekers don't meet this criteria but I'd be very susceptive of the

administrative data and how well it captures the clinical detail.

Charles Denk: True enough.

Dr. Bill Grobman: Right. That's really the problem we think now is that the administrative data is not able

to accurately. I mean there's no doubt that it's a problem in general. I mean I think we all know

that.

But we don't believe that the administrative data as it stands now can adequately capture the

magnitude of the problem.

Page 11

Charles Denk: Well sure. I've heard that argument before. And in fact the study that I did used - I don't

know when you say administrative data but do you mean vital registration data or whether you're

also including hospital discharge and billing date? We use both.

Male: Right.

Charles Denk: So we try to get somewhat closer.

Kim Gregory: Yes, the data - the study I'm referring to used birth certificate data. And I can't comment on

the other.

Dr. Bill Grobman: Yes. I wouldn't have dared. I would not have dared to use just birth certificate data (in

that study).

Kim Gregory: So to summarize then the developers rated quantity high and quality moderate and

consistency high. And I felt it was moderate, moderate and high.

Dr. Reva Winkler: Okay.

Kim Gregory: So that's my...

Dr. Reva Winkler: All of those would meet the criteria for sufficient evidence.

Kim Gregory: Yes, it would meet the criteria, absolutely.

Dr. Reva Winkler: Yes. Okay.

Confirmation # 4679691

Page 12

Kim Gregory: So then on your liability, you know, I couldn't decide between high and moderate but I

ultimately went with high.

Dr. Reva Winkler: Okay. In general the rest of the Work Group rated it mostly high. I think there was one

medium and on validity there were two mediums, the majority were high, so...

Kim Gregory: So this is where my hesitation is that there's not adequate ICD-9 codes for active labor or

spontaneous rupture.

And so many times in order to validate the data you either, you know, you end up doing some

type of primary chart audit at least for your numerators. And so that adds to the burden and

decreases the reliability if people don't take that extra step.

Dr. Reva Winkler: Okay.

Charles Denk: Yes. This is Chuck Denk again. And as I said we were - we've been working with the

March of Dimes. We just had three separate CME Sessions in different hospitals across the state

and I got to hear a lot of feedback about that. And yes, there's disagreement about those things

and even a couple of cautionary tales.

Could we talk about the list of exclusions for just a second?

Dr. Reva Winkler: Sure.

Charles Denk: I actually found that appendix on the Joint Commission site. And there were a couple of

things that I wanted to ask about. I mean there are some things there which, you know, are kind

of like it's trivial to say that they go on light post terms, you know. But who cares.

NATIONAL QUALITY FORUM Moderator: Dr. Reva Winkler

11-17-11/2:00 pm CT Confirmation # 4679691

Page 13

Diabetes, you know, I was under the impression that ACOG was moving away from calling well

managed diabetes an indication for cesarean or anything else.

And there's a couple of - yes, okay, there's a couple more probably that other people are more

qualified to wonder about and I am too that it weren't here. I was surprised to see where previous

section and mal-presentation because I was getting the idea that this is supposed to be deliveries

before it - we're looking at deliveries before 39 weeks. And we're trying to asses how many of the

uncomplicated ones are interventions.

Kim Gregory: Right. So right now the understanding is that if you've got a prior C-section except unless

it's a classical then it's scheduled at 39 weeks or after.

Charles Denk: Not if you live in New Jersey it's not because it's scheduled a lot at 38 weeks.

Kim Gregory: That gives you something to do.

Dr. Bill Grobman: Well yes, that's actually a valid. Yes, I mean that's a valid bad thing.

Charles Denk: I agree. I wanted to point that out. Anyway, mal-presentations aren't here. Again it's not

clear that they should be done at 38 weeks at all.

Dr. Bill Grobman: They shouldn't be as a rule.

Charles Denk: But the denominator is 38. We're asking how many of the uncomplicated deliveries at 38

weeks are, you know, are an intervention and that seems to me to be, you know, means that how

you define what's uncomplicated is, you know, is important.

Confirmation # 4679691 Page 14

Kim Gregory: Well I guess we could, you know, probably debate this for a bit. As it is now I would agree

that the two you mentioned that are not on there should not be on there.

And while I agree or understand that issue about diabetes I think that as a first path going after

low-hanging fruit they want it to exclude any obvious, you know, placental or obstetric or medical

conditions.

And then, you know, after we got really good at that I'm sure people would go back and perhaps

want to ratchet down again.

But as a first path, you know, because then you'd have to decide, you know, what controlled

versus uncontrolled. And how would you tell.

Charles Denk: Right.

Kim Gregory: And so it would take the opportunity of it being sort of valid and reproducible.

Charles Denk: Yes.

Kim Gregory: Away and introduce a lot more subjectivity.

Charles Denk: Okay.

Female: Rob.

Rob Watson: Could - this is Rob Watson. And I agree. I mean I agree with everything everybody has

said.

Page 15

And I think the biggest problem that we've had is trying to implement this across a large hospital

system is the exclusion criteria and the fact that it does not include previous classical cesareans,

previous myomectomies and even macrosomia. I mean those are probably the majority of our

fallouts.

And most of the pushback we get for this metric is because of a lack of an adequate exclusion

criteria.

Nancy Lowe: However, this is Nancy, I think you - when you start talk about macrosomia we're getting

into pretty squishy ground in terms of a diagnosis.

And, you know, I would not support macrosomia being an exclusion criteria.

Male: Yes, neither would it.

Kim Gregory: Neither would I.

Rob Watson: What about the others?

Male: Yes, prior classical.

Kim Gregory: Prior classical, yes.

Rob Watson: And prior myomectomy.

Male: Yes.

Dr. Reva Winkler: I'll let you guys call that one.

Page 16

Kim Gregory: I could be twisted.

Nancy Lowe: The other thing I'd like to see on here is trauma. You know I guess you could subcategorize

that under eruption but...

Dr. Bill Grobman: Cholestasis of pregnancy I don't think is on there. I'm not looking at the list now.

Nancy Lowe: Yes, it's not.

Kim Gregory: But liver disease is and so it would...

Rob Watson: Yes but I mean it would be nice if we clarify that because from a physician documentation

standpoint our physicians write down cholestasis of pregnancy and what we have to tell them is

for it to not to fall out the coders have to have it state...

Male: Right.

Rob Watson: ...liver disease of pregnancy. Well that's just another one of those trivial things that doctors

aren't going to remember.

And so and the same thing with clotting disorders of pregnancy when they have a thrombophilia

and so there are a couple of semantic issues that I think are causing some fallouts as well.

Kim Gregory: Right. And I guess that that's one of the advantages of the toolkit and especially if you go

with the hard stop documentation tool. We actually make our doctors fill out the form and sign it.

And by signing it we therefore have physician documentation of the indication that directly codes

to an ICD-9 code.

Confirmation # 4679691 Page 17

Charles Denk: Yes. This is Chuck Denk again. And if you'll indulge me just a little bit more I want to tell

you the cautionary tale that I got when we were doing the rounds here. And that is that, you know,

the issue of what is a really hard diagnosis, you know, is important when you try to put in these

hard stop policies and things like that.

And I heard from one hospital that the week after they initiated a hard stop, hard review policy by

the Chairman's office they had five cases reported the following week, (aligo) as a justification for

an induction in 38 weeks.

At the same time another hospital reported that they had a sudden upsurge of cases where mom

was already, you know, mom presented at the office in labor at the - in the 38th week and was

admitted to the hospital and the doctor ordered immediate augmentation of labor so.

Dr. Reva Winkler: And well - I think while we've all heard tales similar when, you know, how Perinatal

Quality Collaborative looked at the sort of diagnosis creep, we didn't find it.

And so while I think some of that may exist in some places there's also evidence that you can

have a statewide improvement policy on this issue and not get that.

Charles Denk: Yes.

Kim Gregory: And what usually happens is not even peer review but peer pressure because, you know,

the nurses...

Charles Denk: Right.

Kim Gregory: ...know, the residents know. But anyway I'm going to move us along.

Page 18

I did not have any issues with the denominator and they are not adjusting.

I did want a point of clarification on page 11 when they talk about the data source and the vendor.

Can some members help clarify with me on that?

If I read that correctly people who are using this aren't actually doing the data extraction

themselves. They're paying a vendor to do it.

Dr. Reva Winkler: (Ann) or (Celeste) do you want to respond from the Joint Commission?

(Celeste): This is (Celeste). And actually the way this works with all of our core measures is that we have

contracted with performance measurement system vendors who act as an intermediary between

the hospital and the Joint Commission. They provide the hospitals with the data collection tool.

The hospital does all of their data extraction and sends it to the vendor and the vendor in turn

then transmits it to the Joint Commission doing a number of quality checks on the data to make

sure that we have data that doesn't have any defects in it so to speak.

So the hospital actually does do their own extraction.

Kim Gregory: So I guess what I'm saying is especially as we start going with all the EMRs and stuff and

in fact I can say very clearly, we just went to a transition to an EMR where we lost our ability to do

things that we were doing really well and so now we're sort of recreating it.

But we're not using a vendor to recreate it. And I just wonder how - is that really what the

expectation is as we go forward that everything is going to sort of go through a gatekeeper?

Dr. Reva Winkler: Yes.

Female: No.

Male: This - sorry.

