NATIONAL QUALITY FORUM

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CHILD HEALTH QUALITY MEASURES STEERING COMMITTEE

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MONDAY
NOVEMBER 8, 2010

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The Steering Committee met at the National Quality Forum, Suite 600 North, 601 13th Street, N.W., Washington, D.C., at 9:00 a.m., Thomas McInerny and Marina Weiss, Co-Chairs, presiding.

PRESENT:

THOMAS McINERNY, MD, Co-Chair
MARINA WEISS, PhD, Co-Chair
MARTHA BERGREN, RN, DNS, NCSN, National Association of School Nurses
SARAH BROWN, MSPH, The National Campaign to Prevent Teen and Unplanned Pregnancy
CARROLL CARLSON, RN, BSN, Group Health Cooperative of Eau Claire
ALEX CHEN, MD, MS, Keck School of Medicine
DAVID CLARKE, MD, The Children's Hospital
NANCY FISHER, MD, MPH, Washington State Health Care Authority
FAYE GARY, EdD, RN, FAAN, Case Western Reserve University
JAMES GLAUBER, MD, MPH, Neighborhood Health Plan
MARGARITA HURTADO, PhD, MHS, American Institutes for Research
KATHY JENKINS, MD, MPH, Children's Hospital Boston
PHILLIP KIBORT, MD, MBA, Children's Hospitals and Clinics of Minnesota

ALLAN LIEBERTHAL, MD, FAAP, Southern California Permanente Medical Group
MARLENE MILLER, MD, Msc, Johns Hopkins Health System
DONNA PERSAUD, MD, Parkland Health and Hospital System
JAMES QUIRK, MD, PhD, Stony Brook University Medical Center
GOUTHAM RAO, MD, University of Pittsburgh School of Medicine
ELLEN SCHWALENSTOCKER, PhD, MBA, National Association of Children's Hospitals and Related Institutions*
BONNIE ZIMA, MD, MPH, UCLA Dept of Psychiatry

NQF STAFF:

HEIDI BOSSLEY, MSN, MBA
HELEN BURSTIN, MD, MPH
EMMA NOCHOMOVITZ, MPH
EUGENE CUNNINGHAM
SUZANNE THEBERGE, MPH
REVA WINKLER, MD, MPH

ALSO PRESENT:

SEPHEEN BYRON, MHS, National Committee for Quality Assurance
SEAN CURRIGAN, MPH, American College of Obstetricians and Gynecologists*
DENISE DOUGHERTY, PhD, Agency for Healthcare Research and Quality
JOHN EICHWALD, MA, Centers for Disease Control and Prevention
MARCUS GAFFNEY, MPH, Centers for Disease Control and Prevention
GAIL HUNT, Institute of Clinical Systems Improvement*
JOYCE MARTIN, MPH, National Center for Health Statistics*
CRAIG MASON, PhD, Centers for Disease Control and Prevention
MICHELE PURYEAR, MD, PhD, Health Resources and Services Administration*

SARAH SCHOLLE, MPH, DrPH, National Committee
for Quality Assurance
SCOTT STUMBO, Health Management Associates*

*Present via telephone

T-A-B-L-E O-F C-O-N-T-E-N-T-S

P-R-O-C-E-E-D-I-N-G-S

9:04 a.m.

CO-CHAIR McINERNY: Good morning, everybody. Thank you all for being here on time and hopefully have some time to do some very interesting work and maybe get to enjoy this wonderful city. It looks like our weather is going to be pretty good for us. And we'll start with some introductions.

A very important thing to remind everybody. We do need to use the microphones at all times for a couple of reasons. One is this is being recorded and, two, the people on the speaker phone will not be able to hear you if you do not use the microphone. So please use the microphone when you want to speak.

We'll start with some introductions. We'll go around. I'm Tom McInerny. I'm a primary care pediatrician and the Associate Chair for Clinical Affairs in the Department of Pediatrics at the University of Rochester Medical Center.

DR. WINKLER: Okay. Hold on just a second. I'm Reva Winkler. I'm the Senior Director for Performance Measures here at NQF and I'd like to ask Heidi.

(Off the record comment.)

My colleagues, Heidi Bossley, who is Managing Director is going to -- With your introductions, we'd like you to make your statements of your disclosures as a way of being somewhat efficient as we go around the table.

CO-CHAIR McINERNY: Okay.

DR. WINKLER: And Heidi will help with that.

MS. BOSSLEY: Sure. Typically, it's our General Counsel who does this. And she's given me a script so I remember how to say it. So I'm just going to make sure that I hit the key points.

As you all may remember, we asked you to fill out disclosure forms and include anything that would be relevant to the work of

the Committee as well as anything you would want your colleagues to know. One of the things we want to remind you is you're here as an individual, not representing an organization.

Also as you go around the table as Reva asked, give a little information about yourself but also let us know if you've anything that you feel you need to disclosure. And then if you don't, just tell us that you do not.

What usually happens though is then I'll ask you all once that occurs if you have any questions or anything that you wish to discuss amongst yourselves regarding those disclosures. I just want to let you know that I will ask that. And then we will move on from there.

Dr. McInerny, do you want to start?

CO-CHAIR McINERNY: Sure. I have nothing to disclose.

CO-CHAIR WEISS: Good morning, everybody. I'm co-chairing with Tom and delighted to be back with so many of you. And for those of you who are new, please welcome to this august group that NQF has put together, Reva and Helena and others.

I'm Marina Weiss. I'm Senior VP for Public Policy and Government Affairs at the March of Dimes. And I was deeply involved in the beginning of NQF, served as a Board member, a founding Board member and sat on the Board for nine years. In addition to that, I was together with Ellen Schwalenstocker who is on the phone I believe and a handful of folks from the Academy of Pediatrics deeply involved in the development of the section on Quality in the CHIPRA Bill that was signed by President Obama shortly after taking office and again, in the Health Care Reform Initiative provisions that pertain to quality.

So I come at this whole enterprise from a slightly different direction than many

of you in that I'm not a clinician. But I'm deeply interested in seeing to it that children are adequately covered by the whole quality arena, if you will. Regrettably, I think we are a little bit behind some of the adult measurement activities. And so we have some catching up to do. But with this group around the table I have no doubt that we'll do it and we'll do it with gusto.

So thank you for being here and, along with Tom, I have nothing to disclose other than what you're just heard.

MS. CARLSON: I'm Carol Carlson. I'm the Director of Government Programs for Group Health Cooperative in Eau Claire, Wisconsin. We've a cooperative HMO. I'm responsible for the Medicaid programs that we serve for Wisconsin. We're responsible for about 75,000 members enrolled in Medicaid and the elderly and disabled as well.

I do sit on the Board of Directors for Medicaid Health Plans of America and I

chair their Clinical Leadership Committee. And I was also involved with the NAC subcommittee for children's health measures for CHIPRA last year. Thank you.

MS. BROWN: Good morning. My name is Sarah Brown. I'm a new member here and the first thing I want to disclose is that I think I'll be playing catch-up all day because I don't fully get what we're doing. But that's okay.

I'm the head of the National Campaign To Prevent Teen and Unplanned Pregnancy, a group that I helped to start about 15 years ago. Before that, I was a study director at the Institute of Medicine and led a large number of studies in the area of paternal and child health perinatal medicine and adolescent health.

I served many years on the board of the American College of OB/GYN as one of their public members. And in my current job I continue to be very interested in obstetrics

and adolescent and in particular family planning.

Thank you for inviting me to join this group. Oh, with regard to conflicts, I have no conflicts that I can think of except that I've taken a number of public positions on issues such as contraception, prenatal care and related issues.

DR. HURTADO: Hi. I'm Margarita Hurtado and I'm a principal researcher with the American Institutes for Research and Consumer Reported Measures, particularly CAPS and others as well. And I have no conflicts of interest. And this is my first time with this group as well.

DR. RAO: Hi. I'm Gouthamn Rao. I believe this is my second year on this particular committee. Maybe longer than that, I don't know. So I'm with the University of Pittsburgh. I'm the Director of the Pediatric Obesity Center there. I also teach clinical epidemiology and biostatistics at Pitt Med

School. And I'm an Assistant Dean for Faculty Development at the School of Medicine.

MS. GARY: I'm Faye Gary. I'm a Professor and Associate Dean of the School of Nursing at Case Western Reserve University. I'm a child psychiatric nurse. I'm also a board member of the National Mental Health America which the former name was the National Mental Association. And I'm a board member for NAMI which is also an advocacy group for the mentally ill.

CO-CHAIR McINERNY: Do either of you two have any --

MS. GARY: I don't have any conflicts of interests.

DR. RAO: No conflicts of interests for me.

DR. CHEN: Hi. I'm Alex Chen. I'm a general pediatrician at Children's Hospital Los Angeles. I'm also a health service researcher.

I don't have any conflict I don't

think. But I sit on the California State Children Health Insurance Plan Quality Advisory Board and I have a couple of federal grants. But that's it.

DR. ZIMA: I'm Bonnie Zima, Child Psychiatry Health Services Researcher. I'm Professor in Residence, UCLA, Associate Director, UCLA Health Services Research Center and I receive research money from the National Institute of Mental Health as well as the State of California Department of Health Care Services.

DR. CLARKE: I'm David Clarke. I'm a retired pediatric cardiothoracic surgeon from Denver, Colorado. And although I do have some interest in outcome research, I don't believe I have any significant conflicts of interest.

DR. LIEBERTHAL: I'm Allan Lieberthal. I'm a pediatrician with Kaiser Permanente in Southern California. I'm also with Tom a member of American Academy of

Pediatrics Steering Committee and Quality Improvement and Management.

And I have no conflicts of interest.

DR. QUIRK: I'm sorry. My name is Jerry Quirk. I'm the Chairman and Professor of the Department of Obstetrics and Gynecology at Stoneybrook University. I've been active in the March of Dimes at a local both in previous lifetime in Arkansas when Hillary was the First Lady. And now I'm on the Board of Arkansas March of Dimes Board.

My interests are Prodium and I have no conflicts of interest.

DR. PERSAUD: I'm Donna Persaud. I'm a general pediatrician and Director of Pediatrics at Parkland's Community Medicine Division and I have no conflicts of interest. I think this is also my second year on the Committee.

DR. JENKINS: I'm Kathy Jenkins. I'm a pediatric cardiologist at the Children's

Hospital in Boston and a professor at Harvard Medical School. I'm also Senior Vice President and the Chief Safety and Quality Officer for the hospital.

I have measurement activities in both of those domains. From a cardiology perspective, I am on the American College of Cardiology and American Heart Association Performance Measures Task Force. I'm also the chair of a project at the ACC which is specifically a quality metric work group to create quality measures in cardiology for children and adults with congenital heart disease.

Also as someone said Children's Hospital of Boston has been actively involved in measurement development and did put measures forward through this process earlier. I'm glad to say I don't think I've any conflicts relevant to the discussion today which is my first time at NQF.

DR. BERGREN: I'm Martha Bergren.

And this is my first time and I also thank you for inviting me. I am Director of Research at the National Association of School Nurses. I just recently left my appointment at the University of Illinois Chicago College of Nursing and relocated to Wisconsin where I hope to pick another academic appointment.

I am on the Board of Directors of Healthy Schools Campaign and on a couple of advisory boards. But I also do not think any of those pose a conflict of interest. Thank you.

DR. GLAUBER: Good morning. I'm Jim Glauber. I'm a primary care pediatrician and this is my first time joining the NQF Committee. I'm formerly a pediatrician at Kaiser Permanente in Northern California, but currently am the Senior Medical Director at Neighborhood Health Plan in Boston. And NHP is a Medicaid predominant managed care organization who primarily works with community health centers throughout the state.

Clinically, I'm an asthma specialist and direct the Pediatric Asthma Program at Harvard Vanguard Medical Associates.

I don't have any conflicts, but just in terms of disclosures I'm on the Board of Directors of the Massachusetts Health Quality Partners and I'm on the state's steering committee for the Massachusetts CHIPRA grant. Massachusetts is one of the grantees for that grant and I'm on the steering committee.

MS. THEBERGE: Do we have any Committee members on the phone?

DR. SCHWALENSTOCKER: Can you hear me? This is Ellen Schwalenstocker from NACHRI.

CO-CHAIR McINERNY: Yes, we hear you.

DR. SCHWALENSTOCKER: Okay. Thanks. Nice to hear everyone and I'm sorry I can't be there in person.

My name is Ellen Schwalenstocker and I'm Acting Vice President for Quality

Advocacy and Measurement for the National Association of Children's Hospitals and Related Institutions, a big mouthful.

And I do not have any conflicts of interest to disclosure. I also serve as NACHRI's liaison to the AAP Steering Committee on Quality Improvement and Management.

CO-CHAIR McINERNY: Anybody else?

DR. WINKLER: Is Marlene Miller on the line?

(No verbal response.)

Is Nancy Fisher on the line?

(No verbal response.

Okay. Hopefully, they'll announce themselves when they join in.

DR. BOSSLEY: So the one final question that I have, is there anything that your colleagues have disclosed today that you would like to discuss?

(No verbal response.)

I take that as we're okay. Thanks.

MS. THEBERGE: Okay. We'd like to have the NQF staff and the folks at the back table introduce themselves as well. So I'm Suzanne Theberge. I'm the Project Manager for this project here at NQF.

DR. WINKLER: Hi everybody. I'm Reva Winkler. I'm a Senior Director for Performance Measures here at NQF.

DR. BURSTIN: Good morning, everybody. I'm Helen Burstin, the Senior Vice President for Performance Measures at NQF.

I just want to make one comment. Some of you may note that two of our past members for those who were together last time are not here, Charlie Comer and Lee Partridge, who we dearly loved. It turns out Charlie was the Chair of the NCQA Measure Development Work Group and Lee was on it as well.

So just to be very clear, we are trying as much as possible to really stick to avoiding conflicts of interest. So, as much as we miss them, I want you to at least know

it wasn't they didn't choose to leave the Committee. We had actually unfortunately had to ask him to do so.

Thanks.

MS. PURYEAR: Michele Puryear from Health Resources and Services Administration.

MS. DOUGHERTY: Denise Dougherty from the Agency for Health Care Research and Quality.

MS. BYRON: Sepheen Byron from the National Committee for Quality Assurance.

MS. SARCOV: Debbie Sarcov also from the Health Resources and Services Administration.

(Off the microphone introductions.)

MS. HIGHTOWER: Dorrie Hightower, NQF staff.

DR. WINKLER: Thank you all for joining us today. As has been alluded, the majority of folks on this committee worked with us last year when we were focusing in on

outcomes for children and volunteered to continue with us as we moved into this second project of focusing in more on process measures or other measures that aren't restricted to outcomes.

So Suzanne I think wants to just spend a little bit of time kind of orienting us on where we are. But we do have a lot of work to do over the next two days, a goodly number of measures, and so we do want to get into the work at hand fairly quickly.

So, Suzanne, do you want to --

MS. THEBERGE: Good morning, everyone. Just before we get started just so everyone knows there's coffee and water and food in that room back there. The women's restroom is over that way (Indicating). The men's restroom is over that way. And they should both be unlocked. And if you have any problems, need any help getting on line, just let me or Emma or Gene know.

Let's get started. The goals of

this project are to identify, evaluate and endorse measures that can be used in public reporting at the population level. As you can see, we have a big range of topics to cover both today and on the follow-up conference calls. And we're also looking to you to help identify gaps in existing measures and recommend areas for future development to fill those gaps.

This projects is also looking to increase NQF's portfolio of child health measures that can be used in programs such as CHIPRA, Medicaid or at the state measurement level. We are looking at some measures from the CHIPRA Core Measurement Set. Several of those measures have already been endorsed by NQF. The ones that have not are up for discussion today and tomorrow.

This is a project timeline which I've sent to you all in email, but wanted to go over again today. The in-person meeting is today and tomorrow as you know. We have the

three follow-up conference call dates set for November and December.

Following that for those of you who are new to the NQF process, we have member and public comment period. That's 30 days when NQF members and the public are allowed to make comments on the measures. Following that, the measure developers and the NQF staff draft responses to all of those comments.

And then we bring the Steering Committee back together to discuss those and discuss any issues that may have come up during the comment period. And that call will be scheduled later on. It will happen in March barring any unforeseen delays.

Then the next step is NQF member 30-day voting period. That's slated to take place in April.

Following that, the measures go to our Consensus Standards Approval Committee in June. They make a recommendation to the NQF Board and the NQF Board will ratify whatever

measures end up being recommended at the end of June 2011.

As you know, you received a very large number of measures for this project, too many to go over in one meeting. So we're going to try and address about 40 of those measures today and tomorrow. And the remaining measures will be covered on the phone on November 29th, December 3rd and December 17th. We'll send out more information, agendas, call-in information, all that in the weeks before those calls. But hopefully you can make at least some, if not all, of those.

Next steps are the meeting, the conference calls and then we move through the steps of the NQF process.

And for those of you that were on the previous committee, I just want to let you know the status of those measures. They were brought to CSAC last week, November 3rd, and CSAC recommended all 15 of those measures for

endorsement. They will be reviewed by the NQF Board in late November and at that point they will be endorsed if the Board agrees.

And here's the project staff and contact information. Although you've received so many emails from me, I'm sure you have my email address somewhere.

I would like to turn this over to Reva now.

DR. WINKLER: Okay. For those of you who are new, essentially what we're going to be doing over the next two days is going through the measures as we have outlined in the agenda. We've had to make some last minute scuffing because of different schedules.

We have invited the measure developers to be with us during the discussions. So some of them will be calling in at designated times. We may have to adjust our agenda to be sure that we can have those conversations at those times.

So just please bare with us as we try and coordinate all of this. There are fair number of folks to get together at one given time.

The folks who worked with us in the Outcomes Project have been through this process before. The folks who have just joined the Committee we spent some time on an introductory phone call going through the NQF Measure Evaluation criteria.

It's important as we look at these measures that we ground the discussion and the evaluation in those criteria. They've been very thoughtfully developed by and evolving over the years by NQF. And there are constantly changes and improvements ongoing. But your recommendations on measures to go forward for endorsement should be based because they meet all of the criteria, those being important to measure and report, scientifically acceptable, useable and feasible.

Now all measures have different histories. They will have different -- They will meet those criteria and the various subcriteria under those four to a greater or lesser extent. There are no absolute thresholds. There is no absolute scoring system. It is that's why we bring you all in to help us evaluate them. But please it's most useful to us in our ability to convey the sense of the Committee if your discussion is grounded in the measure criteria to the greatest extent possible.

So anybody have any questions at this point? We're a little bit ahead of schedule which is not a problem since we need -- the time is not, but I'm concerned about perhaps any of our measure developers who may be expecting different time. We may have to adjust the first group.

But are there any questions about the Measure Evaluation criteria?

DR. GLAUBER: Are there any

assumptions going into this process about how many of the proposed measures will be endorsed? It could be any or none?

DR. WINKLER: Each measure is being -- should be evaluated on its own merits. All right. At the end, we will want to ask you to come back and look at the final result a more global perspective.

But, no, there are no preconceived or predetermined numbers. It could be zero or it could be all. Typically, it's somewhere in the middle of that.

DR. RAO: Reva, the last time I was here, I mean, we did table a few measures. I'm assuming that with the large number of measures we have that that probably isn't an option. We should try to come to a decision.

DR. WINKLER: Well, I think it will depend on the reason. You might have issues. If there are questions that we can legitimately expect to get answers that will make a significant impact on your decision

making, then certainly we can do that.

But you are absolutely right. That can be a process that can just bog us down forever. So we really don't want to encourage that. But if it's a legitimate request for additional information that's important, by all means, we can certainly try and get that.

DR. JENKINS: Could you give us a sense of the harmonization part which I think is going to be a theme? How does that happen in this process? Are we still evaluating each measure on its own merit and that happens later?

DR. WINKLER: Yes. Essentially, the harmonization -- And you're absolutely right that it's a challenging exercise. We wish to look at each of the measures on their own merits first and then look at the areas where harmonization are important.

I think the biggest harmonization issue that this group is going to have is age,

the age inclusions. And so if as you can see if you look at all of the variety, particularly at the upper end, we seem to be kind of all over the board. So I think we'll need your guidance and recommendations on how we might handle that.

Helen.

DR. BURSTIN: And just one additional note, the way we've been trying to operationalize comparing measures that are similar is they both need to be fully evaluated on the criteria first. We then will look at the two ratings of the criteria and subcriteria side by side and then look to see if there's any issues in terms of determining best in class.

As many of you know, that's not always an easy thing to do. But as much as possible harmonize within the measures on the science, the evidence, the age and then if necessary even pick one if in fact they're directly in conflict.

MS. BROWN: Are we going to be asked to vote on measures? You probably don't require unanimous approval. But what's the sort of boding waiting situation?

DR. WINKLER: We do ask the Committee to make their decisions via a formal vote. We want to hear your vote on the forming of an evaluation criteria as well as the recommendation for endorsement.

At this point, we will take a majority is usually what will move it forward. But certainly anything that's very close we'll want to really sort out the issues to see what the real concerns are on both sides to see if they can be addressed.

DR. HURTADO: For some of the measures that were asterisks that were left completely blank, it doesn't say no or it doesn't say not applicable. So for those I wasn't sure what the approach to those is.

DR. WINKLER: Well, one of the reasons we have measure developers attend

these discussions is so that we can ask them to fill in the blanks, if necessary, though we certainly try and encourage the developers to give us as complete an answer as possible. So hopefully we'll be able to understand what their intent was by leaving it blank by asking them directly.

Anybody else?

DR. SCHWALENSTOCKER: Reva, this is Ellen. Can you give us a little guidance on how we should consider situations where we have multiple measures for the topic?

DR. WINKLER: Ellen, you are breaking up and I really only heard bits and pieces. But I think you're asking -- What I thought I heard was you want a guidance on evaluating measures on sort of the same topic.

DR. SCHWALENSTOCKER: Yes. There are nine -- Can you hear me better now?

DR. WINKLER: Yes, that's better.

DR. SCHWALENSTOCKER: There are nine measures on hearing screens and I'm just

wondering how the Steering Committee should deal with that because I imagine we want to limit the number of measures on the same topic or.

DR. WINKLER: Well, I think that that ultimately a Committee decision. But, first, looking at the individual measures to be sure they meet the criteria. Then perhaps the Committee will want to have a subsequent discussion on do we have the right number of too many of one type or too many similar measures or the whole group doesn't make sense. So any of those are available to us, but in the beginning we'll look at them individually.

DR. SCHWALENSTOCKER: Okay. Thanks.

DR. WINKLER: Are any of the other Committee members on the line? Marlene Miller, are you there? Nancy Fisher? No? Shannon Daugherty?

(No verbal response.)

Okay. All right.

DR. HURTADO: Just a quick question. This is actually logistics. Are we supposed to be in a particular area and I see the PDFs here and you're going to go through that?

DR. WINKLER: Right. We'll get you -- One of our problems for us to get started at 9:30 a.m. if we start with the first measure on the agenda, we may not have our measure developer available. So we may have to start with the second one. So hang on a sec.

Do we -- Who is the measure developer?

MS. THEBERGE: Dr. McDorman.

Dr. McDorman, are you on the line?

DR. WINKLER: All right.

MS. THEBERGE: I think we'll have to wait until maybe closer to 10:00 a.m.

DR. WINKLER: Right. So we're going to start looking at the measures in the

first group. This was in the folder under Work Group 2 and the folders that we sent you have the measure evaluation forms in them. And they are listed by number.

So we'll give 1382 a pass for right now. We'll get back to it a little bit later.

But we do have folks from NCQA here. So we'll start with Measure 1391, Perinatal Care. And, Dr. Quirk, this is yours I believe.

This measure was submitted by NCQA as two measures on the single form. And they sort of say that. We've had follow-up talks with NCQA and they had decided that the two measures really are separate. And we will treat them that way going forward. We will generate the second measure evaluation form and give it another number.

But for today it might be even more efficient that they're all on one form. But please realize that they are going to be

distinct. So we will need your evaluation of them independently.

Dr. Quirk, do you feel like you can start?

DR. QUIRK: I'm new to the Committee and this is the first measure. I have no idea what I'm doing. I am the person that didn't -- It said skipped questions. That was me. I mean I have answers today, but I didn't have them for the deadline.

But if I interpret this correctly, the importance of the measure impact completely it would be three out of the four. I would vote for complete on the gap. I voted complete so that would be a two and a two. So complete and partial. And relationship to outcome also complete. So that was a three and one minimally.

DR. WINKLER: Right. It might be just helpful for the folks listening that Measure 1391, the first measure, is the frequency of ongoing perinatal care. And just

the description is "the frequency of ongoing -- - the percentage of Medicaid delivers between November 6 of the year prior to the measurement year and November 5 of the measurement year that received the following number of expected prenatal visits." And they're broken into five different strata of less than 21 percent, 21-40 percent, 41-60 percent, 61-80 percent and then more than 81 percent. So that's the measure we're referring to.

If I heard you, you're saying you felt that of the three subcriteria for importance to measure and report, you would rate it highly.

DR. QUIRK: That's correct.

DR. WINKLER: Does anyone have any comments? Anybody else on Work Group 2 like to --

DR. QUIRK: I'm the only obstetrician here. I just want to amplify something. I see this as a perinatal

continuum. So much of the other measures that we're going to look at today deal with newborns. In that there are real opportunities in the antipartum period which is I suppose the rest of you call it prepediatric. I would call it obstetric.

But in that area, I think that this is very important to be there and to be developed over future eons. People sometimes forget the material and material child health.

DR. WINKLER: Great.

Any other --

DR. CHEN: Can I make a comment? Jerry, I agree with you. I think from the scope of importance this is one such topic that must be covered. I'm a little bit concerned about the way the measure is specified. I don't have any reason why the categorization is done the way it is done.

From a measure development and perspective, it would seem to make sense to have it as a yes or no criteria where you just

have one threshold that everyone has to meet. An absolute minimum standard of prenatal care or the frequency access of prenatal care rather than some sort of five category. I just don't quite understand why it's done that way.

DR. QUIRK: I had a similar question just to amplify on that and if there is a strong relationship to outcome -- and I would assume the outcome here is low birth weight delivery -- is there any evidence for a dose response here which would justify such a tiered approach?

I think ultimately what one would want to look at is it important. You have an early prenatal care, second trimester prenatal care. Can you just show up before you're in labor one time?

There's data that -- An old dataset that suggested that if you have one prenatal visit before labor you significantly decrease the risk of material eclampsia and

intrapartum still birth because that's an opportunity to do an intervention before a bad thing happens. And then you can go back from there.

I think the other reason to -- But that's the most dramatic. The most important visit is a visit before labor starts. But we've layered on a whole lot of other quality measures for prenatal care that add expense and need to occur earlier. And there are a lot of third party carriers and in some states Medicaid who are not anxious to enroll women for prenatal care until well into the late first trimester because so many women will have spontaneous miscarriages. They don't want to spend the money on a woman whose pregnancy isn't going to continue.

I think that's another reason to do it stratified because you want to look at measured outcomes by when they appeared for care. Sometimes it won't make any difference. But it might otherwise. Is that responsive

to the inquiry?

DR. RAO: Could I raise, I think, a similar concern to Alex and it's based upon the number of prenatal visits. I mean what if you have a woman who's pregnant and she had eight visits. But they're all between the eighth and ninth months of pregnancy. Is that good or should they be appropriately timed as well? That doesn't seem to be part of the mixture.

DR. QUIRK: They need to be -- NICHD did a study -- generated a document about 15 or 20 years ago that deals with this whole issue of how you design -- what should be the appropriate design of prenatal care. That's even a more fundamental issue.

The classic issue -- Anybody in this room that's over the age of 45 that was pregnant the model for prenatal care was prevention of eclampsia. So that's why you meet. You go once a month because the probability is that your blood pressure isn't

going to get bad in a month if it's early in pregnancy. But you lose confidence as the placenta gets bigger.

So in the last month of pregnancy you go in every week and it's not to listen to fetal heart tones and it's not to measure the fundus. It's check a blood pressure and have a woman urinate in a cup and dip it for protein.

We do so many other things whether it's screen for depression, partner abuse, all these prenatal genetic diagnostic steps that we do that earlier visits are more important. So this old document from NICHD was an attempt to say, "Well, you know, we should have a visit at this time. And there should be a genetic screening. By history we should meet at this time. And there should be a visit with a nutritionist," so forth and so on.

That has not been widely adopted. So this measure might do that if it was

better defined.

MS. BROWN: This is Sarah Brown. I don't understand -- I think this is because I'm new -- what the measure is that's being proposed. First of all, it talks about Medicaid deliveries. Is that because that's the source of the data for the measure or is this the recommended population of which it applies? That's question number one.

And question number two is are you suggesting that in order to meet this measure data have to be collected on -- as I think was raised earlier -- not only the number of visits but their distribution? That strikes me as a complicated measure.

DR. QUIRK: I don't know. But I think that Medicaid makes sense because it's a standardized electronic database. You're dealing with an administrative database. You've got one carrier. It's called Medicaid across the country. That's more than half of the deliveries in the United States.

MS. BROWN: So this is a measure that would be applicable only to Medicaid deliveries, not to people in other --

DR. QUIRK: No, it's easier to get for Medicaid deliveries and they might be at risk. And it could be argued that they are the group that's at risk for most adverse outcomes of pregnancy.

DR. GLAUBER: When we say Medicaid, roughly 50 percent of Medicaid lives are in managed care organizations. Would this be inclusive of those entities or just fee-for-service state-based programs?"

DR. WINKLER: Perhaps our measure developer could respond to some of the comments.

MS. BYRON: All right. Just to give you an overview, this is a health plan level measure. This is a measure that is in HEDIS. And it applies to a Medicaid population meaning it applies to Medicaid plans. So we are looking at Medicaid claims

and I actually am trying to get the specifications from my office. But I don't have Internet yet. And I'll be able to answer more detailed questions. I don't have them in front of me unfortunately to see if it applies to the other product lines.

But essentially you're pulling from claims data to see that these visits occurred. And I think this is a good example of us having to bridge the gap between what needs to happen and what's feasible to pull from administrative data. So it's an account measure and it's something that we have found that can be collected from Medicaid plans.

CO-CHAIR McINERNY: I'm wondering. I think this could also be applied to commercial plans as well as Medicaid plans because they tend to collect that administrative data as well.

DR. QUIRK: But they don't talk to any other.

CO-CHAIR McINERNY: And I'm

wondering also about drilling down to practicas at the practice level or the physician level even. Presumably you said they would get that administratively as well. I'm not sure we have to just restrict it to Medicaid.

DR. QUIRK: If I could, could I just respond to that being an obstetrician and having to live with this insanity in New York? The administrative database is that various third party carriers don't talk to one another. They hardly talk to each other inside a plan. You could have one organization of insurance programs and they can't talk to one another let alone set rates.

The nice part, there's still a feasibility issue. But the nice part about Medicaid is they pretty uniformly define certain criteria to make it nonfraudulent to post a bill. So you have to have -- If you're going to bill for Medicaid delivery, you have to see the patient seven times in the

antipartum period. It's easier. It's where you start with it.

Depending on what happens with the next Presidential election, maybe there will be meaningful use criteria for electronic medical records for Medicaid. But we can't depend on what's going on in Washington now to provide that for commercial carriers or Medicaid.

DR. HURTADO: This is just a question in terms of the definition. Why is it a percentage value than I hear everybody talking about number of visits? Does the denominator change depending on the risk of the woman?

DR. QUIRK: Yes.

DR. HURTADO: Thanks.

DR. LIEBERTHAL: Before it was raised that when during the pregnancy these visits occur is important and as I read the measure it doesn't account for that. And I'm wondering from the people who raised that

would they recommend that the wording be modified to indicate the timing of the visits.

DR. RAO: If I could just address that. I think that measure developer's concern is that these visits are coded the same way whether they take place at -- and Jerry would probably know this better -- their first trimester or second trimester. It's the same billing code, same diagnostic code, for the most part. And it's difficult to ascertain the timing of measures.

DR. QUIRK: You're right. What you could do if you were designing the study is you could say the billing is going to establish what the expected date of delivery is. And then you could use the date of the visit to back calculate when in the pregnancy it is. That would be a simple thing to do stirring up the database.

MS. CARLSON: This measure looks very similar and maybe the representative from NCQA can confirm to a Medicaid measure that we

used to use back in the old days of Medicaid HEDIS when HEDIS wasn't just a single set of measures. And the issue with this measure is that can be measured with administrative data.

However, it requires in order for it to be measured accurately significant change in provider billing practices. So it was costly back then to get this data given the fact that Medicaid is always paid last result and probably the poorest payer in the country.

Typically, the services are billed related to a global charge. There may be some package billing if you're only seeing the patient for a portion of the prenatal or post natal care. And what it required health plans to do is to get providers to agree to send in data on every visit they had with the member in order to report it accurately.

So if we can find a way to remove that administrative burden and extra cost to the system, the measure would make sense. We

do care about how much prenatal care people who are in Medicaid receive. And it is important in terms of outcome to pregnancy. But I'm also concerned about the feasibility of this measure.

MS. BYRON: Just to know I have the specs in front of me now. This is -- You can do it either administratively or you can pull from the medical record. So it's a hybrid measure. So you have both ways.

Feedback from the plans that we've had on this measure is that it is feasible to report and it's actually one of the measures where you actually get kind of a scan of Medicaid plans in a different project asking what measures that they use. And this measure did come up as one that they found feasible I think particularly because there was an administrative claims component to it. I mean the plans tend to prefer administrative specifications over medical record because medical record is more burdensome for them.

That's the feedback that we've received.

CO-CHAIR WEISS: I think Kathy had a question or a comment.

CO-CHAIR McINERNY: Yes, Kathy.

DR. JENKINS: I have a just very general question that will apply to some of the other measures that I looked at in my group. And it's coming up here now for the visit count measures which is really at the level of which people can be accountable for this

And the concern I have here is that although it's an important potential population health indicator of all the services rendered or something like that at the plan level is it really possible for the plans to have individuals show up for their prenatal care and should they be accountable, for example, in a high stakes environment for that activity. And that would be a theme that I'll bring up whether it's vision screening or other things like that later.

So I would just be curious how the people on the panel feel about that because I think it's going to come up over and over again today.

CO-CHAIR WEISS: Just before we move off of the point Kathy makes and those that have been made earlier, let me just mention that both Congressional intent and also if I understand correctly CMS who obviously oversees the Medicaid program would like to see as much consistency between the private plans and the public plans as possible.

And so even though today in many states that are dramatic differences between the administrative reporting requirements and so forth for Medicaid and those for private plans I'm not sure that we can assume that that will continue to be the case and in fact quite the opposite.

So just as you're thinking about this keep in mind that one of the driving

forces within the Federal agencies that are looking at implementing health reform is to bring some of these administrative requirements into alignment regardless of whether they're on the private side or the public side.

DR. QUIRK: Just for clarification, not to advocate for a position, if you look at the beginning of this thing because it was collapsing of two measures into one, measure two, in fact, was timeliness of prenatal care defined as the percent of deliveries that received the prenatal care visit as a member of the organization in the first trimester or within 42 days of enrollment into the organization.

