NATIONAL QUALITY FORUM

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PERINATAL AND REPRODUCTIVE HEALTHCARE
ENDORSEMENT MAINTENANCE STEERING COMMITTEE

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TUESDAY
NOVEMBER 29, 2011

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The Steering Committee met at the National Quality Forum, Suite 900, 1030 15th Street, NW, Washington, DC, at 8:00 a.m., Laura Riley and Carol Sakala, Co-Chairs, presiding.

PRESENT:
LAURA RILEY, MD, Co-Chair
CAROL SAKALA, PhD, MSPH, Co-Chair
JOANNE ARMSTRONG, MD, MPH, Aetna
JENNIFER BAILIT, MetroHealth Medical Center
SCOTT BERNS, MD, MPH, FAAP, March of Dimes
JENNIFER BRANDENBURG, RN, MSN, Decatur Memorial Hospital
SARAH BROWN, MSPH, National Campaign to Prevent Teen and Unplanned Pregnancy
WILLIAM CALLAGHAN, MD, MPH, Centers for Disease Control and Prevention
KATE CHENOK, MBA, Pacific Business Group on Health

CHARLES DENK, PhD, New Jersey Department of Health and Senior Services
ELIZABETH DRYE, MD, SM, Yale School of Medicine
REBECCA GEE, MD, MPH, MS, Louisiana State University School of Public Health
ANDREA GELZER, MD, MS, FACP, AmeriHealth Mercy Family of Companies
CRAIG GILLIAM, BSMT, MT (ASCP), CIC, Arkansas Children's Hospital

KIMBERLY GREGORY, MD, MPH, Cedars-Sinai Medical Center
WILLIAM GROBMAN, MD, MBA, Society for Maternal-Fetal Medicine
MAMBARAMBATH JALEEL, MD, University of Texas Southwestern Medical Center
BARBARA KELLY, MD, A.F. Williams Family Medicine Center
TERI KIEHN, MS, RNC, Intermountain Healthcare
MARYI SALGADY LESLIE, CNM, MSN, EdD(c), The George Washington University
NANCY LOWE, CNM, PhD, FACNM, FAAN, University of Colorado Denver
LEE PARTRIDGE, National Partnership for Women and Families
JOCHEN PROFIT, MD, MPH, Baylor College of Medicine
KATHLEEN RICE SIMPSON, PhD, RNC, FAAN, St. John's Mercy Health Care
SHARON SUTHERLAND, MD, Cleveland Clinic
ROBERT WATSON, MD, MMM, CPE, Baylor Andrews Women's Hospital
JANET YOUNG, MD, Carilion Health Systems

NQF STAFF:
HEIDI BOSSLEY, MSN, MBA
JANET CORRIGAN

SHEILA CRAWFORD
EUGENE CUNNINGHAM
ANN HAMMERSMITH, JD
LAURA MILLER
SUZANNE THEBERGE
REVA WINKLER, MD, MPH
DON WASHINGTON

ALSO PRESENT:
JOSEPH CARPENTER, MS, Vermont Oxford Network (via telephone)
JEFFREY HORBAR, MD, Vermont Oxford Network (via telephone)
ELLIOT MAIN, MD, California Department of Public Health
JANET MURI, The Joint Commission (via telephone)

TRUDY MURPHY, MD, Centers for Disease Control

PAUL NORDBERG, MS, Massachusetts General Hospital

MAMATHA PANCHOLI, MS, Agency for Healthcare Research and Quality (via telephone)

PATRICK ROMANO, MD, University of California - Davis

JAY SCHURR, MD, Brigham & Women's Hospital (via telephone)

CATHERINE SULLIVAN, California Department of Public Health (via telephone)

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9:30 a.m.

DR. WINKLER: Good morning, everyone.

I'm Reva Winkler. I am a Senior Director, Performance Measures, here at the National Quality Forum.

Welcome, all of you.

Joining us here today for this meeting of the Steering Committee for Perinatal Reproductive Health, our endorsement maintenance project for 2011 -- apparently, two of our colleagues are experiencing travel delays, and so they will be joining us when those are corrected and they arrive in town.

But just a couple of things to orient you.

This call, as you notice, we are on the phone. This is an open and public call. Anyone out there could be calling in and listening into your conversation.

This discussion is also being

recorded and will be transcribed. The transcript will be posted on our website. So, everything you say is on the record.

We will be giving folks on the phone and anybody in the audience here an opportunity for public comment at different opportunities through the agenda as we go forward.

So, I wanted you to be aware that your audience might be a little bigger than just in this room.

With that, I think it is time for us to get to know each other. And so, I would like to turn it over to Ann Hammersmith, who is NQF's in-house counsel, and we will do introductions and disclosures.

Ann?

MS. HAMMERSMITH: Good morning, everyone.

If you recall, several months ago you received a conflict-of-interest disclosure form. What we would like to do now is go

around the table, have you introduce yourselves, tell us who you are with, and disclose anything that you believe is relevant regarding your service on this Committee. We do not expect you to recount your CV to us, just things that are relevant.

We are particularly interested in your oral disclosure of any consulting work that may be relevant to the matters before this Committee, any grants or contracts, and any speaking engagements that are relevant to the matters before this Committee.

I would like to remind you of two things before we begin the disclosures. You serve as an individual on this Committee. Very often, Committee members will say, "I am Suzie Smith and I am here representing the American College of" whatever. You are not here representing anybody but yourselves. You sit as an expert. You don't represent the interests of your employer or of someone who may have nominated you for service on the

Committee.

The other thing that I would like to remind you of also relates to something that I often hear Committee members say, which is, "I have no financial conflict of interest." Certainly, a financial conflict of interest is important and relevant, but for the purposes of the kind of work we do in these committees, it is possible to have an apparent or real conflict of interest where no money is involved whatsoever.

You may have served on a committee. You may have done work with a professional organization where you were uncompensated, but you have a very direct interest in it, perhaps to the point where there might be some question about objectivity even.

So, those kinds of things are also relevant to your disclosure. So, it is not just whether or not you have received money.

With that, I am going to start

with the Chairs, and if we could just go around the table?

CO-CHAIR RILEY: Good morning, everybody.

I am Laura Riley. I'm a high-risk obstetrician at Mass General Hospital. That is probably my major disclosure, is I am at Massachusetts General Hospital, and there are two measures put forward by that hospital. The only thing I have to do with that is that I am a doctor there. And so, I have to do those measures.

I am also an active participant at the American College of Obstetricians and Gynecologists, but I don't have anything particularly else.

MS. HAMMERSMITH: Thank you.

CO-CHAIR SAKALA: Good morning.

I am Carol Sakala. I am Director of Programs at Childbirth Connection. We prioritize performance measurement as a strategy for maternity care quality

improvement and are involved in things such as being active participants in NQF and working with ACOG and offices on Capitol Hill for a bill, partnering to improve maternity care quality.

I would say, with respect to disclosure, my interest is in bringing good measures into the pipeline and having them be used to improve quality. I don't know that there are specific concerns.

Thanks.

MEMBER BAILIT: Hi. My name is Jennifer Bailit. I am a maternal-fetal medicine specialist at MetroHealth Medical Center in Cleveland, associated with Case Western University.

I think the only thing I have in terms of disclosures is, along with Dr. Grobman, I am co-PI for the APEC Study from the Maternal-Fetal Network. This is a study looking at developing new measures and validating older, more established measures.

This has not yet been presented or published, and none of the measures that we are discussing for this study are being presented at this meeting.

MEMBER GREGORY: Hi. I'm Kimberley Gregory. I'm also a high-risk specialist. I am at Cedars-Sinai Medical Center and UCLA School of Medicine and School of Public Health.

I have an AHRQ grant on maternal quality indicators. I was a member of the AMA PCPI, where they looked at perinatal measures. I am also a member of the California Maternal Care Quality Collaborative, which I believe put forth the healthy newborn measure. And I am a member of ACOG and have been involved in a lot of their activities, as well as on the Board of Directors of the Society of Maternal-Fetal Medicine.

MEMBER PROFIT: Hi. I'm Jochen Profit. I'm a neonatologist at Texas Children's Hospital, Baylor College of

Medicine.

I have an NICHD grant to develop a composite indicator of neonatal intensive care quality.

I am a consultant for the Vermont Oxford Network's most recent Quality Improvement Collaborative, which looks at improving value of quality of care, and especially improvements of quality of care, so whether quality of care results in value savings or higher costs.

I am a member of the American Academy of Pediatrics' Technical Advisory Committee for Neonatal Quality Measures. And let's see, well, the composite measure that I am working on for NICHD includes several measures from the California Perinatal Quality Care Collaborative, which are largely identical with those of the Vermont Oxford Network, and there are several measures before us that are part of that. Some of the work has been published already.

MEMBER GILLIAM: I'm Craig Gilliam. I'm an infection preventionist at Arkansas Children's Hospital in Little Rock, Arkansas.

As far as disclosures, I am on the Speakers' Bureau for CareFusion and for Johnson & Johnson Ethicon.

MEMBER CALLAGHAN: I'm Bill Callaghan. I am an obstetrician and gynecologist and preventative medicine specialist working in the Division of Reproductive Health at the CDC. I also serve as CDC liaison to ACOG's Committee on Obstetric Practice.

There is one measure here, proposed measure, that was proposed by CDC. I was not involved in the development that measure. It was developed in another part of CDC outside of my Division, outside of my Center.

MEMBER GELZER: Hi. I'm Andrea Gelzer, and I'm Corporate Chief Medical

Officer of the AmeriHealth Mercy Family of Companies. We do Medicaid managed care. I am an internist by training. I am a Fellow of the American College of Physicians. I have been a previous Board member of a chapter of the March of Dimes, and I serve on their Public Policy Council. And I have also participated in several PCPI Committee measure development activities, none related to this group.

Thank you.

MEMBER JALEEL: Hi. My name is Mambarambath Jaleel. You can call me Jaleel. I am a neonatalogist and I work at UT Southwestern Medical Center. I am the Medical Director for one of the neonatal intensive care units at Parkland over there.

No disclosures.

MEMBER BERNS: Hi. Good morning.

I'm Scott Berns. I'm Senior Vice President of Chapter Programs at the March of Dimes National Office.

I am a pediatrician by training; also, a pediatric emergency physician. I am also on the voluntary faculty at Brown University where I am a clinical professor.

As far as disclosures, I work at the March of Dimes. We are in the midst of a national prematurity campaign, and my responsibility is to help our chapters, basically, our state-based chapters around the country implement programs to improve the health of moms and babies, which includes partnerships with hospitals to initiate quality improvement programs, particularly to help eliminate elective deliveries before 39 weeks.

And we are actually embarking this quarter on selling a service package to hospitals to help them implement those initiatives. I wanted to make sure that I disclosed that as well.

MEMBER KIEHN: I'm Teri Kiehn. I'm from Intermountain Healthcare.

I am on the Board of Directors for the March of Dimes in Utah. So, I also have a significant interest in the initiatives they are putting forth of the 39-week induction. And other than that, I have no disclosures.

MEMBER BRANDENBURG: I'm Jenny Brandenburg from Decatur Memorial Hospital in Illinois. I am the Director of Women and Children's Services.

The only thing I have to disclose is I have done a number of speaking engagements for the March of Dimes and A-1 as well on eliminating the elective deliveries less than 39 weeks. And I am the project lead sponsor for -- we are part of the Big Five in Illinois for eliminating the elective deliveries less than 39 weeks.

MEMBER SUTHERLAND: I'm Sharon Sutherland. I represent -- actually, I don't represent the Cleveland Clinic. I am an OB/GYN there, and I'm in the Quality Improvement Office. I oversee maternity

quality at six community hospitals.

MEMBER KELLY: I'm Barbara Kelly. I am a family physician at the University of Colorado, Medical Director in a family medicine residency program, and perform maternity care.

I have no disclosures.

MEMBER LESLIE: Good morning again.

I am Mary Leslie. I am a Certified Nurse Midwife. I am currently on the faculty at George Washington University School of Nursing.

My participation with NQF, in the past, I was on the Consumer Council in 2008, during the last measure round.

And my only disclosure, I think, is that I am formerly from Yale University and was there during the adverse outcome index work that they were doing, which is a little relevant to today. And I don't think I have any other disclosures.

MEMBER WATSON: Good morning.

My name is Rob Watson, and I am an actively-practicing obstetrician/gynecologist. I also am a physician executive for the Baylor Healthcare System in Dallas-Fort Worth. My role is primarily overseeing perinatal quality for about eight or nine different hospitals.

And I don't believe I have any disclosures.

MEMBER PARTRIDGE: Good Morning.

I'm Lee Partridge, Senior Health Policy Advisor at the National Partnership for Women and Families here in Washington, D.C. And I am not a clinician. Instead, much of my role is devoted to promoting the use of measures once they are endorsed by the NQF process.

I have been particularly working recently in conjunction with the March of Dimes and Childbirth Connection and several others to promote the use of the elective deliveries measure prior to 39 weeks. It

seems as though it is working.

MEMBER CHENOK: I'm Kate Chenok from the Pacific Business Group on Health.

I have participated in other PCPI and AAOS committees about orthopedic surgery measures, but they are not related to this. So, I have no disclosures related to this.

MEMBER DENK: Thanks. I'm Chuck Denk. I am from the Department of Health and Senior Services in New Jersey. I am also not a clinician, never delivered a baby, never even been visited by a drug rep.

(Laughter.)

What I am responsible for is measurements about quality and community health. I am responsible for report cards on breastfeeding and cesarean delivery and community needs assessment kind of analysis. So, I am that kind of statistician, and I am addicted to administrative datasets. Sorry.

(Laughter.)

And my background is in sociology.

Disclosures: I am on the leadership of New Jersey's Perinatal Collaborative and I speak at conferences there for them all the time. But I represent the State of New Jersey, and so nobody else.

And I also work a little bit with the March of Dimes chapter in New Jersey and have been involved in the 39-week initiative and pushing it out to clinicians in that State. And I work with other community groups, too, as a speaker and sometimes providing data.

Thank you.

MEMBER DRYE: Hi. My name is Elizabeth Drye. I am a general pediatrician by training, but I spend most of my time now developing quality measures, but for the other end of the age spectrum, mostly for Medicare recipients, working at the Center for Outcomes Research and Evaluation at Yale New Haven Hospital and Yale Medical School.

And I am funded by the Center for

Medicare and Medicaid Services to do that work, but none of those -- we have developed many measures, all outcomes measures that have come through NQF are in front of NQF right now, but there is no overlap with the group we are looking at today.

MEMBER YOUNG: Good morning.

I am Janet Young. I am an emergency physician at Carilion Medical Systems in Roanoke, Virginia. I am core faculty at Virginia Tech Carilion Medical School and also the Department of Emergency Medicine Residency Program.

I have very few disclosures, except that I am an international and national speaker for gynecologic emergencies. I have been funded to do that for the last several years. I do not currently having any speaking engagements, nor am I paid by anybody present, March of Dimes or other.

Thank you.

MEMBER LOWE: Good morning.

My name is Nancy Lowe, and I am professor and Chair of the Division of Women, Children, and Family Health in the College of Nursing at the University of Colorado.

In terms of disclosures, I serve on the Board of Directors on the Nursing Alliance for Quality Care. I also have an ongoing consulting contract with A-1, which is to serve as Editor and Chief of JOGNN, which is the Journal of Obstetric, Gynecologic, and Neonatal Nursing.

And I have been co-I on AHRQ-funded projects to study training for obstetrical emergencies in rural and critical-access hospitals in the Pacific Northwest.

MEMBER SIMPSON: I'm Kathleen Simpson. I'm a perinatal clinical specialist in St. Louis, Missouri, at Mercy Hospital.

I have participated on the NQF Committee that previously developed the measures, some of which we will be looking at again today.

I am the Chair of the National Advisory Council for the March Dimes, which is also promoting the 39-weeks, elimination of elective birth before 39 weeks.

I am the Co-Chair of the A-1 Patient Safety Committee, and we have been looking at patient safety measures.

And I am the PI of the Michigan Keystone Obstetric Safety Project -- and I just wanted to disclose that as well -- where we have 77 hospitals in Michigan and we are using some of these measures to evaluate care.

MEMBER ARMSTRONG: Good morning.

I am Joanne Armstrong. I am an obstetrician. I am the Director of Women's Health for Aetna, a large national health insurance plan, and I am also in part-time clinical practice at Baylor College of Medicine.

Most of my work at Aetna is trying to drive some of these quality efforts, including 39 weeks, which was mentioned here

before.

I also work on the edges of Pay for Performance activity, trying to take some best practices and translate those into contracts.

I don't have anything to disclose.

MEMBER GROBMAN: I'm Bill Grobman, a perinatalogist from Northwestern University.

In terms of disclosures, I am on the Board of the Society for Maternal-Fetal Medicine, I'm a member of ACOG, on the Practice Bulletin Committee. And as Dr. Bailit said, I am on a project with her looking at development of quality indicators.

MS. HAMMERSMITH: Are there any Committee members on the phone?

(No response.)

No? Okay.

Thank you for those disclosures.

Do any of you have anything you would like to discuss with each other? Or do you have any questions of me, based upon the

disclosures that have been made this morning?

(No response.)

Okay. Thank you.

DR. WINKLER: Thank you, Ann, very much.

Well, that's an impressive group of people. Thank you for taking time out of your clearly very busy lives to come work with us for these two days.

I am going to take the opportunity now to just do a little bit of introduction. I would like this to be informal. So, if you have any questions, don't hesitate to jump in.

Once we are finished with that, it is time to get to work, and we will start looking at measures very shortly.

Could I have the next one?

Just a reminder that the purpose of this entire project is to look at NQF's portfolio of measures for perinatal and reproductive healthcare. Some new measures have been submitted. The majority, however,

are the 20 NQF-endorsed measures that are due for maintenance review.

Most of those measures were endorsed three years ago. A lot has changed in the world in three years. And so, it is important that we look at those measures through all of the standard criteria that we evaluate all measures. Lots of things change in evidence. Lots of things change in experience. As people gain experience with use of these measures in the field, certainly feedback with potential logistic problems, unintended consequences, and all of those are important areas for us to explore to be sure that the measures do retain good, robust utility out in the field.

Go ahead, next.

Just to recall, on our orientation call we talked about how the work of NQF is grounded in support of the Department of Health and Human Services' National Quality Strategy, and the AIMS Patient-Centeredness

Family Engagement I think is something that we are all very familiar with in obstetrical care. Quality care for patients of all ages, which I think a lot of these measures address. Elimination of disparities and alignment of public and private sectors.

So, affordable care. We do have some measures that address appropriate use. Certainly, quality of care and various processes for mother and baby. So, the work that we are doing is very much supportive of this national quality enterprise.

Our task today, essentially, is to evaluate these submitted measures against NQF's measure evaluation criteria. Over the last few weeks, in preparation for this meeting the Committee has had the opportunity to become familiar with the criteria through your orientation conference calls, the tutorial conference calls on the measure evaluation criteria, and then the four Work Group calls where the preliminary reviews were

discussed. So, hopefully, everybody has had the opportunity to become very familiar with the evaluation criteria.

As a result of the Work Group calls that were held several weeks ago, measure developers have responded to some of the discussion points and the questions that you presented. As a result, we have had some juggling of the submissions for the measures. In fact, one measure has been withdrawn; two pairs have been combined into single measures. And so, it is really hard to keep the math up-to-date on these. So, when somebody asks me how many measures, it is a little hard.

So, just also, within NQF's portfolio of measures, there were 10 endorsed measures from prior efforts that were not resubmitted by the developers for continued endorsement. And so, just to be aware that those measures will drop from our portfolio at the end of this project.

So, go ahead. All right.

What we are going to do today to evaluate the measures using our evaluation criteria, we have collated all of the preliminary reviews and discussion points by the Workgroups. We have created slides. We have shared those with you prior to the meeting, but we will be projecting them up on the screen.

Each of the measures has an assigned lead discussant, and that lead discussant will lead discussion of the measure through the criteria. We will go in order through the main criteria: importance first, scientific acceptability, usability, and feasibility. There have been, as I said, responses and modifications.

And how we are going to do this is, as we discuss each of the main criteria, first, importance, all discussion points, and then the Committee as a group will vote on those criteria. We will talk in a minute about how you are going to do those votes.

At the end of the assessment of the four main criteria there will be a vote on whether the measure meets criteria for endorsement. All right? This is sort of the first preliminary assessment for the measure.

Then, we do have a measure tomorrow that is a composite measure that has 10 component measures. So, that will be a somewhat different analysis as we look at the components, though they are not presented for individual endorsement, just the overall composite.

Then, the last thing we will address are related and competing measures, those measures that are very similar, identified by the Work Group, particularly measures around hospital-acquired infections. We will look at them side-by-side and try to determine if all the measures meet the criteria, whether some perhaps are better than others. Are they all needed? Do they add, having all of them or only some of them, add

value to the portfolio?

Once all of those discussions have taken place, then your recommendations become final. And we are hoping that, having gone through the Workgroups and everybody having a lot of good preliminary discussion and evaluation of the measures, that the votes and discussions we have today will pretty much get us to the point that we have a good set of final recommendations when you finish tomorrow. So, that is our plan.

Does anybody have any questions about what we are going to do?

(No response.)

Okay. We will walk you through the first couple of ones, but it will sort of get pretty obvious, once we get rolling.

Okay. In terms of voting, now each of you were handed a little keypad. Okay? And it is important that you keep your keypad. It is assigned to you. They are assigned numerically. All right? And we keep

a roster of them with the voting results spreadsheet that we get out of this voting tool. If we had to -- it would take some tedious work -- we could go back and figure out who voted what. Most of the time we don't have any interest in doing that. But, if it were needed, we could. So, it is important that you maintain the keypad you were assigned and not switch them are change them.

The keypad is automatically on. We start off with a 60-second timer to cast the vote. You press the number that corresponds with the voting slide, which would be on the smaller screen when we do it. Then, once everybody has cast their votes, Gene will conclude it and the results will come up on the screen. Okay?

So, we are going to give it a couple of tests.

Gene, do you have yours up there? Okay.

So, your first voting exercise,

here's the question: did you have any difficulties traveling to Washington, D.C.?

So, everybody, you can just press it.

Gene, go ahead and get started.

Now go ahead and press.

(Whereupon, a test vote was taken.)

I can't see how many have responded. There should be 26 of you.

You don't need to press Send, just as long as you pressed it. If there's any question, you can press it again.

Okay, Gene, go ahead and close it down. Close it. There you go. Okay?

So, this is what we will do for each of the voting opportunities. Want to try it again or do you feel comfortable you're good with it? I think we're good with it. Okay.

And there are 23 votes. There should be 26. We will see if we can figure

that one out. Okay.

All right. Just a couple of issues I wanted to raise to you. We have talked probably around the edges of these in some of these preliminary discussions. But, again, just to emphasize, we do want to think about disparities in terms of these measures. Are the measures able to provide information about disparities of care around that particular topic or process of care? And how has the measure been developed to address disparities? It is an important priority for NQF and HHS.

Also, we are in the several-year conversion to ICD-10 codes. Everybody is really excited about that. Some folks are farther ahead of the game than others. We have had submitted ICD-9 to ICD-10 conversion codes. We are certainly going to be asking the measure developers what their status is because, hopefully, very shortly we will have conversion codes from everyone.

The other issue is harmonization. Harmonization is the concept of defining and coding the same concept in the same way. I think for those of you in the field the idea of harmonization comes home most apparently when you are trying to implement two measures that define the same term slightly differently, and it drives everybody crazy.

So, some of the biggest feedback we get from the field is, if you are going to give us more measures, make sure they are all defined the same way. Harmonization is truly a critical thing.

So, when you see elements of harmonization issues or concerns, particularly a lot of you have experience with the measures, be sure to bring them up. They are important discussion points as we go forward.

Any questions on those?

(No response.)

Okay. The last one, I think, is just, as we discuss the measures, we have got

39 measures in our portfolio. Twenty of them are under review. Ten are not being resubmitted. We have given you a list of all the measures in the portfolio. There are nine measures that are not up for maintenance review because they were endorsed within the last, I think, 18 months. And so, it is a little too soon. But we need to get a big picture of the whole portfolio. We have provided that list for you.

So, frequently, during discussion you will say, "Gee, it would be really great if we had a measure do this" or "This measure is okay, but it would be great if it did something else," or more or had some other characteristic. So, we will be capturing those suggestions and ideas into a set of maybe the recommendations or wishlist, if you will, of measures that we would like to see.

Also, we know that there are measures in the development pipeline, particularly the measures that some of you

have worked with with PCPI. When those measures are available and fully developed and tested, we will come up with an opportunity to bring them into NQF for evaluation, for endorsement.

So, with that, are there any questions from anybody?

Okay, Lee, go ahead.

MEMBER PARTRIDGE: Excuse me. I probably should have said this one slide back, Reva, but how much weight do you want to encourage us to put on whether or not a measure is now, or could easily be, suitable for electronic measurement?

I raise this because in some other committees that I serve on there's a lot of pressure to move toward e-measures.

DR. WINKLER: Yes. Under feasibility, I think we have talked about it in a lot of the Workgroups. The amenability of the measure for use in electronic health records, I think it is an important

feasibility subcriteria. It has come up in discussion.

So, again, none of these are absolutes. That is why we have got a group of people, and you are all going to sort of offer your opinions for a collective conclusion. So, I think it is an important thing because certainly there is a lot of movement and lot of emphasis on use of electronic health records, and we want measures that certainly can be used there.

So, I think it is an important criteria. Again, there's no one single subcriteria that is going to sway the day for any single measure, but I think it is important for consideration, as members of the Workgroup have brought up during the preliminary discussions.

MEMBER DENK: Can I comment on that, Reva?

DR. WINKLER: Yes.

MEMBER DENK: Do you mind?

I have the opportunity a couple of summers ago to sit on a State working group with the National Center for Health Statistics' Task Force to sort of create functional profiles and definitions for transfer of data between electronic hospital-based record systems and vital record systems. And that time track is still a long way off.

The standards just to get things into vital records, which is a thing of great concern to me. To get a medical record transcribed automatically and submitted to the state as opposed to being done manually, we are still probably three, four, five years away from that. And after that comes the public health profiles where data is transferred from hospital-based medical records to other public health uses which are reportable events, and so on and so forth.

So, considering that this activity happens every three to five years, is that the usual thing for these maintenance --

DR. WINKLER: Every three years.

MEMBER DENK: Yes. So, it will probably come up again as closer to being reality at the next cycle.

DR. WINKLER: Maryi, I think you had a question?

MEMBER LESLIE: Yes, I have a question regarding the composite measures. In the guide about evaluating composite measures, it was both different and additional criteria, but the form submitted by the developers is basically the older form, which doesn't really provide answers to those criteria.

Are we going to get that information?

DR. WINKLER: We are going to talk about evaluating the composite a little bit more before we do that tomorrow. Okay?

MEMBER LESLIE: So, as somebody who is preparing that, we don't have all the information.

DR. WINKLER: Okay. We will check

that.

Okay. With all the preliminaries out of the way, I am going to turn things over to our Co-Chairs, Carol and Laura, and it is time to get to work.

CO-CHAIR SAKALA: Great. So, first up, we are going to look at 475, which is administration of a hep B vaccine to newborns before facility discharge.

And we will start with Teri. Thank you.

For the beginning, we are going to look at importance, questions of impact, opportunity for improvement, and evidence.

Thanks.

MEMBER KIEHN: Do you want me to read it outloud or how do you want me to --

CO-CHAIR SAKALA: Well, you could do it in your own words, just cover those areas, and then we will open it up for comments that people may have, and then vote. So, it is a fairly structured process to go

through all four criteria.

MEMBER KIEHN: All right. Initially, I will just go over exactly what this is. It is put forth by the CDC. It is the percent of live newborns that received the hepatitis B vaccine prior to discharge from the birthing facility. The numerator is the number that received the vaccine, and the denominator is the number of live newborns born at the birthing facility during the calendar year.

There is a possibility of exclusions, once the ICD-10s come in, if parents choose not to give the newborn their immunizations. It is a process measure.

Again, a bit of a summary: HBV causes acute infection and chronic infections. Women with high viral loads transmit 90 percent to their infants, and most of the morbidity and mortality occurs among infants who develop chronic infection. Approximately 90 percent will develop chronic and about 25

percent of these infants will have premature death from complications of the chronic infection.

As we looked at this as a Workgroup, our importance to measure and report, three of us felt it was a high impact, two moderate. Felt the opportunity for improvement, again, high, three; moderate, two, and we all felt that it did meet importance.

Some of the rationale for whether it was high impact or a moderate, we were wondering if the case incidence of hepatitis B was decreasing, and we were wondering what percent gets the entire series. We are really measuring the initial impact.

Without vaccination and the globulins, 6,000 to 9,000 of these infants would become chronically infected HBV and approximately 2550 would be expected to die of chronic liver disease.

The primary goal of getting this

started at birth is to prevent the chronic HBV infection when the risk is highest, at birth through five years.

Do you want me to keep going here or how do you want to go forward with this?

CO-CHAIR SAKALA: Are you finished with your comments about importance to measure?

MEMBER KIEHN: I am right now, yes. I don't know how much you want me to go through.

CO-CHAIR SAKALA: Sure.

MEMBER KIEHN: This is my first time.

CO-CHAIR SAKALA: Well, I think now we can open it up to see if any members of the Steering Committee have comments on those issues.

(No response.)

Okay.

DR. WINKLER: I guess the question I would ask is, it seemed to me from the

Workgroup, the whole question of impact was really, I think, the cornerstone of the conversation. A relatively small number, the incidence seems to be decreasing. So, the opportunity to drive further improvement seemed to be the discussion point.

CO-CHAIR SAKALA: And we have our developers here for consultation. So, thank you.

Trudy?

DR. MURPHY: Thank you for the opportunity to speak.

There is actually an increasing number of women who are hepatitis B surface antigen positive, women in the U.S. This is primarily from people who are immigrants and refugees, many of whom may not be in the system.

So, I don't think we can say, overall, hepatitis B infections in the U.S., the acute infections, are decreasing. The number of women delivering babies has actually

increased and is estimated now to be around 25,000 a year.

CO-CHAIR SAKALA: Okay. If there are no other comments, I think we can all vote on the question of importance.

DR. WINKLER: Let's wait until Gene gets it up on the screen.

You are voting on just the importance to measure and report criterion.

It is not a matter of concurring with the subgroup. It is a matter of, having heard all that input, how do you rate the measure on that criterion?

CO-CHAIR SAKALA: So, 1 would be saying that you agree that it meets the criteria.

(Whereupon, a vote was taken.)

DR. WINKLER: The results are yes, 22; no, 2.

CO-CHAIR SAKALA: Okay. So, let's move on to scientific acceptability, which is reliability and validity.

MEMBER KIEHN: All right. The number of newborn infants, again. The reliability, it is available within pharmacy records, vaccine/medication administration. A lot of this is manual abstraction right now, which is an issue.

Difficulty because there is no ICD-9 code with a parental refusal. It is common for parents to refuse a vaccine, especially when the mother is not infected. It is difficult to look at for public reporting if there are differences in the populations for refusal rates.

Our group felt high, 3; moderate, 2. And as far as the validity, high, 3; moderate, 2.

Again, our concerns were there are some disparities. It is difficult to tell if the disparities are due to the populations or if it is due to refusal rates from the parents.

DR. MURPHY: Right. When we

submitted the proposal, we submitted it as an overall measure that would not have included refusals. We were asked by NQF to include refusals in the measure.

Because, currently, there are not data available in every hospital to account for refusals, we proposed two ways of reporting the measure. One, an overall coverage, hepatitis B vaccine coverage at birth, and the other, the measure that we would hope would improve or increase over time would be one that included refusals as that information becomes available.

DR. WINKLER: Which one are you intending to be endorsed?

DR. MURPHY: Well, we would hope that both would be endorsed, but certainly the overall would be the most critical to be endorsed.

MEMBER GROBMAN: Could I just ask about that, the overall being the most critical? It does seem that if it is really

like the underlying quality that you are trying to get at, that patient refusals of the parent, that there is no way to overcome that if we are honoring autonomy. And so, why is that the more important one to endorse than the patient refusal? In fact, it seems like it would be key to have patient refusals in there.

DR. MURPHY: Right, and your question is really pertinent, and it depends on the perspective. So, if it is from the public health perspective of preventing disease, the overall coverage would be the most important. But if it is from the perspective of autonomy of the parents and making a decision for their child, then, of course, the refusal would be the more important.

MEMBER GROBMAN: So, I guess my question would be -- and this might be the lack of my understanding of sort of the design of these measures -- but it seems like it is

a very different thing if it is sort of the public health sense that we are trying to get, which I totally see as really important, versus a quality indicator for a hospital, institution, or provider, which it seems to me hard to hold them accountable if their population -- let's say they take care of a very particular population -- jointly and fully refused to accept the vaccine. And it would look like they were providing low-quality care if we were using it as a quality indicator, when, in fact, they weren't. In fact, from some perspective, if you look at quality as autonomy, they would be high-quality care.

So, I guess I would advocate that refusals be the key measure or included in the key measure.

DR. MURPHY: Well, we are not arguing that refusals should be excluded. We are saying that that is an alternative or, let's say, an ancillary measure that could be

added as the information becomes available.

But I guess from a public health perspective, we might say that the quality measure really is in helping parents to understand what the implications are of not giving a vaccine and making sure that all infants receive the vaccine before discharge from the hospital. So, that really is the quality: did the infant get protected before leaving the hospital?

MEMBER GELZER: This is an Advisory Committee on immunization practices recommendation, is it not?