Dr. Reva Winkler: Yes. This is Reva. I think maybe I can jump in here. I mean what we are asking the

committee to do is look at the measure specifications.

Now there might be any way - number of ways that these measures are implemented. Certainly

the Joint Commission is one significant implementer of this measure.

But and the way they implement it in their program uses this data collection system.

However there are likely other programs that collect the data and that may not be aided through

vendors.

Kim Gregory: I see, okay. Thank you. That's helpful. Okay, then I think I'm on page 12, validity, and I put

moderate and again it goes back to the fact that many numerator cases could still be reasonable

clinical exclusions.

Dr. Reva Winkler: Okay.

Kim Gregory: And potential threats to validity. I think I'm good.

Dr. Reva Winkler: Okay. So in general everybody on the Work Group who submitted their ratings felt that

this measure does pass the criteria for scientific acceptability.

Kim Gregory: I agree.

> Confirmation # 4679691 Page 20

Dr. Reva Winkler: Okay.

Kim Gregory: And then with regard to usefulness for public reporting, I put high for both.

Dr. Reva Winkler: Yes, mostly highs by the Work Group, a couple mediums ((inaudible)).

Kim Gregory: And feasibility, so for 4(a) data generated as a byproduct of the care process, I put

moderate. And again that goes back to the fact that a big exclusion is labor and ruptured

membranes and currently that's not easily extractable.

And then for electronic sources I couldn't decide between high or moderate. It depends on

whether you've got, you know, data fields that are categorical or write-in. And then the quality of

your nursing in terms of whether they're hard stop or considered critical fields.

Dr. Reva Winkler: Okay.

Kim Gregory: But I think that it is theoretically possible that it could be very easily ten.

And then susceptibility to inaccuracies, I put moderate to low. I think these are very easy things to

diagnosis and code if they are diagnosed and coded.

Dr. Reva Winkler: Okay.

Kim Gregory: So overall I put for data collection strategy implementation is high.

Dr. Reva Winkler: Great. Okay and...

Page 21

Female: I think though Reva, this is the one when you look at 4, let's see which one is it? It's 4(c)

susceptibility to error...

Dr. Reva Winkler: Yes.

Female: ...which is the one where we had more spread among the group.

Dr. Reva Winkler: Right.

Kim Gregory: Yes, I couldn't decide between medium and low quite frankly so.

Dr. Reva Winkler: Okay.

Kim Gregory: And for feasibility I put somewhere between high and moderate but probably high.

Dr. Reva Winkler: Okay. And the rest of the Work Group agreed with you. There were three highs and

three moderates.

Kim Gregory: Oh good.

Dr. Reva Winkler: And so but everyone did feel that the measure met the criteria.

So unless there's some other issues with this particular measure I think it's an important topic. I

think it's one that generates lots of discussion. There's a lot happening out there so want to share

all of your thoughts when - with the whole Steering Committee at the meeting.

But in general it looks like the Work Group thought that this measure meets the criteria.

Confirmation # 4679691 Page 22

So in the interest of time I'm going to ask that we move onto the next one unless there's

something burning. I guess the sort of fundamental question I have is if there's any additional - if

there's an additional information or questions you have please raise them so we could, you know,

if we need to get information or get information from the developers to help everybody else

understand the issue, that's one of the major goals for these calls.

Rob Watson: Well Reva this is Rob and...

Female: Could I just ...?

Rob Watson: ...it just seems like what I'm hearing most everybody had some concerns about the

exclusion criteria and maybe wanted to have a couple of extra things added to it.

So how do we make our recommendation go forward?

Dr. Reva Winkler: Well...

Rob Watson: Is that something we do in the live meeting?

Dr. Reva Winkler: Yes, you will. And also I think that the folks from the Joint Commission are hearing it

and I think that it'll give them a chance to talk among themselves and be able to respond to that

at the in-person meeting.

Rob Watson: Okay, great, thank you.

Dr. Reva Winkler: Okay.

NATIONAL QUALITY FORUM Moderator: Dr. Reva Winkler

11-17-11/2:00 pm CT Confirmation # 4679691

Page 23

Carol Sakala: So and this is Carol. If I could just put out one quick request to encourage consideration of

additional levels for use of this measure for greatest impact possibilities in addition to facility and

population national would be health plan, clinician group, ACO and population at the state level.

Dr. Reva Winkler: Okay.

Charles Denk: And this is Chuck Denk. I just want to tell you. I'm sorry. Bring this up one more time. My

comments were sort of about the potential for sort of gaming this whole system by, you know,

hiding all of your cases in various exclusion categories.

And so I just I'll ask for the very last time whether or not it's really worth considering forgetting

about the exclusion criteria and using a much more just accrued ratio of all cases and saying that

we're, you know, for now there's, you know, there's probably a lot of cases that are, you know,

that could where there's room for improvement without worrying about these exclusion criteria

right now. In other words getting the rate from, in New Jersey it would be like from 30% to 15%.

Dr. Bill Grobman: Yes. And this is Bill Grobman. And I was - I mean I understand the reason for that but I

guess at the end of the day I feel that people can lie about anything.

And we're not going to be able to guard against sort of miss, you know, miscoding purposely.

And I think actually if we used accrued rate this goes back to the people kind of pushing for more

exclusions. This actually has a significant downside in that then people do become

disincentivized to deliver at appropriate times. But the appropriate early term, you're only

punished for doing that.

NATIONAL QUALITY FORUM Moderator: Dr. Reva Winkler

11-17-11/2:00 pm CT Confirmation # 4679691

Page 24

And that has a real - a significant downside tearing - and maybe much greater than the harm that

we're trying to prevent if we lead to a still birth or a maternal morbidity by not delivering someone

that needs to be delivered.

And I think then it actually loses all face validity to clinicians.

Female: I think that's an important point. I would agree.

Kim Gregory: I would agree too. This is Kim.

Female: I think the other thing is all patients are not the same at all hospitals. And so the lower ranking -

I'm sorry the lower risk hospitals are going to look a whole lot better on that than the high risk

hospitals if we don't differentiate some.

Charles Denk: Okay, fair enough. Thank you.

Dr. Reva Winkler: Okay. Is everybody ready to move onto a different topic?

All right, the next measure to discuss is 471, cesarean section rate. Again this is another measure

that was previously endorsed by NQF and had been previously developed by the maternal - what

is it, the California Maternal Quality Care Collaborative.

And again the Joint Commission has selected this for part of their core set and have taken over

stewardship of the measure.

So I think Rob you're the discussant for this one.

Confirmation # 4679691

Page 25

Rob Watson: I am. And I think, you know, as it says, you know, this is probably one of the newest quality

measures that we have out there having just really been started the Second Quarter of 2010.

And it seems like everybody when I look at everyone's comments that we're pretty much in

agreement. This has got a strong database with over 1000 related articles. ACOG considers it to

be the optimal focus for measurement in quality improvement in the area of C-sections and they

feel that it's more consistent than the total or the primary C-section rate.

And I think trying to get our arms around the rise in C-section rate has been an enigma for all of

us for decades now. It appears that after only four quarters of data that's been collected the

national rate is around 27.7% and recommendation for ACOG would be at 15.5%, in healthy

people (20.20) recommends a 23.9% rate.

When I look at what the - there were five I believe that reviewed this and everybody was in

agreement on the importance that pretty much everybody was in agreement on the evidence and

things of that nature as well.

So as I look across here I don't see much. I see some in - some variation in usability and some

comments there.

But everybody rated it high for feasibility and high for suitability. So in my impression I think this is

a fabulous metric. I think it's something that we can work with going forward. I think it's again

something that's at least in our area since it hasn't been out very long I don't think a lot of the

physicians are really familiar with it. And we're still in the education process.

Dr. Reva Winkler: Okay, any other comments from any other Work Group members?

Confirmation # 4679691 Page 26

Charles Denk: Yes. This is Chuck Denk again. And I agree with what Rob said. I'm very strong on this

especially the focus on, you know, Singleton Vertex Nullip which is what we've been doing in our

state for a couple years now. It has as somebody pointed out high face validity with the providers.

But I'm also the one who accounts for a couple of medium scores. And they're all related to one

issue. And that is that this measure is risk adjusted for age of mother in five year age intervals.

And I think about that in terms of variations in our New Jersey hospitals. And I will just tell you

that first of all I don't - I'm not an expert on this metric. But I haven't seen a lot of strong evidence

that says that there should be, you know, this continuous increase and although we certainly

have empirical evidence that cesarean rates increase with age that, you know, exactly what is the

medical (unique) underlying that. You know I haven't heard very many convincing arguments

even when I talk to physicians in the state.

What it does do is it let's talking about hospitals not all having the same patient base. It let's

hospitals in New Jersey particularly in the north part of our state who service - who serve a lot of

mothers who are, you know, first time mothers in their late 30s and early 40s, you know, it gives

them a lot of points back on this scale.

There wasn't any evidence presented in terms of how much impact with risk adjustment has on

the final outcome of the measure.

But I would be concerned because some of our hospitals with the highest C-section rates blame it

on advanced maternal age without a lot of supporting evidence.

Female: Charles?

Charles Denk: Yes.

> Confirmation # 4679691 Page 27

Female: I'm struggling though. When I looked at 2(b)(4) unless I'm missing something where is the risk

adjustment strategy?