So I think if you use that first trimester that to some degree obviates the concern that they show up for nine visits the last month. And since you're blending that with measure one which is 21 percent of expected, then what you've got is you know how

many patients came at what point in pregnancy for their first visit and then what was the expected show rate for subsequent visits. Whether it's feasible and how much it's going to cost is another issue. But I think it defines it well enough. Thank you.

DR. WINKLER: Do you -- Given Jerry's comments, do we need to look at the second measure or can we make some conclusions about the first measure before we move on to that one?

(No verbal response.)

Why don't we try and see what we feel about this particular measure? I got a sense from everybody that you feel it meets the criteria for importance to measure and report. Nodding heads.

DR. JENKINS: Could we ask about the level though? Could you answer my prior question because I can't go forward without having an answer to that? In other words, what level are we answering the question for?

DR. WINKLER: Well, I think that the individual one may have been submitted for whatever level the developer feels it has been developed and tested and submitted for. So that's the level of analysis that you are evaluating.

MS. BYRON: For this measure, it's a health plan measure and it actually applies to both Medicaid and commercial. So you would be saying what is the health plan accountable for.

And when we create the health plan measures we expect that the health plans are gathering this information. If their rates are low, then we then to see the health plans going out and educating physicians on getting their rates up. And so that's how NCQA kind of effects quality improvement by holding the health plans accountable. And this is because members may switch around different physicians. But everyone -- You know, the idea is that you have the same health plan and

that's how the health plan measures work.

MS. CARLSON: Just two comments. Marina, I appreciate your comment about for both public and private plans. My assumption looking at all of these measures was that they were measures for everybody or obviously for a certain population, not that they were measures only to be used in X, Y or Z. I think that's really important to clarify.

And then secondly if you go to page eight on this particular -- What do you call this document? The --

DR. WINKLER: Measure Evaluation Form.

MS. CARLSON: Measure Evaluation Form. It has specifics both for the elements of prenatal care as well as the elements of postpartum care. And I just would appreciate comment on sort of the basis for these elements of the prenatal visit. And what I'm trying to understand is whether or not the measure is not just about coming for prenatal

care, but also whether these particular services are covered.

And it says "evidence of one of the following" which suggests that you don't have to do them all or that they're distributed differently over the prenatal care. I just didn't understand how this list, clinical list, crosswalks with the periodicity.

DR. QUIRK: I can't answer that based on the way this document was developed. Some of them would be regular periods. Very time you visit there's routine you do. Then there are other elements that might never be done like torch titres. There might some that might be done once in a selected population like a fetal echocardiogram or maternal echocardiography.

MS. CARLSON: But that's not part of the measure then. That's not -- This is not the quality that we're looking for. Just did they show up.

DR. QUIRK: Yes, that was my sense.

DR. WINKLER: The question I would ask to the developer. Is this list that she's referring to under the medical records specification? And so if you're looking at a record those elements will be available.

But if you're only using administrative data you probably aren't going to see anything like that. Perhaps a lab test, but that might be it. And so the administrative specification is based on just the codes that are in administrative data.

So are the two data sources really comparable?

MS. BYRON: So this is a Visit count measure only. To be clear, we're not looking at content unfortunately. We recognize the limitation of Visit count only measures. But this was developed at a time when there were no measures and we wanted to take baby steps. And we wanted to see what

was feasible to collect from administrative data and also medical record data.

So what you're seeing in the medical record portion is a way to show abstractors how to identify a visit was a perinatal visit and not just sort of other visit. So you know if you see these things it's highly likely that this visit was a perinatal visit. So you can count for the numerator hit.

For administrative purposes you don't need that because you have a code. So that's why they're different. But it is a Visit count only measure and it was our way of saying "Okay. Here's a good first step sort of measure that says 'Are you at least coming in for the visits?'" And we're going to have to trust that good things happen then that are you coming in for your visits.

(Off the record comments.)

MS. CARLSON: This is a question for the developer. Is it safe to say that

since this can be used, this measure can be used, in commercial and Medicaid health plans that while you haven't tested it in the Medicaid fee for service world you could use it in a similar method in Medicaid fee for service?

MS. BYRON: We have found that some Medicaid fee for service plans are using this. It's hard to say. We haven't tested it in there, but we do know that people are using it.

MS. CARLSON: So you could have some comparability across managed care plans and Medicaid state-run fee for service programs.

MS. BYRON: Yes. Likely.

MS. CARLSON: Okay. Thank you.

MS. DOUGHERTY: Can I say something? One of respecifying some of these measures -- I'm not going to say all of them -- but the ones that were in the initial core set for CHIPRA and posted by the Secretary,

respecifying those is one of the charges to the Pediatric Quality Measurement Program which is going to be seven to nine centers of excellence in quality measurement.

So I think it's not an easy task. And it requires resources which is why I think the CHIPRA legislation included resources to do those improvements and enhancements.

DR. JENKINS: I have a question for the measure developer. Can you speak to the breakdown, the five category breakdown, of percentage of visits whether those track specifically to outcomes versus whether a simpler breakdown could be used?

MS. BYRON: Those are what we determined. We developed all of our measures with the help of a measurement advisory committee. It's a measurement advisory panel called MAPS and during development the MAP determined that this was sort of the

prescriptive buckets that they wanted to be able to compare against just to give us some sort of a breakdown year to year to track trends.

I'm not sure if they track to anything other than just a way of breaking down the visits in order to be able to follow some trends over time.

DR. JENKINS: Again, it's a similar follow-up question. I understand completely this measure is a quality indicator and breaking it down into five categories. I'm still struggling over as an accountability indicator. So could you please help me understand how it's an accountability indicator at the Visit count level and at the five categories that Donna's asking you about?

MS. BYRON: I say that the categories are descriptive. The measure itself holds health plans accountable for ensuring that their members get a certain number of visits because that's what's

indicated to improve quality. Studies, research, has shown that having a visit can improve your outcomes. It is a visit count measure and we recognize that as a limitation. But it is a first step measure.

DR. JENKINS: Just to help me understand. There's a percent of women that are pregnant that come in one day before they deliver. How is the health plan supposed to incidence that? That's the part I'm -- It's really back to basics that I'm stuck on here.

MS. BYRON: Well, I think this will be an issue with all the health plan measures. I mean the issue they are supposed to -- Right. They look at their rates. If their rates are low, what we have seen is that the health plans will then go out to the physicians and educate the physicians on why it's important for a woman to have a prenatal visit. And then the physicians tend to work -- Often at the time it's an issue of simple education. And we've seen them be able to

focus their quality improvement efforts on whatever area the measure is for.

DR. JENKINS: But that sounds to me like the definition of a quality indicator as opposed to an accountability measure.

DR. GLAUBER: Can I ask a question that reflects my naivety? What do you mean? Explain to me what accountability is.

DR. JENKINS: Accountability for example would be that a health plan would be paid more money or less based on the number 82 versus 83 percent which is how state accountability measures mean.

DR. GLAUBER: But you start off with they come in for the visit and then you go to what's the document, the content, of the visit and whether you can read the note.

DR. JENKINS: Sure. I understand all that. But to get paid more money or less and to be on a public report card is a high accountability measure and that's my question. I don't doubt at all that this is a quality

indicator or that it's a great population health indicator. It's as an accountability measure that I'm struggling with it.

MS. BYRON: Helen, did you want to --

DR. BURSTIN: I just wanted to weigh in that there are many different ways accountability can happen. Payment is certainly one vehicle. Public reporting is another. And the way we proceed with new measures is the idea that these are measures that are appropriate public reporting and accountability.

I think the idea that health plans be measured on this potentially pay differentially. Potentially having public reporting done is already happening with many of the HEDIS plans anyway. I think it's an element of the way we would already view that as actually being an accountability indicator.

DR. JENKINS: Right. And to note these are -- All of the HEDIS measures are

publicly reported. And so even if they're not getting incentives from -- And actually some of them do get incentives from the states. But it's difference across the country. But I will say that public reporting really does affect the plans.

MS. GARY: Yes. I wanted to get back to a question that was asked here. I'm still not clear in my mind whether these measures will be used to indicate quality for all women or just the Medicaid based women.

And if the latter is true, then what is the value added for these measures with regard to some points that Kathy made. When you consider the social context within which people live, should the measures be different? Or if we are calling these individuals high risk, so what is the value added here?

I'm not so sure what the differences are, what we are supporting in terms of measures for one group versus another

group. And what are the similarities? Shat are the differences? And are we clear about those differences that we wish to support? And the service of quality health care for our people?

DR. WINKLER: In response, I just want to pick up on something that Sepheen said. You said that this measure is for both Medicaid and commercial plans. Correct?

MS. BYRON: Right.

DR. WINKLER: Then perhaps including the term Medicaid deliveries might not be accurate in the description.

MS. BYRON: If that's in there, then -- I can check. Let me pull the specification just to make sure I'm not wrong. But if so that would be a mistake. I apologize for that.

(Off the record comments.)

It would be claims that a commercial claim is able to pull.

DR. CLARKE: To change the subject

just a little bit, I was -- I'm a little bit struck by the fact that there has been no objective reliability testing and likewise the validity testing is essentially totally based on expert opinion and is subjective. And since these measures have been in use at least in the Medicaid population it seems like for some time now, it would seem fairly feasible to do objective testing on this measure and perhaps give it a little bit more support.

DR. WINKLER: Sepheen, did you have any comment for that?

(Off the record comment.)

DR. GLAUBER: I was talking about the fact that there is no reliability testing and only subjective validity testing when the measure has been in use for time enough it would seem like to accumulate data and objectively support these areas.

MS. BYRON: When we looked at the criteria that were laid out on the forms, it actually made it reliability testing as being

very specific reliability testing such as interrated reliability. We have not done that field testing.

You know one could infer the reliability just from the fact that the measure has been in use for a while. It's true with validity as well. We run this a measurement advisory panel. And using expert consensus we're able to infer something about -- It's kind of the faith validity of whether or not we are measuring what we want to measure.

In this case it's a visit count measure. So we're saying that number of visits. We're able to pull it from claims. We're able to compare it against medical records and see that the claims are matching.

And that's what we did in field testing. And this is actually a long-standing HEDIS measure that's been in for a long time. So we've been able to monitor it across time.

DR. GLAUBER: But just to the

issue for validity, it's my understanding as a Medicaid plan that this is one of the measures that's commonly augmented by chart review by plans because administrative data doesn't adequately capture actual visit frequency.

MS. BYRON: Well, that is why it is a hybrid measure. Whenever possible, we try to keep measures to administrative just because of burden. We've heard a lot about burden in terms of pulling medical records. But when it's insufficient then we do specify it for medical records so that they can augment their data.

And over time we do watch to make sure that if something happens where administratively they're starting to be able to build systems and identify measures that way. We watch to see what we call the lift between administrative and medical record data. And eventually there have been times when we've been able to modify measures during re-evaluation to retire or sunset the

administrative claims -- oh, I'm sorry -- the medical claims portion of it and make it administrative only. But in this case we do think it's important to have it be a hybrid measure just as you noted.

DR. WINKLER: Do we think we've discussed the characteristics of this measure enough? We'll separate the two parts. The first part is the count measure that is listed as Measure 1. And I get the sense that everyone feels this is an important area, that it means there is room for improvement and so it meets that criteria.

Scientific acceptability. I think there were some discussions of concerns of (1) the lack of reliability and validity testing. There were some discussion around the data source issues. Was there anything else on scientific acceptability?

DR. CHEN: Hi. Sorry. I think Kathy made a point about scientific acceptability in terms of case mix and risk

adjustments. And I think that's actually a pretty common theme. When I go through all the measures for this session is that a lot of the reliability and validity testings are empty or not done I'm afraid. There's minimal evidence for them.

And that's pretty common for measures. I mean you can expect everybody to measure them and test them. It's a very tedious process. And all of them have face validity which for me is enough in itself.

However, risk case adjustment may be an important because there are some groups that's at high risk. I guess that Kathy's point that should we sitting at this table make health plans accountable for those disparities and distribution of patients and mix.

We may decide that's the case because we may say that's important for health plan to reach out like Sepheen said to make that difference. But is it really their

responsibility? And that's true for a lot of indicators. There's not a lot of risk case adjustment as well.

I think that's one common thing that we'll probably face throughout the day. But I just wanted to sort of reaffirm that as well.

CHAIRPERSON REYNOLDS: Can I just address that for one moment? I assume that most of the time they're comparing apples and apples. So one Medicaid managed health care plan to another. In that case, maybe they should be held accountable for the process measure.

DR. CHEN: Right. I think that's a good point. But we're also talking about commercial versus Medicaid and generally you want Medicaid to compare with commercial. You don't want to give the perception that Medicaid has worse reporting versus commercial plans.

But to comment on your issue,

there's a lot of cultural issues. Can I just give an example? It will take a few minutes. Appendicitis, one measure is to measure the rate of rupture of the appendicitis of any surgical cases that you keep count of.

In our particular hospital, we have the highest rate of rupture appendicitis in the country by a lot. And the reason for that is we actually service about 80 percent Hispanic patients. And they -- their delay in showing up for care the moment they have pain is about 48 hours. That's about how long it takes to rupture an appendicitis.

So we actually have a lot of cases that were ruptured when they showed up. So the surgical time from the time they show up at the ER to the time we take them to surgery to take out that appendix is shorter than most of the hospitals across the country. But we have the highest rate of rupture appendicitis.

So if you don't adjust for that, then it's not fair I guess. But some things

need to be transmitted for success and it's not just population. A lot of it is culture. It's jobs, you know, opportunity, cost and transportation and other issues.

DR. FISHER: This is Nancy Fisher. I'd like to make a comment when he talks about case mix adjustment and other issues besides culture and who you can hold responsible. When you start looking at Medicaid patients and you start looking at coming in for the first prenatal visit, I agree with whoever was speaking that there are cultural issues.

There are suppressive issues that have to do with Medicaid. So one of the things is people having difficulty getting on and being eligible. And then also they're trying to find a doctor that they trust. This is especially true for teenagers that get pregnant.

So when you think about the accountability and things that are holding the

health plan or holding the physician, they're only part of it because the individual may not be able to get on. They have difficulty getting on and then they have to be assigned to a practitioner. So there are all those things that go into this, too, that there are people getting prenatal.

CO-CHAIR McINERNY: New York State has been reporting on this kind of measure and many other measures for Medicaid patients, Child Health Plus patients and commercial patients for many years now. And what's been interesting is that ten years ago there was a significant gap between the Medicaid patients and the Child Health Plus patients and the commercial patients. But over time, that gap has lessened significantly.

And I think the important thing is you can't manage what you don't measure. So you've got to measure and start to look at things and then measure for improvement would be the other issue. And we do have a rather

large Medicaid managed care plan in Rochester that did address the issue of poor number of prenatal visits and was able over time to work to increase those number of visits to a much more acceptable level.

So I think that you have to think about case mix, etc. But in the long run I think if we're doing more measurement for improvement that to me is what's very important.

CO-CHAIR WEISS: Could I just weigh in here a minute from kind of a 30,000 foot level if you would? It seems to me that the point that was made earlier about it's plan-to-plan comparison that's going on here it's not just an evaluation of a plan in a vacuum.

And it may be that some plans are doing certain things that encourage people to come in a timely manner. And it would be useful for other plans to be aware of that, to know of it and so on. And case mix within the

plan is critically important because if it's a plan that's seeing a lot of Medicaid patients such as you guys that's important to know as opposed to a plan that has maybe a very high compliance rate but a very small percentage of Medicaid patients.

So it would seem to me that both the composition of the patient population as well as the actual number of visits and whether they occur in the first trimester or when they occur, both these elements are important.

MS. BYRON: Can I make a quick clarification? So I misspoke earlier. This measure, frequency of prenatal care, is Medicaid only. It's the next measure, prenatal and postpartum care, that is both commercial and Medicaid.

And the continuous enrollment requirement is 43 days prior to the delivery through 56 days after delivery. So the issue is these are women who have insurance. They

have coverage. So we're comparing among them and we are comparing Medicaid plans to Medicaid plans.

Even for measures where we have Medicaid and we have commercial we show a Medicaid rate separately from a commercial. So we don't combine them. We do understand that there are differences and we do tend to see that Medicaid rates often are lower than commercial. And it's understandable. We know they are different populations.

One might argue that it's even more important for the Medicaid plans who are covering vulnerable populations to see the rate and as one person noted to start to measure to know where they need to focus quality improvement efforts. And that is the intent of these measures.

CO-CHAIR WEISS: Let me just follow on that comment with I hope a response to Kathy and this is very much an accountability issue because the states do re-

up certain plans and they choose not to contract with other plans. And there's no question but that they will be looking at the compliance information that can be had here.

DR. GLAUBER: And to Alex's point about case mix, that certainly does influence what your performance will be but also influences what health plans or at least in more sophisticated health plans improvement strategy will be. So my plan as well as others is investing significant resources in identifying the race ethnicity of each of our members and measuring our performance by race ethnicity so that when we identify those certain subpopulations it is inevitably influencing our rates so to speak. We try to understand that and try to target improvement in outreach efforts to that subpopulation.

So I don't think it's something that should disqualify the measure. But it should spell out how we're accountable.

DR. QUIRK: Can I just ask a

question? Can we go back to the beginning of what the measure is? We've been all over the universe on what we think about prenatal care and case mix index and all that kind of stuff.

But if we go back to the description of what the measure is, it's really simple. What percent of patients got prenatal care, at what point in the pregnancy? What patients got prenatal care 37, 42 days before they delivered? How many of them received care in the first trimester?

I think what we're trying to do is like the marathon. We're sprinting to the finish and we haven't got to the one mile post in the middle of the Verrazano Bridge to use an allusion to yesterday's marathon.

So I think that what this measure is all about is getting our arms around the issue so it can be better defined. And until we do that, you almost can't talk about the gap and you almost can't talk about the impact on interventions because you don't know if any

of that original definition of the description of the measure whether the date is good, whether it's valid, whether it's reliable, whether you can afford to collect it and if it makes a difference to define outcomes because you haven't talked about outcomes at all.

So all we want to know is who showed up and when. Is that important to know? Yes or no? Up or down?

CO-CHAIR WEISS: Well, I would just only make the point that we're suppose to be focusing on process measures in this session. Outcomes measures.

DR. QUIRK: I understand.

CO-CHAIR WEISS: Okay.

DR. QUIRK: But we've been all over things that can effect outcomes and accountability and the content of the visit. They're all terribly important. But this is like let's see who shows up and how we define, how we stratify, that original data.

CO-CHAIR WEISS: You're absolutely

right.

CO-CHAIR McINERNY: Well, I think this points out that this measure development and acceptance is in its infancy in health care and maybe even prenatal. I don't know.

(Laughter.)

DR. QUIRK: Especially.

CO-CHAIR McINERNY: And we all can see that there are ways in which a measure like this could be better, could be improved. But to quote Don Berwick, you know, "Perfect is the enemy of good enough." And I think we have to start somewhere with measuring things and asking plans to do these measures and letting them know they're going to be reported. And in that respect they'll be accountable. And then over time we can improve on the measures in ways that we've discussed here this morning.

DR. CHEN: Hi. Sorry. Follow-up question for Tom. Then are the expectations from NQF that the Committee members should

vote on the measure because it's important? And then we can sort of worry about a lot of the details of improvement later because they may be improved. Because Denise has mentioned that there will be centers that would try to improve some of these older or more previous - -

DR. WINKLER: From NQF's perspective, we want you to look at the measures and apply the criteria remembering that importance to measure and report is the first criteria and it is the threshold. So importance is definitely there.

But that doesn't mean we want you to ignore the other criteria. And bringing out the issues that you've identified around those criteria will help explain what your ultimate recommendation is. And we need to be able to capture that and convey it to the audiences that will ultimately care about the decisions you make and the recommendations you make.

So I'm trying to ground everything in those criteria. Important isn't the only thing. It's certainly the first thing. But then the others do have an impact on ultimately your recommendation as well.

If it's a measure that just simply isn't feasible, if it's a measure that doesn't provide useful information, if it's a measure that you feel is so flawed that the results are very questionable because of the science behind it, those are important aspects that should go into your ultimate recommendation.

DR. WINKLER: Just one more comment though. I think we are still forced to look at the measure as it is presented to you today. So I don't think you can consider the future tense measure. You can make recommendations for how to improve the measure.

We do have an ad hoc review process. So this measure was endorsed. as the improvements are made to the measure it

can be resubmitted and we can just do a rapid evaluation to see if it actually met the recommendations you guys made. But you need to look at what's on the table today.

MS. CARLSON: I would just say that looking at this measure and knowing that there are very few measures that in and of themselves are a good indicator of outcome that you take this measure as you would other measures in this realm and use it as a market basket approach, a proxy if you will, to a single measure for outcome.

This measure along with a low birth weight measure and other measures of prenatal care and perinatal care and neonatal measures will give you that outcome that you're looking for. So it's a tested measure. It's been around for a long time.

DR. WINKLER: All right. So I'm trying to get you through just the elements of the first measure. So we've talked about the scientific acceptability. I'm getting a sense

--

(Off the record comment.)

Yes. Always. The first one takes forever.

(Off the record comment.)

Right. So in terms of scientific acceptability, how many think it meets the criteria completely?

(No show of hands.)

Not a surprise. How about partially?

(Show of hands.)

Twelve. How many minimally?

(Show of hands.)

Four. How many not at all?

(Show of hands.)

Okay. Good.

All right. The next criteria is usability. How many people think it meets the usability criteria completely?

(Show of hands.)

Seven. Folks on the phone?

Nancy? Ellen?

DR. SCHWALENSTOCKER: Partially. Partially.

DR. WINKLER: Okay. Thanks.

DR. FISHER: I would say partially. Completely.

DR. WINKLER: Okay. And what is the feeling of feasibility for this measure for folks? Completely?

CO-CHAIR McINERNY: Wait. We didn't finish usability.

DR. WINKLER: Oh.

(Off the record comment.)

Did I? I'm sorry.

Usability? How many think it only partially meets the criteria?

(Show of hands.)

There we go. Eight. Okay. So it became a partial.

Anybody minimally?

(Show of hands.)

One. Anybody not at all?

(Show of hands.)

Okay. All right.

Now feasibility. How many think it meets it completely?

(Show of hands.)

Six. How about on the phone?

DR. SCHWALENSTOCKER: I would say partially.

DR. WINKLER: Okay.

Nancy?

DR. FISHER: Partially.

DR. WINKLER: Okay. So how many here think it's partially?

(Show of hands.)

Twelve plus two is 14. Partially it is. All right.

So, going through all that, how many would recommend this measure going forward?

(Show of hands.)

Fourteen. How about on the phone?

DR. SCHWALENSTOCKER: This is

Ellen. I would say yes.

DR. WINKLER: Okay.

Nancy?

DR. FISHER: Yes. I'm sorry. I didn't mean to speak over her.

DR. WINKLER: No problem. Is anybody else on the phone?

(No verbal response.)

Okay. How many do not recommend it?

(Show of hands.)

Two.

(Off the record comments.)

Time limit endorsement is only for measures that have not been tested. So these measures don't qualify. They've been around.

(Off the record comments.)

Okay.

DR. CLARKE: I mean my point is is that I think the opportunity for objective testing has been there for a long time and nobody has done it yet. And I think that

that's really necessary.

DR. JENKINS: And I agree.

PARTICIPANT: I support that decision as well.

MS. CARLSON: Sepheen, just a question for you. Obviously these have been in use in HEDIS for a long time. I assume you must have -- Fairly routinely you do display data by different data sources, etc. You have nothing else to share with the Committee on this? Because I think otherwise we are in a bit of quandary of no reliability data and the submission form. So could you speak to that?

MS. BYRON: This is a measure that has been in HEDIS for a long time. It was field tested before we released it and then just to tell you a little bit about the process. After a measure is released for one year we do not publicly report it. So we give plans an opportunity to start to pull in the measure, understand the measure, ask questions about the measure. And then we bring it back

through our whole Measurement Advisory Panel process and the Committee on Performance Measurement and show them the data from first year. We call it first year analysis.

And then from there we make sure that the data do not have any strange outliers or other strange things. So it is evaluated in that way.

And then the Committee votes to either move it to public reporting or not. There have been cases where we have measures that do not pass this test and they get held back a year. And they get held back for another analysis.

So this measure moving forward to public reporting has passed the criteria that we outline in terms of feasibility, usability and validity. And, after that, it's used and then we release data. Every year it's publicly reported and we can track the trends along the way, ensure that things are moving in a way that we would think that they would

move.

About every three years or so, we re-evaluated every measure. And when we do this we actually in addition to looking at the data query all health plans, all health plan users, and ask them about their experiences with the measure, how they feel about it, whether they feel like it's accurately portraying performance.

And we take all of this information, all of these data, and we bring it back through the process and go to the Committee on Performance Measurement and show that they understand. In addition to that, they're all released for public comment in the very beginning as well.

So, in that sense, we know that the measures are feasible and they do seem reliable. I mean if you're asking whether we do formal interrelater reliability, no. But we do -- These are long-standing used measures.

MS. CARLSON: Sorry. Just to follow up on that a bit, I do know that you do routinely sort of parallel testing of the chart review versus claims. I mean if nothing else that I would think be some indication of the reliability. Is that something that you could pull and bring to the Committee?

MS. BYRON: Yes, we can pull that. We do look at -- Right. Thanks, Helen. We do look at the comparison between administrative data sources and medical record data sources and we look to see what the list between the two, whether or not they're comparable. And we do that for every re-evaluation and we also do it for first year analysis. So we would have data on that.

MS. CARLSON: I was just going to add to that. Health plans are audited by independent third parties auditors when they are ready to collect and submit their HEDIS data. As a part of that audit, each health plan has to show evidence of interrator

reliability. That's been done on all of their measures where there is medical record extract involved. So there is interrator reliability performed at the health plan level.

DR. JENKINS: I would just like to say that my prior comments were not so much about the accuracy of the percentages as reported by the plans. They are about understanding the relation in those as an assessment of the plans in the absence of case mix adjustment. That's one of the areas that I'm most concerned about.

MS. BROWN: And I would just like to add I think the fairly obvious point that I think all of us feel that this measuring of number of visits is really a very crude instrument. The issue for most of these things is what's going on

And I think prenatal care is one of the best examples of sort of a black box approach where many things can't -- It's a lump of things. It's like well child visits

or a lot of other things. And I think this is better than nothing. But I think it would be important to have a footnote or an explanatory something that points out that there's an enormous amount of work to be done on the relationship of elements of prenatal care to neonatal outcome, maternal outcome, and so forth. It's really to this day poorly researched.

DR. CLARKE: Well, I'd like to say that it sounds like you really do have objective data, but you just haven't shared it with us. And that's the reason that we're concerned because it's just missing.

DR. ZIMA: And actually I had to chance to look at the NCQA website. And I think the issue is power. You don't have enough statistical power if you have only 20 physicians recruited nationally and ten records. Yes. You may not have the capacity when you're comparing the medical record in your agency data to address some of these

issues.

MS. BYRON: Are you talking about during field tests or?

DR. ZIMA: Yes.

MS. BYRON: In general? Because when the measure is in use, we actually look at the data that we get from everybody. All plans.

DR. ZIMA: Is that available?

MS. BYRON: So we do publicly -- I think what's in the forms are the rates of performance over the years. So probably you put like the last three years worth of data and we showed the performance.

What we did not show was medical record versus administrative data sources. But we did show rates of performance. And so it would be for all plans. It's not just ten.

(Off the record comment.)

DR. WINKLER: Well, I just want to be sure given this added discussion in terms of votes to recommend this measure. The last

thing I did was the three no votes. Is that where we're landing? Okay.

Are there any other --

DR. JENKINS: Unless some of the issues of case mix adjustment are available and are accounted for in the measure and maybe we just haven't seen that they're accounted for somehow. Otherwise, I would not change my vote.

DR. WINKLER: Okay. That's all I want to know.

Were there any abstentions?

(No verbal response.)

Okay. Great. I think we can move on to another measure, but it's the same. Don't we still have to act on the second part of this measure? Right?

CO-CHAIR McINERNY: By the way, for those of you new to the Committee, don't be discouraged. This is how the previous committee started off. And I think one of the things that I learned very quickly on the

first committee is how difficult this measurement business really is.

And we ran into the same thing -- I'm an Academy of Pediatrics representative to the Physician Consortium for Performance Improvement. And very similarly, the measures that were proposed became very complicated very quickly. And some of the measures that were accepted were felt to be sort of pretty exceedingly low bars. And yet that was the place to start.

And then we start there and eventually as we become a little bit more sophisticated as we learn more hopefully we can start to improve upon the measures and make them more robust. And I certainly agree somewhere along the way it would be very important to look at the content of the visit in addition to the number of visits, so get into the quality of the visit in addition to the quantity of visits. But it's not possible right now, but maybe in the not too distant

future we can do that.

DR. WINKLER: Great. All right. So if we go back to the description Measure 2 that's embedded in the same form, the prenatal/postpartum care measure, there was some discussion of it earlier. This is the percentage of deliveries of live births during the year.

There are two parts to this measure. So the first rate is the timeliness of prenatal care percentage of deliveries that received a prenatal care visit as a member of the organization in the first trimester or within 42 days of enrollment in the organization. So this has a timing element.

And the second part is the percentage of deliveries that had a postpartum visit on or between 21 and 56 days after delivery. So this measure has the two elements to it. So there would be two results for this single measure going forward.

Discussion?

CO-CHAIR WEISS: Can I just ask an informational question. Where did the 56 days come from?

DR. WINKLER: Eight weeks.

MS. BYRON: Determined by a measurement advisory panel to be an important milestone. I'd have to look into more information as to why. But I think they were just choosing six weeks.

CO-CHAIR WEISS: The reason I ask is I know that the Medicaid and the CHIP standard is 60 days as opposed to 56. It's silly, but you know just a little odd.

MS. BROWN: Also what's the relationship between this prenatal measure and the previous one? Just are these duplicative? Are they meant to be the same or is it Medicaid versus all?

MS. BYRON: This measure has a timeliness component to it. So whereas the other one was just did you get your visits, this one is did you get it within a certain

time period. So trying to build on the measures and trying to slowly step up and take more baby steps and add this timeliness component onto it.

CO-CHAIR WEISS: Plus the second measure applies to all births, right, not just Medicaid?

MS. BYRON: Yes, this measure is commercial and Medicaid. And it's two different rates. The first rate is timeliness of prenatal care and then the second rate looks at postpartum care.

DR. QUIRK: I still don't know that I'm thinking about this properly, but I think it makes sense to me. But this is a first step to addressing the issue made that Kathy's addressed about when you start doing a case mix index, when you're talking about Alex, you know, why patients don't come in when they have belly pain and then they rupture their appendix. What you're now saying is given all the barriers or a lot of

the barriers to care once you become a member of an organization. So it's a subset. It's people that accept prenatal care and in whom the organization has responded to their need by letting them join up.

So once they've gotten their union card, okay, do they come in and take advantage of the care? I think it is different, but I think it has the same strengths and weaknesses as the prior measure.

DR. GLAUBER: Even though we're looking at these two measures together, I'm concerned that they may diverge in terms of importance. You know to your early comments --

DR. QUIRK: Agree.

DR. GLAUBER: -- about the timeliness of a woman initiating prenatal care versus postpartum care which is a process measure that I'm not sure what relationship that has to any outcome. And at the practical level since this is a long-standing HEDIS

measure, health plans have finite resources to dedicate to improvement efforts and health plans definitely do work hard to improve their postpartum care rates because particularly in Medicaid these are not great numbers.

So there is a risk for misdirection of resources if this particular measure is not measuring anything that really is linked to health outcomes.

DR. QUIRK: Well, I disagree. I think the postpartum visit is underutilized particularly by the Medicaid population. And we come to know what some of those measures like "I can't bring the baby," "The baby's got an issue," I had to go take the baby to the pediatrician in two weeks," Now you want me to come back in six weeks," and "It takes me two hours to pack up the car, take the bus with the baby and it's not working." So you've got those issues.

In a commercial population, they tend to come to the visit. But in both

populations that visit is not valued by anybody. It's just something I have to do and if you're obedient and you went to Catholic school, you go, you know, that kind of a thing.

But there are some important things that are supposed to take place at that visit. There should be some issue addressing depression. That's supposed to be important. We'll talk about that hopefully tomorrow.

And then the other is you're supposed to be screening for gestational diabetes, for diabetes, at that visit in that population of -- in that subgroup of the population that had gestational diabetes. And, of course, that number is skyrocketing. It's gone from three percent to 15 percent, 20 percent, in some populations.

So there's real important reasons to come in for a postpartum visit that did not necessarily exist as reasons 20 years ago. Thanks.

CO-CHAIR McINERNY: I have a question for the NCQA developer. Is it possible for when you're doing these to split those two, the early prenatal visit, and measure that only and then measure the post natal visit only as well?

MS. BYRON: They are two different rates. The first rate is prenatal and then the second rate is postpartum. So you can look at them separately.

CO-CHAIR McINERNY: Okay.

DR. WINKLER: But the way they're presented to us they are both part of the same measure and we are acting on the entire measure.

MS. BYRON: They are but -- They are the same measure. It's true. So it's one measure, two rates.

MS. SCHOLLE: This is Sarah Scholle from NCQA. I've joined the call.

CO-CHAIR McINERNY: Thank you.

MS. BROWN: Jerry, just to build

on this content issue of postpartum care, notably absent in the list back to page eight is family planning. One of the key reasons to have a postpartum visit is for contraception, for child spacing, maternal health and so forth. And I think that's a notable absence in this document and others.

MS. SCHOLLE: This is Sarah Scholle from NCQA. May I speak to the point about the content versus --

CO-CHAIR McINERNY: Yes, you may. Thank you for joining us.

MS. SCHOLLE: I'm sorry. I was listening to the conversation, but I was on mute before. I just want to emphasize that the measures that we're bringing forth for perinatal care right now are based on claims data. And from claims data it's not possible to see what the content of the measures are.

When we're developing measures, one of the things we have to balance is the feasibility of data collection and the burden

on organizations of collecting information about the content of care. In fact, we at NCQA are very interested in moving away from visit based measures to measures that look at the content of care.

But as we've looked at the feasibility, our sense is that the way to do this is to begin to take advantage of the new opportunities with the deployment of electronic health records. So on our future plans, in fact, we've already convened a group to look at what it should be in content, a measure that's looking at the content, of prenatal care and postpartum care.

Unfortunately, we don't have those measures even specified or tested yet. But in the field these measures of perinatal visits about access, the frequency visits and the availability of visits access to prenatal and postpostum care, these are measures that are used by states, by health plans, to look at access. It doesn't get us all the way to

where we'd like to be at evaluating the content of care.

But we're trying to balance feasibility issues. And I know at least someone else on the Committee pointed this out. But I want to emphasize that these measures are used in just about every state by Medicaid and CHIP programs to evaluate access to care.

DR. WINKLER: And just to confirm, Sarah, you all look at this not only in terms of prenatal and postpartum, but also you differentiate between the private plans and the publicly supported plans, Medicaid and CHIP. Is that right?

MS. SCHOLLE: That's right. And I think Sepheen mentioned that in -- These measures have been used I guess probably over a decade by NCQA. And when we report measures for health plans, we only report and make comparisons within product lines. So we only compare Medicaid plans to other Medicaid

plans, commercial plans to other commercial plans. And so when we're making comparisons, when we're doing public reportings to benchmarks, when we're using the data, we are always looking within just comparing Medicaid plans to other Medicaid plans. That's an important part of our use of the measure. We realize that there are differences across these population groups.