DR. MURPHY: It is.

MEMBER GELZER: It is? And so, I would not think that the measure -- the measure isn't valid if you don't include the refusals, and folks will be measured side-by-side. So, I would advocate strongly, also, that the refusals be included in the denominator.

DR. MURPHY: Right, and it was

simply a practical issue because not all facilities, in our feasibility study not all facilities had the information available to put in the refusals. So, we felt, as a beginning, the overall coverage plus refusals when the information is available. The refusals make the numbers look better, the coverage rates look better. So, it would be in the interest of the hospital to develop methods for being able to report refusals.

So, we are not against doing that, but it is simply that not all hospitals have the capability of doing that at this time. They do have the capability of doing the overall measure.

CO-CHAIR SAKALA: Yes?

MEMBER DRYE: So, I assume this isn't the first time this has come up in an immunization rate measure. I am wondering if there are examples of NQF-endorsed measures of how refusals have been handled.

DR. WINKLER: You're right.

Refusals are always an issue because that is just a difficult data element and it is challenging.

I don't think there is a standard yet, though I think around the criteria of, and so the priority of partnering with the patients and the patient/parent engagement, you certainly need to balance those with perhaps the public health issue.

So, there isn't a standard way of doing it. I think at this point you all can see what you think is the most important at this point in time. Yes, there really isn't a standard.

CO-CHAIR SAKALA: Jennifer? Yes, Rob?

MEMBER WATSON: Yes. I assume that there are probably regional differences in the refusal rate, but do we have any kind of an idea about a national? Are we talking a 0.5 percent or a 20 percent refusal rate? Does anybody have any idea?

DR. MURPHY: For hepatitis B, I do not have any information, but overall it is less than 3 percent. There are parts of the country, pockets of the country, where it is considerably higher than the 10 percent, maybe even 12 percent range. But, overall, it is quite low, less than 3 percent.

CO-CHAIR SAKALA: Jennifer?

MEMBER BAILIT: I just have a practical question. I am not so familiar with ICD-10. Does anybody know if there is a refusal code in ICD-10.

DR. MURPHY: There are several. There are several, but maybe not as specific as we might like. But at least the direction is to include those codes.

MEMBER BAILIT: So, the possibility exists that, when ICD-10 is implemented, the refusal issue goes away because you won't have to handpick through that data, that it should be available?

DR. MURPHY: Well, it will be

interesting to see how that plays out, but certainly that is the potential.

MEMBER BAILIT: Can you comment about the ICD-9 coding for refusal? You said it wasn't specific. What neighborhood of not specific is it?

DR. MURPHY: No, I am not familiar that ICD-9 coding has any coding for refusal.

MEMBER BAILIT: ICD-10?

DR. MURPHY: For 10, yes, it is in your information, the codes that are for refusal, and I can look for it.

In 2A(1)(a)(8), under the denominator exclusion, "not carried out because of immune-compromised, not carried out because of patient allergy, patient decision for reasons of belief or group pressure, not carried out because of patient decision for unspecified reason, not carried out because of patient refusal, patient decision for other reason, not carried out because of caregiver refusal." Those are the current codes in 10.

CO-CHAIR SAKALA: So, Lee had a question.

I need to encourage us to wrap this up because we have five more minutes and two more topic areas to deal with.

MEMBER PARTRIDGE: I just wanted to volunteer the information that I have served for a number of years on the American Academy of Pediatrics' Medical Home Advisory Panel. In the course of the most recent discussions of our face-to-face meeting this year, the subject of parent refusals on vaccines came up repeatedly among the pediatricians. And they recognize that it is pushing their quality scores in the wrong direction, but they also recognize that they feel they have a role in educating the parents.

Now it is a little harder in the discharge situation, but certainly the doctors that I have spent a lot of time with take this very seriously as part of their job.

CO-CHAIR SAKALA: Yes, Nancy, quickly, and then maybe we will need to do the vote.

MEMBER LOWE: It was just a question. Is it appropriate for us to vote on whether it is, the patient refusal is in the denominator or not?

DR. WINKLER: If you read the specifications that are presented, it includes those exclusions. Now we have certainly seen measures where not everybody could implement them today because of data sources or availability or all sorts of logistical reasons.

However, that does not preclude you from recommending the measure. Certainly, as measures gain use and adoption, they figure out how to collect the data.

So, I think that in this particular question, you have got denominator exclusions optional. Now optional causes a bit of a problem when you are trying to

standardize things, and some choose to select the option versus not select the option.

So, I think that in this particular case, you may choose to leave it open-ended like that. However, you may choose to recommend the measure only by including the exclusions. That is within your decisionmaking.

MEMBER LOWE: Yes, could I make a motion then, that we approve the denominator with the exclusion in it of refusal? So that the measure becomes, the denominator becomes with the exclusions?

CO-CHAIR SAKALA: A second for that?

MEMBER GROBMAN: I would second.

MEMBER DRYE: Can I just clarify? Do you mean exclusively? I am sorry to use that word, but basically the measure would only be approved for use with the exclusions? So, we are disapproving the overall --

CO-CHAIR SAKALA: Chuck's previous

point that we have a system in transition, so this is for now, is also well-taken.

So, do we have the capability to jump into a vote for that?

DR. WINKLER: Well, remember, what you are doing is voting on whether the measure, as specified -- and you have specified it to remove the option to include the exclusion. So, you are voting on that. Does that meet the criteria of scientific acceptability to measure properties?

MEMBER DRYE: Sorry, can I clarify further? This, to me, feels like a vote -- I just want to be clear -- that would be a vote against reporting the measure without the exclusion. Can that be separate from a final vote?

DR. WINKLER: We can do both.

MEMBER DRYE: Yes.

DR. WINKLER: Sure. Okay. It sounds like you would like to take two votes.

MEMBER DRYE: I think it is two

separate questions. One, do we want to -- we are treating it as two different measures, basically, yes. Right?

DR. WINKLER: Okay, sure. You can do that.

MEMBER PROFIT: Just to clarify, Reva, there's no more option for a time-limited endorsement.

DR. WINKLER: Right.

MEMBER PROFIT: Because this would seem like a great measure to just get a little more information on --

DR. WINKLER: Okay.

MEMBER PROFIT: -- for a couple of years.

DR. WINKLER: A couple of things. I know there is no more opportunity for time-limited endorsement. This measure was granted time-limited endorsement three years ago, and the new information is what you have in front of you.

So, then, I think what we will

need to do is take two votes on scientific acceptability. The first one will be as presented in this document where it is optional. All right? So, an overall rate might include refusals or not. Is that clear?

Is everybody ready to vote on that?

All right, Gene, go ahead.

(Whereupon, a vote was taken.)

So, 11 yes and 13 no on scientific acceptability for the measure as written.

Now you want to revote for the measure where the optional exclusions part is eliminated and it is with the exclusions for parental refusal, is that correct?

MEMBER PROFIT: So, I think this really becomes very complicated because the decision we make right now has consequences on all the other measure criteria, like feasibility and usability. So, we would have to vote on all of these twice. I am a little worried that it is going to get really

confusing.

DR. WINKLER: All right.

MEMBER PROFIT: Because an overall measure will be a lot more feasible than a measure where everybody has go dig into ICD-10 codes.

So, I would just caution that I feel like this is getting confusing.

DR. WINKLER: If the vote you have just taken is the one you want to stick with for this measure, we are finished with this measure because it did not pass scientific acceptability. If that's what you would like, that's fine.

MEMBER GELZER: I think we should vote, at least take the next vote.

CO-CHAIR SAKALA: Okay.

DR. WINKLER: This is a vote on the scientific acceptability of the measure where the exclusions for patient/parent refusal are not optional, but are part of the measure specifications. Correct?

All right, Gene has got to get us up there.

MEMBER PROFIT: Could you comment on the reliability of extracting the refusal codes from the chart?

DR. MURPHY: Again, the reliability was determined -- well, again, it is a little bit confusing the way the reliability versus validity was interpreted in the instructions when the feasibility study was done. So, validity was determined by chart review and estimates from chart review.

So, without the ICD-10 codes, it would depend on each hospital's system for determining that information.

In a given institution that is not using ICD-10 codes, using the same system, it should be very reliable from one year to the next. However, across institutions, it would not be as reliable without using ICD-10 codes.

MEMBER PROFIT: And are there any studies looking at what the chart review as

compared to then going back to the parents maybe and checking with them whether they truly refused or not?

DR. MURPHY: No. No, they're not. No, the chart reviews did look to see whether the parents had refused. So, from that standpoint, there was some reliability estimate.

CO-CHAIR SAKALA: Okay. So, can we have a vote now on keeping parental refusals in the denominator?

(Technical difficulties with attempting to take the vote.)

MEMBER BERNS: So, Reva, for the sake of time, Dr. Profit alluded to this; actually, he was specific about it. This is sort of moot, isn't it? Because you already said we can't move forward with the measure is written. So, even if we vote yes here, I mean, I already had feasibility questions without the exclusions in the denominator. So, I don't understand where we are going to

be going with this.

DR. WINKLER: Well, essentially, what you are doing is giving a conditional recommendation. You believe it meets the scientific acceptability criteria conditional on the exclusions being non-optional. So, I mean, since they are in there, you are not really changing anything. What you are doing is taking just the optional out and saying that your opinion is the measure needs to maintain those exclusions.

MEMBER BERNS: Again, I'm new at this as well. But that is the usability and feasibility assessment, so --

CO-CHAIR SAKALA: So, we will come to those quickly.

MEMBER BERNS: Okay. Thank you.

CO-CHAIR SAKALA: Okay. Are we ready, Gene, it looks like?

DR. WINKLER: Okay. Let's do it by hand.

How many for the measure that is

take the option out; the exclusions are a mandatory part of the measure? Who feels it meets the criteria of scientific acceptability?

(Whereupon, a vote was taken by hand.)

Twenty-two.

CO-CHAIR SAKALA: Do you want no for the record?

DR. WINKLER: Yes.

CO-CHAIR SAKALA: Yes. Noes for the record?

(Whereupon, a vote was taken by hand.)

DR. WINKLER: One, two, three.

CO-CHAIR SAKALA: Okay. Thank you.

So, now we will move on to usability, which is internal quality improvement and external public reporting.

MEMBER KIEHN: All right. Currently, it is not being used in public

reporting, although the National Immunization Survey does currently produce hepatitis B birth dose rates. And again, our concern was how we capture and report patients who refuse with contraindications and, as this last discussion brought up, there is no way right now to capture it accurately, validly.

Is it even useful without it? There is a big question that we brought up in our group.

Again, the suitability, we felt it seems to be a largely-solved problem, although you mentioned that, especially in the minorities. While it meets criteria, we had questions regarding the implementation and hospital capacity to report the measure. ICD-10s, again, was our big issue right now until ICD-10s come up. And they are wondering if the value had decreased over time as we are moving forward.

CO-CHAIR SAKALA: Comments on usability?

Jennifer?

MEMBER BAILIT: So, when we do these kinds of things at our hospital, you look at the patients who didn't get it, which already whittles down the number greatly, and you do it by hand. We are talking about handfuls except in the largest hospital systems or in these pockets.

So, I think nationally this is doable. It is a little more work-intensive than if ICD-10 is implemented, but I still think that this is feasible, at least in the interim time until ICD-10 comes along.

CO-CHAIR SAKALA: Anything else on usability?

(No response.)

Okay. Can we take a vote then?

MEMBER BERNS: I'm sorry, just clarification: are we voting on the measure as written now or with the --

CO-CHAIR SAKALA: Yes, excuse me, the developer wants to make a comment.

DR. MURPHY: Yes, in terms of usability, currently, the National Perinatal Hepatitis B Coordinators, once every five years, review the charts in 90 percent of the hospitals that birth or deliver 90 percent of infants. The resources to continue doing that will not be continuing. They simply will not.

And this quality measure would be a way for hospitals to look at their own outcomes as well as help the coordinators identify hospitals or birthing centers that do need some help with how they can facilitate getting the birth dose.

So, I think there is a great value to public reporting of this measure. I would strongly urge your support for it.

CO-CHAIR SAKALA: Okay. Let's vote, then, on usability.

DR. WINKLER: This, the rating scale is high, moderate, low; 1, 2, 3, 4, where 4 is insufficient information.

MEMBER BERNS: I apologize, Reva.

I just need clarification. Are we voting on the measure as written or with this amendment that we -- I mean, what are we voting on here?

DR. WINKLER: I think you will have to be voting on the one that you, the conditional one that was approved.

(Whereupon, a vote was taken.)

Okay. It is high, 4; moderate, 14; low, 6.

CO-CHAIR SAKALA: So, now, finally, we have feasibility, which would be things like errors, unintended consequences, and burden to report.

Teri, any comments?

MEMBER KIEHN: From someone who actually pays for the person to pull it out, I am really concerned with, now the way we have got it written, with the exclusions, it is going to be very costly for someone to pull out, go through all the charts to find the family refusal piece. That is a big concern with the feasibility for me.

CO-CHAIR SAKALA: Other comments?

MEMBER PROFIT: Well, I think I would like to second that. I think, as the day progresses -- and maybe this is because this was the very first measure that we chose. And so, I wonder whether there is like a harsher, there is going to be maybe like a harsher cutoff for this than maybe for others.

But I think we have to be careful about entering a Faustian bargain about every single possible thing that would make a measure as valid as could possibly be, and then trading that off for feasibility.

CO-CHAIR SAKALA: Trudy?

DR. MURPHY: Yes, on the feasibility study, for those that did look at exclusions, the cost was actually relatively low for those who had the information, even if it was on the paper forms.

I think the advantage to eventually going to electronic systems and having this measure in place would be that it

can be programmed into the electronic medical records as people go forward. The highest cost was for the programming initially. So, people who had paper systems were usually the smaller facilities and the cost was relatively low.

CO-CHAIR SAKALA: Other comments?

(No response.)

Okay. Let's take a vote, please, on feasibility.

And again, it is going to be the scale from high to insufficient.

(Whereupon, a vote was taken.)

DR. WINKLER: Three high; 19 moderate; 3 low.

CO-CHAIR SAKALA: Okay. Now there is one more vote for this measure, and then we will be moving on. And that is, overall, is it your view that this measure meets the clearly-demarcated NQF criteria for endorsement? As amended.

(Whereupon, a vote was taken.)

DR. WINKLER: Everybody push the number again.

When we tested them, it worked. I don't know.

Twenty-two yes; 3 no.

CO-CHAIR SAKALA: Okay. So, we will be recommending that this measure be endorsed.

DR. MURPHY: Thank you very much.

CO-CHAIR SAKALA: Yes.

So, we are going to move on to 582, which is avoidance of oral hypoglycemic agents with diabetes and pregnancy.

Do we have a developer here who wants can join us on this or on the phone? Okay, great.

And this is Barbara Kelly.

So, we will begin with importance to measure.

MEMBER KELLY: So, our group discussed this at length. This measure initially is identifying pregnant women with

diabetes, not gestational diabetes but pre-existing diabetes, who are not taking oral hypoglycemic agent. The denominator was pregnant with a diagnosis of non-gestational diabetes, and the numerator was those not taking hypoglycemic agent.

And we discussed a few things. One was the performance gap did not seem to be huge. The numbers we got were between 81 and 100 percent in terms of the reported measures to us.

The other issue raised that it was not taken an oral hypoglycemic agent, but it wasn't that they were on insulin or that they were well-controlled. So, this is a process measure and not a clinical outcome measure.

And the biggest debate within our Workgroup was that there is increasing use of oral hypoglycemics for these women, including metformin and glyburide, and that this measure may not meet the importance criteria.

I have to admit that my vote

initially was the one that said, yes, for meets importance. And after the conversation in the Workgroup, I moved my vote to no.

So, our Workgroup actually did not take this measure any further. We voted that it did not meet the importance criteria.

Now, since that time, I think the measure has been revised to take metformin and glyburide off the list of banned agents. However, I think this measure needs more work. In our opinion, it did not meet the importance criteria. So, we actually did not go further to discuss any of the rest.

So, I guess I will leave it open for discussion or to answer questions.

CO-CHAIR SAKALA: Can we have comments from the measure developer about interim proposals?

PARTICIPANT: Sure. Yes. We updated the guideline to the most recent (phone technical difficulties) knowledge in 2011, which does reiterate some of the

concerns that were said on the Workgroup call, that although (phone technical difficulties) would prefer a treatment approach, metformin and glyburide have been shown to be effective alternatives and without adverse effects.

So, essentially, we took glyburide and metformin out of the numerator. We basically said, if a woman is on those medications, it's okay. But, beyond that, we thought that it was, I guess, representative or in line with the guidelines.

Those were the changes that we made, and we wanted to hear what your feedback was.

CO-CHAIR SAKALA: Do you have any data on what happens when you make that change?

PARTICIPANT: No, we do not. Do you mean like writing the percentages and finding out what the compliance is?

CO-CHAIR SAKALA: Yes.

PARTICIPANT: Taking those off the

table?

CO-CHAIR SAKALA: Yes.

PARTICIPANT: No.

MEMBER ARMSTRONG: So, it sounds like that measure, then, hasn't been tested before. This new measure that you have come up with has not actually been tested?

PARTICIPANT: Not run against a (phone technical difficulties).

MEMBER ARMSTRONG: Okay. Thank you.

CO-CHAIR SAKALA: Okay. Any other comments?

DR. WINKLER: I would just like to go back to Barbara's comment on the 1B criteria, which is opportunity for improvement. And that was another issue and is an important subcriteria.

Any discussion from the group?

CO-CHAIR SAKALA: Okay. Nancy?

MEMBER LOWE: Yes, only that, as I reviewed the materials, there was insufficient

data to even evaluate whether or not there was a performance gap.

CO-CHAIR SAKALA: Okay. Any other comments?

(No response.)

So, I think we can vote on the question of importance to measure and report, whether it meets the criteria for impact, high impact, opportunity for improvement, and evidence all together.

(Whereupon, a vote was taken.)

DR. WINKLER: Yes, one; no, 24.

CO-CHAIR SAKALA: Okay. So, according to the guidelines, that means that this measure will not go forward in our process, and we will move on to the next measure.

MS. MURI: Excuse me. Hi.

CO-CHAIR SAKALA: Yes.

MS. MURI: This is Janet Muri.

I apologize, I was on a different time zone and didn't realize my timing in

joining this Committee meeting, on behalf of Dr. Stephen Clark.

And I just wanted to make sure that the measure for appropriate DVT prophylaxis, has that been opined on yet?

CO-CHAIR SAKALA: We are just getting to it. Thank you.

MS. MURI: Thank you. I appreciate it.

CO-CHAIR SAKALA: Okay. Glad you could be here.

MS. MURI: Thank you.

CO-CHAIR SAKALA: So, this is 473, appropriate DVT prophylaxis in women with cesareans, and it is a Hospital Corporation of America measure.

And Bill is going to lead the discussion.

MEMBER GROBMAN: So, in terms of importance, I think sort of the discussion on the Committee and sort of the conflict, if one exists, is that it is designed to prevent

catastrophic event, that is, maternal death, from deep venous, DVT, but it is an uncommon event.

So, in terms of just the importance, that is sort of the discussion that went on. I think largely the subgroup agreed that it was important. You can see the votes up there: high, 3; moderate, 4; low, 1.

But the moderates and lows were sort of the discussion was just about the relative infrequency. Of course, the highs were that, even albeit infrequent, it is such a catastrophe. And if we are thinking about maternal death, it is oftentimes cited as the No. 1 cause of maternal death.

In one of Steve Clark's papers from HCA, it was certainly the No. 1 preventable cause of maternal death in their HCA series of maternal deaths. And so, that is really what it is about in terms of importance to measure and report.

In terms of opportunity for

improvement, this is a little sketchy in that there is just not great data on what people are or are not doing. I think from a sort of anecdotal perspective the use of DVT prophylaxis is certainly not widespread for every cesarean. I think there are many institutions that still do not do it universally. And I can even speak from our institution, which is just to say that we weren't doing it universally until relatively recently.

It was not an ACOG explicit recommendation. So, people weren't following it for that reason. And I think we only have reason to believe that there is opportunity for improvement in the application of DVT prophylaxis during every cesarean. It is just not terribly well-described.

In terms of evidence, the quantity of evidence is relatively moderate to low. There just aren't that many studies about it because it is a rare event, so really hard to

do. An institution like HCA, with many thousands, hundreds of thousands of births, has the capacity to do it. There's just not that many studies about DVT in pregnancy and prophylaxis. It is a relatively-uncommon event, like we discussed.

And most of the work about DVT prophylaxis, quite frankly, that has been done has been done, if an OB/GYN at all, on the gynecology side and not in OB specifically.

Also, it is difficult to get good data because so many of the DVTs that occur are post-discharge, oftentimes patients going to other hospitals. So, it is very, very difficult in terms of ascertainment.

So, the quantity of the studies that have been done is relatively small. As you can tell, the quality, accordingly, is relatively reduced as well, although what exists is consistent in that, of maternal deaths that occur, it is high on the list of causes.

It is preventable, largely from all data that exists in other specialties, if not in obstetrics specifically. There is some cost-effectiveness data. It is a relatively low-cost intervention, easy to do.

And so, anyway, that would be my take on the evidence and sort of reflects what the Subcommittee discussed as well. So, overall, we came down that it was important to measure and report because it is the potential to drive practice that is relatively easy and could prevent a true catastrophe.

And I have nothing more to opine.

MEMBER ARMSTRONG: I have a question.

Any insight into, beyond these general limitations you talked about, why ACOG hasn't recommended it?

MEMBER GROBMAN: Literally, a practice bulletin just came out, I don't know, three months ago where they did. Yes, so they did. So, now they do.

So, now I think it would have been hard to hold people's feet to the fire before that, but now with an explicit recommendation from ACOG, literally in a practice bulletin, that says that all pregnant women undergoing cesarean should receive DVT prophylaxis, it is kind of hard to, you know --

MEMBER BERNS: Just in terms of numbers, I did see the number in here for fatal PE rate in terms of a goal in terms of reduction. It is a relatively rare occurrence, but a catastrophic one.

What about numbers in terms of the incidence or prevalence of DVTs in this scenario? Is there any --

MEMBER GROBMAN: In which scenario specifically?

MEMBER BERNS: Well, you have a woman just in general in terms of a woman who comes in for a C-section. Or, I mean, does it depend on their weight? Do we have any data on that? I am asking the developer, I guess.

MEMBER GROBMAN: Yes.

MEMBER YOUNG: I can speak to some of those numbers, actually.

My name is Janet Young. I am an emergency physician.

This is a problem that we deal with on a daily basis, if not shiftly basis. So, patients who come in with DVT who are currently pregnant is a relatively-common issue, actually, especially in the second and third trimesters.

Most patients who do present with PE do it in the postpartum period, in the first three to five days postpartum. So, the emergency department oftentimes sees these patients as a first pass caregiver.

It is not uncommon at all. So, it is not relatively rare. I just don't think you are seeing it on the OB/GYN side because those patients are coming back into the emergency department, and the diagnosis is made in the ER, and then they go to the ICU,

oftentimes where they are not cared for by an OB/GYN. They are cared for by pulmonologists and critical care medical specialists. So, sometimes you are outside of that care window in changing providers from service to service, from OB/GYN to critical care medicine.

About 4 to 8 percent of patients who come in with shortness of breath in the postpartum period have a PE. And unfortunately, it is not at all uncommon.

So, as far as your numbers for DVT, usually, it is second and third trimesters, and those patients who are more overweight have underlying comorbidities. It is just like every other health system problem; when there are additional comorbidities, your rate of DVT goes up.

In the postpartum period, patients who undergo C-sections seem to have a higher PE rate. That is just my anecdotal experience, having done emergency medicine for 15 years. I can't give you numbers as to

exactly how many C-sections versus regular standard or, sorry, normal spontaneous vaginal deliveries, but I do know that it is slightly increased. So, maybe perhaps because those patients are on bed rest for a longer period of time. I don't have that data.

MEMBER GROBMAN: So, yes, I could speak to that. I think a couple of things are relevant.

One, of course, is that this wouldn't take care of any of the ante-partum DVTs. But a significant portion, whether it is the total majority, like 50 percent, or a third, occur sort of intra-postpartum.

Cesarean section, in terms of a relative risk, is thought to convey about a fivefold increase risk of deep venous thrombosis. The frequency of deep venous thrombosis in the pregnant population is probably on the order of 3 per 1,000. And so, if you then imagine that cesarean is a fivefold increase, you can see that maybe half

of those are occurring intra to postpartum, and cesarean increases it by fivefold, and is, I think, in some ways the most important thing, right.

So, it is a low-frequency event, but, conceptually, an easily and cheaply preventable one. I think that is at the end of day.

But it is not like DVTs are -- yes, there's huge ascertainment problems. In the ER or anywhere, they are not a huge frequency event, but, again, they are an event that in PE causes death and in terms of DVT causes long-lasting morbidity, like post venous thrombosis syndrome.

MEMBER BERNS: Well, you said 3 per 1,000, right? Is that what you said?

MEMBER GROBMAN: Right, 3 per 1,000 overall about. Again, ascertainment issues, but, yes, so 3 per 1,000, but that is not per cesarean. That is the overall obstetric population, three-quarters of which

are having NSVDs, more or less.

MEMBER BERNS: But if there are 4 million births, that is still a significant number.

MEMBER GROBMAN: Oh, totally.

MEMBER BERNS: Okay.

MEMBER GROBMAN: Yes, it is a low per-capita event, but it is a cumulative risk, absolutely.

MEMBER CALLAGHAN: There are longstanding recommendations for DVT prophylaxis in gynecologic surgery, other pelvic surgery. And yet, we have not done a good job in another pelvic surgery in women who also are in a hypercoagulable state. So, that inconsistency has existed longstanding. And pulmonary embolism accounts for about 10 percent of all pregnancy-related deaths in the United States, as best as we can determine. So, again, low frequency, but maternal death is the worst thing that can happen.

CO-CHAIR SAKALA: Other comments

on importance?

(No response.)

Okay. I think we could take a vote then.

And a yes would mean that you agree that this measure meets criteria for high impact, opportunity for improvement, and evidence.

MS. MURI: This is -- I am getting an echo.

As (phone technical difficulties) this measure, (phone technical difficulties) I am not sure, but the voting rights, are we allowed to vote on the measure or is this something that we are not allowed to participate in at this point?

CO-CHAIR SAKALA: Yes, this is just members of the Committee.

MS. MURI: Thank you.

(Whereupon, a vote was taken.)

DR. WINKLER: Yes, 20, and three no.

CO-CHAIR SAKALA: Okay. So, that means that we will go on to consider scientific acceptability, validity and reliability.

MEMBER GROBMAN: So, in terms of scientific acceptability, we can start with reliability. You can see that the Committee was kind of split: high, 3; moderate, 2, and low, 2.

In terms of, well, I will just say validity at the same time: high, 3; moderate, 4, and low, zero.

The discussion that went on, you can see the bullet points up there. Essentially, the data elements were fairly straightforward. It is pretty easy to ascertain whether or not someone had compression boots on, and there was only exclusion, which was that someone was already on pharmacologic prophylaxis for some other reason.

There is confusion in the section

as terminology switches to -- I am not sure what the "PCD" means. Ah, pneumatic compression devices.

So, I think the confusion about this was we had a long discussion about the exclusion criteria, meaning that you are already on some form of anticoagulation. If you are already on some form of pharmacologic anticoagulation, there is no compelling evidence that you require additional mechanical anticoagulation for just a general run-of-the-mill cesarean.

And so, from sort of a validity perspective, it makes total sense that for these rare patients who are on pharmacologic prophylaxis during their cesarean, that they need not be counted because they don't need to get compression boots.

And then, there was a whole bunch of discussion about how easy this was to ascertain and how frequent this population was, and should we just throw compression

boots on them anyway. And at the end of the day, well, I am not sure we completely had agreement -- (laughter) -- but there was at least a general sense that it was okay to keep the exclusions; it was certainly most valid to keep them, although there was a remaining strain of concern regarding just the ability to extract those from the medical record.

There hadn't been a great amount of reliability analysis, testing, certainly widespread outside of HCA.

And the rest of it is about heparin versus boots. So, it is really about the heparin versus boots. This is unlikely to cause a big problem, anyway, since it is a very small number of patients who are on pharmacological heparin at the time of their cesarean. It occurs, but uncommon.

So, anyway, we were generally on the side of yes.

CO-CHAIR SAKALA: Okay. Comments on scientific acceptability?

(No response.)

Okay. I think we are ready to take a vote then on this.

(Whereupon, a vote was taken.)

DR. WINKLER: Twenty-four yes, 1 no.

CO-CHAIR SAKALA: Okay. So, we will go on to usability then.

MEMBER GROBMAN: Usability, we thought was relatively high. Basically, it is an easy-to-understand metric. It is easy to sort of drive practice at hospitals. It is easy to get insight in between practice and your outcome.

In any case, we thought usability was high. It is understandable, and it is easy to drive quality improvement.

CO-CHAIR SAKALA: Comments?

(No response.)

Okay. I think we can vote on usability then, please.

MEMBER DENK: While we are voting,

can I ask a simple question?

If the measure of when we are done voting is that all 25 people have voted, that sort removes the possibility that one would quietly abstain.

DR. WINKLER: Yes, I mean, we really have asked you here to participate. So, abstaining, unless there is a really, really strong reason for it, is probably not something we want to encourage.

MEMBER GREGORY: I just want to raise one question or comment. That is that this measure as written, or as read it, is only talking about at the time of delivery or at the time of surgery. And so, some of the data on especially the compression stockings is that they are supposed to be worn at least 23 hours a day. How long do you wear them, until after the delivery or until discharge?

I guess I am a little concerned in terms of the scientificness of this. The real benefit may even be a little further

downstream, and we are not really capturing that with the measure. We are just knowing that at the time of surgery they had the boots on.

MEMBER GROBMAN: Right, and so this was talked a little bit about in the Committee as well. I think I would say a couple of things.

One is, again, leveraging from sort of gynecologic surgery, because it is practically, from a usability and feasibility perspective, practically impossible to collect whether people are wearing it usefully after their operation. I mean, yes, you can have whether it is like written for and you can have whether the nurse -- but, you know, whether it is actually on their legs, the machine and cycling, but that is pervasive throughout all the literature, essentially.

And so, again, all of this is in the context of leveraging from gynecologic and non-gynecologic surgeries, which is that at

the time of surgery is the greatest import for DVT reduction. But it is absolutely an extrapolation, admittedly.

(Whereupon, a vote was taken.)

CO-CHAIR SAKALA: Okay. So, the vote was 18 high; 6 moderate, and 1 low.

And finally, we can do feasibility, please.

MEMBER GROBMAN: So, feasibility, we thought was also, I mean, you can tell that most of the Committee thought it was high. Of the two people who did not, one thought it was moderate and one thought it was low. Generally, it is feasible. It is easy to ascertain. It is oftentimes, for hospitals that have EMR, it is in the order itself. If not, it is in a written order. If not, it is easy to ascertain from what happens at the time of the surgery. Most often it is easily documented. So, that was really the rationale for most people believing it to be feasible.

DR. WINKLER: Just to ask about

the question Lee asked, for any of you who are using this measure, is it something that is in your electronic records at all yet?

MEMBER GREGORY: Yes.

DR. WINKLER: Okay.

MEMBER KIEHN: Interestingly enough, though, at Intermountain Healthcare, this was our Board goal this year, was to do this. What we found, we did do exactly what Bill said. We went to the bedside and we found that only 55 percent of the time were the moms even wearing them, even though they were ordered and documented they were on. So, we actually went to manual just bedside. So, it is a hard one to actually see if you are making a difference.

MS. MURI: This is Janet, speaking on behalf of AHCA.

Our standard electronic orders has it as well as our computer-based documentation system.

CO-CHAIR SAKALA: Thank you.

Jennifer?

MEMBER BAILIT: I think whether the compression boots are on at surgery is fairly easily ascertainable. It is the exceptions to the rule. So, whether they are on heparin, whether they have been on heparin but they have been off for 12 hours, whether that was appropriate or not, the devil is in the details there.

So, while the compression boots is the easy one, it is part about the heparin and the medicalization and those exceptions that are going to soak up the resources to ascertain. So, in my mind, that lowers the feasibility of this. If this were just, are compression boots on, yes or no, this would be much more feasible.

MEMBER GROBMAN: Yes, and I think the way that the Committee kind of reasoned that out was kind of what you said about hepatitis thing, which is that the vast majority -- you know, heparin use is a less-

than-1-percent event. And so, we didn't want it to ding hospitals that might have particular high-risk populations or choose -- I mean, it is an acceptable practice if you wanted to use prophylactic pharmacologic heparin instead of compression boots. I wouldn't say it is common practice. But if, for whatever local reason, someone wanted to do that, it certainly wouldn't be wrong or bad quality.

And so, if those hospitals want to go to town and delve into their medical records -- but for most hospitals, for these rare, rare instances, it is literally going to be per thousand. We thought it wasn't going to soak up. That would be my argument for it.

CO-CHAIR SAKALA: Nancy?

MEMBER LOWE: Yes, Teri, I wanted to ask you, what you just talked about, though, you were talking about postpartum use, correct? Or time of surgery? This measure is at time of surgery.

MEMBER KIEHN: It was very interesting because what we found, the nurses thought they had pushed the button; they were on correctly, and that was during our initial piece. Then, we went forward. Once we really made sure everyone was really aware of all the pieces -- and again, that was just the spot-checks over a month -- but, then, postpartum also was included, yes.