Kim Gregory: Later. It's in the (stat).

Female: So it's not under 2(b)(4) because it says not applicable all through that section.

Charles Denk: Is that so? Well it's - no. It's testing of the risk adjustment. There's somebody here

representing the developers, right?

Dr. Reva Winkler: Right. (Celeste)?

Charles Denk: I mean...

Dr. Reva Winkler: ...did you want to explain?

(Celeste): Hi. Yes this is (Celeste) at the Joint Commission. It's not really a true risk adjustment model.

As my statistician will say, this is what we call direct standardization.

And it's done more in an aggregate level versus on a patient level data which is typically how you

would do risk adjustment. That's why the sections on risk adjustment are not applicable. But we

do address the fact that we're using direct standardization with the age bands stratifying the

measure by the various age bands and doing the adjustments in an aggregate according to the

number of patients that would fit into each of these age bands.

The actual direct standardization model was developed by the California Maternal Quality Care

Collaborative and tested out there. So we modeled it after that particular model.

Page 28

Charles Denk: Well I'm sure it's being done correctly.

Female: Right ((inaudible)) but it's a rationale for doing it that you're getting at.

Charles Denk: Yes. It's the rationale and it's - yes, I mean it's the single biggest reason I hear from

physicians in our state why our C-section rate is so high. And they say well it's because all our

moms are so old.

And to the extent there are hospitals who really are serving populations like that, I don't really feel

like giving them, you know, a pass.

Kim Gregory: And this is Kim. If you go to page 9 as I interpret it as well, although many people don't

bother, but it actually looks as though they want you to calculate your (NPSV) rate by strata. So

it's not I mean...

Charles Denk: Yes.

Kim Gregory: And if that is true you're right that some - I mean you don't discount and make the

differences go away because you could do cross hospital comparisons by age. But assume to

some extent allow doctors to discount age or to account for their rate based on their case mix.

Dr. Bill Grobman: Right. I mean - this is Bill. I guess I would say a couple things. I mean one, I don't have

Elliott Main's paper right in front of me. But my recollection of it is that age was the one thing in

his paper where that where risk adjustment actually made a difference and was still important in

the model. Almost every paper that has looked at age over the long - over decades really has

shown that it is a epidemiologically the factor associated with an increased risk for cesarean.

Page 29

I don't think we can possibly answer. But it adds because people are actively doing. You know

they're saying (hey Peroria) this is a 45 year-old. I'm going to have a low risk threshold to do a

cesarean for her.

But it's not that it's biologically implausible. I think I would absolutely agree with what Chuck said

that we don't have the exact biologic mechanism.

But certainly I would think it's not biologically implausible that as a person gets older there could

be differences in, you know, uterine tone and things like that.

But in any case if - that shouldn't be a give to the hospitals because then hospitals really are just

doing more cesareans and they stratify by age. You see that across the whole spectrum.

Isn't that right? So they wouldn't be able to just use their sort of old more mature women to get

away with higher section rates. Stratification actually is a guard against that.

Charles Denk: Well I think that what's going on here is yes, you stratify the rate but then you really (rate)

them by a standard population of age.

So for example if one of my hospitals in northern New Jersey, you know, serves a population that

has 15% more women over 40 than any other hospital in the state then they get to - and they

have a higher C-section rate in that group, then they down weight it by that, you know, by that

overage in, you know, over representation and then the final number they report is actually

adjusted downward by 2 or 3 percentage points.

Dr. Bill Grobman: But why is that necessarily given the epidemiologic data we have, why is that

necessarily a bad thing? It's not really giving them anything. It's admitting that their population is

different in a way that may have implications for the sort of, you know, why...

Confirmation # 4679691 Page 30

Kim Gregory: Bill I just can't. I don't think we're going to solve this today because the measure is already

designed the way it's designed.

But I think that what clearly did happen is there are - I mean forget the biologic part meaning that

they went into labor and they had the section. Because you're right, those studies are really clear

that there's about a, you know, 1.4% increase risk for every, you know, year increase in age or

something like that.

But what we do know for a fact is there are tons more less new cases because of age.

Dr. Bill Grobman: Oh totally different story. And Elliott and if I recall correctly, Elliott's measure was just in

laboring people ((inaudible)) and what...

Kim Gregory: But that's what this is.

Dr. Bill Grobman: Right.

Kim Gregory: Right? I mean this includes the (elected).

Dr. Bill Grobman: Oh absolutely.

Charles Denk: Right. And I'm not arguing that it's implausible. I agree with you. It has a lot to do with

whether we're talking about plausibility or whether we're talking about, you know, an actual

proven connection.

And, you know, women who are delivering first children are socially different, you know, I mean

they're older, you know, that...

Confirmation # 4679691

Page 31

Dr. Bill Grobman: Absolutely.

Charles Denk: And that's the counter argument is that there's a lot more maternal requests. There's a lot

more physicians collaborating with, you know, I mean this, the whole decision process is different.

And so, you know, and like I said, it's just the - I would like it if the developers could although it

maybe it's not - there's just not enough time, to say, you know, does this make a difference in

several percentage points for a hospital, you know, with one age distribution over a different, you

know, over another age distribution?

Elliott Main: Hi. This is Elliott Main. I'm sorry. I was on mute or the folks couldn't let me speak on this

((inaudible)).

Female: That's okay.

Elliott Main: So I'm sorry. I've been listening as you've been going along. I had to call back in.

We looked at this age stratification. And both is (ULS) data, California data and then the detail is

a hospital system.

There's actually a straight line in the rate of C-section with the correlation coefficient of .996. It's

as much - as tight as you'll ever get from the age of 18 up to 40.

So the - actually there's a big difference in the C-section primary nullip C-section rate if you're 28

than if you're 18 and if you're 35 than if you're 28.

NATIONAL QUALITY FORUM Moderator: Dr. Reva Winkler

11-17-11/2:00 pm CT Confirmation # 4679691

Page 32

Well the - everybody talks about the 40 (year-olds). They're a tiny population of nullips even in

San Francisco or New York City.

Male: Exactly.

Elliott Main: It's not a big number. But it's really the difference between being 20 and being 30 or 35 that

appears to make a difference. And that's not the area that people may be hedging and saying,

well she's the elderly primigravida. Let's just do a C-section on her that drives the issue.

You know in California it's about the Central Valley where the average of birth is 22 versus some

of the urban areas where it's 32 or 38. When we looked at this people asked - were asking about

the relative - how it much it changes.

It actually changes it by about 2% to 3% in some hospitals. But it actually doesn't change the

overall ranking very much except in hospitals actually that have very low age populations that are

sort of high to begin with that does make them considerably higher.

Hospitals with a lot of 20 year-olds and you have a high C-section rate you're going to stand out

with the age adjustment.

In California we're actually doing it both ways where you give the unadjusted and the adjusted

people rate. And we've been doing that for awhile.

And it sort of - that way you can see where you are and where you should be both based on age

and moms.

Confirmation # 4679691

Page 33

So I hope that's helpful. But it's, you know, in response to Bill Grobman's comments there's - in a

paper we wrote earlier looking at this we actually made some comparisons to how fast you run

the mile, and the analogous to a long labor.

And there's a age dependent cutoff for the record for the mile that's very - almost a straight line

from 20 to 40 in women.

Male: Okay.

Elliott Main: And so we thought there was some justification in examining the effect, biological plausibility

of age on uterine muscle function as well as the length of labor and the length of (second stage)

also increases with maternal age.

Charles Denk: Okay thanks. I mean that's the kind of...

Elliott Main: Sure.

Charles Denk: ...that I'm hoping would exist. Just for the record, I know these are all sort of renewals and

just maintenance but if we have a, you know good reason to suggest tweaks to them then is that,

you know, sort of, you know, like inbounds or out of bounds?

Dr. Reva Winkler: Well and certainly you can make the suggestions or offer the recommendation and the

measure developers are here to look at them.

But we aren't in the process of developing measures. So they can incorporate your feedback as

they wish and are able and then you'll just evaluate the measure as it is.

Charles Denk: Okay. Thank you.

> Confirmation # 4679691 Page 34

Kate Chenok: Reva?

Dr. Reva Winkler: Yes.

Kate Chenok: Reva on that note, this is Kate, and we have Elliott on. I don't know if it would be out of line

to have his input on the first trauma measure because Elliott I know you had some feedback

about that.

Elliott Main: Well only to the extent as we've looked at in California in our published data, is it's a

composite measure.

And there is quite a bit of variation or quite - among the different components when you look at

the ICD-9 codes there are some that are very rare and some that are very common.

And the common measures, the ones that have high frequent, you know, they're all low

frequency. But the ones with the highest frequency, you know, are the sort of general grab bag

other categories, other birth trauma.

And I think where people have shown the greatest ability to change their outcome on the

(RPSMT) is by changing the other category rather than changing the actual birth trauma itself that

we'll find.

And so that's been a curious one as we try to implement it in California looking ((inaudible)). It's

low frequency but it's the other categories that bothered us because those are the ones that are

variously coded from hospital to hospital.

Dr. Reva Winkler: I'll ask...

Page 35

Elliott Main: I don't want to...

Dr. Reva Winkler: Yes. I'll ask the group. Did you want to continue finishing the discussion on measure

474 and pull it out of order or do we want to go back and take up the next measure according to

the agenda, measure 470?

