

## **NATIONAL QUALITY FORUM**

**Moderator: Reva Winkler  
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2:00 pm CT**

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

Reva Winkler: Good afternoon everybody. This is Reva Winkler at National Quality Forum. Here with me are Suzanne Theberge and Gene Cunningham from the Project Team.

Thank you all for joining us for this conference call Workgroup Number 3.

We did Workgroup Number 2 earlier today, so it's a busy day. But we've had great and productive Workgroup calls by the first two Workgroups so I expect this one to be equally so.

So just to let you know what our plan for the day is, four of you have reviewed all of the measures and submitted ratings and provided sort of a preliminary sense of how you're thinking the measures meet the criteria. That was sent to you earlier this morning and we're going to use that as sort of a starting place for our discussion.

What we're looking to do today is find out the issues or concerns about these measures, if there are any questions or clarifications needed or any responses from the developers that will kind of clear up anything, or respond to anything prior to the in-person meeting so that we're pretty much

got the issues on the table and everybody knows what the discussion points are as we go into the meeting.

So today what we're going to do is talk about six measures, the main materials for the call are the Measure Submission forms. Whether - however you want to access them is up to you; whether you're printing them out and looking at them, whether you're looking at it on our computer, or we do have them displayed on the webinar but you don't have as much control over what's viewed that way -- so whatever works for you is fine.

In terms of the initial submissions, we did get some preliminary reviews from four of you. And I would ask that the folks who have yet to review the measures, if you're able to complete those in the next couple of days that would be very helpful so that we can give a full accounting when the Steering Committee meets.

So just to start us off, I'd like the Workgroup members to briefly introduce themselves and we'll go through the list. Scott can you just introduce yourself and say a couple of words?

Scott Berns: Sure, hi everyone I'm Scott Berns, I'm Senior Vice President of Chapter Programs at the March of Dimes National Office. I'm a Pediatrician and Pediatric Emergency Physician by training and I'm Clinical Professor of Pediatrics at Brown University.

Reva Winkler: Super, thanks so much. Elizabeth Drye? Liz?

Elizabeth Drye: Hi, this is Elizabeth Drye; I am at Yale School of Medicine at the Center for Outcomes Research and Evaluation. And I'm a Pediatrician by training, but I've been spending most of the last five years developing quality measures specifically outcome measures focused on hospital quality.

And although we've moved many of our measures to the ((inaudible)) this is my first time being on a committee reviewing measures. So I'm really excited to participate both because of pediatrics and I really appreciate all the work that NQF has done in reviewing our measures and wanted to contribute as well.

Reva Winkler: Thanks Elizabeth. Rebekah?

Rebekah Gee: Hi everyone, I'm Rebekah Gee. I'm an Obstetrician Gynecologist by training. I work for both Louisiana State University in the Schools of Public Health and Medicine as well as Directing a Birth Outcomes Initiative for the State of Louisiana with the goals of decreasing prematurity, infant mortality and poor maternal outcomes.

I've spent a great part of the last year looking at quality metrics for our own reporting and report card and benchmarking, and I'm delighted to join the group.

Reva Winkler: Thank you very much Rebekah. Did Craig Gilliam join us? We're missing a person, okay. Teri, your next.

Teri Kiehn: I'm Teri Kiehn, I work with Intermountain Healthcare. I'm the Operations Director for their Women and Newborn programs and I also work as a consultant with the State Department of Health moving towards looking at reporting our information specifically on our preterm births.

Reva Winkler: Okay, thanks very much. Dr. Profit?

Jochen Profit: Hi I'm Jochen Profit. I'm a Neonatologist and a Health Services Researcher at Baylor College of Medicine. I have an NIH Grant on developing composite indicators of quality for neonatal intensive care and I've been involved in quality measurement and development and public reporting and patient incentives, I guess for the last six or seven years.

I had the opportunity to be on a previous steering committee I think in - I think about three or four years ago. So I'm very happy to be back and I'm excited to participate again.

Reva Winkler: Great, thanks everybody. Just to let you know, we do have several other of our steering committee members who are listening in to your conversation and we do have representatives and ((inaudible)) developers joining us to respond to any questions or concerns of each of the measures.

So first question I'd just like to ask everybody is, "Everybody's got the measure submission materials, correct, and are you having any particular issues accessing them on SharePoint?" Okay good. That was initially an issue but it seems to have been resolved, so that's good to know.

Okay with that I think we'll be able to move into the discussions of the individual measures. So the first measure that is up is Measure 475. This is Hepatitis B vaccine coverage among all live born infants prior to hospital or birthing facility discharge. This is brought to us from the CDC. And this measure is for maintenance review, it was endorsed in NQF's previous perinatal project in 2008. And Teri, I think is this your measure?

Teri Kiehn: Yes it is.

Reva Winkler: Great, so I think what I'd like to do is go through each of the main criteria and look at the preliminary evaluations. And then have you sort of start the discussion around any issues the committee feels needs to be brought up around, let's start with the importance criteria.

Teri Kiehn: So as we look at the importance criteria and separate them, I'm the only one that thought it was moderate, everyone else felt it was low. So I don't...

Reva Winkler: Really...

Teri Kiehn: No, it was interesting. Again, there's only four of us that have given input on this. So the ones that are on that did not give input; it'd be interesting to hear their thoughts.

Reva Winkler: Yes, I'm looking at the importance criteria and under the 1a Impact, I've got two mediums and two highs; under the gap which is 1d, I've got three highs and one medium. So I guess I want to be sure we're all on the same page.

Teri Kiehn: Maybe I'm looking at the wrong - maybe it's sorted wrong.

Elizabeth Drye: Maybe we can just - I don't know, could someone just recap the measure briefly ((inaudible)) before we...

Reva Winkler: Yes this...

Elizabeth Drye: Okay because I'm still just pulling them up. I'm sorry, again...

Reva Winkler: Not a problem.

Elizabeth Drye: ...and I'm pulling my notes and I just think...

Reva Winkler: That's fine.

Elizabeth Drye: Yes.

Reva Winkler: Yes, and you can sort the list of measures to just look at 475 on the Excel spreadsheet.

Teri Kiehn: That's why; I sorted by 479. Give me a minute here.

Reva Winkler: Not a problem. Just to talk about this measure is, "The percent of live newborns that received hepatitis B vaccination before discharge at each single hospital or birthing center during a given time period, typically one year." Okay?

Teri Kiehn: All right, I'm sorry; I sorted by the wrong one so you'll just have to give me a minute here.

Reva Winkler: Not a problem.

Teri Kiehn: So I don't know if you want to lead it while I am...

Reva Winkler: Well in this case, while Teri is pulling hers up, the importance criteria to recall is; the first one is Impact.

The second 1B is the gap or Opportunity, in other words, "Do we have data presented that demonstrates that there's still opportunity for improvement?"

And then the third is the Evidence. And since this is a process measure we are looking at the body of evidence to support providing hepatitis B vaccine for newborns and specifically how strong that evidence is regarding the quantity, quality and consistency of that evidence.

In general this was rated Moderate to high on most of these categories by the four people who've already given their preliminary review. So Teri are you?

Teri Kiehn: You know, I must have saved it. I had four other things going in. Can you just resend it? I don't know what I did I'm sorry.

Reva Winkler: Okay. Let's see if we can do that. It may take a second.

Teri Kiehn: Yes I apologize. Can we start with one other one and then go back?

Reva Winkler: Yes okay, we can do that. Just to kind of give Teri a chance to reorganize herself, let's move to Measure 479 then, which is, "The birth dose of hepatitis B vaccine and Hep B immunoglobulin for newborns ((inaudible)) Hep B surface antigen positive mothers."

This is brought to us from the California Department of Health. Again, this is a measure that was endorsed in our previous go around with perinatal measures. And I believe, let's see who's...

Rebekah Gee: It's me, Rebekah. So let me just...

Female: Hi Rebekah.

Rebekah Gee: Hey everybody. Let's just talk briefly through it. So this is a California Department of Public Health measure rather than the last measure that focuses on hepatitis B broadly.

This measure focuses on mothers that are actually infected with Hep B surface antigen - I mean with serological evidence of hepatitis infection in their newborns receiving the vaccine.

And so I was thinking I could go through just a little bit about the measure, the evidence behind it, and then just sort of briefly through the categories.

Many of you marked this as low or Intermediate - medium Importance, which I would agree with.

And let's - let me just say why. So the numerator is the number of infants born to Hep B surface

antigen positive mothers who received a birth dose of Hep B vaccine and Hep B immunoglobulin upon delivery.

You need both the vaccine and immunoglobulin to be - to have maximum effectiveness. Then the denominator is the number of infants born to mothers who tested positive. Exclusions are stillbirths, miscarriages obviously because they would not be eligible.

This measure is collected from electronic clinical data, it's not - you know, there may be chart abstraction, certainly from laboratory data that was not available, so it's not a - certainly birth records. You're looking at clinical data, predominantly electronic records.

So why - what's the problem; well prior to the development of the Hep B vaccine in the 1980s, you know, there's research out of London and other places looking at how many infants are actually infected. Well if you have a mother, and you have - particularly in the Asian populations with the Hep B antigen, transmission can be as high as 90%. In other - depending on other types of hepatitis B you can have 7% transmission.

So depending on your population, transmission can be high although not the case in every population. And certainly since the development of the vaccine, the problem has been ameliorated greatly. So the goal of this is to reduce the transmission of hepatitis B when possible to these mothers.

One of the questions I had about this measure, was you know, it specified that it be given within 12 hours of delivery. There's evidence that there is effectiveness up to 24 hours after delivery although, the sooner the better.

One of the things I'm wondering that I wasn't clear to me was, "How are we defining or measuring when it was given; how do we know it was within 12 hours?" So that's one thing I would ask the



measure developer. Because I'm not sure how we're defining -- through a data perspective -- the timeliness, or the time that the vaccine was given. Where would we find that?

So that was one question. Looking at high Impact, 1A, I would say low impact just because even though it's a priority, even giving immunoglobulin and vaccine, there still would be a small chance that the infant would get hepatitis B.

Even in California they're still - when they looked at their data for a year, there were 2000 infants born in 2009 and almost all of them -- 97.1% -- received the first dose, although they don't give you -- of Hep B and immunoglobulin.

So this is a very high percentage and it's still as I said, "Not 100% of these infants will get chronic Hep B and have ((inaudible)) later in life. There is what seems to me be also a measurement difficulty given that this comes, you know, from medication records and electronic data records, it for some facilities may or may not be easily - this measure may not - may or may not be easily gotten to.

So looking at high impact, I voted low and the group generally lived in the low to medium category, just because this is not a common problem and given that the vast majority of infants are already getting this, the number of cases -- and I did not do the math -- would be very small.