MEMBER LOWE: Okay. So, what you are reporting on is just not documenting at the time of surgery?

MEMBER KIEHN: Surgery, correct.

MEMBER LOWE: Okay.

MEMBER BRANDENBURG: We have this measure as well, and what we record is in surgery, but we also look at postpartum because that is typically what we are looking at, is trying to make sure that they are on after the surgery, when they are typically in bed for a little bit after the surgery.

So, that would be the kind of

difficult thing for us to change, is looking at just surgery. That would be change for us because we would look at it after surgery. That would be in our data elements.

The other thing is we do use pharmacologic, not just the compression boots. And I think a lot of our docs, I think we would probably meet the measure just simply from that. So, it would be easier for us to track it electronically in our medical record, looking at the pharmacologic and being able to meet the measure that way versus the compression boots. They are documented, but, like she said, I am not sure how accurate that would be. Pharmacologically, it would be easier to track.

CO-CHAIR SAKALA: Other comments on feasibility?

MS. MURI: This is Janet.

I think a shift that has occurred, too, is what we have done is we have changed our definition to go ahead and align and

harmonize with the ACOG definition. So, I think some of the comments that are being brought up right now will be some of the shifts that we will see in our own uses and aligning our definitions.

DR. WINKLER: Janet, this is Reva.

It wasn't totally clear. You say you have made changes to align or you are planning to make changes?

MS. MURI: We are in the process. So, Reva, what we are doing is we are making sure that, where we have these elements in our documentation, we are making sure that we are aligning with ACOG's data points.

MEMBER GROBMAN: But ACOG just asks -- but, right now, we are voting on this measure, right? And ACOG really doesn't weigh-in on terribly a great amount of this. I mean, it basically just says put them on at C-section for women who aren't pharmacologically anticoagulated.

MS. MURI: That's correct. All I

wanted to say was making sure that we were harmonizing with the national definition as a process that (phone technical difficulties) occurs (phone technical difficulties).

MEMBER GROBMAN: Okay. So, we are going ahead and voting on everything we have talked about.

CO-CHAIR SAKALA: Comments?

(No response.)

Okay. Let's vote on feasibility then.

(Whereupon, a vote was taken.)

Okay. So, we have 13 high, 11 moderate, and 1 low.

And we have one final vote, and that is your judgment overall whether this measure meets all four of the main NQF criteria.

MEMBER GROBMAN: Am I supposed to say anything about that or do we just --

CO-CHAIR SAKALA: If you have anything to say.

MEMBER GROBMAN: Good. No, nothing to say.

CO-CHAIR SAKALA: Yes?

MEMBER BERNS: I just have a question. On page 10, there is a note about other competing or related measures. If you can help me reconcile or perhaps harmonizing my brain how these relate or not, which are surgery patients who receive appropriate venous thromboembolism prophylaxis?

I mean there are three of them listed there. So, is this the same? Is it different? I mean, I know this is specific for C-section, but it looks like there are a number of other measures that are very close, and C-section is a surgery.

MEMBER GROBMAN: Yes, but C-section has never -- this is like Dr. Callaghan was saying -- we can debate the historical reasons for this, but C-section has never fallen under, even though it is a major abdominal surgery --

MEMBER BERNS: Okay.

MEMBER GROBMAN: -- has never somehow fallen under the rubric of other surgeries. I mean, it has just been whatever. It is out there in its own little bubble.

(Laughter.)

CO-CHAIR SAKALA: Kim?

MEMBER GREGORY: Yes, I would actually say that the benefit of those other measures is that you can tell the hospitals to do everything you did for those other measures. Just now they are pregnant women. And it actually increases the feasibility, and it means that the recording process and the documentation process is already in place because almost all hospitals are either reporting these to the Joint Commission or as part of their SHIP measures. So, every hospital could do this tomorrow, if they wanted to.

MEMBER GROBMAN: Right. It just let's pregnant women join the club.

(Laughter.)

MEMBER GREGORY: Yes.

CO-CHAIR SAKALA: Other comments before the overall vote?

(No response.)

Okay. Let's go.

(Whereupon, a vote was taken.)

So, 21 yes and 2 no.

We will be recommending that the Board agree to endorse this measure.

Okay. Elliot, we would love to have you join us.

The next measure is the California Maternal Quality Care Collaborative measure, No. 477, that infants who weigh less than 1500 grams are born in the appropriate facility.

And Sharon Sutherland will lead this.

So, we will begin with importance to measure.

MEMBER SUTHERLAND: Okay. So, this measure was endorsed in 2008, and it has

been developed by CMQCC. It measures the number of infants weighing less than 1500 grams not delivered at a Level 3 facility. The denominator are all live births of 24 weeks or more, and the numerator is, of those infants, how many are born weighing less than 1500 grams?

The consensus within our Workgroup is that under importance to measure all three areas were either high or moderate, and we had a consensus that all five of us felt that this measure met importance.

Based on impact, there is evidence to show a 60 percent higher mortality of very-low-birth-weight infants are born outside of a Level 3 nursery. There is evidence in California data of a performance gap. It was felt that some of this gap was due to economic factors, when, in fact, there were Level 3 centers located in a very short proximity to hospitals with lower levels of care.

There was anecdotal information on

the telephone call with the developer that they felt that economic factors may be more of an issue, and that transfer facilities are not being taken advantage of in a way that they should be.

The benchmark proposed by the developer is 1 to 3 per 1,000 births would be expected to occur in less-than-Level-3 centers due to precipitous labor or geographic barriers.

Evidence since this was initially proposed, a meta-analysis came out in 2010 by Lasswell that showed significant survival benefit for infants weighing both less than 1500 grams and less than 2500 grams born in high-level centers.

Any comments?

CO-CHAIR SAKALA: Comments about importance?

MEMBER BERNS: I mean, clearly, it is important that these high-risk babies go to these higher-level facilities, but my comment

here is that the Level 3 status is not consistent across the country. I think it is just important for us to recognize that may be consistent in California. And I think as long as we are comparing apples to apples, we are probably okay. But I am wondering if maybe Elliot has a comment on that.

DR. MAIN: Thank you.

First of all, this is an older public health measure that has been around a long time. What we did in California was to operationalize it to be a measure of hospital performance because it has been used at the State level for a long time, and there have been large gaps in performance and differences among states.

When we initially proposed this at the last meeting of this group three years ago, that point was brought out. What we have done is to use the American Academy of Pediatric definitions of Level 3, recognizing that different states tweak that slightly

differently to meet the local state needs.

And I don't see any other way around it, other than using the states' definitions of what a Level 3 center is, as we go around state-to-state on that. I don't think there are huge differences, though, I must say, between states on that.

MS. MURI: Dr. Main, this is Janet Muri from the AHCA.

I have doing an extensive study on the various states and the levels of services, and how they have been defining level of service, and then, also, looking at new definitions and then comparing those to the American Academy of Pediatrics.

There are significant differences in various states. Florida, in particular, comes to mind. They definitely have a higher (phone technical difficulties) newborns to be cared for in Level 2 hospitals. Their Level 2 definition aligns with the American Academy of Pediatrics' Level 3.

So, again, I do support the theory of newborns, low-birth-weight newborns being born in an appropriate environment (phone technical difficulties). I do caution on drawing generalities on the notion that this (phone technical difficulties).

MEMBER PROFIT: Could you try to get to a better phone because we can hear only about every second word you say?

MS. MURI: Does that help at all?

(Chorus of yeses.)

CO-CHAIR SAKALA: Thank you.

MS. MURI: Okay. That's fine. I'm sorry, I had you on speaker phone. Let me see if I can go back, just make this very brief.

We did do an extensive analysis on looking at hospitals, trying to do this leveling activity to assure that high-risk newborns, low-birth-weight babies were born in the most appropriate care setting.

Based upon our extensive study in

all of our various states that we have representation in, we found that there was a significant disparity between the way the states do define level of service as it aligns with the American Academy of Pediatrics' level of service.

And as I said, Florida was one that probably came to mind with the most discrepancy between having a finer level of service as compared to the AAP's.

So, while I do support the mission and the vision of this proposal, I am just a little bit cautious in making assumptions that the states aren't going to vary that much from the AAP's definition.

CO-CHAIR SAKALA: Thank you.

Because of time constraints, I think we are going to have to limit developer input to the measures that they are stewards of.

Lee, did you have comments?

MEMBER PARTRIDGE: Actually, I was

on the Workgroup that discussed this at some length. I am very cognizant of the NICU issue. At the Medicaid Directors' Annual Meeting a couple of weeks ago, Texas presented on this very subject and said that preliminary to looking at this issue is to conform their NICU definitions across the State.

The more compelling evidence in the presentation that Dr. Main sent us to consider, I think, is what you might think is that the incidence of this kind of inappropriate delivery would be in the rural area, the tiny, small hospital, and so on. That did not prove to be true in California.

That, for me, was a pretty compelling thing, that if an innercity, a major city with all these facilities was not delivering women who are high risk at the right place, there ought to be an effort at that city's level to do better.

CO-CHAIR SAKALA: Jennifer?

MEMBER BAILIT: Just as a

researcher and having worked with birth certificate data locally in Ohio and done a project, I would concur this data is unpublished except in the abstract form.

The rural communities do a great job of getting the babies out. It is the innercity where we want the dollars is my speculation as well, where they keep the deliveries and ship the babies.

Having said that, while it is difficult if you are looking at a national dataset to figure out who is really a Level 3 and who is not, at the local level it is painfully obvious.

So, if these are looked at at state level and people are looking at it at state level, and each state sort of knows what their true Level 1s and 2s and 3s are, I think this is a very reportable measure, and that there is the possibility for AHA or somebody else to harmonize across these measures.

So, I wouldn't let the varying

state definitions get in the way of this being a useful measure.

CO-CHAIR SAKALA: Other comments on importance?

(No response.)

Okay. Let's vote on importance, please.

Oh, I'm sorry.

MEMBER DRYE: Hi.

This is the first time I have seen -- I develop hospital measures full-time pretty much -- this is the first time I have seen a measure that is so system-dependent. Really, I am surprised at what Lee is saying, which is the rural areas do better.

I can totally see how it works as a system- or a state-level measure, but at a hospital level are there hospitals that just this is not actionable for them because there is nowhere to transfer these babies in a safe way, pregnant women prior to delivery in a safe way; the time, it is just too far?

How do you account for that in the measure, to make sure it is really a true measure of quality at all the hospitals you are considering including?

DR. MAIN: When we took this down to the hospital level, we looked at a couple of factors that would take that under consideration, including we had data on the length of time that the mother was at the hospital before she delivered, which gets to the issue of did she come in to deliver. The average time that the mothers were there was between eight and twelve hours. So, there was plenty of time to transport moms, and they just weren't.

In most every state I believe that there are networks now for transferring babies to Level 3 centers. What has happened is deregionalization, driven by economics. This is a balancing measure to address that issue.

MEMBER DRYE: So, just to clarify, you are wanting to report at the hospital

level to drive system change, not hospital change per se? In other words, unless those regional -- I am just trying to understand the difference between reporting this at a regional level or a state level and a hospital level, because you are really wanting to switch the focus.

What if you are in a state that isn't going to support the infrastructure you need to have transfers within a reasonable amount of time?

DR. MAIN: I am not aware of any state that doesn't support transfers of these kinds of babies.

MEMBER DRYE: You want the hospital to do the right thing because they have incentives to maybe do the wrong thing.

MEMBER BRANDENBURG: I'm from a Level 2 facility. So, we do ship a lot of our babies out. Getting the babies out is usually not a problem and it is not hard. I mean, there's multiple places we can get the babies

to. But there are certain circumstances that we run into -- for instance, weather sometimes is an issue for us. I mean, typically, we fly them, especially if we are in a hurry, and they can't fly under the weather conditions. And we have even had blizzards where they can't come by ambulance. And so, we have ended up with a baby delivering that we really didn't want to deliver.

So, I mean, there are certain circumstances that happen, but they are rare, but it does happen.

CO-CHAIR SAKALA: And I think that fits with the 3 percent. We are not looking for zero here.

MEMBER DENK: I just want to comment on New Jersey. We are one of the states that licenses facilities. We don't rely on AAP definitions for what is a Level 1, 2, 3. We actually license hospitals. We have, you know, Certificate of Need calls and the whole thing. So, there can't be any

mistake about where a baby is supposed to wind up, and we have a fair degree of compliance.

But I just wanted to point out that the definition of appropriate level of care is often a matter of licensure rather than a squishy definition of who meets care. And there are some hospitals that aren't transferring babies because they are in hospital systems where they can call on staff that make them meet AAP standards, even though they are not licensed.

And so, this is a really good measure if it is licensure that is the metric.

MEMBER JALEEL: This is my first time at NQF. But if we think, as I am not sure what NQF can do with this, but if we think that truly this is an important measure, can we not endorse what the AAP criteria is for the definition?

DR. WINKLER: If you look at the specifications, that is what is included. So, that is what is in front of you to opine on.

MEMBER JALEEL: Because it says, "as defined by the State Department of Health or a similar party". Why not directly say "American Academy of Pediatrics"?

DR. MAIN: I wish I could tell states what to do on this.

MEMBER JALEEL: Yes.

DR. MAIN: But AAP has been used by many of the states, though there are individual circumstances in different states. Interestingly, some of the very rural states, like North and South Dakota, have done very, very well on this with 96-plus percent of babies delivering in Level 3 centers. So, it certainly can be done in rural areas.

We are 50 states and it is tricky sometimes.

CO-CHAIR SAKALA: Okay. Time-wise, I think we would like to move on, unless there is any other urgent comment.

Could we have a vote, please, on importance to measure and report?

(Whereupon, a vote was taken.)

DR. WINKLER: Twenty-five yes, zero noes.

CO-CHAIR SAKALA: Okay. Sharon, so scientific acceptability, please.

MEMBER SUTHERLAND: The Workgroup felt that for scientific acceptability the definitions were precise and there was standard reporting under state vital statistics that made this measure very reliable.

The validity will require reporting of all events due to this being a rare occurrence. So, we cannot sample.

And I don't know if anybody has any comments about their experience with EMTALA violations. That was something that came up with the issues in the Workgroup, if anybody has any comment on that.

CO-CHAIR RILEY: I was on the Workgroup. I mean, I think we may have misinterpreted the EMTALA violation situation

because really what it says is that you need to evaluate. You are required to evaluate someone who shows up in labor. It doesn't say that you can't, then, appropriately transfer them to the right place.

So, I think it has nothing to do with this. I think we sort of misinterpreted that on the call. And then, as Elliot already said, those patients tended to be there for eight to twelve hours, which has nothing to do with the EMTALA violation.

So, I think we may have taken care of that one.

MEMBER PROFIT: When I read this, I was kind of surprised. In my -- I guess about 10 years now -- practice, I had never heard that being given as a reason for why a baby was born at an outlying hospital and not transferred. So, it was an interesting, but I had just never heard of that as a very common problem, I guess.

MEMBER KELLY: I come from a rural

state, Colorado, with a lot of small hospitals and weather issues. I am wondering why or if there is a way to track those small hospitals with less than 50 deliveries that have been excluded.

DR. MAIN: California actually has a very large amount of small, rural hospitals, big, big State that it is. We have a lot of weather issues in northern California, not with snow, but with fog.

And there's very rare occurrences, though the problem with this being a rare event is that one occurrence throws you off greatly. And so, we did exclude very small hospitals from the measurement for that reason, that there can be one event, and if you have 50 births, that is five years of events right there in that one case.

MEMBER KIEHN: I'm from Utah, and we have a small amount also. Within our system, we have hospitals that are less than 50 births, and we do track this internally and

it does throw it off. It is a significant issue, and, again, weather-related. So, I agree that we should have the exemption of the less-than-50.

DR. MAIN: And, indeed, they account for a very, very small amount overall of the babies not delivered at Level 3 centers.

CO-CHAIR SAKALA: Other comments on scientific acceptability?

(No response.)

Okay. I think we can have a vote then on this criteria.

(Whereupon, a vote was taken.)

Okay. We have a unanimous result of 25 supporting and no one saying no.

So, we will move on, then, to usability, please.

MEMBER SUTHERLAND: So, the usability criterion was the one with the lowest consensus ratings in our Workgroup. CMQCC proposes this measure to increase

scrutiny of practice patterns and encourage hospital administration to transfer pre-term labor patients when appropriate.

Medi-Cal has started to track this metric in California, and it is unclear if performance will impact reimbursements.

The consensus of the Workgroup was that the public may not understand this measure. And I think, as was already brought up by Elizabeth, the issue is more that of a hospital level or an administrative level rather than one that is made one-on-one as far as at the bedside, as far as a quality measure.

CO-CHAIR SAKALA: Comments from others?

MEMBER BAILIT: I guess my question is, is public reporting all about the consumer necessarily or some of the other stakeholders? For example, insurance companies? I would actually be very curious to see what Joanne Armstrong says about this.

Because I can envision a system where you have to write a response about why that baby didn't get to the right center. And maybe it is because it was in the middle of a snowstorm, and then Medicaid accepts it or Aetna accepts it. But you have to have some sort of explanation for why.

MEMBER ARMSTRONG: Yes, I would say, from a health plan point of view, systems issues are very important. I think as we move into the ACO, accountable care organization, environment, they are going to become even more so. So, I think that is fine.

Some of the health plan issues are, when we go in and try to independently confirm some of the reporting, and then we have this issue of whether you are using ICD-9 and what the administrative database limitations are, but it is not this one.

I would say, for this one the challenge we have when we try to look at this is what you define a Level 3 NICU to be. And

it is all over the boards.

CO-CHAIR SAKALA: Kim?

MEMBER GREGORY: I think another issue down the road, actually, if and when this gets implemented, is the ambulance. There are times when the ambulance doesn't take them to the right level of care. If we really want this to happen, probably that needs to be thought about as well, because the ambulance is going to take them to the closest hospital, even though the most appropriate hospital may be a little bit further down the road.

MEMBER YOUNG: I can actually speak a little bit to that because we have a very large transfer center, and we also support several county EMS systems in our emergency department.

Their standard of care is to take the patient, if the patient is in active labor -- and that to most EMS or at least basically EMT-trained people is screaming loudly every

three minutes -- then that means that that patient needs to go to the nearest emergency department or nearest hospital. They don't get to bypass care. That is not their standard of care. But their standard of training is that they go to the nearest emergency department or the nearest hospital to be evaluated, treated, and stabilized.

CO-CHAIR SAKALA: Lee?

MEMBER PARTRIDGE: I served for -- is this on (referring to microphone)? As a former hospital board member for five years in a hospital that delivered a lot of babies because it was the public hospital here in the District of Columbia, I can tell you that public reporting of this kind of information would make a major impact on the hospital's trustees. It is the kind of thing that you might not know anything about as a member of the hospital board, but if it showed up, particularly if it was picked up by your local news shows, you would ask questions and you

would try to encourage changes.

DR. MAIN: If I might add, I think one of the directions of this kind of a measure is to change systems, including things like EMS. In San Francisco, the EMS providers do bypass hospitals and take them to designated higher-level obstetric facilities.

So, it is possible. But, again, I think you need direction from quality indicators to do that.

CO-CHAIR SAKALA: We are a little tight on time. Any other urgent comments?

Sorry. Yes?

MEMBER DRYE: I just wanted to clarify really quickly that I think philosophically it is fine to hold hospitals, to put the locus of reporting on a hospital to drive system change to a certain degree because hospitals are clearly critical actors within the health system. So, I wasn't objecting to that per se.

And what I have heard from the

group is hospitals can act and it is rare that they don't have the option they need here to perform on the measure.

CO-CHAIR SAKALA: Okay. Could we have a vote, please, on usability?

(Whereupon, a vote was taken.)

Okay. So, 17 high, 8 moderate, and no lows.

So, let's turn, finally, to feasibility, please.

MEMBER SUTHERLAND: So, the Workgroup felt that this measure would be easy to report because it is collected in the state birth certificate data. The survey showed that less than 1 percent of this data was missing information that would be needed for this measure. So, this, in general, got a score 4 high and 1 moderate for feasibility in our Workgroup.

CO-CHAIR SAKALA: Comments?

(No response.)

Ready to vote?

Okay. Let's vote.

(Whereupon, a vote was taken.)

DR. WINKLER: Twenty-three high, 2 moderate, zero low.

CO-CHAIR SAKALA: Okay, and finally an overall suitability-for-endorsement vote, please.

MEMBER PROFIT: Maybe I could just have a comment in the meantime. I would hope to retire this measure soon because I think it could be fixed with appropriate incentives. So, hopefully, next go-round it won't be an issue anymore.

CO-CHAIR SAKALA: Nancy?

MEMBER LOWE: Yes, just related to that, though, I have been in this business more than 40 years. And I remember the beginning of perinatal regionalization in Illinois, and here we are still talking about the same problem. So, I doubt it highly.

(Laughter.)

CO-CHAIR SAKALA: Okay. One

equals yes and 2 no, please.

(Whereupon, a vote was taken.)

Okay. Twenty-five yes and no noes.

Thank you.

Okay. Now we are going to move on to two measures that were moved to the morning session. One is 474, birth trauma, injury to neonate, an AHRQ measure.

Do we have a developer here or on the phone? Good.

MS. PANCHOLI: Hello. Yes. Mamatha Pancholi from AHRQ.

CO-CHAIR SAKALA: Welcome.

And this is Chuck Denk, right?

MEMBER DENK: That's right.

CO-CHAIR SAKALA: Oh, I'm sorry. Is that okay? Yes. All right.

MEMBER DENK: We are doing them out of order. Is that okay?

Okay. Just as a little bit of context, I just want to say that this

particular measure, entry to neonate, is part of a portfolio that is implemented by AHRQ at the state level at least; I don't know if it is implemented at other levels.

It is a whole package of patient safety indicators, and it is rolled out with computer programs for analyzing universal billing records. And that is how it is used in New Jersey in any case.

So, the methodology which you see here is driven by the normal sort of ICD-9 codes, but this is all done electronically, to my experience. New Jersey does it and reports it back to hospitals more than it does to the public.

Given that, this measure ran into some problems. They basically fell into two categories.

The first one was a bit of confusion because brachial plexus injuries are, in fact, excluded from consideration in this measure. That was felt to be a pretty

strange exclusion. The rest, you know, the other birth injuries, most of them are associated with -- well, let's see. I won't say that.

I will say that, as originally submitted, there was no real explanation for why BPIs were excluded, but the literature review that you see in the measure's presentation focuses explicitly on brachial plexus injuries as an important thing to be avoided.

Since that time, the developers have submitted an appendix or something which I found on my drive here. Didn't know it existed. But, anyway, I got a chance to skim it. And I will just read you a summary paragraph because it is not available anywhere else.

"In summary, the clinical evidence indicates that most depressed skull fractures and some intracranial hemorrhages are related to application of forceps, vacuum-related.

Subaponeurotic hemorrhages are related to how the vacuum device is applied. Most spinal cord injuries are related to entrapment of the fetal head, and most cutaneous lacerations are related to scalpel manipulation during the delivery process."

So, that sort of shortcoming was addressed by the developers, but still leaves a sort of an issue of whether or not brachial plexus issues should be excluded. I imagine that the logic is because shoulder dystocia is an unpredictable and hardly preventable thing.

But I think it is appropriate, right, that we should ask the developers to comment on that?

DR. ROMANO: Yes, I can comment on that. This is Patrick Romano. This is Patrick Romano from UC-Davis, representing AHRQ.

So, first of all, let me apologize for the confusion in the submission form. Because we have separately submitted and

discussed the literature for shoulder dystocias and for other types of birth injuries with our expert panels. And so, unfortunately, we put the wrong literature review in the document. So, we apologize for that confusion.

So, we did present -- we have two separate expert panels, one focused on the obstetrics side and one focused on the neonatology side, that reviewed this indicator. And both of those panels recommended excluding the brachial plexus injuries, the shoulder dystocia-related injuries, the clavicular fractures as well, from the numerator specification for this indicator.

So, that is why this indicator, as specified, now focuses on intracranial hemorrhages, skull fractures, long bone fractures, scalpel lacerations, and the other types of nerve injuries that you see there.

And the rationale for the

exclusion was, as you say, primarily because of concern that many of the shoulder dystocia-related injuries are transient injuries. They have no particular clinical significance. The duration of the injury may be unpredictable, and the degree of preventability was uncertain.

Many of the panelists felt that these complications were, therefore, very difficult to avoid relative to the other types of complications that remain in the indicator numerator specification.

MEMBER DENK: Thank you.

And that brings me to the second issue under importance that the Subcommittee sort of struggled with, which is actually an extension of your comment, which is that all of these injuries seem to be sort of diverse, a little bit difficult of ascertainment perhaps, and specifically not relatable to any specific kind of quality improvement strategy which would reduce those kinds of injuries,

except one. That is one that I can vouch for being a very important one in New Jersey, which is to just section everybody.

(Laughter.)

So, one of the issues that we are supposed to be considering here is the adverse consequences of measuring a certain thing in a certain way and then having the measure be gamed. And so, that became a serious consideration.

Basically, it was a pretty split vote. It was the most diverse ranking of any of the measures in my Working Group. It was based on that, the lack of a connection between a positively-oriented quality improvement strategy and the sort of mixed bag of injuries that fall under this category.

MEMBER BAILIT: Hi, Dr. Romano.

When I have used this measure in the past, it has been completely dominated by lacerations of C-section, which, I think, the vast majority of which are minor and of no

long-term consequence.

Can you comment as to the construct of this measure, about what proportion is taken up by the lacerations?

DR. ROMANO: Yes. I think that when we examined this, actually -- well, the data that I have in front of me are that two-thirds of them were actually skeletal injuries. Most of those skeletal injuries were skull fractures, and the remaining one-third were mostly in the category of lacerations. Specifically, they fall into 767.8, which is other specified birth trauma.

So, those two codes account for the majority. The intracranial hemorrhages, the spinal cord injuries, and the other cranial and peripheral nerve injuries together account for less than 10 percent.

And I would say, just to follow up on your comments, that, well, this is sort of precisely why our expert panels wanted to retain this definition where you have some

components that are more common with cesarean delivery and other components that are more common with vaginal delivery or instrumented vaginal delivery.

Because, obviously, the cutaneous lacerations, although they are not very clinically-significant, they are very difficult for parents to deal with, and they are largely limited to the cesarean deliveries.

On the other hand, the other types of trauma here are more common with vaginal deliveries, and specifically instrumented vaginal deliveries. And those categories are clearly associated with higher length of stay and higher charges. So, we do have a mixture of some that are cesarean-related that don't have a lot of clinical consequence, but are distressing to parents, and others that have serious clinical consequences that are more common with instrumented vaginal deliveries.

MEMBER DENK: Please, Bill

Grobman?

MEMBER GROBMAN: So, I guess I would just say a couple of things. I mean, one, I think, Dr. Romano, what you brought up is this sort of balancing, though. They really are so profoundly different, you know, lacerations, although clearly sad for parents, much less sad than a spinal cord injury or a major subaponeurotic bleed. That would be No. 1.

No. 2, I would actually question whether or not, just from a personal experience in the last few days, whether lacerations are really just related to C-section. For example, we just had a baby coded with a laceration from a scalp bleed that was literally just a tiny, little -- it was .3 millimeters, it was in the chart, but it got coded; it was denoted on the physical exam by the pediatrician and subsequently coded as a scalp laceration by coding people.

And then, the other thing I would

tell you is there is -- and this was mentioned -- a tremendous amount of ascertainment bias. Because, true, for a facial palsy or something, that might be picked up, but the intracranial hemorrhages, that is so dependent on what kind of radiologic investigations is done.

And actually, I would view the documentation that was sent as of greater concern in the sense of it is well-described that those things occur with spontaneous deliveries, both bleeds and skull fractures, but yet it is rare that babies who are delivered from spontaneous deliveries get the kind of workover that babies, even asymptomatic babies, that are delivered by operative vaginal delivery receive.

And so, there is a tremendous amount of ascertainment, and it is also not entirely clear, then, that this drives quality toward any particular way. Because if my rate was bad, I wouldn't know what to do.

MEMBER DENK: Well, I was putting this off until the next slide, but probably it is worth talking about it right now. One of the scientific questions had to do with why the measure is not stratified by the method of delivery. And so, there may be a past history of that, but we would sort of like to think about that, too, as to whether stratifying it by cesarean delivery versus an attempted vaginal delivery, because I guess you could have both occur, would actually greatly improve -- we'll talk about scientific validity in a minute, but talk about how we can sort of get rid of this problem of having adverse consequences and gaming.

Dr. Berns, did you have something to say?

MEMBER BERNS: Oh, I just had a quick question. I am just curious, in the denominator exclusions, the first one, pre-term infants, I get it, but with a birth weight less than 2,000 grams. I am just

curious as to why you choose 2,000. Was it because it was halfway between 1500 and 2500? I'm not sure.

MEMBER DENK: Maybe that is what we should talk about when we get to the next slide.

(Laughter.)

After this vote, that is the next thing, isn't it? Denominator, that kind of stuff is usually the second vote?

CO-CHAIR SAKALA: Yes.

Mary, and then we are going to need to move on because of time.

MEMBER LESLIE: Okay. I just wanted to clarify, we don't actually have the evidence then for this measure. The evidence that was submitted was on shoulder dystocia? So, we can't actually evaluate the evidence for this measure, is that correct?

DR. WINKLER: This was sent to you last night after we received it from AHRQ. It is also on the flash drive. So, we have given

it to you as soon as we got it.

MEMBER DENK: Right. I can summarize. The last paragraph I think is what is relevant here. There was a study of 669 newborns at Georgetown University Hospital who had a discharge diagnosis of birth trauma. It basically concludes to say additional validation work is planned, but has not yet been completed in collaboration with the National Perinatal Information Center.

So, do you want to expand on that, Dr. Romano?

DR. ROMANO: No. I would just point out I am not sure if Janet Muri is on the phone.

MS. MURI: Yes, I am. Hi.

DR. ROMANO: Okay. So, the National Perinatal Information Center has been a co-steward of this measure with AHRQ. And so, I will let Janet speak.

MS. MURI: I think that we have used the measure for reporting back to our

hospitals for a number of years. I think that there are a total of about 12 ICD-9 codes, I think, that can be generated for birth trauma. This is a subset. AHRQ uses a subset of codes that are the most serious codes and are not prone to miscoding by the coders or overcoding. So, it really is a subset that gets to the seriousness of the injury.

We have not stratified by type of delivery, which might be something to think about. As I said, we have given our hospital a lot of data over the years, and many of our member hospitals have actually used this to drill down and look at their processes around labor and delivery to see whether or not there is opportunity for improved training or decisionmaking during the process of the delivery to mitigate birth trauma.

So, we have gotten good feedback from our hospitals. I think they appreciate monitoring this measure on an ongoing basis. And many of them will include this measure on

their dashboards that they bubble up to the board of directors or the quality management group.

CO-CHAIR SAKALA: Thank you.

Laura?

CO-CHAIR RILEY: A quick question for you, and this may be an unfair question. But do you have any idea of what the C-section rate is in those hospitals that you do this reporting, just out of curiosity?

MS. MURI: Yes. I think we have about, let's see, I think it is averaging right now about 34.5 percent. I can check that for you and give you a specific number. This is data as of 3/31/2011.

CO-CHAIR RILEY: For the non-clinicians, that is high.

(Laughter.)

MEMBER DENK: Yes, yes.

CO-CHAIR RILEY: A little bit high.

MEMBER KIEHN: From a health plan

perspective, that is low. The national rate is 38 percent in 200,000 commercial births.

MEMBER DENK: Right. Yes.

I think we could go ahead and probably --

MS. MURI: Yes, I think it is in the neighborhood of about 35 percent.

CO-CHAIR SAKALA: Okay. So, could we please have a vote, importance to measure and report? Yes says you agree that it meets criteria for impact, opportunity for improvement, and evidence.

(Whereupon, a vote was taken.)

Okay. So, 4 yes and 20 no.

And that means that we are moving on to the next measure, which is -- and apologies for getting this out of order -- Craig Gilliam will lead the discussion on 478, nosocomial bloodstream infections in neonates.

DR. WINKLER: Craig, just a second. Let me jump in.

Is Rebecca Gee on the phone?

Rebecca, have you joined us yet?

(No response.)

Rebecca got bumped from her flight last night and is flying in this morning, but she just emailed in saying she is on her way and wanted to call in. So, we just want to see if she is there.

CO-CHAIR SAKALA: Okay. Thank you.

MEMBER GILLIAM: So, the description of this, this is a percentage of high-risk newborns with an ICD-9 code for bloodstream infection. The numerator is discharges among those cases that meet the inclusion and exclusion rules, and the denominator is those newborns or outborns that are between a birth weight of 5 to almost 1500 grams or a gestational weight of 24 to 30 weeks or those that have maybe a high birth weight of greater than 1500 grams, but have a death, an operating room procedure, mechanically ventilated, or they stay in the

hospital less than two days and are transferred to another facility.

And I apologize, I was not on the call, but I am summarizing the notes from the group. I will let them also give their opinion as well.

This is, in our opinion, high impact. It is something that is measured in many facilities. There is room for improvement.

If you look at the data, the Centers for Disease Control, their NHSN system would suggest that the rate is significantly higher for those that are lower birth weight. And when you actually look at individual quartiles, or quintiles I guess is the latest one, those that are of very low birth weight, the rate of infection is higher in that particular group.

CO-CHAIR SAKALA: Comments on importance to measure?

DR. ROMANO: Could I just make a

prefatory comment?

CO-CHAIR SAKALA: Please.