Dr. Bill Grobman: I'm sorry. Are we done with cesarean?

Dr. Reva Winkler: No.

Dr. Bill Grobman: No, let's...

Dr. Reva Winkler: Yes. Is there anything else on that ...?

Dr. Bill Grobman: Well I just had one comment which is the issue of lower equals better. I think although

in general that's true to - that's only true to a point.

And either I released a couple of papers that actually - and I think Jennifer Bailit who's also on the

line is author of one who showed that's not true (add-in some item). You could get to a low

enough section rate that there's potential harm for the baby and even potentially - I don't think

Kim looked at this, but I think conceptually for the mother.

And so although we want to drive this down I just wonder if we want to formulate that construct a

little differently.

Elliott Main: I would agree with Dr. Grobman. Jennifer wrote one of those. I wrote the other.

> Confirmation # 4679691 Page 36

And I think there is a huge (head) curve here but we're so far from the (tail) of the (youth)

nowadays so...

Dr. Bill Grobman: Oh yes. Totally agree.

Elliott Main: ...you know that I wished that was a struggle we were having.

It does look like - the way I've looked at it is that you want to have a balancing measure which we

have with the healthy turn newborn measure which went through pediatric (new) committee. So

what you want is a, you know, reasonable or low C-section rate with a very good healthy turn

baby outcome rate.

So if you had the two together the balancing, that would address the concerns that we found in

both of our papers. You'd like a hospital that does well in both.

Dr. Bill Grobman: For sure.

Charles Denk: Right. I - that's true for - I mean I think it's really ironic that the last - when I started to work

on New Jersey's C-section rate in, you know, 2000 when we were so high I did, you know,

literature reviews. And all I could turn up was papers from California asking if the C-section rate

was high enough so.

Elliott Main: Those were the days.

Charles Denk: Those were the days. And there hasn't been a whole lot - as the pendulum swung there

wasn't a whole lot of literature so we're back to - now we're out here again.

Male: And I...

11-17-11/2:00 pm CT Confirmation # 4679691

Page 37

Dr. Bill Grobman: Yes. I don't disagree with anything that's been said. I mean it's just my only point was

just that is that taken alone is not completely true.

Elliott Main: Yes, that's a fair comment.

Dr. Reva Winkler: All right. Just so we'll be sure to get through all the measures on our agenda, can we

move ahead to measure 470 which is the incidence of episiotomy?

And I think Jennifer that I think is a measure you were assigned to lead.

Jennifer Bailit: Correct. So let me just first say, right, overall I'm pretty happy with this measure. And I'm

usually picking them apart.

So and the - Kim Gregory I'm going to hit to the chase here. I gave this a high impact and a high

opportunity for improvement. I thought the evidence on this was quite high both in quality and

quantity and consistency that episiotomy leads to worse health outcomes.

I'm flipping through here, bear with me.

So threshold of importance to measure and report I said yes.

Reliability I said medium. I think there's some evidence and Bill I think you maybe have written

this paper about this measure is not risk adjusted really at all and apparently there can be some

risk adjusting.

11-17-11/2:00 pm CT Confirmation # 4679691

Page 38

And that's more for the outcome than the process. So just keep that in mind. I also believe that

the data quality and the coding of this is a little bit inconsistent in terms of whether episiotomy is -

how it's coded. So I gave that a medium.

Validity testing, I gave high.

And disparities in care, sort of against the usual way we think about disparities, I'd say they're

high with the overeducated white women being at risk for this.

I do think it's a useful reporting. I gave that a medium just because of the question about the data

quality. I said there was a high usefulness for quality improvement, high usability that the data is

moderate in terms of being generated as a byproduct of care processes. It is in moderate in terms

of electronic resources - electronic sources. And moderate in terms of susceptibility to

inaccuracies and errors.

Data strategy implementation I gave a moderate. And feasibility met, I gave a moderate.

So overall I think this should be endorsed. I haven't looked yet at the spreadsheet to see if...

Dr. Reva Winkler: Yes.

Jennifer Bailit: ...far off I was from everybody else.

Dr. Reva Winkler: No. Everybody I think pretty much agreed with you Jennifer. I think, you know, mostly

high, a few moderates and under the various importance categories.

I guess Chuck you were the only holdout on that one. Did you want to raise your issue as to why

you said no?

> Confirmation # 4679691 Page 39

Charles Denk: I was not the only person to enter a comment that was basically that the proposal itself

doesn't really talk about any kind of model of what would be a benefit of episiotomy or, you know,

versus the relative risks.

And ACOG guidelines simply calls - as quoted, simply calls for restricted - that restricted use of

episiotomy is preferable to routine use. And that's - I've seen that with ACOG before. It's very

vague.

And so to me I'm not an expert on this at all. And so to me it's just like the application is kind of

incomplete because the front-end of it doesn't really cite evidence that I thought was supposed to

be cited for a process measure.

That's the source of my objection really is that it's - and it's not an objection. It's just to ask a

request for clarification and maybe a little bit more rigor in the front-end of the application.

Dr. Reva Winkler: Okay. Do we have somebody from the measure developer with us?

Matt Hoffman: Hi. It's Matt Hoffman.

Dr. Reva Winkler: Hi Matt. This is Reva. You heard Chuck's comments. We'd certainly be able to help

you if you wanted to fill that submission form in a little bit more.

Matt Hoffman: Yes. I'd be happy to add additional material. In terms of benefit there really isn't a clear

benefit in the trials that have been shown. I agree with you. ACOG's position is vaguely worded. I

believe it intentionally.

Confirmation # 4679691 Page 40

But I think their fundamental upshot of this is that without clear benefit overuse, it's primarily an

overuse measure with little proof of benefit with the potential exception of shoulder dystocia which

is addressed through this mechanism that is risk, you should be limited.

So we can definitely cite some more of those papers a little bit more specifically.

Charles Denk: Was I the only? I thought there was another person who said that there could be benefit

and that the target rate isn't necessarily zero. Am I mistaken in thinking that?

Is anybody else on the call?

Matt Hoffman: To your point of saying target rate is zero. It is difficult to say what exactly the target rate is

because it's not been clearly defined.

I'll tell you in my own institution we're down to 3% through a Quality Initiative Project. And the

changes in fetal outcomes and that rate has been reported in other papers as well.

Kim Gregory: Yes, that's about what it is in to the 10 percentile for California which seems reasonable.

I just want to go on record that I actually like the fact that they include shoulder dystocia. I thought

that was pretty forward-thinking.

Male: I would agree with Kim.

Charles Denk: Okay, well on that basis I'm not - I'm also in favor of endorsement.

Dr. Reva Winkler: Great. Okay are there any ((inaudible))...

> Confirmation # 4679691 Page 41

Female: And this is...

Nancy Lowe: If I can add - hello? This is Nancy about the shoulder dystocia issue. The - I agree

conceptually. However the problem is what is shoulder dystocia and I think that clinical diagnosis

is so squishy that, you know, it is not a very accurate - an accurate indicator of doing an

episiotomy. I don't think.

And I have trouble with that being included as an exclusion criteria when that diagnosis is so

much simply in the eye of a (would be) holder.

Matt Hoffman: So if I could just sort of interject a little bit. Actually Kim and I and Jennifer wrote a paper

together looking at shoulder dystocia and the consortium of safe labor.

In a quarter of a million deliveries we saw an incidence a little over 1% with ranges between zero

and 3.5%.

So the overall effect on the total measure is going to be fairly de minimis. It is an issue and I

agree with you that there's some subjectivity in the definitional issues.

Having said that I don't think it's going to largely impact particularly when you see tremendous

variation in its use with, you know, institutions reporting as high as 35% to as Kim talked about

our center and other centers getting down to 3%.

Female: Okay, that makes sense.

Carol Sakala: So this is Carol. And I would like to go on record as supporting this. Somehow that came

out blank for me.

> Confirmation # 4679691 Page 42

And I wanted to ask a question of whether this measure should be stratified by a parity because I

think probably rates, at least lots of previous reports had much higher rates for first time mothers.

Dr. Bill Grobman: Right. But I - this is Bill.

Kim Gregory: No because I don't want them to get credit for that.

Dr. Bill Grobman: Right. I would agree. There's no indication and being a no, a best practice is not

indication.

Carol Sakala: So I agree too. And that's why I am saying that we should be looking at the first time moms

and not getting a pass on that. I'm not suggesting that they should get higher rates.

But institutions that have fewer nullips or higher nullips would be not so comparable.

Dr. Bill Grobman: But they should be using it...

Carol Sakala: But they shouldn't be using it all. So they shouldn't get a pass on it but we should stratify

by - as if to give them a pass on it.

Dr. Reva Winkler: Okay.

Matt Hoffman: We would concur.

Dr. Reva Winkler: Any other questions about this measure? Generally it seems like there's good support

that everyone agrees it meets the evaluation criteria.

Are there any further questions or areas for clarification before we move onto the next measure?

NATIONAL QUALITY FORUM Moderator: Dr. Reva Winkler 11-17-11/2:00 pm CT Confirmation # 4679691 Page 43

Mary Leslie: Reva, this is Mary.

Dr. Reva Winkler: Yes. Oh hi Mary. Great, glad you could join us.

Mary Leslie: Hi. I just wanted to say I have been here since 3 o'clock. They had trouble getting me off mute.

