

NATIONAL QUALITY FORUM

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PERINATAL AND REPRODUCTIVE HEALTH  
STANDING COMMITTEE

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MONDAY  
MAY 2, 2016

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The Standing Committee met at the National Quality Forum, 9th Floor Conference Room, 1030 15th Street, N.W., Washington, D.C., at 8:30 a.m., Kimberly Gregory and Carol Sakala, Co-Chairs, presiding.

PRESENT:

KIMBERLY GREGORY, MD, MPH, Vice Chair, Women's Healthcare Quality & Performance Improvement; Department OB/GYN, Cedars Sinai Medical Center, Co-Chair

CAROL SAKALA, PhD, MSPH, Director of Childbirth Connection Programs, National Partnership for Women & Families, Co-Chair

J. MATTHEW AUSTIN, PhD, Faculty, Johns Hopkins School of Medicine

JENNIFER BAILIT, MD, MPH, Clinical Director, Family Service Line, MetroHealth Medical Center

AMY BELL, MSN, RNC-OB, NEA-BC, CPHQ, Outcomes Specialist, Carolinas HealthCare System

TRACY FLANAGAN, MD, Director of Women's Health and Chair of the Obstetrics and Gynecology Chiefs, Kaiser Permanente

GREGORY GOYERT, MD, Division Head, Maternal-Fetal Medicine, Women's Health Services, Henry Ford Health System

ASHLEY HIRAI, PhD, Senior Scientist, Maternal and Child Health Bureau, Health Resources and Services Administration

MAMBARAMBATH JALEEL, MD, Associate Professor of Pediatrics; Medical Director, Parkland NICU, University of Texas, Southwestern Medical Center

DIANA R. JOLLES, CNM, MS, PhD, Quality Chair, American College of Nurse-Midwives

JOHN KEATS, MD, CPE, CPPS, FACOG, FAAPL, Senior Medical Director, Cigna

DEBORAH KILDAY, MSN, RN, Senior Performance Partner, Premier Inc.

NANCY LOWE, CNM, PhD, FACNM, FAAN, Professor, University of Colorado-Denver College of Nursing

SARAH McNEIL, MD, Core Faculty and Director, Contra Costa Medical Center

JENNIFER MOORE, PhD, RN, Executive Director, Institute for Medicaid Innovation

KRISTI NELSON, MBA, BSN, Women and Newborns Clinical Program Manager, Intermountain Healthcare

JULIET M. NEVINS, MD, MPA, Medical Director, Aetna

SHEILA OWENS-COLLINS, MD, MPH, MBA, Chief Medical Officer, Johns Hopkins Healthcare, LLC

CYNTHIA PELLEGRINI, Senior Vice President, Public Policy & Government Affairs, March of Dimes

DIANA E. RAMOS, MD, MPH, FACOG, Medical Director, Reproductive Health, Los Angeles County Public Health Department

NAOMI SCHAPIRO, RN, PhD, CPNP, Professor of Clinical Family Health Care Nursing, Step 2, School of Nursing, University of California-San Francisco

MARISA "MIMI" SPALDING, JD, MPH, Policy Analyst, National Health Law Program

KAREN SHEA, RN, MSN, Vice President, Maternal Child Services, Anthem, Inc.

SINDHU SRINIVAS, MD, MSCE, Associate Professor  
and Vice Chair, Quality, Obstetrics and  
Gynecology, University of Pennsylvania  
Health System and Perelman School of  
Medicine

RAJAN WADHAWAN, MD, MMM, CPE, FAAP, Chief  
Medical Officer and Medical Director of  
Neonatology, Florida Hospital for Children

CAROLYN WESTHOFF, MD, Msc, Director of Family  
Planning and Preventive Services, Sarah  
Billingshurst Solomon Professor of  
Reproductive Health, Columbia University

JANET YOUNG, MD, FACEP, Carilion Clinic,

Virginia Tech-Carilion School of Medicine

**NQF STAFF:**

ELISA MUNTHALI, MPH, Vice President, Quality  
Measurement

MARCIA WILSON, Senior Vice President, Quality  
Measurement

NADINE ALLEN, Project Manager

KAITLYNN ROBINSON-ECTOR, Project Analyst

SUZANNE THEBERGE, MPH, Senior Project Manager

REVA WINKLER, MD, MPH, Senior Director

**ALSO PRESENT:**

MARY BARTON, MD, MPP, National Committee for  
Quality Assurance

DEBRA BINGHAM, DrPH, RN, FAAN, Association of  
Women's Health, Obstetrics, and Neonatal  
Nurses (AWHONN)