DR. ROMANO: So, I think it is important for the Committee to know that we have been through, I think, about a three-month process with the Joint Commission to harmonize the specifications for this indicator with the corresponding Joint Commission measure that will be reviewed tomorrow morning.

I am not sure if Celeste Milton from the Joint Commission is on the phone.

There are some remaining differences between the measures that really relate to the Joint Commission's use of chart data as well as ICD-9-coded data. But as far as the ICD-9 CM codes are concerned, we have harmonized exactly with the Joint Commission.

DR. WINKLER: Just to follow up on that, what is your timeline and plan on the conversion to ICD-10?

DR. ROMANO: We both have draft

specifications based on ICD-10 codes, but, as I think most people here know, the ICD-10 CM codes are significantly more specific than the ICD-9 CM codes. And so, they raised some clinical issues about which of the codes we want to capture. In some cases, the exact mapping may not be what we want for the indicator specification.

So, I think we have planned a process of going back jointly to a clinical group to get input regarding the ICD-10 CM specification. That would be done over the next few months.

CO-CHAIR SAKALA: Other comments on importance?

MEMBER BRANDENBURG: This is just one more comment. This is kind of like the DVT measure. This is one of those ones where NICU and obstetrics is just catching up to all the other specialties that are already looking at nosocomial infections.

CO-CHAIR SAKALA: Jochen?

MEMBER PROFIT: I just had a question. It is not really about importance. But since we are now starting to like talk about all these infection measures, many of these infection measures are good, but maybe we don't want hospitals to report five different infection measures.

So, I guess I am not sort of clear about how our vote on each individual measure is kind of converted into a real endorsement of the measure. So, I don't know if we could specify that.

Now my other question for the measure developer was -- and maybe we will get to that in feasibility, but the difference between the AHRQ measure and the Joint Commission measure. AHRQ does everything on the back-end without the hospital and everything actually having to do something to collect a measure (sic) versus Joint Commission will require the hospital to collect some data.

So, I guess if you could clarify that along the way, that would be important for me. Thank you.

DR. WINKLER: In terms of multiple similar measures, yes, the Work Group certainly identified that there are at least four measures that are very similar. The question is, do we need them all?

The way we do this is in a stepwise approach. What we want to do is evaluate each of the individual measures on their own merits to determine if they do meet the criteria. That is why that last question is really, does it meet criteria?

Then, tomorrow afternoon, if you notice the agenda as well as the memo that came, we will put them side-by-side and see how they are different and how they are alike, and ask you to address that question of, are any clearly superior? Do we need all of them? What would be your final recommendation, based on that comparison.

But the first step is to be sure that all of them meet the criteria. If, for instance, one of them doesn't, then they are less in the side-by-side.

CO-CHAIR SAKALA: Other comments on importance?

(No response.)

Okay. Let's take a vote on importance.

(Whereupon, a vote was taken.)

Okay. Unanimous. For those who voted, 25 yes, no noes.

So, scientific acceptability, please.

MEMBER GILLIAM: So, as far as the scientific acceptability, the reliability, as you can see, two voted high and three voted moderate. I think the issue is, as alluded to earlier, one of the issues is that this is using coding data after discharge versus prospective that the Joint Commission would suggest.

So, you can see there is a concern about biases related to transfer and if that would have any impact or not. I am going to let the other members, if they had any comments to make, about that.

MEMBER DRYE: I think this measure is in use already, right? And I would just be interested to hear the experience of users because it is a really complex measure the way it is specified. What is the experience?

MEMBER GILLIAM: We don't use it in my facility currently.

CO-CHAIR SAKALA: Do you have a comment on that?

DR. ROMANO: Yes. This is one of our more recently-developed measures. This is one of the neonatal quality indicators, which is the most recently-developed module of quality indicators. And therefore, we haven't yet undertaken a detailed kind of chart-based validation work.

We do have extensive user

experience and user feedback that comes into us as well as from the Joint Commission. So, as part of the harmonization process, we basically reviewed that feedback with the Joint Commission. In every case where hospitals told us that they found some discrepancy or some error in their own internal review of those cases, we tried to identify the cause of that and fix that in the harmonized specifications.

So, that is why, unfortunately, the specifications that have been submitted here are slightly different from the specifications that are posted currently on the website, because of that user feedback process that we have incorporated into the revision.

Just to comment on the transfer status, so the way that we have dealt with that is to have the risk-adjustment model include a variable for patients who are transferred in from another facility. And so,

that has a positive coefficient in the risk-adjustment model. So, those patients get a little bit extra credit for a little higher risk of mortality. Of course, that may not take into consideration local factors that may drive differences in referral across hospitals and different communities. But at least, overall, it is an average effect of transfer in that is accounted for.

CO-CHAIR SAKALA: Thank you.

Other comments on scientific acceptability?

MEMBER PARTRIDGE: I'm a little confused. Are the specifications that AHRQ is currently using different from the measures before us?

DR. ROMANO: Yes, that is what I am saying. The measure before you is a result of the harmonization with the Joint Commission to ensure that we are using a consistent set of ICD-9 codes. If you want me to go through the details of --

MEMBER PARTRIDGE: No.

DR. ROMANO: -- how it is different, I can.

(Laughter.)

They are minor differences, but there are some slight differences.

MEMBER PARTRIDGE: So, in the future your AHRQ specs will change to be what is in front of us? Okay.

DR. ROMANO: That's correct. I think that is slated for Version 4.4.

DR. WINKLER: Patrick, do you have any sense of the degree of changes that have some impact on your previous evaluations of reliability and validity of the measure?

DR. ROMANO: Actually, our preliminary estimate is that it has very little impact on the overall rate of the indicator and the distribution of the indicator. I think it actually has more of an impact on the Joint Commission measure because the Joint Commission measure, it had a broader

denominator exclusion, that it was excluding a larger group of patients that are now recaptured in their denominator.

So, what we are finding is very little impact overall on the mean rate and the distribution of rates.

MEMBER PROFIT: I had a question about -- I'm sorry if I make a fool out of myself here -- but under Section 2A1.9, the denominator exclusion details, I just can't figure out why all these bacteria or septicemias are excluded from the denominator.

DR. ROMANO: Right. That is a little bit tricky. You have to look at the beginning of that section, and they are excluded if the patient has a principal diagnosis or a secondary diagnosis present on admission. So, in other words, if the hospital says that the patient was transferred into us with this infection, then we exclude the patient from the denominator.

MEMBER PROFIT: Okay.

DR. ROMANO: So, those exclusions only apply if they are reported by the hospital as present on admission or the principal reason for admission.

MEMBER YOUNG: And regarding the future for ICD-9 versus ICD-10 conversion, have you all already done that because you clearly have listed ICD-9 codes in --

DR. ROMANO: Right.

MEMBER YOUNG: -- Section 22A1.9, and also for your 22A1.3.

DR. ROMANO: Here we go.

Yes. So, I am looking at a draft ICD-10 CM specification, which is based on the application of the code maps. But in the case of some bacteria, in other words, our expert panels helped us identify the specific bacteria that were felt to be the most important causes of nosocomial bacteremia in this neonatal population. In some cases, the ICD-10 CM codes are a bit more specific. And so, we will want to review those more specific

organisms with some clinical consultants. But we have a draft specification that will go through review over the next few months.

CO-CHAIR SAKALA: Jaleel?

MEMBER JALEEL: Yes, I had a question about the denominator statement, which No. 3 is birth weight greater than or equal to 1500 grams, plus all those other criteria, hospital death, operating room procedure, mechanical ventilation.

I know that, yes, these factors will increase the risk for infection, but is this going to muddy the water? Why not clearly cut it at 1500 grams because those are the babies which we are really worried about having bloodstream infections? Why include them in this denominator?

DR. ROMANO: Well, I can tell you the clinical concept was to include babies who are high-risk, and that is predominantly babies who are likely to be in an NICU. So, given that people operationalize this

indicator without knowing exactly which babies were in the NICU and which ones were not, this represents an effort to identify the babies who are likely to have been in an NICU, either because of their birth weight or because of their congenital anomalies or their need for a major operation during the neonatal period or the fact that they were transferred in for high-risk conditions. So, that is the clinical concept of the indicator.

As with the previous indicator, it is common practice in the RQIs to stratify. And so, that would be an option. But, currently, it is not part of the specification, but that would certainly be an option.

MEMBER JALEEL: Is there any scientific basis? Is there any literature to back it up, that, yes, these are factors which are important?

DR. ROMANO: There is certainly ample evidence on babies admitted to NICUs

being at risk, even if they are not low birth weight. We have not specifically validated whether this set of denominator inclusion rules captures babies who were in a neonatal intensive care setting. So, that is something that we could evaluate over the next year or two, if it is of interest to NQF.

MEMBER GILLIAM: Can I just mention, I mean, from a clinical standpoint from doing surveillance, we are going to survey all of those neonates, whether they are above 1500 grams or not. They are not a huge population, but they are ones.

And for us, excepting those neonates that have a central line as an additional risk factor, those are mechanically-ventilated. Those are the ones that we more likely are going to have an operative procedure and have post-operative problems and at risk for developing a bloodstream infection.

So, from a surveillance

standpoint, it is not that much more work. In fact, it is harder to exclude them, from our perspective.

CO-CHAIR SAKALA: Thank you.

Other comments? We are getting a little behind schedule here.

MEMBER DRYE: I am always following that comment.

(Laughter.)

I just wonder, in particular, using mechanical ventilation as an indicator, how consistent -- can you speak to how the ICD-9 code is consistently used across hospitals and whether CPAP or intubation, or is there some clear threshold for use of that code that is consistently coded? Because I know in our work we have been reluctant to use it to classify patients.

DR. ROMANO: That is an interesting question. I think our experience, and the feedback that we have received from users, has been that it is very well-coded

because it is how they justify the prolonged stay of the patients in the hospital. Without those codes, it is hard to justify why these babies are staying so long in the hospital.

But we haven't specifically validated that. It is just the feedback we have received from users.

CO-CHAIR SAKALA: Final comment?

MEMBER DRYE: Yes, final comment.

To me, it is interesting to see death as part of the denominator definition when, obviously, death is a potential outcome of bloodstream infection. I just wonder from a surveillance standpoint, you know, how does that group of babies fit into what you would normally do in surveillance to look for preventable bloodstream infections?

MEMBER GILLIAM: It doesn't, to be honest, it doesn't impact one way or the other. I mean, the only way that it might impact is when we talk about prevention strategies. If we look at why that neonate

died related to infection, then we may go back and address something. It is not inconsequential, but it is not a huge impact I think in most NICUs.

DR. ROMANO: Yes, again, this was a product of user feedback where a user said, "Well, we had some neonates who were in the NICU for a short period of time, and because of their profound anomalies, it was determined that they would not be mechanically ventilated."

But during the time that they were in the NICU they were at risk for nosocomial infection. And so, we decided to capture them to maintain that clinical concept. But it is, I agree, it is a bit unusual.

CO-CHAIR SAKALA: Last comment, please.

MEMBER DENK: Yes, from the non-clinician, from a statistical point of view, this one shares probably some characteristics with the last one in that it is really a

composite measure. There's several different clinical things going on. There's several different denominator bins for people to fall into.

And maybe it might be more helpful if measures like this get treated explicitly as composites from the very beginning because the mixing and matching seems to be throwing a lot of people off; whereas, a weighting scheme, even if it turned out to be equal weighting, you know, might help clarify to people sort of what's the justification for combining them as a composite.

CO-CHAIR SAKALA: Okay. Could we please have a vote now on scientific acceptability of the measurement properties?

(Whereupon, a vote was taken.)

So, 23 yes and 2 no.

So, we will move on to usability, please.

MEMBER GILLIAM: So, the usability, it was high and then two were

moderate. As we may discuss, in the future it is going to be harmonized with the Joint Commission. We have already briefly mentioned that transfers is not a huge impact.

CO-CHAIR SAKALA: Other usability comments?

(No response.)

So, if not, we can vote on that, please.

(Whereupon, a vote was taken.)

So, 13 high, 11 moderate, and no low.

Finally, feasibility, please.

MEMBER GILLIAM: Feasibility, I mean, you may or may not be aware there is ongoing initiatives through the Centers for Medicaid and Medicare that bloodstream infections related to central lines will be reported. There are at least 25 states or more that have mandatory reporting.

And so, for those hospitals that are in the IPPS system, beginning in January,

they are required to have that data to be reported as part of their reimbursement process. So, it is something that all of us are going to be doing or are already in the process of doing. And there are several avenues that you have as far as reporting that.

So, from feasibility, it is doable. I mean, we are going to have to do it. So, it's doable.

(Laughter.)

CO-CHAIR SAKALA: Other comments?

DR. WINKLER: Just a question. Just to clarify your comment, Craig, is it this measure?

MEMBER GILLIAM: It is not this specific measure, but it is reporting -- under the IPPS system, they are going to require that you report central-line-associated bloodstream infections in an ICU setting. And so, this would be one of the settings that you would be expected, but it is not this

specific.

CO-CHAIR SAKALA: Other comments?

Okay. Please vote for feasibility.

(Whereupon, a vote was taken.)

Eighteen high, 7 moderate, no low.

Finally, an overall vote, please, on the suitability of this measure for endorsement.

(Whereupon, a vote was taken.)

Okay. Unanimous. Twenty-five yes, no noes.

Now we will move to public comment about anything that we have discussed in this session, first in the room and then on the phone.

Anyone in the room want to say anything?

Patrick?

DR. ROMANO: Yes, I just wanted to say that, with respect to PSI 17 on birth trauma, I can't speak for AHRQ on this

question, but they may be interested in resubmitting a revised version of this indicator at sometime.

So, it would be helpful for us to understand the reasons for the Committee's vote on importance and whether it was due to the lack of inclusion of shoulder dystocia-related injury or whether it was due to the heterogeneity of the indicator and the fact that it mixes different types of injury. So, those would obviously be responded to in two very different ways. So, that would be helpful for us to understand.

CO-CHAIR SAKALA: Okay. Other public -- Committee about this now? Or in the report?

DR. WINKLER: Well, we will need to capture it. I may need to get back with you all about it, once I have gone through the notes and everything, to see if we can respond to Patrick's comments. But we will certainly want to be able to clearly delineate the

rationale.

CO-CHAIR SAKALA: Other public comments in the room?

(No response.)

On the phone, please?

Operator?

THE OPERATOR: Thank you.

CO-CHAIR SAKALA: Yes.

THE OPERATOR: If you would like to make a comment over the phone, please press *1 at this time.

(No response.)

We have none at this time. CO-CHAIR SAKALA: So, we are going to break for lunch now from 12:30 to one o'clock.

And where is it located? Right around the corner, okay.

Thank you, everyone.

(Whereupon, the foregoing matter went off the record for lunch at 12:26 p.m. and went back on the record at 1:12 p.m.)

A-F-T-E-R-N-O-O-N S-E-S-S-I-O-N

1:12 p.m.

DR. WINKLER: If everybody can take their seats, then we can get going and work again.

Dr. Gee, would you like to introduce, Rebecca. I can do that because she was my former resident.

MEMBER GEE: Good afternoon, everybody.

Rebecca Gee. I am an obstetrician/gynecologist, former Robert Wood Johnson clinical scholar and live in New Orleans, which is fabulous except when they cancel a flight because there is not a lot of transportation. We have infrastructure problems, as some of you may have heard with Katrina.

But I direct the Birth Outcomes Initiative, which is a targeted effort to decrease infant mortality and prematurity and improve outcomes for women delivering babies

in the State of Louisiana. We fare 49th in the nation on most metrics, unless Mississippi does better than us, in which case we are 50th. We have the highest cesarean section rates in the nation.

We are developing a number of initiatives. One is -- and I have heard many of you are involved in this -- we are changing our vital records system so that we can accurately collect data on non-medically-indicated elective inductions prior to 39 weeks. We are doing statewide benchmarking and report-carding. We are doing an IHI collaborative with all of our large maternity hospitals.

And my work is cross-sector. So, I work across Medicaid, our Department of Public Health, and Title V program. I am also chairing the ASTHO Presidential Challenge, the Data Committee, where we are working on creating a regional collaborative around improving prematurity in the southern states,

which are the most affected by health disparities and prematurity.

So, I am delighted to be here and so sorry to have been late.

CO-CHAIR RILEY: Rebecca, we all had to tell our disclosures, if there is anything in particular that you want to disclose that would relate to what we are doing today or tomorrow, I should say.

MEMBER GEE: So, I use metrics for benchmarking and for quality improvement in my State. I am not a measure developer. I am not on any boards that would have any conflict of interest, and have no financial interest in the outcome of this meeting.

CO-CHAIR RILEY: Thank you.

MEMBER GEE: That's enough? Yes.

CO-CHAIR RILEY: Are the measure developers from Vermont Oxford on the line yet?

PARTICIPANT: Yes, we're here.

CO-CHAIR RILEY: Awesome. Thank

you.

So, we are on to No. 483, which is proportion of infants 22 to 29 weeks gestation screened for retinopathy of prematurity. And so, that would be Dr. Gelzer, or Andrea.

MEMBER GELZER: So, this measure was submitted for maintenance review, and it has been previously endorsed. The measure was developed and submitted by Vermont Oxford.

The screening is recommended by the American Academy of Pediatrics and the American Academy of Ophthalmology and measures the proportion of infants 22 to 29 weeks gestation who are in the reporting hospital at the recommended postnatal screening age and who receive this screening.

So, if the screening is done in a timely manner, then ablative surgery can be done in a timely manner and vision can be preserved, is the theory and the evidence presented.

As far as impact, retinopathy

prematurity affects significant numbers of low-birth-weight premature infants and leads to blindness in a significant portion. So, the timed retinal exams are recommended.

And most Committee members felt that the impact was high.

Do you want me to stop there?

CO-CHAIR RILEY: Yes.

Comments or questions?

(No response.)

Do you want to do the improvement?

MEMBER GELZER: Oh, the improvement? Okay.

There was general agreement that there was moderate opportunity for improvement. There was one study that was published that supported that, and then there have been surveys done by Vermont Oxford Network that show that there is a significant, there appears to e a significant performance gap. But, again, there was a lot of discussion because that is not published

evidence.

There are a couple of studies. There has been a lot of work on this and study that appropriately timed retinal exams are required, and the infants do benefit. So, the evidence exists. The opportunity for improvement is moderate.

There was Committee discussion also regarding the American Academy of Pediatrics recommendations for screening to extend to infants with a birth weight less than 1500 grams or a gestational age of 32 weeks or less. So, we had considerable discussion around why were we not screening infants; why did the measure just go to the 29 weeks.

And that would be it.

CO-CHAIR RILEY: And so, on that conference call, just out of curiosity, did anyone from Vermont Network have an answer for why they stopped at 29 weeks as opposed to --

MEMBER GELZER: I think there was

some input. I am sorry, I don't know who the person was.

MR. CARPENTER: Joe Carpenter.

MEMBER GELZER: I think she is asking for some input.

CO-CHAIR RILEY: Can you comment on have you now extended it? I just want to be sure. I thought I read an email that you had extended it to 32 weeks, but I just wanted to be certain.

DR. HORBAR: No. What we said was that we agree with the point that the Committee made to rescind. We have not at this point rescinded.

This is Jeff Horbar from Vermont Oxford.

I think part of the problem here is that many of these babies get discharged and transferred to other hospitals. The higher their gestational age, the more likely that hasn't happened.

And so, we had originally felt

that targeting a population where most of these babies would still be in the hospital at the time of the first recommended visual exam would give a better measure than having an expanded denominator for whom the data would be unobtainable by most hospitals.

CO-CHAIR RILEY: Okay.

DR. HORBAR: So, that was the logic for restricting it. And clearly, although the recommendation does cover larger babies, the risk is highest at lowest gestational ages. So, as a measure that would give a hospital a good indication on their highest-risk population, what's going on, we felt that this was a reasonable alternative in trying to cover the full population recommended by the AAP for whom we know there will be missing data on a large proportion of higher gestation.

CO-CHAIR RILEY: Okay. Thank you. That is very helpful.

Other people? Yes, Nancy?

MEMBER LOWE: I did have a question about the data on the performance gap. I was really struck by the fact -- and perhaps our representative from Vermont Oxford could answer this -- I was really struck by the fact that we are still dealing with 2007 data, and nothing since the measure was originally endorsed was presented to show a continuing performance gap or whether there has been improvement or anything in the subsequent years.

MR. CARPENTER: Yes, I am looking at the measure maintenance that we did.

This is Joe Carpenter again.

I thought for sure that we looked at the last five years, up to 2010. Now there is a gap in our reporting because we report based on birth year. And so, as far as the network as a whole is concerned, we are always a year behind, if you will.

But I thought I reported -- and again, I am looking at the measure

maintenance. Let's see. Excuse me. Yes, I reported data for 2006 to 2010.

There were two things we looked at. One was what percent of babies were excluded and then what percent of babies was screened prior to discharge of those infants who were hospitalized at the recommended age. And we also provided percentile data on that measure.

So, I'm not sure why you only have up to 2007 data.

MEMBER LOWE: So, if I could just ask you for clarification, I am looking on the report under 1B.2. So, you're telling me that what it says about unpublished data, that is from 2006 to 2010?

MR. CARPENTER: I'm sorry. I am going to have to find that.

I was looking at 2B3.3 and 2B4.3. So, you said 1B -- I'm sorry, say that reference again?

MEMBER LOWE: It is 1B.2, summary

of data demonstrating performance gap.

DR. WINKLER: Page 16.

MEMBER LOWE: It wasn't where I expected to find it. I found it.

MR. CARPENTER: Yes. Okay.

MEMBER LOWE: It is just in a different place. Thank you.

MR. CARPENTER: Right.

CO-CHAIR RILEY: Other questions or concerns? Questions for the developer?

Yes, Lee.

MEMBER PARTRIDGE: I am just curious to know if we have any sense of what group, how large a group we are excluding if we cut off at 29 as opposed to 32. Is it tiny? Is it large?

MR. CARPENTER: Yes, we do have a table in 2B3.3 which shows the exclusion. Now that is percent of babies excluded, including all infants 401 to 1500 grams or 22 to 29 weeks. So, we are looking at that by, you know, the data are presented by year from 2006

to 2010.

But it doesn't really address your specific question. Basically, you are asking, for infants, you know, how many 30-to-32-week infants are we excluding --

MEMBER PARTRIDGE: Right.

MR. CARPENTER: -- if I understand you correctly.

MEMBER PARTRIDGE: Yes. I just wondered if it was tiny or significant.

MR. CARPENTER: Well, I guess it depends what you mean by that. I mean, there would be 30-to-32-week infants who were never admitted to an NICU or cared for in some kind of other lower-level-of-care unit, which we don't capture in our database. So, we wouldn't even know how many of those there might be.

I think if you are looking for a population-based number, for a measure like this it is going to be extremely difficult.

MEMBER PROFIT: I think an

important component will be the at-risk population, sort of population that truly develop severe retinopathy prematurity at 30 to 32 weeks; it is not very significant compared to the lower-birth-weight babies or lower-gestation-rate babies.

MR. CARPENTER: Yes, I would agree with that. I mean, that was why we decided to target those who were at the highest risk for whom the denominator would be likely to be obtainable.

MEMBER JALEEL: Hi. This is Dr. Jaleel.

I was on the Workgroup, and I was the person who brought this up in the Workgroup.

So, my question would be the American Academy of Pediatrics, at least until 30 weeks, says that, definitely, you should be screening for that. And 31 and 32 weeks are where it is optional depending on the severity of the criticalness of the patient's

condition. So, why not extend it to 30 weeks and why 29?

I know that Vermont Oxford Network collects data for 22 to 29 weeks. But if the American Academy of Pediatrics is saying that, yes, we have to do this for 30 weeks, how difficult is it to get the data for those 30 weeks? And why not be consistent, send a consistent message with the American Academy of Pediatrics instead of putting another variable in there?

MR. CARPENTER: We could do that, I mean if the Committee felt strongly. The issue would be that we collect data on infants either 401 to 1500 grams or 22 to 29 weeks. So, we have complete denominators in either of those categories.

There will be probably some 30-week infants who are outside of the birth-weight category. So, our members wouldn't currently be collecting data on a very small fraction of those.

But if the Committee felt it was critical to change the denominator from 29 to 30, we would be pleased to do it. I don't see the merit of it, frankly, but I don't think it would be any problem for us to do that.

CO-CHAIR RILEY: Others? Okay?

MEMBER PROFIT: Can I just clarify? Isn't the Academy's still less than 30 weeks? And we are capturing 29 and six-sevenths, anyway. So, is it 30 completed weeks?

MEMBER JALEEL: It is up to 32 weeks, and up to 30 weeks you definitely have the screen, and 31 and 32 weeks are the ones who are optional.

MEMBER PROFIT: Right. I guess my question was, the obligatory screening, is that up to, so 29 and six, essentially, or less than 30 weeks?

MEMBER JALEEL: No.

MEMBER PARTRIDGE: Or is it 30 and six weeks?

MEMBER JALEEL: It is 30 and six.

MEMBER PROFIT: Thirty and six? Okay. All right.

Okay. I would vote for not changing it, but whatever the rest of the Committee would feel about it.

MEMBER BAILIT: Hi. This is an OB question. This is a question for the neonatalogists from an OB, and whether the developer or the people in the room can answer it.

Are there kids who would be eligible for this screening but are too sick to get it? And is there an exclusion for that? So, for example, if they are still on a vent, they are still on an oscillator, are those kids all still eligible for screening or is that something that only occurs when they are well enough to get it?

MEMBER JALEEL: Yes, that is an important point. There are some kids who will be so sick that will not tolerate the eye

exam, and that happens sometimes. But that is a minority of the patients.

MEMBER BAILIT: But, to the extent that those are not randomly distributed, either because the tertiary care centers get the sickest kids or because other quality problems in the hospital create those sick kids, that would lead to some heterogeneity in the reporting measure, correct?

MEMBER JALEEL: I would, yes, think so, but the number is so small that it would be very significant, I would guess.

MEMBER PROFIT: Please correct me if I understand the measure wrong, because I had some trouble understanding this measure for a long time, but I think what it means is that the baby is still in the hospital at the time when he would be eligible for the screening. It is actually not sort of a great measure for whether that screening really occurred in that week that is recommended by the AAP.

So, if the baby is a 25-weeker and, let's say, should be screened when he is about 30 weeks old, it could be screened when he is about 33 weeks old and would still be captured as a yes to baby is screened. Is that correct?

MR. CARPENTER: That is correct.

MEMBER PROFIT: So, in that sense, it is a low bar really for accuracy.

MEMBER KELLY: Are there issues with babies who are transferred versus discharged? Because the measure seems to measure those who are discharged. I wonder if the developer could address that.

MR. CARPENTER: If the baby is discharged or transferred prior to the day at which the first exam would have been required, they are not in the denominator.

CO-CHAIR RILEY: So, we need to make a decision about how strongly we feel about going up to 30 weeks versus what they have given us, I am just going to point out,

versus what they have given us data for, which is 29 weeks. So, that is what we have all read about. Obviously, they have mentioned that they are willing to go up to 30 weeks. Yet, we don't have a good idea of how well that works because it hasn't been tested.

So, I just throw that out there as we go forward.

MEMBER PROFIT: So, our NICU is a VON member, and I am just a little hesitant because a lot of effort goes into data collection. One of the nice things about that is it is pretty simple to remember 22 to 29 weeks for all the people that extract the data to collect it.

So, I am just worried that we will introduce an extra week for just this specific measure, and then it will start to spill out to data collectors for something that may be really low yield. I understand, yes, and appreciate that trying to be in compliance with the AAP guidelines is really valuable.

I am just wondering about the practicalities, I guess the gain for the pain kind of thing.

MR. CARPENTER: Yes, there should not be a data collection issue from the VON standpoint because we collect whether or not the baby received the exam or not.

As Jeff said before, Dr. Horbar said before, we will be excluding some babies that are 30 weeks that are over 1500 grams. But as far as additional data collection, I mean, we would not be adding, we would not be changing our eligibility criteria for this measure.

DR. HORBAR: And this is Dr. Horbar.

I would agree with Dr. Profit that the change for the sake of consistency will not be much of an improvement in the measure. It really is hard for me to see why it would be justified.

MEMBER JALEEL: I probably have a difference in opinion. We are also a member

of the Vermont Oxford Network. So, on one side, I feel that, yes, we should not change it because it is a measure which Vermont Oxford collects and it has been collecting for some time. But at the same time, I also feel that this is not just for the Vermont Oxford Network. It is for neonatal units all over the country.

So, if the American Academy of Pediatrics is recommending something, it would be better to be consistent with that is what my feeling is. But I'm okay --

DR. HORBAR: Can I ask a question? Because I am not sure that I fully understand the philosophy behind the NQF decisions at this point.

Originally, when we proposed these measures, I thought that other people could propose related measures, such as if the American Academy of Pediatrics wanted to propose a measure that included exactly their own criteria, that they would be able to do

that.

I mean, we are proposing a measure because 900 hospitals are currently collecting it in a certain way and have been doing so for a number of years. I guess I am not sure what the philosophy here is. I mean, if hospitals can and are collecting a measure that is of use to them, is that enough? Or it now has to meet some higher standard, and there is really only one right way to do this, even if nobody is doing it or could do it?

DR. WINKLER: This is Reva from NQF.

Just to respond to your question, generally, NQF is looking to endorse measures that can be used widely in a standardized fashion for comparative purposes. Therefore, we do not encourage multiple measures addressing the same topic that are specified differently.

So, part of the evaluation criteria that the Steering Committee is using,

that we use for all of our measures, looks at some of these issues. None of them are black-and white. That is why there is a Committee here to weigh the pros and cons, risks and benefits, and all of that. So, there are no absolutes here. But these are very important issues for the Committee to grapple with.

DR. HORBAR: No, I understand that, and I guess I would just ask you to consider, if the goal is a widely-used measure, I am not quite sure where else you are going to get a widely-used measure on this topic. If you set it for 30 weeks and we decide it is not worth changing after so many years, then you are not going to have any measure.

So, I guess I am just trying to understand what is good enough versus what would be considered perfect in an ideal world, and how the Committee is going to sort of weigh those kind of tradeoffs, because it seems that is what is involved in this

decision.

CO-CHAIR RILEY: Thank you.

So, I think in order to move this along, we need to make a decision. So, we're going to vote. We are going to vote -- sorry, is that okay?

(Laughter.)

DR. WINKLER: Yes.

CO-CHAIR RILEY: We are going to vote to look at the measure 22 to 29 weeks gestation, which is what was presented to us, for which they had evidence, first. And then, we will vote on whether we should actually ask them to go 22 to 30 weeks gestation.

And just for clarity, I think we want to do 22 to 29 and six-sevenths -- is that what it really is; is that the important piece? -- versus 22 to 31 or 30 and six-sevenths. Thirty and six-sevenths, right? Six days. Okay.

Is that all right?

Okay. So, the first one that we

are going to vote on is 22 to 29 weeks gestation. Yes or no, as presented, 22 to 29 weeks gestation.

(Whereupon, a vote was taken.)

DR. WINKLER: Twenty-one yes, 4 no.

CO-CHAIR SAKALA: Okay. So, now we can move on, right? Okay.

So, now we will move on because I think we all are deciding that we are going to go with the evidence that was presented for 22 to 29 weeks. And now, we can go to the next step. Is that okay? It's up there? Okay.

MEMBER GELZER: So, with regard to reliability and validity, again, the eligibility, gestational age was questioned. Otherwise, there are no questions really and a high rating.

CO-CHAIR RILEY: Are there any final questions or concerns about this?

(No response.)

Okay. Let's vote on this.

(Whereupon, a vote was taken.)

DR. WINKLER: Twenty-three yes, 2 no.

CO-CHAIR RILEY: So, we can move on.

MEMBER GELZER: With regard to usability and feasibility, in the usability discussion we talked quite a bit about the fact that this has been mainly used for quality improvement, internal quality improvement activities and not accountability. And this may be a good thing to move toward, going forward.

And other than that, the usability and feasibility were both generally rated high.

Oh, there was also a question about followup. So, we are measuring, you just got to have this screening during the hospitalization. And if you get this screening, then you are going to, hopefully, get this timely ablative surgery and,

hopefully, have a better health outcome. And I know I am oversimplifying.

But having said that, what happened? So, you got the screening. Did you get the surgery? Did you get the surgery in a timely manner? There are lots of other questions that remain following discharge.

CO-CHAIR RILEY: Questions, comments?

MEMBER DENK: I just want to say real quick that it is a good question about screening, but following up on screening is an incredible resource commitment. It is one thing to work with your own internal charts, but to make sure that a screening got done and got done properly, you know, that it was actually there was a content to the screening and things like that. We would be really upping the ante on a lot of these process measures.

CO-CHAIR RILEY: Right.

DR. WINKLER: I just had one

question just of everyone around the table. Do you know whether this measure is being used in any other way except for the internal QI that VON does with its members?

MEMBER JALEEL: We are a part of the Neonatal Research Network, the NICHD Neonatal Research Network. And the Network does collect data on this, and it collects data on all the infants who are less than 1500 grams, I think.

So, yes, we do collect it, but it is for internal quality assurance. It is not published outside. Every once in a few years, that data is published as a journal article and with all the centers de-identified.

MEMBER DENK: I'm sorry, a quick question. The real question, though, is, is it suitable for public reporting as opposed to is it actually done. Because I don't see the difference between this and reporting about aspirin therapy for chest pain admissions. It is just that maybe there is no audience for

it, or whatever, right? But it is certainly interpretable by the general public and could be an accountability measure in the future, right?