Dr. Reva Winkler: Oh dear. I'm sorry. Well welcome.

Mary Leslie: That's okay. Well it's just...

Dr. Reva Winkler: Glad you're here.

Mary Leslie: Yes. No and actually...

Dr. Reva Winkler: Great, thank you.

Mary Leslie: ...I just wanted to agree with this measure. And I actually agree with what Carol brought up.

And I just - I guess stratification is not the answer, but I'm concerned that the practice is very, as
everybody knows, high in (primis) and I just wonder if there's not a way for the measure to
somehow target that but I don't have an answer for that.

Dr. Reva Winkler: Okay, all right, great. Thanks for joining us and joining the conversation.

Anything else before we move on?

Confirmation # 4679691 Page 44

Okay, so the next measure we have is measure 472. And that is - somehow I've gotten myself -

okay, that is appropriate prophylactic antibiotics received within one hour prior to surgical incision

or at the time of delivery for a cesarean section.

And this measure is Carol. This is yours.

Carol Sakala: Okay. So the aim is to reduce the incidence of infection after cesarean by using antibiotics.

And since we have well over 1 million women with this procedure annually and a high infection

rate it is almost - we almost all agree that it was high or yes for importance.

But Mary, did you want to make a comment about your no rating?

Mary Leslie: Yes, hang on. I would like to be able to see my - what I said. But I think my comment had to

do with - and firstly, I should admit that I'm new to this process so.

Hang on. I think it had to do with the evidence.

Down a little bit.

Carol Sakala: So for the scientific acceptability we all said high.

Mary Leslie: Okay, just a couple more.

Carol Sakala: There, yes. So would you like to pop back in after you take a look at your ...?

Mary Leslie: Sure. Go ahead. That'd be great.

11-17-11/2:00 pm CT Confirmation # 4679691

Page 45

Carol Sakala: Yes, okay. So on scientific acceptability I think the specifications are clear. I felt that the

exclusions were appropriate. And we all agreed about this.

But I have to say that several of us made comments about uncertain implications to the baby. So

I think that those high ratings were with respect to the maternal benefits and harm data and this is

the one area of concern that I had with this measure. I wanted greater confidence about the

timing component.

And I did find two recent meta-analyses that showed less maternal infection with pre-incision

administration versus post-clamping. And no differences in short term newborn outcomes.

However I am concerned about possible unintended longer term consequences of fetal exposure

at these high rates to antibiotics in this sensitive period and both cesarean section and exposure

to peripartum antibiotics have been associated with colonization of the newborn gut with

undesirable bacteria.

And unlike in older people the risk has been shown to be stable over a long period of time. And

possibly is a mechanism for various child chronic diseases. And I've looked at articles written

about gene activation and immune function and metabolic programming and so forth showing

mounting evidence.

But at the conference, 2010 Update Review on Antibiotics Prophylaxis underscores we're really

missing the newborn data regarding these questions.

So one way to raise this measure is high for certainty about maternal benefits and harm and low

about newborn benefits and harm and a post-planting administration would be the cautious thing

to do for newborns but of course less beneficial for women.

11-17-11/2:00 pm CT Confirmation # 4679691

Page 46

So if we go forward and recommend this I think we need to do so with recognition about this

uncertainty and the potential for unintended consequences.

And I don't have any good answers or recommendation except I would say that a partial answer

is the cesarean measure which would help us avoid this dilemma in many cases by eliminating

avoidable cesarean.

And I imagine some of you have comments about this.

Kim Gregory: This is Kim. I think you raise excellent points. I just want to bring up two thoughts. And one

is that just having a C-section is confounding to the baby. There's some European data that says,

you know, being born by C-section changes your immunologic profile to begin with.

So you're right that the antibiotics may further compound that but you'll never know the cause and

effect.

And the second point is that if we put the caveat - we know that it's better to do it before the skin

incision so we - if we were to theoretically push it back to with cord (clamping) then you'd actually

want to show benefit because if there's no benefit then you shouldn't do it then either.

So I think this is one of those ones where the horse is out of the barn because it makes common

sense and we may not be able to put the horse back in the barn.

Dr. Reva Winkler: Okay, and any other thoughts?

Dr. Bill Grobman: Can I just have - this is Bill. Can I just have a question about sort of - not about the

measure it self. I mean I agree actually with everything that's been said so far.

> Confirmation # 4679691 Page 47

But I have just a question about the sort of reliability and the ability to code this well.

Jennifer and I were involved in a project where we were kind of looking at some of this stuff. And

it is just a total bear to figure out when the C - when the antibiotics were administered.

Female: Yes.

Dr. Bill Grobman: You know you can - you have EMRs and you can know when they were ordered and

which is good if you even have that.

But like how - it just seems like this must be missing an unbelievable amount of time. How is this

reliably obtained on a large scale I guess is my question.

Kim Gregory: This is Kim.

Female: Yes.

Kim Gregory: You do it on the anesthesia record and you make the anesthesiologist accountable and

that's how they were able to do it for the shift measures.

And you can believe anything they can do for Med-Surg, they can do for OB. You just have to

have Med-Surg do it first.

Kate Chenok: Yes, but this is Kate. And actually it actually is a real struggle even in orthopedic surgery.

It's really hard for us to get them to collect anything other than that it was given.

But in terms of the time it was started and the time it was stopped, it's very difficult.

Page 48

Dr. Bill Grobman: Boy I know. I just - I mean is this realistic that we are going to be able to cross the

country to believe this is going to be able to reliably done, not as part of a QI specific but that we

really entering accurate data.

Female: Well you know it's a skip measure so I mean people have...

Kim Gregory: It's a skip measure and it has been done. I'm telling you.

Female: They need to do it. That doesn't mean it's reliable. But it's...

Dr. Bill Grobman: Yes, so...

Female: ...definitely something - it's a real issue because of the systems that collect it typically don't

integrate with other systems so it gets kept in different, little different bins within any hospital.

Dr. Bill Grobman: You're right. Right, so I guess that's my question. I mean we say it's a skip measure

and it's being done. But at the same time we say but it has this inherent unreliability. Do we then -

and I completely support it like scientifically, not really asking more about process, if we believe in

our gut that its not being done reliably does that make us pause and again asking it rhetorically

not knowing the answer in regard to whether or not - how strongly we endorse it.

Female: Yes.

Carol Sakala: And so I think you've all really raised good points. And I had the same reaction to this

when I read it. I thought oh it makes sense. You know the science is fine, signed it. Concern

about the baby but then my whole question was is just thinking through how you get that data. I

just kept...

Page 49

Dr. Bill Grobman: Terrible.

Carol Sakala: ...coming up against all these (blocky) systems to really get accurate data on this one.

Female: Well I think what you really want - I'm sorry.

Kim Gregory: It's going to - I mean it's - this is - the skip measures are tied into hospital performance

measures and it's that 1.5% margin on the profit line.

And I'm going to tell you the way we got it is our Vice President's incentive bonus was tied to it

and so it had...

Donna Frye: Hey this is Donna Frye with HCA. I'm sitting in for Dr. Clark today. And with our 112 facilities

over the last couple of years the facilities are reporting, you know, this is an easy measure. They

get it right about 95%, 98% of the time.

Kim Gregory: Yes, that's where we are. I mean look, every single variance, I'm telling you that the Chair

of Anesthesiology sits in front of the Vice President and tells them why that did not happen.

I know. I think because that opportunity cost but that's...

Male: It's hilarious.

Kim Gregory: That's how it happened.

Dr. Reva Winkler: Okay. Carol, anything else on this measure?

Confirmation # 4679691

Page 50

Carol Sakala: Well we did move into usability and feasibility. We were very high in general on usability

and I now understand Bill's rating of low because the other ones were high for feasibility. And the

initial response was for all but Bill's to suggest that this goes forward although I would say that my

guess is there was a lot of ambivalence because of the uncertainty issue.

But hard to not, you know, have some others avoid infection. It's just a really tough two patient

problem here.

Kim Gregory: You know I was going to say two more things too. You know with the CDC recently putting

out this SSI quality measure, I think that we're going to end up getting a lot better data and

evidence to support some of this probably totally coincidentally.

But I think that, you know, that measure is going to actually really help support this which leads

me to my second point and that's an issue of exclusion or you were supposed to have gotten the

antibiotics within an hour and really it should be less than that but within an hour of the incision.

And they're saying it's okay if you're being covered for (correo) then it doesn't matter and you

don't have to have gotten it within the hour.

But if you were on GBS prophylaxis then you still needed the correct surgical prophylaxis.

And I think that that's going to - that actually is going to be an opportunity for misclassification.

And I just wanted to...

Female: I agree.

Male: I agree.

> Confirmation # 4679691 Page 51

Kim Gregory: So on the whole we're not excluding it but we're not jumping up and down about it.

Dr. Reva Winkler: Okay, all right, anything else about that measure before we move onto the next one?

Mary Leslie: This is Mary. I was just going to say, if that says no for me that's a mistake because that's

not one I had a problem with.

Dr. Reva Winkler: Okay.

Mary Leslie: Okay.

Dr. Reva Winkler: All right, so let's move onto the next one which is 473, appropriate DVT prophylaxis in

women undergoing cesarean delivery. This is from HCA.

And Bill I think this is your measure to lead.