SEPHEEN BYRON, MHS, National Committee for  
Quality Assurance

ERIKA EDWARDS, PhD, MPH, Vermont Oxford Network

LORRIE GAVIN, MPH, PhD, U.S. Office of  
Population Affairs

PHILIP HASTINGS, PhD, Far Harbor LLC

MATTHEW HOFFMAN, MD, MPH, National Perinatal  
Information Center

LAWRENCE KLEINMAN, MD, MPH, University Hospitals  
of Cleveland

BARBARA LEVY, MD, American Congress of  
Obstetricians and Gynecologists

SUZANNE LO, University Hospitals of Cleveland

ELLIOTT MAIN, MD, California Maternal Quality  
Care Collaborative (CMQCC)

JANET MURI, MBA, National Perinatal Information  
Center \*

PAMELA OWENS, PhD, Agency for Healthcare Research  
and Quality \*

SARAH SCHILLIE, MD, MPH, MBA, Centers for Disease  
Control and Prevention \*

\* present by teleconference

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

2 8:39 a.m.

3 MS. THEBERGE: Good morning, everyone.

4 Welcome to the Perinatal Standing Committee  
5 meeting.

6 I'm going to open with a couple of  
7 quick housekeeping announcements before we all  
8 introduce ourselves.

9 The restrooms are out the main exit  
10 over there and then past the elevators on the  
11 right. We'll be having three breaks today, one  
12 in the morning, one at lunch and one in the mid-  
13 afternoon.

14 We do have Wi-Fi available. The  
15 username is "guest" and the password is  
16 "nqfguest." Let us know if you're having any  
17 trouble connecting and we'll get you online.

18 This call is, as all of our meetings  
19 are, open to the public. So if folks are dialing  
20 in please remember to mute your lines to help  
21 with the noise.

22 All of the committee materials are

1 available via SharePoint. You can pull those  
2 down at any time if you need to.

3 And we'll be screen-sharing today.

4 And we have a webinar running. So if you're  
5 having any trouble connecting please email the  
6 project team.

7 For the committee members we have made  
8 reservations tonight at 6:30 p.m. for dinner. So  
9 it's at a place called McCormick & Schmick's just  
10 right around the corner.

11 And we'll be confirming the numbers at  
12 lunch so that we can finalize that. So let us  
13 know if you're interested.

14 And I think we'll go ahead and get  
15 started. Marcia?

16 MS. WILSON: Good morning, everyone.  
17 My name's Marcia Wilson. I'm senior vice  
18 president of quality measurement here at NQF.

19 And today in the absence of our  
20 general counsel, Ann Hammersmith, I'm going to do  
21 the disclosures of interest.

22 And you did receive a disclosure of



1 interest form before you were named to this  
2 committee. We asked you a series of questions.

3 And today we do an oral disclosure of  
4 interest to have you talk about anything you  
5 think you've worked on that is relevant to this  
6 committee.

7 And we also do this by way of  
8 introductions. So we'll ask you to introduce  
9 yourself, where you're from, and then if you have  
10 any disclosures of interest.

11 We ask you please do not summarize  
12 your resume, it's not necessary. But we are  
13 interested in any work that you participated in  
14 that you think is particularly relevant to what's  
15 coming before the committee today and tomorrow.

16 Now, this is not only financial work,  
17 something for which you were paid. It may have  
18 been you volunteered, you served on a board. If  
19 you were involved in some way with any of the  
20 measures coming before this committee that's the  
21 kind of information that you would be disclosing.

22 Now, the other thing I will remind you

1 is you sit on this committee as an individual.  
2 You don't represent your organization nor the  
3 party who may have nominated you.

4 And just because you disclose it  
5 doesn't mean you have a conflict of interest. We  
6 do this at NQF in the spirit of transparency.  
7 We're always into this transparency thing so this  
8 is part of it.

9 And what we'll do is we'll go around  
10 the room. And I don't believe we have anyone on  
11 the phone today. Everyone is here in person  
12 which is great.

13 And I'd like to start with Carol, our  
14 co-chairs. And again, introduce yourself, where  
15 you're from, and please let us know if you have  
16 anything to disclose. Carol?