MEMBER KIEHN: We have been talking about using it in the State of Utah, but have not made a decision yet as to whether we are going to use it for a measure.

CO-CHAIR RILEY: Did you mean for measurement and then public reporting?

MEMBER KIEHN: Eventually, yes, but we are in the very early stages now because not all of our sites within Utah participate in VON. So, we are having to look at other measures.

CO-CHAIR RILEY: Is there another question? I saw a hand.

MEMBER JALEEL: One of the other questions which was brought up in the Workgroup was the denominator exclusions, outborn infants at maternity reporting hospitals more than 28 days after birth. I

was not sure what the reasons for excluding those babies are. If those babies are between 22 and 29 weeks at birth, they are equally at risk for developing retinopathy of prematurity. So, why exclude them? I was not sure about that.

CO-CHAIR RILEY: Can our developers answer that question?

MR. CARPENTER: Our eligibility criteria for enrollment in the database is admitted within 28 days of birth. If there were no cutoff, it would become very difficult to decide what the right population of infants to study is. It is arbitrary, but it is functional.

I think the NICHD Network, which was mentioned earlier, I think they only collect data on babies within seven days of birth. Someone can correct me if that is not right.

So, I think we made that choice as a practical matter to make it clear who the

population of eligibility for our database is. Once you get over 28 days, babies are going to be going to multiple locations within the hospital, not necessarily in NICU.

And so, that is how we came to that choice as eligibility criteria. I agree that there will be infants at risk in that population that this measure wouldn't capture.

MEMBER PROFIT: With regard to use, I think essentially all of the measures or most of the measures we will be discussing from the Vermont Oxford Network are also being used in California by the California Perinatal Quality Care Collaborative, and the CPQCC transmits those data to the state. So, I guess in a sense that is public reporting. I don't think it is released to the public, but the data is released to the state.

MEMBER DRYE: Can I just make one more comment? I think it is great to use registries to build quality measures, and we have worked with the American College of

Cardiology to build great measures. But I think you are making a really important point about this transition of a measure from the use just within the registry to the rest of the world, which is something that really there is not a lot of that done yet.

And the point, as I am understanding it, is that the registry has a set of infants in it. And so, the denominator criteria here is specified and limited by the infants the registry collects data on, and that is probably, if we started de novo and created a measure like that, not how we would define the denominator, is what I am hearing.

You know, the measure is in use, and people are finding it constructive, but I think this is an important thing to think about. I will just give you an example.

So, registry measures we have built for the Center for Medicare and Medicaid Services specified off of the American College of Cardiology registry, we have built

measures, hospital-based measures for PCI, mortality and readmission and ICD complications. And there, there I think -- and I am not allowed to speak for CMS -- but what we have talked about in implementation potentially is that you would just specify the data elements. You wouldn't limit the universe to what the private physician and registry is set up to do when you implement it.

And so, I think this is just a really critical kind of thing to be thinking about, transitioning measures. I think it is great to build it on registries. It is fantastic data. It is usually physician- or clinician-initiated data collection and self-monitoring within a subspecialty. But this is a transition I think we have to be thinking about as people are thinking about moving measures more broadly into use.

I am not sure what the right answer is. I just wanted to frame it more

broadly. It is not just an issue for this measure.

MEMBER JALEEL: Thank you for that. I think I was finding it difficult to put those words into good sentences.

(Laughter.)

And you put it very well. Thank you.

CO-CHAIR SAKALA: So, I strongly support that sentiment. I think the question is, what does the data support, not a group, an organization, whatever, but what is supported by the data? And I felt a little at a disadvantage because I didn't know, for example, the AAP guideline, what is in it.

MEMBER PARTRIDGE: One of the roles that NQF Steering Committees have is to make recommendations for the future. And I think what Elizabeth has just said might be one of those; i.e., as we go forward, all of the measures we are about to consider are VON measures and they are dictated by the

registry.

But we now do have some new resources to develop measures. There are, through the CHIPRA reauthorization and also the adult Medicaid provisions, there is substantially money available to develop new measures or refine existing ones.

And I think perhaps that, Reva, might be one recommendation for the future, that when measures like this come up, we consider encouraging the field to move toward a less-registry-limited kind of specification.

CO-CHAIR RILEY: I think we are ready for a vote on usability.

(Whereupon, a vote was taken.)

DR. WINKLER: High, 11; moderate, 13; low, 1.

CO-CHAIR RILEY: Shall we move on?

DR. WINKLER: Yes.

CO-CHAIR RILEY: Feasibility?

DR. WINKLER: You're ready to vote? Yes? Okay.

(Whereupon, a vote was taken.)

DR. WINKLER: Fifteen high, 9 moderate, 1 low.

CO-CHAIR SAKALA: And we're ready to go on. So, we will now vote on overall.

(Whereupon, a vote was taken.)

DR. WINKLER: Twenty-three yes, 2 no.

CO-CHAIR RILEY: Thank you.

So, let's move on to the next measure, which is proportion of infants 22 to 29 weeks gestation treated with surfactant who are treated within --

DR. HORBAR: Can I ask a question? We heard your voting, but are you making final decisions today or what? I am just trying to understand how to interpret the voting, your voting in the background.

DR. WINKLER: These votes will become final if no further issues are raised during the course of the discussion today and tomorrow that might affect it, such as with

related or competing measures or whatever.

DR. HORBAR: Okay. So, we shouldn't pay much attention to you voting in the background?

DR. WINKLER: No, the votes they are voting right now are the ones that are going to count.

So, this particular measure I don't think has any of those issues that we are likely to deal with subsequently. So, these are likely to become final votes.

DR. HORBAR: Okay. Thank you.

CO-CHAIR RILEY: Okay. So, we are going to move on to 484, proportion of infants 22 to 29 weeks gestation treated with surfactant who are treated within two hours of birth.

Jaleel?

MEMBER JALEEL: Yes. So, this, as you see on the slide, after the Workgroup call, the developer asked to withdraw the measure because of the discussions which we

had in the Workgroup call.

So, this is an extremely high-risk population, 22 to 29 weeks, who have a high incidence of developing hyaline membrane disease. And for severe hyaline membrane disease, one of the treatments I surfactant therapy.

And the measure was previously endorsed a few years ago based on the evidence which was available at that point, which mainly was multiple studies which have been done in the past and a meta-analysis which looked at all these studies. And the conclusion from the meta-analysis was that early surfactant, within the first two hours of life, is beneficial in terms of reducing the incidence of chronic lung disease and some of the other pulmonary outcomes as well.

But in the last two to three years there has been new evidence which has come in terms of two major studies. One was called the COIN trial, which had 610 infants in that

trial. And then, there was another study called the SUPPORT trial, which is from the NICHD Neonatal Research Network, which had a significant number of babies, 1,316 babies, who are randomized either to CPAP or to intubation in the delivery room and early surfactant.

And it was a multi-center trial. When they looked at the outcome, there was no difference in the primary outcome which the primary outcome was mortality or incidence of bronchial pulmonary dysplasia or chronic lung disease. So, there was no difference whether you were intubated in the delivery room and given early surfactant or you were tried on CPAP and then followed up.

So, based on that study, the practice has changed in the last two to three years, that more and more of the units, they are trying to see if we can start them on CPAP, and if the CPAP doesn't work, then you intubate the baby and then you give

surfactant.

So, now with that evidence coming out, this measure as a quality measure is not as important as it used to be previously. So, that is the gist of it.

DR. WINKLER: This is Reva.

Just for the folks from Vermont Oxford, I just will allow you to withdraw the measure and indicate it that way, as sort of a retired-by-the-developer measure going forward, because it was previously endorsed.

Any comments from the developer?

DR. HORBAR: We are pleased to have it removed as a quality. There actually has been a large third trial now that was conducted by the Vermont Oxford Network that also concluded that there is no major difference between early surfactant treatment and early CPAP.

I think what the trials haven't answered, though, is whether by delaying the use of surfactant in an attempt to give CPAP,

whether some delay will ultimately lead to worst outcomes. I don't think that answer has been fully answered.

And originally, the Working Group had asked us, because of that, to stratify the measure by whether the baby had been tried on CPAP or not. So, although I think it still will be a useful measure for hospitals to use in tracking their own internal practices and what the tradeoffs may be because of these new attempts at early CPAP, I would agree with the presenter that the new evidence would suggest we should withdraw this.

CO-CHAIR RILEY: Okay. Thank you.

Okay. So, now we are going to move on, and these next two measures, we are going to consider them separately, correct, Reva, consider them separately, recognizing that there may be some combination? Is that fair?

DR. WINKLER: I think that the Workgroup discussed these as individual

measures and had some questions about how they worked together, and the followup from the developer indicated a willingness to combine them. We will have to talk about what that means and how that might happen.

So, why don't we just talk about these measures as they were submitted and then where we might want to go with them?

CO-CHAIR RILEY: Jennifer?

MEMBER BRANDENBURG: The first measure, it was temperature measured within one hour of admission to the NICU.

The group sort of felt like this was a low-bar standard that most hospitals wouldn't have trouble meeting. It did have high impact, but it was a common practice at this point. But, yet, a lot of the discussion was that it didn't hold much weight on its own, that it was kind of a low-bar standard. So that combining the other measure, which is 482, which was measuring temp less than 36 degrees, combining the two actually made the

one measure stronger, which is what a lot of the conversation was about.

We did think it did have a high impact. Three of us thought it was high; two of us thought it was moderate.

As far as improvement, though, there was not a lot of improvement because a lot of hospitals were already meeting the standard. Ninety-eight percent of them were already meeting the standard. Even though we all thought it should be 100 at this point, 98 percent of them were meeting it already.

A vital sign in the NICU, that is sort of a critical thing that is a standard of care at this point. However, it was more important what the temperature was when you got the baby to the NICU versus that you just actually took one. So, that is why we thought combining the two made the measure more powerful.

CO-CHAIR RILEY: Other comments?

MEMBER PROFIT: I guess another

thought would be to just omit this measure if 98 percent meet it anyway. I am not sure whether combining it with a performance assessment of hospitals would truly change if the baseline is already 98 percent rather than just using the hypothermia measure.

DR. HORBAR: The 25th percentile is 98 percent; the 10th percentile is 92 percent.

MEMBER PROFIT: So, would you treat it as a missing variable? Or I guess how would you handle the missing if you combined them?

DR. HORBAR: Yes, that was my question. I mean, one way to combine them would be to consider a not-done, a failure would be a low temperature. The other way would just be to restrict the denominator to those who have it done.

Since we collect both items, we could create a measure doing either of those. So, I would leave it to the Committee's

judgment to recommend to us which way to use the two individual data elements to create a combined measure.

MEMBER BRANDENBURG: I guess that was one of the things I didn't go over, was some of the exclusions that they excluded. Outborn infants admitted more than 28 days after birth are excluded. Infants outside the birth weight of 501 to 1500 grams, and then outborn infants who have been home prior to admission, and then infants not admitted to the NICU. Those are all excluded from the first temp taken within one hour.

And then, on the 482 measure, they also exclude infants' temperatures who were just not measured at all within the one hour of admission to the NICU. So, there is one more exclusion on that measure.

CO-CHAIR RILEY: So, I think that probably the most reasonable way of handling this would be to vote on this measure first and then go to the second measure and figure

out if there is anything that we want to do differently there, because I don't know else we are going to reconcile this.

DR. HORBAR: Could you get a sense from the Committee whether people really want to combine them? Because I think having the discussion about what the options are for combining them, if that turns out to be a choice that the Committee wants, that will influence the votes on both.

CO-CHAIR RILEY: I think we will vote separately, and then we will go backwards, if we need to.

Okay. So --

MEMBER GILLIAM: Can I ask, just for clarification --

CO-CHAIR RILEY: Absolutely.

MEMBER GILLIAM: -- if we approve the first, we still vote on the second?

CO-CHAIR RILEY: Yes.

MEMBER GILLIAM: And I we don't approve the first, we still vote on the

second?

CO-CHAIR RILEY: We still vote on the second.

MEMBER GILLIAM: All right. Thank you.

CO-CHAIR RILEY: Exactly.

Okay. So, can we vote on importance to measure and report for 481?

(Whereupon, a vote was taken.)

DR. WINKLER: It is 4 yes and 21 no.

So, now we can move on. Okay.

CO-CHAIR RILEY: Okay. So, now we will move on to 482, and I'll turn it back over to you.

MEMBER BRANDENBURG: Okay. On 482, this was taking the first NICU temp and having it measure if it was less than 36 degrees Centigrade. Okay. This one was measuring the temp, the first NICU temp, and having it be whether or not it was less than 36 degrees Centigrade.

It was infants with the birth weight of 501 to 1500 grams and the temp measured within one hour of admission to the NICU, and whether or not it was below 36 degrees Centigrade.

Let's see, essentially, it is the same as the other one. It is just what the temp actually was, not whether or not they just took the temp.

The exclusions, the only difference in the exclusion is that they excluded infants who temps were not measured within the one hour. So, anybody that they didn't take a temp on, they just didn't include in this measure at all.

CO-CHAIR RILEY: Comment?

MEMBER LOWE: Yes. Laura, if I understood our earlier discussion, it would be to include in the numerator babies who didn't get a temp taken within the first 24 hours. Do we want to talk about that now before we move forward? Because it is the idea that if

it wasn't taken -- I said "24 hours"; I meant within the first hour -- if it wasn't taken in the first hour, we should treat that the same as though it was low, correct, the neo people?

MEMBER PROFIT: Yes, I think that is one of the options, to treat it that way. So, I am a little bit agnostic, quite honestly, to say why people would not measure a temperature, and I don't know if Dr. Horbar has any thoughts about or gets feedback why that is.

I wonder, if you are actively coding a baby, probably you are not taking a temperature at that time, you know, if there is a really difficult delivery in a very high-risk situation. Otherwise, it should probably always be done.

So, I don't know if the 2 percent represents part of that, but I would think it would be quite uncommon to code a baby for an hour. So, I don't have a great sense for what it might be. But if they are coding a baby,

you probably shouldn't penalize them for not taking the temperature, but if they just forgot, then maybe you should.

But I don't really know what the answer. I feel like the underlying reasons for not measuring kind of determine how you would treat it, and I just don't know what the truth there is.

MEMBER JALEEL: The only babies you would list with this is babies whom they have not measured the temperature within the first one hour and their code. So, that is something we should nest with this measure.

CO-CHAIR RILEY: So, getting back to Nancy's question, though, wouldn't a way of in some ways combining 481 and 482 be taking that exclusion out?

MEMBER JALEEL: Yes. Yes, in some way, if we can make it that if the baby's temperature has not been measured in the first one hour, you take it that that baby's temperature is less than 36 or --

MEMBER CHENOK: This is undoubtedly a stupid question. So, if the baby's temperature is taken and the baby is cold, don't you want them to do something other than just record they took the temperature and the baby is cold? I mean, is this actually actionable?

MEMBER JALEEL: Oh, yes.

MEMBER CHENOK: But, then, don't you want to know, did they take an action?

MEMBER BAILIT: The action is actually before the baby gets cold. So, you start using things like warm T-shirts, making sure the baby doesn't lay cold and wet. So, it is the prevention of the cold temperature rather than the treatment of it.

MEMBER CHENOK: Okay. Oh, I might have been out. I'm sorry, I had to take another phone call.

Thanks.

CO-CHAIR RILEY: Bill?

MEMBER GROBMAN: So, this is

probably also an undoubtedly stupid question from an obstetrician. So, this is the first temperature less than 36 degrees. So, for example, if you had a transport that came in -- and it didn't seem to me, are transports excluded?

MEMBER JALEEL: It says one hour after admission to the NICU.

DR. HORBAR: Transports are not excluded. We stratify the reporting based on whether they were inborn or outborn.

MEMBER GROBMAN: But even to stratify, for example, I guess I would question. You bring a transport, they hit the door, you take their temperature like in a minute, and they are 35 degrees. That is not really your fault, right? They came from somewhere else. So, I am not even sure why they would be stratified as opposed to completely excluded, right, because it is within the first hour? So, the first one you get, you are kind of responsible for it.

I don't know how oftentimes they come down form like the LDR just cold. I guess that is in your -- yes, you should fix that. Yes, okay, fine.

But the transport, you definitely have no control over.

MEMBER PROFIT: But a lot of the transport units, like a lot of the transport services are actually your own transport teams. So, they are your own teams. So, they can do things to keep the baby warm.

MEMBER GROBMAN: They're your own team? Really? Okay, well, then, right. So, I'm an obstetrician.

(Laughter.)

And then, my other question, which I just sort of forgot -- you go.

MEMBER DRYE: I was just going to mention that combining them you lose some information, right, because if hospitals don't have the one-hour temp for some reason -- maybe it is not good at getting it to the

registry; I don't know why. They may have taken it and it got lost. That is a different question than, are they keeping babies warm in the first hour.

And so, I am not sure I like the idea of combining it because, if we are really concerned about hypothermia primarily, you are going to lose some of the resolution of the measure by combining them.

MEMBER GROBMAN: Yes, that was my second thing, which is that it seems that, if you combine them, you suddenly lose any granularity. You don't know if you are hypothermic or just a bad measurer.

MEMBER JALEEL: I do agree with that.

MEMBER DRYE: And just one option is, which it is a little unorthodox, but you can report the results, the hypothermia result, with a percent missing number, so that you know for that hospital here was their rate of babies with below temp and this was their

missing rate. And that aids an interpretation of the result.

MEMBER GEE: I am just concerned about unintended consequences if they are only being measured on the temperature and not whether they took it or not, where there might be an incentive not to measure so you don't get dinged. So, having that be represented somehow in this might be important.

MEMBER KIEHN: One way to address that would be we would just say the first NICU temperature, was it less than 36 degrees? Then you would catch those that were measured at one hour and 10 minutes.

MEMBER DENK: This is essentially the same question about every piece of missing data that ever existed, right? On the substantive side, you can't take care of a hypothermic baby if you don't know it is hypothermic. On the other hand, you're right, if you think it is hypothermic, don't take its temperature.

Plus, you have the issue of the quality improvement is directed in different directions for the two outcomes. If you didn't measure it, you have got to fix what you do. If you did measure it and the baby is hypothermic, it is probably not on you; it is on the transport team.

So, you know, I mean this question gets asked all the time. And the answer is, you know, that we do all the time, is that we collect the missing data and we collect the yes/no clinical outcome data, and we report them both. Whenever there is any kind of a issue at all, we report the missing data rate, too.

So, I think we are back to 481 and 482, if those are the right numbers, are two elements of the same measurement process, and there are two outcomes to report from the same measurement process. So, they should be a combined, they are a combined measurement process with two outcomes. That is what we

always decide.

CO-CHAIR RILEY: I think the other thing is that when we talked about 481, we felt as though there wasn't as much room for improvement. It was -- what was it? -- it was 2 percent in the highest and then 8 percent at worst.

So, I think that is just something else to consider. I understand what you are saying is that you may lose a little bit, but it sounds like there is not as much of a need in that particular area.

MEMBER JALEEL: But I still feel that it is still an important measure because, why is it 98 percent? Why is it not 100 percent?

And if we take this measure off, then are we giving them some slack, saying, hey, it is okay not to measure the temperature within the first hour because NQF has said this measure doesn't apply anymore?

MEMBER ARMSTRONG: Are there other

measures where you have one that exists mostly so that you can't game the measurement of the second one?

MEMBER DENK: I'm sorry, maybe I wasn't clear enough.

(Laughter.)

In everyday statistical practice where missing data exists, we do not report no plus missing as one number, right? We always report missing data values separately, and we report yes or noes out of the total available data. I mean, that is normal practice.

So, I would never say -- I think it would be very confusing to the rest of the world to have a measure that was either they were hypothermic or we didn't measure it, right. I think you have to report -- well, you don't have to do anything, but it is just a standard practice to combine those, a missing outcome with a substantive outcome.

MEMBER PROFIT: So, this is actually an approach that ended up happening

in the project that I am working on. So, for my research project, in the composite index we actually used registry measures from CPQCC, which is essentially identical to Vermont Oxford and had a representative expert panel, a Delphi panel, to look over these measures. And they selected nine measures, among which the hypothermia was included and the temperature measure was recommended to be just reported as a missing variable.

MEMBER DENK: That's why you never say never. Okay?

MEMBER KELLY: Can I ask the Workgroup to address two things? One is the conversation around 36 to 36.5 degrees, and your votes on the last measure, which was meets importance, because it doesn't appear to be listed here.

MEMBER BRANDENBURG: It was a recommendation in our Workgroup that they change it to be 36.5 instead of the 36 degrees. And I'm sorry, I don't know which

person on the Workgroup brought that up.

MEMBER JALEEL: Once again, me.

So, the recommendation is for normal temperature is 36.5 to 37.5, and neonatal resuscitation program, their recommendation is also 36.5 to 37.5. So, why are we having 36 as the measure and why not 36.5?

And even with 36, the data shows that even 30 to 40 percent of these babies are less than 36. So, if you are putting that bar low, you are giving more chances for having lower temperature. So, keep it at 36.5 rather than 36 was my thought on that.

DR. HORBAR: Can I answer the logic that we used?

MEMBER JALEEL: Sure.

DR. HORBAR: When we originally discussed this measure with the technical committee that was in charge of these at sometime in the past, we actually had originally had it at 36.5, and the Committee

recommended that we lower it to 36 because the World Health Organization defines 36.0 to 36.4 as cold stress and 32.0 to 35.9 as moderate hypothermia. And I think it was based on that classification by the World Health Organization that they asked us actually to lower it.

We collect the exact temperature and could report any cutoff that the Committee felt was important. I think one possible reason for raising it, in addition to what the previous speaker just said, is that there has been considerable improvement in this measure, although still the performance is quite poor at many places. It has been improving. And so, raising the bar at this point in history might make sense.

But, anyway, that is the reason we did it.

CO-CHAIR RILEY: Other questions or comments?

MEMBER PROFIT: Yes. So, I would

just have concerns whether a temperature of 36.3 would have any clinical relevance, and if you use 36.5 as a national cutoff, you know, I think the neonatal community would just look at you and say like, "So what? Demonstrate to me that this had any negative effect on the baby whatsoever."

Even the data on the less than 36 degrees, I mean I think the data is reasonable, but certainly not very strong. Even there, you will have people kind of arguing whether that is really a very tight, like an intermediate outcome that is tightly-linked to an long-term outcome.

So, I feel like, yes, I agree with what you are saying, it would capture more people, but I would be concerned that the acceptability among the neonatal community would be quite low about temperature is now in the 36.4 or 36.3 region.

MEMBER JALEEL: Okay. Here is, again, two neonatalogists disagreeing with

each other.

(Laughter.)

So, it would come back again to consistency with what we are saying. If WHO and AAP are saying one thing, why should we be off that as one of the things?

And the second thing is about the data which we are talking about. The data which is available, the literature which is available is very scant, I would agree.

But one of the prospective studies which was done by Dr. Laptook and the others, which we talked about in the Workgroup meeting, is to look at the temperature and look at the outcomes. And for every one-degree drop in the temperature, from 37 to 36 and from 36 to 35, and less than 35, there was an increased incidence of late-onset sepsis and an increase in the incidence of mortality.

So, again, I agree that it is a prospective analysis of the Neonatal Research Network Centers, but that is the only evidence

which we have. We don't have anything against it.

So, for those two reasons, I would say raise the bar up to 36.5.

DR. WINKLER: Just a question. This is just a type of a measure construct in which there is a threshold, but you can handle the data differently, in that you can report the percentages at each, at a strata, you know, 36 to 36.5 --

DR. HORBAR: We do that. We report the data by half-degree strata.

DR. WINKLER: Would you be willing to say that the measure should be reported that way rather than having the cutoff of debatable thresholds?

DR. HORBAR: I think it is up to you what the measure says. We currently do report it in strata. I think for a hospital that is trying to use this for quality improvement, having a threshold level that they can monitor over time is easier than

trying to decide whether a distribution has shifted. But I would defer to you on how you want to define this from the NQF's perspective.

Our current reporting allows people both to see the distribution and we use the dichotomous cutoff of 36. As I said, we did that because of the recommendation from the NQF Technical Committee and because of the World Health Organization recommendation for what the level of moderate hypothermia was as opposed to cold stress.

So, I think you will get a lot of different opinions on this, if you ask multiple different people.

CO-CHAIR RILEY: Any others?

MEMBER BRANDENBURG: There was one other concern raised by the Committee with this measure, in that the measure doesn't exactly spell out how temperature is to be taken. Because depending on whether they are recording rectal temps or axillary temps, it

doesn't really spell that out in the measure.

DR. HORBAR: I will just address that briefly.

We don't feel like we can mandate to the hospitals how they have to take the temperatures, and if we did, the number of missing values would go way up because it is not routine policy across the nation to do it one way or the other.

MEMBER GROBMAN: So, then, an obstetrician has a question. It might not be routine policy, but aren't they systematically different? Yes, right.

(Laughter.)

So, I guess my question would be, if they are systematically different, shouldn't there, then, be different thresholds? I mean, one way we were talking about gaming the system is just like -- I don't know -- take everything in the armpit, or whatever.

Like it seems to me you would want

to have one threshold for oral, one threshold for rectal. I mean, otherwise, it seems like I would know what I would do in my NICU if I didn't really care about the babies.

CO-CHAIR RILEY: That might be the argument to use the higher threshold.

DR. HORBAR: What would you do? I'm missing the point. What would you do?

MEMBER GROBMAN: I would take it the way that it gives me the highest measure and that gives me the highest temperature. So, from a public accountability standpoint, I always had the lowest hit rate.

I mean, there is no incentive --

DR. HORBAR: That would make complete sense, but I don't see why we should mandate it. If people inspect their data and come to the conclusion that their rate looks higher than the benchmark, and it is because they are taking it in a systematic way from a different body location, if the improvement is as simple as changing the method of taking the

temperature, that would be a success to the measure, I guess.

MEMBER GROBMAN: No, but that, to me, wouldn't be improvement at all because the underlying state of the baby --

DR. HORBAR: I think having the complexity of either asking people to record the method and reporting separately by the method or trying to mandate it would be more complicated than we would be interested in taking on.

MEMBER ARMSTRONG: But it might be an argument to use a higher threshold temperature, right, given there is variability in how you take it?

MEMBER JALEEL: Yes, I would agree with that because the NICHD trial which was done looking at it prospectively, these are 16 big centers in the United States, and 77 percent of the them take their temperature in the axilla; 15 percent take the rectal temperature, and skin would be 7 percent.

So, if the majority is taking it by axilla, and we know that the axilla temperature is lower than the rectal temperature, if it was me, I would recommend an axillary temperature of 36.5. So, it is a slightly higher temperature and you are doing it in the axilla.

MEMBER KELLY: So, I have a process question as to how we might move ahead with this decision point.

CO-CHAIR RILEY: Okay. So, one thing is that we do have the data for meets importance from that last group that is up there now. And that was a resounding yes.

So, we are going to vote on the measure as it exists in front of us now without tweaking it. Correct? Okay.

So, if we look at importance to measure and report?

(Whereupon, a vote was taken.)

DR. WINKLER: It's 19 yes, 7 no.

MEMBER KELLY: So, does that mean

there is no proposal of a different degree level?

DR. WINKLER: At this point, well, you still have to vote on scientific acceptability. But at this point I think that voting on what is presented to you is the decisionmaking with all your discussion and recommendations and feedback to the developer for them to consider. At this point, I would say, if you really can't live with the measure as it is, vote against it, if it really doesn't meet your criteria.

Is everybody aware you are voting for scientific acceptability? Just checking.

(Whereupon, a vote was taken.)

Oh, 13 yes, 12 no.

Is everybody okay with that? Okay.

So, how many of you are voting yes, to make sure we capture everybody?

(Show of hands.)

One, two, three, four, five, six,

seven, eight.

Okay, did I miscount?

(Laughter.)

Okay. So, yes is 8.

No?

(Show of hands.)

One, two, three, four, five, six, seven, eight, nine, ten, eleven, twelve, thirteen, fourteen, fifteen, sixteen, seventeen, eighteen.

Okay, the final votes are for scientific acceptability, yes, 8; no, 18.

I actually think that with more anonymity the votes are different than in a more open kind of thing. We have tested this many times, and it comes out exactly the way you punch the buttons. So, I don't think so. But on a close one like that, when it looks like one was missing, that is why I wanted to be sure we captured everybody.

Let's put it this way: is everybody comfortable with the result of that

vote? You all feel good about it? Yes?

MEMBER GELZER: Can we not ask the measure developer to submit with the 37.5 degrees instead of the -- I'm sorry -- 36.5 degrees instead of 36?

DR. WINKLER: Is that the kind of thing that would change your --

MEMBER GELZER: It might, uh-hum.

DR. WINKLER: It might? Okay. Then, what you could do is a conditional, that on the condition it were changed, how would it change your criteria, and then it would be up to them as to whether they changed it or not.

MEMBER GELZER: So, what exactly will we be voting on?

DR. WINKLER: Remember that the last vote was on scientific acceptability. And so, the question is, if that were changed, hypothetical, if it were changed to a different threshold, 36.5, would you feel differently about how well it met the criteria?

MEMBER YOUNG: So, I think the measure developer has already said that he is willing to change that, correct?

DR. WINKLER: Yes.

DR. HORBAR: Yes, we would be willing to change it to 36.5.

CO-CHAIR RILEY: So, I think there are two issues, though, because I think under this it was two pieces. One, the temperature itself and, two, the reliability of the site.

DR. WINKLER: Correct.

CO-CHAIR RILEY: So, we have to be able to take into consideration that I think some of us -- I personally would feel differently if they said they were going to record rectal or, you know, make a mandate or somehow standardize it, so we could actually believe in whatever temperature you chose.

So, I don't know how we would go about dealing with that, but I think it might change the vote for some people if we changed two things as opposed to just the temperature.

MEMBER YOUNG: But did we ask this group about the importance of the site of the temperature? If the threshold changes, is the site where the temperature is taken, is that still important?

MEMBER BAILIT: Is it worth just a quick poll to see which issue is more important? Because if the issue is the site and the validity of the data, then it doesn't matter the threshold; the developer doesn't have -- it is a different kind of feedback.

DR. WINKLER: Sure.

CO-CHAIR RILEY: So, should we do a hand vote for that?

DR. WINKLER: Probably.

MEMBER BERNS: Or both.

CO-CHAIR RILEY: Okay. A hand vote, okay. All right.

MEMBER KELLY: You need to put your microphone on.

CO-CHAIR RILEY: I think the issue is we want to vote, would a temperature change

change your idea about the validity of this? That is one question.

The second question is, would you be willing to change if it was temperature and site?

And the third one would be just site?

I don't know. There's those two. Okay. All right. Is that fair? No? Okay.

MEMBER PROFIT: So, actually, I would disagree with that because, to me, I would be concerned that the validity would go in the other direction. Like a temperature change would make this measure more concerning for me than it is now in terms of acceptability of the neonatal community to accept this as a quality measure.

And I would want to say that, for instance, currently, in California about 50 NICUs are engaged in a delivery room improvement project where hypothermia is like their primary outcome, and it is recorded like

this, 36.0, yes.

MEMBER BAILIT: But, then, the vote on the first question, would raising the threshold help, then your answer would be no?

MEMBER PROFIT: I think it would make it worse.

MEMBER BAILIT: Which is no.

MEMBER DRYE: Well, I think you can just rephrase the question. Not would it change your answer, but would you support the measure if it was respecified as --

MEMBER GREGORY: I'm sorry, there is a part of me that totally understands where we are going, and then there is a question of, okay, but where is our data that says we should change the temperature when the developers have given us data saying what the temperature should be?

MEMBER YOUNG: It goes back to harmonization, I believe, across the World Health Organization and the American Academy of Pediatrics.

MEMBER GREGORY: There is data?

MEMBER PROFIT: Yes.

MEMBER GREGORY: Okay.

MEMBER JALEEL: The literature recommends 36.5 to 37.5 as a normal temperature. And NRP during resuscitation wants to keep the temperature, maintain the temperature between 36.5 and 37.5. So, that is their recommendation, too.

So, there are two bodies, reputed, recognized bodies, who are just saying that is the normal temperature. Now what you want to measure is another story.

DR. HORBAR: Could I ask about the NICHD data? I thought that they were only collecting data under 1,000 grams. Is that now some kind of broader recommendation of that temperature for all below-birth-weight babies?

MEMBER JALEEL: No.

DR. HORBAR: Or could you just clarify that? I'm uncertain.

MEMBER JALEEL: Yes, I'm not talking --

DR. HORBAR: I thought the generic database was now only under 1,000 grams.

MEMBER JALEEL: No, I am not talking about NICHD Neonatal Research Network. What I mentioned was WHO and the Neonatal Resuscitation Program of the American Academy of Pediatrics.

DR. HORBAR: Thanks.

MEMBER DENK: I would like to point out that one of the issues here has to do with how the data is analyzed once it is collected. And that is a lot more flexible. You know, as the developer said, they could report 36.5 to 36.0. You know, they could report it in ranges.

But, for me, the issue was the site, right. If you are not going to make a recommendation about site, that is where I have an issue. And there is no way to fix it after the fact.

So, that is a question of how you influence, how this process influences the way data is collected, right? How data is analyzed once it is collected in a standardized way isn't really that hard to change as life goes on or as different hospitals want to interpret their data differently.

MEMBER PROFIT: So, I think that is a question about longitudinal measurement for quality improvement versus comparative measurement in public reporting. Because for an individual NICU, you know, they probably won't change it just from one year to the next just to look a little bit better. They usually work on ways to improve the fact of keeping babies well in the delivering process.