Dr. Bill Grobman: Yes, great. You know I'll be sort of brief and summarize and then people can weigh-in.

I mean the bottom line is I think this is a - I think it's a good measure for several reasons.

I think first and foremost ACOG actually now has a - which they didn't before but now has a

explicit statement recommending this approach. And so before that I think it would have been

very hard to kind of tell everyone perhaps that they need to be doing it.

But now that's sort of explicit. I would agree that the evidence is sort of - I think it's kind of - it's

consistent that DVT prophylaxis in general lowers the chance of DVT. It is not very well studied in

the obstetric population specifically and so sort of the quality of the evidence is relatively low.

11-17-11/2:00 pm CT Confirmation # 4679691

Page 52

But, you know, it is a - it's an important health outcome. It is relatively infrequent in the schema

things but when it does happen it has potential to be mortal.

And it is to a large extent preventable by application of these boots. It should be relatively easily

measurable particularly in an EMR situation. And, you know, I think there's a high upside because

not many - it's not widespread at this time or I think we don't even know how widespread it is.

So I supported it. Other people can weigh-in.

Kim Gregory: All right, I'll jump in. Kim. I think that moderate at best and in many cases low, one because

it is low prevalence although it's high morbidity if it happens to you.

While the intervention in and of itself is relatively benign the way we've actually set it up it's to

define the use of intra-op use of SCD but, you know, greater than two-thirds of the events happen

postoperatively.

And there's no mechanism to support or even endorse if they continue wearing them.

Male: Oh.

Kim Gregory: I mean not in this documentation that we provided...

Dr. Bill Grobman: So I would - no. I would say a couple things. I mean one I would say I agree that the

events are postoperative. But I think many people would say that they drive from intraoperative

like many other things from intraoperative events and they just manifest postoperatively.

I think what you bring up is a really good point. And this is just sort of a tradeoff between, you

know, we just spoke about appropriate antibiotics and that's to prevent maternal infection which is

> Confirmation # 4679691 Page 53

a high prevalence but relatively in the scheme of things for any given event low morbidity event

versus this...

Kim Gregory: I agree.

Dr. Bill Grobman: ...which is a counter. A low prevalence but very - you know high morbidity.

And so it just sort of depends how we look at this. If you look at Steve Clark's HCA data and I

think this is probably why it's coming from, I meant their number one preventable in their series of

maternal deaths, they thought the biggest impact they could make was a DVT prophylaxis.

Now that's a relatively small impact because if maternal deaths are about 10 per 100,000 in a

general pop - in this country's general population, about 2 or 3 of those are from DVTs. And so if

we cut that by a half or two-thirds we've knocked out, you know, 1 to 2 per 100,000. It's really

good not to have a maternal death but it's obviously not a highly frequent event.

So that's - I thought I was more focused on the magnitude of the morbidity as opposed to the

frequency of the morbidity. And I think Kim has annunciated why someone would take a counter

argument.

Kim Gregory: And I do - but I agree with you 100%. And I guess my only other question. This is a point of

clarification perhaps for the measure developer but on page 5, the denominator. I'm a little and

I'm sure I just misunderstood.

You get credit if you use SCDs or heparin derivatives. But then in the denominator you take all

your heparin derivatives out.

And I just thought, I mean I'm not clear on that. Help me.

NATIONAL QUALITY FORUM Moderator: Dr. Reva Winkler 11-17-11/2:00 pm CT Confirmation # 4679691 Page 54

Dr. Bill Grobman: I was a little confused by that at first too. And I convinced myself it made sense but I'm not sure I could - can rephrase that convincing and I actually think it would just be easier to say why take those people out. They're going to get...

Female: Right.

Dr. Bill Grobman: It's more of a pain to take them out.

Kim Gregory: Right.

Dr. Bill Grobman: Than it is just to leave them in because they're on the darn thing anyway.

Kim Gregory: And you're getting credit for it.

Dr. Bill Grobman: You're getting credit for it, right.

Kim Gregory: And then that makes it a real rate instead of a ratio.

Female: Right.

Dr. Bill Grobman: Yes. I totally agree with that. It's more of a pain to take them out. I think you should just include every one.

Kim Gregory: And then I think that when it goes to the reliability and the feasibility some of the same issues we raised with the last measure. I mean you're going to have to create a way to track this.

Page 55

Jennifer Bailit: And this is Jennifer. I guess my issue with this and I don't know what happens at other

people's hospitals. But we do, you know, do (put them) on during the section. And then the

patient has them on in bed or they take them off or they're not being blown up.

Or, you know, it's so hard to measure what they actually do. Yes, there's an order on the chart.

Yes, the patient has access to comp boots outside of the OR.

But they so rarely get used consistently because patients find them uncomfortable. So it's hard to

know what full implementation of this is really going to do.

Dr. Bill Grobman: But I think but this is only about intraoperative. I mean I think if we...

Jennifer Bailit: But the duration is the hospitalization. It doesn't say intra-op that I could find.

Kim Gregory: Well the measure actually says...

Female: Prior surg.

Kim Gregory: page 5, prior to surgery. And that's...

Dr. Bill Grobman: Right.

Kim Gregory: ...the only mention...

Dr. Bill Grobman: I mean this is...

Kim Gregory: ...who had pneumatic compression devices placed preoperatively. So that's...

NATIONAL QUALITY FORUM Moderator: Dr. Reva Winkler 11-17-11/2:00 pm CT Confirmation # 4679691 Page 56

Dr. Bill Grobman: Yes.

Kim Gregory: ...really the only mention of...

Jennifer Bailit: Yes, okay.

Kim Gregory: ...how it's being used.

Dr. Bill Grobman: I mean I think is sort of effectiveness versus efficacy, you know. And it's like I mean I think this is first off, none of this is OB data, right. It's all leveraged essentially. It's not from Steve Clark's data. It's all leveraged from gynecology. It's not other special (features).

Kim Gregory: Well and the England. I mean, right, I mean the Royal College data and that...

Dr. Bill Grobman: Yes. Well yes.

Jennifer Bailit: But nobody's got data saying we put them on in surgery and then we took them off the rest of the time.

Dr. Bill Grobman: Right.

Jennifer Bailit: And therefore that just in surgery is good enough.

Dr. Bill Grobman: Right. But I think I guess what I mean to say is the - this mimics, this would be true for gynecologic or other operations as well which is...

Female: Fair enough.

> Confirmation # 4679691 Page 57

Dr. Bill Grobman: ...you know for sure you have them on during surgery. You're not exactly sure when

they - how well they're used afterward. But pretty consistently, I mean it would be hard to find a

properly powered study that doesn't show that these reduce by about half the chance of DVT

however pragmatically they're used, you know.

Jennifer Bailit: ((inaudible)) yes.

Kim Gregory: But the difference is they don't have the added, you know, increase risk of being recently

postpartum.

So I guess I think that we're probably going to come down on moderate and not - and, you know,

perhaps continue to endorse it.

But I really want to say very strongly that I think that there's no reason why there can't be a

randomized control trial, you know, that exactly decides what - how this should be done instead of

taking the default that it's impossible to do because we've already proved that it works.

Dr. Bill Grobman: I completely agree with Kim, like definitely the quality of the data could be much higher.

I have nothing. I wouldn't say anything else actually.

Female: I have a question. And that's on page 6. And the surgeons may be able to answer this question.

All of a sudden the score is all patients undergoing cesarean who received PCDs. It doesn't even

mention heparin.

Dr. Bill Grobman: Let's see, page 6.

Female: Yes, under 2(a)(1.20) calculation algorithm, the measure logic.

Page 58

And throughout the rest of the document heparin isn't even mentioned. It's only the compression

devices that are mentioned.

So I got confused.

Kim Gregory: So when they say not receiving medical prophylaxis, they've done something weird with

this heparin that I don't quite understand.

Dr. Bill Grobman: Yes.

Female: Yes, I don't get it either.

Dr. Bill Grobman: Yes, that's definitely a little fuzzy. And I think that could - if the measure developers, I

don't know if they're on the call, but I guess our advice to them would be just to make it all

patients undergoing cesarean who receive PCDs or medical prophylaxis.

Female: Correct.

Dr. Bill Grobman: Over all patients undergoing cesarean.

Kim Gregory: Agree.

Female: Yes.

Dr. Bill Grobman: It's easier. It's less complicated. It's more straightforward to understand.

Female: I...

> Confirmation # 4679691 Page 59

Jennifer Bailit: I would like to take out the heparin completely. This is Jennifer. I don't want people getting

the idea that heparin increase C-section is appropriate.

Dr. Bill Grobman: Right but Jennifer what if someone's on heparin already then it's total redundant to put

them on ...?

Jennifer Bailit: Yes. But that's just a small number of people. And honestly if I've got somebody with

thrombophilia and I'm going to stop their heparin around the time of surgery, I'm darn well going

to put on boots.

Dr. Bill Grobman: Well, you know, it's legitimate to and actually I mean it's legitimate to give people

perioperative prophylactic medical prophylaxis. And in fact if you look at the American Chest

Physicians they actually recommend pharmacologic prophylaxis for some high risk people.

So I don't - I think we should...

Jennifer Bailit: Okay.

Dr. Bill Grobman: ...allow that possibility.

Jennifer Bailit: In replacement of as opposed to in addition to. I'm not saying don't give - you see what I'm

saying?