Opportunity for improvement again, low given that more than 95% of infants are already getting the vaccine. Evidence, you know, there's very good evidence for vaccines, we can't argue with that. ACIP recommends it, we know that it works.

It's an important health outcome to avoid hepatitis B certainly. So that maybe I'll leave - now we can go through the rest of these boxes, but I'd just start with maybe stop there and then let the group comment at this point on what (I just said).

Jochen Profit: Yes, this is Jochen Profit, I think I had exactly the same thoughts as you did regarding, you know, regarding this measure.

I mean this is a very worthwhile, you know, undertaking with regard to the, you know, the importance of the, you know, providing the vaccine to the - to these infants and immunoglobulin, but it seems like the problem is largely fixed. And it didn't seem necessarily that the burden to the hospitals of reporting this would really be in any relation to the additional benefit that we could accrue from this.

So I felt like there is maybe more important measures that also then would allow you to truly measure differences between hospitals, with regard to quality of care. The numbers, those 3% within California is so small that I would feel like it'd be almost rather a random event in any given hospital for it not to occur.

And so public - I don't know how meaningful a public reporting would be on this measure.

Reva Winkler: Right; comments from anybody else? Scott, you and Elizabeth also weighed in on this one.

Scott Bern: Yes, I mean I think it's all pretty much been said. I'm not going to be redundant here but I did notice the 97% number and perhaps the writer of this measure can talk about any other national data that he - that might be available.

You know, I - I'm just looking across my comments here. I did struggle a little bit with this measure and also the other measure around hepatitis B in terms of whether it really met the - an outcome measures sort of criteria, but ultimately you're really trying to prevent, you know, those Hep B infections.

And let's see, what else did I have here, I just had a question about, "What about parents; what about those who refuse the vaccine? How are they accounted for?" And you know, my main issue was really around what was just discussed in terms of, from a public health, from a measurement standpoint, it's already 97% in California, what's the real evidence that this would be helpful as a national measure?

Rebekah Gee: And just to add the developers agree that some of this may need to be extracted from paper charts. And so given the burden of reporting it's not like going to, you know, measure other measures where it's right from vital records or something where it's easily extracted.

When folks have to go into paper charts, you're really using a lot of will for improvement up. And so you know, I think I feel and agree with the other two comments that it doesn't seem that the opportunity for improvement warrants necessarily the burden of reporting.

Reva Winkler: Okay.

Teri Kiehn: This is Teri; I feel the same way also. Looking at the cost per data element that there are other measures that could - we could get more benefit for the community as a whole with the cost per data element.

Reva Winkler: Okay.

Elizabeth Dye: Hi it's Elizabeth. Also agreeing with the general conclusion that there's already high performance and it's a very - it's a relatively small party of population.

And I also wasn't clear how the eligible infants would be identified vis-à-vis their documentation, their mother's status. So I just didn't know where that came - you know, because I don't - can it

always come off of infant's newborn record, I don't know. I think in a lot of places probably you'd have to look in the mother's chart. And if your chart abstracting that's a lot of work. So I didn't - I also just thought maybe the staff ((inaudible)) could comment a little more.

This is a narrowly focused measure along the measures that we're looking at today, and you know I - there may be certain hospitals or certain environments or certain cities where this would be an important measure, versus nationally.

And so I think we're talking about whether it meets important criteria. And that's the fundamental criteria ((inaudible)) need right, to move forward onto the rest of the - to be - to continue to be considered.

So how do you think about measures that are - you know, I'm not - I don't see that it's needed necessarily in any particular regions or states or areas. But if it were, you know, how do you think about a measure that is really focused on a potentially a small population that's up for re-endorsement that really doesn't at this point nationally seem to be important.

Rebekah Gee: And this is Rebekah, let me just comment quickly that I think that there's a reason why this comes out of California. I mean Hep B transmission is very high; it's highest among Asian populations -- California having one of the highest Asian populations in the country.

So I'm not saying it's not valuable for California. But that's the other question I'd ask is, similar to the last question is, "When we take something that may be regionally valid but say it's of national validity, you know in California, just calculating, there would be 24 infants that - and of those not all of them would have long-term disability in the entire state in a year, I would think that would be much lower in other states, per population."

So any historical information about, you know, when you have a measure that's specific to a certain area, how we think about that?

Reva Winkler: Not really. Yes, this is Reva, not really. I think the questions you raise are particularly appropriate. And I think when it comes to the usefulness, that's sort of what you're addressing is some usability criteria, as well as I think the other big one you landed on was really the opportunity for improvement.

Also impact; and this is one where perhaps you're really also talking about impact with the small population at risk, particularly when it's regionally based.

You had a couple other questions about the measure which even though the importance criteria is a threshold criteria, we want to be sure that any other questions about the measure are addressed in case the steering committee doesn't - the entire steering committee doesn't totally agree with the workgroup.

So I guess I'd like to hear from the measure developer if they have any response to any of the comments, but realize that there were other questions embedded in some of the specifications about, "How do you - the documentation for the timing of administration, how do you determine the maternal status from the neonatal chart, and what about parent refusals?" So do we have somebody from the measure developer with us?

Chrissy Cheung: Hi, my name is Chrissy and I am from - I wasn't the original developer and - but I'm from the offices of the developer and the form was submitted by California DPH. (Catherine) submitted the form, unfortunately she couldn't have been on this call with us and she is probably actually the best person to address these questions. But I will try my best.

As far as the timing questions; from what I know (Catherine) told me that the, though the measure is getting the vaccine and the HBIG within 12 hours of birth, because these are the ACIP recommendations, actually what is reported from California DPH to the CDC is actually whether or not the infant has received it within 24 hours. So I don't believe that there is a specific timestamp on it for us to know whether or not it was within 12 hours.

And as - I'm sorry, so the other questions, in terms of regionally, "Yes, so regionally California would have a high number of Asian population, but there are also other states in the U.S. where I think that this would be equally valid -- where there are high Asian populations.

We have a lot on the East Coast in New York and Maryland, I believe Virginia's pretty high up there, and Texas has also a large Asian population. So while you know historically there is the larger Asian population here in California, I - we do believe that it's equally important in the rest of the country.

Can you remind me what your other questions...

Reva Winkler: So the other questions were about parent refusal...

Chrissy Cheung: Okay.

Reva Winkler: ...and getting the information on maternal status from the newborn chart.

Chrissy Cheung: So for parent refusal, I believe that it was just counted as not receiving HBIG, is that the question? Does that answer the question?

And then for the maternal status should be listed in the newborn chart. So I don't - so I - when they went and took the - when they went and reviewed the maternal infant delivery charts, I

believe that the maternal - the status of the mother was already listed on the infant chart. But I actually am not sure on that one.

(Tanya Walker): May I interject for a minute? This is (Tanya Walker) from CDC. It actually is a recommendation as part of the Peri-Hep B Program, they're supposed to have a copy of the hepatitis B ((inaudible)) test results in both the mother and the infant chart -- so it's a requirement.

Rebekah Gee: And this is Rebekah. One of the things I'd like to know, if you don't mind ticking back potentially for the broader discussion is, "Why was 12 hours chosen for this measure when the 24 hour has been reported?" And what was the - I would like to know the thinking on that.

Chrissy Cheung: Maybe (Tanya) can help me with this but the 12 hours is the ACIP recommendation. So that's the way that the measure was developed.

(Tanya Walker): Yes the ACIP recommendation is 12 hours, specifically for these infants because they are born to hepatitis B surface antigen positive women.

And we actually do - or I'm in charge of managing a side project in which they - ((inaudible)) which represent about 28% of the births of hepatitis B surface antigen positive women have to provide their information to me, just to see if it's - if it is occurring when it's supposed to occur.

Female: And how do you...

(Tanya Walker): I myself have been trying to work to get that changed. I think that if we're saying that the - they should receive the shot within 12 hours, then we should be asking that you all report it that way.

Female: Right.

Rebekah Gee: And the other question I had was on, "How are you measuring timeliness of the vaccine being given?" I don't know where in a chart - I mean you would have to paper abstract that I would assume to know exactly what hour it was given, or is there another way?

Female: Are you - I'm sorry, are you saying this is for reporting purposes, how we know when the immunization is given?

Rebekah Gee: So your metric is based on timeliness of the vaccine...

Female: Right.

Rebekah Gee: ...I'm wondering how are you measuring that? Because usually in an electronic record you may not - you know, you'd have to go back to when the birth was, when the vaccine was given. Is that easily available or what is happening...

Female: Yes. With the electronic records that's actually much more easily available than before with the paper records. I mean, you can still go back, even with paper records, and you know, do a chart review and get that information pretty easily, that's very clearly documented.

But with the electronic records nowadays it's, you know, it's - I bet they could even pull the data from the back end. But it's very easy to pull. If you were to do any chart review or abstraction of data, you can find that.

Female: Thank you ladies.



Reva Winkler: Okay. So those were some questions I think that speak to the specifications and the - any issues around scientific acceptability. Were there any particular questions around the usability criteria or the feasibility criteria? I think we did address some of the feasibility issues.

I just want to point out that the importance criteria actually is a threshold criteria. If it does not pass the majority of the steering committee ((inaudible)) that it's important then we'll stop right there. So it will be important that when we're ((inaudible)) discussing it that we lay out the material ((inaudible)).

And just as a preview, what we'll do is ask you to present, you know, kind of a concise summary of the issues around the importance criteria, entertain whatever discussion we'll, the rest of the committee wants to have, and then we'll ask the committee to vote as a group on the importance criteria. If it passes, then we'll move on to scientific acceptability, usability and feasibility. But if it doesn't pass we'll stop right there.

Female: And I'd like to just echo what Chrissy was saying about the kind of importance and applicability to the entire U.S., I mean we - our particular focus happens to be on Asian-Americans because we're the Asian ((inaudible)) center and there's a large Asian population in California.

I mean Asians in general constitute about 4% of the U.S. population. And with 10% being chronically infected, that's a not insignificant amount of the population. But in addition to that, the actual recommendations for screening and those coming from high risk populations actually include Eastern Europe, much of South America and Africa as well.

So you know, when we wrote the - I don't know that measure has a chance today, but I mean we have - you have a lot of kind of Eastern European populations all along the East Coast, in a lot of refugee populations among Asians that are kind of scattered in the South and the Midwest, and those populations have higher than a 10% chronicity rate.

Scott Bern: Right.

Female: So I don't want to just say that it's only applicable to the U.S., because there are actually quite a few kind of foreign - children of foreign born whose parents are from an equally high ((inaudible)).

Scott Bern: Yes, Reva?

Reva Winkler: Yes?

Scott Bern: Reva this is Scott I know we have to move on, but I think that what really was an issue in this section, at least in my perspective, was the lack of the other data outside of California.

So I think that's a key point here in terms of meeting that threshold in terms of, "What's the magnitude of this issue outside of California since they're already at a 97% compliance in California?"