Now I think there is a concern when you do public reporting on this that people will start gaming the system and try to elevate the temperatures with ways that don't really benefit the baby per se.

MEMBER DENK: But there is also the issue that the VON network is a network, right? I mean, you are comparing data across sites for performance improvement reasons, too.

MEMBER GEE: I would just like to note we are focusing so much on the variation/location of measurement, how relevant is that? How much variation is there? Are we talking one degree? Are we talking .1 degree? I'm not sure. I don't understand the variation to the extent that I could make a reasonable decision on how important it would be to have the site documented.

CO-CHAIR RILEY: Jeff, can you speak to that?

DR. HORBAR: I am not aware of good data on that. There probably are data. But has someone on the Working Group reviewed that? I haven't.

MEMBER GROBMAN: I mean, in adults

it is substantial. It is a degree. So, I have no idea about baby human beings, but adults, I mean, it is substantial.

MEMBER PROFIT: I can't cite any studies. I have heard more frequently data about .5 degrees Celsius, but I can't cite anything right now. And that is between axillary and rectal.

MEMBER BRANDENBURG: In nursing, when we chart, we add a degree. So, it is a degree. It is the same as the adult.

MEMBER SUTHERLAND: So, I would say that the lack of putting the site on the measure is an unnecessary confounding variable, and that would be an argument from one site to the other as to why their results are different.

And so, part of it is I think the goal of this group should be to take out as many confounders as possible. So that, if we are going to develop a national measure, focus on what is really best for the baby and take

away all the variables, if possible, in the measure.

DR. WINKLER: At this point what I heard from you all is that the last vote we did is you felt that the measure as existing did not meet the criteria for scientific acceptability. The question was, was that primarily because of the temperature threshold number or was it because of the site issue?

The developers have indicated that on the temperature-level issue, that is something, since they already collect the data, is something they can work with. But the site isn't something that is part of the way they capture data and do the work in the Vermont Oxford Network.

So, one seems like it is a possible, and the other does not seem well. So, I think we have to determine where that vote on scientific acceptability really comes from. Is it the issue of the variation in the site the temperature was taken or is to around

the threshold level of the temperature? So, I think that is what has to be determined, to determine exactly the rationale behind your vote that it doesn't meet the scientific acceptability criteria.

CO-CHAIR RILEY: Lee?

MEMBER PARTRIDGE: If the VON network isn't willing to go to the second route, in other words, to specify the site as part of their measurement, do we need to vote on it? I mean, they have indicated that they can deal with the temperature threshold, but if they are unwilling to change their measure, then the measure as submitted to us without change failed, right?

MEMBER DRYE: Can you just take a vote on whether the measure specified with a threshold temperature of 36.5 meets the scientific criteria? And if it does, then it would not fail. And if it doesn't, it failed, right?

MEMBER BAILIT: But that also

saves them a lot of work to stop revising if the answer is, it doesn't matter what you do, we don't like it unless you change the site, and they are not willing to do it. Then they are done, and that saves a lot of people-hours.

DR. HORBAR: Yes, if I could just say something? I mean, I think the tension that is arising here, which is an interesting one, is between the perfect measure and the measure that is good enough for a site to use for quality improvement. Our philosophy has been to provide measures that are good enough and simple, so that individual sites can use them for quality improvement.

If your bar is for national public reporting, pay-for-performance, et cetera, that was never the purpose of our database and never will be. I think that it probably is worth getting that issue out now because we could save all of ourselves a lot of time.

If what you are looking for is the

perfect national measure rather than the good-enough-for-quality-improvement measure, many of ours are probably not in that category. I think, as Dr. Profit mentioned, it is being used for that purpose in California and in many other places, and it is turning out to be quite useful.

But would you want to pay for performance based on this measure? No, you wouldn't. So, if that is your bar, I think we ought to get that clarified.

DR. WINKLER: Okay. We've got a lot of background noise.

I will be happy to clarify. NQF, from its very origins more than a decade ago, has been all about endorsing measures for public reporting and accountability. That is what these evaluation criteria are attempting to identify, are those measures that are suitable for that level of use. We are not looking at measures that are solely useful for quality improvement internally.

CO-CHAIR RILEY: Okay. So, with that clarification, can we take a vote in terms of, first, temperature, right? Would changing temperature alone make this work? How's that?

DR. WINKLER: Your vote on scientific acceptability, does it meet the criteria, if the threshold temperature was changed from 36 to 36.5? If it were 36.5, does it meet the criteria? That is your question.

Because we did it as a hand vote last time, let's go ahead, just for reproducibility, interrater reliability.

Yes or no? A temperature threshold at 36.5 degrees, does it meet the criteria for scientific acceptability, yes or no?

How many say yes?

(Show of hands.)

Seven.

How many say no?

(Show of hands.)

So, it is 7 yes and 18 no.

And I am going to interpret from that that one of the major reasons you are voting against it is the site variation, correct? I am seeing nodding heads around the room. Okay.

Thank you.

MEMBER ARMSTRONG: Can I just ask a question to Jaleel?

Did WHO stipulate it should be 36.5 rectally? Do they stipulate what the site is?

MEMBER JALEEL: No.

MEMBER ARMSTRONG: No?

MEMBER JALEEL: WHO is looking at the whole newborn population as a whole, not just the babies who are less than 1500 grams.

And in one of the locations, it doesn't specify, but in one of the locations it does mention axillary. But it doesn't specify in the main area where it classifies

as cold stress normothermia and hypothermia, it doesn't mention that it is axillary or rectal. But in one of their discussions they do mention axillary. That is all I could see.

MEMBER ARMSTRONG: And AAP has no guidance whatsoever on this at all?

MEMBER JALEEL: No.

MEMBER ARMSTRONG: So, maybe you could take that back to AAP -- maybe.

(Laughter.)

CO-CHAIR RILEY: Okay. So, we are now on 303, late sepsis or meningitis in neonates, risk-adjusted.

Dr. Profit?

MEMBER PROFIT: Okay. So, late sepsis or meningitis, again by the VON. Essentially, this is a standardized rate and morbidity ratio for nosocomial bacteria infection after day three of life for very-low-birth-weight infants, other infants who are admitted to a NICU within 28 days of birth, which is one of the exclusion criteria,

and other infants who die in the hospital within 28 days of birth.

The numerator of this measure is -- this measure is somewhat different from the AHRQ measure. In this measure, an infant is eligible if any or one of the bacterial pathogens that are listed further down in the list below is recovered from a blood or cerebral spinal fluid obtained after day three of life, or if three criteria are met: the infant has coag negative staph plus has sort of positive culture with coag negative staph, either central or peripheral or from a CSF source; has signs or symptoms of a generalized infection, and is being treated with five or more days of IV antibiotics after the cultures are obtained. And if the infant has died or was discharged or transferred prior to the completion of the five days, this condition would still be met.

So, the denominator, essentially, it is all the infants reporting to the

hospital after day three.

So, just to kind of preface this a little bit, this is very similar to Measure 304 except that 304 is a subgroup of very-low-birth-weight infants, and the risk-adjustment model is slightly different because of the two different patient populations, but, otherwise, a similar measure.

And so, when the Workgroup looked at this measure with regard to impact, 4 highs and 1 moderate. Opportunities for improvement, very similar to the AHRQ measure, I think, overall, people thought that this was important.

And I guess I will just leave it here with regard to importance.

CO-CHAIR RILEY: Questions, comments?

(No response.)

(Whereupon, a vote was taken.)

DR. WINKLER: Yes, 24; no, 1.

MEMBER PROFIT: So, then, moving

on to the next section regarding evidence for this measure, this measure actually has been -- well, sorry, I will take this back. I think the VLBW Measure 304 has been actually used and proven in quality improvement interventions conducted by Vermont Oxford and has been successfully reduced.

I think, otherwise, there are, of course, other studies that have been published on reducing infection rates in neonates and in other populations that have been successful.

So, there are a few randomized trials on these things, though, which I think is why some of the validity data was rated around moderate or low. So, for validity, 2 highs, 2 moderates, and 1 low.

And with regard to reliability, we had 2 highs, 3 moderates. There were some concerns about a complicated denominator and the need for relatively substantial data abstraction. There are a lot of bacteria listed, and there were questions about what

they call important on many of the bacteria since the vast majority of infections clusters probably more into a handful of bacteria.

And then, what is the data quality of the Vermont Oxford Network registry was one of the concerns.

Suggestions: maybe about combining this measure with the VLBW measure. I am not sure I would necessarily advocate this. The rates of occurrence are very different in the very-low-birth-weight baby to the higher, the larger babies. And so, I am wondering whether we would be diluting things if we actually combine those. But that is up for the group to discuss.

I think with regard to the risk-adjustment model, I would just mention that there are the smaller hospitals with the smaller "N" because of the shrinkage used, which I think is also used by AHRQ and the Joint Commission or similar measures. But a very small hospital may have an infection rate

of zero, but may not be an outstanding provider because of that shrinkage; the results are being essentially pulled towards the median of the group.

The risk-adjustment model includes race as a co-factor. I think several members were concerned about that. While there may be differential rates among different racial or ethnic groups, it didn't seem that necessarily that that should be adjusted for in a risk-adjustment model.

I think I will open it up to you. Do the developers have some comments?

(No response.)

Anybody else from the Workgroup?

MEMBER GROBMAN: I just have one question about your bullet point 4, the suggestion to combine with 304, but 304 uses the synchronous model.

I mean, isn't it possible that a risk model that encompasses both could be obtained that uses some interaction factors or

something? I mean, are these thought in very-low-birth-weight infants or non-very-low-birth-weight infants to be truly different quality indicators or aren't they just a continuum of the same thing?

MEMBER PROFIT: So, I think what you are referring to, are the things that we do for bigger babies different than the smaller babies to avoid infections? I would probably say the answer is no. It is just for the larger babies, like if you include everybody, I think the overall rates just become quite smaller. And so, I would be a little more concerned about not being able to show change as well as in a higher-risk population. That would be my main concern.

DR. HORBAR: Could I just say a clarification? For our measure that covers all NICU infants, that measure includes both the very-low-birth-weight and the bigger babies. So, that, in a sense, is the combined measure. But we have many members who only

report to us on their very-low-birth-weight infants. That is why there is a separate measure that only applies to them.

I think what Dr. Profit is saying also makes sense, that the rates are extremely different, and that focuses on the very-low-birth-weight infant where the rates are much higher also makes sense.

But if what you are looking for is a combined measure, our measure for all NICU infants is a combined measure. It includes all the birth weights.

MEMBER GROBMAN: Yes, I don't know that it was a combined per se that I was looking for. I was just trying to understand why we have two distinct, but extremely related measures. It seems that if the rates are so low in term neonates, then that goes back to the discussion we had before about birth trauma. And maybe, then, the only good one to use is very low birth weight or you want to get everyone and then you get

everyone.

DR. HORBAR: Well, ours is everyone in a NICU, not all infants of any birth weight regardless of where they are cared for. So, even the bigger infants included in our measure are a higher-risk population than the normal term infant.

MEMBER BERNS: Yes, I think that is key.

Jeffrey, can you give us a sense -- I'm sure it is in here somewhere -- but in terms of the rates? When you have this combined measure that includes all NICU babies, what is the rate of infections compared to those for the very low birth weight, just round-about numbers?

DR. HORBAR: It will take me a minute to find those. If you will just move on to something else, I will come back to that as soon as we have pulled up -- we have a screen here where we can pull it all those data.

MEMBER BERNS: I mean, the reason I asked the question is, if there is really that big of a difference and we are concerned about not being able to see a change, then that is a real concern, as Dr. Profit mentioned.

However, the NICU was a high-risk environment, period. And so, this would help me have a sense of which measure is more sort of usable and feasible, particularly from an accountability and public reporting standpoint.

MEMBER PROFIT: So, on page 10 in the body, under 2A2.1, we do have a breakout by birth-weight category.

DR. HORBAR: I just looked it up. It is 3 versus 15 percent.

MEMBER PROFIT: Okay. Thank you.

MEMBER DRYE: Is there a reason you don't, then, adjust for the birth -- I am just looking at your covariate list on page 9. So, I see gestational age squared, for

example, but not birth weight. If it is that much of a difference in this measure that combines both cohorts, is there a reason you don't risk-adjust?

DR. HORBAR: We have debated back and forth many times whether to include both birth weight and gestation, which are highly correlated, in the same models. And I think there may be someone on the Committee who has better knowledge about those kinds of modeling issues than I do. But I think in testing the fit of the models and the performance of the models, we came to the conclusion that gestational age was the better variable to include.

Some people do include both, even though they are highly correlated. And again, I am not going to try to weigh-in on the statistical merits of including highly-correlated variables in these models.

MEMBER ARMSTRONG: So, one other question. It looks like in the Workgroup

people were concerned about the complexity of the data abstraction. Is that really a problem? Do you get back complete data for the registry?

DR. HORBAR: Yes, we do.

MEMBER GEE: And, Jeff, another thing we discussed was length of stay and whether that should be a covariate and what the impact of that is on rates. Could you speak to that? Because it depends on your level. We talked about levels of NICU and how this measure would be different depending on those levels and length of stay.

DR. HORBAR: It is an interesting question. I don't think we have looked at them systematically. Clearly, there will be babies who stay for a very long time and have a much longer period of time at which they are at risk.

On the other hand, infections themselves and other preventable morbidities can lead to increased length of stay. So,

giving people credit for the increased length of stay may be problematic. It is a tough one.

MEMBER DRYE: I wanted to comment on race. There is adjustment for race. And I know Reva mentioned at the beginning that NQF has more recently asked committees to focus on the question of whether there are disparities present.

And I think about quality measures as a tool for uncovering disparities in care or disparities in outcomes. And what happens, as you know, when you adjust for rates, is you are going to mask any differences by race across hospitals because where there is higher poor outcomes, in minority populations, for example, if you adjust for race, you are going to give a higher expected number in the denominator in this kind of a model. So, in a way, you are basically setting a different benchmark for those hospitals.

What the NQF guidance, as you

probably know, is to not adjust for race in risk-adjustment models, but, rather, to look at differences, and if, for fairness, you really have to think about holding hospitals to the same standard, to stratify the measure, the populations in the measure, rather than adjusting.

So, I think this is a major concern with this particular risk-adjustment model.

MEMBER DENK: But isn't one issue that a lot of these short-term health outcomes, in fact, follow different age and weight profiles by race? I mean, you know, it is not exactly the same outcomes for babies of different race who are of exactly the same gestational age and birth weight.

MEMBER DRYE: So, then, the question is, what do you want? You want your measures to be able to capture those differences, and over time hospitals to address those differences in outcomes rather

than masking those differences in the measure calculation, is what I was trying to say.

DR. HORBAR: I can tell you that the racial terms, you know, our model, don't really matter very much, and probably don't lead to any significant changes in the reporting across hospitals.

We have actually been debating internally whether to drop rates as a risk-adjuster. So, I would appreciate guidance from the Committee on that question.

MEMBER PROFIT: I don't mean to speak for the Committee, but I did not include race in my attempts to risk-adjust quality measures, for the reasons that Dr. Drye suggested. Because I feel like there may be some outcomes in which you really have a biological rationale for different outcomes and which maybe there is a good rationale for including a race variable, but there may be many other outcomes where there's a lot of concerns about quality of care or resources

available for quality of care or things that might be masked by including the race factor.

On the other hand, of course, hospitals will say that, well, they treat a much higher-risk population maybe and feel like they are being unduly punished for that. On the other hand, they may get special monies from the states to take care of high-risk populations. And so, it is like maybe you can't have it both ways.

So, I don't know if there is a perfect answer for this. I think it is important to report it, but I am not sure I would risk-adjust it away.

MEMBER GEE: The goal of reporting health disparities is the goal of reporting when care is worse based on race, when there is not level quality of care. And I don't think that that is what we are looking at here. So, I don't know that it is as relevant.

DR. HORBAR: I can just tell you

that, when we have tried to look at the disparities issue, the conclusion that we were able to reach was that the differences are based at the hospital level, that in minority-serving hospitals all of the infants appear to have worse outcomes across many of our outcome measures, but that is true for all the races within those minority-serving hospitals, which probably is a stand-in for other aspects of those hospital services.

MEMBER DRYE: That is a great analysis to present, and I appreciate your mentioning it. To me, that makes it more compelling to pull the race variable out of the patient-level risk adjustment because, if it is really a hospital effect, you definitely don't want to erase it through risk adjustment.

And I think I am also hearing you say the risk adjustment for race doesn't matter much in this matter, which is another reason just to pull it out, consistent with

NQF guidance.

DR. HORBAR: Yes, and if that were the guidance from the NQF, we would be pleased to do it. And truthfully, we are considering doing it anyway.

MEMBER PROFIT: I had a few more maybe questions about validity that I don't think are really specific to this variable, but really cover all of the infection variables. And I just wanted to bring them up because we may hear from other people once this gets open for public comment.

So, I think Rebecca Gee mentioned one of those, like the back-transfer rates. So, similar to length of stay, those hospitals that do a lot of back-transfer might have a lower infection rate because the infant's exposure time is lower.

NICUs with higher mortality rates might actually be a better performer because exposure time is less.

And I guess another one that they

had was, how would you ascertain whether a patient had a nosocomial infection at the sending hospital? I think the AHRQ measure takes care of that. They had a code for that.

But I think those are sort of some concerns about biases that creep into these measures in general.

MEMBER GEE: We also talked a lot about the bacteria issue. That requires chart abstraction and a lot of work on the part of the hospital to collect it versus infection as a measure. So, I know we are discussing other measures as well, but that is a consideration.

And, Jeff, you talked about the coag negative staph was something like 8 percent of your infection rate, but it is something to think about. Is it important to break it out that way, because it is a higher reporting burden?

DR. HORBAR: Is that a question?

MEMBER GEE: Yes.

DR. HORBAR: Well, coag negative

staph has traditionally been the most common neonatal infection in North American NICUs. There has been a lot of debate, which I am sure your Working Group must have discussed, about, are these all real infections? Are some of them contaminants?

And so, we collect those data separately from other organisms, so that people have the opportunity to evaluate the percentage of all their infections that are coag negative staph. So, that is why we do it.

But in the current measure that you are considering, they are in there.

CO-CHAIR RILEY: Okay. So, if there aren't any more comments or questions, I think we want to vote on the scientific acceptability for this measure. Yes/no?

(Whereupon, a vote was taken.)

DR. WINKLER: Okay. Twenty yes, 6 no.

CO-CHAIR RILEY: Can we move on?

MEMBER PROFIT: Usability is the next criteria. We had 4 highs, 1 moderate.

And I think a similar question to all the other questions, it appears to be high usability for VON members and it is not so clear for hospitals that are not part of the network.

I will just open it up for comment, if anybody wants to say anything about this.

(No response.)

CO-CHAIR RILEY: Can we vote on usability?

DR. WINKLER: This is high, moderate, and low.

(Whereupon, a vote was taken.)

High, 9; 14 moderate; 3 low.

MEMBER PROFIT: On feasibility, we had 3 highs and 2 moderates. I think that was mainly based on the fact that our Work Group had a total of four infection measures to contend with. And so, I think there was just

a general feeling that maybe hospitals are getting overburdened with infection measures. But we will be discussing this tomorrow, I guess tomorrow. So, individually, I think we can probably just come to a vote on the feasibility of this measure.

CO-CHAIR RILEY: Can we vote?

(Whereupon, a vote was taken.)

DR. WINKLER: High, 6; moderate, 17; low, 3.

CO-CHAIR RILEY: And then, finally, vote for overall suitability for endorsement.

(Whereupon, a vote was taken.)

DR. WINKLER: Twenty-three yes, 3 no.

CO-CHAIR RILEY: Can we go on to the next one?

MEMBER PROFIT: So, the next measure is really very similar except for a minor detail on the risk-adjustment method in that it includes very-low-birth-weight babies

only, which, as Dr. Horbar mentioned, is due to the fact that some members only report data on very low-birth infants.

I think any of the other criteria applies. So, I don't know --

MEMBER GROBMAN: So, I guess my question is just the same question I sort of asked before, which is, is there a point in having both? I know, when you say "the members", you mean the members of the Vermont Oxford Network, but that is not really relevant to whether or not we support this as a national quality measure.

I mean, aren't these two -- or I guess I should ask the question -- are these two incredibly highly correlated, and they don't basically assess the same underlying domains of care? And if so, don't you get from one what you essentially get from the other? Like would you ever do QI, and it wouldn't help both?

MEMBER KIEHN: I have facilities

that have NICUs. Some of my NICUs have a large percentage of larger babies, and my other NICUs have a large percentage of smaller babies. And so, it would be very different. I want to look at them very separately because, again, the rates, as Jeffrey mentioned, are significantly different. So, I don't want to have them all lumped in one group.

MEMBER PROFIT: I guess I just wanted to make a reminder point. And again, I am not on the Board of Vermont Oxford, or something. But I just want to advocate that about 900 NICUs already collect this data. That is worldwide. I am not sure how many in the U.S., but a large proportion of those 900 come from the U.S. There's maybe about 1900 NICUs overall. So, that is maybe close to half of the NICUs in the country are already collecting this data. So, I feel like this is not an insignificant number for us to tell those NICUs to end up collecting a whole bunch

of measures because they are already doing this.

CO-CHAIR RILEY: So, there's 1,000 NICUs that are not? Did you say 1900 in --

MEMBER PROFIT: About 1900-2,000. If I had the numbers wrong, please correct me, but I think it is about 1900-2,000 NICUs in the country, somewhere around that. If somebody has a better estimate --

DR. HORBAR: I thought the survey the Perinatal Section recently did, they came up with a number between 1100 and 1200 for the number of NICUs in the U.S.

MEMBER PROFIT: Okay.

DR. HORBAR: But many of those are very tiny, and because there's no standard nomenclature of what a NICU is, it is hard to know what that means.

We figure that in our current very-low-birth-weight database about 80 percent of the very-low-birth-weight infants born each year in the U.S. are enrolled in

that. So, that is probably a better gauge of the scope of it than the number of NICUs.

MEMBER PROFIT: Thank you. Thank you for that clarification.

DR. HORBAR: If I had to choose, I would choose the very-low-birth-weight one. I mean, I think they are both relevant, but I think the utility of the measure I think is greater in the very-low-birth-weight population. At least a number of states have utilized it in their statewide quality improvement efforts. And I think most of them have chosen the very-low-birth-weight population as the one to focus on.

MEMBER PARTRIDGE: Jeff said what I was going to say. I find this a much more compelling measure than the one we just debated before it, because these are your most vulnerable. If we can do a good job with them, we are doing a good job.

DR. HORBAR: Yes, I guess the other side of that is the comment -- I'm

sorry, I don't know who made it -- that the percentage of very-low-birth-weight infants in a NICU, because NICUs are not defined in the standard way, is quite variable. I mean, there may be places where 15 or 20 percent of the NICU infants are very low birth weight and other places where it is 80 percent.

CO-CHAIR RILEY: So, that makes the argument that you should really have two. And if, in fact, you are talking about 80 percent of those very-low-birth-weight babies are already represented in the Network, we are not talking about an astronomical amount of extra work, right?

MEMBER PROFIT: Yes, I mean, I think that is kind of the point that I am trying to make. I am not trying to just say, well, because there is a registry that has defined these things this way, this is what the whole country should do. But a large portion of the country is already doing it. And so, I think we just ought to be mindful

about adding a whole bunch of new measures to what the country is already doing. You know, that entails additional work for maybe very little additional marginal gain.

MEMBER DRYE: I just had a question about -- and I don't mean to keep bringing up the same thing -- but if we wanted to recommend not adjusting for race in these two measures, how do we do that as a process matter beyond just mentioning it in this discussion?

DR. WINKLER: Yes, I think the fact that you have mentioned it, and the measure developers have heard it, and it is something that seems to be very pertinent to their considerations. However, as you very well know, changing risk models and developing is not something you do overnight or over lunch.

And so, given that feedback, I would think that, if they want to run with that -- you need to determine whether the

measure is good enough right now -- perhaps in future iterations, in their annual updates, they may make those adjustments.

MEMBER SUTHERLAND: I guess I had a comment for my NICU colleagues about the differences between Level 2 and Level 3 NICUs. So, when we talk about domains of care, is one measure more likely to hit a Level 2 versus a Level 3? I would just be curious to see what comments you have about that.

MEMBER PROFIT: There are other neonatalogists here.

Oh, yes, go ahead, please answer.

MEMBER JALEEL: Definitely, I mean, I think it would matter for a Level 2 unit. As Teri mentioned, there are units which take care of bigger babies and not these small, extremely-low-birth-weight babies. So, if they want to take this up as a quality measure, then, yes, I would prefer to have it as two different measures, is what I would say.

CO-CHAIR RILEY: So, with that, we will go on to vote. We are going to look at importance measure and report. This is a yes/no.

(Whereupon, a vote was taken.)

DR. WINKLER: Twenty-six yes, zero no.

MEMBER PROFIT: I think the issues with regard to validity -- I don't want to delay this too much -- I think it is essentially the same as for the other measure.

Maybe one thought about the other measure, or for Jeffrey or for us to think about, is the other measure, we just stratified by babies above 1500 and below 1500. Would that kind of take care of it? You know, just have one measure, but stratify it? Would that be a reasonable solution?

DR. HORBAR: I would have to think about that. I mean, if you stratified the measure for -- you are talking about just take the combined measure for all birth weights and

report it stratified?

MEMBER PROFIT: Yes. Now the risk-adjustment model may not work.

DR. HORBAR: The way we do it, which is reporting it overall and in the lowest strata, I am not sure I see the advantage, but I could be convinced.

MEMBER PROFIT: I guess I am thinking for the NICUs that take care of maybe largely larger babies, you know, what additional benefit would they get from the combined measure? Like they might be more interested really to figure out what is happening to the larger babies? And so, if it was stratified, maybe that would fit more what they usually do.

DR. HORBAR: Yes, I mean, you know, in our current reporting, we report the absolute rates within very-small-birth-weight and gestational-age categories. So, I mean, in our reporting to members, people are able to tease that out. We don't do that for the

risk-adjusted, and that would require a whole different approach, I guess, to risk-adjust in only that larger birth-weight strata.

CO-CHAIR RILEY: Okay. Is everybody set? No?

MEMBER JALEEL: I would like to make one additional comment.

CO-CHAIR RILEY: Please.

MEMBER JALEEL: Babies who are extremely low birth weight or less than 1500 are near and dear to the unit because they stay for a longer time, and we have invested a lot of our time and effort into that.

But the number of babies in the bigger age group, even though if we say that the percentage of those babies who are getting an infection is 3 percent, but the volume of those babies is much larger. So, in that respect, I would say it would be good to have those two measures together.

CO-CHAIR RILEY: So, with that, if we can vote on scientific acceptability?

(Whereupon, a vote was taken.)

DR. WINKLER: Twenty-five yes, 1 no.

CO-CHAIR RILEY: Usability? Can we vote?

DR. WINKLER: Voting.

(Whereupon, a vote was taken.)

DR. WINKLER: High, 13; moderate, 11; 1 low.

CO-CHAIR RILEY: Feasibility? Can we vote?

(Whereupon, a vote was taken.)

DR. WINKLER: High, 11; moderate, 14; 1 low.

CO-CHAIR RILEY: And then, lastly, overall suitability for endorsement?

(Whereupon, a vote was taken.)

DR. WINKLER: Twenty-five, yes; 1 no.

CO-CHAIR RILEY: Okay, then, so now we get a break.

DR. WINKLER: For folks who are on

the line, we are running just about a half-an-hour behind, and the Committee really needs to take a mid-afternoon break. So, we will come together again about 3:45. We appreciate your patience.

DR. HORBAR: Well, can I just ask, are there more measures of ours that you are going to address or are we finished?

DR. WINKLER: We have looked at all the measures from Vermont Oxford. Thank you very much for being with us this afternoon.

DR. HORBAR: Well, thank you, and thank you for everyone on the Committee who spent the time of reviewing it. We appreciate the hard work you did and look forward to seeing your advice.

CO-CHAIR RILEY: Thank you.

(Whereupon, the foregoing matter went off the record at 3:32 p.m. and went back on the record at 3:57 p.m.)

CO-CHAIR SAKALA: Okay. So, Paul,

would you like to join us over here at the table?

Next, we have two measures from MGH -- actually, one -- two, yes, from MGH. And I am going to start with No. 472, prophylactic antibiotics for cesarean section.

And I think this had a lot of skewed favorable responses with one issue that is an exception. Obviously, with over a million cesareans every year, and high rates of infection in that population, it is a high-impact issue. There are opportunities for improvement.

And as far as evidence goes, it is very clear that giving antibiotics versus not lowers the likelihood of infection. And moreover, I was curious to understand better the timing issues.

And I did find two meta-analyses that were not cited in the material that we got, two recent ones, showing that giving the antibiotics before the incision reduced the

likelihood of infection relative to giving them after cord-clamping. So, so good for the moms.

And as far as the short-term outcomes for babies goes, these studies seem to show in general no difference one way or the other.

But I do want to say that I feel there is a little cloud over this measure because of uncertainty for longer-term outcomes for babies. That would be with respect to unintended consequences of fetal exposure to antibiotics.

We know that both cesarean section itself and perinatal antibiotics are associated with colonization of the newborn gut with less desirable bacteria. And unlike in older people, that initial colonization is remarkably stable over a long period of time and may be the mechanism for the association of those events with chronic diseases in children, some chronic diseases, and, of

course, not the total explanation, but increased likelihood. And that would be the developmental origins of disease material.

And so, I feel like the best thing for the baby would be, the cautionary thing would be administration after cord-clamping, but that would have a lot of excess infection in the moms. So, that would be my one concern here about this measure.

I have to say, when forced to vote myself, I would vote favorably, just because of the relative uncertainty on the baby's side, but it is a cloud for me.

Comments?

MEMBER PROFIT: I was wondering if you had any sort of specific data on -- I am not quite aware of epidemiological studies that would suggest a higher. Like do you have epidemiological -- I mean, I understand this theoretical concern. Are there any true data indicating --

CO-CHAIR SAKALA: Right. So, I

don't have them, I'm sorry, I don't have them with me, but they are appearing; other people on our call commented as well. They are coming out fairly, you know, frequently in terms of this whole -- there's theories of imprinting and programming and epigenetics. I have to say it is beyond me to understand the science well, but there is starting to be a consistent profile of this association.

MEMBER GILLIAM: Can I ask, as the non-obstetrician, strictly on the pediatric side, so prophylaxis would be a dose of cefazolin delivered within an hour of incision. And as you said, it is a million deliveries potentially a year or a bunch.

And then, on the other side, there doesn't seem to be any reservation about giving moms ampicillin to prevent Group B strep meningitis in the baby and the outcome on that baby, giving mom a dose of ampicillin or multiple doses of ampicillin, and there doesn't appear to be any concern about

changing the gut flora of the newborn when you give ampicillin. Why would there be concern about giving cefazolin?

CO-CHAIR SAKALA: Well, I am not talking about one particular antibiotic or another. And if I were presenting that measure, and it was given in a way that the baby was exposed, which it generally is, I would raise that as a concern as well. And it is over a million of cesareans. So, that is the figure, yes.

MEMBER WATSON: I think where some of the concern came from was on the penicillin-allergic mothers when they are given clindamycin and gentamicin. I think that some concern is, do you really want to give gentamicin and expose the fetus?

So, there are some places where the obstetrician will say, "Go ahead and give the clindamycin" prior to surgery or prior to incision, and will give the gentamicin after you clamp the cord. So, there are some

workarounds.

But there is enough of this concern in the community -- now whether there is data to support it, I don't know, but I think it is just anecdotally they are concerned about giving gentamicin before you cut the cord.

CO-CHAIR SAKALA: Kim?

MEMBER GREGORY: Well, actually, it is a little more complicated than that. That is that there is some very clear European data that the gut flora is altered just because you had a C-section. And so, if you take that and then you compound it by the fact that it is now sterilized, it makes empirical sense that you are even further altering the gut flora.

But, having said that, the measure is designed to decrease the incidence of surgical site infection, and all of the data related to surgical site infection clearly shows that you should have the medication

ideally within 20 minutes of the incision. So, maybe if you cut fast, you can get it out before the baby gets exposed.

(Laughter.)

CO-CHAIR SAKALA: Right. And just to give you like one study that I do have in my head from the Netherlands, and it relates to their kind of care, there were four separate risk factors for adverse colonization: being born in a hospital, not breastfeeding, having a cesarean, and receiving antibiotics. So, those are the kinds of things that are coming along right now.

And obviously, those kinds of longer-term associations are trickier design-wise, but that is what is coming. It is one piece of evidence after another that is suggesting that it is time for us to pay attention to this.

Why we don't, I think we have a lot of short-term views of the matter. Many

of our trials, because of the cost, don't even follow people up once they leave the hospital. So, it is a thing that I think we all need to become better aware of and do the better studies to understand.

Yes?

MEMBER DRYE: Sorry, we are having a side conversation.

Can you just give examples of the outcomes for the baby that you are concerned about or that are discussed in the literature? I am just not familiar with it.

MEMBER GROBMAN: Yes. So, it is not epidemiologic data like of illness or anything like that. It is studies of the microbiome. And so, these studies where people just take and sort of do a blast of the microbiome, see the DNA of every single organism that is around. And the capability to do that is relatively recent.

So, (a) these studies are all relatively recent and still even

methodologically being worked through; (b) it shows what Kim has already referred to, which is that there are these sort of systematic differences depending on route of delivery, antibiotic exposure, but just related to the microbiome. In other words, not any clear health outcome; a very intermediate outcome.