Now, in terms of risk adjustment and I know that there were some concerns about risk adjustment, again part of this gets back to feasibility. Part of this gets back to issues about equity. Available through the claims data, we have limited information that gets at socioeconomic status and actually being eligible for Medicaid is a marker of socioeconomic status.

That's why we don't compare Medicare versus commercial against the same benchmark. We don't create a single benchmark. We stratify.

But we don't have good data on race and ethnicity so that we can't look at the performance rates by race and ethnicity. We've been working on that. We actually have a new distinction program for health plans to try to encourage them to collect race, ethnicity and language data so that this will enable us to be able to look at stratified results by race/ethnicity so that we can try to pinpoint those differences.

We know that within states and within health plans to the extent that health plans have those data we know that they're using it.

DR. WINKLER: Thank you, Sarah. We need to kind of continue our conversation on the evaluation criteria here for this measure from the Committee.

MS. SCHOLLE: Okay.

DR. WINKLER: So, in terms of this second measure even though it's on the same form that includes the two rates of prenatal

and postnatal, does the Committee feel this meets the importance criteria? Yes? No? Okay.

(Show of hands.)

The majority says yes. So it is important.

How would you all rate the scientific acceptability of the specifications for this measure as indicated on the form here? How many think it completely meets criteria?

(Show of hands.)

Five. Nancy and Ellen, on the phone?

DR. FISHER: Partially.

DR. WINKLER: Okay. Nancy?

DR. FISHER: That was me.

DR. WINKLER: Okay. Sorry, Ellen?

(No verbal response.)

Okay. Not there.

How many in the room partially?

(Show of hands.)

Ten. Okay. Eleven. Minimally?

(Show of hands.)

One. Not at all?

(No response.)

Okay. How about usability? How many in the room think it's completely meets the usability criteria?

(Show of hands.)

Three. Okay. Usability completely meets criteria.

(Show of hands.)

Six. On the phone, Nancy?

DR. FISHER: Partially.

DR. WINKLER: Okay. How many in the room partially?

(Show of hands.)

Nine. So that's ten total.

How about minimally?

(Show of hands.)

One. Not at all?

(No response.)

Zero. Okay. Finally, feasibility.

How many think it meets the feasibility criteria completely?

(Show of hands.)

On the phone?

DR. FISHER: Yes.

DR. WINKLER: Is that completely or partially?

DR. FISHER: Completely. I'm sorry.

DR. WINKLER: Okay. Thank you.

How many partially in the room?

(Show of hands.)

Is there anybody on the phone except Nancy or besides Nancy?

DR. SCHWALENSTOCKER: I'm here. This is Ellen.

DR. WINKLER: How did you vote?

DR. SCHWALENSTOCKER: Partial.

DR. WINKLER: Thank you.

All right. Anybody minimally?

(Show of hands.)

Not at all?

(Show of hands.)

Okay. All right. Generally partially seems to -- Feasibility is completely. All right.

Recommend for endorsement? Everybody in the room, who votes yes for recommending for endorsement?

(Show of hands.)

That's 15 here. How about on the phone?

DR. FISHER: Yes.

DR. SCHWALENSTOCKER: I agree. Yes.

DR. WINKLER: Okay. So that's two more. How many -- Were there any no votes?

(Show of hands.)

One. Were there any abstentions?

(No response.)

Okay. We've finished the first measure.

CO-CHAIR McINERNY: Congratulations.

DR. WINKLER: Congratulations, one and all. All right.

I think the question is do we have the developer for the low birth weight measure.

Suzanne.

MS. THEBERGE: Dr. McDormand, are you on the phone?

(No verbal response.)

DR. WINKLER: That's 1382.

MS. THEBERGE: Percentage of low birth weight births, Division of Vital Statistics.

DR. WINKLER: Thirteen eighty-two.

MS. THEBERGE: They just didn't want to be the first like we had to be. She was going to be on the call.

DR. WINKLER: I think we might as well at least start talking about it. We can see if there are any questions that we'll need to -- I was going to say --

(Off the record discussion.)

Measure 1382 is a measure brought to us from the Division of Vital Statistics. This is the percentage of low birth weight births. It's the percentage of births less than 2500 grams. This has been a measure that's been collected from the states to the National Center for Health Statistics for a long time.

And this is a population level measure, primarily at the state but it could be regional, national and, of course, international. We've certainly all seen data on that.

Dr. Quirk, this was yours/

DR. QUIRK: There might be an outcome measure when I was born because everybody had a scale. But we didn't understand growth restriction and the fetus. So I don't like this outcome at all ever anymore though it's used because there's fetal growth restriction and just premature babies. And their issues are different. The

pathophysiology, the disorders, are different. The outcomes are different. Likely interventions to improve the outcome are different.

So why do we keep using this 2500 gram low birth weight? It's like -- That's my comment. Though it's important, I mean. But there are two big groups at least in there that we deny.

DR. WINKLER: Comments from anybody else?

MS. BROWN: Another comment. I actually think NCHS also reports 1500 grams or less. And I'm wondering which is really where the greatest risk.

DR. QUIRK: That's very low birth weight, not low birth weight.

MS. BROWN: Very low.

DR. QUIRK: They're by definition.

MS. BROWN: I understand. I'm just wondering that was not put in here. Why 2500, not 1500?

MS. THEBERGE: I believe it's because the 2500 was a CHIPRA measure and the 1500 was not. And we reached to the developer to ask him to submit this measure and they just decided to do this one.

DR. QUIRK: There might be another reason and it's because if you look at the incidence of premature delivery which is probably the major contributor to low birth weight, if you look at the subcategories of newborns, the rate of preterm delivery in the very low birth weight infant really hasn't changed in the last 20 years. The change in low birth weight, the increase in low birth weight and premature birth, has been in the 1500 to 2500.

And the March of Dimes and in my state, in New York, there are these major initiatives to stamp out late preterm deliveries. And they are a very distinct group of women. And the issues of the babies in the nurseries are very, very different. It

take a different skill set for the neonatologist to care for that late preterm baby compared to the very preterm baby, the very low birth weight baby.

MS. BROWN: So that argues for being able to track 1500 to 2500 in particular to your point which this doesn't differentiate. It doesn't divide them.

CO-CHAIR WEISS: Maybe I can shed a little light on this. I was on the task force that worked with AHRQ and CMS on the initial so-called core set of CHIPRA measures.

And what we were attempting to do in that effort was to pick up recognizing that states are up against some pretty tough budgetary times right now. And developing and fielding new measures was going to be difficult for the Departments of Health. We were trying to get at and use those measures that were most likely to be implemented and widely used by states. And this happens to be a measure that is widely reported which we

felt that it was necessary to pick up something in the arena of low birth weight. And this seemed to be in talking with the folks representing state departments of health mostly widely utilized.

MS. MARTIN: This is Joyce Martin from the National Center for Health. I'm here for the developer, Mary Ann McDormand. I apologize. I was actually online before, but you couldn't hear me.

DR. WINKLER: Okay. Thank you very much.

MS. MARTIN: Obviously you can hear me now.

DR. WINKLER: We can definitely hear you. Thank you very much for being here.

CO-CHAIR WEISS: I think Denise had a comment to add.

MS. DOUGHERTY: The reason why this was put into the initial core set was that some states actually collect data on the insurance coverage of the mother or the baby.

And other state Medicaid programs actually have developed algorithms that can be used to link the Medicaid roles with the birth certificate data.

So one of the improvements and enhancements that's foreseen is getting a standardized algorithm that could do that. And that would take the burden off of the states to try and get this data out of health records so they could actually perhaps once it gets validated rely on the data that's already collected under National Vital Statistics.

DR. LIEBERTHAL: Recognizing this measure is long-standing and kind of sitting in stone and is easy and maybe gets the ball rolling for the CHIPRA program doesn't make it a good measure. Jerry stated it much more eloquently than I could. But I think that perpetuating measures that no longer apply to our state of knowledge of medical care is not a positive.

DR. JENKINS: Can I ask how high

do we think for the states to go to the next step? Like is not BLBWs coded differently than LBWs? How hard is that to make the leap from under 2500 to the under 1500 and then the 1500 to 2500?

MS. MARTIN: That should not be a problem.

PARTICIPANT: It's a subset.

MS. MARTIN: Very low data is also collected in birth certificate data.

DR. WINKLER: Anybody else want to comment?

CO-CHAIR McINERNY: Is length of gestation also recorded on birth certificate data?

MS. MARTIN: That is information both on the gestation. The response is there's some concerns about the quality of this data is very controversial. Birth weight on the other hand is considered to be reported.

CO-CHAIR McINERNY: Thank you.

DR. WINKLER: All right.

DR. CLARKE: I'd like to ask Jerry how well, if at all, does that stratification address your issue?

DR. QUIRK: Oh, I think that's part of it. But the other part of it is you have to somehow have databases that you can stir so that you can get gestation age adjusted birth weight. Because that's how you get the fetal growth retardation.

The problem with that, however, that was just mentioned is that birth certificate data is kind of problematic when it comes to data that you have to derive. And that's frequently what the EDD is, the expected date of delivery, because if all the women knew their last menstrual period most of them wouldn't have gotten pregnant I think. And I think that they come late for care. So you don't have a secure sense of how pregnant they are.

But a weight is a weight. That's

the advantage to the weight. But this will -- But it's a problem because birth certificates will frequently in many state ask you by what method did you determine the due date. And that's a little bit better because then you can say "Well, it was a certain LMP" or "It was an ultrasound the first trimester" and that would be nice. But that's going to be hard to operationalize I think.

MS. BROWN: Jerry, can I ask you another question? A couple of years ago I was talking to some people in Delaware about this measurement issue. And they said one of the things that they were doing now a lot was separately out multiple births particularly from the assisted reproduction from sort of plain vanilla.

Is that relevant at all, that issue? Big enough or relevant to this proposed measure? It's the only thing I've ever heard. I just don't know how big an issue it is?

DR. QUIRK: Well, that's kind of emblematic of what you get into when you just mush together low birth rate and gestational age because the average length of gestation for twins is 37 completed weeks and for triples it's 34. But what happens if there was a loss early on. How does that affect the length of the gestation and growth? They are very complicated issues.

So I think at the end of the day to use the old quote, we don't want "Perfection to be the enemy of good." But we have to go in there with eyes wide open knowing what the limitations of the data set is and that we're never going to make that a perfect data set.

CO-CHAIR WEISS: Let me just ask the NCHS rep who is on the phone. Is this -- Does this measure only apply to singletons or are you picking up all births including multiples?

MS. MARTIN: I understand the way

it was developed. But does this include only in our national reports and we could modify it to be for singletons only. Is there some question that has to do with low birth weight.

CO-CHAIR WEISS: Kathy.

DR. JENKINS: I would just like to make the comment, perhaps the reverse of my comments on the prior measure, that I do think a lot of these issues are really about case mix adjustment or risk adjustment. And since this has only been proposed as a compilation indicator for a plan or a practitioner or a lower level I think some of them may be less important.

DR. BURSTIN: Two questions. So is this intended to be used, the level of analysis, as state?

DR. WINKLER: State region is.

DR. BURSTIN: Okay. State region.

DR. WINKLER: National, state, region.

DR. BURSTIN: It's not very clear.

The second question I have is there's clearly evidence given here of differences by race and ethnicity for this measure. So the NQF policy would suggest this is a measure that should be stratified. And if they have the data, one consideration for all of you whether you actually want to recommend that potentially as a modification to this, it would be a real shame to have this measure go forward and not have the advantage of in fact seeing where those disparities exist if possible.

DR. SCHWALENSTOCKER: They do get published every year, the low birth weight, at least by state and by race.

DR. HURTADO: I think there's a statement in the document that says that it can be stratified by any variable in the birth certificate.

DR. SCHWALENSTOCKER: That's correct.

DR. CHEN: I think Helen makes a

very good point. I have a little bit concern about I have a double personality when it comes to this issue about stratifying racial/ethnic data. There's obviously scientific evidence that African Americans would tend to have low birth weight babies mostly because of socioeconomic and maybe sort of racial prejudice and pressure.

But we're in a day and age where you have a lot of genetic markers that doesn't have to do with race and ethnic data. And I assume in the very near future we'll have better classification of the risk based on genetic markers rather than this racial/ethnic status.

I do think it's important to know that there's a difference and it's already known. But I don't know how important it is to perpetuate that sort of classification based on race and ethnicity particularly on low birth rate. I don't know. If it affected intervention or the amount of resources going

to different racial/ethnic groups then I'm a proponent for it.

But it leads to sort of biases and stereotypes and prejudice, then I'm not. And I don't know if we can sort it out. But I just want to leave it out there because that's my concern particularly for population data.

DR. QUIRK: That goes -- That's why you have to do multi-variant. I mean what's the contributor if -- In our population you're right. If you look at an African American population you've got more obesity. You've got more hypertension. You've got more diabetes.

And maybe that's what the issue is. Maybe the issue is not race. And if we could homogenize the racial complex of this country, then maybe it would be medically based.

The other is that -- A lot of that, too, you know, when you talk about preterm delivery an not insignificant number

of those deliveries are not the result of uncomplicated premature labor or rupture of the membranes. A lot of them is an intervention by an obstetrician because of the co-morbidity in the mother or a co-morbidity -- the recognition of severe growth restriction in the fetus. It gets to be a mess after a while.

But I agree wholeheartedly with Alex. I think that race is a marker for something else in our society.

MS. GARY: I want to agree both of my colleagues and also at the same time point out that when you look at low birth rates among African American women it has been a sustaining kind of statistic for years and years and years. And we even know that middle class African American women who get good prenatal care also tend to have complications. And we don't quite understand that.

So I think we need to identify race and ethnicity and then break it out and

do some substratification to see what the real issues are. And I think it's more than socioeconomic because we know that the data don't change across socioeconomic groups among African American women.

Is it nutrition? Is it the Institute of Medicine unequal treatment? Is it in the clinical encounter? We don't know that and I think for us not to identify it is to say that we are denying it.

I think we need to identify it. We need to specify what we need to unravel those variables and to state what's going on. The problem in the past is we've identified it but we've done nothing about it. And I think if we don't measure it then we will have another excuse to not do anything about it. And I think it's a serious problem.

And even the other issue, too, is that those women who are exposed to violence in relationships. We know that they tend to produce low birth weight babies. And that's

not identified here. And, of course, those populations are African American women, Hispanic women and American Indian women.

I think it's a very complex issue. But I don't think we should back off from it because if we do the outcomes may remain as they are now and we can still say we don't know why. And I think it's time for us to go forth and to unravel those complex issues.

DR. HURTADO: I don't think that the way the measure is specified doesn't allow for that. Actually, it specifies that you can stratify by that variable and whatever else is on the birth certificate. So they're not advocating for what I can see here to not stratify. Rather they're saying that it is possible to stratify so that they can look at those factors that are on the birth certificate, not others that are not on the birth certificate.

MS. GARY: So what does that give us? Where does that lead us?

DR. HURTADO: That you can look at race and ethnicity accuracy because -- maternal age and maternal education and whatever else is there. They're not saying that you should not do it.

DR. GLAUBER: And obviously the human cost of low birth weight is what the primary importance of this measure is. But as we know we are increasingly concerned about the affordability of health care. I mean this is one of the major drivers of health care costs in the pediatric population is the care of premature and low birth weight infants. I think that needs to be acknowledged as well.

DR. QUIRK: A concern going forward when we walk through this is going to be how good is the data. If you're dependent on birth certificate data, it's terrible data.

DR. SCHWALENSTOCKER: Hi. This is NCHS. Birth weight as appears on the birth certificate have been shown for decades to be very accurate and reliable.

DR. QUIRK: But not race. Not comorbid condition.

DR. SCHWALENSTOCKER: I'm sorry. I would disagree on race. Race is self-reported by the mother. I think you're thinking about the death certificate and infant death race data is problematic but not birth certificate data.

DR. QUIRK: Not the birth weight on a birth certificate.

DR. SCHWALENSTOCKER: Birth weight is very well reported.

DR. QUIRK: I understand that.

DR. SCHWALENSTOCKER: And the birth race is self-reported by the mother.

DR. QUIRK: But we're talking about -- A minute ago we were talking about staying any field on a birth certificate and being able to use it in an analysis and I don't think that we're there yet.

The other thing is that a lot of states add these additional worksheets behind

the minimal data set on a birth certificate and I run an OB service with 4,000 deliveries a year. So it's kind of medium size. And the residents refer to this data as the birth novel. It takes a very long time to fill out and it's done 24/7 with various amounts of sleep, none of which contributes to the accuracy of the recording of all of the fields on all of these forms. And nobody ever goes back and audits the quality of that data in a local or regional level.

DR. SCHWALENSTOCKER: Well, actually we do try to audit the quality of the data and there's no question that some of the health and medical information on the birth certificate is questionable. And it varies a lot by state. But we're talking here about birth rate weight and actually plurality and those are understood to be very well reported.

DR. WINKLER: Okay. I think -- Anybody else have anything to -- I heard two things that I think we want to kind of be sure

we're all in agreement on. And one was the possibility of restricting this data to singletons. That was brought up and I don't know how the whole group feels. It sounds -- Our developer said that was a possibility. Or just leave it open as population data for all births.

And then the issue around stratification for the disparities issue that can be the recommendation that goes with the measure as is and we recommend it's stratified by disparities using the data collected on the birth certificate without getting into the issues of all the other data fields that may be there.

CO-CHAIR WEISS: Reva, I think I was the one who asked about the singletons and I wasn't proposing that it be stratified or that we eliminate the data on multiples, just that it be differentially reported.

(Off the record discussions.)

CO-CHAIR McINERNY: Ready to vote

on this?

DR. WINKLER: Well, that's what we have to clarify. That's what I'm trying to clarify what exactly you're saying yes/no to.

The measure as it is just less than 2500 grams, none of the other things and with the recommendation to be stratified by the race and ethnicity because it's indicated, none of the other modifications we've talked about or would like to see. How many think that that's important to measure and report? Would meet the criteria just as it was submitted?

PARTICIPANT: Depends on what you want to do with it.

(Off the record comments.)

DR. WINKLER: What it is now. Realize that they say they can stratify it. So your recommendation would be that it be stratified.

PARTICIPANT: By?

DR. WINKLER: By race and

ethnicity.

(Off the record comment.)

Right. For the disparities part right now. Okay. So that's the measure as submitted. All right.

DR. QUIRK: Can I ask a question before -- Maybe it will help them form, other people. Why are you collecting this data in the first place? Because maybe that will inform what data you want to collect. What are you going to do with this data?

If we say, let's collect every birth certificate on 4.2 million deliveries a year, unrestricted by plurality, based on weight, ethnicity and whatever you think is valid on a birth certificate. What are you going to do with that data? Because that should drive what it is you want to collect.

DR. CHEN: I can't speak for the developer. But I think for me the reason we collect this data at the population level is really for WHO type purposes where we know

that US has a really negative rate when it comes to low birth weight babies. And it's important to perpetuate that so we can improve on that.

DEVELOPER: Hi. This is the developer. I guess I didn't understand the question because these data are already collected every year and happen --

DR. QUIRK: I guess what I'm asking is why is this on the table today if that's already the case. And are we doing something different? I mean, you know it's kind of like your ruptured appendix. If you just keep collecting the same data and every year show the same thing, you know, come on.

CO-CHAIR McINERNY: I think by trying to determine how many -- what's the birth weight for singleton births versus multiple births I think that's an important improvement on the measure recognizing that with in vitro assisted fertilization we're seeing many more multiple births and that's

making the birth weight numbers, low birth weight numbers, go up. And I think that's somewhat of an artificial number.

It would be nice to see how many singleton births are below 2500 grams over time and see whether that's getting better or worse.

DR. JENKINS: I guess that your question is really back to this core issue about what does it mean when we say something is NQF endorsed because that's what we're here at this table to do. We're not here to talk about what the government is going to continue to collect or not collect or plans or anyone like that.

What are we really saying when it's NQF endorsed? And I guess what I thought and maybe I'm wrong is that when we say that we're saying that when there's a chart somewhere with this measure as specified that it is an indicator where if the number is higher that group is doing better on that regard. And if

that number is lower they're doing worse on that regard for comparable benchmarking purposes.

And that's I think a performance indicator is. It's an indicator of performance of someone. In this case it's a population based performance indicator of the country or a state or a region. In the last discussion, we were asking it whether it was at the level of a plan.

So if that's not what we're doing here, I need more clarity about that.

DR. WINKLER: I would say you're accurate. NQF is looking to identify measures that meet our evaluation criteria for the purposes of public reporting and calling that performance measurement. Correct.

CO-CHAIR McINERNY: I think that's a good question, Kathy. And I think that based on some of the conversation we've had endorsing the measure as it is, an old measure which we feel has lots of problems due to some

changes in what's happened over the more recent years, is maybe not something NQF wants to do.

On other hand, if we try to improve the measure by trying to separate out singleton births number one and two, trying to look at less than 1500 grams, then we've improved the measure and that to me is something that may be NQF would like to endorse.

DR. WINKLER: You do have the option of making your recommendation conditional on these other refinements if you will. Frankly, what you're doing is just breaking it down a little bit more rather than making any wholesale changes. And the developer indicates that the data is available. So looking at it from that perspective isn't a feasibility issue.

So I guess the question is do you feel that this topic is important to be moving ahead with a recommendation of any kind of

version of the measure. So that's the first step.

(Chorus of yeses.)

Good deal. Nancy or Ellen, anything you wanted to say on this subject?

(No verbal response.)

Okay. Now I heard a couple or recommendations for the measure and was limited to singletons.

(Off the record comment.)

Differentiating -- So you want to stratify it by all and singletons, so all births versus singletons. So you're talking about multiple stratifications I think in the data. So it's all versus singleton. It is the less than 1500 and the 1500 to 2500.

(Chorus of yeses.)

Okay. And by race and ethnicity. Okay.

DR. ZIMA: What about differentiating on the age of the mother? Can that be done also?

DR. SCHWALENSTOCKER: Yes.

DR. ZIMA: Because that would be important from a community standpoint and teen births. And if this is population, then we're looking at the community's ability to decrease teen births and increase birth weight.

DR. SCHWALENSTOCKER: Yes. Actually that is available and others also.

DR. WINKLER: Do you have any specific recommendations on how you would break those ages down?

DR. SCHWALENSTOCKER: Under 20 and then maybe in five year age groups and then maybe 40 plus.

MS. BROWN: If I could suggest I think that the risk of low birth weight really doesn't attach as much to older teens and I don't think we can settle this here. I think it's 15 and under or under 15. And there's an answer to that. But I think the point is well taken, but I don't think it's all teens. It's really the younger teens.

DR. QUIRK: It's the younger teens. Younger teens are more likely not to get prenatal care. And that's most seen in girls under, young ladies under, the age of 17. So you're back to the prenatal care issue.

DR. WINKLER: Okay.

DR. QUIRK: But women who -- Teens who come in for prenatal care don't have more co-morbid outcomes, a little bit more anemia and if they're under 15 they have a higher cesarean section rate. That's it.

DR. WINKLER: Okay. Is the age of the mother a deal breaker?

DR. QUIRK: No, because you've already said that the birth certificate data is available. That's probably one of the accurate fields.

DR. WINKLER: Okay. Right. So stratification by race, ethnicity and possibly by maternal age. Those are the recommendations to the measure you would think

would improve it and make it more usable.

DR. QUIRK: Right.

DR. WINKLER: Since it all seems to be equally feasible.

DR. QUIRK: Yes.

DR. WINKLER: And more scientific acceptable because -- Kathy?

DR. JENKINS: Because understanding the variation according to the stratified variables is very important to understand who is doing better and who is doing worse in this regard.

DR. WINKLER: Okay. So given these sort of conditions I guess if you will or revisions that you would like to see to the measure how many here feel that it would meet the scientific acceptability criteria but only with those?

(Show of hands.)

All right. That's everybody here.

Ellen, Nancy, anything you want to say?

(No verbal response.)

Okay. Usability. Feasibility. Then this would be a conditional recommendation of the Committee. You would recommend the measure if these things can be incorporated into the measure and that would be -- those revisions would be what you recommend. Go ahead for endorsement. We're all in agreement with that. How many vote yes to what I just said?

(Show of hands.)

Sixteen. Ellen and Nancy?

DR. SCHWALENSTOCKER: I vote yes.

DR. WINKLER: Nancy?

DR. FISHER: Yes. I didn't realize I was on mute.

DR. WINKLER: Okay. That's a unanimous vote in favor. Okay. So we will follow up with the developers and see if we can put the wording together with the measure to add in those things and see what we can come up with. And it will come back to you

for you to see for final determination.

DR. WINKLER: Measure No. 1417, screening for hyperbilirubinemia.

PARTICIPANT: 1401.

DR. WINKLER: Oh sorry. 1401.

DR. SHEPHERD: Hello. This is Dr. Art Shepherd. I'm representing that particular candidate measure.

DR. WINKLER: Oh, wait a minute.

(Off the record discussion.)

MS. THEBERGE: Sorry. That's the revised agenda. That's not the one that was on the --

CO-CHAIR McINERNY: No.

DR. WINKLER: Sorry. I missed it too.

MS. THEBERGE: There is a revised agenda on your flash drive with a couple of last minute changes. Sorry about that. I missed announcing that this morning.

DR. FISHER: I can't hear what you're saying.

MS. THEBERGE: Sorry. There's a revised agenda on the flash drive that was handed out at the meeting. I apologize for not mentioning that earlier.

PARTICIPANT: What's the name of the --

MS. THEBERGE: Maternal depression screening which is an NCQA measure, Measure No. 1401.

PARTICIPANT: What's the revised agenda?

MS. THEBERGE: It should just be whatever the agenda is on the flash drive should be the revised agenda.

(Simultaneous comments.)

Sorry. Yes. AG, CHQM no SC meetings.

DR. WINKLER: Okay. I didn't know that.

MS. THEBERGE: I'll pull up the title for it. It's the one dated 11/05/2010.

So, Dr. Shepherd, you measure will

be next after this one.

DR. SHEPHERD: Okay.

DR. FISHER: Aren't both of those measures mine?

MS. THEBERGE: Is that Dr. Fisher?

DR. FISHER: Yes.

MS. THEBERGE: Yes, they are.

DR. FISHER: And since he's on the phone, wouldn't it be better to do this measure first?

MS. THEBERGE: Sure. Whichever.

DR. FISHER: Because would that be a problem for people?

MS. THEBERGE: Do 1417 would be the --

DR. SHEPHERD: That would be most gracious. I would be very grateful to you.

DR. WINKLER: Okay. All right. Fourteen seventeen is hyperbilirubinenmia screening in term and near term neonates. This is from work group two.

PARTICIPANT: Which measure are we

doing?

DR. WINKLER: Fourteen seventeen. All right. Just by way of introduction this measure is the percentage of newborn infants greater than 2500 grams of birth weight who receive either serum or transcutaneous bilirubin screening prior to hospital discharge.

And, Dr. Fisher, this is your measure. Correct?

DR. FISHER: Yes. So just to give a summary of what I think.

DR. WINKLER: Yes.

DR. FISHER: Okay. Looking at this measure of looking at screening all infants over 2500 grams who are discharged from the hospital for hyperbilirubinemia, when I looked at this measure I was not, from what was presented, convinced that although the severity of having connectors to bilirubin encephalopathy has dire outcomes. I was not convinced that this was a problem or a leading

cause to mortality and morbidity as it exists today.

When I looked at the information provided the American Academy of Pediatrics emphasizes difficulty in judging early stages of -- in people of color. But when I looked into this further this seems to be an ongoing problem with other nations, not in this nation. And I couldn't find any data that supported that for the U.S.

Also my other concern is that there was not a -- the U.S. Task Force recommendation that evidences any physician to recommend this widespread screening. So I was not convinced from reading this as presented that it did have a high impact of access to health care and needed to be --

DR. SHEPHERD: All right. May I speak to that?

CO-CHAIR McINERNY: Certainly yes.

DR. SHEPHERD: I understand your concerns. But you know as a practicing

pediatrician and neonatologist I would disagree with the assessment that visual based screening in infants of color is not a problem in the United States.

You know, I live in Charleston, South Carolina and we have a lot of infants of color here. And I know from experience that it is very difficult to judge clinically or visually evidence or degree of hyperbilirubinemia.

And it is an old and long-standing tradition that practitioners have the false sense of security that they're able to say "Well, if they're yellow to the eyes and -- If it's yellow to the chest it's -- If it's yellow to the toes, then we need to do something about it." And there are papers that demonstrate that that woefully inadequate way to assess a degree of hyperbilirubinemia at the time of discharge.

And I think one of the values of this particular measure, and I have been on

the discussion for the last hour and a half, I think that counter-distinction to the other measures the thing that's great about this measure is it really does evaluate process in a very multi-pronged way. And if you're trying to sort of nail down some outcomes that actually evaluate clinical processes that occur within the health care organization that are feasible, usable and valid, this is an excellent one.

Because in order for this to work, in order for this to be successful and in order for it to achieve its desired outcome, it has to do a number of things. It has to exist in a health system that has functioning protocols that guide a majority of newborn infants. It has to have a valid system for educating nurses, both one time when you roll it out and also continuing for new hires and people that are being reeducated in the workplace. It has to have a valid system of educating physicians that care for infants.

It has to have functional multi-disciplinary communication throughout the care provider network. There has to be a functional system for making contact with patients after they're discharged especially over the weekends, if they're discharged on a Thursday or a Friday and you're worried about the jaundice they're going to have on Saturday or Sunday.

And, ultimately, there has to be a successful program of perinatal peer review for both nurses that take care of babies and physicians that take care of babies to reeducate and guide performance when people are noncompliant about follow-up. You know we've really gotten away from an appropriate level of follow-up care for newborns.

A lot of people still function with the two weeks/two months rule. And given the fact that so many of our facilities are trying to encourage an increasing rate of breast feeding, I believe that's going to be a

Joint Commission on Perinatal Care core measure.

We're going to have hopefully a lot more babies that are breast feeding and consequently quite frankly a lot more babies that are at risk for severe levels of hyperbilirubinemia. And having this process measure in place at a particular facility puts pressure on the whole care provider team to make sure that they've got a functioning loop that closes adequately to make sure that babies get the appropriate amount of care in that critical post discharge period of time and also avoid the potentially catastrophic consequences of severe hyperbilirubinemia.

DR. FISHER: I think what I would like to say is that I don't feel that the way the measure is presented that it is addresses the problem specifically that you say about infants of color being difficult to assess hyperbilirubinemia. And I'm not saying that it is not a problem.

What I'm saying is that the measure as presented I do not feel shows the justification for everyone. I don't think it targets or addresses the single problem that was presented. And that is my concern about not knowing the incidence or where the problem is why we would have to measure everyone as a way to address the problem, whether or not to leave it up to the practitioner about who needs to be tested before they leave depending on what they see as the problem. If you are equivocal and you don't know what the problem is, say you're not sure. I'm not sure it was justified why you had to say everyone.

DR. SHEPHERD: Well, the reason why you have to screen everyone is that doctors and nurses are not very good at determining who's at risk and they're not very good at planning follow-up based on risk assessment unless there is universal screening. You know people are -- If you're depending on people to look at a baby and

eyeball and determine whether or not they need to have a bilirubin prior to discharge, there are studies that demonstrate that they're going to be wrong a substantial number of times.

DR. FISHER: Yes. That's not what I'm saying.

DR. SHEPHERD: Okay.

DR. FISHER: What I'm saying is you have babies of all different colors in a nursery.

DR. SHEPHERD: Yes, we do.

DR. FISHER: And there are some babies you can look at and you can assess whether they are jaundice or not. And what I'm saying is in this presentation it hasn't justified to me why I should be testing those children and why should I not be targeting the ones that are equivocal or I feel like I can't make a judgment about.

So what I'm saying is as presented the data doesn't show me when the increased

cost of doing this and to test everybody and to do the universal screening that it justifies it being done. What I'm saying is that as a training pediatrician and having looked at that there are things that we do that are equivocal and you're not sure about, then you test.

I just haven't seen the justification on the paper that this is something that you bring in universal screening because those predictors as we know it are really the rare condition. And I'm just saying I don't see as it's presented in the paper.

DR. SHEPHERD: Well, I believe it's a rare condition, but it's actually on the rise. And it's on the rise because physicians are not doing a good job with risk assessment or visual screening.

DR. FISHER: If those papers were not here to show that, there was not the incidence to indicate that. But this is on

the rise. There is a trend and where the problem is and why it should be targeted and U.S. Preventive Service Task Force says, "No, this should not be done." I'm just saying that as presented there isn't the argument or the evidence presented to support the cost.

DR. SHEPHERD: I understand. Okay. I see what you're saying.

Now the AAP, the American Academy of Pediatrics, does recommend some sort of systematic assessment before discharge for the risk of hyperbilirubinemia. That's their sort of blanket recommendation. And their recommendation is sort of -- It's certainly ambiguous exactly what their idea about systematic assessment is.

But I think if the AAP recommends that universal systematic assessment before discharge and we know that clinicians are fallible when it comes to a visual assessment about degree of jaundice, then I understand what the U.S. Task Force. But that's a little

bit at odds with what the AAP says.

CO-CHAIR McINERNY: Can we go around the table? We have a lot of questions.

DR. GLAUBER: Yes. So to get me to the point of endorsing this measure as an important process measure I'm looking at the type of evidence. We see observational study. I would at last want to hear that there's been a case control study of a cohort of babies readmitted with severe hyperbilirubinemia that compares them to appropriate reference population and shows that one key difference between these two populations was the presence or absence of screening at discharge.

So my question is have those studies been done. And, if so, what was the magnitude of that increased risk?

DR. SHEPHERD: And you're talking about other than the HCA study. Or do you have -- I don't know what you have.

DR. GLAUBER: Well, we only see

here that there's been observational studies. So I'm just asking you to comment on what the nature of that study is and the strength of evidence that provided specifically to the point that the presence of absence of screening at discharge differentiated babies with severe hyperbilirubinemia.

DR. SHEPHERD: Gotcha. Well, the study that we participated in which was published in Pediatrics in May of 2010 looked at over a million babies, a million infants, who were born in 116 HCA hospitals between May of 2004 and December of 2008. About 130,000 of those were delivered before implementation of universal bilirubin screening and 900,000 of them were delivered after implementation of the screening program. So it's sort of historical control.

With the program of universal screening in place, the incidence of infants that had a total bilirubin in the 25.0 to 29.9 milligram per deciliter to climb from 43 per

hundred thousand births to 27 per hundred thousand births and the incidence of infants who had a total bilirubin of greater than 30.0 milligrams per deciliter dropped from nine per hundred thousand to three per hundred thousand. Of course, both of those are statistically significant declines.

The first one a p value of less than 0.0019 and the other one is 0.0051. The changes associated were small but statistically significant increase in phototherapy use which probably accounts probably the increased awareness of the issue and the --

DR. WINKLER: We're having trouble hearing you.

DR. SHEPHERD: Sorry. I don't know why.

And you don't have that information. Is that correct? Hello?

DR. QUIRK: I would like to know. This is kind of like a -- I know it's a

steak, but there's no sizzle here. So the question is if there's an article from May we should have known about it beforehand. That would help us with our homework before we came here.