And what was written in the proposal, in the measure, didn't really reflect that. I think that at least is an important point for me.

Reva Winkler: Okay.

Rebekah Gee: And to add to what Scott just said, the other point was we don't - there was no note of how many infants had actually been affected and infected with Hep B and I think that would have been - also helped the argument.

Reva Winkler: Okay. Chrissy...

Elizabeth Drye: Just to broaden it even more, this is Elizabeth. I'm just wondering, so we're going to talk about a measure that looks at Hep B vaccination for all infants and it affects a much broader population, but it affects this population as well and just from my reading of the ((inaudible)) all, you know, it is getting a Hep B vaccine ((inaudible)) if you don't get immunoglobulin is an important benefit to babies of Hep B surface antigen positive mothers.

And so I'm just wondering, "Should we be thinking about the value of this measure as a marginal value on half of the other measure?" In the sense that what - you know, if we're making sure everybody gets a Hep B vaccine at birth, what's the added value of this? That would be one way to think about whether its value in national public reporting or even in more regional ((inaudible))...

(Stephanie Chow): Well I certainly don't want to - I think the bigger measure certainly is getting the vaccine to every newborn, that much - certainly has much bigger - greater impact. I can say that though the addition of the HBIG for mother - for children born to mothers with hepatitis B is that it confers about an additional 25% protection. So...

Elizabeth Drye: And who's talking? Sorry, I'm wondering within the early part of these discussions we can still identify ourselves ((inaudible))...

(Stephanie Chow): Oh I'm sorry; this is (Stephanie Chow).

Elizabeth Drye: Okay.

(Stephanie Chow): I joined the discussion late, so I apologize if I'm duplicating what's already been said.

Elizabeth Drye: So even if you think - even if it was that, you know, 25% incremental benefit, if it's over a very small population and there's a high burden to collecting the data, due to the chart abstracted

measure if we're involving more than the infant's chart, but maybe not, that's how I would think about it, is you know, after you get - after you measure and report on Hep B immunization, what are you conferring in terms of health benefits by measuring and reporting on this across all these hospitals.

Reva Winkler: This is Reva. Just to respond to Scott's question is, this is exactly the kind of thing we're going to ask the steering committee to think about.

One of the sort of basic approaches is to look at each measure individually to see if there are any, you know, major sort of structural or fatal flaws to the actual measure. But then, once we've done that to step back and look at the group of measures to see how they work together.

And you're asking the right questions about things like additional value, of you know, a group of measures on a similar topic; do we need all of them, do they all add value?

So the questions you're asking are appropriate and should be factored into your evaluation ((inaudible)) measure.

(Stephanie Chow): Yes I mean, what I can say is that these measures really are complimentary to each other.

I think that's a large part why the ACIP and the CDC kind of advocate these recommendations apart from the measure, but these recommendations hand in hand -- we don't really advocate them separately. You know, and I think if you are going to be doing the chart abstraction for the other measure, this one is not much more difficult to abstract.

I think we can give you population based data for other states to show that this hepatitis B chronic infection is an issue in other areas as well as California. You know, but I you know, I don't

because this was - we - the California Health Department helped us grab this data I'm not sure that we, in the period of time that we have left, can get the equivalent data from the other states right now.

Rebekah Gee: And do we have data on number of affected infants?

(Stephanie Chow): I think the CDC does but we have to go back and look that up. Part of it is - you know, there's a - there is a problem in that you only know that the infants are infected if you go back and test the infants.

And compliance is actually not great. So you know, we know the overall infection rates of infants if they're not infected - if they're not immunized, which is you know, 90% of those who come into - in fact come into contact will develop chronic infection.

But the problem is that we don't - in our country we have such poor follow-up with these infants oftentimes that you don't know if they end up developing it without the infection because those mothers are not, you know, kind of included in the system. So the data is incomplete.

Rebekah Gee: That gets at one of my other follow-up questions and I don't know how much more time we want to spend on this measure but, that's what I was looking at the data, it's really the problem with this issue is more the follow-up and the lack of getting the full vaccine dose, the lack of follow-up on testing the babies to see if their positive.

I - and I wonder if our focus ought not be on that issue rather than be an issue where over 97% of infants already are getting the appropriate treatment. I mean, why don't we focus where there's the major problem?

(Stephanie Chow): Well so it's - I mean they do go hand in hand right? So they - part of the issue is that without measures that kind of support the importance of immunization, the follow-up is really non-existent. So we need measures and data to demonstrate the importance of immunizing in time, giving the HBIG in time. And this data has been around for a while and a lot of it comes from Asia.

And once these are quality measures then you can hold the hospitals accountable. And this has been an issue that we've been dealing with for a long, long time which is that, you know, if the hospitals have to follow-up, the health departments have to follow-up.

And without kind of these quality measures, then money gets spent elsewhere. So it's kind of like a Catch 22 in a way.

Rebekah Gee: Can you give us - I mean I would be curious what the SCHIP measures are, and you know, I just - I think - it seems to me more of a pediatric rather than a hospital issue. But I would like to see - if there are other measures out there that look at the follow-up in measuring success and number of vaccines I'd love to see that too, if we could have that presented.

(Stephanie Chow): You mean in terms of other vaccines?

Rebekah Gee: No, Hep B; what happens in terms of, "Are there any metrics that look at children receiving full dosage and then follow-up testing of infants - and I don't know what's appropriate, six months or one year or what's appropriate timing, but you know, looking at appropriate timing of retesting as well as full vaccine administration.

Reva Winkler: Okay, this is Reva. I'll be happy to take a look through our inventory for any of our child measures. This is something that Suzanne, Gene and I do also, for any measures in terms of the

later, more outcome of the disease kind of measure. But I think it's - I think we need to move on to just go back and discuss Measure 475, which is - Teri are you with us?

Teri Kiehn: I am with you.

Reva Winkler: Great, so this is the hepatitis B vaccination administration to all newborns prior to discharge. So why don't you go ahead and kind of take us through the criteria?

Teri Kiehn: So do you just want me to do the ((inaudible)) go on to the - so the brief description again is, "The percentage of all live newborn infants that receive vaccination during a given time period, to one year. The numerator is the number of live infants getting the vaccine and the denominator is the number of the live newborns born at the birthing facilities."

The exclusions again, are based on ICD-10s which are very difficult at this time to get. It's a measure - it's a improvement process. And as we look at this, do you want me just to go through what, since we're running short on time, just what we all said because we're all pretty consistent here.

Reva Winkler: Yes, let's hit the high points of what we all said, right.

Teri Kiehn: Okay. So as we're looking at the impact, we were all moderate to high on that. And if it met the importance, we all felt, "Yes." Again, the scientific measures, we all felt, "Yes."

With the usability we've got one low, two moderates and a high. So as we look at this is the feasibility, three moderates and a low. And then as far as met criteria, evenly split with two yeses and two nos.

Reva Winkler: Great. Okay so it looks like everybody is pretty consistent in terms of the importance criteria and the solidness on the evidence and opportunity for improvement. Again very similar, everybody had a rated the scientific acceptability.

I think you raising the point about the exclusions being an ICD-10 can be noted. But I guess where it starts to really diverge is under usability and Jochen you rated it low.

Jochen Profit: Yes.

Reva Winkler: You want to comment on why?

Jochen Profit: I'm trying to find right now what I thought about this. Sorry, not to have all of these on the top of my head, these ratings.

But I guess the usefulness for public reporting on this was whether or not a baby receives hepatitis B during the birth hospitalization. I think there was an issue with the - didn't the measure developer even say that there's an issue with the parental refusal?

So I didn't think parental refusal was probably a problem in the case of a hepatitis B positive mother, because I'd feel like it's probably a rare event that they would refuse their child to be vaccinated. But I think it's a really - it's quite a common - it's actually quite a common event of parents refusing hepatitis B for regular newborns.

And then I think there was a mentioned - I can't quite find exactly where it was, but there's a mention somewhere in the description I've stated that really parental refusal was very difficult to actually ascertain.



And because of that it sounds it might be quite difficult to look at this measure with regard to public reporting if there were systematic differences with regard to populations and how they - and how frequently they might refuse this vaccination. So I think that's mostly where I was concerned about this measure.

Scott Bern: Yes Reva this is Scott, you know, just to add on to that because I had some questions here really around what appear to be, as written in this measure, a varied capacity for hospitals to provide this data and to actually report on this measure.

So I was really questioning the challenges to implementation in terms of actually getting valid data in order to track ((inaudible)) to add on to what Dr. Profit just said there.

Reva Winkler: Yes, okay. Can the folks from CDC tell us what the current state of the use of this measure is and whether it's publically reported anywhere that you know of?

(Tanya Walker): The measure itself is not used per se because it is a new measure. But every year the states have to provide information on birth dose within three days, which essentially is birth dose information based on hospital discharge because of course the average hospital stay ranges from 1.9 to 2.9 depending on complications of the women. And it ranges around 60%.

But even though the recommendation - ACIP recommendation is that, "All infants are vaccinated with that first dose prior to discharge." Did that answer your question? If not then...

Reva Winkler: Well I guess - so that - I'm sorry.

Elizabeth Drye: Sorry, this is Elizabeth.

Reva Winkler: Yes.

Elizabeth Drye: I guess I wasn't sure of the ((inaudible)) like there's testing going on in - with the measure, even around the issue we were just discussing, I'm looking at 2b, ((inaudible)) Plan 1, Meaningful Differences in Performance and 2b ((inaudible)) users to say I'm on Page 14 of the measure but - on the form.

But if - I wasn't sure what the status was reading as of the testing around, you know, parental refusal and documentation of that and ease of that and what the intent was even. Is it under ((inaudible))...

(Tanya Walker): It was suggested...

Elizabeth Drye: ...with or without that exclusion?

(Tanya Walker): Well it was suggested when the measure was time limited endorsed, the - we didn't have the feasibility of study at the time when Dr. (Wong) submitted it. She was the developer; she is not with us, she's with WHO now.

But when you got - well when we got the time limited endorsement it was suggested that the feasibility study include taking the parental refusals out of the denominator so that it wouldn't count against the hospitals. Did that answer your question?

Elizabeth Drye: Yes, but it sounds like there was a little bit of an effort to look at that.

(Tanya Walker): Right, right.

Elizabeth Drye: Or there was an interview - a clear - I wasn't sure exactly did you just ask hospitals whether they could do it?

(Tanya Walker): The - we - I mean I think the hospitals were asked to try to do it and report it on - and then that way reported on whether they could by - whether they were able to find the information or not so.

Jochen Profit: But there were problems with that right? This is Jochen Profit again. I think...

Elizabeth Drye: It states 38% of hospitals clearly were able to make the adjustment for a vast number of people.

Jochen Profit: Yes.