And there is concern, given other data, that the microbiome itself is associated with other sort of long-term outcomes, you know, obesity, blah, blah, blah, nutritional stuff. And so, there is no long-term data linking antibiotics to the microbiome to DOHaD, developmental-origins-of-disease type stuff. So, it is a very intermediate outcome based on the microbiome and the seeming persistence based on antibiotic exposure.

CO-CHAIR SAKALA: Right, and there are studies, for example, of increased association with asthma and allergy, but the mechanism is not clear. So, the idea is this is a possible explanatory factor that is very

plausible.

MEMBER PROFIT: So, I would just be a little hesitant personally. We have very good data on the effectiveness of the antibiotics on the mother, and it sounds like the effects on the baby or child are largely evolving.

CO-CHAIR SAKALA: Right.

MEMBER PROFIT: And so, I agree that it should be studied, but I am not sure that at this point that concern really overrides the benefit, the proven benefit, to the mother. Because the association with asthma and allergies has been made for just about everything.

(Laughter.)

So, I am just a little -- I don't know; I guess we have some proven benefit to the mother. And here's a neonatalogist saying that.

(Laughter.)

CO-CHAIR SAKALA: Right.

MEMBER PROFIT: But the babies need their mothers, too.

CO-CHAIR SAKALA: And that is where I come down, too, but I felt like I really needed to raise this --

MEMBER PROFIT: Yes.

CO-CHAIR SAKALA: -- as an issue because people are saying very clearly the long-term data on newborns are not there.

MEMBER PROFIT: I wonder whether some of this could be included the National Children's Study or something. I mean, it seems like that would be a perfect kind of vehicle for a study like that.

CO-CHAIR SAKALA: Yes. Yes.

So, any other comments on importance to measure and report?

(No response.)

Okay. So, shall we take a vote?

(Whereupon, a vote was taken.)

CO-CHAIR SAKALA: Okay. Good.

DR. WINKLER: Twenty-six yes, zero

noes.

CO-CHAIR SAKALA: So, the next is reliability and validity. I have very little to say.

This measure has been used over several years. In Massachusetts, it has been well-tested. I think the specifications are good.

It includes urgent and emergent cesareans, with the idea that there will be no perfect performance, but encouraging teams to work that into their practice.

As you can see, we had seven highs and one moderate. No. As you can see, we have five -- the majority on reliability and the majority on validity as well.

And this is the rationale here. Really, it is my fault; it should have been more in the previous slide.

So, any other comments?

MEMBER GILLIAM: Can I just ask, from the reliability standpoint, do you

specify which antibiotic? I mean, as they said, penicillin-allergic or penicillin-sensitive, you would go with a different. But do you specify cefazolin or what?

MR. NORDBERG: Right now, clearly, people are talking about cefazolin or other first-generation cephalosporin for the allergic combination of gentamicin and clinda. And for a few women who have multiple drug allergies, I think we are better off just setting them aside totally and leaving them out of the measure.

IDSA has a guideline update expected this spring. It has been expected for the last year or two in a row. I think they will come down in the same place.

DR. WINKLER: I wanted to point out, in response to Craig's question, I think you were asking about how specific is the measure requirements. The numerator details are, for the purposes of reporting, there may be one numerator whose antibiotic selection is

appropriate and a second number of antibiotics, to receive antibiotics within one hour. While both components are necessary in the overall quality-of-care measure, separate reporting may be necessary. So, there are the two elements of both timing and appropriateness.

And though I think it could be more explicit, the reference is to the ACOG guidelines which call for first-generation cephalosporin as first-line and then the combination of gent and clinda for relevant allergies. So, although it doesn't say it exactly that is what is required, it is implied, and perhaps the wording might be such just to say that is what is expected, if, indeed, that is the case. Maybe you can clarify.

MEMBER GILLIAM: What our recommendation would be is timing, not selection, is that correct?

CO-CHAIR SAKALA: It is actually

both.

MEMBER GILLIAM: Okay.

CO-CHAIR SAKALA: And one kind of attractive feature of this is you get one measure and you can break those out to do quality improvement in both ways.

Okay. Other comments?

(No response.)

Okay. Let's vote, please, on scientific acceptability.

(Whereupon, a vote was taken.)

Okay. Twenty-six yes and no noes.

And as far as usability goes, this has been used over several years in Massachusetts and with steady improvement in the compliance over those years. It has not been publicly reported, but I would say it is very amenable to public reporting in the sense that it would be readily understood by consumers and purchasers and other interested stakeholders.

Any other comment on that?

MEMBER GREGORY: I would just add that the mechanisms are in place in most hospitals now because they are already doing it for other surgeries.

CO-CHAIR SAKALA: Good.

Anything else?

MEMBER ARMSTRONG: I just have a question about the denominator. Why were cases with other surgeries within three days following sections excluded?

MR. NORDBERG: That is a generic SCIP exclusion. We are trying to follow SCIP as much as we can.

The feeling seems to be that, if a lady really has two major surgeries during a short period of time, she probably has something else going on with her than a routine delivery. Probably the case is a little too complex to fit in under first-line therapies. That is the theory at least, and I think it is reasonable.

CO-CHAIR SAKALA: Any other

issues?

(No response.)

Okay. Let's vote on usability then.

(Whereupon, a vote was taken.)

Okay. Twenty-four high and two moderate; no low.

So, for feasibility, this cannot routinely be collected electronically, and there were no plans indicated for conversion to e-measures, is that correct?

MR. NORDBERG: Well, it obviously depends on what IT system the hospital has. At my hospital, where we have all kinds of fancy gadgets, when they are all working, yes, we do it electronically in real-time, but not everybody is going to have that option.

I'm cursing at my iPad right now. Excuse me.

(Laughter.)

CO-CHAIR SAKALA: Right. Right.

But, in general, the group highly

rated this measure on feasibility as well, and I would concur with that. But people may -- I don't know; are others using this here? Yes? Any comments from people who are using it about that?

(No response.)

Ready to vote? Okay.

(Whereupon, a vote was taken.)

Okay. Nineteen high and 7 moderate; no low.

And the last vote is on the overall suitability for endorsement. I imagine we are ready to vote on that, too.

(Whereupon, a vote was taken.)

Okay. Twenty-six yes and no noes.

Thank you.

Okay. So, the next measure is 1746. It is intrapartum antibiotic prophylaxis for Group B strep.

And Kathleen has that measure.

Also from MGH.

MEMBER SIMPSON: Right. This is

the percentage of pregnant women who are eligible for and receive appropriate intrapartum antibiotic prophylaxis for Group B strep.

This was reviewed by the group, and everyone thought it was important to measure and report. Generally, there were some opportunities for improvement.

And when this came up several years ago, there was a thought that everybody was doing this. It was 100 percent or near 100 percent. And so, it wasn't worthy of going forward, and there was a lot of discussion about that.

However, it looks like that might not be the case. In The New England Journal article that is cited, it looks like there are significant opportunities for improvement. So, that was pretty good evidence that we needed to take a look at that.

And then, it has been in use in Massachusetts for the last three years, 2008,

2009, 2010, and looking at the ability to, indeed, improve, so you have that opportunity.

There is a discrepancy among black infants. So, there are some issues related to disparity. So, that would be an important thing to consider.

The guidelines are from the CDC, and they are extensive and quite well-written, offering recommendations for who to screen and who to treat. And those were recently summarized by ACOG in their Committee Opinion.

So, I think that you have pretty good, solid recommendations for what to do.

Okay. So, that is that for that part.

CO-CHAIR SAKALA: Okay. Questions or comments on importance to measure?

MEMBER GROBMAN: Just a question about the denominator exclusion, and it could be that I'm just missing this. It says, "The excluded populations are patients screened negative for GBS at 35 to 37 weeks." But how

is it dealt with about pre-term infants who have been screened and are negative and then deliver within the acceptable CDC interval?

MR. NORDBERG: Right, that is a good question. The CDC recently came out with, as you know, more clear guidelines for those cases.

With my iPad down, I don't have that in front of me, but I think, generally, we are trying to follow the CDC's guidelines as closely as we can with those.

As the issue comes, you know, sometimes the hospital is only responsible for a certain part of the care. If the information from the other parts is suboptimal, then we can't hold the hospital accountable for not having the information. We just need to hold them accountable for what they do with the information.

MEMBER GROBMAN: Right, but, for example, if they couldn't get the information and it was a GBS unknown baby or mom, then

they would need to treat that mom because they would be classified as GBS unknown.

But I guess my point would be, like particularly for hospitals that have high pre-term birth rates, and if they are testing those children and those children are tested negative, they are appropriately not receiving antibiotic prophylaxis prior to delivery, we would not want to ding those hospitals for doing the right thing that they are directed to do by the CDC.

MR. NORDBERG: Correct. Yes.

MEMBER SIMPSON: Well, in the recommendations there are separate recommendations for term versus pre-term. And my interpretation of this -- and maybe I was wrong -- was that you would get it based on following the CDC recommendations. So, there is a lot more involved than that one brief sentence. So, you would get the antibiotics based on following all the recommendations, using each of the algorithms that have been

presented by the CDC and adapted by -- does that make sense?

MEMBER GROBMAN: It does, although --

MEMBER SIMPSON: That is my interpretation.

MEMBER GROBMAN: -- the excluded populations in 2A1.9, I mean, are very specific for people who are GBS-negative at 35 to 37, people delivering by planned cesarian, people on antibiotics, blah, blah, blah. But it has nothing there about -- it just seems like a hole to me.

MR. NORDBERG: I think your point is well-taken. The language is sloppy and maybe we should clarify that. It seems like everyone is saying the CDC has guidelines that we want to follow. So, can we just clean up our exception language to deal with that? Would that work?

MEMBER GROBMAN: Right, that the exclusion should be anyone --

MR. NORDBERG: The exclusion.

MEMBER GROBMAN: -- the CDC says is excluded from meeting it.

MR. NORDBERG: Right, right.

MEMBER SIMPSON: Well, my interpretation of this, and I think in the group as well, was that, since that was cited as the basis for the recommendations, that that was implied that you would be following that. Did I overreach on that?

MR. NORDBERG: It is implied, but I have learned that we need to be very, very explicit, compulsive about these things.

(Laughter.)

MEMBER SIMPSON: Okay. So, are you saying that you would be willing to fill this in and be more --

MR. NORDBERG: Certainly, the language about exclusions, as just pointed out, and we can review the whole issue without changing the intent, that we are following the CDC guidelines. We will just clear up the

language to make it explicit rather than implicit.

MEMBER SIMPSON: Okay. That's good.

Reva, can we do it that way?

DR. WINKLER: Yes, uh-hum.

MEMBER SIMPSON: Okay.

DR. WINKLER: Yes, because we are not talking about a change; you're talking about a clarification.

MEMBER SIMPSON: Okay.

DR. WINKLER: And that is one of the real benefits of having the developers here with us.

MEMBER SIMPSON: So, I think it is important to measure, it is shown to be efficacious when treatment is given appropriately. There are some opportunities for improvement. So, we can vote on that criteria.

CO-CHAIR SAKALA: Okay. Other questions or comments?

(No response.)

Shall we vote, then, on the importance to measure and report?

(Whereupon, a vote was taken.)

DR. WINKLER: Twenty-six yes, zero noes.

CO-CHAIR SAKALA: Okay. Scientific acceptability.

MEMBER SIMPSON: I think that there is ample data that the treatment is efficacious and the CDC guidelines are compelling. So, the group thought that that was pretty good.

DR. WINKLER: Yes, but scientific acceptability specifically asks about the reliability and validity of the measure.

MEMBER SIMPSON: Oh, okay, I can get into that.

DR. WINKLER: The evidence is under importance.

MEMBER SIMPSON: Well, the group rated reliability and validity as generally

high, 3 for high for both of those and 1 for moderate.

There was a question about the CDC recommendations ignoring risk factors in the study of negative cultures.

Also, in The New England Journal article as well as discussion in the group, there were issues of the mother had a false-negative result and ended up with a baby that had GBS.

Now with The New England Journal article, that was based on the recommendations from 2002. With the newer recommendations, with better testing, that may be minimized, but there is no way to know that for sure.

CO-CHAIR SAKALA: Questions or comments on reliability and validity?

(No response.)

Okay. Shall we vote on that then?

(Whereupon, a vote was taken.)

Okay. Twenty-four yes and 2 no.

Next is usability.

MEMBER SIMPSON: In terms of usability, it has been in use in Massachusetts for the last three years. It does require some manual record review. Hopefully, with better EMRs, that would be lessened over time, but right now it does require some manual record review.

The group felt that usability was generally high, 1 with moderate. And again, the time-intensive situation of manual record review was the rationale.

CO-CHAIR SAKALA: Questions or comments on usability of this measure?

MEMBER BERNS: Yes, Paul, I am just curious. I was really struck by this sentence here on page 11. "The barriers to reporting the current measure are not intrinsic but logistic, developmental, and to some extent political." I am just curious, what did you mean? Is that in terms of CMS and public reporting and where we are there? What do you guys mean by that? I am just

curious.

MR. NORDBERG: Well, I am referring to the State of Massachusetts. CMS at this point is interested in Medicare patients. They haven't gotten to Medicaid yet.

In the State, we are in the curious position that hospitals are in a pay-for-performance program or they required to report the data to the State Executive Office of Health and Human Services, but that office does not have the State mandate to do public reporting of the data to the general public. That is another branch of State government that has that reporting capability. So, these two arms of the State government are in conversations with each other, but given the Affordable Care Act going through the courts, nobody is rushing forward to get this stuff out on the internet.

Now I think, inherently, the data reflects SCIP data is reported all over the

place. It is reportable.

CO-CHAIR SAKALA: Other usability issues?

MEMBER PROFIT: You showed an increase in the measure over the last three years from -- what was it, like in the 71 to 83 or 87 percent range? Any idea on the effect on children, on sepsis rates over that time?

MR. NORDBERG: No. That is a very, very good question, but, no, we don't have information on that.

CO-CHAIR SAKALA: Yes, Jaleel.

MEMBER JALEEL: I have a comment.

CO-CHAIR SAKALA: Please.

MEMBER JALEEL: Ours is one of the only hospitals, Parkland Hospital in Dallas is probably one of the few hospitals who do not go by CDC recommendations, probably the only hospital now.

(Laughter.)

That is based on data which comes

from their own dataset which they have looked at babies, the rate of infection and based on best strategy. It has been quite effective, and they don't want to change that model.

But, as mentioned in one of the controversies, now it is so much ingrained into the system, that it is even difficult to do any controlled trials now.

So, my obstetricians and my fellow neonatalogists will beat me up when I go back and when I say that I have accepted this, but --

(Laughter.)

CO-CHAIR SAKALA: We won't tell.

(Laughter.)

Anything else on usability?

Lee?

MEMBER PARTRIDGE: I can't resist, again, a recommendation. It is hard to track the particular case. That is, these 14 women got this and then their children's outcome was "X". But, as a population measure, if you

were in a region where you were systematically tracking this measure in your hospitals, you, presumably, would have some corresponding public health data about the incidence in your children, wouldn't you?

So, it would be nice to down the road have a companion measure that would go along with it. Linking them is not going to be neat and tidy statistically, but it might be of interest to see whether it was really impacting your rates.

MEMBER JALEEL: Yes, that data was published in the 1980s now, and showing what the difference was. We keep track of that data. We have a large population. Parkland has around 15,000 deliveries a year. That is 1 in every 250 Americans are born at Parkland. So, it is a big number.

(Laughter.)

And they have a big dataset. So, I think it would be, yes, good to know that.

CO-CHAIR RILEY: I mean, we do

have some population data to suggest that GBS sepsis in newborns is a really tiny number now. It is not zero; it is never going to be zero. But, clearly, what we have done over time has made a difference.

Then, the only other issue, obviously, is that, unfortunately, the rates of gram-negative sepsis in newborns have gone up. So, I don't know what to say about that, other than I don't know whether that is an unintended consequence or you are going to get sick with something. So, if you wipe out the GBS, if you wipe out the gram-positives, given the antibiotics we are using, you may get more gram-negatives. I don't know the answer to that.

CO-CHAIR SAKALA: Other usability comments?

(No response.)

Okay. So, let's vote then on usability.

(Whereupon, a vote was taken.)

Okay. Fourteen high, 11 moderate, and 1 low.

And finally, feasibility, Kathleen.

MEMBER SIMPSON: Well, feasibility, the group thought that feasibility was high. Two thought high; two thought moderate. Basically, again, it was related to the electronic medical record versus the manual chart review.

The algorithms, while clearly stated, are complicated if you are doing a manual chart review. So, it is a simple one data element in the electronic record. So, at the moment, it does require a manual review. Perhaps that will change, but right now it does. And we do look at this measure at our hospital, and it requires a manual review.

So, it is worthy, it is feasible to do, but it takes some time.

CO-CHAIR SAKALA: Comments on feasibility? Questions?

(No response.)

Okay. Can we have a vote, please, on feasibility?

(Whereupon, a vote was taken.)

Okay. Six high, 19 moderate, and 1 low.

And the last vote would be the overall suitability for endorsement.

(Whereupon, a vote was taken.)

Twenty-six yes, no noes.

Thank you.

Okay. So, do we have someone here or on the phone from the California Department of Public Health?

MS. SULLIVAN: Hi. This is Catherine Sullivan.

CO-CHAIR SAKALA: Hi. Thank you.

So, we are going to turn to 479, birth dose of hep B vaccine and hepatitis immunoglobulin for newborns of mothers with chronic hep B.

And that is Rebecca. Thank you.

MEMBER GEE: Great. So, this measure is from the California Department of Public Health, the numerator being the number of infants to hep B surface antigen positive moms who get a dose of both the vaccine and the immunoglobulin upon delivery, and then the denominator being the number of infants born to mothers who tested positive for hep B surface antigen during prenatal screening or upon admission.

I know earlier today there was a lot of discussion about the former measure, which was more broad. But, specifically on this one, in terms of importance to measure and report, in our group discussion we had several comments about the usability of this being that in California, for example, more than 97 percent of eligible patients received both the immunoglobulin and the vaccine. And so, it seemed like there was a very small percentage, less than 3 percent, that would be eligible to receive that had not.

In addition, and when we did this factoring out the population of California, that would mean about 60 babies in the entire State in an entire year that may or may not be missed. So, a fairly small number, maybe not even one per hospital setting.

In addition to that, there is the issue of needing to receive additional doses of vaccine. And so, whether this one dose was enough, that it may not prevent hepatitis B in the infant. So, this is not 100 percent preventive of vertical transmission.

In addition to that, we discussed the issue of population variation, that in California the hep B e antigen is much more transmissible, that that antigen is more common in folks of Asian descent, and that depending on the state that you are in, the transmission may be higher or lower. And so, this may be more or less useful.

We discussed that certainly California is not the only state with a large

percentage of Asian folks, and there are other populations in addition to Asians that have the hep B e antigen. But this may be geographically more relevant, depending on the population of the state. So, it may not be generalizable nationwide in terms of when you are looking at effectiveness of the vaccine.

The other issue was opportunity for improvement. Again, fairly low, more than 97 percent are already getting the vaccine. And so, we felt no, four of us, and only one that it met importance.

So, I know you have discussed this a lot. We felt that this was not a high priority of the group in general from a population level, given the small numbers, the variation due to what type of antibody modification, I mean antigen modification, as well as the issue of not 100 percent prevention of vertical transmission.

In addition, there were no data available from California about the number of

babies that were actually affected long-term then with hepatitis B who had not received the vaccine. So, we were not able to see really what we were solving from a public health standpoint.

And this measure -- again, we will get into this later -- requires lab abstraction both from infant and mom, which is quite a bit of work in obtaining the metric.

So, I will stop there and get the comments.

CO-CHAIR SAKALA: Katherine, did you want to add any comments, based on our discussion and what you just heard?

MS. SULLIVAN: Yes, sure. This is my first time in talking to NQF. So, hopefully, I can do my best, and based off of your comments, I am definitely getting a better understanding of how this measure can be used or exactly how you guys operate. So, thank you for giving me the opportunity to work with you guys on this one.

In regards to the data about infants in the long term who do not get PEP, unfortunately, our surveillance data does not capture that. We mostly follow -- and by "we", I also mean the Health Department -- mostly follow infants all the way up until we either lose them to followup, for the simple reasons of loss of followup, as well as only up until we get (phone technical difficulties) tests, so anywhere from 15 to 18 months or even later. So, unfortunately, it is true we cannot provide data about infants long term specific to the California population.

But there are, especially in the MMWR cited references to, if an infant is not appropriately prophylaxed within a given time, well, within the recommendation, and born to a positive mother, approximately 90 percent of those unprotected infants will end up developing chronic hepatitis B. And then, of course, there are complications with that. Unfortunately, like I said, it is not specific

to the California population.

And in terms of the small percentage and the small opportunity for improvement, that is true, actually. We do have pretty much near coverage for infants born to positive mothers.

But the CDC definitely deems this program and this measure still important. I mean, they weren't partnered with us in writing this NQF measure, but overall they do deem and really do strive to improve that number, just because it is a preventative measure.

We do have the vaccine and we have the structure in place to be able to get that 97 percent pretty much 100, especially since now they are trying to recommend laboratory reports and all of the other hospitals going into electronic reporting of the mothers' surface antigen status as well as trying to -- I mean, some states even have tried to, or not have tried to, but they have made pregnancy

with infection actually reportable to try to get around or to try to emphasize reporting mothers who are surface antigen positive to the state, so that the perinatal program can monitor the infant prophylaxis.

So, I think that 97 percent is pretty high, but it is a highly preventative measure, and infection of an infant at an early age can set them up for chronic disease in the long run.

And although California does have a very specific and diverse population to be able to have even this number, I think that this is still a problem across the board.

I believe it was Christy who had stated, or not stated, had sent along as supplementary -- I think everybody else got that also?

MEMBER GEE: And just to add another concern of the group was the timing, that CDC guidelines, there was a 12-hour and a 24-hour, and they were not consistent. So,

the way it is reported -- Catherine, would you be able to speak to that, the timing of it and why this is a 24-hour timeframe and not the 12-hour?

MS. SULLIVAN: Oh, sure. Because I had actually asked my boss that as well because it is a bit interesting. Because the CDC does recommend 12 hours as well as the APIP recommends 12 hours. Everybody recommends 12 hours, actually.

It is just our specific report for our grant that we sent to the CDC, which is what I used for the validity/reliability analysis, was day one, because those were the official numbers that we had submitted for 2009.

In terms of why it is day one, I really can't tell you that reason. I think Ellen Chang from the Asian Liver Center tried querying the CDC to ask them why, but we didn't get a response to that in time.

But I think it is partially a

surveillance logistic and, also, by asking us information about how many of the infants born to positive mothers received it within day one, then we can compare it to how many infants were born to either unknown or negative mothers received it also on day one, which is the typical recommendation -- I'm sorry -- the standing recommendation.

Why they would also add an additional question to the report for within 12 hours, I have no idea. So, that I really don't know, but the basic thing is that the California Perinatal Hepatitis B Program does gather information for basically a specific hour, so that we can calculate anywhere from hour zero to however many hours that the CDC would end up, or anyone for that matter, would end up wanting information.

So, sorry, I apologize, I can't really answer that question. It is just a report that sent along to the CDC.

MEMBER GEE: So, there was a

discrepancy in terms of guidelines and the timing of how that is reported in relationship to the guidelines. And the consensus was certainly that the evidence is that HBIG is --

MS. SULLIVAN: But have people received the document that Christy or Ellen had sent along to you? It starts off with an excerpt from the IRM report regarding how, with immigration increases, especially from Asian countries where perinatal hepatitis B is endemic, that this would be an important measure --

MR. THEBERGE: We posted all those up on the --

MS. SULLIVAN: -- because of the increase in immigration from countries not only affecting California, but the rest of the United States.

MR. THEBERGE: We posted all the supplemental information to SharePoint in the measure folder, so it should be on there.

DR. WINKLER: If we received it,

then we put it in the folders for the Steering Committee.

MEMBER GEE: So, just to summarize, the group felt that there is obviously very good evidence that there is an effective intervention that is not in doubt. Our concerns were more about the impact of this, the differences in population, and the issue of the timing being two different timings, and the 24-hour veering from the 12 hours.

But, predominantly, it was the low numbers and the burden of collecting it, given that we didn't really have good evidence that there was a lot of quality improvement needed in this area.

CO-CHAIR SAKALA: Do members of the Steering Committee have other comments or questions for one another or the developer?

CO-CHAIR RILEY: So, I have a comment. I mean, I am not sure that we definitely can solve this, but I wonder if,

although the numbers are low right now, I am a little concerned that the numbers are low because there are public health dollars to chase these patients down and identify the moms who are hepatitis B surface antigen positive and then go after their kids.

So, in Massachusetts, it is a reportable disease. They chase you down until they are sure that you have done what you are supposed to do.

And as the public health dollars dry up, that chasing situation isn't going to occur, in which case these numbers may look good now. But as that money goes away from adult immunization programs, those numbers may go down. So, that is the only other -- and this may be the only carrot to keep people's eyes on the prize.

And then, the other issue that she brought up at the tail-end is the immigration issue, which is the numbers are what they are today, but as more people come to this country

who are from places where there are no immunization programs, diseases we never thought we would see we are going to see. So, I just throw that out there.

And then, the only other thing I would say about the discrepancy in the numbers, 12 hours versus 24 hours, the one group that is not going to get it in 12 hours is if you have a lot of no prenatal care showing up at your hospital, because you need to wait until you get back the hepatitis B information on the mother and then you go ahead and give the dose.

So, I think that part of it is so that you can capture as many people as are appropriate. I don't know.

Bill, you are from CDC. You can probably speak to it better than I can. But that seems to make sense to me, why you would do it.

MEMBER GEE: Well, Laura, I think those are really great points. One of the

things I question, though -- and, Reva, you may be able to speak to this -- is certainly, if we look forward at population trends, things may be different and very important from that standpoint. But if they are not today, should we use today as -- how should we be thinking about this?

And can a measure like this -- my assumption is we could revisit it at a time when if immigration patterns change and we saw a lot higher numbers. I mean, in California we are talking just 2,000 cases in a year, 97 percent of which are treated. If that number changed, could we relook at this?

CO-CHAIR SAKALA: Jaleel?

MEMBER JALEEL: I need some clarification on this. I am not clear how the immigration pattern changes this.

These are mothers who are positive. So, you are already identifying the mothers who are positive and then giving those babies the hep B. So, how does immigration

play into this because you are already identifying those mothers.

MEMBER GEE: The hep B e antigen is much more highly transmissible. So, 90 percent or even more than 90 percent versus with the non-e it is in the range of 50; it is less. And so, it is just transmissibility. It is still important, obviously. You have a positive mom. It is a positive mom; the baby needs to be treated. But it is just the issue of what percentage of those infants will be affected may change with immigration patterns.

MEMBER JALEEL: We are checking for the hep B sAG status, right?

MS. SULLIVAN: Yes.

MEMBER JALEEL: So, where does hep B e --

CO-CHAIR RILEY: Well, if we get a hepatitis-B-surface-antigen-positive mom to start, then we want to figure out, is this chronic active hepatitis? So, we go down the whole list of all the other hepatitis

serologies and you get the hepatitis e antigen. So, those people have much higher viral load, much more activity, and they have a higher rate of transfer. So, it is like 90 percent, 75 to 90 percent versus 20 percent if they are e antigen negative.

MEMBER JALEEL: I have another question. These last two measures, the GBS antibiotic prophylaxis and this one, these are CDC recommendations. And so, why is CDC not involved as a joint developer in these programs? Would you want to encourage that?

DR. WINKLER: Well, CDC has developed measures, performance measures at provider levels, though, typically, CDC tends to historically have been much more around population health and your typical infection surveillance-type measures. And there can be some differences.

But, indeed, it depends on, if you notice the very first measure we did, it was a measure from CDC. So, they are involved,

but they probably have limits on everything they can get involved as well.

And this comes, again, from a Department of Health of a State, a big State. So, you are talking, again, about the public health world doing these.

MEMBER PROFIT: So, we were struggling with this measure a lot in our Workgroup. To some degree, I think all of us think it is very, of course, worthwhile that every baby that is at risk for this should be treated. So, nobody, I think, disputes that this is a very important aspect.

I think where we had our biggest concern was, I mean this is about performance measurement of hospitals. And so, what are we going to be able to say about performances of hospitals if the baseline rates are just so low? So, what is the meaningful, is there a meaningful conclusion that we can draw, as stewards of the public in a sense, to say that, okay, this hospital has a 5 percent

rate; this hospital as a 1 percent rate? Is that truly -- you know, the numbers get so small; I just don't know whether this is the right forum for this measure, I guess.

MEMBER GEE: In Louisiana, we have around 60 maternity hospitals even in our State, and there would be many hospitals that would have zero cases. And so, the question is with this burden, which we will get to next, of collecting the data. Is it worth using your chits on that when you don't even have a single case in a year?

MS. SULLIVAN: (phone technical difficulties).

The instructions are to collect the data, and I think our other concern, too, is that we are getting some refusals. I mean, granted, that won't drastically shift it, but it would be interesting to see those, in addition to the immigration profile changing, the immigration population profile changing potentially in the next few years.

There is also a shift in the idea of vaccinating a kid, especially at birth. And so, we are starting to get some refusals. So, that is one thing that pops into my head.

MEMBER DRYE: I just wanted to echo, it was a really good discussion we had in the Working Group, and I wanted to echo the thought about the difference between a public health measure and a quality measure. So, if the trends are changing and you are using this for surveillance, that is just not a hospital quality assessment tool. That is a different kind of tool.

And I also wanted to say I don't know exactly how to weigh this, but another consideration is the hep B vaccine measure we discussed earlier. Because even if you are not giving immunoglobulin, you are giving the hepatitis B vaccine.

If that goes into public reporting, then the marginal benefit you get from this is even lower because you are

preventing some vertical transmission through that mechanism. So, it starts to get really, really teeny, tiny numbers, and the reporting burden is great on this particular measure. That is why we ended up where we did on the importance criteria.

CO-CHAIR SAKALA: Are we ready to vote on importance to measure and report? Okay.

(Whereupon, a vote was taken.)

Okay. Six yes and 20 no.

So, this one will not continue to go forward with our process.

The last measure of the day is 502 from the American College of Emergency Physicians, pregnancy test for women with abdominal pain in the ER. Is that right?

And that is Janet.

MEMBER YOUNG: Thank you for inviting me into this den of obstetricians and perinatalogists and immuno-natalogists. Thank God I did part of an OB/GYN residency, so that

you guys aren't speak Greek to me in some of our technical discussions today. So, at least I have been able to follow some of the more esoteric or technical components of prior measures today.

We are going to talk about Measure 502, pregnancy test for female abdominal pain patients.

When I first got this measures, I thought for sure that, why wouldn't you get a pregnancy test in non-traumatic abdominal pain? Doesn't everybody? And surprisingly, no. The answer is no.

So, the importance to measure and report abdominal pain, especially non-traumatic abdominal pain, it is one of the top five, probably No. 3, cause for emergency department visits, slightly higher for females than men.

And in our surveys, at least in the measure developer, the Ambulatory Healthcare Survey showed that about 67 percent

of patients did not have testing for abdominal pain.

There was a dearth or a lack of data in both the Cochran database review and a Medline or a PubMed review for my initial evaluation of this topic. So, I actually went and did my own research.

I belong to an eight-hospital system. We have about, I want to say, roughly 180,000 patients a year in the emergency department, and this is for our last 12 months of data. So, these are female patients between the ages of 11 and 50 -- and I will talk to the number age 11 first -- between the ages of 11 and 50 years old who presented with abdominal pain who were tested for pregnancy in our emergency departments.

And these are, by and large, Board-certified emergency physicians, many of whom have an American College of Emergency Physicians Fellowship. There is an abysmal 44 percent patient testing rate.

Now one of my colleagues pointed out that, back in the old days, when emergency medicine --

DR. WINKLER: Excuse me. Whoever is on the phone, you need to mute yourself. We are getting lots of clatter from you.

Thank you.

MEMBER YOUNG: Back in the old days of emergency medicine, and that would only be back in 1982 because we have not been a specialty that incredibly long compared to surgeons and obstetricians, that the first thing the service attending would do on the female patient is find out if they were pregnant or not, because they got to shift the burden of care to the obstetrician/labor deck, correct?

So, unfortunately, we are not taking care of patients up 20-22 weeks of gestation. And so, that standard of care has really fallen off by the wayside.

So, hence, the delay in diagnosis

of ectopic pregnancies and complications of ruptured ectopic pregnancies have been increasing, although we don't anecdotally have that data. But I don't have that data in our dataset because there is just not a lot published out there at this point in time.

So, again, this is my original data. About 44 percent of patients getting tested in the emergency department, and this is in the western part of the State of Virginia.

And I am going to stop there because I really want to keep this brief.

CO-CHAIR SAKALA: Okay. Are there questions about the importance of this measure?

MEMBER ARMSTRONG: What are the barriers to not testing? Just didn't think of it or --

MEMBER YOUNG: I'll be quite honest with you, I have no earthly clue. Urine pregnancy tests are non-invasive.

They're quick. They're done in two minutes. Perhaps getting the urine? They are a standing order in our department hospitalwide for the emergency department patients who present with abdominal pain of childbearing years. That is a standing order for the triage nurse to do.

And this is not just with Carilion's hospital systems. This is across the country. The Ambulatory Healthcare Database that Dr. Schurr found testing of 33 percent.