The second thing is it's interesting that we're going to do this in the same group that's going to look at blood spots for metabolic disorders because these -- What we're doing is a heel stick. We're doing a delivery. We're satisfied with the fact that maybe only one in 40,000 babies is going to have X. But we do it anyhow because it's catastrophic outcome if we don't diagnose it.

A heel stick bilirubin is I guess safe because we do it for newborn screening to add it to the panel. It's accurate. It does measure bilirubin. But it doesn't do two things. It doesn't tell me -- All it tells me is today what the bilirubin is. It doesn't identify the baby who might develop hyperbilirubinemia in the next week or ten

days. And in most of the country the babies get discharged home on the first or the second postoperative day for the -- I'm sorry. Not postoperative.

PARTICIPANT: Postpartum.

There are so many sections it's always postpartum. So on the first or the second postpartum day and is that time enough? Because when I went to medical school, newborn hyperbilirubinemia term was third and fourth day stuff. So is this the time to screen?

DR. SHEPHERD: Well, actually a successful program of hyperbilirubinemia screening is partnered with plotting that value at 24 hours against what we call the Bhutani Nomogram which is a nomogram that identifies or stratifies risk for severe hyperbilirubinemia based on the value of the bilirubin at 24 hours of age. And so you wind up doing an evaluation either serum or transcutaneous. The great thing about

bilirubin determination is that it doesn't require blood. It can be done with a transcutaneous bilimeter. So it's noninvasive. And you plot that on this Bhutani Nomogram which is divided into, stratified into, four risk levels based on a population distribution of subsequent development of severe hyperbilirubinemia.

And so there is a risk stratification that occurs at 24 hours of age based on that bilirubin at 24 hours of age. And then there is subsequent to that a specific follow-up plan that is based on the risk stratification that occurs at 24 hours. So if babies are in the less than the -- Or in the less than 25th percentile for that bilirubin, then they fall into the low risk category and they have routine follow-up two, three, four days down the road. Sooner if they're breast feeding.

If they're in what we call Zone B or the low-intermediate risk criteria those

babies usually need to be seen within 48 hours of discharge. If they're in Zone C which is high-intermediate risk which is 75th to 90th percentile, those babies are seen back within 24 hours either in the office or for a follow-up bilirubin level so that you can have two points on the graph and be able to plot rate of rise. And then babies that are in the greater than 90th percentile are in Zone D and those babies are obviously at serious risk and need to be very, very closely followed.

So it's the entire thing. It's not just the 24 hour value. It's the 24 hour value that's associated with a population based risk stratification nomogram that then directs the length of time between discharge and follow-up. And that's how these babies get back into the system in an appropriate amount of time to get either home phototherapy or in-patient phototherapy before their bilirubin levels are high enough so that they can be at risk for Kernicterus.

DR. QUIRK: So what you're proposing then is that there is universal screening and that depending on what are your four or five strata the newborn falls into they get shunted down a different path for follow-up.

DR. SHEPHERD: That's correct.

DR. QUIRK: So that the reliability or the accuracy of the test we know is accurate and the reliability of it for -- the positive and negative predictive values of the various numbers is repeatable and reliable.

DR. SHEPHERD: That's correct.

DR. QUIRK: Thank you.

DR. GLAUBER: I have a follow-up question. I want to ask what's the nature of the evidence. And just to clarify something, you cited pretty convincing historical trends about decreasing rates of severe hyperbilirubinemia since universal screening was implemented. But you also said earlier on

that rates of Kernicterus are rising. Wouldn't we expect that if this program is successful that coincident with this there should be lower rates of Kernicterus?

DR. SHEPHERD: Well, yes. But currently there isn't universal screening in place. You know, you're talking about a million babies within the HCA system. But that still represents only five percent of the annual birth core. So you're talking about a high risk, low frequency catastrophic event.

If you implement a successful strategy for screening and intervening, but it only reaches five percent of the population you're not really going to have the impact that you would otherwise have if you had true universal screening across the entire birth corridor as opposed to just babies born at HCA hospitals.

DR. WINKLER: All right. Does anyone else have any comments on this?

(No verbal response.)

Then I think let's move to the Committee's assessment. Does this measure meet the criteria for important to measure and report and the subcriteria being impact, the opportunity for improvement and the evidence and relationship related to outcomes?

DR. SCHWALENSTOCKER: Reva, this is Ellen. I do have one question.

DR. WINKLER: Ellen, can you speak up just a little bit? We can barely hear you.

DR. SCHWALENSTOCKER: I discovered that I need to pick up my phone. I do have a question and I don't know if anybody is there that works with the Academy can answer this question. But do you know where the Academy is with regard to universal screening versus other methods? And I wondered if there were any guidelines in place.

CO-CHAIR McINERNY: The question is has the Academy of Pediatrics recommended universal screening for bilirubin and the answer to that question is no.

DR. JENKINS: So this is very similar to the issues in congenital heart disease around oxygen saturation catastrophic misses. But most of the conversation has been about exactly the questions the panel is asking here which is what are the missed population in the country, what is the number of babies that will be found with a universal screening protocol, what are the consequences of the false positive rates, what's the overall expense and burden on the system compared to other things.

And that's where the Universal Screening Task Force and all that who vet all these really true population based screening questions usually are having their conversations. And I personally feel a little uncomfortable setting out a universal screening plan as a population indicator without more.

And the comment that that the Academy hasn't endorsed that is making me

uncomfortable. And I'm feeling like I'm passed my point of knowledge on the subject about what is appropriate.

CO-CHAIR McINERNY: Let's vote.

DR. WINKLER: All right. So any other comments?

(No verbal response.)

All right. So how many on the Committee feels that this measure meets the importance criteria?

(Show of hands.)

Nancy and Ellen?

DR. SCHWALENSTOCKER: I'm sorry. Yes, for importance. This is Ellen.

DR. WINKLER: Okay. Nancy?

DR. FISHER: Written, no.

DR. WINKLER: Okay. And how many at the table vote no?

(Show of hands.)

Fourteen. All right. That was one yes and 15 no's.

CO-CHAIR McINERNY: Try one more

before lunch.

DR. WINKLER: Okay. We are at a logistics question. We are scheduled to do just a brief public comment and then lunch. Does anybody need a break or do we want to try and do one more measure?

CO-CHAIR McINERNY: All in favor for one more measure?

(Show of hands.)

DR. WINKLER: All right. One more.

DR. SHEPHERD: If I could just make one sort of comment before I go. You know, I'm sort of new to this whole process. But I'm certainly affected by it on a daily basis. And you know if you're looking at measures to evaluate processes that make health care institutions better or health care providers better, it's really difficult for me as just an enduser of the product which is your target audience essentially to understand why low birth weights which means essentially

nothing to me about process. Qualifies and universal screening for hyperbilirubin doesn't.

And so as you move forward you need to do a very good job educating the enduser population about exactly what it is you intend to influence through the use of these numbers and why endusers should buy into your process. Because as an enduser I'm completely mystified.

DR. FISHER: I think that what the problem is that you gave us a lot of information that is not in your justification for why you want to see it. And so for when you're talking about you want the measure we need to know what the trend was, what's the incidence of what's going on, what the cost is of the problem.

And you mentioned a lot of things that were important but they were not put down in the reason that you gave for the impact. And we're judging it just by the way that --

The same thing is if you want to go for a grant. When you go for a grant, what people look at is what you put down for your reasons for doing it, your citations behind it, where you got the scientific evidence. And that was not clear in the presentation.

DR. SHEPHERD: Understood. But I'm just saying that as a end user the presentation is about 2500 grams didn't mean much to me either. You know, as a person who sees babies that weigh 2501 grams and 2499 grams, you know, I don't think about those babies as being the culmination of a particular process that can be influenced because it's watched more carefully.

So you just kind of have to help all of us on the other end figure out what we're going to do about that number and how we're going to change that. Because otherwise it's not a useful process measure. That's what I'm saying.

CO-CHAIR McINERNY: Well, thank

you for your comments. But we now need to move on to -- We're going to do a measure hopefully before lunch, 1401, maternal depression screening which is an NCQA measure. And I believe we have -- Do we have one of the developers on the phone or here?

Here.

(Off the record comment.)

Okay. And Dr. Fisher, did you want to lead with your comments on this please?

DR. FISHER: Yes. I'm looking at the maternal depression screening. I think that it's an important problem. I think that many times it does get missed.

My concern with this measure is when you look at who is responsible. Is it the pediatric doctor? The OB doctor? Or the family practice doctor? And if they are all responsible because no one can say who is primary or responsible, does this lead to duplication of services? Or does it lead to

no one doing it because no one is responsible?

The other thing I wanted to point out is it was in here that this measure by the U.S. Preventive Task Force says it needs to be measured in and systems in place to assure accurate diagnosis, effective treatment and follow-up for the general population. And to me that means that you have to have it within a system where it's being measured.

But if you're only measuring what's in the system are we really affecting people that are in a special system who are only going to be seen in a small practice? And that's also important, too, because if I'm the pediatrician and I decide to do the screening or the family practice person, I mean, the pediatrician, I only have the child's records, not the mother's records. And I don't know if it's been done or not.

So I think it is an important issue. I just wanted to bring up some of the points that I saw in reading about the

measure. Thank you.

Are you there?

DR. WINKLER: Yes, we're here.

CO-CHAIR McINERNY: We're deep in thought.

DR. FISHER: Okay.

MS. BROWN: This is Sarah Brown. I wanted to ask two questions about the measure to just display my total ignorance. Is there any evidence that screening for maternal depression leads to effective treatment? And, secondly, is there a standardized screening tool? I mean if we say screening --

CO-CHAIR McINERNY: Yes.

MS. BROWN: There is a standard?

CO-CHAIR McINERNY: Yes.

MS. BROWN: All right. Then the first question. What do we know about the effective screening?

CO-CHAIR McINERNY: I think if you

look on page four, the U.S. Preventive Services Task Force gives us a recommendation of screening and it calls it a grade B recommendation which I think is a pretty good recommendation.

As a primary care pediatrician, we've wrestled with this over the years. And I think ten years ago most of us would have said it's not our problem. But now as we really look more carefully at our role as primary care pediatricians in trying to provide the best outcome and the best environment for children, maternal depression is clearly an important adverse event. And we feel that, yes, we need to do something about it.

I agree though that the problem is what is that something to do. Most of us obviously are not going to be treating the mother for maternal depression. And so what we need to do probably is to make a referral and I think that's a very good first step.

Now the problem is what does the mother do with that recommendation and then how do we follow up on that. I think that's where things get a little bit sticky to say the least.

But I think that more and more pediatricians are coming around to the notion, yes, it is important to screen for maternal depression. The Academy of Pediatrics has recommended that we do this along with the USPSTF.

DR. GLAUBER: And to just echo your point, material depression is not just something that affects the mother. So the issue of accountability it's something that's going to affect the infant's welfare and development. So if you're caring for the child you need to know about that and how you monitor their development.

And to the issue of feasibility, you know, I come from a state where the state Medicaid program has mandated universal

screening of children in pediatric primary care for behavioral health conditions. And by and large the pediatric community has accepted that for all kids, not just Medicaid kids, and has pretty robustly implemented to systematic screening by different questionnaires at different ages.

So it would be very straightforward to extend this to doing an Edinburgh for the two weeks or one month visit.

CO-CHAIR McINERNY: I forgot to ask a second question. The Edinburgh screening test is a pretty simple ten questions screening test that's readily and easily administered. Usually in some places we do it more than once in the first six months of life.

MS. BROWN: But can you also address this issue of what we do know about the results of screening? Does it change the care of the new mother? Does it lead to a

decrease in maternal depression? I have no idea.

DR. QUIRK: I think you can say that it's a chronic condition. So it's a chronic disease. You know, postpartum depression is just a depression diagnosed in the postpartum period in the vast majority of cases. So that's why it's recommended that there be screening done during the pregnancy so you can get the ball rolling. And then but you get them into a system of care and it's as effective for that woman as it is for me if I'm depressed and see a shrink. All right.

I mean depression is a chronic disease. There are treatments for it if you get the diagnosis. So there you go.

Now the other issue though is psychiatrists are pretty pernickety about sharing information with other people about the diagnoses of their patients. So I think there are real issues about if I'm one of those obstetricians that screens that patient

and I have made that diagnosis, you complicate the care because I'm going to have to get the explicit informed consent of the mother to communicate this to the pediatrician because the pediatrician is not a subsequent caregiver for her. Okay.

It's easier -- She can sign the consent and I send her to a psychiatrist or a clinical psychologist pretty easily. But there may be real obstacles in certain jurisdictions with communicating that to pediatrician. And that gets into the issue of who should do it and how do you move that information around. That's the pragmatic thing.

DR. PERSAUD: I'm just looking at this measure and I mean there are two parts of it. One is whether they were screened. And the next one is and proper follow-up performed. So there are two bits of information that have to come. So it's in the pediatrician's office. I mean my first reflex

and I'm in a large system we're almost there is, okay, we'll just screen. But then -- and I didn't read the rest of this measure -- how are you going to pick up and follow up was performed. Because a limitation if the child payor has to provide administrative data is that I'm -- I can't even get it on pediatric patients from the mental health people. I am not going to be getting it on mom.

DR. QUIRK: Right. It's a real problem.

DR. BERGREN: But you're going to be able to evaluate the infant and whether or not environmental changes have taken place to support the mother and provide the proper social interaction in the family.

DR. PERSAUD: Well, that all just depends on what you define as "and proper follow-up."

DR. BERGREN: Right.

DR. LIEBERTHAL: Currently, the insurance companies and the state of mental

health in general is so poor that on a feasibility level completing this is very no feasible. It would be getting that first part of knowing how many mothers have maternal depression might push the industry to have adequate care services.

But at the moment you get the information and there is this big question that comes up. What do I do with this now because now I know something? I'm going to be seeing this mother at regular intervals. There is no system.

It's the rare mother who has the insurance to get into good mental health care or the private resources. So I de facto become the mental health professional as the only one who sees the mother regularly. It's a real can of worms.

DR. RAO: I just -- I see this as a child health measure and that's the most important thing.

PARTICIPANT: So do I.

DR. RAO: It's almost like screening for lead, you know, in the environment. Did the mother have maternal depression screening? So I think the issues of a fragmentation of care and follow-up to me are less important. It's true.

I think a lot of pediatricians, people who care for child, are going to miss depression in the mother. But this is something they ought to be doing even if they can't follow up with it and if they can't treat it. So that's just my perspective.

CO-CHAIR McINERNY: What do you do with the data?

DR. RAO: Well, that's a good question. I mean I think once you have data that demonstrates that people are not doing this so much I mean you could educate pediatricians first of all, child health care providers, that they ought to be focusing more on screening for maternal depression as part of the environmental assessment for children.

CO-CHAIR McINERNY: There is I think a little precedent in that when it was discovered that the incidence of children with mental health problems had nearly doubled over a period of time between the 70s and the 90s. Then the Surgeon General really became aware of that and called for improved programs to try and improve the mental health care for children with mental health problems.

And I think if we can do similarly for maternal depression, document the significance and the incidence of it, then hopefully that will lead to development of programs which I agree currently are not very readily available.

DR. PERSAUD: I'm looking carefully at the numerator details here and I agree completely with Goutham around that this is a child health issue, the issue of screening and providing psychosocial support and referral for the mother. I take issue and I feel it's maybe premature to stress the

pediatric system out right now when we know the infrastructure is poor regarding the follow-up.

I feel like it's going to happen anyway because the pediatric system when they screen tend to make referrals. But there is a part of it that I'm just struggling around what they are and are not in control over. And what the numerator detail regarding the follow-up is does your note document evidence of treatment for any behavioral condition or a medication. And I'm just concerned about the ability for us to get that information.

(Off the record comments.)

CO-CHAIR McINERNY: Go ahead. NCQA.

MS. BYRON: I just wanted to make a clarification to the specification. We actually tested it at a couple of different levels. You know these issues of accountability did come up in our Measurement Advisory Panel. We decided to move forward

with field testing to see what we would find in the charts.

And we tested it to see (1) whether screening was done; (2) whether it was done with a standardized tool; and (3) whether or not there was appropriate follow-up. And based on the results we decided to actually specify it as screening done.

This was one of the indicators where you saw the lowest performance rates across the field test. And so we took the results to the Measurement Advisory Panel. And their job was really to weigh and balance the importance of what we were trying to get with the feasibility of pulling it from the medical record.

And often times you see tradeoffs between those two. And in this case the feasible measure was that screening was done at all. So we decided to actually specify it at that level.

I think there is a mistake in the

very end of this form where it said we decided to specify it this way or another. And I apologize for that. We actually had I think over 50 forms to do. So I apologize.

But we did decide to set this level at screening done period because the rates were really low for other ones. So we had to put the bar where the field was and also try to stretch them towards that. We did not limit it to pediatricians.

MS. BROWN: Can I ask you? Did you have any evidence that screening led to care?

MS. BYRON: That is based on a U.S. Preventive Services Task Force finding that depression screening does lead to it. And I can say going to those meetings as a partner organization that they really leave no stone unturned when they're looking at the evidence. And their recommendations tend to -- - For some people they think they're a bit conservative even because they are holding so

true to the evidence. And so based on that we felt comfortable moving forward the measure.

DR. QUIRK: One of the things that I think you have to be sensitive to is -- and this is kind of where public health collides with individual therapeutic relationship between a care provider and a patient -- that it's nice to say that, well, yes, you know, screening for X leads to treatment of Y. But it's probably in less than 100 percent of cases.

And if I institute -- When you start talking about instituting screening tests, I've always been taught that there has to be the likelihood that the person is going to get treatment for the disease. And I don't believe that there is. I mean I just -- certainly if I'm a Medicaid or a self-pay patient.

So when you're going to mandate universal screening what do you do for these folks? And who administers the screening?

Realize that if the pediatrician administers an Edinburgh screening device in his office there's an argument that he has established a therapeutic relationship with the mother as a patient. And if he can't get or doesn't get and doesn't follow up and makes sure that she gets some kind of entry to the mental health community there are tort implications for that failure.

So maybe that was behind the failure of the American Academy of Pediatrics to endorse universal screening. I don't know. But I know that if this came up at the American College of Obstetricians and Gynecologists when I was on the OB Committee that would have been a big issue. I just wanted to put that on the table. That's kind of like --

CO-CHAIR McINERNY: The Academy of Pediatrics has endorsed this.

DR. QUIRK: But to be administered by pediatricians.

CO-CHAIR McINERNY: Yes.

MS. BYRON: It is part of Bright Futures. It is.

DR. QUIRK: Okay. Good. A big issue.

DR. ZIMA: This issue is going to come up again and again on our mental health measures as far as how accountable are we going to be to the limited access to mental health particularly under managed care Medicaid.

One question I had for you was how is follow-up defined when you were talking?

MS. BYRON: To be clear it does not require it. But we did look at it and we did field test it and we defined it as appropriate follow-up as being once you screen either a re-screen or a referral of abnormal or indeterminate results or treatment. That's the third one.

DR. CHEN: I'm in favor of lunch. Could I just clarify and summarize? So I

think I'm hearing that we are maybe all supporting it because we think that it's an important measure but only to the point of screening. Right? Even with a valid instrument, we'll be okay with that. But the follow-up issue it's a little bit more complicated.

CO-CHAIR McINERNY: Right.

DR. CHEN: So if that's the case I think maybe we can just go on.

DR. WINKLER: I think what Sepheen basically said that the follow-up is not part of the measure at this point in time. So just for that clarification.

DR. GLAUBER: This is a question to NCQA about feasibility. Did it come up in field testing the issue of visits in which the caregiver at the visit was not the mother? And how often that came up and how that affected use of this as a performance indicator?

MS. BYRON: That issue did not come up in field test and in addition to field

testing it and looking at the data we also do a debrief call with all of our field test participants to ask them about how it went. And it actually didn't come up. I think it happens less than is worrisome. And we felt comfortable moving forward with that.

It did come up of whether we needed to make it an actual exclusion in the measure. Based on the results, we didn't feel that that was necessary.

CO-CHAIR McINERNY: I think that this is an example of where we are raising the bar and then finding out that when you raise the bar there are some issues that happen after you jump over the bar. Oh-oh, what's going to happen after that? And that's another problem.

But let's see if we can at least get a vote on the importance of the measure.

DR. WINKLER: Yes. All right. For the Committee, do you feel that this measure as submitted meets the importance

criteria? How many --

DR. PERSAUD: Disregarding the submission, the language is wrong on the submission. The submission language has to be corrected for screening.

DR. WINKLER: For screening only.

MS. BYRON: Yes. As I look at it on the form, the numerator statements as written are fine. I think there was just one field at the very end that said how did you change the measure.

DR. JENKINS: Actually, even your measure description is wrong. Your measure description on the second line is inconsistent with what you've said.

MS. BYRON: Okay.

DR. JENKINS: That's what's caused the confusion.

MS. BYRON: I see. In the measure specification in 2A is the way it's supposed to be.

CO-CHAIR McINERNY: So we're

voting on screening only.

DR. WINKLER: Right. So how many feel it meets the importance criteria?

(Show of hands.)

Sixteen. And on the phone, Ellen and Nancy?

DR. SCHWALENSTOCKER: This is Ellen, yes.

DR. FISHER: Yes and yes.

DR. WINKLER: Okay. Those were two more. So it's unanimous. That's 17. Okay.

In terms of scientific acceptability, how does the Committee feel? Does it meet the criteria completely?

(Show of hands.)

I'm seeing two. Does it meet the criteria partially?

(Show of hands.)

Thirteen. Minimally?

(Show of hands.)

One. Not at all?

(No response.)

And how about Nancy and Ellen? Where did you want to come in?

DR. FISHER: Nancy, partial.

DR. WINKLER: Okay. Ellen?

DR. SCHWALENSTOCKER: Partial.

DR. WINKLER: Thank you. All right. So partial.

And how about usability? How many on the Committee think it meets the criteria completely?

(No response.)

I see none. How many think it meets it partially?

(Show of hands.)

Twelve. How many minimally?

(Show of hands.)

Four. Nancy and Ellen?

DR. FISHER: Partial.

DR. WINKLER: Okay.

DR. SCHWALENSTOCKER: And this is Ellen, partial.

DR. WINKLER: Okay. Two partials. All right.

And now for feasibility. How many believe it meets the criteria completely?

(No response.)

I'm seeing zero. Partially?

(Show of hands.)

Eleven. Minimally?

(Show of hands.)

Five. And Nancy and Ellen?

DR. FISHER: Partial.

DR. WINKLER: Okay.

DR. SCHWALENSTOCKER: Ellen, yes.

CO-CHAIR McINERNY: On this, can I ask again a question for the NCQA? If this is done, many insurers will pay for doing this on a 96110 which is administration of a screening test. And there are several developmental and behavioral screening tests that fall under that criteria and I believe the Edinburgh falls under that.

So it would be possible to measure

this administratively without doing a chart review. I don't know whether NCQA plans to look into that.

MS. BYRON: Consider that in the beginning I think we felt that code was not specific enough. And so it went with the medical record.

CO-CHAIR McINERNY: Okay. Thank you.

DR. WINKLER: Okay. So any further discussion?

(No verbal response.)

So let's vote on whether to recommend this measure as specified for just the screening to recommend it for endorsement. How many yes?

(Show of hands.)

Fifteen. Ellen and Nancy?

DR. FISHER: Nancy, yes.

DR. SCHWALENSTOCKER: Ellen, yes.

DR. WINKLER: Ellen, I can't hear you.

CO-CHAIR McINERNY: Yes.

DR. SCHWALENSTOCKER: Yes.

DR. WINKLER: Okay. Thank you. Were there any no votes?

(Show of hands.)

One. All righty. I think we're done. I think it's lunchtime.

CO-CHAIR McINERNY: Very good, everybody.

DR. WINKLER: I'm sorry. Public comment.

We take breaks at the end of each half of the day for public comment period. Operator, can you open the line and instruct anyone on the line about how to make a comment? And if there's anyone in the room who is not a member of the Committee who would like to make a comment please go ahead.

(Operator comments.)

Anyone in the room? Yes, we have one comment.

MS. PURYEAR: On the issue for

screening for hyperbilirubinemia, this is just for your information. The Secretary's Advisory Committee on Heritable Disorders is reviewing universal screening for hyperbilirubinemia at the end of January and has developed an evidence review of that issue. So I will keep NQF informed of that.

DR. CURRIGAN: Sean from the American College of Obstetricians and Gynecologists. Just wanted to add for the National Center for Health Statistics if we could in your report when you report out on the low birth weight if you could also included recommendations on all states using the national birth certificate as updated in 2003 because we still don't have that yet.

(Off the record discussion.)

DR. WINKLER: All right. We're scheduled for lunch for a half an hour. So we'll reconvene at 12:50 p.m.

CO-CHAIR McINERNY: Okay. He's a tough one. All right.

MS. THEBERGE: And lunch is in the room behind us. Off the record.

(Whereupon, at 12:21 p.m., the above-entitled matter went off the record and resumed at 12:50 p.m.)

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

12:50 p.m.

DR. WINKLER: All right. Starting off after lunch, we're going to start with Measure 1351. This is the proportion of infants covered by newborn blood spot screening. This is brought to us from our friends at HRSA. It's what percentage of infants had blood spot newborn screening performed as mandated by the state of birth? And, Dr. Clarke, I believe this was yours to discuss.

DR. CLARKE: Yes. There is a real paucity of surgical measures, so I guess I'll have to settle for a heels --

(Laughter.)

DR. CLARKE: This measure in all of the states -- it appears that all of the states require at least four screening, blood screening measures in newborns, their PKU, sickle cell, glycemia, and hyperthyroidism, I think are the four that are required in every

state, and some states require as many as 20 or 30, and more measures.

This measure just sort of focuses on three of those four, all except glycemia, and just checks electronic databases in the states to evaluate the percentage of newborns that actually receive the screening tests.

The importance of this really is not based, primarily, on numbers, because the impact of these diseases are quite rare. You would pick up maybe out of 4 point some million births in this country a year, you pick up maybe 5,000 cases that are positive for these diseases. However, the ones that are not picked up, severe mental retardation and possibly lethal problems are the result most of the time, and these are preventable by early appropriate treatment completely, almost. So, from that standpoint, the impact is pretty high, particularly if you have one of these things, to get it treated early.

So, I thought it did meet the

threshold for importance, just because these are serious problems, and they can be dealt with successfully, so those two things sort of helped it out.

In terms of the specifications, it's pretty obvious the number who got screened versus all the births in a particular state, and the data I believe is available, essentially, totally electronically, which really helps. There are no exclusions for this one. And I thought the usability was pretty straightforward, and pretty high.

The only thing that was really kind of an issue is what it doesn't deal with, and it doesn't deal with what happens to them after they've determined they've had the screen, but that's kind of dealt with by the second measure that I reviewed, so it may be that we ought to think about asking to put these two measures together; although they're by different developers, so that may not be possible. I don't know.

I think the simplicity of this measurement is a strength. I want to make sure that I was correct about -- oh, they do have an exclusion, and the exclusions are if a patient expires. I guess that's probably a pretty good one. I think that one is probably okay.

Okay. So, that's really about all. I thought it probably was a good measure. It's very simple, easy to use, very feasible to do, and it seems like a good idea to me.

DR. PERSAUD: I have a technical question about the measure. Are most states -- do most states have to do two tests, one at birth, and then one after, or is it just one, and some states have two, because we have two?

DR. CLARKE: I think most have only one. I'm not sure.

MS. PURYEAR: Most states don't have to do two. Most states do one.

DR. PERSAUD: So you just have it for one.

MS. PURYEAR: Less than half, although only eight states require a second screen. I think it's eight. About half of the states actually do a second screen.

DR. WEISS: Could I just weigh in a little bit here? The March of Dimes has been very much involved in moving an agenda to get mandatory screening across the country, so I think states are actually today by rule, or by law, by statute, or by regulation screening for at least 26 treatable conditions, and some states are screening for more, some of which have interventions for treatment or management of the disease, but some of which do not. But it's 26, or more.

DR. LIEBERTHAL: I thought that the requirement for screening, part of the principles are that it can be diagnosed with the newborn screening, and there is a treatment for it.

DR. WEISS: I think that's the classic definition, and that is the position

the March of Dimes has taken nationwide, but it's a little more complicated than that, in that in some states there is screening for conditions for which there is no known intervention at this time. So, it varies by state. But the floor is 26, and the corpus of that list of 26 is, by and large, treatable conditions, or manageable conditions.

DR. WINKLER: Jim.

DR. GLAUBER: So, if this is mandated by statute or law, do we need to see some evidence that there is a performance gap here in order to recommend this as a performance indicator?

MS. PURYEAR: The performance gap, although even wasn't completely -- I'm not the nominator for this condition, but the performance gap is those states that are actually tying the reporting to their birth certificates, so that you have an accurate number of births in that state. Right now, they depend in a delayed manner, but the

statistics from the National Center for Health Statistics, and those aren't -- don't come out on a daily basis, so it's actually directly tying the reporting of those that are screened with the actual births in the states. So, there is a performance gap there. Less than half of the states, although they have the capacity to tie, actually tie their birth certificates with newborn screening reporting. So, otherwise, you're right, there is no performance gap.

DR. McINERNY: Marina, based on what you said, is this bar too low with just three tests? Should we raise the bar to 26 tests?

DR. WEISS: I think what it's saying is compliance with state requirements.

MS. PURYEAR: It is 26. They're talking about all the --

DR. McINERNY: Oh, okay.

MS. PURYEAR: They gave the examples in the nomination package of sickle

cell disease, PKU, and congenital hypothyroidism, but it's actually whatever states are screening for.

DR. McINERNY: Okay. Thank you.

DR. WINKLER: So, am I to understand that, essentially, we really don't know to what degree there are babies who are not being screened? We just really don't -- is there any data --

MS. PURYEAR: Not on a state basis, because it is not tied directly to an accurate data source for the denominator; namely, the birth certificate.

DR. WEISS: Thanks to the work that HRSA has been doing, that Michelle is reporting on here for the very first time within the last what, three, four years we've begun to aggregate this data using uniform definitions, and uniform reporting standards, so it's relatively new that we even have the capacity to look across states to see what is being done in the states by rule, or by law.

And the whole issue of the performance gap, as Michelle says, there's just no -- we know that there is a requirement that the children be screened, but whether or not the individual child is being screened is not easily discernible at this point.

DR. WINKLER: So, this would change that chance to improve that performance gap. It also aligns with the Healthy People 2020 measures for newborn screening, which is similar in this regard.

DR. WEISS: And we also ought to say that the Secretary of the Department of Health and Human Services has embraced the recommendation of the Secretary's Advisory Committee on Heritable Disorders that every child be screened for at least -- how exactly do we say it, Michelle? What are the words?

MS. PURYEAR: It's 30 conditions in the recommended uniform screening panel that's been recommended by the Secretary --

DR. WEISS: The Advisory Committee.

MS. PURYEAR: Yes, the Advisory Committee.

DR. WEISS: So, the standard, the best practice standard is 30 conditions, or more.

MS. PURYEAR: And this recommendation is, therefore, also part of the Affordable Health Care Act Prevention Guidelines, along with Bright Futures. This panel of recommended screens is there.

DR. WINKLER: The way this measure is worded, if a state does not choose to do more than whatever they're doing right now, this measure doesn't require that. This is whatever your state says will qualify you. Correct?

DR. McINERNY: Right.

MS. PURYEAR: Correct.

DR. CLARKE: One other thing that I'd like to say regarding the difference in some states is, some states allow a parental waiver to be used. And I'm not very much in

favor of that, because that could have a huge effect on a child, and the economy, basically.

DR. WINKLER: This measure, HRSA has indicated, and as Marina just said, is relatively new, so it really hasn't been tested in this format with this set of specifications. Am I correct?

MS. PURYEAR: It's been -- not in this format. A very similar format was used for 20 years with -- as an NCHB performance measure, but tying it to the birth certificate, this is the first.

DR. WINKLER: This is the new part.

MS. PURYEAR: Yes. And if that's not clear, that it's tied to the birth certificate, then we need to make sure. Because, otherwise, you're not going to see a performance gap, if you don't do that.

DR. WINKLER: Okay. Any other comments or questions, discussion points? Okay. How many on the Committee think that this measure meets the importance criteria? I

see everybody here. Who's on the phone? Ellen, are you still there?

DR. SCHWALENSTOCKER: I'm still here, and I agree.

DR. WINKLER: Okay. Nancy, are you still here? Okay. Marlene, did you join us? No. Okay. So, the importance we all agree.

All right. Scientific acceptability, given that this measure is not tested, it makes it a little hard to know some of the details, but in terms of precision of specification, data source, those sorts of details that we do know, does the Committee feel that it meets the criteria completely? One, two, three, four, five, six, seven. Partially? One, two, three, four, five, six, seven, eight, nine. Minimally? No. Ellen?

DR. SCHWALENSTOCKER: I vote partial.

DR. WINKLER: Thank you. Okay. Usability, how many think the measure completely meets the criteria for usability?

One, two, three, four, five, six, seven, eight. Partially? One, two, three, four, five, six, seven, eight. Ellen?

DR. SCHWALENSTOCKER: Partial.

DR. WINKLER: Okay. Anybody minimal? Okay, great. All right. The last one is feasibility. How many believes this completely meets? Is it feasible to do? One, two, three, four, five, six, seven, eight. Partially? One, two, three, four, five, six, seven, eight. Ellen?

DR. SCHWALENSTOCKER: Partial.

DR. WINKLER: Okay, great. All right. So, in terms of recommendation for endorsement, this being a non-tested measure would be a recommendation for a time limited endorsement. Yes? Everybody in favor? One, two, three, four, five, six, seven, eight, nine, ten, eleven, twelve, thirteen, fourteen, fifteen, sixteen. Ellen?

DR. SCHWALENSTOCKER: You know, I'm on the fence with this one, because of the

next step, and I'm wondering -- I think I'll abstain for now.

DR. WINKLER: Okay. All right.

MS. GARY: Now that we voted, it's related to the measure. But with regard to confidentiality of data that could potentially be harmful to some people, specifically, let's say sickle cell data, should we have any concern about how those data might be used that would impact the lives of children in a negative way, such as academic opportunities, et cetera, et cetera?

MS. PURYEAR: This is not a practice measure measurement, so it's aggregate data, and you wouldn't be using identifiers. So, it's population-based. You're looking at that system. Does that answer your question? So, there's no identifier. Does that answer your question?

MS. GARY: So, when you get a sample from a child, it'll just be a sample, and no identifiers will be placed on that

sample?

MS. PURYEAR: No. I'm not saying that. I'm talking about the measure itself.

MS. GARY: Yes, I -- but if the data are available, there is a way to match the outcome with a name. And if you look at what's happened previously, that has been a real problem with children and their families. And it has affected career choices, et cetera, et cetera, et cetera.

MS. PURYEAR: So, for those databases that are using identifiers, those are not instituted without parental permission.

DR. WINKLER: The data that's collected locally where the action of responding to an abnormal result would occur is then sent onward to local, and maybe state-level in a de-identified form. Correct?

MS. PURYEAR: Yes.

DR. WINKLER: And then aggregated from the state to the national in a de-

identified form, so the identifier only stays at the very local level. Is that correct?