Elizabeth Drye: So that's pretty ((inaudible))...

(Tanya Walker): Right.

Elizabeth Drye: ...people.

Jochen Profit: So I think that's my primary - I think actually like as I'm looking through this again I think I rated 3B low, that's probably not - I would probably revise that higher ((inaudible)) again because I think for quality improvement it's quite useful.

But I think as long as the - you know, as we - or if we at least have a good measure of how much of a difference it would - this parental refusal makes across hospitals. If it doesn't - and it's possible this kind of appears like a big problem to us but it actually isn't. You know, in that case I think it'd be fine to just go ahead with the measure.

But I feel like I would need some more data on how much the parental refusal actually influences, you know, performance ratings.

(Tanya Walker): Okay.

Elizabeth Drye: And another thing I think would be helpful would be to know the status of other immunization measures that are ((inaudible)) process centers like this, you know, ((inaudible)) I mean it could be differ by immunizations, some are refused more than others. But I just - I - it would help me to sort of benchmark against where other measures of this sort are point.

Reva Winkler: Okay yes, this is Reva. That's something I could certainly provide to you, I think offline because I think we don't want to spend the time on that now because...

Elizabeth Drye: Yes, definitely.

Reva Walker: ...it's actually a giant issue. It absolutely is a giant issue on, "How do you capture and report patients who got vaccinated, patients who refused vaccination and then patients who have contraindications" -- all of which add, you know, contribute to the overall outcome of the measure.

But I can send that to you offline if you'd like.

So Teri, are there any other issues? I think you all have talked about the scientific acceptability, your concerns about how refusals are handled, the capacity for data collection, and then the feasibility, which a lot of those are feasibility issues...

Teri Kiehn: Yes.

Reva Walker: Are there any other questions or additional information the group would need to kind of clarify some of these things? Anything we can ask CDC to provide for us before the meeting that may help the evaluation of this measure?

Elizabeth Drye: I mean another thing that would help, again just thinking about the value of the ((inaudible)) measure would be to know what ultimate Hep B series compliance strength is for newborns.

Not you know, this is - you get it in a hospital where - because you - I don't know what the percent are that get it.

(Tanya Walker): The compliance rate for the birth dose or the entire series?

Elizabeth Drye: Well this is the birth dose, right? But the - but I think even just for the first dose right, if you look in and out of hospital, do we have a number for that?

(Tanya Walker): "In and out of the hospitals," no we don't. We only ask for the information by Day 3, which is generally you know, by discharge.

Elizabeth Drye: But CDC doesn't have a number for immunization rates for, you know, the number of infants or the proportions ((inaudible))?

(Tanya Walker): I think I might find the information but I know that for a fact that the only information we report out and then - or ask in the national immunization survey is by Day 3. And I know that that's around...

Elizabeth Drye: Okay.

(Tanya Walker): ...that's between 60 to 65. But in terms of who completes the - who got - who gets that first dose overall at any time, at any point; I might be able to get that information. Or I know I can get the information to you I've just got to find it. I can't give it to you right now so.

Reva Winkler: Okay well we'll be happy to follow-up and if you send that to us we'll share it with the committee. Okay?

(Tanya Walker): Okay thanks. Any other...

Jochen Profit: This is...

Reva Winkler: Yes?

Jochen Profit: This is Jochen again, I think if I maybe hear that comment correctly, one of the things that I've been wondering about, the hepatitis measures is we've been giving hepatitis now for how long to the newborns? Maybe about like ten years or eight or nine years, something about like that.

And with the general increase in hepatitis immunizations within the population, I kind of wonder, you know, whether the actual hepatitis cases over time will really drop off in newborns and whether, you know, you could always measure whether the process is being done in the hospital.

But the value of that measurement worth is likely to decline over time because of the success of vaccine programs so...

(Crosstalk)

Jochen Profit: So I guess, you know, maybe this is where we felt like we were with the other measure, that you know, maybe at some point, you know, the actual value of the actual measurement declines. Not that - the process itself is important.

Female: Yes.

Reva Winkler: Anything else from anybody on the hepatitis measures before we move on?

(Stephanie Chow): I guess on the - this is (Stephanie Chow) from the Asian Liver Center. I've - just to address that last question that was raised, is the concern that there's no more need for this measure or that there's not enough data on the affect? I was unclear for that - about what that question was asking.

Jochen Profit: No, so I - mine was less of a question then a comment. So you know, I would just think that over time hepatitis rates in newborns will decline based on increased hepatitis immunization rate within the population.

(Stephanie Chow): Yes but I - I think that is somewhat true but I think the - there - in the last year or two the recent data that came out showing acute infections in children really declined dramatically with the implementation of the birth dose of hepatitis B. So and...

Jochen Profit: Right.

(Stephanie Chow): ...with the continued immigration, of you know, hundreds of thousands of immigrants from high risk countries I wouldn't say that we've quite reached the point where this is a, you know, obsolete measure.

Jochen Profit: Okay.

Reva Winkler: All right.

Jochen Profit: Okay.

Reva Winkler: Okay so let's move on. The next measure is Measure 478. This is nosocomial

bloodstream infections with ((inaudible)). This comes from the Agency for Healthcare Research and Quality, AHRQ. It's the percentage of high risk newborn discharges with an ICD-9 diagnosis code of bloodstream infection. This is an outcome measure.

This measure was endorsed during the previous perinatal project. And this one I - (Craig Gillium) was the lead discussant; did (Craig) join us? Okay so we're going to have to kind of limp along without (Craig).

Four of you ((inaudible)) I'm sorry? Hello? Okay, so on the preliminary ratings from all of you, everybody rated it as having high impact, three - there were three highs and one medium on opportunity for improvement.

This is a health outcome so the evidence rating isn't the same as for process measures, but it's felt that there is evidence that there are actions and ways of reducing nosocomial bloodstream infection.

And all of you - all of the four of you said that, "It, the measure would pass the importance criteria." Were there any particular issues about this measure you wanted to bring up? Or does that pretty much summarize it?

Jochen Profit: That summarizes it for me.



Scott Bern: Yes, good job.

Reva Winkler: Okay, all right. So under scientific acceptability again, I think we have a mixture of medium and high for reliability and validity. This is a measure from AHRQ it's based on administrative data.

Just one other thing I want to see, the level of analysis is at the level of the hospital facility. So I would guess that some of you have had experience with this measure, or your hospital has been measured by this measure perhaps?

Teri Kiehn: Yes.

Reva Winkler: Okay. Any - okay, Teri was that you who said yes?

Teri Kiehn: Teri, yes.

Reva Winkler: Any comments about it? Any comments on your experience with this measure?

Teri Kiehn: It is very hard to look at some of the elements if you don't have an electronic medical record, which is one of the concerns. ((inaudible)) pulling out some of the - I'm sorry, someone just came in my office of course. But looking at this, it is a little bit hard when you're looking at some of the finer elements. But again, it's a definite need for reporting.

We're working on reporting in our state for the newborns. So I just feel like it is a good measure and as - I - hold on just a minute, let me just put you on mute and then I'll get back with you.

Reva Winkler: Okay so...

Rebekah Gee: This is Rebekah, I would agree with the other reviewers. And I also think the focus on the highest ((inaudible)) infants is appropriate, you know, those less than 1500 grams, premature or you know, significant adverse event.

Reva Winkler: Okay.

Rebekah Gee: So I like this measure, I think it's meaningful for improvement. Some folks are starting to focus just on ((inaudible)) that's not an aspect of this measure but I certainly don't argue with the relevance of it.

Reva Winkler: Okay. We're going to talk a little bit later, once we get through all these measures, about other related measures. And so hold that thought on a class c measure. We'll get there.

Scott Bern: Yes Reva, but this is Scott, I'm glad we're going to get there because I just feel like the greatest challenge is going to be doing exactly that. Because some of these measures just so close...

Reva Winkler: Exactly.

Scott Bern: ...that that will be probably the most robust discussion for us to have about these four measures, from my perspective.

Reva Winkler: Okay. Okay and so I'd like to be able to just kind of go through each as an individual, which is the first step, and be sure there aren't any serious issues or fatal flaws if you will, on any of them.

So in terms of the usability and feasibility, pretty much there was a mixture of high to moderate for the ratings for both of those criteria from the four preliminary reviews, in that everybody felt the measure was suitable for - that it meets the criteria.

So does anybody else have any comments on this one?

Jochen Profit: I did have a couple of questions that I just wasn't sure about but they're - I mean I think that's maybe what Scott gets into, like to some degree some of the detail of these measures become really complicated and I have got to say just from reading them I wasn't 100% sure about what would happen. But if the measure developers are there I'd have a couple of questions.

So for this measure I was wondering like, "What if the patient dies?" Is there, you know, does that make a difference? I think it doesn't but as long as infection is in the diagnosis code I think it's included. But does that - you know, so if the hospital has a very high mortality rate, they put themselves at a lower risk for infections, right? Because that...

Reva Winkler: That's right.

Jochen Profit: So is there any...

Elizabeth Drye: Meaning there - it increases their denominator. Is that what you're...

Jochen Profit: Right, so if you spend more days in the...

Elizabeth Drye: Right.

Jochen Profit: ...you know, if you have a higher survival rate, and there's more days that the patient is at risk...

Elizabeth Drye: Right.

Jochen Profit: ...for an infection so you know, I guess I'm just - I'm not saying like anybody will have a perfect answer for this, but is this something that is being investigated at least in these measures?

And then another question was about transfer; what if the patients are transferred back to other institutions? It's the same kind of question, like if a unit transfers a lot of patients out early, then they're going - you know, they might have a lower infection rate because the patient is at risk for a lower - lesser time.

Rebekah Gee: Also the death and transfer both in the denominator -- and I don't know if the denominator adequately addresses them, but their addressed. And I don't know, you know, certainly...

Jochen Profit: Is that transfer in or transfer out?

Rebekah Gee: Transferred from another health facility...

Jochen Profit: Right. So I think that's from transfer out, or transfer in right? So if the patient was out-borne, does that mean out-borne? I think that means out-borne usually.

Rebekah Gee: I think it means they've come in from another facility.

Jochen Profit: Right, but if - I guess what I was thinking is like, you know, some hospitals will essentially keep babies until they're close to going home, and other baby - and other hospitals will send a lot of them out to, you know, some of their satellite facilities.

So if you send out a lot of babies, maybe for a while they're having IV nutrition, et cetera, then you know, you put your - you can lower your infection rate by, you know, having these patients be at risk for a shorter amount of time while they're in your hospital. I mean those are real details, I'm not sure it's worthwhile getting into but I was...

Reva Winkler: Okay.

Jochen Profit: I thought I should raise them at least for the developers to kind of say they are thinking about these are trying to address these.

Reva Winkler: Right, let me ask...

Rebekah Gee: One thing...