Dr. Bill Grobman: Correct.

Jennifer Bailit: I'm saying that even those people you're going to want to put the boots on anyway.

11-17-11/2:00 pm CT Confirmation # 4679691

Page 60

Dr. Bill Grobman: Oh I don't know that that's - no I think if - wait, are you saying that if you have someone

who's getting medical prophylaxis they require boots as well?

Jennifer Bailit: I'm saying if you've got somebody who's high enough risk that you're going to heparinize

them right before surgery, you're probably going to put boots on too.

Dr. Bill Grobman: I don't know that everyone would.

Jennifer Bailit: Okay.

Dr. Bill Grobman: I mean other people should weigh-in.

Charles Denk: Yes. I mean I agree with that. And I can't really think of many instances where you would

be actively medically prophylaxing somebody at the time. I mean I agree with Jennifer. I think

even if you've got - even if you've prophylax somebody all the way through the pregnancy you're

going to stop at 12 hours ahead of time.

Dr. Bill Grobman: No, not necessarily. You can give just like in gynecological orthopedic surgery you can

give a legitimate alternative is to give medical prophylactic heparin and there's some rare people

though I agree with Jennifer, very rare people who would require - people with a recent DVT or

recent PE who you would continue low level heparin even throughout a surgery conceivably.

So I mean I think the bottom line is if they're on that already, we're not demanding that they go on

it. But if they're on it already why would we make them put people on compression boots too?

That's a resource waste.

Charles Denk: Well I mean I...

Confirmation # 4679691 Page 61

Jennifer Bailit: You're talking about (cancels)... I mean (cancels)...

Charles Denk: Yes. I mean I think if I, you know, most hospitals have a policy where all C-sections get

SCD.

And so if you've got somebody even that high risk that you're getting medical you're probably

going to put the SCDs on them anyway.

Dr. Bill Grobman: Yes I would - actually I would say - I would disagree with that. I would say if they're

getting medical prophylaxis SCDs are redundant. If anything people would say that the medical

prophylaxis is better than the SCDs.

And that would be discordant with recommendations that exist in a - in the - like we can go back

to the American Chest Physicians' recommendations.

And this is an argument over little, extremely small number of people.

Male: Right.

Jennifer Bailit: Well it's little numbers of people but it's huge amounts of time and effort to try to collect

that data and take them out.

Dr. Bill Grobman: I agree. So I would just say that if there - that there's no - I completely agree. That's

why I don't think we should take them out. But I don't think we should ding people who haven't

put boots on these people who...

Jennifer Bailit: Right. But if you're not going to ding them then you have to collect the data on who they

are, you see what I'm saying?

Confirmation # 4679691 Page 62

So I have to assume you're going to get boots on everybody and just give you a wash on the

three people you might heparinize before a section rather than try to have to pick out who those

people are. Look at all the people who didn't get comp boots and look for that complication by

hand in their chart.

Dr. Bill Grobman: Then it - well right. Then it's up to the group about feasibility. I mean then it becomes a

feasibility not a - then we're just basically saying it's not feasible.

Jennifer Bailit: It won't be zero but...

Dr. Bill Grobman: Or it's not worth it. And it's not going to be zero or like what - then I would just leave it

up to the group to decide what - whether it's so infeasible that it's not worth to...

Female: I honestly don't think it's infeasible anymore than the collecting the data on the antibiotic

administration. If you can search the chart, if you search the record for compression boots and if

you can search it for heparin, that's the point.

Jennifer Bailit: You can but I'd much rather as a hospital system or any of these other things adopt

measures that I don't have to spend, you know, 14 bucks an hour having somebody go through

charts.

Donna Frye: Again this is Donna with HCA and we have been collecting this for the - probably the last

three years.

And again the facilities are reporting a 95% to 100% compliance rate with this.

And as we're moving forward with our EHRs this is certainly a report that we can generate.

> Confirmation # 4679691 Page 63

Female: But my point is this, it's that the description of the measures, the numerator statement on page 1

which is 2(a)(1.1) and the calculation of the algorithm on page 6 are not the same. That's the

problem.

And while it may not represent a lot of people, I think from a scientific standpoint that lack of

consistency from my way of thinking is problematic.

Kim Gregory: I agree.

Dr. Bill Grobman: I agree.

Kim Gregory: But easy to fix.

Female: Right.

Dr. Reva Winkler: And this is Reva. I would just say to the measure developer, you just take a look and

review that and see that perhaps it isn't as clear as you intended it to be. We'll be happy to work

with you too to revise it so that the form reflects consistency.

Donna Frye: Certainly we'll do that. Dr. Clark was flying today so he was unable to join the call. So we'll

get the information to him and see what we can do to remedy the inconsistency.

Dr. Reva Winkler: Thanks. Okay, anything more on that measure, 473, any other issues, any other

questions, any other clarification?

Okay, so then we have one more measure left. And we started talking a little bit about that earlier

and that is measure 474. That's the first trauma measure.

Confirmation # 4679691

Page 64

This is a measure from the Agency for Healthcare Research and Quality. It's PSI Number 17, first

trauma injury to the neonate. It is an outcome measure.

And Chuck Denk I think you were the leader for this one.

Charles Denk: That's right. Thank you. Yes, we did start talking about it. But let me go back to the very

beginning because there's a problem or two in the presentation which is a bit - makes it a bit

confusing.

PSI 17 is part of a program that AHRQ promotes at the state level. They - we use hospital

discharge data. New Jersey is one of the ones that actually publishes the results for all hospitals

and, you know, it's a very complicated algorithm and computer programs provide it for everybody.

The numerator is all first injuries and they give ICD-9 codes which they're drawn directly from

these electronic records.

Numerator and denominator both exclude brachial plexus injuries explicitly. So that's a sort of a

set aside, not to be attended to.

And there's one source of confusion right there because the importance, all of the evidence

offered for importance actually focuses on shoulder dystocia as a major contribution to neonatal

injury.

And so there's - it seems like a complete disconnect. I'm not the only person who noted that in

the spreadsheet.

Confirmation # 4679691 Page 65

And there is quite a bit of heterogeneity in the way people scored the importance measure and

the improvement - the room for improvement. And I think that was probably part of it.

It's also true that if you - whether you exclude that or not you get low rates. And there's an

interesting comment on page 2 provided by AHRQ in the summary of evidence of high impact

(1a.3) that said one study that used multivariable matching in the 2000 whatever file, did not

attribute significant excess length of stay charges or mortality to this quality indicator.

So I mean even the developer seems to be discussing that it's not a high impact measure, it has

low rates.

Dr. Reva Winkler: Right.

Charles Denk: I also noticed in both Section 1 and later on in evidence presented for I think it - well it was

either reliability or validity that a lot of the empirical evidence from previous collection of this data

shows that there are disparities but in the opposite direction from the way that we usually look for

disparities. This is a public health bias that I have.

But, you know, a disparity that says that there is a poorer outcome for, you know, lower (SCS)

groups is what we look for and try to ameliorate. I know we had a case of that earlier where it was

the opposite and people were interested in that too.

But there are a number of situations in which, you know, its suburban hospitals, non-teaching

hospitals, higher income brackets that have higher rates of these injuries and that's like I said just

not what - that's not - doesn't make it a public health priority.

There - other people have comments too and I would like to invite them to join in. I just want to

say one more thing before we move on and that is under the evidence thing even though it was a

> Confirmation # 4679691 Page 66

health outcome and so I guess we weren't really supposed to rate the quality and quantity of

evidence.

Half of the people rated it as low and still scored the criteria 1(c) for the quality of evidence as

yes, consistent with endorsing the measure.

So I would - I don't know exactly how to characterize all of this except as extreme ambivalence.

So I think I want to just stop here and let other people speak their mind.

Kate Chenok: This is Kate. And I agree with what you said especially with the fact that the evidence that

was presented conflicted with all about the shoulder and brachial plexus injuries and that if you

read the premier article that was cited, it also just kind of raised a whole bunch of other

discussion.

So I would say that I must have incorrectly rated 1(c) as a yes because overall I did not feel that

this met the criteria.

Charles Denk: Okay, others.

Dr. Bill Grobman: This is Bill. I agree completely with what's been said. It doesn't - it's low impact. The

justification doesn't support its use. And its even hard to understand when you get the measure

how to do quality control around it because it's such a grab bag of things.

Kim Gregory: This is Kim. And I echo some of that. I've actually always struggled with why they took

brachial plexus injury out because as a mother, as a patient centered outcome that's something

that they really are, you know, affected by and care about.

> Confirmation # 4679691 Page 67

And it would actually probably contribute to there being more variation around the number.

But the other issue that I had with this is the other specified birth trauma. It - we actually do report

this when - through UAC. And it's kind of interesting. The two things that I've learned though is

one, that frequently misclassification based on genetic syndromes that the coder doesn't know

that that's genetic. And the other thing is how many actual injuries happen at C-section that we

don't really know.

I was - I found that intriguing. But the only reason why we know that now is because we've taken

out shoulder dystocia which is the more common birth trauma.

So overall I was pretty underwhelmed. And I just don't know what interventions we could do to

truly make an impact on such sporadic events.

Jennifer Bailit: This is Jennifer. Oh sorry.

Kim Gregory: I'm sorry. Oh and the other thing is that the last time I saw this measure though they did

stratify it by operative vaginal versus not. And I didn't see that this time.