MS. PURYEAR: That's correct, because you need the identifier to follow-up.

DR. WINKLER: Right.

MS. PURYEAR: Contact the family, make sure the child is treated. But as far as putting it into a national database, those identifiers have been removed.

MS. GARY: Well, I understand that they've been removed from the national database, but let's say at a local level, is there a need to reinforce the whole issue of confidentiality about the data, so that individuals won't feel that they are being compromised if those data are available? Because there is a history related to that.

DR. WINKLER: Are you asking me?

MS. GARY: I'm bringing it before the group for discussion.

DR. WEISS: Let me just say, I don't see that there's any downside to saying

that we expect that the data would be maintained -- will be confidentially handled. But there does need to be the transfer of information about that particular child to the child's pediatrician, as well as to the family.

DR. QUIRK: Isn't this covered under HIPAA already?

DR. WEISS: Yes.

DR. QUIRK: So, it's restricted, you can't move it out of that system, except to insure or to a provider. So, it's already done.

DR. WINKLER: Okay. So, let's go to the next measure, which is on a similar topic. And this is Measure 1403. This is newborn blood spot screening. This is a measure from NCQA, and I believe Dr. Clarke, this is yours also.

DR. CLARKE: You are correct. This is sort of the next step in the process. This is a measure to evaluate how often the

information gets passed to the primary care provider, or in some way is passed to somebody who can do something about it. So, the same things apply to the screening items, and assuming the screening process gets done, the gap is really that the physicians don't find out about it, a very high percentage of the time. Hopefully, most of the time they don't find out about it, it's normal, and that may be the reason, partly. But, clearly, it's important that a provider finds out about the abnormal ones. That's very important.

So, anyway, this is what this measure plans to do, which I think is kind of a good idea, because Measure One doesn't do much good if nobody ever finds out the results.

DR. WEISS: Let me just weigh in in support of Dr. Clarke's point. There is this issue, because the blood spot is taken from the child as an inpatient, but the information about a child who screens positively needs to

be transferred to an outpatient setting, so there is an issue of information transfer in a confidential way, but to insure that there's follow-up once the child is being seen by his or her pediatrician. So, that's why this is broken down into two parts. It is not, necessarily -- the follow-up is not, necessarily, going to happen without focus on the need to make it happen.

DR. CLARKE: One of the things that I also noticed is that the denominator, as it's described, doesn't really take into account whether the child had the test done, or not. It sort of assumes that every child had the test done. So, that's why I'm kind of thinking that these two measures might somehow be put together. I don't know if that's possible, or if people think that's a good idea, but they're taking all children who turn six months of age in the measurement year, and seeing if they have a report of the results of their blood spot screening. And, probably,

all children didn't get it done.

DR. WINKLER: Go ahead, Tom.

DR. McINERNY: Yes. What bothers me a lot about this is the time, six months. You know, if the child has PKU, or hypothyroidism, then you're -- the barn door has long been opened for that one, and the horse has long left the stable. That's really not at all appropriate. It really should be more like six days, or certainly a week or two. And I don't quite understand that, why they do six months.

The other problem, and this probably varies a lot state by state, but in New York State, they have established regional centers where reports go to the appropriate specialist, so if there's an abnormal PKU, a metabolic specialist at Rochester who probably covers, I don't know how many counties, gets that report, as well as the primary care physician, but the state expects really the specialist to act on it. And the same is true

if it's a low thyroid, it goes to our endocrinologist, if it's an abnormal sickle cell, it would go to our hematologist. So, you have this situation where the primary care physician, and it could be a family physician, as well as a pediatrician, may get the report, but they know that it's also going to the specialist, and they're expecting the specialist to act on it. So, they may or may not record it in the chart that they got the results. Now, that may not be the best situation, but that's reality.

So, I think the problem of timing, and then the problem of this overlap where the specialists in some states get this, may confuse the issue.

MS. BYRON: Can I respond to the timing issue?

DR. McINERNY: Sure.

MS. BYRON: Okay. So, the Measurement Advisory Panel did acknowledge that this is something that should happen

right away. The reason why it's by six months, for a couple of reasons. One is a feasibility issue. We actually look to see if it was -- we looked at different time periods, and found that six months works. Secondly, we are tying it to -- this a measure actually exists in a greater framework of comprehensive well-care for children, and you'll be seeing the composites later. So, what we have done is choose several age milestones along a child's development time period, and created five key age groups at which we believe certain things should happen. And the lowest age group is by age six months, so that's when all the newborn indicators fell. So, that's another reason.

And then, third, it's to give -- if this were to eventually become a health plan measure, it's to give them some time to make sure that they can look back, and look for that information. We found that it's difficult when we have to place a threshold

and a time period. When we make it too tight, we hear oh, well, what if it happened one day after, we would not meet the measure. So, it's -- again, it's the baby steps issue, and we're giving them time, plenty of time to say okay, get that information so that you can meet the measure. We just want to make sure it's happening.

So, those are sort of all the reason why we set it by age six months; though, we do recognize that it's something that should happen immediately.

DR. McINERNY: Allan.

DR. LIEBERTHAL: I think there is a missing link in the chain, that is present in the next group of measures. And that is that if it is not done, that it be done within a certain period of time. And that would obviate the concerns you have, Tom, about these things that really need to be treated within the first week or two.

As far as the documentation in the

physician's chart, two things about that. One, that is recommended in Bright Futures, and is part of the Bright Futures documentation forms. But, also, very often the physician, the primary care physician may never get the results, and the parent asks well, was the newborn screening normal, and they don't have results to look at. So, by having a measure that requires them to document in the primary care physician's chart that there was -- that the screening was done, I think is important.

The problem is in the feasibility, because if you're using written charts, unless you have a very standardized way of documenting it, it becomes very, very difficult to tease out from a written chart.

DR. GLAUBER: Another issue with feasibility, which may not be a problem if it's just a health plan measure, but if it's a practice-level measure, is for the child who may shift between providers in the first six months of life, and those kids may be at

higher risk for loss to follow-up, who do you attribute responsibility to?

DR. JENKINS: Along those same lines, there is some lack of harmonization, where some of the other similar measures use the concept of in the medical home. And then, of course, we need a definition of when is a patient in the medical home. And the kids the most at risk are probably the ones not in the medical home. But I think that that was no issue here, too, thinking about the accountability of the practice. And they have an interesting definition here in the denominator about any face-to-face encounter less than six months after the birth -- before the birthday or something, and I don't know. I've heard other definitions that require two visits to sort of be in a so-called established patient, but I think that's going to be an issue here.

MS. BYRON: Can I respond to that? I think that's -- what you're saying is the

fact that it's only -- you only have six months, so it's the smallest age group. So, by age six months, you may only have one visit. We tend to set it where we think that we are able to balance feasibility with importance.

The other point I wanted to make is that this is a care coordination measure. That's how this is set up, so we're not saying that you don't have to do the screening until six months. We're saying we want to see it in the medical record by that time. So, just to be clear, we're not advocating for later screenings. We're just -- we are looking, specifically, to see that results showed up in the medical record. And when we did the field testing, this is another one where we tested different bars, and the lowest being just that there's some sort of notation that screening was done. The second one being that results were also in the chart, and the third being that there was follow-up. And we were pleased

to see that, actually, it met that whole results in the chart level, which we were a little surprised, but were glad to see. And so that's where we set the level for the measure.

DR. McINERNY: I agree with Al regarding paper charts. Before we switched to electronic medical record we would get a slip of paper from the state that the patient had the testing, and it was normal, or it was abnormal. Fortunately, almost always it was normal. So, that piece of paper would get slipped into the chart somewhere, where exactly hard to know. And the pediatrician in our group would have seen it first, and then probably they initial it, and then put it to be filed, but where it gets filed in the chart is hard to say. And then if you're looking through the notes of the visits, you probably would not see a notation that you got it, because we already initialed it, and put it to be filed. So, that's means for paper charts,

you're going to have to go through the whole bloody chart, see if you can find that slip of paper.

DR. LIEBERTHAL: With electronic charts, it may not be that much difference unless you provide a field that you have to fill in. Under the current state of our EHR, which is epic-based, is we get a paper from the state which goes to our scanning office. It gets scanned in, and gets put in a specific place in the chart, but a lot of charts don't have it. And some of that may be they weren't born at our hospital, or nobody identified them as Kaiser patients, or the scanning office didn't get all of their stuff done. I don't know.

DR. BERGREN: I have a question. How does the states -- how do the states know to send it to you? How is that determined?

DR. LIEBERTHAL: I don't know in other states. In California, the state is divided up into a system of newborn screening

offices, and each office is responsible for a geographic area. Kaiser being so big, Kaiser has its own newborn screening section in southern and northern California. And I will tell you that these offices are very, very good at getting -- hitting the positives, and getting them to the right providers.

DR. McINERNY: In New York State, the patient identifies their primary care pediatrician or family physician for the child sometime during their stay around the time of delivery, so that -- presumably, that information is used then as to where to send the newborn screen. However, that can be -- there can be some inaccuracies, obviously, in the patient reporting of who the child's physician is going to be.

DR. ZIMA: I'm wondering if we could just clarify, because I feel that there's been some drift in the denominator in this discussion. I mean, the denominator right now requires a face-to-face visit. Is

that what we're going to continue to hold to? Because it does relate to systems issues. Just one, but it does relate to the problem, missing data, high-risk populations not coming, drop of enrollment. It does have system-level factors, as well.

DR. WINKLER: All right. Any other comments? All right. Shall we see how we evaluate this measure. How many on the Committee think that this measure meets the criteria for importance to measurement report? Yes? Yes, you feel it meets the criteria? One, two, three, four, five, six, seven, eight, nine, ten, eleven, thirteen, fourteen. Ellen?

DR. SCHWALENSTOCKER: Yes.

DR. WINKLER: That's fifteen. No? No nos. Abstains? Two. Okay.

All right. Scientific acceptability of the measure properties. How many feel that the measure completely meets the criteria, as specified as submitted?

Okay. How about partially? One, two, three, four, five, six, seven. Minimally? One, two, three, four, five, six, seven, eight, nine. Ellen?

DR. SCHWALENSTOCKER: I guess minimally.

DR. WINKLER: Okay. All right. Usability. How many feel it meets the criteria completely? I see none. Partially? One, two, three, four, five, six, seven, eight. Minimally? One, two, three, four, five, six, seven, eight. Ellen?

DR. SCHWALENSTOCKER: Partially.

DR. WINKLER: Okay. And feasibility. How many think it meets it completely? None. Partially? One. Minimally? One, two, three, four, five, six, seven, eight, nine, ten, eleven, twelve, thirteen, fourteen, fifteen. Ellen?

DR. SCHWALENSTOCKER: Minimally.

DR. WINKLER: Okay. All right. So, recommendation for endorsement, how many

would say yes? You really can. All right. How many would say no? Ellen?

DR. SCHWALENSTOCKER: I guess no.

DR. WINKLER: Okay. How many abstain? Had to be at least two. Okay. Great. All right. So, we finished the first section from before lunch. Congratulations.

(Applause.)

DR. WINKLER: If you notice, we are moving quite a bit faster, the learning curve.

All right. Our next set of measures are from Work Group One, and these about hearing screening. We have a large group of measures that have been submitted from the CDC, and it's an interesting set of measures, so it takes -- it's going to take a minute to just describe them.

Three of these measures, 1354, 1360, and 1361 are measures that have been Public Health measures, and reported nationally for a decade. 1354, 1360, and 1361. So, those have all been well known.

There is national data. And there's the Public Health version of the measure.

Additionally, the CDC has been working on an electronic health version of those three measures, plus one, two, three, four, five other measures to complete this suite of measures that follows in fairly granular detail the initial screening of a newborn through all the various sort of things that could happen along the way, and it gets quite detailed.

To help with the evaluation of these measures, we convened a Technical Advisory Panel who have some hearing specialists to help us sort through this. Dr. Lieberthal acted as the Chair to the TAP, and he listened in to their discussion. We've included their comments in on the evaluation forms that you were sent. So, Dr. Lieberthal, did you want to say anything to introduce these?

DR. LIEBERTHAL: Well, they follow

a sequence, and if you look at the agenda, they're Eddy 1A, 1B, et cetera. And the intent of them actually follows that sequence, and one tends to build on the other. So, I would suggest that the order we take them in is using their eddy number, rather than the sequence on the agenda. 1354 would be first, 1356 second, et cetera.

DR. WINKLER: And I think for the three measures that are well known Public Health measures, we want to look at both of the versions of them, because, again, there has been significant use and experience with those three measures in a Public Health fashion; whereas, the others are new and untested.

DR. LIEBERTHAL: The other comment is, we can each look at these and determine on our own whether they're important or not, but the verbiage used for the importance section of the application, the CDC uses verbiage that really deals with the importance of newborn

screening, and then used that same verbiage for all of them, so it didn't differentiate. The description if importance was not differentiated among them.

DR. WINKLER: So, do you want to -- we'll start with the first measure, which is the 1A, or it's 1354. Dr. Glauber, I think that's you.

DR. GLAUBER: So, I think that we should also add to this, to buttress the importance, is that there's evidence that early detection of newborn hearing loss, significant newborn hearing loss, if followed by timely diagnosis and early intervention, improves developmental and social outcomes for these children. So, thus, you get the set of recommendations to screen in the newborn period, so this is a Healthy People 2010 goal to both increase the proportion of newborns who are screened for hearing loss by one month of age, who have an audiologic evaluation by three months of age, and for those who do have

hearing loss, receive appropriate intervention by six months of age. So, thus, you have the suite of measures that are evaluating components of this process.

And newborn hearing screening received a Grade B recommendation by the U.S. Preventative Services Task Force, so the measure that I was tasked with reviewing is really sort of the foundational measure, which is what percentage of newborns are screened before hospital discharge for hearing loss? And just a little background reading, according to NCHB, greater than 90 percent of newborns in the country are screened before discharge, but the documents say that there are some small urban and rural hospitals that have problems with screening, so there may be some performance issues here, in that 1 to 3 percent of children who are screened require follow-up audiological evaluation.

It seems like where the greater variability exists is in the loss to follow-up

rate, in that NCHB said there's state-by-state variability from some states having under 10 percent loss to follow-up, to some states having as high as 50 percent loss to follow-up. And that there are grants to 53 states and territories to support systems of care for -- to support newborn hearing screening and evaluation.

So, specific to this measure, it is in use. The data are available electronically, so I think that addresses the feasibility issue. And there's minimal exclusions; basically, parental refusal, or if a child dies before hospital discharge. Anything else? I think we -- the importance is pretty self-evident to making an early diagnosis, in that the most feasible strategy for accomplishing this is to screen newborns before hospital discharge, rather than relying on other mechanisms after the child leaves the birth hospital.

MS. GARY: I just wanted to ask, I

notice there was such a tremendous variability across states with regard to follow-up and screening, 10 to 50 percent. Could you just give some kind of explanation about why such a variability? What accounts for it?

DR. GLAUBER: I, personally, can't. I don't know if we still have anyone from HRSA, but this is something I just --

MR. EICHWALD: I'm John Eichwald. I'm the Team Lead for the EdD program at CDC. Right here, sir. Yes, the EdD team at CDC. The variability is due to a lot of issues, and one of them is also whether it's documentation, are these kids actually receiving services, and those results not being reported to the state program. In other cases, we have states where not all children have to be screened. State legislation varies among -- we only have 41 states that have legislation passed, plus D.C., and the territory of Guam. And not all states require

the reporting of the audiological diagnosis to the state, so there's a lack of conformity of state legislation. So, there's the documentation, and the state legislation that probably has the greatest impact.

DR. McINERNY: Well, another issue is sometimes it's difficult for the hospitals to follow-up on the patients, because they leave the hospital, and although, supposedly, they have an address or a phone number, sometimes it turns out that that's not actually where they are. And one of the things that I've learned recently is that a lot of people from the inner city lower income populations, they're using cell phones only, and they have no land lines, number one. Number two, their cell phones are often ones that have a month's worth of -- so many phone calls per month, and if they exceed the number of phone calls by the 20th of the month, and you call them on the 22nd, you can't get through to them. So, I think the hospitals

need to expend a significant amount of resources in terms of personnel and dollars to follow-up on everybody who fails a hearing screening. And some hospitals are just more diligent about that than others.

DR. LIEBERTHAL: To respond to that, this is not in place in California. But, as I said before, with the newborn screening, the blood spot, these newborn screening centers are incredibly good about finding people. And I don't know exactly how they go about it, when the address is changed. And, as you know, we have a very large non-documented population in California that doesn't want anybody to know where they live. And we also have a large population whose address is under the freeway bridge. But if these programs were put into the newborn screening program, I think it would be more effective than relying on each hospital.

DR. GLAUBER: Well, I just -- this underscores -- the discussion sort of morphed

from the actual active screening to appropriateness of follow-up, so I think this just underscores that if we were to endorse this measure, we really need to endorse at least some of the complementary measures about follow-up.

DR. WEISS: This is just in the nature of just informational, commercial, I suppose. And that is that the hearing screening programs are often separate from the blood spot programs. They're a different bureaucracy, a different reporting requirement. In some cases, they are joined, but not everywhere. So, it does get complicated, as our folks from CDC I think will attest.

DR. PERSAUD: I have a technical question about the denominator. The denominator statement has all live births during the measurement time period born at a facility and discharged without being screened, or screened prior to discharge? So,

which one of those is it?

DR. LIEBERTHAL: I think you're reporting both screened and non-screened.

DR. PERSAUD: Reporting both screened and non-screened. Okay.

DR. LIEBERTHAL: That wording isn't very good.

MR. EICHWALD: Was your question answered?

DR. PERSAUD: I think so.

MR. EICHWALD: Okay.

DR. WINKLER: I just wanted to point out that with all of these submission forms from the CDC, they have been developed with additional specifications to be used strictly for EHRs. It's really one of the first ones we're getting in that format, where I can't read it just looking at the page. You need the human readable side of it, as well. So, this is -- we're breaking a little ground here. But in this particular case, there is the bigger sort of measure that's been around

for a long time. It's the more Public Health measure, so if there are issues with perhaps one data source, one level of analysis on these two that anybody wants to bring up, or potentially identify, that would be -- okay.

So, in this particular measure, I think we were looking at the measure as is done in the Public Health realm, reported, has been for quite a while, as well as moving into data collection via EHRs as that becomes more and more possible moving forward. Is that C- I'm seeing nodding heads. Okay. I want to make sure we're here.

Does anybody want to discuss further this, or shall we -- all right. So, how -- everybody on the Committee feel this meets the importance criteria? I'm seeing all hands. Ellen?

DR. SCHWALENSTOCKER: Well, I guess the one question I had was it looked like performance was really high on this measure, so then a little bit -- it's not a gap in

performance, it's --

DR. WINKLER: Okay. Ellen, basically, was pointing out that performance is currently quite high, and I think that was already mentioned. I think Jim mentioned that. And that is one of the criteria for importance, but I don't think it's impacting everyone else's assessment. Okay.

So, how about the scientific acceptability of the measure? How many think it meets it completely? Ellen?

DR. SCHWALENSTOCKER: Yes.

DR. WINKLER: Partially, or completely?

DR. SCHWALENSTOCKER: Oh, completely.

DR. WINKLER: Okay. How many here partially? One, two. Okay. Great. And usability? How many completely? One, two, three, four, five, six, seven, eight, nine, ten, eleven, twelve. Partially? One, two, three, four. Ellen?

DR. SCHWALENSTOCKER: I'd actually say minimally, given the high level of performance.

DR. WINKLER: All right. Now, feasability, completely? Okay. Partially? One, two, three. Ellen?

DR. SCHWALENSTOCKER: I would say at least partially.

DR. WINKLER: Okay. Thanks. All right. So, recommendation for endorsement? Everybody yes? One, two, three, four, five, six, seven, eight, nine, ten, eleven, twelve, thirteen, fourteen, fifteen. Ellen?

DR. SCHWALENSTOCKER: Oh, sure.

(Laughter.)

DR. WINKLER: Any nos? Any abstains? Okay. All right. That's another one down.

The next one in this group is the EHDI 1B, Measure 1356. And this is the hearing screening refer rate at hospital discharge. This is not a measure that's been

reported. This is a new measure, and the specifications, again, are with a focus towards incorporating them in EHRs. Dr. Lieberthal, this one is yours.

DR. LIEBERTHAL: Again, the importance, it's a follow-up to 1A. Once you've screened, what do you do about it? The way this is -- the numerator is worded, this is not a performance measure, it's just a data collection.

On the TAP call, was it you, Bob, who -- were you on that call? Okay. So, the CDC folks commented that when a child fails or is unable to complete the newborn screening, they're automatically referred. And I had a problem with that concept of automatic, because I don't think anything that's automatic ever works well, unless you go back and follow it up. So, this really -- the way it's worded, it's not really a performance measure.

If you added wording to say that

during the time window of not past hearing screening before hospital discharge are referred for further evaluation, or referred to a specialist, however you would want it, then I think it would fulfill our needs more. As far as the -- so then I think it is important measure worded that way.

The usability, I think if the data is collected, again, it's very usable. The feasibility becomes a problem because the fact of referral is frequently not well documented in a hospital chart, whether it be an EHR or written, so I'm not -- I think in order for it to be feasible, there has to be a standard way of documenting it. It may take a long time to go through a chart to find whether the patient was referred or not, and he or she might have been referred, but it's not really documented. So, I think that's a problem with the measure.

MR. EICHWALD: May I address that? It's unfortunate that we use the word

"refer." This is a historical term where when EdD programs first started, people didn't want to say the baby failed their screening. So, what it is, is now it's passed or referred. This really is a measurement of the failure rate, so it's how -- what's the positive predictor value of the screener; that is, the denominator is all kids screened, the numerator is those kids that do not pass, which the equipment -- even the equipment puts refer. It doesn't say fail. So, it's not really a measure of referral, it's the validity of the screening.

DR. LIEBERTHAL: As such, it's a data collection tool, but not a performance measure, because the machine may say refer, but was anything done with that setting on the machine.

MR. EICHWALD: That's exactly why we want the measure to see is the machine out of calibration, do the screeners need to be retrained because they're doing the procedure

wrong, we've got too high of a referral rate, too high of a failure rate?

DR. LIEBERTHAL: I don't see it as a -- I still don't see it as a performance measure.

DR. JENKINS: I agree. Could you just explain to us how it would be, let's say at the institutional level for high stakes accountability measurement that the institution should be held accountable to having a higher or a lower failure rate, and I think that would help us out here.

DR. MASON: I can give an example of -- again, you need to think of -- it's not -- when it says "refer," think of it as failed screen. It's just the language of the culture and community that uses refer to mean a failed screen. A referral to follow-up is completely independent of this. This is just measuring the failed screen. It becomes an issue, for example, we've seen hospitals where they will have a 30 or 40 percent failure rate on the

screens because they're doing them physically in a bad location, where it's picking up ambient noise and that, so it's a mechanism -- keeping track of this is a way that at the state-level, they're able to go back and look at a hospital that has a failure rate that's too high, and then work with them and say okay, let's come in and visit, see how you're doing this to see what's going on in the process that's resulting in such a high number of failures.

DR. PERSAUD: So, is there some other gold standard by which you judge that screen, or is there a specific rate you're supposed to have of normal versus not normal screens?

MR. EICHWALD: Part of the issue here is there's two different technologies. One of them is acoustic emissions. The failure rate, the refer rate is about twice as high as it is on auditory brain stem response screening, automated ABR testing, so we

actually have two technologies with different refer rates, different failure rates. And that technology is -- maybe even within the same hospital they may be using two technologies. There's also the protocol that comes in in terms of some people will actually do a two-stage screening, where they'll start with the aud acoustic emission screening first, and then go to ABR, automated ABR. So, I mean, there's some --

DR. JENKINS: That gets back to my prior point. This sounds like a quality metric, where it's important to know about, it's important to ferret out why, but in the world of high stakes accountability measurement, where someone could be held accountable for having a higher or lower rate, it's too complicated and confusing about what's going into that.

MR. EICHWALD: It's either -- I mean, the equipment basically tells you, this is automated equipment. But the question is,

is it being performed adequately by the screener. So, this is really a measurement of the --

DR. JENKINS: Well, then maybe there's a false positive rate, or a false negative rate that could, in fact, be an accountability measure, but it's not simply the rate of babies that fail. But you could hold the institution accountable for it, because underneath that, I assume there's some children who are supposed to fail the screen because they had a hearing problem. But we can't find those from the false positives in the way this measure is set up.

DR. HURTADO: I'm confused about the denominator, because it says that it's the total number of infants born that have been successfully screened. And from what you're saying, it sounds like the measure is actually of not screening successfully -- not screening appropriately with the right instrument, and the right location, so the denominator seems

to already define that it is correctly performed?

MR. EICHWALD: There are some cases where a screener will attempt to screen, and because the baby is too fussy, the screen can't be accomplished, so we didn't want to include that in the denominator.

DR. HURTADO: A definition of what successfully screened is would be useful.

MR. EICHWALD: It probably was a poor choice of words on my part.

DR. LIEBERTHAL: There's an inconsistency in what you said there, Bob, because if you're making the assumption that the baby couldn't be successfully screened because the baby was restless, and on the other hand, if there is ambient noise they may not be -- they'll get an unsuccessful screen, but not a fail. So, you're looking at different aspects, and I agree with Kathy, that this is a quality control issue, and not a performance measure. So, I would reconsider

this as a --

MR. EICHWALD: That makes sense.

DR. LIEBERTHAL: For this group.

DR. WINKLER: How many on the Committee believe this meets the importance criteria? How about no? You have to vote one way or the other. It would be useful. Ellen?

DR. SCHWALENSTOCKER: I think it meets the importance criteria, but I agree with the comments about its suitability as an accountability measure.

DR. WINKLER: Okay. She said she thinks it might meet the importance criteria, but she doesn't think it meets some of the others, so she can be the one yes vote, because otherwise there were 15 nos. So, that's the end of the discussion of that measure.

So we go on to the next one, on 1357, which is the EHDI-1C outpatient hearing screening of infants who did not complete screening before hospital discharge. Dr.

Lieberthal.

DR. LIEBERTHAL: This proceeds with the sequence, and what it, basically, says is that the -- if a child did not get a hearing screening in the newborn period, they need to get it by 30 days of age. And measures whether children do get screening done by 30 days of age.

As far as the importance, I think it carries on with the importance that if you didn't get everybody in the newborn period with 1354, you now have a mechanism for getting the rest of them. Usability, I think is the same as 1354, and the feasibility, again, deals with the ability to extract the data from the charting.

DR. WINKLER: Okay. Any other comments? This measure does not have a historical Public Health version. John, are you looking -- you're making faces over there. So, this is a new measure that has been specified for use with electronic health

records. I think that's where they feel it could be most feasible, rather than chart records. Did you want to say something, John? You look like you were going to.

MR. EICHWALD: The first measure is actually a HRSA measure, the hospital discharge, and that's what they've been collecting. CDC has actually has been collecting this on survey for all screens, so this would include those kids that were screened with the HRSA measure, and that were seen on the hospital outpatient. So, we can actually extrapolate this number out based upon what's reported to HRSA and what's reported to CDC.

DR. CHEN: Can I make a comment? So, my question is, who is responsible for screening at 30 days? I like the idea. I mean, I don't think hospitals screen all kids, and even those that fall through the crack, somebody have to catch them. So, I like the idea. I just don't know who's held

responsible to screen in 30 days. And a corollary question, why 30 days? You either have a visit at two weeks of age, or you have a visit at two months, depending on which state, or what kind of requirement they have.

MR. EICHWALD: The screening is jurisdictionally based, depends on who's responsible to do the follow-up. The 30 days is picked because that's our national objective, is the one, three, six plan, so by one month they're 30 days.

MS. SCHOLLE: What proportion -- what's the absolute number of babies that would fall into this group that were not successfully screened at discharge, or percent, either way.

MR. EICHWALD: My epidemiologist --

DR. GAFFNEY: You mean for the kids that are not passing the screening?

MS. SCHOLLE: That are unsuccessfully screened, and, therefore, we're

going to try and catch them a little later.

DR. GAFFNEY: That is -- it's probably we see a range, Jim, between states. Some states it's as little as half a percent, all the way up to maybe 5 or 6 percent of kids that were not screened, or they didn't pass, so there's a range.

MS. SCHOLLE: And is it randomly distributed across SCS, or is it --

DR. GAFFNEY: We don't have the independent data to tie it with SCS. It's just aggregate at our level, so I can't answer that question.

DR. QUIRK: Just for clarification, you said that either were not screened, or didn't pass. That was your --

MS. SCHOLLE: I was asking about not screened.

DR. QUIRK: Yes, she was asking about not screened, and you lumped in there the not passed.

DR. GAFFNEY: I'm sorry. Yes, I

mean, there is kids not screened, in some states it ranges anywhere from half a percent of kids not screened, all the way up to maybe 5, 6 percent not screened.

DR. GLAUBER: To the feasibility, it's not clear, where are we going to be looking for the evidence that this group was screened? How is that defined?

MR. EICHWALD: That's data that's reported to the state jurisdiction, to the state EdD program, we hope. I mean, that's part of this issue. Again, it depends on state legislation.

DR. McINERNY: My read, 2A1 on page 4 of the numerator is just the number of infants with no documented hearing screening performed prior to patient discharge, and then who were screened sometime as an outpatient by 30 days of age. So, it really doesn't take into -- it doesn't talk anything about those who fail the hearing screening, it's just those who didn't have it. Correct?

MR. EICHWALD: That's right.

DR. McINERNY: That's a different measure. And the question about who's responsible, I think is clearly a very important one. I believe that in New York State, it's the hospital where the child was born that is responsible to follow-up and make sure that the child does get a hearing screening as an outpatient by 30 days of age. But does that vary from state to state?

MR. EICHWALD: Yes.

DR. McINERNY: So, who else is responsible?

MR. EICHWALD: In most cases, it's either the hospital or the state program, itself.

DR. McINERNY: Oh, okay. So, it's not the primary care physician.

MR. EICHWALD: Well, they collaborate very closely with them.

DR. PERSAUD: I'm not sure I'm getting where exactly this data is going to

come from. It looks like it could come from a number of different places. And where it would live. I mean, let us -- just playing the devil's advocate around -- the issue here is who gets dropped, so the baby doesn't make it to primary care, and isn't screened in the hospital, and I guess gets a referral to an outpatient testing facility. Then you would be chasing that outpatient facility's testing result. Is that right?

MR. EICHWALD: Correct.

DR. PERSAUD: So, there are different -- there's complexity in getting this numerator. It could come from a number of different places.

MR. EICHWALD: And, in fact, we actually have some midwives that are actually doing some screening, so we're getting data that way, as well. That's very limited. It's a challenge.

DR. LIEBERTHAL: Does this account for babies born outside of a hospital?

MR. EICHWALD: Yes. That's why we're using the denominator of vital statistics, and not the hospital discharge. That's sort of the difference between the HRSA measure and the CDC measure, in fact.

DR. WINKLER: Are you ready to make a determination about importance? Yes? All right. How many on the Committee feel that this measure meets the importance criteria? One, two, three, four, five, six, seven, eight, nine, ten, eleven, twelve, thirteen, fourteen. Ellen?

DR. SCHWALENSTOCKER: I'm sorry. Yes.

DR. WINKLER: Thank you. Were there any no votes? I didn't see any. Yours was a no? Okay. All right.

Moving on to scientific acceptability of this measure. How many think it meets the criteria completely? I see one. Partially? One, two, three, four, five, six, seven, eight, nine, ten, eleven, twelve,

thirteen, fourteen. Ellen?

DR. SCHWALENSTOCKER: I think partially.

DR. WINKLER: Okay. I can barely hear you.

DR. SCHWALENSTOCKER: Oh, sorry. Partial.

DR. WINKLER: Okay. How about usability, completely meets? Well, partially meets? That's clearly the majority. Okay. Feasibility, completely meets? Oh. Partially meets? One, two, three, four, five, six, seven. Okay. Minimally meets? One, two, three, four, five, six, seven, eight. Ellen?

DR. SCHWALENSTOCKER: Minimally.

DR. WINKLER: Thank you. Okay. So, in terms of recommending this measure for endorsement. Yes, we were mentioning that you can jerry rig this measure, this data with this --

DR. PERSAUD: The little box is checked off.

DR. WINKLER: Right, I know. So, I think we'll have to go with the time limited, because really the focus of this was to use it at the EHR spec, rather than a little data from HRSA, and a little data from CDC. So, yes, recommendation for time limited endorsement. How many say yes? Fourteen yes. Any nos? One, two. Ellen, what's your vote?

DR. SCHWALENSTOCKER: Yes, time limited.

DR. WINKLER: Okay. So, fifteen yes, two no. All right. That's another measure down, moving quickly.

All right. The next measure on our list is the EHDI 2A, or Measure 1358, infants identified with risk factors for hearing loss within the medical home. Dr. Lieberthal.

DR. LIEBERTHAL: Okay. This one, the numerator states number of infants in a practice born during the time window that have completed risk factor analysis for delayed

onset or progressive hearing loss. And the denominator is, I guess, all kids who are still alive, if I read it right.

I had a couple of problems with this one. The -- I guess there are some standardized tools for risk factors for hearing loss that are named in the document. I'm not familiar with them, but I assume that's what they refer to. These are not normally, I don't believe, PCPs usually used. You have a population of patients who have failed the hearing test who you already know have hearing loss, and I really don't know the frequency of children with progressive hearing loss who passed in the newborn period. So, if somebody has that answer, I'd appreciate it. And you can do the analysis, and then they have to have -- the next one has audiologic diagnosis. So, it's basically that a risk factor analysis be done. The scientific merit depends on the validation of the tools. The usability depends on the frequency of picking

up anything that you can do something about. And the feasibility I think is the major problem, because as with other tools for asking questions, it has to in some way be at a locatable place on the chart with all the tools answered and scored. There are ways of doing that, but not used by most physicians. And from what I can tell, this would be a measure at the clinician level. So, I have several problems with this measure, primarily related to its usability and feasibility.

DR. GLAUBER: I'm not sure to what extent we're supposed to talk about other measures, but we do have a measure we're going to be considering about developmental screening, so to the extent that this cohort that has acquired hearing loss is going to present with speech and language problems that are going to be picked up through developmental surveillance, it's pretty typical that when such a kid is assessed that a hearing evaluation is part of that

assessment. So, I'm not sure if pediatric providers are doing a good job of surveillance, how much we need to focus on this explicit behavior.

MS. CARLSON: I just have a question as to what the population is for this measure. Is it infants who in the hospital or discharged did not evidence a hearing loss, but later on a risk factor screening they're at risk? Is that who it is?

DR. LIEBERTHAL: According to the denominator, it's all infants born in a practice.

MS. CARLSON: So, including those who have already had a hearing issue identified, as well as those who haven't.

DR. LIEBERTHAL: Correct. That's the way the denominator is written.

DR. McINERNY: I really have a big problem with this one, because, to my knowledge, doing a risk assessment for hearing loss is not very accurate, not very reliable,

number one. And, number two, if we can get all children universal hearing screening, that makes this measure, I think, moot.