Reva Winkler: Yes is anybody from AHRQ on the line?

Elizabeth Drye: Before - can I say something? It's Elizabeth, because I would just like before we get far to address it.

I would agree with all those things that somebody who develops outcomes measures, and we're always thinking about issues like, you know, how the - we try to do standard follow-up periods so the length of stay is ((inaudible)) affect the outcome rate. But here it clearly, the hospitals that keep babies longer are going to be at risk for having a higher - for suggested infection rate.

What I - my impression when I looked at this measure, and I think this is the one that the Joint Commission is working to align, right?

Jochen Profit: Yes, I think so.

Elizabeth Drye: This is the ((inaudible)) and the JC has a chart of extracted ones. I'm really impressed with the amount of like careful consideration of each of these issues.

But some of the design features if somebody thinks that outcome measures in that ((inaudible)) guidance on outcomes measurements are a little bit - I mean I would like to understand them better too which I wanted to squeeze my question in before AHRQ talks. Which it - for example, you know, I mean some of the relevant outcomes that you would care about that are ((inaudible)) infection, like defined in denominator and I think that's kind of unusual.

That's another, you know, you have to think about whether that can introduce some bias into the measure and there are other issues like that. But I feel like the measures have been worked on really intensely by people who are the users of them as well as the developers.

And I was just - I think there - it's really worth understanding them better if we can and spending some time on those details because certainly for these measures we don't - we all agree on the importance criteria but the details are going to define whether they're a really scientifically sound measure or not. And that's another important criteria.

Reva Winkler: Okay.

Rebekah Gee: This is Rebekah; just quickly, I would love to know what percentage of infants are transferred and what that problem - what is the scope of that issue. I'm sure it depends on your level of NICU but just in thinking that's a really important point and I'd just like to - I don't know if we have data on that.

Reva Winkler: Right. Do we have anybody from AHRQ with us?

Elizabeth Drye: So even just the data - sorry, just in the variation on the transfer rates and the variation of the length of stay across hospitals that would be measured. That would - both those things would be informative.

Reva Winkler: Okay. Is anybody from AHRQ on the line with us?

(John Bosworth): Yes hi, it's (John Bosworth), AHRQ.

Reva Winkler: Hi (John).

(John Bosworth): So what - that last question, maybe we can look into before the November 29 meeting is the person inquiring about the percent of infants transferred out to another facility?

Elizabeth Drye: Yes, what is the percentage of infants who were transferred during a NICU - you know, an infant goes to a NICU, what percentage of those infants are transferred at some point during their NICU experience.

(John Bosworth): Transferred from - to another - from the NICU experience to another hospital?

Elizabeth Drye: Exactly.

(John Bosworth): Okay I'm not sure we'll - we'll see if we can look into that for the meeting.

So there was a question about in hospital deaths though and the denominator statement. So these are, you know, folks at higher risk of the infection. So the third denominator criteria is birth weight greater than 1500 grams, and potential for some conditions to be met and one of those is in hospital death. That's the only case where - so in that case somebody meets the denominator.

The way I read the ((inaudible)) for this, the first two denominator case is birth weight 500 to 1499 grams, that the person could die or live and be in the denominator, gestational age between 24 and 30 weeks, the person could live or die and be in the denominator, but if the baby's at - over 1500 grams, one of these two conditions under that have to be met to make the denominator.

And you know, there's another question about transfers out, they're in the denominator unless the length of stay was less than two days. Is that right; those were the questions ((inaudible)) that I believe somebody asked.

Jochen Profit: Yes well yes, thank you for that. I guess the, you know, the question is essentially about the potential biases that arise with transfer and can we - are we able to, you know, to at least sort of account for them or figure out what the magnitude of that bias might be? ((inaudible))...

(John Bosworth): Yes so a covariant is a transfer in, so obviously we saw that that was substantially related to the outcome of interest. So we have one case in the covariates of what we call modified DRGs where the person died or was transferred to another acute care facility, that's also a covariate so that's taken into account in the risk adjustment.

So that's - trying to - be responses to at least some of your questions. So a couple of those situations are accounted for in the risk adjustments.

Jochen Profit: Okay. I...

Elizabeth Drye: And just another thing that would be helpful to know if you do know, you may not have the data but administratively - in administrative data it's kind of hard to find, if you could just describe the variation in length of stay of the infants in the cohort because if you have, you know, hospitals that have, just by policy have a ((inaudible)).



So ((inaudible)) chance there is for them to develop an infection and some of that's going to be transferred, but some of it may also just be, you know, differences in home support and exactly ((inaudible)), et cetera.

(John Bosworth): Go ahead.

Rebekah Gee: It's Rebekah, just to get to follow-up on that question as well, has this measure or other infection measures been stratified by level of NICU? Because I would think that would account for some; certainly if you're a higher level NICU you're likely to have higher risk infants for longer periods of time? Has that been looked at?

(John Bosworth): Well there's what we call (Canned Stratifiers) and our quality indicators I'm almost positive that's not one of the (Canned Stratifiers) but there's, you know, always the potential for the user of the software to stratify the data in ways that they're able to or that the ((inaudible)) one status that allows them to.

So if - I haven't seen that information, but if somebody has that granularity in their data they could stratify that way through the AHRQ software. But I can ask if we have that, but I haven't seen it.

And also I've made a note of the variation in length of stay and denominator ((inaudible)) if we can gather ((inaudible)) few things before the meeting.

Jochen Profit: So for this measure as well as for the Joint Commission measure, could you explain a little bit to us - I'm sorry I don't know this maybe as well as my other colleagues, like how those ICD-9 codes are gathered; are all of them gathered from a chart review or this is all from what people submit as claims or is it - like sometimes health plans will only have - like they will only record like the first two or three ICD-9 codes and/or they will maybe they'll extract them all but they will only look at like the first two or three. So would you have like a long list of diagnoses, whatever is

being recorded on an individual patient, or you know, or are only the first couple kind of extracted? How does it sort of practically work?

(John Bosworth): Well for the AHRQ quality indicator, I'll let the Joint Commission talk about their version of the measure, which I'm not ((inaudible)) Dr. (Patrick Romano) who worked the most closely with the Joint Commission in the harmonization of the measure.

So there'll be a much richer conversation of this on the 29 of November when (Patrick) will be there in person. So with the AHRQ (QI) software, it's approximately 30 diagnosis codes and roughly 30 procedure codes are accepted into...

Rebekah Gee: Okay.

(John Bosworth): ...the AHRQ (QI) software for processing to compute this measure.

Jochen Profit: Okay, thank you.

Reva Winkler: Okay. Are there any other questions around this particular measure, 478, this is the measure from AHRQ, you've been talking with (John) about before, because the next measure is essentially the same measure, but it's specified by the Joint Commission for a different form of data collection. So does anybody want to - have anything further they want to talk about 478 before we move on to 1731 and talk about the specifics of the Joint Commission version of the measure? Okay then let's do that.

And let's go to 731. Scott I think this is your measure. And we have (Anna Celeste) from the Joint Commission on the line. So I, if my...

Scott Bern: All right.

Reva Winkler: Yes.

Scott Bern: Okay.

Reva Winkler: Go ahead Scott.

Scott Bern: No go ahead Reva, what were you going to say?

Reva Winkler: I just wanted to mention the measure that we just talked about, 478, was originally endorsed during the prior perinatal project. And the Joint Commission had selected five of the measures from that project to put into their new maternal child health measure set.

And this measure is submitted using the data collection system that the Joint Commission uses for all of their measures, which is different than the data collection that AHRQ uses, and so therefore we have a second measure.

So but my understanding is there's been tremendous effort on both of their parts to keep the measures as harmonized as the data allows. So with that I'll let you take it Scott.

Scott Bern: Well I think we're finished with this measure - no just kidding. I just want to first start out by saying that, "I thought this was very, very well written. This measured title of healthcare associated bloodstream infections in newborns.

As you know, it is submitted by the Joint Commission. The measure assesses the number of septicemias ((inaudible)) in high risk newborns. And you'll note that the - I think the numerator and denominators are pretty much exactly the same as the last measure. Is that correct; did I read that correctly Reva?

Reva Winkler: I believe so, we can have (Celeste) and company verify it.

Scott Bern: Yes I think there was one typo perhaps under denominator statement it says, "Or birth weight equal to 1500 grams," I think it meant greater than or equal to, I think, 1500 grams.

Reva Winkler: Yes.

Scott Bern: It is noted on Page 16 that this is adapted from Measure 478, and Reva answered one of my questions which was, "What actually prompted this being adapted from 478?" So why don't we just go to those who reported here on the spreadsheet. And I think we all ranked, in terms of importance, either high or moderate, and importance all, "Yes."

So I don't see any comments, except from me. What did I say here? Consistency results cross study section blank; oh yes, that section's left blank but there was plenty of information in other sections to help me answer this. So I'll just put a little note in there about that.

Any questions about importance or other comments from those who have reported in here or those who've read it and haven't been able to respond to the survey? All right.

(Crosstalk)

Scott Bern: The next section we all, looks like in terms of acceptability of measure properties, reliability and validity, looks like we were pretty much in the moderate range.

Elizabeth you might want to make a comment as well. I think we did both note, I think if I remember correctly, the note in the measure right at that further liability studies would be done

late in 2011. Not quite sure exactly how that impacts whether this gets indorsed or not, but I'd like to hear more about that or from the Joint Commission.

And then I was curious that some of the measure exclusions were not derived directly from the evidence. So I think there was a mention in there about CMS and just curious about on that comment in there. Anything else on this section, on Section 2 from anybody?

Rebekah Gee: I put a - one of the things, this is Rebekah, I wondered was, "Why 120 days? Where was the thinking for length of stay?" More a curiosity in terms of was there a data point inflection there.

Reva Winkler: Did you want to have the developers respond to those questions about the scientific acceptability right now?

Scott Bern: That - I think that would be helpful for the group, don't you?

Reva Winkler: Yes. (Celeste) can you?

(Celeste): Sure Reva. Hi, this is (Celeste) at Joint Commission. The reason for the exclusion for those patients that are there greater than 120 days had to do with how we've aligned all of our measures with CMS. Basically has to do with billing cycles, being billed on a quarterly basis and sometimes measure specifications change from quarter to quarter.

We did do an analysis of that exclusion and it does appear that we - about 3.64% of the time we do have some patients that stay longer than 120 days. So it's only been applied because we do it consistently with all of our core measures. That would have been the rationale.

Rebekah Gee: Sounds reasonable, thank you.

Scott Bern: Hey (Celeste), maybe you can answer the question about the reliability studies that were coming, or maybe they're already here, and then the measure exclusions that were not derived directly from the evidence.

(Celeste): Okay, it's timely you're asking about reliability because I'm in the throes of that right now, I'm leaving to do another visit tomorrow.