MEMBER CALLAGHAN: I will first say this is a no-brainer.

(Laughter.)

But I will also say that, for a whole bunch of other reasons likely, that deaths from ectopics in the United States are falling fairly dramatically. Falling, yes. And it likely is due to early pregnancy testing overall, not just amongst people going into the emergency rooms, but people going

into people's offices, people buying pregnancy tests at home, knowing they are pregnant, and earlier evaluation and ultrasound, and all those things that happened over the past 30 years.

CO-CHAIR RILEY: But if that is the case, that would argue against this because if it is not this big of a deal --

MEMBER CALLAGHAN: Well, death is the final outcome.

CO-CHAIR RILEY: I mean, death is a bad thing.

MEMBER CALLAGHAN: Yes.

CO-CHAIR RILEY: I get that.

(Laughter.)

MEMBER CALLAGHAN: If that is the only thing we are going to try to prevent, then --

MEMBER YOUNG: I think that emergency physicians have also become more sophisticated in OB ultrasound. We do bedside ultrasound on a patient who, granted there

might not have been pregnancy testing done, but the physician can come by and put a probe on a patient's belly and go, "Oh, there's a fetus there." Well, you don't need to have a pregnancy test now. There is an ultrasound with irrefutable evidence that there is an intrauterine pregnancy, and we often do that.

That is a whole subset analysis of this, and we will eventually get there, at least in our literature. I am working on that right now.

MEMBER CALLAGHAN: And preventing rupture is something to prevent.

MEMBER YOUNG: Preventing mortality from ectopic I think is the health outcome metric we are working on.

MEMBER CALLAGHAN: Yes.

CO-CHAIR SAKALA: Yes, Jennifer.

MEMBER BAILIT: So, I think that is a key thing. If the incidence is dropping, increasing screening for a problem that is already on the decrease strikes me.

I am just wondering -- and I know Elliot is here from the Maternity Mortality Review -- do we have a sense of whether this is still a major cause of maternal death in this country.

PARTICIPANT: It is one of the major (phone technical difficulties).

MEMBER YOUNG: Is that Dr. O'Connor?

PARTICIPANT: It is Dr. (phone technical difficulties).

MEMBER GREGORY: This is Kim.

We don't know really, we don't have very good data at all about the incidence of ectopic pregnancy. It is becoming even more obscure because it is being diagnosed earlier and treated in offices.

So, before, we knew a lot about it because you presented to the hospital, and you either had a ruptured ectopic or you got ruled out for ectopic. But now that it is being medically-managed or managed in a surgery

center, there is no registry of data that we can call on.

So, the answer to your question is we have no idea.

MEMBER BAILIT: So, understanding we don't have a denominator, when you look at maternal deaths, is ectopic a major cause of the bad outcome?

MEMBER GREGORY: Women, I mean --

MEMBER BAILIT: It is sort of the opposite way to look at it, since out of a cohort, it is --

MEMBER GREGORY: Ectopic pregnancies are still a part of maternal death in the United States.

MEMBER BAILIT: And of those that are still a part of the death, is it that they have contact with the healthcare system and it is missed or that they just stay home? In other words, is the ER the place to increase screening? Don't know?

MEMBER GREGORY: I can't answer

that.

MEMBER YOUNG: I'm sorry, I'm on the CDC website to see if I can find that information.

MEMBER CALLAGHAN: Jen, actually, we have an MMWR that is in clearance. I hope they are going to take it. But we couldn't get at that.

We found that there was a cluster in recent years in Florida. It was associated with substance abuse, but there was a big pop there, and whether or not they had contact with the healthcare system prior to presenting with sudden collapse was difficult to untangle.

MEMBER GEE: Janet, can you speak to why the 45- to 50-year-olds are needing a pregnancy test? I just wonder, from the standpoint of your cutoffs, how was that chosen? Obviously, menopause being average of 51, but really the numbers of pregnancies in 45- to 50-year-olds who are not being

monitored and in fertility clinics would be extremely low.

MEMBER YOUNG: Sure. The measure developer had actually set that as their initial cutoff, as 50 years or the age of menopause, the average age of menopause. Their initial data was set up on ages 14 through 50.

During our Workgroup discussion, many of us, including myself, have delivered 11-year-olds. We know that the average age of onset of menarche is 11 and a half. So, we know that 11-year-olds are becoming pregnant at an increasing, well, certainly an increasing rate for this generation as opposed to prior generations.

I can't speak to age 50, but we know that patients still get pregnant during that time. As pregnancy becomes a little less likely, the risk potentially of ectopic pregnancy may perhaps increase because we are not thinking about that as a differential

diagnosis on their initial presentation.

MEMBER DENK: I was just going to ask, because you brought up the minors, is there a consent issue here, either for the adults for a pregnancy test or for minors?

MEMBER YOUNG: In the emergency department, we have to get consent from either a parent or, if there is an emancipated minor, they can consent to their own treatment. That is for all emergency care. So, if at any point in time a patient needs any kind of treatment or testing, they have to have parental consent or they are an emancipated minor.

MEMBER DENK: But there is a blanket consent for treatment once they come in or --

MEMBER YOUNG: Yes.

MEMBER DENK: -- a separate consent for a pregnancy test?

MEMBER YOUNG: No, they consent for emergency treatment.

MEMBER DENK: Okay.

PARTICIPANT: And otherwise you are excluded if you refuse, if the patient refuses.

MEMBER YOUNG: Yes, that is a good point. If the patient refuses, also, we don't have to perform a pregnancy -- they actually fall out of the denominator.

MEMBER ARMSTRONG: Is there another benefit we should be thinking about here, early entry into prenatal care or early timing of pregnancies for terminations, if desired?

MEMBER YOUNG: I think there are many outcome measures that we could consider because you are diagnosing a pregnancy earlier. Oftentimes, the emergency department is the only portal of medical care a patient has in their first 18 to 20 weeks of pregnancy, at least in the rural population and some innercity patients as well. The emergency department diagnoses their pregnancy

and then their followup care is delayed by quite some time, either unintentionally --

CO-CHAIR SAKALA: Excuse me. Could you please keep the noise down on the phone?

MEMBER YOUNG: -- either unintentionally because of scheduling issues or the patient just doesn't have access to the healthcare system because they live so far away.

MEMBER CALLAGHAN: I think that is an important point, though, because you are also looking -- this is females with abdominal pain -- so now you are looking at abdominal pain in a pregnant woman potentially, which is a different workup.

MEMBER GROBMAN: Yes, I would sort of second this issue of I think looking just at mortality from ectopics is an extremely-narrow window, and that if you really blow it up to be early pregnancy diagnosis, regardless, and think about the avoidance of

teratogenic medicines, early entry into prenatal care, avoidance of other unnecessary procedures because they are pregnant, so they don't end up in the CT scanner looking for like whatever.

Then, just a couple of very specific questions. One, why is it ordered versus actually resulted? Because it strikes me that it is great to order it, but that is really not what you want. You want to get a result.

And the other thing is, I am just a little curious about actually the other side of post-menopausal, which is that a patient's verbal report of being post-menopausal, I would submit, is highly subjective and not accurate much of the time. It is, yes, unreliable, I think is a fair statement.

(Laughter.)

And so, I don't know that that is a great exclusion criteria.

MEMBER YOUNG: I am going to have

to defer the latter of the two questions about the patient self-diagnosis of menopause to be an exclusion criteria, and I will let them speak to that.

But in terms of your first question, which was --

MEMBER GROBMAN: Ordered. So, we're good. I order it a lot, but I never get the result.

MEMBER YOUNG: Right, so a test ordered. So, in many of our EMRs the pregnancy test that is ordered can be a point of care, a urine pregnancy test that is done in the emergency department in a CLIA non-linked system. Yes, it gets complicated.

And then, you can always check if an order was done. To be honest with you, you are not going to order something if you don't check the results, most of us in any case.

(Laughter.)

MEMBER GROBMAN: You must work in a really different hospital.

(Laughter.)

MEMBER YOUNG: However, the measure developers actually set up order, but they were willing to discuss, actually, resulted. There are oftentimes many things that are ordered and resulted, but not actually documented. And unfortunately, this is a difference between EMR and paper T sheets.

Most of the emergency medicine divisions in this country work on paper systems still, unfortunately. Larger systems are going to electronic medical records, but that, outside of large hospital systems, is painfully slow. The paper T system is actually the most common-used system outside of here or outside of emergency medicine -- or sorry -- electronic medical records. And it is very difficult to actually figure out what was ordered and what was resulted in a paper system.

So, I am going to let the measure

developers discuss the more technical components of ordered versus resulted and, also, for post-menopausal women, if they are available.

PARTICIPANT: Am I allowed to talk?

CO-CHAIR SAKALA: Yes. Please, go ahead.

DR. WINKLER: You're breaking up a bit. Are you on a speaker phone?

PARTICIPANT: No, this is a cell phone.

DR. WINKLER: Oh, okay. It is very difficult to hear you.

PARTICIPANT: All right. This is (phone technical difficulties) from Hospital of Central Connecticut.

On the issue of orders versus results, the data (phone technical difficulties) we get results. I didn't count if they just ordered it because (phone technical difficulties).

And then, as far as the major issue we had in implementing it, it was that we didn't have any change in physician (phone technical difficulties) pattern with just giving them their rate of testing. They said, well, (phone technical difficulties) less than the other physicians.

But with this quality measure, it is a 100 percent measure. So, if you are not 100 percent, you know you are not up-to-speed. And two, that also meant it found cases that were a reasonable number that we could review, and that is how we found people with adverse events getting CT scans of their abdomens. We found that that was running around 3 to 4 percent of all patients. All women of eligible age were given CT scans without pregnancy tests. This was (phone technical difficulties) and 105,000 visits a year.

So, I think there is quite a gap, and it is feasible. So, I developed the other measures for our College, but I really think

this a great measure.

CO-CHAIR SAKALA: Judging from --

PARTICIPANT: (Phone technical problems) the telephone line.

CO-CHAIR SAKALA: Okay. Thank you.

Judging from the looks on people's faces, I think many people did not grasp the gist of what was just said. If anyone did, maybe you can tell us, because it is hard to hear, to understand on that phone.

MEMBER YOUNG: I was able to at least follow the last part of his thought process, when he was talking about their subset analysis of 105,000 patients per year in 2008-2009. It was actually feedback on patients who actually did serum testing or urine testing for pregnancy.

And when they were notified of their quality measures, or when they were notified that their lack of testing had an adverse outcome like IECT, unintended

radiologic studies done on a pregnant patient who was not at that time known to be pregnant, the rates of testing significantly increased. That was the last part of his discussion.

CO-CHAIR SAKALA: Thank you.

And did the second developer have comments to make?

DR. SCHURR: Jay Schurr from Brigham's and Women's Hospital, on behalf of American College of Emergency Physicians.

I got cut off from the call. I am not sure if there has been any discussion yet about the age limit.

But, also, to echo the question about timing and ordered the test versus performed the test, this measure has been part of the PQRI measure set. It was specified with codes for having the test ordered rather than having the test performed.

So, while in theory we are happy to switch from ordered to performed, that would require a fair amount of work and would

be something that would have to be done through the PQRI process.

CO-CHAIR SAKALA: All right. Okay. Thank you.

Other questions or comments from the Steering Committee?

MEMBER KELLY: It appears in a chart analysis that 97 percent -- I'm looking at the top of page 3 -- actually, 89 percent of the eligible group did receive testing. And so, I really am wondering about the performance gap on this measure because that doesn't fit with your data, Dr. Young, at all. And I am wondering if the developers can speak to that because I really honestly wonder whether this is meeting our criteria for a performance gap.

DR. SCHURR: So, I can probably speak to that. Jay Schurr.

We did an analysis of a national dataset which revealed a 66 percent gap, or sorry, a 56 percent gap. I think that is

probably incorrect, and it is probably a problem with the dataset.

So, we followed it up by doing a four-hospital chart review. Now these were four teaching hospitals, two in Philadelphia, two in the greater Boston area. And the gap was about 10 percent, so not a large gap.

Subsequently, Dr. Graff has done an analysis at the community hospitals that he mentioned and showed a gap of 20 percent. And there is preliminary data that Dr. Young has mentioned, and also from a group out in Colorado. Neil O'Connor, who is also, I think, on the call, has done an analysis that showed a gap of about 15 percent.

So, although not a huge gap, we think there is a gap that exists. But there is just not national data. We have data at this point from about four different areas in the country that shows a gap of between 10 and 40 percent.

MEMBER KELLY: Could you also

address the --

PARTICIPANT: The thing to keep in mind is that CT scans are done very frequently on these women with abdominal pain. So, that gaps translates at our hospital to 3 to 4 percent of all those women were given CT scans without knowing their pregnancy status. So, that for the fetus is a very major issue. Once we implemented the measure, we got rid of that problem of CT scan, not knowing the woman's pregnancy status.

CO-CHAIR SAKALA: Jennifer?

MEMBER BAILIT: So, in theory, we have talked about a lot of things this could potentially do. It could prevent the CT scans. It could get earlier pregnancy care. It could avoid ectopic mortality.

But I don't see any studies that show that it actually does. And so, while we all agree in theory this is a really good idea, I would like to see a little bit more data saying that it actually works before we

go forward with this.

Does anybody either know of data or have thoughts on that?

MEMBER DRYE: I would just echo what you are saying, Jennifer. This is Elizabeth.

I don't know. For example, if what you wanted to do is prevent CT scans in pregnant women, you might come up with a totally different approach to that. So, we seem to be getting sort of pieces of a lot of problems potentially, but there is no direct evidence presented at all on any of them.

There is evidence that there may be some variation in the rate of testing, but nothing about what that leads to down the road in a way that we can stand on. So, that is frustrating. It feels early in the study of this problem and may be premature to say this is the way you should work to change clinical practice.

CO-CHAIR RILEY: I think the other

concern is that, if you do a chart review and you get vastly different numbers than an electronic review, I just wonder, which one of those -- I mean, a chart review on that many patients, that is going to be labor-intensive for a measure that we are not convinced is really going to do what we say it is going to do.

And if the electronic capture has such a huge variation, what do you believe. I would feel badly if we --

DR. SCHURR: Can I speak to that?

CO-CHAIR RILEY: Uh-hum.

DR. SCHURR: The large gap is not between electronic data capture and chart review. The NHAMCS dataset that showed a large variation is a chart review. It is done by the CDC National Center for Health Statistics. And it is a chart review, but it is a general chart review, not looking at one specific measure. They have one data element, which is whether or not the patient received

a pregnancy test. And we think that that large gap was due to the fact that that chart review itself has some problems.

The data from Dr. Graff's group is from an electronic health record. The data from Dr. O'Connor's group in Colorado is from an electronic health record. And it sounds like the data from Carolina is from an electronic health record.

So, we think that this is saying that it will be able to be specified in electronic health records accurately.

MEMBER KELLY: Could you also speak to the diagnosis by ultrasound without a pregnancy test?

DR. SCHURR: Yes, you can diagnose pregnancy by ultrasound without a pregnancy test.

(Laughter.)

But there is a cutoff, and ultrasound is not done in every emergency department in the country. And so, the

standard practice is still to do a pregnancy test, usually a urine pregnancy test because it is extremely sensitive and cheap and rapidly-available.

PARTICIPANT: I also found that the non-diagnosed women in early pregnancy with low hormone levels (phone technical problems), and these are the women whose fetuses are at most risk if they get a CT scan.

CO-CHAIR SAKALA: Could you please interpret for everyone?

DR. SCHURR: The discriminatory zone for beta hCG between the time when you can determine pregnancy by hCG testing or urine hCG testing and ultrasound is somewhere between four and six or seven weeks, depending on the technique of ultrasound. And missing pregnancy in that period, if you are thinking of the outcome of a CT scan, those are the highest-risk fetuses, first-trimester fetuses.

MEMBER GROBMAN: So, I would just

say a couple of things about it. This is Bill speaking.

One, I mean, seven weeks is really long. A urine pregnancy test is positive at four weeks, and on an ultrasound, a vaginal scan, I mean six to seven weeks easily. So, that is, I think, really at a maximum about three weeks.

And then, in terms of the risk, I mean, no one is looking to irradiate pregnant people, but it is not a clear -- I think it is fair to say a CT scan in the first trimester is not a clear-and-preset danger to the fetus. It is not.

They don't lead, there is no good evidence that it leads to miscarriage, that amount of radiation. So, again, no one is advocating for it, but the harm is not -- you know, it is an all-or-none, even if there were a harm, as opposed to long-term adverse outcomes, neurological impairment, leukemia. It is really it would be an all-or-none. But,

in any case, that is below the threshold that is considered. So, it is just not a horrific event if it were to happen.

DR. SCHURR: If it were to happen incidentally, I think it is actually a bad event. I don't know of radiologists or obstetricians who would say that it is not a bad event if there is an unintended CT, if one was not aware the patient was pregnant.

MEMBER GROBMAN: I think if it was unintended pregnant or not, it is a bad event. I mean, it is the --

MEMBER BAILIT: Yes, I mean, I think it is an unfortunate medical misadventure and it is certainly something, a quality thing that should be improved. But when I see those patients in my office to say, "Do you need to terminate this pregnancy because you had a CT scan in the first trimester," the answer is no.

MEMBER YOUNG: But I think one of the points he is trying to make is that there

are alternative imaging modalities that can be easily used if you know the patient is pregnant. We can go to MRI. We can go to ultrasound for alternative diagnosis of, let's say, anything other than inflammatory bowel disease. We really do have other imaging modalities at most of our institutions, except for the far-flung ones.

MEMBER DRYE: I just wanted to follow up. I have to say hi to Jay, too. He used to work with us at Yale.

So, hi. I haven't heard your voice in a while.

But if your real concern is CT of pregnant women, why not just do a measure of that? I don't know; I am just curious. I am asking those of you who focus on this area to kind of address that directly.

DR. SCHURR: That wasn't the original concern of the measure. The measure was developed to try to make sure that clinicians were not missing ectopic pregnancy

at a presentation of abdominal pain, which there is not good literature nationwide about this. But there are definitely cases reported in the medical legal literature, and if you talk to insurers, they know about cases. And so, that is how the measure was developed. It is sort of a secondary effect of the measure that you can prevent unintended CTs of early pregnancies.

MEMBER BRANDENBURG: I would just question, if your concern is to prevent the CTs, then the measure should perhaps look at the result, not the order.

CO-CHAIR SAKALA: But that isn't their intention right now.

Yes, Chuck?

MEMBER DENK: I just wanted to ask, I mean, there is a clinical guideline from a professional society about this, right?

MEMBER YOUNG: There is.

MEMBER DENK: So, I mean, it is late in the day, and I guess, are we falling

into the temptation of second-guessing clinical guidelines? Because I think that we have now worked through the thing and there is a performance gap somewhere, right? And there is clear benefit. I think we can all see various kinds of benefit, and there is a clinical guideline from somebody.

MEMBER YOUNG: It is from the American College of Emergency Physicians.

MEMBER DENK: Right.

CO-CHAIR SAKALA: Yes, and it is a PQRS measure.

MEMBER DENK: So, I think maybe we have talked about it enough.

(Laughter.)

MEMBER YOUNG: I happen to second that.

We were on the side of recommendation, but it was pretty evenly-split.

MEMBER PROFIT: One of the attractive things about this measure is that

it is so easily fixable. It seems like, I mean, this is just a system -- you could see a lot of ways in which it could really upfront fix this problem at triage.

MEMBER YOUNG: At triage, that is correct, especially when it becomes a reportable quality measure on the side of the hospitals. Then, there is a buy-in from everyone from the nursing assistant on through the entire healthcare team. That is correct.

CO-CHAIR SAKALA: Are we ready to take a vote on importance to measure? Okay.

MEMBER KELLY: Sorry, I know it's late.

Can the developer speak to the ectopic prevention or diagnosis as an outcome, as that may be more important?

DR. SCHURR: We don't have national data on this, but we know that diagnosing pregnancy early can diagnosis ectopics.

I'm not really sure I understand

the question.

MEMBER KELLY: Well, I am just wondering if we are going to -- I don't know -- diagnose it better and prevent some maternal deaths. I guess we don't have the data for that.

PARTICIPANT: Well, if we look at the data on malpractice from Massachusetts or the national databases, it is like No. 7 in (phone technical difficulties) and dollars spent at the malpractice.

So, (phone technical difficulties) certainly doesn't make it when there is a diagnosis (phone technical difficulties) and there is an adverse outcome.

DR. WINKLER: Somebody is clattering again (referring to noises on the phone line).

CO-CHAIR SAKALA: On the phone, could you please keep the extra noise quiet?

DR. WINKLER: Yes. I will bring up my long-ago history as a gynecologist, but

I would echo the issue around failure to diagnose an ectopic pregnancy is a significant issue that has any number of ramifications, both medical and legal. And it is not just death that you are trying to prevent. It is actually you are trying to intervene as soon as possible to preserve fertility and to avoid the catastrophic race to the operating room, the need to remove the entire tube instead of doing a lesser surgery that may maintain fertility.

So, the actual interventions can be very time-dependent, and the earlier it is diagnosed and determined, it gives you many more options that do much better things for her long-term fertility. So, that is the gynecologist in me.

CO-CHAIR SAKALA: Okay. Let's vote on importance to measure and report.

(Whereupon, a vote was taken.)

So, we have 18 yes and 8 no.

Janet, could you please proceed

with reliability and validity?

MEMBER YOUNG: Okay. So, scientific acceptability and reliability, we kind of went off in a couple of different angles, but pretty much scientific acceptability, we know that urine pregnancy tests and serum pregnancy tests are pretty darn reliable and sensitive and specific for diagnosing pregnancy.

What we don't have any idea in the literature is whether or not patients in whom abdominal pain is the chief complaint who get pregnancy tests versus patients who have abdominal pain who don't get pregnancy tests, is there a difference in those two patients' outcome data? There is no data out there. There is no randomized controlled trial to avoid pregnancy tests in some patients and get pregnancy tests in other patients. That data just doesn't exist.

So, as far as scientific acceptability, it is a standard of care. This

is not something that is new, novel, or even remotely cutting-edge. It has been a practice pattern since pregnancy tests were introduced in 1978.

We talked about lack of discrete fields in the existing electronic health records. I talked with our IT Division to see how difficult it would be to engineer a data catchment set for this. It is not incredibly difficult. It does require money, and that is kind of the consensus for all electronic health record changes. So, it is an easily-capturable dataset. Quite frankly, it is not that difficult, but it is the onus.

So, reliability and validity. As far as the patients who fall in the denominator, hysterectomy, prior tubal sterilization, a patient who states they are currently pregnant, which is actually well-documented in the literature. If a patient thinks they are pregnant, the likelihood that they are pregnant is about 98 percent. So, in

patients who say they are already pregnant, those patients do fall out of the numerator.

And let's see what else. Sorry, I'm trying to rush. I apologize.

And also, if somebody had a test done elsewhere, well, if patients tell us that they had a positive pregnancy test, we didn't necessarily test them again, although most clinicians would turn around and get a beta plot serum hCG to figure out what their quantitative status is, to determine if this early or late pregnancy, and also to determine whether we should do a transvaginal or transabdominal approach to ultrasound.

MEMBER GROBMAN: Did you say "tubal ligation" by mistake?

MEMBER YOUNG: Tubal sterilization.

MEMBER GROBMAN: Did you say that by mistake?

MEMBER YOUNG: Yes, I did. Sorry.

MEMBER GROBMAN: Okay.

MEMBER YOUNG: I meant a tubal ligation, yes. Thank you.

MEMBER GROBMAN: So, the same thing --

MEMBER YOUNG: Yes.

MEMBER GROBMAN: -- but that is not in and it shouldn't be an exclusion.

MEMBER YOUNG: No, I'm sorry, that was in --

MEMBER GROBMAN: It would be concerning if it were an exclusion.

MEMBER YOUNG: No, I apologize.

MEMBER GROBMAN: No worries. Just making sure.

MEMBER YOUNG: Yes, I did. I did. You're right. I'm so sorry. I'm trying to hurry.

That is under the -- let me find it.

DR. WINKLER: The denominator exclusions are on page 7, 2A1.8.

MEMBER YOUNG: Yes. And also,

initially, on page 1.

So, acceptability and validity and reliability.

CO-CHAIR SAKALA: Okay. So, comments or questions on this criteria?

MEMBER ARMSTRONG: Can I just ask a question going back again? In your clinic, of those 50 percent of people in the ER who didn't get a pregnant test, did you follow them to see how many of them come back to the ER? You know, is there churn in the healthcare system because they are not diagnosed?

MEMBER YOUNG: I only had about seven days to do this data. The answer is no.

(Laughter.)

That was a fast turnaround time from our IT Division, and they actually fast-tracked that particular dataset.

I can go back and do lots with it, given the next 12 months perhaps, but for right now, no, I just had seven days to do it.

CO-CHAIR SAKALA: Other issues?

(No response.)

Okay. So, let's vote on scientific acceptability, please.

(Whereupon, a vote was taken.)

Okay. So, 17 yes and 9 no.

And the last two issues to address are usability and then feasibility.

MEMBER YOUNG: So, in terms of usability, everybody knows what a pregnancy test is and how it can be used. Whether or not the hospital decides to publish that data, I think patients would generally grasp that performance measure.

Feasibility, again, if you don't have an EMR, it can be a pretty hefty chart review. As we talk about going to universal EMRs, I think that the difficulty in converting any medical document into an emergency -- sorry -- an electronic medical record is going to be an onus that we are going to have to take at some point in time.

So, I think that if we look at measures and we negate them out of just desire not to put the burden of proof on folks who are currently using paper systems, I think that we do ourselves a disservice in the future. But I think that, again, this could be a workable and usable dataset for folks who currently use paper systems, but it is going to be more labor-intensive. For EMRs, this is pretty simple to do.

CO-CHAIR SAKALA: Questions or comments?

(No response.)

Okay. So --

MEMBER BERNS: I'm sorry.

CO-CHAIR SAKALA: Yes, go ahead.

MEMBER BERNS: So, this goes to an earlier comment, just in general. This was originally endorsed as a measure in 2008, correct? Am I reading that correctly?

MEMBER YOUNG: That is correct.

MEMBER BERNS: So, I don't know

how we would do this -- and this is my first time on this Committee -- but it would be helpful to have, there must be information out there about folks who have taken up this measure and whether they really saw improvements, including decreases in ectopic pregnancies or identification of ectopic pregnancies.

These other outcomes that we are talking about, like identifying pregnancies early, it doesn't necessarily mean they are going to be getting access to prenatal care early. But I think these are all sort of theoretical things.

So, I don't know how we get to that, Reva, but have you guys talked about this in the past?

CO-CHAIR SAKALA: There is a call for implementation comments when the request for new measures comes out, but I have no idea what that yields.

DR. WINKLER: One of the things

that I think is highly variable about measures that again are endorsed by NQF is the uptake, some of them much quicker, sometimes quite slow. It depends on whether they are adopted into a national program or not.

This measure is being used in PQRI/PQRS. However, they don't publish the data. So, we don't even know what the results are. So, that is a real problem.

And I think that we are so early on in the game for this kind of a measure, to really have people use it in ways that might begin to answer those more long-term questions about what is the overall benefit, though certainly those are important questions and we should keep asking them.

So, these are the kinds of issues you are weighing, you know, the information from a measure versus the burden of collecting it. And there is no black-and-white, no easy answer. So, these are all the considerations that you guys need to factor into your

ultimate decisions.

MEMBER YOUNG: And at least in the American College of Emergency Physicians, we aren't able to look at those data over short periods of time, at least in the time from 2008 or 2009, when this was first adopted, until now. Because, as you know, the rate of ectopic is very low, and you have to have a certain number of patients in order to define that rate. So, you may not be able to have a single hospital system like mine that only has 180,000 patients a year in the emergency department. It may take three or five or ten years of data over a larger hospital system or multiple hospital systems, and we haven't undertaken that, at least from ACEP side of the research yet.

I don't know if the OB/GYN literature can identify trends in ectopics going up or going down. It sounds like from the CDC that they were going down, but I can't find that on their database, actually.

MEMBER CALLAGHAN: It's only deaths.

MEMBER YOUNG: Okay.

MEMBER CALLAGHAN: Ectopic pregnancy --

MEMBER YOUNG: So, we don't know if the rate of ectopic is going up or going down or staying stable --

MEMBER CALLAGHAN: Those data don't exist anymore.

MEMBER YOUNG: -- and if that is changing because we are identifying it early in the emergency department or not. I can't answer that.

MEMBER GROBMAN: The little data that I have seen from sort of smaller systems is that it is going up concordant with the rise in PDI, for example. So that, historically, the rates are about 1 percent, and there are some documents that the rate it as high as 2 or 3 percent now. I don't know.

MEMBER CALLAGHAN: Yes, single

institutions but national --

MEMBER YOUNG: So, you would have to have a pretty nice meta-analysis of single institutions or hospital systems in order to find that data. I don't think we have that out there. I know from my literature review we just don't have that data.

MEMBER ARMSTRONG: You could look at administrative claims data because they are very discrete fields.

Do you know, is a point-of-care pregnancy test a billable service? Do you bill for that?

MEMBER YOUNG: I can't imagine we wouldn't.

(Laughter.)

We bill for single-stick glucose, and that is a point-of-care test. I mean, these are CLIA-certified tests, and even in your point-of-care lab those have to be CLIA-certified. So, I can't imagine that we wouldn't try to recoup a cost.

MEMBER ARMSTRONG: Yes.

MEMBER YOUNG: I'm sure that is probably --

MEMBER ARMSTRONG: It should be pretty easy, actually, to look at it in the administrative data.

MEMBER YOUNG: So, maybe that is something we can do further analysis on.

But I would strongly encourage you to consider this measure.

MEMBER BAILIT: But I guess my thought still is, though, we think it is useful, but we don't know. And you are saying, yes, we can do this; yes, it might be easy; wouldn't it be interesting? But we don't know yet.

MEMBER YOUNG: Uh-hum, that is true. And unfortunately, this was one of those cases where we wish we had the ability to do a time-limited analysis, but the NQF doesn't do time-limited assessments anymore. It is either all or none.

DR. WINKLER: Well, the thing is it was time-limited the first time --

MEMBER YOUNG: Yes.

DR. WINKLER: -- three years ago.

(Laughter.)

That wouldn't have been an option for it under any circumstances.

MEMBER YOUNG: Thank you.

CO-CHAIR SAKALA: Are we ready to vote on usability?

(Whereupon, a vote was taken.)

Okay. So, 9 high; 11 moderate; 3 -- 2 low, and 4 insufficient.

Okay. Anything to add before we go to feasibility?

(No response.)

Let's vote on that then.

(Whereupon, a vote was taken.)

MEMBER PROFIT: When will this measure come up for measure maintenance, if it were endorsed?

DR. WINKLER: Three years.

MEMBER PROFIT: Three years?

Is there like a rising bar for measures that -- no? -- that need to answer more questions that are being asked?

DR. WINKLER: The whole measure enterprise is evolving, and we have seen over the last 10 years that, yes, the criteria have evolved; the bar is raising. And the expectation is that the measures are more robust and can really measure performance in a much stronger way. So, yes, it is a very dynamic environment.

CO-CHAIR SAKALA: Okay. So we had 1 high, 14 moderate, 8 low, and 3 insufficient information.

The final vote of the day is on overall suitability of this measure for endorsement.

(Whereupon, a vote was taken.)

So, 12 yes and 14 no.

Okay. So, that's it on that.

It's time for public comment.

Anyone in the room who would like to add something?

(No response.)

Okay. Can we open up the phones to see if there are any comments?

DR. WINKLER: Casey, are you there?

(No response.)

Operator? Hello.

(Laughter.)

THE OPERATOR: Yes. Yes, all phone lines are open.

DR. WINKLER: Oh, great.

Are there any questions out there?

(No response.)

All right. Hearing none, okay, folks, thank you all very much. It has been a long day, a very intense day. Your conversations have been, you know, phenomenal.

We will be meeting again tomorrow, again in this area. However, tomorrow we will be in the other half of the room. This room

we are having to share tomorrow. So, it will be a little bit on the cozy side.

Breakfast is available at 7:30. We will want to begin promptly at eight o'clock.

We do have a full agenda. I just want to remind you we are going to finish the six measures in a similar fashion that we did today.

Then, we are going to spend some time looking at the composite measure. Now we did not discuss the composite during the Workgroup calls. There have been assignments for lead discussants.

What we will want to do is look at the component measures because the definitions, the specifications are in the individual component measures, though there is no indication that those measures would be endorsed as individual measures. But they do feed into the composite. So, we want to look at the individual components as well, and then

we will look at the overall composite.

In the afternoon, we are going to want to talk about the similarities of the measures around infection. This is related and competing measures. We have sort of alluded to that conversation, and tomorrow will be the time when we will look at it.

You have a memo that talks about the side-by-sides. It would be good if you could review that before tomorrow.

Otherwise, are there any questions from anyone about what we are doing? Anybody have any needs we can try to deal with?

The flash drives you can take with you, but the little voting gizmos please leave. Yes, the flash drives, that is where all your materials are, if you didn't bring them with you.

(Whereupon, at 5:43 p.m., the meeting adjourned for the day, to reconvene the following day, Wednesday, November 30, 2011.)

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This is to certify that the foregoing transcript

In the matter of: Perinatal and Reproductive Health

Before: NQF

Date: 11-29-11

Place: Washington, DC

was duly recorded and accurately transcribed under my direction; further, that said transcript is a true and accurate record of the proceedings.

Neal R Gross

Court Reporter