MR. EICHWALD: The reason this was put in was the Joint Committee on Infant Hearing. This is a recommendation of the Joint Committee on Infant Hearing, which is comprised of a number of organizations, American Academy of Pediatrics, American Academy of Head and Neck Surgery, American Speech Language Hearing Association, American Academy of Audiology. Primarily, it's looking for children that have later or progressive hearing loss that would have passed the newborn hearing screening in the hospital. And it's based on risk factor analysis. It's done both from hospital, certain information we might be able to get out of the hospital, but also it needs to be captured within the medical home.

In terms of the developmental screening, that's actually one of the

indicators, and any parent that has a delayed speech -- that reports speech and language delay is to be referred to -- that's part of it. There are some factors that don't pick up as easily, that would be like CMV, asymptomatic CMV. The sooner we do the intervention the quicker those kids wouldn't be -- it would take a while for them to -- we identify them sooner before they have their speech and language delays.

DR. QUIRK: But they're going to pass the screening test?

MR. EICHWALD: Some may, sure. If they've got a progressive hearing loss or late onset.

DR. QUIRK: But it's not like bilirubin and the trajectory. I mean, there's no way of adding this to the screening process, or screening out otherwise high risk infants.

MR. EICHWALD: I think I agree with you, if I understood what you said. Yes.

DR. QUIRK: It's not a node in a diagnostic algorithm.

MR. EICHWALD: Right.

DR. QUIRK: It's separate.

MR. EICHWALD: Right.

DR. QUIRK: Okay. Thanks.

DR. JENKINS: Can I just ask, was there any quantification of how many of those children there were, and what the performance gap was, and how many of them would be picked up by the risk factor screen?

MR. EICHWALD: It's an untested measure. We've got some historical basis that was -- before universal newborn hearing screening, we did have programs that were doing risk factor analysis. We probably were looking at the neighborhood of about 8 to 10 percent of kids would have a risk factor. That included hereditary hearing loss, but then it gets down to the definition of what's hereditary hearing loss.

DR. PERSAUD: I noticed that

there's somewhat of a variation in this denominator. The measurement time period varies depending on the user, calendar year, quarterly, total number of patients during the specified time, and I'm just trying to get an understanding of who -- what age group is this that you're supposed to risk assess, all infants up to one year, up to two years, because I don't see any of that indicated, and it doesn't seem to me that it would be all children.

MR. EICHWALD: The Joint Committee on Infant Hearing recommends all children with a risk factor be seen by a audiologist no later than 30 months of age, or is it 36? That may be some of the variability here. Go ahead, Craig.

DR. MASON: Also, I think that the wording of that can be tied in with a definitive number. I think part of when we were writing this, it reflected discussions that had been going on in the -- for the EdD

Data Committee, which is a national group of epidemiologists, health informatics people, Public Health officials on how to start to collect some of this data. So, we talked a lot in terms of programming sort of language, and it's the algorithm. It reflects kind of the algorithms of how you would, for the EdD programs, kind of how they would generate this. So, do you want a monthly report, a quarterly report based on -- so, it's got that flexible -- it's written with deliberate flexibility to make it as most usable for the EdD programs trying to collect data themselves back, but it should be tightened up to, as John said, with specific recommendations in that sense for this one specific reporting purpose.

DR. PERSAUD: I have a question. I don't know, Allan, if you got to see what does the risk assessment look like? Is that an added half a dozen questions for the practice per visit? Do you have a feel for that?

DR. LIEBERTHAL: Yes. The members of the TAP, one of them -- I think one of them was an audiologist, listed a number of questions, so it becomes a structured screening with at least a half dozen more questions to ask at the visit, which we've already got lots and lots of questions to ask. And, again, to me, it's the -- how many questions are you going to ask before you find something, and what are you going to do about it? In my practice, if I had a child who I felt was at risk for a hearing deficit, I would just be watching his speech and language much more closely, maybe get another hearing test at 12 months. I think those are few and relatively far between.

DR. WINKLER: All right. Are we ready to decide on it? So, Committee members feel that the measure meets the importance criteria? Yes? No? Ellen?

DR. SCHWALENSTOCKER: Yes.

DR. WINKLER: Okay. All right.

So, not passing that, we can move on to the next one, which is sort of a corollary, if you will, measure. EHDI-2B, Measure 1359, Dr. Kibort isn't here, but this, essentially, is the follow-up measure to the one we just discussed, which is infants identified with risk factors have an audiological diagnosis. And my understanding is that means they were evaluated, their audiological diagnosis could be normal, but they had a follow-up with an audiologist. Is that correct, John?

MR. EICHWALD: I was just going to say that, just for the Committee, if the first one didn't pass, I mean, can we withdraw this one? I mean, I don't want to waste the Committee's time, because it's -- without the previous one, this one is meaningless.

DR. WINKLER: Everybody okay with that? Oh, moving faster. Okay. We go to EHDI-3. This is Measure 1360, audiological evaluation no later than three months of age. And this is, I believe, one of the measures

that's been around for a while. It's been talked about, the screening measure. This is -- the measure assess the percentage of newborns who did not pass the hearing screening, and had an audiological evaluation no later than three months. So, this is the follow-up measure.

DR. LIEBERTHAL: It's actually that it's -- wait, is this the three month one?

MS. PURYEAR: That was 1359, right?

DR. WINKLER: No, we skipped 1359. This is 1360.

DR. LIEBERTHAL: 1360, now let me see if I've got the right one up.

(Off mic comment.)

DR. LIEBERTHAL: In other words, that they had been seen by a specialist, and a diagnosis has been made by three months. I think the importance is clear. Usability is clear, and it should be pretty easy to find out from either an electronic health record, or billing data whether they have seen a

specialist.

DR. WINKLER: All right. John, did you want to say anything about the measure?

MS. SCHOLLE: What I like about this is that it answers this constant two-part question, screening and then what happens.

DR. WINKLER: Right.

MS. SCHOLLE: And this addresses did anything happen. I think that's really important.

DR. WINKLER: Okay. Any other comments anybody wants to make about it? Okay. How many on the Committee feel this measure meets the importance criteria? I'm seeing everybody. Okay. Ellen?

DR. SCHWALENSTOCKER: Yes.

DR. WINKLER: Okay. There were no no votes? Okay. And scientific acceptability, how many feel it meets the criteria completely? It looks like the same, everybody except for -- Faye, what's your vote, partial?

MS. GARY: I think partial.

DR. WINKLER: Okay. Good. Ellen, what's yours?

DR. SCHWALENSTOCKER: Partial.

DR. WINKLER: Okay, works for me. All right. Usability, how many feel it meets the criteria completely? Partially? One, two. Ellen?

DR. SCHWALENSTOCKER: I would say completely.

DR. WINKLER: Okay. Thank you. Is there anybody who is minimal? No, I didn't think so. All right. Feasibility, completely? Ellen?

DR. SCHWALENSTOCKER: I think completely.

DR. WINKLER: Okay. Great. Are there any partials? Great. All right. So, recommendation for endorsement? Ellen?

DR. SCHWALENSTOCKER: Yes.

DR. WINKLER: Thank you. Were there any no votes? I didn't catch any. All

right.

The next one is Measure 1361. This is intervention no later than six months of age. Ellen, I believe this is your measure to talk about.

DR. SCHWALENSTOCKER: Yes, I was assigned this measure. Can you hear me okay?

DR. WINKLER: Started out fine, then you got soft again.

DR. SCHWALENSTOCKER: Okay. Is that better?

DR. WINKLER: That's better.

DR. SCHWALENSTOCKER: Okay. So, 1361 is titled "Intervention No Later Than Six Months of Age." The numerator is number of infants born during time period diagnosed with permanent hearing loss who are age --

DR. WINKLER: Ellen, hold on a second. Are you using a handset?

DR. SCHWALENSTOCKER: Who are age less than six months at time of referral to intervention.

DR. WINKLER: Ellen, are you on a speaker phone?

DR. SCHWALENSTOCKER: No.

DR. WINKLER: Okay.

DR. SCHWALENSTOCKER: Let me try speaker, maybe that will be better.

DR. WINKLER: No, they prefer you use the handset.

DR. SCHWALENSTOCKER: Okay. The denominator for this measure is the number of infants born during the time period diagnosed with permanent hearing loss. And this kind of reviews the sites for the measure by the work group. I think there were four people that voted, all suggested that this measure met the importance criterion. They were split between completely and partially on scientific acceptability. And the one comment there is the measure is titled "Intervention No Later Than Six Months of Age," but it actually appears to be that a referral happen, not that an intervention was received. And then the

work group members who voted were also split on usability, half saying completely, half saying partially, with the same comment, it seems to be a referral versus an intervention.

And, last, on feasibility, one person graded this as completely feasible, two as partially, one as minimally, and I can't read my own handwriting as to the comment that occurred here. I think it had to do with exactly how the documentation is done.

DR. WINKLER: Any other comments?

DR. JENKINS: Ellen, I think the numerator and the denominator here included all children with audiological evaluation, but I think it was only supposed to include children who had permanent hearing loss diagnosed on the evaluation. It seems that that was an oversight. Is that right or wrong?

DR. SCHWALENSTOCKER: I read that the denominator was the number of infants born during the time period diagnosed with

permanent hearing loss.

MR. EICHWALD: It should say that. We'll verify it.

DR. WINKLER: It does. Sarah?

MS. SCHOLLE: I don't know anything about this clinically, but aren't young people who have hearing problems, that they're not, necessarily, a permanent hearing loss, don't they merit diagnosis and follow-up? I just don't know, is that a lot of people, or not many people?

MR. EICHWALD: It is a lot. I may kick this back over to the Chair of the Data Committee, but we wanted to focus on those children with permanent loss.

MR. DR. MASON:: There's variability state to state in terms of how they address, and work with children that have an identified non-permanent hearing loss. I think some keep track, and work with those; others, it's not jurisdictionally part of what they're legislatively working on. So, it was

a judgment call in terms of for the official numbers we're focusing on the permanent hearing loss, but a lot do still try to provide support, and referrals for those with non-permanent hearing loss.

DR. McINERNY: Hopefully, I can help a little bit. Typically, with the audiological evaluation documenting a sensorineural hearing loss, that hearing loss is almost always permanent, as distinguished from conductive hearing losses, which are totally different, and those can come and go. But, usually, if they've done the hearing screening, and then go ahead and see the audiologist, and the audiologist does complete testing, they can document that it's going to be a permanent loss. And then you know that you have to go ahead and do something. Whereas, if it's conductive, and maybe partial, and come and go, you would just retest.

DR. LIEBERTHAL: On the face of it,

this is inconsistent with 1360, which says, essentially, the same thing only in better wording, at 91 days. In 1360 it says they have had intervention; whereas, here it's at the time of referral, so I'm not sure what the intent was of having a 31, and then a 60, and then 1362, the next one has 48 hours of diagnosis. So, there's inconsistencies among three measures, that I didn't understand --

DR. SCHWALENSTOCKER: Al, I took 1360 to mean if the child didn't have hearing screening, then the matter was referred for an audiological diagnosis. And I took 1361 to be sort of the next step in that process, and I may be wrong, but -- so, then a child received the audiological diagnosis, and, if needed, was referred to intervention.

DR. LIEBERTHAL: So, Ellen, you feel that the two are harmonized enough to consider them as separate measures?

DR. SCHWALENSTOCKER: That was my read, but I would welcome other comments.

DR. CHEN: That's how I took it, as well. But I do have a little issue with 62, because, as Ellen pointed out, 61 is a referral, not actual service rendered.

DR. LIEBERTHAL: Right.

DR. CHEN: Then what's the point of referral within 48 hours, if you're going to make sure they are referred by six months of age?

DR. McINERNY: That's my concern, also. So, the referral is made, but we don't know -- there's not a measure that says they actually went and got treatment.

MR. EICHWALD: Yes. The issue here is reality, and that is that there's a law in education called FERPA, Federal Education Rights and Privacy Act, that makes it very difficult for Public Health to get any information from early intervention. So, at this point in time, the best we're doing -- we think we can document very well that the referral was made. Now, there is federal

legislation that once that referral is made -- first of all, the referral has to be made within 48 hours, but then within -- it's the IDEA Act, Individuals Disabilities Education Act, that that evaluation has to be done in 45 days. So, once -- if we can document the referrals made, then we've done our job on the Public Health side, and we turn it over to Education. It's not perfect, but it is definitely a --

DR. McINERNY: That's helpful. Thank you.

DR. BERGREN: I guess I'm the school health person, and what I would suggest is that we try to build into the measures the data sharing, and have the permission signed in order to do the follow-up and the sharing. Because if that's the system, which school health is a health care system, if that's the system that's providing the intervention, then that should be the system that's providing the data point.

MR. EICHWALD: Can I clone you, and put you in 50 states?

DR. BERGREN: Yes, yes.

(Laughter.)

DR. BERGREN: And that's one of our goals. That's all.

DR. PERSAUD: So, there is, actually, I think a subtlety between 1361 and 1362, where one is asking you to have a referral by six months of age versus being referred 48 hours after the determination of permanent hearing loss. And the difference there is for the -- it matters if the child is very young. The older they get, the worse it is, so the less time you have to get that referral started because you're losing that valuable language development time, so I think I might see a theoretical difference there.

MS. SCHOLLE: The concern I have is just the shear number of measures. I don't fully understand all the interstices here, and how they overlap. But even though we

eliminated two, we still have one, two, three, four, five, six, seven that I just, from a common sense point of view, that just seems like a lot. I don't know. Is that an inappropriate question, or comment? It is. Yes. No. I think it would be better to have two or three really strong measures.

MR. EICHWALD: I think part of the issue here is that we're trying to capture this electronically, so there will not be an undue burden on the system in data collection. We're really trying to capture this electronically, so that it -- even though it does seem like a large number of measures, once we've developed the code in the electronic health record, it's captured automatically. And that's one of the reasons we put forward more than -- to actually show it through the progression of --

DR. MASON: And if I could inject, as well, as the Co-Chair for that Data Committee, I mean, we've been doing this now

for a decade, and this -- the states are actually at this point very invested and interested in collecting this data. The IDEA one is one actually a lot of the states are telling us, they know that it's supposed to be happening. They want to start to document pragmatically that it's not happening, to then try to help to encourage that process along. So, the states are actually -- have, over time, gotten very invested and supportive of this. And, again, it's that whole process. It's a number of measures, because we've really kind of well-defined the entire process from birth all the way up into early intervention, kind of step-by-step, so that you can start to -- the states can start to see for themselves kind of where are they struggling, where are they succeeding, what is our loss to follow-up? So, it's a lot of measures, it's a lot of steps, but I think there's widespread buy-in from all the key players, that they see the value of this.

DR. GLAUBER: Yes. I'm not troubled, per se, by the number of measures, just the fact that we don't have a rubber meets the road measure, and just would want some assurance that over time we will actually know the percentage of kids who are actually getting timely services, which is the point of the whole process.

DR. LIEBERTHAL: Yes. I think that the sequence that would make sense to me, we have newborn screening, if not screened in the newborn period, they get screened by 30 days. And then we have -- we haven't really discussed yet, but coming up 1362, referred within 48 hours. And I guess that would be the referral filed. And then pick a date for the date of intervention. You've got two different dates here, you have 91 days and you have six months. And the wording of the six-month one doesn't really say that they're being seen for intervention, it's just that they've been referred for intervention. So, I

think you have to go through a time sequence, and I think it's confusing to have your measuring patients who have been seen by the specialist by 91 days. And then you have it again, but they've been referred by six months. And those seem to be inconsistent to me. And one of them isn't necessary. And I don't know what the right date is for the intervention, but I think you have to pick the date, and then have that as the measure. And I think it should read have been seen by the specialist with intervention by whatever date is best medically.

MR. EICHWALD: What you're referring to is the one-three-six plan, and so it's by one month screening, by three months diagnosis, by six months intervention. And there's really been a shift now from not just by, but no later than. So, therefore, we want to try to get them in as soon as possible.

We're getting a number of kids into intervention within the first couple of

weeks of life fitted with hearing aids. I mean, that's the ideal. But the one-three-six has been vetted now for the last decade.

DR. LIEBERTHAL: Well, that's the way I would suggest you write the measures then to fit that plan, and I don't think that this set completely does that.

MR. EICHWALD: I may have been in a rush then, because I thought I hit them that way.

DR. MASON: Yes, the 91 days is for the diagnostic evaluation. It's not early intervention. It's diagnostic evaluation for 91 days. Then it's the six months for the early intervention.

DR. LIEBERTHAL: Okay. Again, I don't think it's working that way.

MR. EICHWALD: But it's the numerator, and that numerator matches that first three month one that we talked about. The denominator is the six months. Right?

DR. LIEBERTHAL: No, I think you're

dealing -- should be dealing all with numerator, and the denominator is those children who failed the measure. I'd have to go back to 1360. Let me see if I can pull it up. 1360, okay, that is by 90 days they've had an audiologic diagnosis. Okay. And then 1361 is the sixth month of your one-three-six. And that's whose age is less than six months at the time of referral to intervention services. The time of referral means when the -- however the mechanism of the referral is done, not that they're receiving intervention. And then the 48 hours is 48 hours of diagnosis, so that's different than the 30 days.

MR. EICHWALD: Yes, the 48 hours is a separate measure. And that one was based on, again IDEA. Any child diagnosed with a condition that's eligible for early intervention is to be referred to education within 48 hours. So, it's actually just sort of an ideal, the child is diagnosed by 90

days, by three months, and within that 48 hours, the referral has been made, and gets enrolled quickly. Our national goals are set at the one-three-six. But I agree, I mean, the sooner we get the kid into the process, the better, but these are just -- is the one-three-six plan.

DR. LIEBERTHAL: So, I think the wording -- if you change the wording of the six month, 1361 a little bit, you'll have what you want.

MR. EICHWALD: Okay. Thank you.

DR. JENKINS: Can I just ask, because we're kind of flowing into the 1362 discussion that I was supposed to be involved with, the 48 hours, how does that start? That was my question about that. How is that magic time point, where now we've confirmed that permanent hearing loss start, because that's from a validity perspective, and measurement perspective, where I got stuck on for 1362.

MR. EICHWALD: Yes. I mean, I

might have to defer to my colleague from Education. That's part of IDEA. I don't know how that's -- how Education wants to measure from the time of diagnosis.

DR. JENKINS: What does that mean, that the minute the test is over, the report is filed, it goes to medical -- I just didn't understand where the 48 hours started.

MR. EICHWALD: Time of diagnosis. I wish I had a better answer for you.

DR. McINERNY: I appreciate, Kathy, you want to go to this, but I think we ought to do 61 first, and then we can do 62. Otherwise, we're going to get kind of lost.

DR. WINKLER: Any more conversation about 1361, the intervention earlier than six months of age? Okay. Then how many on the Committee feel it meets the importance criteria? Any no votes? Okay. Ellen?

DR. SCHWALENSTOCKER: Yes.

DR. WINKLER: Okay. Scientific acceptability, how many feel it completely

meets? How many partially? Ellen?

DR. SCHWALENSTOCKER: I would vote completely if the measure was titled something like referral to intervention no later than six months of age.

DR. WINKLER: Okay. All right. On the usability criteria, how many think it meets it completely? One, two, three, four, five. Partially? One, two, three, four, five, six, seven, eight, nine. Minimally? One, two. Ellen?

DR. SCHWALENSTOCKER: I'd say completely with --

DR. WINKLER: Okay. And feasibility, how many feel it meets it completely? Partially? Minimally? Two. Ellen?

DR. SCHWALENSTOCKER: Partially.

DR. WINKLER: Okay, thanks. All right. So, this is a measure that's been around a while. Recommendation for endorsement, all in favor, yes. One, two,

three, four, five, six, seven, eight, nine, ten, eleven, twelve, thirteen, fourteen. How many nos? One, two. Ellen, where are you?

DR. SCHWALENSTOCKER: Yes.

DR. WINKLER: Thank you. Fifteen yes, two no. Okay. So, we're going to move on to 1362, and now we can go back to the discussion Kathy started on the referral to intervention within 48 hours. Kathy, did you want to continue on?

DR. JENKINS: Sure, I think we've already had quite a bit of prodromal conversation about this, to use a medical term. This says referred to intervention within 48 hours. It's the last in the series. It's, again, a timing of referral for infants who have had the audiological evaluation, and have been diagnosed with permanent hearing loss. I think my original question has been clarified, which is why 48 hours, and where the importance of that very rapid referral came from.

My major concern about it, other than not understanding that point related to the question I was just asking about, which was 48 hours from exactly when? Because that's a very, very short time frame for a medical system to respond to. Usually, life-threatening conditions have to be dealt with within 48 hours, and this doesn't quite feel like that to me. And then, obviously, the other question, which was the accountability, and who is accountable for this. So, those were my questions.

DR. WINKLER: Yes. Go ahead, Jim.

DR. GLAUBER: I think I might just be repeating in different words what Allan was saying, but I'm not sure in terms of harmonization we could have endorsed the previous measure, which talks about six months, and then endorse this measure, which if kids are receiving a diagnosis by three months of age, they need to be referred within 48 hours. It's a much tighter standard.

MR. EICHWALD: One of the reasons we use it is, since we're going to electronic health records, it's something we could measure relatively easily. We could just document when that referral was made after the diagnosis. And, as I said, it is part of IDEA for any child diagnosed with a condition for early intervention. We were actually sort of hoping this might actually open the door to Education. We say look, we've got some data you might want.

MS. SCHOLLE: But I still don't understand the 48 hours. That means if someone is diagnosed Friday at noon, they have -- it has to be done by Sunday. How does that work?

MR. EICHWALD: That's what in the federal legislation. I didn't write it.

DR. McINERNY: Go ahead.

DR. QUIRK: Yes. My question is, who makes the diagnosis?

MR. EICHWALD: In this case, it's

an audiologist.

DR. QUIRK: It's an audiologist. So, the audiologist can make the referral. Does the audiologist have to send the report to primary care physician?

MR. EICHWALD: Have to? Probably not, but it's certainly recommended in all cases.

DR. QUIRK: But that's -- but this is important. I mean, are you going to confer to the audiologist the authority to make the referral?

MR. EICHWALD: Anyone has authority. A neighbor can refer to early intervention, but that --

DR. QUIRK: Well, there's a permissive, and then there's a required. All right?

MR. EICHWALD: Yes.

DR. QUIRK: Because, you know, certainly the pediatrician isn't going to get through that stack of paperwork for four days,

unless he receives a call.

DR. MASON: I think in a lot of the cases, it is the audiologist who's making the referral directly to their Part C program.

DR. QUIRK: So everybody knows that, that doesn't have to be clarified. Since we're dealing with 48 hours, so that C-

DR. MASON: Yes.

DR. QUIRK: Because you said 48 hours is from the time of the diagnosis.

DR. MASON: Right.

DR. QUIRK: So, audiologists don't transfer data like other technology people, they make diagnoses.

DR. MASON: Yes.

MR. EICHWALD: And then we should be able to capture that electronically.

DR. QUIRK: Okay.

MR. EICHWALD: I mean, obviously, we're building the system to also send the information to the medical home, as well. I mean, that's the system that's being built.

DR. MASON: And there is a lot of -- there's EdD programs that are working on facilitating that mechanism, so that they get the --

DR. QUIRK: But the burden is on the audiologist.

MR. EICHWALD: On whoever makes the diagnosis. That's what's written in IDEA.

DR. QUIRK: Okay. That's good. Thank you.

DR. McINERNY: For practical purposes, aren't in many cases the audiologist is in the same system, or the same group that does the treatment?

MR. EICHWALD: In many cases, yes. Probably more often than not.

DR. McINERNY: Yes.

MR. EICHWALD: You're saying the treatment? I'm sorry, is that what you said?

DR. McINERNY: Yes, does the appropriate intervention.

MR. EICHWALD: I'm not sure what

you mean by intervention. I mean, fitting of the hearing aids, or are we talking about --

DR. McINERNY: Yes.

MR. EICHWALD: Yes, fitting of the hearing aids would probably be done by the same audiologist, in most cases.

DR. McINERNY: Right. The same agency.

MR. EICHWALD: If I understand your question, yes. The audiologist does the diagnosis would most likely fit that child with amplification, if the parent chooses that. But the referral is made to early intervention, which is generally under Education. There may be an Educational audiologist in that setting, may or may not be, but they're probably not the audiologist that would do the fitting, or make the primary diagnosis.

DR. WINKLER: I have a question. Is there any data to know how often it happens within 48 hours, or doesn't happen within 48

hours? Do we even know what kind of current -- what the current state-of-the-art is?

MR. EICHWALD: I don't have it.

DR. WINKLER: Despite the fact that it's a legal requirement.

DR. LIEBERTHAL: I think the state-of-the-art is hearing aids, if they will provide hearing.

DR. WINKLER: Yes.

DR. LIEBERTHAL: What we were just saying is, who pays for the hearing aids?

DR. WINKLER: No, I was wondering how many did it within 48 hours.

DR. BERGREN: I would suggest that it's probably not very often. And, as to the hearing aids, usually it is the Educational system. That's part of IDEA, also, is that the school system has to pay for the assistive learning technology, which a hearing aid would be included in.

DR. PERSAUD: I think I'm just mentally pondering between having two

measures, that this could be confusing for the practice system. It seems like there are two different standards to meet for the under six month old. And I kind of wish like maybe the 48-hour rule should stand for the older kids, because for under six months of age, if there are two rules, this could be hard for people to figure out what is it that we're supposed to be shooting for. Is it by six months of age, or is it 48 hours?

DR. BERGREN: It's not uncommon at all to have referrals at three, four days of age into the Educational system.

DR. PERSAUD: Yes, but if you have two measure -- two performance standard measures, people are going to look at those two measures and get confused. So, if it is common that it's done three to four days, and what the federal rule is, 48 hours, then make it 48 hours. Why do we have one that says a referral by six months of age, and one -- another measure within 48 hours of diagnosis?

DR. BERGREN: Because the other one is that they're referred for evaluation, isn't it? Am I misunderstanding?

DR. PERSAUD: I thought they said both of them are referral, that there's no way to pick up the intervention.

DR. JENKINS: They're both children who have already been diagnosed with permanent hearing loss. That's where it -- there is some confusing information about the numerator details, that includes normal hearing evaluation. That's not the population for those measures.

MR. EICHWALD: If a child were diagnosed at four months of age, he wouldn't meet the first one, but we'd want him -- all those children need to be referred within 48 hours, regardless of what month it is of the diagnosis. And then in terms of confusing people, this is one of those untested electronic measures that we're trying to build into the system, so that's just captured

automatically.

DR. JENKINS: I should mention that 1362 is only for time limited endorsement.

MS. SCHOLLE: Can we recap here, just to go back to what's already been decided. We've agreed with 1356 that everybody, all newborns have to have a hearing assessment before discharge. Is that right?

DR. WINKLER: That's 1354, but yes.

MS. SCHOLLE: Excuse me, 1354.

DR. WINKLER: We've done 1354, and we've also done 1357, which is for those who didn't get caught in the hospital, they get theirs done within 30 days.

MS. SCHOLLE: Okay. Then 1360 is by three months of age, there has to have been a more complete evaluation than was done either at time of discharge, or in the catch-up thing afterwards. Is that right? A more complete evaluation.

MR. EICHWALD: Right.

MS. SCHOLLE: And then 1361, is

that an intervention has to have occurred or been referred -- someone has to have been referred for intervention, not, necessarily, that it has started or happened.

DR. WINKLER: Correct.

MS. SCHOLLE: Is that right?

DR. CHEN: With the assumption that intervention will be rendered within 45 days per IDEA.

MS. SCHOLLE: And then 1362 is, once there's a diagnosis, no matter where in the six month window, a referral for intervention has to occur, not the intervention, obviously. Is that right?

DR. WINKLER: Correct. So, are we ready to make some decision about 1362? All right. How many on the Committee feel that 1362, the referral to intervention within 48 hours meets the importance criteria? One, two, three, four, five, six, seven, eight. How many do not feel it meets the importance criteria? One, two, three, four, five, six.

Ellen?

DR. SCHWALENSTOCKER: I say meet again.

DR. WINKLER: You said yes? Okay.

DR. SCHWALENSTOCKER: Yes.

DR. WINKLER: I'm sorry. Okay. So, 9-6. So, it met that. So we go to scientific acceptability. How --

DR. HURTADO: You have one abstention.

DR. WINKLER: Oh, one abstention. I'm sorry. Thank you. So, under scientific acceptability, how many feel it completely meets the criteria? Seeing none, how about partially? Minimally? One, two, three, four, five. Okay. Ellen?

DR. SCHWALENSTOCKER: Minimally.

DR. WINKLER: Okay, six. Under usability, completely meets criteria? None. Partially meets criteria? One, two, three, four, five, six, seven. Minimally? One, two, three, four, five, six, seven. Ellen?

DR. SCHWALENSTOCKER: I have to say minimally, I think on either 1361 or 2, but not both.

DR. WINKLER: Okay. And under feasibility, completely meets? Two. Partially meets? One, two, three, four. Minimally meets? One, two, three, four, five, six, seven, eight, nine, ten. Ellen?

DR. SCHWALENSTOCKER: I would say completely.

DR. WINKLER: Okay. All right. So, this one is, as Kathy mentioned, recommended for time limited endorsement. How many would recommend the measure? Yes? One, two. How many would not recommend the measure? One, two, three, four, five, six, seven, eight, nine, ten, eleven. Any abstentions? There are two. Ellen, where are you?

DR. SCHWALENSTOCKER: Well, for time limited, I would probably vote yes, but that 61 and 62 should be analyzed to see which

offers greater value.

DR. WINKLER: Okay. In this particular case, the no votes prevail. All right. So, we finished with that group of CDC measures. And we now have one more measure in newborn hearing screening. Do you want to try and do that one?

DR. McINERNY: Sure.

DR. WINKLER: And then take a break after that?

DR. McINERNY: Then your reward will be a break.

DR. WINKLER: This is Measure 1402, newborn hearing screening. This is from NCQA, and it might make it easier if just, Sepheen, correct me if I'm wrong, but this measure is very -- constructed very similarly to the measure we saw earlier on the blood spot screening in that it's the care coordination, did the result end up in the medical record for the pediatrician/primary care in the outpatient setting.

MS. BYRON: That's correct. So, this is a care coordination measure. And it says that the newborn hearing screening results would show up in the chart.

DR. WINKLER: Ellen, you were the lead for this one.

DR. SCHWALENSTOCKER: Yes. So, at the risk of repeating information, the numerator for this measure is children who had documentation in the medical record of a newborn hearing screening by age six months, and the denominator is children who turn six months of age and have documentation of face-to-face encounter. And I'm trying to find my note of the voting results. Four members of the work group voted on this measure. One felt it did not meet the importance criterion. I really need to improve my handwriting. I think most voted partial on scientific acceptability, and also varied on feasibility and usability, noting in terms of a feasibility issue it appeared to require chart

review. And I think most said partially on usability. And then -- I apologize for not being able to read mine. The one caveat around scientific acceptability is that it seems to be at odds with the AAP guideline, which says that the screening should happen by three months versus six months. So, it didn't seem to match the guidelines. And I think I understand that NCQA kind of has identified this whole set of measures as being six months of age. But I kind of agree with the comment, if the idea is that the screening should happen as soon as possible, then six months is a long time.

DR. WINKLER: Anybody else have anything to discuss on this measure?

DR. McINERNY: Well, I think in some respects this is a little bit like the blood test in the newborn period that gets reported. They get the hearing screening, it's done in the hospital, and a slip of paper, if it's on a -- everybody is still on a

paper system, ends up being sent to the primary care physician's office, and that gets filed somewhere in the patient's chart. Hopefully, first the primary care physician reads it, and sees what it says, and then signs it, and then it gets filed somewhere. And then I don't know, on electronic medical record, Allan, maybe you know a little better, but, again, I think electronically it could be reported, but then, again, where is it filed in the electronic medical record? And how do you find it?

DR. LIEBERTHAL: I don't know all of electronic medical records. Kaiser's version is that it would be reported in the hospital -- I don't know from all medical records. Kasier's version of EPIC, it would be recorded in the hospital chart, and the doctor in the office can look at the hospital chart to see it, but there's no protocol for where the doctor records it in the outpatient chart, so that the information is carried

forward. If it is a sensorineural hearing loss, that would be recorded in the problem list, but the fact that a hearing test was done is most likely in the hospital chart, not the office chart.

DR. RAO: But just to clarify, wouldn't that come into the in box, the results box in the outpatient chart? That's what happens where I work.

DR. LIEBERTHAL: As I said, I don't know what electronic system --

DR. RAO: EPIC.

DR. LIEBERTHAL: EPIC?

DR. RAO: Yes.

DR. LIEBERTHAL: Our EPIC doesn't do that, but I guess it could.

DR. McINERNY: You make my case. I think sometimes -- what I really like is that we will get reports from the hospital sent to us via fax, and we then scan those and enter them into our electronic medical record. So, you'd have to look in scanned documents, which

is not ideal, obviously, but that's the state-of-the-art in many cases.

DR. SCHWALENSTOCKER: This is Ellen. I think this troubles me, because if the idea is that the child with hearing loss gets the intervention as soon as possible, then even though there are obvious feasibility problems, that six months bothers me.

MR. EICHWALD: This is John. Can I make a comment? These are screening results, if I'm not mistaken, not audiological -- and the way at least we're designing it from an EdD perspective is it's going to be in the labor and delivery discharge summary, is where the screening results would be. And that's how the EHR thing of them capturing through that.

MS. BYRON: Can I make another note of clarification? Just conversing with the people who are in the office on my Blackberry, but we had conversations during measure submission with the CDC when we were preparing

these measures. Knowing that we had similar measures, we wanted to make sure that they were harmonized. And as I noted, ours is get the sample using by six months. However, we did test it at three months, also. And we had talked about conforming to the three-month time frame and saying that the results should be there by three months, and putting that limit on the numerator, which we can still do. So, if the issue is timing, then we can make it a tighter numerator easily.

DR. GLAUBER: This is a chart review measure. Would NCQA accept documentation of parental history of their baby having passed the screen, so the result may not be in the pediatrician's chart, but the pediatrician may ask the parent both about their perceived adequacy of the child's hearing, and their recollection of the result. And if both of those are fine, they may accept that as suitable.

MS. BYRON: Right. This is,

actually, similar to the other one. We made sure to test it at different levels, one being just was screening done? Second, do you see results? And, third, do you see some sort of follow-up? And we found that the field test participants were able to meet that middle bar of results being there, so we did make it a little bit more specific than just saying a parental history or attestation would be okay. We wanted to take it a little further than that.

DR. JENKINS: It's interesting, I'm sympathetic to NCQA, that you're trying to do it at the six-month time frame, and also that you're trying to do what you call baby steps, but it's sort of breaking down to have done that in a vacuum. It's interesting, though. The problem with the other set of measures was that we couldn't actually document that the treatment was received. Here we're actually doing chart review. I mean, you actually could go into the medical record of the

pediatrician and ask the hardest question of all, which is by six months of age, or whatever the appropriate time frame is, was the patients at risk actually received the treatment that they needed. And you may not have -- there may be other ways of verifying that information, but the pediatrician's medical record would be a way, where if you would up the bar a little bit, it might have achieved your needs. Now, I don't know if that's going to work in the NQF process, given the measure you already submitted, but I think that's part of the problem here.