So we'll have completed five visits as of tomorrow and we won't have our entire 12 visits completed until the end of January so the reliability visit you saw was some inter-rated reliability from some hospitals that were currently using the measures. But we will have an update on that. And actually I can tell you for the most part we're matching pretty closely when we do these site visits.

Now you had questions about exclusions that were not from the evidence.

Scott Bern: I was curious about that comment that was made in there just - yes.

(Celeste): I'm trying to find it here. I know that my sheet looks different than your sheet.

Scott Bern: You know what, it was - it's a relatively long document I'll take - and I don't have ((inaudible))...

(Celeste): Sure is, isn't it.

Scott Bern: So I can't do a Word search, but there was a note in there about some of the solutions that were not derived directly from the evidence. I was just curious about that.

(Celeste): Well the 120 days would have been one.

Scott Bern: Okay.

(Celeste): The length of stay of less than two days would have been the other. The enrolled in clinical trials would have been the other.

And the clinical trial, once again that would be another thing that is common to all of our core measures, and when we ran the analysis on that it came out that it was 0.02% that patients were enrolled in clinical trials. So that was an extremely low amount. And that was by analyzing 356,671 cases.

Scott Bern: Yes. Yes that's right, it's at Page 19, that's exact - those were the three that were listed.

(Celeste): Right, right.

Scott Bern: Yes.

(Celeste): So - and it's kind of just how we do the measures here. and I think the thought process was on if they're there less than two days they're probably getting transferred to another facility because they're really sick, or they're a very healthy baby and they've gone home.

Scott Bern: Got it. Reva how are we doing?

Reva Winkler: I think you're doing fine. I guess one other question I would ask both (John) and (Celeste) is, "Given you guys have worked hard on harmonization, could you outline how these measures are different after your harmonization work?"

(Celeste): Do you want me to go first Reva?

Reva Winkler: Sure go ahead.

(Celeste): Okay, this is (Celeste) at Joint Commission. There are some differences. One thing that we do allow for with our measure is that we do allow for the hospital to actually view birth weights, because not all birth weights are captured with ICD-9 codes, they actually stop it once you reach 2500 grams unless there's a problem with the baby.

So we do allow for them to interface into their systems to pull out actual birth weights. That would be one thing that's different. And because we are actually allowing for birth weights, we don't use gestational age as another criteria for bringing them into the denominator.

We try to be very straight forward, "They're either 500 to 1499 grams or they're greater than 1500 grams with at least one of the following; they would have to experience death, mechanical ventilation, major surgery, or have been transferred in within two days of birth."

Scott Bern: ((inaudible)).

(Celeste): So we kind of made it a little more clear-cut with our denominator.

Scott Bern: Before you go on, you clearly - you know this measure so well you're going too quickly for me, I'm not looking at it.

(Celeste): I'm sorry.

Scott Bern: No, no. I thought that Measure 478 did that as well, I'm trying to look at that. What did they - because they do it by birth weight, no? Did I ((inaudible))?



(Celeste): They do it by birth weight but they don't allow birth weight, they allow ICD-9 codes which may not always be present on the medical record if this baby's a healthy weight. They won't be coding for a birth weight if they're a healthy weight. Let's say they're 3500 grams; there is no ICD-9 code...

Scott Bern: Right.

(Celeste): ...for a healthy 3500 gram baby.

Scott Bern: Yes, but they were also - but they're capturing those who are above 1500 grams who have the same - I think the same three inclusion criteria that you have, right?

(Celeste): There's actually four when they're 1500 grams, and yes it's the exact same -- we harmonized in that respect.

Scott Bern: Okay, in terms of death and operating room procedure, ventilation. Okay got it.

(Celeste): Yes they're exactly the same.

Rebekah Gee: But one of the differences...

(Celeste): And we've actually worked further to harmonize all of our code tables as well. We realized that there were some codes that were - should be removed, some that should be added to actually a lot of the tables. We worked through each one of the tables and did a side-by-side comparison.

Jochen Profit: This is Jochen Profit.

Rebekah Gee: And this is Rebekah, I think one of the things that's nice about this measure is you don't get gestational age where you know, problems with dating criteria, documentation of dating et cetera, you're not - you're just concerned about birth weight. So I think that - I don't think that any other measure uses only weight. Is that correct?

(Celeste): We'll have to look at them and see. It's usually a combination of the two.

Jochen Profit: Small for gestational age may be a significant predictor of infection now. So I guess you could say it's a benefit and it may be an advantage and a disadvantage at the same time, right?

Teri Kiehn: This is Teri. I feel the same way not having the ability to look at both the weight and the gestational age.

Reva Winkler: Okay.

Jochen Profit: Have you run any correlation analysis between the Joint Commission measure and the AHRQ measure?

Like I just wonder how, they're so similar like that so I find myself - I actually didn't submit this measure because I felt like, okay I feel like I would have to say the exact same thing as for the AHRQ measure and it alluded me a little bit to tease out the exact differences between these measures.

So and I guess one of my concern would be that the steering committee would agree to I guess give the stamp of approval for all measures that are all related to the same kind of greater construct and then make hospitals do work on four or five different measures that all kind of, you know, measure really a very similar thing, which I think is the, you know, the whole point of the harmonization work that you've been doing.

So I guess I just wonder like how close - how closely are these hospitals correlated when you compare them between your measures and is it worthwhile having two measures?

Scott Bern: I think Reva was trying to - Reva you were trying to get us to that, right, that question?

Reva Winkler: Well I think the question that he asked was one I was actually going to pose, "Is there any or do you plan on doing any comparison between the two to really understand how well they compare?" I mean on paper with the specifications they seem as closely aligned as you can get, but how do they behave given the different data systems.

I think that's a question that would be sort of generally useful going forward. My guess is you don't have that data but it would be great if somehow you could capture that sometime. Any thoughts like that (John) or (Celeste)?

(John Bosworth): I don't know if we've done that analysis. Like I say, (Patrick) worked really closely with (Celeste) on this so maybe...

Reva Winkler: All right.

(John Bosworth): ...(Celeste) knows if we produced that during the work. (Celeste)?

(Celeste): I'm not aware that anything was run in that respect. We do have what our rates have been, where we've been ((inaudible)) nationally, and I guess the only thing I can say is that this is one of five measures in a set of measures that when a hospital selects our perinatal peer set, it's one of the five that they would select. So they are reported as a (THAT).

Female: Right.

Scott Bern: So this is Scott. If I'm hearing you correctly then, and basically the Joint Commission adapted Measure 478 so that its members who report their data through your system can report it, to choose the five or you know, the perinatal care core measures. Is that what I'm hearing?

(Celeste): Yes that's correct. We ((inaudible))...

Scott Bern: Right, so...

(Celeste): ...like all of our other core measures.

Scott Bern: So then I guess the question for the steering committee will be from a harmonization standpoint, an endorsement - it's really the same measure but it's actually - and I know you did a lot of work to put this together, I can tell based on the write-up, but it's really meant to - I'm trying to figure out the reason for potentially endorsing this as another measure as opposed to the mechanism through which Joint Commission folks who report on the measures are able to report on this measure.

Reva Winkler: Yes.

Scott Bern: Did that make sense?

Reva Winkler: Scott, this is becoming a huge issue, as you've rightly pointed out, and ((inaudible)) pointed out that you know, many measures on the same topic makes it very difficult for the world out there.

And so one of the next steps that we're going to be discussing on the agenda on the 30th is this issue of related and competing measures, and we actually have, NQF has some guidance around it.

When we look at measures for these two they're essentially the same measure; is it acceptable to have two, what might be the reason for having - for it being acceptable for having to or - and that's a real discussion point for the steering committee going forward.

And I think as someone mentioned, you know that, we've got a whole series of them that are very similar. And we're going to have to apply it and do some - look at some side-by-sides and really tackle what is truly a thorny issue.

And so - but our first step is really to look at the measures individually and find out - be sure we understand everything about them as individuals because if we find the measure has a fatal flaw for some other reason then it's off the table and we don't have to think about, you know, the comparison part.

So that's really what we're trying to do today. And so I just alert you that our next step and some of the materials for the in person meeting will be additional information on that guidance for looking at these very similar measures.

And also I'm going to pull in another measure that I think it was Scott mentioned earlier on (CLABC) that was dealt with in another project so that we can really start looking at the pros and cons of these very similar measures and asking that - the question you're asking, "Is - what's the value of having all of them? What are the differences?" You know, "At the end of the day do we need all of them or do they all provide value?"

And so we'll do that as a next step. But indeed it is probably one of the most difficult issues the steering committee will have to grapple with going forward. But we will do it because it's so very important.

Scott Bern: Well that's really helpful. And this is Scott, I appreciate that. So maybe just to help things keep rolling here, it's almost 4:30 Eastern Time, in terms of the usability and feasibility, the three who reported here did have a range in terms of usability. And Elizabeth may want to comment on here.

And then feasibility was moderate or high and we've all said, "Yes," in terms of suitability. So Reva, I'll turn it back to you for any other thoughts or comments we need to address for this measure.

Reva Winkler: Okay.

Elizabeth Drye: This is Elizabeth, I will squeak in a comment I guess. First of all, I think that was you Reva saying that, we're going to - you're going to have a side-by-side on these measures which would be fantastic.

(Crosstalk)

Elizabeth Drye: So we'll eagerly look forward to reviewing that, along with advice about how to balance them.

And I think I heard someone say that this measure - I just want to clarify this before we go further which is, "This measure - the Joint Commission's thinking about allowing this measure to be used in - I mean the 478 measure ((inaudible)) want this measure," was that true or no? That's what I

thought I heard them saying. Well anyway, we don't have to get into it today we can take it up later.

But what's the big - the two big issues for me were, one was already raised which was, you know, "What is the correlation and the ((inaudible)) for using these, so you know, carefully aligned measures to assess hospitals, are you seeing a correlation in the performance, in the reported rates in the end?" Because that's - if you're saying they're the same measure you'd really want to know that they were ((inaudible)) hospitals primarily."

But more important, I'm just looking at Page 20 of the application, it concerned - and I'm really sensitive to rating this because I had develop outcomes measures and a common critique of our measures is that they, you know, there's - they don't show enough variation.

Well a concern about this measure is just that the range of the outcome rate, the risk-adjusted outcome rate, it doesn't say that but that's what I think they're presenting in 2b 5.3 on Page 20, there is a range from 0 to 1.64, 1.64% in the 90th percentile but none of the differences were statistically significant.

And I again, I don't think that's a killer, but I just - the variation is what it is, I'm not somebody who would say, well that you know, "They don't show enough variation; what the measure should be showing is a measurable variation."

But that's just something to think about when we think about the usability of the measure, is it really - is it you know, is it able, given the sample size we have and the event rate, are we - and the various ((inaudible)) within the hospital where this is just between patients, are we able to move between hospitals ((inaudible)) between patients, are we able to really show that statistic that there are differences?