Charles Denk: Jennifer?

Jennifer Bailit: Yes. And I'm just getting a little nervous that this is changed, not that I missed something.

But when I've done this measure in the past looking at data it's been dominated by laceration at

cesarean which is typically very mild and very minor.

So I'm just not convinced this is an important outcome to look at. And then Kim's last comment

made me wonder if they had taken out cesarean delivery here but I was still checking.

NATIONAL QUALITY FORUM Moderator: Dr. Reva Winkler 11-17-11/2:00 pm CT Confirmation # 4679691 Page 68

Kim Gregory: No. They haven't. But...

Jennifer Bailit: Okay.

Kim Gregory: ...some of the (conceptual) human - not the (separate lima tone) but some of the

intracranial bleeds would have been related to four sets of vacuums and so there seems to be a...

Jennifer Bailit: Correct.

Kim Gregory: ...stratification that, as I recall that's not here anymore.

And what we actually found is that most of the misclassification was due to poor documentation

and so if you improve your documentation your injury rate goes down, you know.

Mary Leslie: This is Mary. And I echo most of what's been said. I had the same confusion.

But I guess are the developers present?

Dr. Reva Winkler: Is anybody from ...?

(John Bott): Just myself, (John Bott) from AHRQ.

Mary Leslie: I just - I guess my question is since we all have kind of the same question, was - what

confuses me is why the rhetoric for the measure is written up being primarily about should

dystocia and the evidence is almost all about shoulder dystocia.

(John Bott): Yes.

> Confirmation # 4679691 Page 69

Mary Leslie: What was the intent of the measure?

(John Bott): So this measure goes back quite a ways. And the folks who could really best address these

questions are (Jeff Gephardt) and Dr. (Petroramono) who will be there at the November 29th

meeting when this is discussed.

So I'm sorry. I can't answer a lot of these.

Mary Leslie: That's okay.

(John Bott): Rather historic technical questions about the measure. I'm largely here to make sure I get

down the questions to pass along to them so they can be adequately prepared with these

questions.

I'm sorry I can't necessarily respond to those questions.

I - one thing I do know is we tend to size the evidence for and against the measure. We're not just

citing evidence that supports the measure. We're trying to be balanced. And if we find evidence

that calls it into question we'd like to cite that as well. That just seems fair.

Mary Leslie: Thank you. That's great, thank you.

Charles Denk: I'd like to go back and reinforce one issue about importance which is room for

improvement. The should dystocia, I mean there was a little bit of an argument about how most of

these injuries are highly unpredictable and therefore hard to prevent.

I - it was my impression that a lot of these injuries are associated with use of forceps.

11-17-11/2:00 pm CT Confirmation # 4679691

Page 70

And so here again I just want to share something about what life is like over here in New Jersey

at one extreme end of the obstetrical practice continuum.

And say that over the past decade or so the use of forceps and other operative techniques in

vaginal delivery has declined by more than 50% and the C-section rate has increased by more

than 50%. You know we're talking about like 10,000 extra C-section deliveries in a, you know, in

an eight year span.

And that was the impression that I got was that the easiest way to avoid forceps related injuries

was to do a section.

And somewhere there's a criteria that says what about the unintended consequences of the

measure?

And you may find it hard to believe. But, you know, I talked to New Jersey physicians,

obstetricians. I talk to them a lot and they use logic like this. I want to avoid the kind of things I'm

going to get sued for. I want to avoid the kind of things that are going to, you know, make mothers

really mad at me.

So I just wanted to add that as a, you know, two sort of dimensions to the importance issue.

Moving on, scientific was also kind of desperate measures. The scientific accuracy and the

usability also got a lot of low rating from various people.

So and the other, I'm sorry, the other implication of what I was saying before is that I was

surprised that it wasn't stratified by method of delivery and was - think, you know, especially

considering the ratings that it got that either that needs to be reintroduced or it needs to be

focused only on vaginal deliveries or something.

Page 71

That's my summary. I'm sticking to it.

Dr. Reva Winkler: Okay. Any other comments or questions from the rest of the group, any other

questions, concerns you'd like (John) to take note of to ask (Jeff) and (Patrick)?

Okay, well it looks like this group has done a - the only task of getting through all six measures.

Now I - since we do have a couple of minutes, I want to be sure was it - did we move too fast

through any of the measures? Was there anything somebody thought about they wanted to go

back to?

Okay, probably tired at the end of the day. And I again I thank you all for all of your discussion.

These are - just been fantastic discussions. This is going to be a phenomenal Steering

Committee Meeting because this is the fourth one of these discussions where these kinds of very

enthusiastic, very, you know, in-depth discussions from obviously from very knowledgeable

people.

And for all of us it's incredibly fun. So we really are looking forward to it.

So let me just tell you what we're going to do next step. I guess first off, are there are any

questions from anybody, logistic wise or anything?

Okay, what you're going to hear from us in the next couple of days probably some tomorrow and

some next Monday or Tuesday are we're going to be gathering the meeting materials together for

the November 29th and 30th meeting.

There will be a couple of additional briefing memos. There are some additional issues beyond the

evaluation of the measures. In this particular group you did not have issues of very similar related

11-17-11/2:00 pm CT Confirmation # 4679691

Page 72

measures however Work Group 3, that's what they were looking at were a lot of measures

around hospital acquired infections.

And so we're going to need to do a second (pass) of the measures to look at do we really need all

of them in the endorsed set.

So and then the last - and then additionally there is a composite measure that is the Adverse

Outcomes Index measure which it has ten components.

And because it's sort of a Work Group all to itself and we were somewhat late getting the

information in from a developer we didn't assign it with one of the Work Groups.

So it will be - there will be assignments made to look at the composite measure. And we've

carved out a section of the morning on the second day to spend sometime about, you know, how

to evaluate composites and the kinds of - how to apply the criteria to composite measures.

So we're going to be sending you some additional briefing materials. So that's what we're kind of

(busily) doing for you.

If any of you wish to change any of the ratings that you've included before after the discussion, if

you'd like to go back in and put your name and put a number 2 on it, we'll know it's a revised

rating. We'll replace any new ones over your old one.

What we're going to do with these ratings is we're creating slides with the summary of both your

ratings and the discussion points. We'll send you a copy of these slides. Hopefully that will help

the lead discussant in your presentation at the meeting.

11-17-11/2:00 pm CT Confirmation # 4679691

Page 73

And we'll also be projecting them at the meeting so that the entire committee can, you know, can

take a look at where the Work Group discuss everything. And use that as a starting point.

We do have a fairly tight agenda to get through all of these measures so we really want to spend

our time efficiently and focus on the measures - the issues around the measures that where

there's some concern or some disagreement and not spend a lot of time on things that everybody

feels very comfortable with.

So that's sort of our plan. You should be getting logistic information from our Meetings

Department. You know they told us they were sending it out by the end of this week. So you

should hear from that - hear from them. If you don't feel free to get in touch with Suzanne or

myself. And we'll try and, you know, mediate or try and figure out to get the information to you.

I guess at this point I'd like to know if there's anything we can do in the staff to assist you in

further preparation for the meeting in two weeks.

Charles Denk: Well I have a question. This is Chuck.

Dr. Reva Winkler: Okay.

Charles Denk: Are we going to continue to be sort of owners of these things as individuals, you know,

presenters or is there a different format for the next meeting?

Dr. Reva Winkler: No, it's going to be very similar. This way, you know, we don't ask you to hop from

measure to measure.

Page 74

So you will maintain your assignments for the measures. Hopefully that will make you more

comfortable with the issues around that measure and presenting it and it's a way of spreading it

around the committee and everybody shares in the discussion.

Charles Denk: Okay.

Dr. Reva Winkler: Okay. Any other question from anybody?

Rob Watson: Reva, this is Rob. What's typically the attire in these meetings?

Dr. Reva Winkler: You know any...

Rob Watson: I mean is it coat and tie or is it more casual?

Dr. Reva Winkler: No. You don't need to - no, no. This is casual.

Male: Shorts and t-shirts.

Rob Watson: Yes.

Dr. Reva Winkler: Yes well, right. Remember you are on - you will be eating Downtown DC however right

across the street, kitty corner from us is Occupied DC. So we're in an interesting environment

right now.

But most folks attending our meetings, it's usually a business casual kind of thing.

Rob Watson: Okay, okay, very good.

NATIONAL QUALITY FORUM Moderator: Dr. Reva Winkler 11-17-11/2:00 pm CT Confirmation # 4679691 Page 75

Dr. Reva Winkler: Okay, just before we close I'd like to ask the Operator to open all the lines to see if

anyone who might have been listening in on today's call had any questions or comments in the

form of public comment. We do this on all of our calls and meetings.

(Karina)?

Operator: Thank you. And I'll go ahead and open everyone's line. And everyone does have an open line

at this time.

Dr. Reva Winkler: Great. Are there any questions from anybody who might have been listening in, any

comments?

All right, hearing none. I think our business for today is concluded. And I thank everybody very,

very much. We look forward to seeing you on November 29th and 30th.

In the meantime don't hesitate to get in touch with us if you have any questions or concerns.

And everybody please have a very pleasant holiday.

Male: Thank you.

Male: Thank you.

Female: Thanks all.

Male: Bye.

END