DR. CHEN: I think I'll echo Allan and Kathy here. I mean, this measure would make sense if we expect intervention by -- or referral for intervention by six months. Then we should either see that in the chart, or see the referral for treatment, or screening, or, actually, for evaluation much earlier than six months.

DR. LIEBERTHAL: As I read the

measure, it really doesn't, necessarily, single out the children who fail the screening, but it wants the primary care provider to know whether the screening was done. So, it's another step in nobody falling through the cracks. So, yes, the kids who C- we have the measures now for kids who fail the screening, but now it's does the primary care provider know that the screening was done, and whether it was successful, or unsuccessful? And I think that's important, because when we take care of the kids in a general office, it's good to know whether they have normal screening, or not.

DR. CHEN: Right, I agree. I think that's a good point, but if you want to catch the kids that's falling through the crack, six months may be a little too late. Rather have it earlier.

MS. BYRON: Well, again, we could change the numerator to three months, and I'd have to check with NQF to see how that works

with their process, but we did test it that way. And I think what we're -- the intent of this measure is just to see that somebody checked, and somebody has those results, especially the pediatrician who is a primary care provider.

DR. WINKLER: Just from our perspective, simply because Sepheen says they tested it at the three month interval, and they'd be willing to go with it that way, you could make that recommendation, that you'd recommend it at the three month level conditional, and then changing it. That's not a problem.

DR. JENKINS: Did you test it at any earlier time points?

MS. BYRON: I can't think of it off the top of my head.

DR. WINKLER: Any further discussion? It sounds like everybody would be much more comfortable if it was a three-month time frame, at least, rather than six months.

Am I interpreting you all correctly? Okay. So, looking at this measure as a -- with a change to three months rather than six months, are we ready to make some decisions? All right. Then how many on the Committee feel that this measure meets the importance criteria? Okay, that looks like everybody. Ellen?

DR. SCHWALENSTOCKER: Yes.

DR. WINKLER: Okay. And on scientific acceptability, how many feel it completely meets criteria? One, two, three, four, five, six, seven. Partially meets criteria? One, two, three, four, five, six, seven, eight. Ellen?

DR. SCHWALENSTOCKER: I'd say partially. And you're saying that both on the three month. Correct?

DR. WINKLER: Correct.

DR. SCHWALENSTOCKER: Okay.

DR. WINKLER: We're going with three months. Usability, how many feel it

meets completely? Oh, I'm sorry, Faye. Minimal. Okay. Great. Thank you for -- not a problem. Completely meets the usability criteria? One, two, three, four. Partially meets the usability criteria? One, two, three, four, five, six, seven, eight, nine, ten, eleven, twelve. Minimally? Ellen?

DR. SCHWALENSTOCKER: Partially.

DR. WINKLER: Okay, great. Thanks. Okay. And feasibility, completely meets? Partially meets? One, two, three, four, five, six, seven, eight, nine, ten, eleven. Minimally meets? One, two, three, four. Ellen? Partial.

DR. WINKLER: Okay. Thank you. So, recommend for endorsement with the condition on it's three months and not six. How many say yes? One, two, three, four, five, six, seven, eight, nine, ten, eleven, twelve, thirteen, fourteen, fifteen, sixteen. Ellen?

DR. SCHWALENSTOCKER: I vote yes.

DR. WINKLER: Are there any nos? I did not see any. Okay. Great. We're done with that one. We're done with this group.

MS. BYRON: My question then is, does this sentiment extend to the newborn blood spot screening measure, as well? Because those two we tested as a pair, and also had the three-month data for.

DR. CHEN: I can't speak for anyone else, but for me that was the deal breaker for the blood testing.

DR. WINKLER: All right. How many of the Committee would prefer to see the blood spot screen be changed also to three months, rather than six?

MS. BYRON: It was a no with six months.

DR. WINKLER: Right. I just want to be sure.

DR. CHEN: I would go even earlier than three months.

DR. WINKLER: Okay. Just checking.

Okay. Break?

DR. McINERNY: Break.

DR. GLAUBER: Is it practical to make these distinctions? You're doing chart review presumably when the child is much older than these cutoffs, so can you really know when an element was first recognized in the child, especially if it's something submitted from the birth hospital, unless it's specifically dated and signed by the pediatrician?

MS. BYRON: Right. In field testing, we did look to see that there was a date in there with it being received. So, that's how we were able to look to see three months versus six months. And it appeared as if we could.

DR. WINKLER: Everybody ready for a break?

DR. McINERNY: You bet. Thank you. Thank you all.

DR. WINKLER: All right. Fifteen

minutes, 3:30.

DR. McINERNY: Fifteen, 3:30. Thank you.

(Whereupon, the proceedings went off the record at 3:16 p.m., and went back on the record at 3:33 p.m.)

DR. WINKLER: The next measure on our agenda from CAHMI. We just want to check, is anybody from CAHMI on the line? Colleen, are you there? All right. Then we're going to skip down to the next measure from NCQA, because we know Sepheen is here. And that is Measure 1396, healthy physical development. And this is in Work Group Three, and this is another one of the measures where I believe there are three measures embedded in one form. And this is the percentage of children who had a BMI assessment and counseling for physical activity, nutrition, and screen time. These are three separate measures. Measure One is the age group by six years of age. Measure Two is by thirteen years of age, and

Measure Three by eighteen years of age. This is 1396.

DR. McINERNY: We should have Dr. Rao, and then NCQA.

DR. RAO: Sure, we can start there. So, this is a measure that's dear to my heart, since this is what I do most of the time. But I did have some concerns with it. And, as Reva said, it deals with BMI assessment, but also counseling for three different important behaviors.

In general, the Institute of Medicine and other organizations are pushing for this sort of thing. And looking over some of the comments from other members of my group, I think we share some of the same concerns. First of all, that the numerator seems very complex, and requires a number of different things to be documented in charts. A BMI assessment is certainly a valid -- is an important starting point, but if you look at what's required of physicians to document,

even with respect to screen time, it seems like a very, very high standard to meet.

Some of the other members expressed a concern that some of these behaviors, and counseling for these behaviors has not been shown to influence not only the behavior, but weight, of course. Which is, of course, true. But it is a process-type measure at this point. So, those were my major concerns with it.

The other question I had for NCQA was, the testing of this measure was done on 18 practices. And just looking over some of the results that they got, for example, for physical activity counseling by age six, 69 percent, and goes up to 81 percent. It seems very, very high to me compared to what I know of primary care practices and chart reviews. And I wonder if there's a bit of a selection bias in the practices, or some sort of priming effect that might have taken place. I guess I'll stop there, and let NCQA respond.

MS. BYRON: Regarding what you said about the high rates, that is probably true. We recruited our field test participants with the help of the AAP, and pulled people from the Quality Improvement Networks, pediatricians, but we also have some family physicians in there. So, it's probably safe to assume that this is a group that is aware of quality improvement. They're motivated to do quality improvement, and their rates are probably higher than what you will see for regular practice.

DR. GLAUBER: If I recall from reading the specs, can you satisfy the criteria by giving some educational information or brochures, so a lot of practices routinely give out at age-specific visits literature of this sort, which you can satisfy the criteria --

DR. RAO: You do, but you have to still document that this was given. I mean, there's so much counseling that takes place in

a typical primary care visit, some of which might be nutrition-related, some of which may not. I mean, we found in the research I've done is that the quality varies tremendously, eat better, exercise more. Those two lines might constitute counseling, but a more detailed inquiry is much more rare.

I mean, as a starting point, I think BMI assessment and documentation is a great measure, great starting point. It's about time that somebody put it together, but the rest I have concerns with.

MS. BYRON: So, this is a U.S. Preventative Services Task Force recommendation. The assessment.

DR. WINKLER: And referral, not the counseling.

MS. BYRON: For referral. Okay.

DR. WINKLER: Just for perspective, NQF has endorsed a measure for BMI assessment in children age 2-18 years of age. It's been on our books for four or five years now, so

it's not -- this isn't a new concept. The thing that makes it, perhaps, different is the addition of the counseling elements.

MS. SCHOLLE: So, as a general matter in these processes, if there's not adequate data on the influence of counseling on a topic of any kind, does that -- how are we supposed to think about that? Is it just that -- is this to raise the consciousness of clinicians, or is it really to get an effective service offered to more people?

DR. ZIMA: I think that's an excellent question, because we're going to revisit this again on the risky behaviors, and the lack of effectiveness of counseling on substance abuse, as well.

DR. GLAUBER: But I think it's not a benign thing to endorse something for which there may not be evidence, because there's only so much that physicians can do in a visit, and there's a risk of crowd-out of more beneficial interventions if there's just a

broader set of recommendations and measures that people have to be responsive to.

DR. LIEBERTHAL: I think that's a very good point, but there's two types of no evidence. One is that nothing is done because nobody has funded it to do, and we haven't done it yet. And one, there is actually a study that show no improvement, or no consequence. And we have to distinguish between the two. If it's the first case, where there is no evidence because there isn't any, then I don't think we should count it against a measure for that particular reason.

MS. SCHOLLE: So, how do these stack up?

DR. RAO: In terms of counseling, or in terms of -- I don't think there's good evidence to suggest that counseling families with respect to these three behaviors has a lot of effectiveness. I mean, obviously, if children cut back on their screen time, there's a randomized controlled trial about

limiting TV time that has shown an effect on nutrition, and weight, and health. But the actual counseling part, I don't --

DR. PERSAUD: Yes, I understand that what the data shows is you need a three-pronged approach for at least six months. There's data on the length of time that you need to do that. So, I think there's no evidence that one time in the office has any effect.

DR. McINERNY: I have a couple of concerns. Number one, I think it would be a simpler measure, instead of breaking it up into these different age ranges, and one of the big problems is I think six is too late to start. I would suggest that there is at least -- let's start with measurement of the BMI percentile, and that should be started at two or three years, at least. And then just at every well child exam, there should be a measurement of the BMI percentile. So, that would hopefully get us out of these different

age ranges, number one.

Number two, there is -- the evidence is non-existent that the counseling does any good. There is evidence starting to come through that more motivational interviewing probably does -- is effective, but there are very few, as far as I know, pediatricians, or maybe there are some family physicians, who really understand motivational interviewing, and have been trained in that technique. That's something that we could, hopefully, over time, but we're not there yet. So, I'm not very happy, or comfortable with putting all of these counseling requirements in. I would just like to stick with at least doing the BMI percentile, and doing it at every well child visit.

DR. RAO: I agree. And I think the other issue for me was the documentation aspect of it. Counseling is notoriously poorly documented, in general. And to rely on chart review for measuring this particular

process I think would be a mistake.

DR. McINERNY: And, although some electronic medical records, the documentation is excellent.

DR. RAO: We have the opposite problem, too.

DR. LIEBERTHAL: I have a question. Measuring the BMI is great, and I certainly agree with it, but if it's abnormal, what are you going to do to address it? It's similar to some of the other things that we've discussed, where you find something, and then what action or follow-up are you going to take. Now, is it giving handouts, is it referring them to a nutritionist? Where do you go from you have a high BMI?

DR. RAO: Yes. The general approach, Allan -- the philosophy in primary care, not just mine, but a lot of people share is that all children can benefit from nutrition and physical activity counseling regardless of their BMI. So, the BMI issue is

a separate one.

In terms of what would you do, there are certain -- I mean, I was on the AMA's committee that recommends certain laboratory testing after BMI exceeds 85, and BMI exceeds 95. But the basic counseling that they're describing here is something that all kids can benefit from.

DR. McINERNY: I think, if I remember correctly, U.S. Preventative Services Task Force did come out with a statement earlier this year that it was referral, I believe, for a moderately intensive program was --

DR. RAO: Yes.

DR. McINERNY: -- effective.

DR. RAO: Right.

DR. McINERNY: So, that's a whole different thing from me saying to the patient you need to try and lose weight, or exercise more, eat less.

DR. RAO: Yes. And that

recommendation came under a lot of criticism, because there aren't that many -- there aren't an adequate number of programs and physicians for children.

DR. McINERNY: Right.

DR. RAO: So, from the primary care context, it's not really something everyone has an option. Can I just ask Reva a question? I mean, the BMI percentile measure that we have, is it identical to this in terms of the counseling part?

DR. WINKLER: Not necessarily identical. In fact, it's a very straightforward basic measure.

DR. RAO: Okay.

DR. WINKLER: It is BMI measurement in children ages 2-18. I can't remember if it's at least annually, or what the time frame is, but I think that's what it is. It's a very straightforward measure.

DR. LIEBERTHAL: So, what is your recommendation with regard to this measure,

throw out the counseling because it's ineffective?

DR. RAO: I wouldn't -- yes, I would throw out the counseling, if we already have a BMI percentile measure that that's straightforward. I don't see the point of even keeping that portion of it. I didn't realize we had one.

DR. BURSTIN: I think we'd have to check. I believe it's one of the measures that's being retooled this year for meaningful use, as well. And I don't believe it's -- I think it's literally a straight -- just the BMI, does not include the percentiles, but I'll confirm that for you.

DR. RAO: Oh, no, if it doesn't have the percentiles, it's not --

DR. BURSTIN: I don't believe it does, but we're working from -- it does not. Okay. It's been confirmed.

DR. RAO: Okay. Yes, then we do need this.

DR. WINKLER: But does this measure specification include the actual result?

DR. McINERNY: Can we bring up the numerator, please?

DR. WINKLER: Yes.

DR. McINERNY: Showing that documentation in the medical record --

DR. WINKLER: It has the percentile.

DR. McINERNY: Then if you go underneath that, BMI weight assessment back t the patient must include a note indicating BMI percentile was documented.

DR. WINKLER: Was documented, right.

DR. WEISS: Can I just ask an informational question here for those who are practitioners? When you have, essentially, three different measures merged into a single performance measure, how do you handle partial completion? What do you do? If one and two, whatever it is, six months, and X number of

years, what is it, six years and thirteen years it's -- the child has had the BMI assessment, and the counseling, all the rest of it, but not at 18. Do you report that as completed, or not completed, or partially completed? How does that work?

DR. WINKLER: These are three separate measures. NCQA just put them together on one page.

DR. WEISS: I see.

DR. WINKLER: But they actually want them treated as three separate measures.

DR. WEISS: I see.

DR. JENKINS: Marina, just as a general answer that I know from some of the experts in the cardiology community, there's a strong feeling of unintended consequence to all composite measures, or bundled measures, where if it's a really high stakes environment where you really aren't going to get paid more money or less based on your compliance rate, that what you'll do is try to move somebody

where you're already 80 percent compliant to 100, and the real performance gap, or the people, for example, that you're not meeting any component of the bundle, so --

DR. WEISS: So, you would, essentially, use a preponderance rule, if you're kind -- if you're almost there, you C-

DR. JENKINS: You're just trying to get the money. So, we have to remember that once NQF's stamp is on these measures, that they are going to be used in these very high stakes environments. And to your point, Goutham, our pediatricians have been subject to this in Massachusetts by one of our major players, and have highly resisted these -- being paid less money for not moving BMIs when they're not sure that they can.

DR. GLAUBER: In my practice, we've taken it one step beyond the BMI assessment, which is we're looking at the percentage of children with an elevated BMI who have recognition of this on their problem list, so

that overweight is recognized, whether it's in the paper record, or in our case the MR. Once you measured it, the next step is culling it out as a problem. So, I wonder whether NCQA has considered at least looking at this level of documentation.

MS. BYRON: So, making it more of a risk-based measure, is that what you're asking? So, if your BMI is above a certain level, then did you get counseling?

MR. EICHWALD: Then you get documentation.

DR. GLAUBER: Yes. You're looking for documentation on a child's problem list in the chart, or at least within that note that this child's overweight, so that infers that the clinician has not merely just measured it, but has interpreted the test, and has culled it out as a significant health issue.

MS. BYRON: Right. I think that our intent to get at that was to make this not just a BMI number, but a BMI percentile. So,

just to give you some context, also to address some of the questions about the age group. So, this is a measure that is included also in our composite measure, which is why you see the by six years, by thirteen years, by eighteen year age breakdowns. And then for purposes of NQF endorsement, we also pulled them apart as separate measures. So, the measure is BMI assessment, and counseling for nutrition, physical activity, and screen times. The four indicators are separate rates within one measure, and we did this because our measurement advisory panel said that we didn't want to just look at BMI percentile. We wanted to also see that there was some counseling done for issues. And it is counseling all children. It's not counseling only children with a problem.

I see what you're getting at. We wanted to make this measure feasible, and we wanted to set the bar at look at a BMI percentile, and then counsel, give some

anticipatory guidance on nutrition, physical activity, and screen time. So, if it's just a straight BMI number, it would not count in the numerator. We want to see a percentile, or something charted with the growth chart. So, that was our attempt to get at making sure it was interpreted.

DR. GLAUBER: I'm not sure if you're connected with Affiliated Pediatrics Practices in Harvard Pilgrim Health Care, but they're doing exactly the same thing that you described. And that's maybe 1 or 2 percent of all pediatrics groups right now that are doing that, that level of documentation.

DR. McINERNY: My problem with a composite measure like this is that what probably would get reported back is that if the pediatrician were recording the BMI percentile, but then did not record or document that they spoke to the parent about nutrition, or screen time, or activity, they would get a fail. And that would get reported

back to them for a fail, even though they really -- at least they did what, one, is considered to be the most important thing to do, and, two, they didn't do what there's no evidence for that it works. And that doesn't seem -- to me, that doesn't seem to be in the spirit of what we're trying to do here.

MS. BYRON: So, it's actually different rates. So, you could get a pass on the BMI, and then you could get a fail on the counseling, and it would be reported separately. So, it's not an all or nothing, so it doesn't mean you would fail the entire measure.

DR. McINERNY: All right. That's a big help. Thank you.

MS. BYRON: Okay.

MS. SCHOLLE: But why would people be asked to do something that's not effective? I don't understand that.

MS. BYRON: It's actually in Bright Futures, and some other guidance that sort of

anticipatory guidance is useful and effective. Denise, did you want to --

MS. DOUGHERTY: Yes. The U.S. Preventative Services Task Force recommendation is to screen for BMI, and refer affected children to medium, to moderate, to high intensity interventions.

DR. WINKLER: Right. That's not counseling. That's a --

MS. DOUGHERTY: But that's not the same as counseling by the primary care provider. Not, necessarily, unless you're going to do a lot of high intensity counseling.

MS. BYRON: When it comes to the child health measures, I think you've got a spectrum of evidence, and one of the unique issues with children is that there aren't a lot of randomized controlled trials, or it's very difficult to establish long-term health care outcomes. And that is a challenge that we have in child health care, so all along the

way with all of these indicators, we were forced, working with our Measurement Advisory Panel, and our stakeholders to place the needle at a place that balances all of the research, all of the importance, and, in addition, the feasibility, those three criteria. And depending on what we saw as feasible, plus important, is this an important area, yes, it's obesity. Everyone -- no one would argue that it is a growing problem in our country.

And then in terms of it's important to refer them, but anticipatory guidance can be shown to be effective. Bright Futures and other organizations do recommend it. This is where we placed the needle for this measure. So, what you're seeing is our attempt to balance all those things.

DR. RAO: And I'd also point out, even those medium and high intensity weight management programs have a pretty modest impact on children, so this is recommended.

DR. McINERNY: Would it be possible to sort of split the resolution, so to speak, and we could vote on the recording of the BMI percentile, number one. And then the second vote would be on the counseling measures, number two. Is that possible to do that?

DR. WINKLER: It's possible to do anything you want to.

DR. McINERNY: All right. I move that we do that.

DR. WINKLER: I think that what you're doing is making a recommendation to NCQA, which will -- it will remain to be seen whether -- how they respond to it. But I'm hearing from you all that the first rate in their measure around documenting the BMI number is where you think there's value, and not so much the rest of it, and if that could be pulled out and isolated.

The other thing you were talking about is the age bands versus an all-inclusive age range. Where did you want to end up with

that?

DR. RAO: You know, in reading this measure, I thought that if we are going to just use the BMI percentile, we could probably just have one big age group. It's the counseling that might vary according to age. Children under the age of six don't watch as much TV as those between six and thirteen, that sort of thing.

DR. LIEBERTHAL: I think that this age thing is a theme that runs through many of the NCQA measures, so maybe we should deal with that as a whole, rather than dealing with them with each measure. I think that at some places it is appropriate, but in some places you have the same measure, and they mark it at each of their age ranges. And I don't know that that's very useful.

DR. BURSTIN: If it's useful, I'm happy to send around the actual USPSTF recommendations for obesity just to the group, if you want to just see the final PDF. It

does say ages six and older, and some pretty clear specifics about what equals low versus medium or high interventions.

DR. BERGREN: I just wanted to ask about what would qualify for meeting the criteria. For instance, in Illinois, you only have to chart that the person is over a certain percentile, so they don't actually document the exact BMI. But if they're over the 85$^{th}$ -- are you looking for the exact percentile on this?

DR. WINKLER: That's what it says.

DR. BERGREN: Okay.

DR. WINKLER: Documentation must include a note indicating BMI percentile was documented and evidence of either of the following, the BMI percentile, or the BMI percentile plotted on an age growth chart.

DR. BERGREN: Okay. Thanks.

DR. McINERNY: I'm very -- really I get more and more unhappy with these age discrepancies. I mean, so you do it at six

years, then you don't have to do it again until 13, that's seven years. Then what you want to do is look for are patients crossing percentile lines over a period of two or three years. If you wait until 13, and they've crossed up from the -- let's say they started the 50th percentile at six, but at age 13 they're above the 95th, your chances of doing very much at that stage are zero to none. Whereas, if you -- I still think we should try and have that assessed at every well child visit, and, hopefully, with some of the other measures we're getting from NCQA, that every well child visit is annually. Then you stand a much better chance of, perhaps, at least informing the parent that the patient is crossing the percentile lines.

MS. BYRON: NCQA does have a HEDIS measure that is BMI assessment and counseling for nutrition, physical activity that is endorsed. And it is, I believe, annual. With this, I think what you're seeing is some of

the difficulties of looking at composite measures separately, so with NQF to get the composite endorsed, we had to also have the individual components looked at. So, all of our measures you will see follow the framework that we came up with, which is try to hit a child's development line along certain milestone ages. So, the ages are by six months to deal with things that you would see for infants, by age two, by age six, by age thirteen, and then eighteen, so we're trying to get at school readiness, and then we're trying to get at adolescents, and then entry into adulthood. So, that's the reason for the ages.

I understand the discomfort, but it's a different denominator, so you've got a denominator saying -- and we're not saying that it only has to happen at a certain visit. We're just saying by the time you reach that age, do you at least have it at least one time. So, that's where we put the bar. It

makes, I think, probably a lot more sense as a complete composite measure that we say by age six months do you get this whole slew, maybe 10 indicators, and we score it as a composite.

MS. CARLSON: We had long discussion about this topic in Wisconsin a couple of years ago, and one of the biggest issues was the feasibility of actually going in and doing the medical record review on every single chart. And there are ICD-9V codes that gives you -- stratify your percentage of BMI such that you can code a claim with that code. And what our state did was recognize that it is very burdensome and costly to go into the medical record, and you didn't get much more for doing that. Whereas, having that BMI documented every year, according to the EPSDT schedule of visits, so the providers are actually paid a little bit more if they include that code on their EPSDT claim for that year, for each child, for every year that they do an ESPDT exam. It's

relatively new. It's just picking up, but it is starting to happen. And I think we found that to be a less costly way to get at the dollars, but also a way to get the attention of providers, make sure that they really are calculating BMI, and they really are documenting it in the record. And they're getting credited for it financially for -- a small incentive, granted, but they're getting that for doing it.

DR. PERSAUD: I think I'm less discomforted by the age separation than I am about the counseling. And I certainly understand the move to given that we're so burdened by adding repetitive actions at every single age. And I do believe that there are now challenges to the periodicity that we're following. Maybe relooking at should we target certain activities at certain ages. So I'm less discomforted by the -- coming up with -- setting some standard by age six, by 13, than the issue of counseling, which I don't

think -- probably Goutham would gag at this. I mean, I even thought well maybe the second statement should be if their BMI is the 95$^{th}$ percentile or older, they have a referral, not counseling, because that, to me, fits more with what people believe the practice standard should be. And there you would be isolating the highest risk group. And really, counseling is not going to help them. If anything is going to work, it would be a referral to at least a moderate intervention.

DR. RAO: Yes. And I've discussed this on a couple of other committees. That would be tremendous if we could do that, but the problem is the lack of resources in most communities. As an alternative, if there is an interest in pediatric obesity measures, we thought the direction that people would go in was a medical evaluation that included certain aspects, documentation of blood pressure percentile, lipids, et cetera. But that's a whole other topic.

DR. WINKLER: What I'm hearing is, that as presented, as three separate measures by age, but with these four rates embedded in them is not something the Committee wants to move forward with. But you would, if NCQA would consider it, you would, perhaps, support a measure of just the weight one, the BMI weight assessment documenting the percentile. And then I didn't get a real sense about the age issue. Within those age bands?

DR. McINERNY: Sure.

DR. RAO: So, just to understand the age issue. It's documentation of BMI percentile just one time in those age bands?

MS. BYRON: At least one time.

DR. RAO: At least one time.

DR. WINKLER: Just what we said, documentation must include a BMI percentile, documented -- I mean, that's --

MS. BYRON: By the age that's listed, and then there's -- we usually offer a two-year look back, so look back in the past

two years to see if it happened.

DR. RAO: Yes. I mean that, to me, seems like a bit of a low standard. Typically, you're supposed to do -- like Tom said, at an annual visit you should be measuring BMI, BMI percentile, and documenting it.

DR. WINKLER: So, what's the pleasure of the Committee? What would be your recommendation, Dr. Rao?

DR. RAO: Annual documentation of BMI percentile.

DR. WINKLER: That sounds to be the measure that the Committee could support.

DR. RAO: Yes.

DR. WINKLER: And not the others. Is that what I'm hearing?

DR. GLAUBER: You know, evidence or not supporting it -- certainly, I'm comfortable with recommending this without any follow-up, so how -- would it be feasible to say for those kids whose BMI percentile is

greater than the 85th percentile that we have evidence of this triad of activities? So, it's sort of a blended approach.

MS. BYRON: I think you really start to change the measure at that point. We field tested that by the time you reach a certain age, is there documentation. We didn't look to see -- if we start to now put requirements on the BMI number, and then seeing if there's -- it's just structured as a very different measure. That one is a little more difficult to change than the other ones.

DR. WINKLER: Sepheen, how about the age denominator issue?

MS. BYRON: I'd have to see if we could change that. I mean, we did test it at each one of those ages. And, like I said, we have an existing HEDIS measure that's just C-

DR. WINKLER: Everybody.

MS. BYRON: Yes, exactly, or starting at age three on up. This is the

physician-level measure that --

DR. WINKLER: So, what I'm hearing is that the Committee probably can't support anything that's not just the rate of the BMI; although, Jim is having some issues about wanting to follow-up, but nobody can support any evidence-based follow-up, particularly, to include in the measure. And then in the age bands, to make it simple, can we look at the measure with just one change; in other words, just rate one. Leave the age bands in the denominator so that that's not changed, but only the rate one, which is just documenting the BMI, the percentile number, and none of the counseling rates. All right? Can we see how the Committee feels about that? How many feel that would meet the importance criteria? Ellen?

DR. SCHWALENSTOCKER: I didn't quite catch the recommendation. I'm sorry.

DR. WINKLER: Okay. Fine. Was anybody voting no? One, two. Okay. Kathy,

can you just -- your issues are?

DR. JENKINS: I think the bar tends to drown out the importance.

DR. WINKLER: Anybody else want to respond to that? You want to change your vote?

DR. QUIRK: That there should be some affirmative statement in the record or a box checked that a sentient being had looked at it, and acknowledged it as being abnormal or of concern without commenting on what intervention should be done.

DR. JENKINS: It sounds like that's what Dr. Glauber was suggesting with the answer earlier to at least put it on the problem list.

DR. QUIRK: At least now it doesn't look like you're walking on the water. You can see the bar above the meniscus.

DR. RAO: Yes. I mean, I do agree with Kathy. It's a really low standard that we've set. However, I mean, if you look at physician practices right now, most of them

are not documenting BMI percentile. They're not even recognizing 85 to 95 as overweight, and passed 95 is obese.

DR. BERGREN: That's what I wanted to comment about, is that in Illinois, all you have to do is check if a child is over the 85th or not. And we actually did a study where we looked at 400 kindergartners, and looked at whether or not they had calculated it correctly. And 10 percent were calculated incorrectly, where they had said the child was not over the 85th percentile, and yet they were. So, I actually do think this is an important measure, because I don't think the physician is actually calculating this. I think it's a high school educated receptionist who's doing it, and I think to force that issue of -- am I talking too loud?

DR. WINKLER: No, no, go ahead.

DR. BERGREN: To force that issue to actually calculate it I think is a very good thing.

DR. JENKINS: You've convinced me, but perhaps NCQA would consider Dr. Glauber's suggestion in lieu of the counseling.

DR. RAO: And that was to add healthy weight, overweight, or obese to the problem list. I don't know if they can do that, but that changes the measure.

DR. WINKLER: Trying to recap one more time. In terms of what's likely to be possible, given where we started, and what NCQA is likely to be able to do, I don't -- it's sounding like from what Sepheen said, that despite the support for your recommendation, Dr. Glauber, that it probably isn't something -- we can ask them to discuss it and consider it.

MS. BYRON: Yes. And we can look into that. I probably just need to touch base again with the rest of the team to make sure. I think the age band is something that's probably pretty doable. But in terms of the mechanics of the rest of it, we'll have to

look at it. So, you're saying that you want an interpretation of the BMI result, and some sort of notation that says healthy or unhealthy statement in the problem list, but not, necessarily, anything about counseling after that. Okay.

DR. WINKLER: Perhaps, it's premature to try and evaluate something that we haven't seen yet, so maybe the best thing is to let Sepheen and NCQA hear your feedback, and redo what you can do based on it, and bring it back. Does that seem like a reasonable plan? Yes. Okay.

All right. Next measure -- let's just see, is anybody from CAHMI on the line? Colleen?

DR. STUMBO: Scott Stumbo.

DR. WINKLER: Excuse me?

DR. STUMBO: Scott Stumbo --

DR. WINKLER: Hi, Scott, how are you? Okay.

DR. STUMBO: Yes, I received from

Denver at the American Public Health Association conference, but this is me.

DR. WINKLER: Okay. All right, Scott. Let me just introduce the measure to the Committee, and let them talk about it briefly, and you can be available to respond.

DR. STUMBO: Okay.

DR. WINKLER: Measure 1350 is a measure from CAHMI that is derived, again, from the survey that I think the folks from the Outcomes Group, remember we saw a goodly number of measures that came from the National Survey of Child Health. And this is also a survey-based measuring.

What's interesting is this measure on emergency room visits, which measures the number of times a child visit the emergency room in the past months was on the 2003 survey, but was not on the 2007 survey. And they're planning to put it back on the 2011 survey. So, it's had an interesting history.

Again, this is a survey of

parents. This is a national survey that's done every four years. All of the data is collected and is housed on CAHMI's website. They have a data resource center, so you can go and look at the results of all of the stuff for different states.

Dr. Chen, I believe you were the discussant for this one.

DR. CHEN: Yes, I'm assigned to this particular measure. So, I'll just briefly summarize, starting with the importance and impact. So, obviously, there's very clear evidence that the number of ED visits is perhaps a proxy of poor quality of care in the general health care setting for children, as well, as well as adults. So, I do believe it is an important proxy to assess. I do believe that affects a large number of people and children so, therefore, it has high impact.

Now, there's a couple of concerns as far as the importance goes, is that this

particular measure is somewhat simplistic, which is not a negative thing, but it's also somewhat crude in the sense that it only measures the number of visits to the ED. It has no assessment of whether or not the visit is appropriate, not appropriate. Obviously, there's no risk adjustment involved, and there's no exclusion.

So, moving on from there to looking at scientific acceptability, since it's a fairly simplistic measure, it's very well defined. It's very accurately defined. The numerator is the number of times a child visits the emergency room during the past 12 months. And the denominator is all children zero to seventeen years of age, which all makes sense. Now, they could stratify, because it's a national survey based on socio demographic, and other demographic information, but they didn't stratify here.

Now, as far as reliability and validity, it, obviously, has some face

validity. Reliability is a little bit of concern, because it's actually a parent survey and the parent recall, therefore, it's subjective to recall bias. I, actually, much prefer using the MEPS to look at this. But, obviously, MEPS is a representative sample, as well, but maybe not. It's not as many people as the National Survey of Child Health. But I have some concern about it being a parent survey, because there's some intrinsic bias there.

Usability, it's, obviously, very useful I think for both health and provider groups, as well. And then, lastly, feasibility. I don't know what kind of cost it would be to each institution and/or health center to conduct this type of survey, and what size of survey needs to happen, so there would be a cost to it.

DR. WINKLER: This measure is presented as a population-level measure, rather than a provider-level measure. Though,

when we talked with the folks at CAHMI, they have for some of their measures worked with plans and provider groups to see how it might be -- changed the appropriate specification sampling, et cetera, to make it applicable to others. But, at this point in time, it's presented as a population-level measure.

DR. HURTADO: Just a comment regarding the recall bias. I think emergency room visits for the past year, it's a pretty salient event, or --

DR. CHEN: I, actually, disagree. I mean, hospitalization is a pretty salient event for past year, but I have kids that visit the ER 30 times in the past year. They can recall 30 times they visit the ER.

DR. GLAUBER: And is this intended to be presented as a mean, or median, or any other descriptor statistics?

DR. RAO: Threshold values.

DR. WINKLER: Scott, did you hear the question?

DR. STUMBO: Sorry, I think I was on mute. Could you repeat that?

DR. GLAUBER: Is this meant to be presented as a mean number of visits per child, or a median, or other descriptor statistics?

DR. STUMBO: We viewed them in a number of ways. It can be used as a count, as well. And the reason we didn't include any stratification with the measure, because the data is from 2003, and we understood they don't want older than five years probably not included as a point.

DR. RAO: I just wanted to echo some of the same concerns that Alex raised. I mean, it's not just a question of risk stratification. I wasn't clear what this is actually measuring, because it is so simplistic. Is it measuring access to care? Clearly, most kids are coming to the ER because they don't have access to primary care, perhaps. And in other settings, maybe

the children just suffer from high rates of asthma, or do have to come to the ER, so I just think it's too simplistic. I think we need more --

DR. BERGREN: One of the reasons that we like it in school health and community health is that it's more of a measure of the multiple types of care that are available. And in some respects, for instance, in LA, and most of California, there's hardly any kind of structure of school health, where there's a nurse in the school to reinforce. First of all, the one research study in pediatrics that thought that the increase in injuries to the ER were because there's no nurse right now at the school any more to say oh, this is nothing. You don't have to go to the ER. So, those of us in community health are really looking forward to this measure as a way to measure all of the support systems within the community to decreasing unnecessary emergency room visits.

DR. STUMBO: We believe the measure is important for 2011, especially, because of the Affordable Health Care Act, and, therefore, barriers to care should be less. And we would like to be able to show that.

DR. BERGREN: Could one of you comment on how this would actually be done? I understand that's it been done nationally through a nationally representative survey, but what would the plan be that individual municipalities, or counties, or how would this actually be done?