And so it's great this is a really complete application and it's just something ((inaudible)) committee to think about. I don't know, AHRQ didn't seem to have similar to AHRQ measured and have similar data show the raw rates but not the risk-adjusted rates.

But I'm just citing my - I think I've confused people, but basically the bottom line is that the results do not show any specifically different - any differences from the target range for the 79 facilities.

Reva Winkler: All right, so you think the usefulness criteria is your concern? Is everybody...

Elizabeth Drye: Well there are ways to address this, you know, that are independent of the measures that are - there's way to work around it, for example combine two years of data. You basically need to give our sample size, right usually? To have statistical significance on a low event rate like this. But I think it's an issue to think about if you're going to report and none of the results are statistically significant, you know, how - we have to think about how useful the measure is.

Female: Right.

Jochen Profit: I think that's a very good point.

Reva Winkler: All right.

Elizabeth Drye: And I think we should have the similar data available for AHRQ, I think they probably have that, but I didn't see it in the application.

Reva Winkler: Okay. See if we can pull out something to do some comparisons.

Okay we have two measures left in the last 1/2 hour. And these are Measures 303 and 304. And they both come from an Vermont Oxford Network. And 303 is late sepsis or meningitis in



neonates, risk-adjusted. And 304 is late sepsis or meningitis, and very low birth weight neonates risk-adjusted. And I just wanted to ask the developers the question, "Is 304 a subset of 303?"

Male: Yes.

Reva Winkler: Okay. So essentially they're both the same measure, it's just one is applied to a narrower weight - birth weight range.

Male: That's correct.

Reva Winkler: Okay.

Male: Yes, it's a narrower population, that's correct.

Reva Winkler: Okay, so given that perhaps we can be efficient in discussing the two measures together.

Male: Sure.

Reva Winkler: And Jochen that's yours I believe.

Jochen Profit: Yes so I guess I'll just start with the, Number 303. So essentially 303 - 304 includes only babies less than 1500 grams and there's some gestational age criteria too. And 303 is a measure that includes also larger babies. Is that a fair?

Male: That's great.

Jochen Profit: I think that's fair to say. And so this is a measure that is already being collected by, I guess over 900 NICUs worldwide that are part of the Vermont Network, the Vermont Oxford Network.

And the numerator, infants either need to have a, essentially a positive blood or a CSF culture obtained after Day 3 of life, so it's sort of the classical nosocomial infection criterion. Or the other criterion is to have a coag-negative staph plus certain other criteria that would suggest that this baby is being treated with the intent of treating it in sections, so treatment for five or more days or generalized signs of infection.

And then in the denominator essentially is all the eligible infants after they are three days or older.

Male: After Day 3 actually.

Jochen Profit: After Day 3.

Male: Yes.

Jochen Profit: Where Day 1 is the date of birth, correct?

Male: That's correct.

Jochen Profit: That's good okay. And so I'm just going to take a look here at the ratings with regard to the importance ratings. Most of the ratings were within the high and moderate range except for Scott, who had an insufficient rating on criterion 1c. Scott would you like to comment on that one?

Scott Bern: Yes I just would have liked to have seen more there. I mean I'm - I know that the studies are out there but I just felt like, you know, I think that answer in that section was numerous. And I just felt like there could have been more written in there, although it did still meet the ultimate threshold to move on from here. That's why I coded it as insufficient.

Jochen Profit: Okay. Does anybody else have any concerns regarding the importance criterion? If not I'm going to move forward to scientific acceptability, which again really was rated mostly in the moderate to high range except for Elizabeth who had some concerns regarding the scientific accuracy. Elizabeth, would you like to comment on your concerns? This was 2c. Elizabeth?  
Hello?

Reva Winkler: Yes, Elizabeth.

Elizabeth Drye: Sorry, I was on mute.

Jochen Profit: Okay.

Elizabeth Drye: When I ((inaudible)), sorry. I just felt like the denominator, and maybe I didn't understand it correctly, was really complicated and there was a lot of data abstraction. There is experience with the measure so it was more of my just finding concern reading the specifications, wanting to understand better how accurately this information can be abstracted and whether there's, you know, mechanisms in the - these are pulled out of a registry, correct?

Male: That's correct.

Elizabeth Drye: And reported for participants in the registry. So I just didn't know what the quality of that data is basically, I mean how well it's reported and whether there's any validation of it or you know, sampling of sites. There's a lot of uncertainty to me about the - what's going into the measure calculation and its end quality. That was the main...

Male: So I think one key point about that is that our manual does give specific definitions of the items. But we do have extensive Business Rules that look to see, you know, are the measures consistent with other information we have about the baby.

So for example if the baby's not, is not in the hospital after Day 3, then they're excluded from the denominator and we have rules that make sure that that occurs.

So you know, there is an issue with any measure of course with data equality that is something we're very concerned with. We have an extensive finalization process each year for example, that we go through to make sure that all the data are collected and that there are no errors in the data again, with these business rules that we have implemented.

So you're right to question that. And I think that what - from our standpoint at Vermont Oxford, we try to make the definitions operationalize to the point where they're reasonably easy to understand and then we verify the data through these business rules and so on. So I think we're doing the best we can with that is all I can say.

Elizabeth Drye: Yes, and I mean it's always hard in an ((inaudible)) data. But I, I mean ((inaudible)) somebody reviewing it, it's hard to know any of that.

Rebekah Gee: This is Rebekah. One of the things I wonder was how important is the type of bacteria? And I'm sure you've looked at that, but would love to know more about it, particularly how important is Coag-negative staph?

Have - did you look at this measure excluding Coag-negative staph? What proportion of cases could be attributable to that, how much - you know, there's some debate within the field about how meaningful, and that's why I think you have these exceptions, or additional criteria with it. How important is that as contributor to actual morbidity?

So I just would love to hear more about that, the thinking behind the bacteria.

Male: So in 2010 for example, which is the last year that we have finalized the data for at this point, for the population that includes very low birth weight and larger babies, we had about 116,000 babies in the denominator.

And the nosocomial bacterial infection rate was around 3%, little over 3%. And we do look at Coagulase-negative staph separately from the latent bacterial pathogen, it was about 2%, 1.6% in fact for Coagulase-negative staph and 2%, 2.1% for latent bacterial.

Now for the very low birth weight population, which is - this is more important measuring that population for sure. We had about almost 53,000 babies in that category in 2010, and the nosocomial bacterial infection rate was around 15%. So and that breaks out to about 8.3% for Coagulase-negative staph and 9.1% for latent bacterial pathogen.

Rebekah Gee: Thank you.

Male: You're welcome.

Scott Berns: You know what can I just pick up on that for a minute? This is Scott. I realize that very low birth weight infants are a higher risk of infection, and that's perhaps why you said it's more important. But this - but I would think the aggregate measure is perhaps more important, because it would give you - even though the percent might be lower ultimately, given the denominator is larger and with some lower risk babies.

Wouldn't it be more reflective of how you're doing - a better reflection of how you're doing overall. I mean you - you know, VON has been doing this for years, so I'm just curious on your answer to that?

Male: No I think that's true; that if you're interested in looking at your NICU as a whole, that for sure, you know, including those bigger babies is important. And in fact, I mean, we do stratify for example, along with doing risk adjustment, we stratify by birth weight category and gestation.

And so, you know, you can look at the bigger babies separately if you choose to do that. All I - and maybe I chose the wrong word, all I was trying say is that, "It is much more prevalent in smaller babies."

Scott Berns: Yes, I agree with that.

Elizabeth Drye: ((inaudible)). Are the data submitted NICUs and the broader pediatric population a hospital, across hospitals or just NICUs?

Male: Well for the smaller babies, it includes any baby that's between 401 and 1500 grams at birth or between 22 and 29 weeks gestation. For the bigger babies we only include infants who are admitted to the NICU or who die within 28 days of life in the reporting hospital. Did I answer your question, I may not have?

Elizabeth Drye: ((inaudible)) regular newborn nursery and you - are you considered in the measure or did they report on you not, for the bigger babies?

Male: For a bigger baby you have to have been admitted to a NICU...

Elizabeth Drye: Okay.

Male: ...or had died in the hospital within 28 days.

Elizabeth Drye: Okay.

Male: So it's based on NICU admission or death.

Elizabeth Drye: Okay, so really you're not really covering the non NICU population.

Jochen Profit: I did have a question about that; I think that's Criterion 3 in the numerator details. So in a lot of tertiary coordinated care centers there's, you know, there's a cardiac ICU, and it seems like a lot of babies might fit, or you know, be cared for in a cardiac ICU.

But that would not routinely really be submitted to Vermont Oxford unless that unit was somehow part of Vermont Oxford too, right?

Male: Well that's the point. The way we define eligibility for the larger babies is that they have to have been admitted to a NICU, which we define as, a location in your hospital that provides intermittent mandatory ventilation.

So I'm not sure if that would always apply to a cardiac care unit.

Jochen Profit: Yes, I think I guess it's just probably very specific to individual hospitals. So like we would have many babies in our IC - cardiac ICU that would be ventilated, but...

Elizabeth Drye: And I don't know if it also just, you know, it's challenging with registries to set a routine data collection...

Jochen Profit: Yes.

Elizabeth Drye: ...that varies across the hospitals. So I'm just wondering if - generally you're just getting data on NICU babies, because that's where they're set up to, and then get in the registry.

Jochen Profit: Yes, I think that's probably right. Yes. I had one question about the statistical analysis with the regard to the shrinkage, and that's probably true for many of the hospitals with the other risk adjustment measures too.

So we've toyed with shrinkage on some of the monitors we have run. And sometime - you know, what happens with the hospitals that have smalls ends, you know, they might be in the middle of the pack even if they have zero infections.

And I guess I just, like, so this is one of the concerns I personally have for public reporting. Because the hospital could - you know, unless the data is presented well you could have, you know, done everything right and not have an infection but list - be listed essentially as sort of a mediocre provider.

Male: Well that's true. I mean if you're small hospital, what the shrinkage does is it controls for noise, if you will. So that if you have few babies, and we don't want to send a signal that you're doing better or worse than expected unless there's good evidence.

For example I was looking at another measure, not this particular one, recently, and there was one hospital that was - that had 32 babies that there was a signal for the entire year. In fact the measure was mortality. And this particular hospital did worse than expected.

So I mean it certainly is possible, they had quite a high mortality rate. But what we don't want to do is just routinely signal that you're doing better or worse...

Jochen Profit: Right.



Male: ...if you're a small hospital without good reason for doing so. So that's the whole idea is you basically are shrinking the value of the observe minus expected statistic or the standardized ratio statistic, toward the mean value based on size.

And you know, there's - I think in the documentation we provided we gave some information about an empirical Bayesian method that we use for shrinkage.