DR. STUMBO: I can't comment --

DR. BERGREN: It would only be done at the national level. There would be no -- it wouldn't be done at the state level. You'd only have a national estimate --

DR. STUMBO: Yes, it's very representative.

DR. BERGREN: Already. And it would stay that way. It's not the individual counties, or regions, or so forth to do, it's

just so it's state level.

DR. WINKLER: AT this point in time, I think that --

DR. STUMBO: That's correct.

DR. RAO: Can I just ask a question about risk stratification? Is it possible to have this measure exclude children who visit, and then are hospitalized, so these are just single ER visits? I think that's what we're really looking at. And it gets to the whole idea of appropriateness of the visit, or not.

DR. STUMBO: There is no measure of hospitalization in the survey.

DR. GLAUBER: I also agree that C -I'm not sure exactly what this is measuring, but maybe if it could be tied to also asking the parent whether they've had a face-to-face visit with their child's pediatrician in the same measurement period, that might get closer to the idea of how many kids are out there who are relying on the ER for primary care, because at least a good percentage of ER

visits should at least be followed up with a primary care visit. So, I think it would capture a more important domain if we were also asking about primary care visits, as well.

DR. STUMBO: There is a measure of primary caregivers in the survey, so it can be related.

DR. CHEN: Is that Scott on the phone there? This is Scott, right?

DR. STUMBO: Yes, I'm sorry.

DR. CHEN: So, I know the data pretty well, but I don't think the primary care visits correlated or connected to the ED visit. It's just visit, in general. So, there's no way to link whether or not that ED visit is followed by primary care, or it was -- there's no association, whatsoever, so that doesn't get at James' point.

DR. GLAUBER: No, it still does.

DR. CHEN: It does?

DR. STUMBO: That's correct they're

not related.

DR. McINERNY: I see this as a sort of a crude but useful measure over time to see whether or not whatever kind of health reform and improvement we're doing, are we having more or less ED visits? Ideally, of course, we'd like to see ED visits go down. And it would be interesting to measure that to just see whether, in fact, is it happening, or not.

DR. JENKINS: But, as a follow-up to that, that evaluation could be done separate from NQF endorsement, if this is a performance measure with the population. So, it's just a number from the survey that can be used. I'm not understanding exactly why it's being proposed as a performance measure for NQF endorsement at the population level given some of these measurement challenges.

DR. GLAUBER: I also think if we're interested in the number of ER visits, that can probably get determined more accurately from payer data, rather than from parent

recall, both as a threshold measure, and as a number of visits.

MS. CARLSON: Payer, and/or hospital reported data, which is typically recorded to most states, I think, state health information systems. The other concern doesn't account for the ambulatory sensitive condition piece of it, which is really what we want to get at, not all hospital ED conditions.

DR. HURTADO: I just had a question. In terms of looking at variability yearly, the survey -- it doesn't seem to have a defined periodicity, does it, from now forward?

DR. STUMBO: It's currently every four years, but the Institute of Medicine may recommend it become the national standard for child health measures.

DR. HURTADO: Yearly, then? Because, otherwise, variability -- you can't recall track every four years, as well.

DR. WINKLER: Yes. Shall we -- ready to see how you feel about it? For the measure, as submitted, how many in the Committee feel it meets the importance criteria? One, two, three, four, five. How many feel it does not meet the importance criteria? One, two, three, four, five, six, seven, eight, nine. Ellen?

DR. SCHWALENSTOCKER: I'll go with a no.

DR. WINKLER: Can't hear you.

DR. SCHWALENSTOCKER: I'll go with no.

DR. WINKLER: Okay. You'll go with the nos. All right. So, that is the end of that. Okay.

Scott, the Committee voted four yes, but 10 nos on moving the measure forward.

DR. STUMBO: Okay.

DR. WINKLER: Okay?

DR. STUMBO: Thank you.

DR. WINKLER: Thank you. Get out

of the wind. Do we have someone from the Institute of Clinical Systems Improvement on the line?

MS. HUNT: Yes, you do. It's Gail Hunt.

DR. WINKLER: Hi. Just because they are kind of waiting, if anybody would mind, we're going to move to their measure to allow them to do their part. And that is Measure 1353 from Work Group Four.

This is a measure of Preventative Services for children and adolescents on time with recommended immunizations. Let me just -- what have you got up there, Suzanne? Okay. Great. You've got it up there.

Just to -- all right. Carroll Carlson has the discussion lead.

MS. CARLSON: This is a process measure, and it is interesting because the measures that I've looked at in the past that measure immunization rates aren't, necessarily, always associated with on time as

being the primary purpose of it. So, from an importance standpoint, of course, having appropriate immunizations all along the way for children and adolescents is very important. We know that adolescents are sometimes the hardest block of children to get in for immunizations. And from the perspective of scientific, having them on time seems to make more sense, too.

I think this measure is -- the purpose is to sort of get rid of the myths, and some of the rationale out there for not immunizing children, when children present for services, other services. And to take the old Public Health motto, you know, never miss an opportunity. If you've got them there, inject them, get them immunized. So, from -- I think -- I would hope that we could all agree from a scientific standpoint that there's merit to making sure we're measuring the immunization rate in adolescents. And that we're attempting to improve that rate.

This is, I believe, a medical record only, but they do include electronic registries. And as we look at the other measure that NCQA submitted, I wasn't able to tell from that measure whether or not they would accept registry data. So, I think it makes it far more feasible, if you're able to hook into state registries, or regional registries for your immunization rates.

The periodicity is based on CDC and ASAP recommendations, so it's recognized. It does not look like this measure has been tested yet. So, would this measure go -- if we were to recommend it, we would recommend it for the temporary?

DR. WINKLER: No, time limited.

MS. CARLSON: Time limited, not temporary, but time limited.

DR. WINKLER: Although, the submission form says that yes, it is fully developed and tested, so you are making your conclusion --

MS. CARLSON: Maybe I looked at the wrong spot on this one. What page are you on for that one?

DR. McINERNY: Page 2, I think.

MS. CARLSON: Page 2 of that. Okay.

MS. BYRON: I've pulled up the testing section, and it doesn't have anything listed.

MS. CARLSON: Right. So, I think that's where I looked. I must have missed that.

DR. WINKLER: No problem.

MS. CARLSON: So, I assume then it's been tested.

DR. WINKLER: I think that there's a question to the measure developer that although you state that the measure has been tested, the information in the section on testing and analysis doesn't really indicate any testing results, or that testing had been done. So, there is confusion here as to

whether this measure has been evaluated for reliability and validity.

MS. HUNT: Yes, I guess when we applied this measure, for the endorsed measure, they viewed the testing as more, were you endorsing the measure, so we do have member organizations who use these measures, but we don't necessarily go back and collect any data from them.

MS. CARLSON: So, I guess the question, would we accept that as testing?

DR. WINKLER: Right.

MS. HUNT: We could certainly go back to some of our member groups and access that data, if needed.

DR. WINKLER: That would be very useful, because, otherwise, we're working under the assumption that we don't have any testing results, so we don't know how to evaluate that information.

DR. LIEBERTHAL: Just looking at it, I don't understand the term "on time."

What is the window within the schedule to be considered on time?

MS. HUNT: On time would refer to the recommendations based on ASAP schedules. So, if it -- okay.

DR. LIEBERTHAL: So, the ASAP schedules would say that the DTAP and IPV, PREVNR, HIB, et cetera be given at two months.

MS. HUNT: Correct.

DR. LIEBERTHAL: So, what would the -- now, I don't know about everybody else, but we don't get our kids in exactly on their two month birthday. What kind of a time frame do you use for calling it on time?

MS. HUNT: So, if somebody is receiving their schedule, completed within the suggested time frame so that they've had all of their DTAP series completed by the time they're six years of age.

DR. LIEBERTHAL: That's very similar to the measures that are currently out there.

DR. GLAUBER: I was also unclear whether HEDIS was actually assessing on time as compared to categorical assessment at a certain age, whether a child has received a given set of vaccines, regardless of timeliness, or not. And if they were actually assessing timeliness for each vaccine, is this still a categorical measure in that if a child didn't receive one of the recommended vaccines on time, that they fail the entire measure, or is each vaccine scored independently? Because if you're going to require that each component of the vaccine be given on time in order to score a hit, you're going to have very low performance rates.

MS. HUNT: The intent is that by the time that they're completed with their C- by the time they're done with childhood, that they've been -- they've received all of their completed immunizations following the projected schedule, all throughout our guideline we recommend that providers use

every opportunity to get the child back into the office to get their immunizations at the recommended schedule, whether it is a two month allotment in between vaccinations, or if it's two years.

MS. CARLSON: So, then how would this be different, except for calculating continuous enrollment from the HEDIS immunization measures?

MS. HUNT: I don't know that they're completely -- I don't know that they're different, but our measure does not count in the number of vaccines that are given. So, it allows the provider some leeway to be able to get the child in. If they don't come in in two months, they can come in when the child's three months of age and still get their recommended series. So, they'll still complete their series on time but the time they're six years of age.

DR. GLAUBER: Maybe to really drill this down, let's say you're looking at a six-

year old, and the child had their MMR at 24 months. Would that be accepted, or would there be some penalty for getting it outside the recommended age range? And how, if there was a penalty, how would that affect the overall measure?

MS. HUNT: That would be accepted, as long as they're able to complete the second dose before the age of four.

DR. McINERNY: Well, a lot of people here are shaking their heads, that that shouldn't be accepted, that really we -- there should be a time window that's pretty close to the time that the ACIP recommendation schedules it. And maybe give a month or depending a little bit on the age, a little bit longer, but certainly, you really want to try and get it as close as possible. Otherwise, we might as well just stick with the HEDIS measures, which only give you credit if you have it by a certain age, rather than timely.

And the other point, while I have the floor, so to speak, you have PCV7, and of course now we're usually PCV, what is it 14, or 13? 13? Anyway, PCV 13 is now the recommended. And, of course, this brings up another problem with this recommendation, is that ACIP and the AAP Red Book Committee are changing the vaccine recommendations, certainly annually, if not twice a year or more, so, therefore, it'll be difficult to try and keep track of what the latest changes are. And this measure would have to change at least annually, probably.

MS. HUNT: And we do revise them annually. We revise this one annually, and we actually do have a process in place where we look at the ACIP recommendations that come out quarterly, and make adjustments, as needed within our guidelines according to the recommendations. The only caveat to that is this past year, that did not occur because we were still updating the H1N1 guidelines, as

well, and our revisions actually ran on top of each other, so we're currently in the process of revising our immunization guideline right now, which corresponds with the Preventative Services guideline of actually a major reference throughout the Preventative Service guideline, and, therefore, something such as a PCV 7 has not been updated yet, but will be updated.

DR. PERSAUD: And you also have males excluded from the HPV. I think it's excluded in both this and the other, and we have another immunization measure that's adolescent, that's a little bit overlapped, so that would be, in my mind, outdated, as well.

MS. HUNT: Correct. Correct. The work group that sits on the specific Immunization Committee has not met yet, they meet next month in December and January, so there will be, actually, revisions to this measure that'll be including those changes that have occurred.

DR. WINKLER: Given that we just heard the measure was due to be changed imminently, perhaps it's premature to be going through the measure right now. We could continue to follow-up, but it seems that we'll find ourselves in the position of recommending something that's going to get changed, and I'm not sure how the timing will work going forward. But we can certainly keep in touch with them and see where they are in terms of any revisions. It might be more appropriate to look at those after the revisions are made.

DR. PERSAUD: And I would ask of the measure developers if this is going to come back, I would like to see more detail written about how the calculations will be made, about whether they're timely, or a certain number by an age.

DR. JENKINS: Just one last issue related to this accountability of the clinic. We actually list something similar in our two-year olds, and the problem is that a

patient can arrive where you can't possibly get the immunizations on time in the window based on when they come in to your accountability purview, so they have to deal with that, as well, in the details.

MS. HUNT: I'm sorry, your voice was breaking up.

DR. JENKINS: The issue is that for an accountability measure, that a child has to present to a clinic, and the clinic is now accountable for the care of that child for this type of performance measure. If a child, for example, came in at 18-months of age into your clinic and had no prior immunizations, my understanding is it would be impossible for you to meet a schedule to have that child be on time, or up-to-date by two years. It's just not possible. So, is that patient accounted for in the numerator and the denominator of this measure, or are they left out of the measure? At the population level it's important, you might count them at the

clinic level, you might not.

MS. HUNT: I guess they would be counted in that measure. However, we do have a catch-up schedule, and we would expect that there would be documentation within the provider's notes that would entail that they have discussed with the parent how to get the child in for catch-up immunizations to get them back on track.

DR. McINERNY: And one other issue to consider is the perennial problem where there's insufficient immunization ABC available due to production problems, or some other bloody issue like that. And, therefore, the patient -- it's impossible to immunize them on time, and you have to somehow do it several months, or a year later when the vaccine becomes available again. And we need to kind of keep track of that, and not make the health care system, or provider accountable for that problem.

DR. WINKLER: So, we're going to

defer this measure until we can get some feedback on revisions or whatever.

Just a sort of a time status check. We're scheduled to adjourn at 5, but, clearly, we haven't quite gotten all the work done today. And it would be nice to get a little bit more, even if we don't complete everything. Would everybody be willing to kind of push our close time to more towards 5:30? I don't want to do too much more. I mean, I know you're all tired, because I am. But if that would be okay, perhaps we could go back up and look again -- start again with Measure 1392, the well child visits. This is from NCQA. This is from Work Group Three. And Dr. McInerny, you are the lead for that one.

This is another set of measures from NCQA that are also laid out by age group, so they've combined multiple measures in the one form. But they do intend for them to be -- right.

DR. McINERNY: Okay. So, we're talking about 1392, and that is well child visits in the first 15 months of life, then well child visits in the third, fourth, fifth, and sixth years of life. And, briefly, they're going to count the number of visits in the first 15 months of life, and tabulate that, and report on that. And then measure two would be the percentage of children three to six years of age who received one or more well child visits with a PCP during the measurement year.

And I think most of us would feel yes, this is, indeed, a very important measure by certainly many, many criteria. Then, as we look at the -- as I, at least, looked at the scientific acceptability, I, indeed, felt that most of this was completely met on the scientific acceptability. I also felt that it was, indeed, very usable. However, I thought that the feasibility was more of a partial, rather than a complete feasibility, because of

some of the issues of collecting the data. So, all in all, I felt this probably was a measure that we should move forward, but I'd certainly be glad to entertain discussion.

DR. LIEBERTHAL: By using the word with a PCP during their first 15 months of life, it limits the visit to being seen by a physician, and I'm not clear if it must be their primary care provider, or somebody who functions as a primary care provider. But one of the things that the specification does not permit is flexibility and innovation.

As an example, one of the things we're doing in our department is the first visit, which is two to three days after discharge from the family center care is with a lactation consultant, an RN, and they do the bilirubin check, they work with the mother on breast feeding, et cetera. And we feel they do a far better job at it than the physicians would do in that area. And, of course, they do call a physician if a bilirubin is done,

and it's high, or if there's a problem with weight, et cetera. So, I'd really want to see other wording that permits innovations like that, where the child still gets the same number of visits, but it could be -- it does not have to be a PCP. And even that wording excludes a nurse practitioner who's not the PCP for the child.

DR. McINERNY: Al, I'm glad you bring that up, because our practice is to have the patient alternate visits with the primary care physician and the nurse practitioner. We have a primary nurse practitioner for that patient, and a primary doctor for that patient. And, frankly, that's in my private practice. In our Continuity Clinic at the Medical Center most of the well child visits are with nurse practitioners, not with the primary care physician, at all. So, I agree that that should be liberalized in some fashion.

MS. CARLSON: I think, and it

probably depends on the state that you're in, but I don't think, and maybe NCQA can help us with this, but I don't think they limit it to a physician visit. I think as long as you are an advanced practice nurse and you're able to bill for that service, that qualifies in this situation.

DR. LIEBERTHAL: HEDIS would nurse practitioner, PA, or a physician would qualify, but in our case, a lactation consultant, who's an RN would not. And that's presented a significant problem, especially when you deal with the 15-month visit, because it says six visits by 15 months, which means that the 15-month visit would be hard to get in before the cutoff date.

DR. RAO: Just to clarify, I think PCP can also be primary care provider, not just physician.

DR. BERGREN: Are you suggesting rephrasing it as PCP or their designee, or something like that?

DR. LIEBERTHAL: I would say medical home, and let the medical home determine the best person to see the patient. I just -- I'm going to put my cards on the table. I have a very strong bias that well child care by physicians is a total waste of time, and that a well child specialist at the RN level are we really need.

DR. WINKLER: Sepheen, did you have a comment on --

MS. BYRON: Yes. So, I've actually sent an email to our Policy and Audit Department to see exactly what counts as a PCP. But I will say that the well child visit must occur with the PCP, but the PCP does not have to be the practitioner assigned to the child. I know that was a question that came up earlier. A child who had a claim or encounter with a code listed is considered to have received the well child visit. So, this is a hybrid measure. It's administrative, and it has medical record component. It's

actually administrative only for the commercial population, so there are codes to identify well child visits, so you could use those codes.

DR. McINERNY: Yes.

DR. QUIRK: Yes, one sure sign of getting old is you hate abbreviations. And it's their abbreviation. Could you tell us what PCP stands for, (a) the words; and (b) what you mean by those words? That would solve a lot of the question.

MS. BYRON: Yes. And that's what I've actually emailed, just to make sure. Actually, wait, hold on. Appendix 3 for definition of PCP. It's Primary Care Provider. We tend to use the word practitioner in HEDIS, and I will have an answer in a second.

DR. McINERNY: Any other comments?

MS. BYRON: All right. So, PCP C -I'm sorry. I found it, if you want me to go ahead.

DR. McINERNY: Sure.

MS. BYRON: PCP is Primary Care Practitioner, a physician, or non-physician, for example, physician assistant or nurse practitioner who offers primary care medical services. We distinguish that from other measures from a prescribing practitioner, because this person must have prescribing privileges, and we know that in certain states, like California, an OBGYN can count as a primary care provider, so that would count in the measure, as well.

DR. JENKINS: I'd just like to make my same comment I did with the prenatal care about this is an accountability measure at the health care level without any risk adjustment as a service account, and it's predominantly in the purview of the mother to bring the child in. However, I understand it's a very important part of the metric as the prenatal care visit is also an important quality metric.

DR. WINKLER: Following up on what -- to clarify what Kathy said, Sepheen, what's the level of analysis for this?

MS. BYRON: This is a health plan measure.

DR. WINKLER: This is health plan. Thank you.

MS. BYRON: And it's for commercial and Medicaid plans.

DR. GLAUBER: But it is often used at the provider group level for pay-for-performance programs.

MS. BYRON: This is also a measure where in asking plans what -- especially Medicaid plans, what measures are useful, most all of them cite this measure as a measure that they use most often.

DR. JENKINS: The point is that you can use quality metrics, but these are an accountability -- the level of attribution to the count has to be a higher bar, or it has to be accounted for for things like case mix

adjustment.

DR. WINKLER: All right. On the issue of importance, to measure and report, does the Committee feel this measure meets the criteria? Do we need to separate it into the two parts, or do you feel that whatever you say kind of applies to both measures?

DR. McINERNY: Both.

DR. LIEBERTHAL: Both.

DR. WINKLER: I'm hearing both. Okay.

DR. CHEN: Are we liberalizing the term PCP to include nurse --

DR. McINERNY: Yes.

DR. CHEN: -- as well, or like a lactation specialist, or only nurse practitioners, and physician assistants?

DR. WINKLER: At this point, I think we have to use the definition that NCQA gave us.

DR. McINERNY: Yes.

DR. QUIRK: In general, health

plans, like would have to be an independent licensed practitioner who practices within the scope of their practice. So, if you have a lactation consultant who's an NP, then that would be okay. But if it's some other version of a lactation consultant, it wouldn't be.

DR. WINKLER: Okay. So, we're really doing two measures at a time, but how many feel that the measures meet the importance to measure and report criteria? Yes? One, two, three, four, five, six, seven, eight, nine, ten, eleven, twelve, thirteen, fourteen, fifteen. Ellen?

DR. SCHWALENSTOCKER: I think my answer is -- I would say yes.

DR. WINKLER: Thank you. Were there any nos? I didn't see any. Okay.

Now, in terms of scientific acceptability, how many feel that the evaluation criteria are completely met? One, two, three, four, five. Partially met? One, two, three, four, five, six, seven, eight.

Minimally met? One, two. Is there anybody I didn't capture? Ellen, where are you?

DR. SCHWALENSTOCKER: Partial.

DR. WINKLER: Thank you. All right. For usability, how many feel they're completely met? One, two, three, four, five, six. Partially met? One, two, three, four, five, six, seven, eight. Minimally? One. And, Ellen, where are you?

DR. SCHWALENSTOCKER: Partial.

DR. WINKLER: Thank you. And feasibility, completely met? Two. Partially met? One, two, three, four, five, six, seven, eight, nine, ten, eleven. Minimally? Three. Ellen, what are you?

DR. SCHWALENSTOCKER: Partial.

DR. WINKLER: Okay. Thank you. All right. Now, recommendation for endorsement. How many recommend this measure go forward? One, two, three, four, five, six, seven, eight, nine, ten, eleven, twelve, thirteen. How many vote no? One, two.

Ellen?

DR. SCHWALENSTOCKER: Vote yes.

DR. WINKLER: Okay. Fourteen yeses, two nos. All right. So, there's that.

There was a request since, I guess, Margarita, you're not going to be able to be with us tomorrow.

DR. HURTADO: That's correct.

DR. WINKLER: Okay. If we could go now to Measure 1411, which pretty much makes sense, adolescent well care. And this from Work Group Four, and it is -- all right. This is the percentage of enrolled members 12-21 years of age who had at least one comprehensive well care visit with a PCP, or an OBGYN practitioner during the measurement year.

DR. HURTADO: And they present the evidence to show that this is an important measure, and that there is -- an important measure to report for adolescents. One of the things that, in terms of the evidence that

they presented is recommended by the AMA, the American Academy of Pediatrics, and the Institute for Clinical Systems Improvement, but they all have a different age range. I think that 10-21 is American Academy of Pediatrics, AMA is 11-21, and the Institute for Clinical Systems Improvement is 12-21, and NCQA is 12-21. Why that is, I don't know.

The other aspect that I was a little bit confused about, it says that they have to be comprehensive annual visits, but from the data that's being extracted from -- this is Claims-based, and from that data, there are a series of codes. And I don't know if any of those represent comprehensive well care visits, and how those are being defined, or is it just an annual preventive visit? Are there a series of tests that have to be completed within that type of visit?

Let's see. In terms of the way that the numerator is being defined, I think it might have been a typo, but it says -- no,

the denominator, it says that it's the percentage of enrolled members in one of these plans, commercial or Medicaid, that are 12-21 year old. I believe that the denominator would not be the percentage, but the actual number of members between 12 and 21 who would be eligible for this measure. There aren't any exclusions. And, again, this is similar as the last one in terms of being a primary care practitioner, or an OBGYN. That's the other practitioner that can be qualified for this measure.

Let's see. I think that's -- there is also, I think, in terms of confusion, that I mentioned that this is an administrative data Claims-based measure according to the data source, but when it describes the calculation algorithm for the measure, it says that the numerator is defined by the children who had documentation in the medical record of the screening or service during the measurement year. So, I'm not sure

if those overlap completely in the health plans. There isn't any reliability testing, but perhaps similar to the prior one, it's not necessary because of practice, I don't know. And it did do some face validity testing, which in addition to the scientific evidence that was already provided, I think that's definitely sufficient.

Usability, this is just for those health plans that NCQA rates, so it's only HEDIS, within the HEDIS measures, the ones that require that are not clear, but that's what I'm assuming. And that's all I have.

DR. WINKLER: Let's just ask Sepheen. Is this for commercial and Medicaid health plans?

MS. BYRON: Yes.

DR. WINKLER: Okay.

MS. BYRON: And this is a HEDIS measure.

DR. HURTADO: And I guess, can you provide clarification in terms of the data

source, is it both the medical record and claims data?

MS. BYRON: Yes, so there are codes to identify comprehensive well visit, and just to let you know, NCQA has a coding panel specifically that reviews all of our codes to make sure that it adheres to what we're trying to get from the measure. And these are the codes that were designated as meaning a comprehensive well care visit.

MS. SCHOLLE: Can I just ask a question? I didn't understand, is this designed to assess whether adolescents get a well visit every single year? That's where it's going.

DR. HURTADO: Yes, between 12 and 21 is what's specified.

MS. SCHOLLE: So, it's a continue -- it's just once a year, same as the previous one.

MS. BYRON: I guess one thing that occurs to me is that it is of note that there

are three different organizations which have three different ages of adolescence, one starts at 10, one starts at 11, one starts at 12. And, also, that we have a group of children left out of measurement, and that is the six to whatever this age cutoff is going to be. That would be the pre-pubescent, that's not one of the measures we have. The other age group was the toddlers, and up to six years of age. This one is going to be 12 or up. We've got in-between left out.

DR. McINERNY: And sorry about the other end, whether it's 18 or 21, I think there -- although, I know that -- I think the Academy does say 21, I'm not sure that that's truly what happens in many physicians' offices, and/or I'm not sure about health plans, how they recognize that, also. And that's -- I think that's going to be -- that age group, the 18 to 21 group is going to be difficult to -- they're not going to be seen annually in many situations.

MS. SCHOLLE: Tom, can you speak to the evidence behind the value of annual visits for this age group, including up to 21? I mean, I think as a general matter, it's a good idea, it sort of feels good, and a lot of people recommend it, but how -- you know, I take my kids and all that, but how certain are we, particularly in a resource constrained environment, blah, blah, blah.

DR. McINERNY: Yes. Well, unless people -- other people know otherwise, I'm afraid that they really -- people haven't really looked at this as an evidence-based recommendation. It's more of a sort of a consensus, and as you say, it feels good, but I don't know as anybody has really looked at doing a controlled in experimental groups yes, they come in every year, and no, they don't come in every year, and whether the outcomes are better or worse. Anybody here -- Goutham, do you know any evidence that says an annual visit for an adolescent leads to better

outcomes?

MS. SCHOLLE: Or, for that matter, someone 6 to 12. I mean, I just --

DR. RAO: Absolutely not.

MS. SCHOLLE: Yes.

DR. LIEBERTHAL: I've actually reviewed the literature. There is absolutely no evidence for the periodicity schedule, none. It is purely a longstanding tradition and source of income.

DR. RAO: There's the other point that a lot of prevention can take place outside of the realm of annual visits and preventive child visits, which is not going to be accounted for by any of these measures.

MS. SCHOLLE: So, what is the general posture of NQF on making recommendations on these many measures in the absence of solid experimental data? I mean, is that like a ticket of admission, or is it one consideration, but not the deciding factor?

DR. WINKLER: Measure Evaluation Criteria 1-C states that, "We are looking for evidence with a relationship to outcomes."

DR. JENKINS: We don't -- I'm having a disconnect, too, with the NCQA. Before we had those time numbers with those quality metrics, but this one is being presented annually, and while children, not to mention accountability at the plan level, which I'll come back to again. I mean, trying to get a 4-year old in is one thing, trying to get an 18-year old in and assigning accountability for the 18-year old not coming into the plan, I find problematic.

MS. SCHOLLE: And just to extend that a little bit, I think with the ability to keep young people and parents' insurance plans up to 26, this issue of sort of the ever-expanding horizon of what constitutes an adolescent is going to get worse, not better. I mean, CDC now, a lot of their data go to 24 on adolescents, so I don't know what the

cutoff rationale is here.

DR. McINERNY: Despite what has been said, if you look what's up on the board now on page 3, 1C.4, several national organizations have developed evidence-based guidelines and recommendations for adolescent preventive services. I don't know quite what they mean by that.

DR. LIEBERTHAL: That's a misstatement, there's no evidence. When I was on the committee, the COPAM of the American Academy of Pediatrics that writes the periodicity schedule, and I had some involvement with Bright Futures, and it is purely based on what we've always done.

There are certain activities that are done at the routine visit where there is an evidence-base, for instance, vision screening in the preschool, and we're going to have measures on that that we're going to discuss tomorrow. But as Goutham described for counseling with relationship to obesity,

the only study that I'm aware of that has shown a relationship of counseling to outcomes is the TIP Program, which is an accident prevention program. But when this study was done, it was very -- it was done in isolation from all the other counseling that is routinely done at well child visits, with more intensity, and there was a very limited benefit of it. But the anticipatory guidance that's recommended in Bright Futures, the physical examination, there's really no evidence that we have affect children's lives, or have an impact on children's lives by doing it in the way we do it. And I think that having a periodicity schedule as it is, prevents people from doing real research to find out what is the best way to impact children's lives.

Now, the risk questionnaires that are part of Bright Future probably have more value, than targeting the discussion to the risk questionnaire, but would that fall within

the -- what NCQA is saying a comprehensive exam?

DR. McINERNY: There are probably a couple of evidence-based, certainly, immunizations would fit into that.

DR. LIEBERTHAL: Yes, immunizations.

DR. McINERNY: But we're already looking at that in some other way. And then, again, recently, within the past year, I believe the U.S. Preventative Services Task Force recommended that adolescents be screened for depression, so that's evidence-based, but that's just one small piece of it.

DR. GLAUBER: So, it seems like we have -- we're going down two tracks here, that we're examining and developing metrics around the components of visits that we think are evidence-based, or promising. At the same time, we're just holding up the visit, itself, as an important metric. So, should we be focusing more on those activities which we

think are -- have the greatest potential to impact children's health, rather than the visit, itself, which we have no idea what goes on during it.

MS. BYRON: I wonder if it would help to ease some of the discomfort of the Committee if you think of this as an access to care measure. I mean, this is something that is in the HEDIS Access to Care domain. This one, the well child visits, and yes, the visit, itself, you can wonder about, I mean, Bright Futures and AAP does recommend annual visits, but I believe it's because the visit is a vehicle to getting these preventative services. So, it is an important access to care measure, so I don't know if that might help frame, or if you adjust your perspective to thinking about it that way.

DR. GLAUBER: But if we're measuring -- let's say we endorse screening adolescents for depression, and the rate is high, then we've already checked the access

box, because, obviously, kids are coming in, if we're screening 90 percent of them, for example.

MS. BYRON: Well, I think in the case of the depression, that would be an effectiveness of care measure, but you would still need the access to care measure to say are kids in Medicaid getting their visits? Are they going in, especially in Medicaid. Commercial, as well, though.

DR. CHEN: I think Allan's point is well taken, in terms of randomized control trial, or clear scientific evidence, but this is one such area where we've been doing this way for a very long time. There's no room for evidence; meaning that there's no opportunity to do actual research on it. So, I wouldn't want that to be a negative thing on the measure, just because we don't have evidence on it, because we've been doing the same thing forever. That doesn't mean it's not useful to the kids per se, especially in light of it as

a access measure. But we don't have any evidence for it, I do agree with that.

DR. QUIRK: I would feel better if the justification for this measure was clearly articulated in that kind of a frame, as opposed to this global all these organizations with their Level 9 evidence, you know, which is the consensus of five people sitting at a bar.

(Laughter.)

DR. QUIRK: But, I mean, again, it goes back to you know what, what's the purpose of all this? And we don't burn witches any more. We didn't do a randomized controlled trial. But the thing is that there's no clear justification in this petition for continuing to have periodic examinations in normal kids. Focused examinations with focused purposes, that go to accountability, and you can measure the content, sure.

DR. McINERNY: I do take a little comfort in using this more as an access

measure, again, because, hopefully, with health care reform, more children and adolescents will be getting some kind of health insurance, and access is certainly something that is going to be recommended to improve the access for children and adolescents to primary care physicians. So, if we could look at this over time and see, in fact, whether or not we've accomplished those goals, I think that would be a worthwhile measure. And one could argue about the content of the visit forever.

DR. ZIMA: I would argue, though, if we thought about this access, we need to get back to Donna's point about the 6 to 12s, I mean, particularly with ADHD.

MS. CARLSON: You know, the one that we just reviewed, 1390\, which is in a different work group, they do measure 12-19 years of age, one or more visits with your PCP, so there really isn't a gap from that C- in that age category. I'm looking -- it's in

the numerator. Well, it says for 7-11 years, the cohorts are 7-11 years, and then 12-19 years with one or more visits.

DR. McINERNY: I think it's just a visit, not a comprehensive well child visit.

MS. CARLSON: You're right. It is access. It does include just ambulatory visits, but also includes preventative care, so you're right.

DR. GLAUBER: And in terms of access, this is a HEDIS measure, so this presumes the child has health insurance, and is continuously enrolled during the measurement year, so to Tom's point, I agree, but as constituted, it couldn't track that broader measure of access to care. That's intended by health care reform.

DR. WINKLER: So, does the Committee feel that this measure meets the criteria of importance to measure and report? How many say yes? Yes? All yeses, say it, raise high so I can see you. One. Ellen,

where are you?

DR. SCHWALENSTOCKER: I guess no.

DR. WINKLER: Okay. Yes, I've got one. All right. How many of the rest of you all say no? It looks like all the rest of you all.

DR. McINERNY: There's one abstention.

DR. WINKLER: Is there one abstention? Okay.

MS. SCHOLLE: Can we soften it a bit, though, because I think what everybody is saying here is that there are a large number of issues that require attention in adolescents, sexual activity, drug use, I mean all sorts of things, so it's not that there's no need for access or for care, but this sort of cookie cutter approach, sort of well person visit, doesn't seem to be working for this group.

DR. WINKLER: Yes. Just so, Sarah, you're not necessarily familiar with it, the

output from this group will be a fairly -- given the number of measures, a lengthy document that will discuss the issues you've raised, and some of these caveats. It's one of the reasons he's transcribing it, and we get your words for word so I can capture them quite accurately.

DR. GLAUBER: And also to your point, I wouldn't have been comfortable with my vote if we weren't also looking at a host of other measures that were looking components of care that we feel are important.

DR. WINKLER: Well, I think that -- I definitely get the message that you've put in a very long day, fatigue has set in.

DR. McINERNY: Public comment?

DR. WINKLER: Huh?

DR. McINERNY: Public comment?

DR. WINKLER: Yes. One last thing, is if there might be any public comment, we certainly don't -- we've had attrition in the room. Operator, could you check and see if

there's anybody hanging in there on the phone lines who may want to make a comment?

OPERATOR: Certainly. Once again, ladies and gentlemen, Star One, please.

DR. WINKLER: Just to be sure.

OPERATOR: There are no questions.

DR. WINKLER: Okay. Thank you very much.

All right. We are scheduled to restart tomorrow morning at 8:00 here. As today, food will be available starting about 7:30. You'll come to the front door again. The doors are normally locked. They're expecting you, so don't freak, but just realize the doors usually don't officially open and free flow -- yes, the garage will be fine. So, we will see you tomorrow morning at 8:00, and we will continue onward.

Thank you all very much. This is a tough agenda. This is a lot of information. These are a lot of measures, and you guys are doing a great job. And we really thank you.

MS. THEBERGE: Just a quick note. If people could leave their flash drives, we'll distribute them again in the morning, unless you need to review something overnight. We don't want to lose them. And we'll be collecting them by the door.

(Whereupon, the proceedings went off the record at 5:23 p.m.)

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