Jochen Profit: Yes. Like so I guess that's these - does anybody have any other concerns about the scientific aspect of this measure?

Elizabeth Drye: I would just add again -- this is (Elizabeth) -- setting, you know, worked a lot on - with similar models and outcome measures. In the end, I mean I'm kind of stating the obvious.

As frustrating as it is when you have very few observations and we can't really draw any real conclusions without those measures. And so your strategy, you know, you can try to accumulate more observations by going over more years of data and...

Jochen Profit: Right.

Elizabeth Drye: ...that we're just a little bit stuck and have to keep going anyway because we want a better outcome. But it's hard to do with very small hospitals.

Jochen Profit: Yes, okay. Then with regard to usability, with regard to public reporting, I guess we have measures going from low to high. I'm not sure if we've already talked about that right now, if somebody wants to maybe Elizabeth you said, "low," and Scott you said, "high." Maybe if you...

Scott Berns: Well I had a caveat on mine they're - just in terms of the usability and maybe, I'm looking to see what Elizabeth - yes I think Elizabeth had the same comment, in terms of the usability for VON members?

Jochen Profit: Right, that's correct.

Scott Berns: Yes, that's what I was commenting on. And no public reporting unless the hospital chooses to do that, and then I think you had a comment on that as too - as well.

Jochen Profit: Yes.

Scott Berns: Anyway, yes.

Jochen Profit: Yes. Okay and then feasibility of course is kind of - I assume that probably has similar comments I would think. Elizabeth again you had a couple of lows.

Elizabeth Drye: Yes I mean again, I just - it's very hard - I don't know, but ((inaudible)) about participating in the registry at this point.

Jochen Profit: Yes.

Elizabeth Drye: And you know, my first question was, "If it merits a NICU, you know, babies in NICUs, I don't know if it's big or small, but it is a big enough ((inaudible)) and it's a measure that you guys haven't ((inaudible)) before that.

And I'm a little more concerned about the broader measure. I think other people have expressed the - because again, if you're not sure which population of the babies you're capturing or not

capturing the measurement is more concerned about implementing the measures similarly across hospitals.

Jochen Profit: It would be kind of interesting to figure out the causation between the VON measure and the AHRQ and the Joint Commission measures to me, because - so the AHRQ measures are all based on claims data and the Joint Commission as well, if I understand that correctly.

And VON measures are based on essentially chart review, either electronic or paper-based chart review. So there's, you know, there may be a trade off in doing chart review and maybe you do get - you might get higher quality data with all the data checks, but you also may have more burden of collections.

Riva Winkler: This is Reva, just to say, the Joint Commission's data collection is also - they use their vendors who use data collection tools which are frequently chart-based whether electronic or paper.

Jochen Profit: Okay.

Riva Winkler: So (Celeste) if you're still on the line, did I get that right? She may not be, but that's the typical Joint Commission - they use vendors to do the data collection for any of the measures in all...

Jochen Profit: I see.

Riva Winkler: ...the different topic areas.

Jochen Profit: Okay.

Riva Winkler: So I think...

Jochen Profit: You know, I think there's - I think for the last question that Elizabeth had I think there's about maybe 1900 NICUs or so in the country, or about 1900-2000 NICUs in the country as far as I know.

And then I'm not quite sure how many NICUs are part of Vermont Oxford, but then maybe contact from VON has that number, how many U.S. NICUs are part of the VON?

Male: One second, let me see if I can find that number.

Male: Well while he's looking that up I can tell you that there are around 800 Level 3 NICUs, which would probably take - which would be taken of those very low birth weight babies.

Rebekah Gee: It says, "293 hospitals," on Page 3.

Jochen Profit: Okay.

Rebekah Gee: And I know we have 17 facilities in Louisiana that report to VON and we're doing a statewide quality improvement effort around this data. And we have not heard a lot of complaints from facilities about the VON metrics.

It's fairly well tolerated, people have bought into VON and, you know, our groups have been much more early adopters of using these NICU measures than they have on the maternity side.

So I haven't - I didn't have any concerns in the regard of usability just because I - my docs love to complain when I go talk about quality improvement, and they haven't complained about VON.

Reva Winkler: Just as we're getting to the last minutes I just wanted to ask if there was anything about the second Measure, 304, which is just limited to the very low birth weight babies. Was there anything in addition to it?

And I guess sort of a question for everybody is, "Why not just stratify and measure 303 by birth weight? Is there a need for a second measure?"

Male: Well we do actually stratify by birth weight, but when we do the risk adjustment is a different population, so, you know,...

Reva Winkler: Okay, all right.

Male: ...to report the measure for someone who's reporting all their babies is a different model.

Reva Winkler: Got it.

Male: And if I might just say, "We have 654 U.S. hospitals that participate in VON."

Reva Winkler: So 654 hospitals?

Elizabeth Drye: Yes, and that's pretty high. I had one last thought or comment on the on the measure, which we think risk adjustment includes race and, you know, ((inaudible)) guidelines and my own view is that we shouldn't be risk adjusting a race because for race in a measure because we'll adjust away differences in quality that we actually want to eliminate in a measure like this?

So that's the concern is that you have for example, worse outcomes for blacks, your - the expected on these measures for black patients will be higher, the expected and hospitals, you

know, are going to get held to different standard when you incorporate race in the risk adjustment.

So that's - I'm not happy with that about this particular measure, and I think it merits discussion at some point ((inaudible)) steering committee.

Male: It's an interesting point and I'm sure we could spend quite a while talking about that one.

But I guess our - don't - there has been quite of discussion here about improving our models and we had looked at that in particular and we don't find that race makes much difference, in fact, as far as predicting infection. We have not changed our models, but it is something that we're considering, you know, for the future.

Reva Winkler: This is Reva, just to mention that in general if you look at NQF's evaluation criteria around risk models and disparities, we generally encourage and support not including disparities type population variance in - still variance in risk models, such as race, ethnicity, social economic status and all that.

Actually we're - NQF is in the middle of doing some further work on measurement of disparities and those kind of recommendations are due out fairly soon. And so it's an ongoing conversation, but it is an important one to begin addressing things in the same way.

Fine, okay. We're right at our last minutes and we don't want to keep anybody X over. As I mentioned this concern about the fact we've know just looked at four measures all talking about essentially nosocomial or healthcare acquired infections, whether they are blood stream or blood ((inaudible)) or any other measure, I'm going to show you is just that the line associated, they're still very tightly related.

So this will be a big issue for this particular set of measures to grapple with.

So in the next couple of days look for further information as we start comparing these. And we're going to want to compare things about, you know, what type of infections are included, what type of babies are included, what time frames are included, what are the definitions of how an infection is determined to be captured in the numerator?

So all of these are important issues, because even if we have multiple measures, we would certainly want them to be harmonized so that hospitals aren't trying to respond to multiple disparate measures and that.

I can go ahead and encourage you all to keep that concern about the users having to respond to multiple different measures in the forefront of your considerations. Because it is certainly a message we hear loud and clear from all sorts of users out there.

Jochen Profit: Could you quickly say something about what happens typically when, you know, an NQF measure is, you know, approved to the health plans, then usually go to a hospital and say, "You know, this is NQF endorsed, please go ahead and submit this information to us or?"

Reva Winkler: Yes. I mean I think there are whole variety of things, but certainly there are lots of potential implementers who looked at the NQF list of measures to develop programs and certainly health plans do it, health systems do it, states do it.

For instance, like Medicaid programs might, you know, have a different set compared to other plans. So we certainly know that there are any wide variety of potential implementers who do it, so it's quite conceivable that a hospital is reporting to the Joint Commission, their state is reporting the AHRQ measure, which is a common thing. You can go to any number of states' Web sites and look at data on the AHRQs.

That same hospital is reporting to Vermont Oxford, okay, and then the (cloud C) measure, which is I'll bring it and show you it's from the CDC.

Jochen Profit: Right.

Reva Winkler: So you know, everybody feels a little bombarded, and when they're not aligned and not harmonized it just can make you crazy.

Jochen Profit: Yes.

Reva Winkler: So we're going to want to keep that in the forefront and really pay some significant attention on asking the question, "Do we need all of the measures and for the ones we feel we need, are they harmonized?"

And wanting to put yourselves in the position as in a sense that in the hospitals we're collecting the data and doing the reporting, which many of you are, you know, how crazy do you want your life to be?

So it will be an important conversation that we're going to address on the second day of the meeting. And it's a difficult one, it absolutely is a difficult one, but it's one that's critically important. So we will be doing that.

I guess the last thing I'd like to ask all of you is because we're trying to get ready for this meeting, is there any other information, any other questions, anything else you think would benefit you and the rest of committee about these measures that we can get or provide for you so that going into the meeting we have everything we need and the committee can make decisions that they feel comfortable with.



Okay, just certainly if there's something that rises don't hesitate to get in touch with us, but we didn't want to overwhelm you up front, but we will be providing additional information. We'll alert you, we'll post it to SharePoint on some of the these other things that we've talked about going beyond the initial review. The side-by-side, the, you know, the answers to all the questions that the developers - that you've asked today.

Similar things are happening in the other workgroups, so we're trying to pull all that information together. Sometimes the developers are updating their major submission form, so we'll have a new version of that for you. And we're going to try and keep all of that clear in terms of what the most up to date information is as we go forward to the meeting.

Elizabeth Drye: Reva, this is Elizabeth. I'm hoping that my early rating and short comments are just for our own internal discussion today, because I've learned a lot today and I don't know how other people feel, but it was kind of a cursory view of the measures.

Reva Winkler: Okay.

Elizabeth Drye: So I just wanted ((inaudible)) to do that, with the survey monthly results.

Reva Winkler: Right, what we'd like to do is we're going use that much as we've done here, we're making flies out of it as a starting point for the entire committee to discuss. So if you'd like to make changes to them, you know, that's fine. We can adapt that. But that's how we're going to use them.

Okay, well if there are no further comments we're at 5 o'clock Eastern and at the hour for finishing. I want to thank everybody for being on the call, thank you for giving us your time. Right, to the operator, is there anybody out there in the audience who wants to say anything?

Operator: And those lines are open if they have a question.

Reva Winkler: Right. Is there anybody out there who wants to comment who's been listening quietly?

Okay that means there doesn't appear to be any public comment.

So my thanks to everybody on workgroup, we really appreciate all the time you've put in so far and look forward to meeting all of you and seeing all of you when we get together in about two weeks.

Jochen Profit: Terrific.

Female: Thank you everybody.

Male: Thank you.

Female: Thanks everyone.

Male: Bye-bye.

Female: Thank you.

Operator: Ladies and gentlemen, that does conclude today's presentation and we do thank everyone for your participation.

Female: Well that was fun.

Female: Thank you.

Female: Thanks Rebekah.

END