17 CO-CHAIR SAKALA: Good morning. I'm  
18 Carol Sakala, director of Childbirth Connection  
19 Programs at the National Partnership for Women  
20 and Families.

21 And I will be recused from three of  
22 the measures because I have had a connection with

1       them in the past. The two HEDIS measures on  
2       prenatal and postpartum care, and what is now  
3       called unexpected newborn complications.

4               MS. WILSON: Thank you for bringing  
5       that up, Carol, and I will remind the committee  
6       that when you are recused from a measure not only  
7       do you not vote on it, but you do not participate  
8       in the discussion. And that's what a recusal  
9       means.

10              You do not have to leave the room.

11       Thank you, Reva.

12              CO-CHAIR SAKALA: And otherwise I have  
13       nothing to disclose.

14              MS. WILSON: Thank you. Kimberly?

15              CO-CHAIR GREGORY: Good morning. I'm  
16       Kimberly Gregory. I'm from Cedars Sinai Medical  
17       Center.

18              And I will be recused from the term  
19       healthy newborn. And I've received funding from  
20       AHRQ as well as PCORI for different projects one  
21       of which is the other reason that I will be  
22       recusing, that's the levels of care.

1 MS. THEBERGE: I'm Suzanne Theberge,  
2 senior project manager on the project team here  
3 at NQF.

4 MS. ALLEN: Hi, I'm Nadine Allen. I'm  
5 the project manager on this project at NQF.  
6 Thank you.

7 MEMBER MOORE: Good morning, I'm  
8 Jennifer Moore. I serve as the executive  
9 director for the Institute for Medicaid  
10 Innovation.

11 I am also on faculty at the University  
12 Medical School in the Department of Obstetrics  
13 and Gynecology.

14 I will be recusing myself from all  
15 AHRQ-related measures because I had a White House  
16 appointment in HHS and led the Office of Women's  
17 Health and Gender Research at AHRQ.

18 MEMBER RAMOS: Good morning, I'm Diana  
19 Ramos. I'm director for reproductive health for  
20 the County of Los Angeles Public Health  
21 Department. Nothing to disclose.

22 MS. WILSON: Oh, your microphone. It

1 is the button on the right and you'll get a  
2 little red circle when your mike is on. Thank  
3 you.

4 MEMBER WADHAWAN: Good morning. Rajan  
5 Wadhawan. I'm an neonatologist by background.  
6 I'm in Florida Hospital, Orlando. I'm the chief  
7 medical officer for Children's Hospital. I do  
8 not have any relevant conflicts.

9 MEMBER AUSTIN: Hi, good morning. I'm  
10 Matt Austin from the Armstrong Institute for  
11 Patient Safety and Quality at Johns Hopkins  
12 Medicine.

13 And the only disclosure I'll make is  
14 I do have a contract with the Leapfrog Group to  
15 provide them with guidance for measurement for  
16 their annual hospital survey. Thanks.

17 MEMBER BAILIT: Good morning. I'm  
18 Jennifer Bailit. I'm the clinical director for  
19 comprehensive primary care at MetroHealth Medical  
20 Center and an appointment at Case Western  
21 University.

22 I was a PI on the APEX project through

1 the NICHD and I serve on Leapfrog as well. And  
2 reVITALize.

3 I will be recusing myself on two  
4 measures that are proposed by a rival hospital in  
5 a town with lots of competition. And to avoid  
6 any appearance of conflict I'll be recusing.

7 MEMBER LOWE: Good morning. I'm Nancy  
8 Lowe from the University of Colorado. And I'm  
9 the also the editor of the Journal of Obstetric,  
10 Gynecologic and Neonatal Nursing.

11 And I do not believe that I have any  
12 conflicts.

13 MEMBER KILDAY: Good morning. I'm Deb  
14 Kilday. I'm currently with Premier, Inc. I'm a  
15 nurse by background. I have nothing to disclose.

16 MEMBER BELL: Good morning. I'm Amy  
17 Bell from Carolinas HealthCare System in quality  
18 improvement for the perinatal service line and  
19 IHI faculty. And I have nothing to disclose.

20 MEMBER PELLEGRINI: Good morning. I'm  
21 Cindy Pellegrini. I'm senior vice president for  
22 public policy and government affairs at the March

1 of Dimes.

2 It's great to see some familiar faces  
3 from Maternity Action Teams past and Medicaid  
4 applications partnerships meetings and things.  
5 And I don't think I have anything to disclose.

6 MEMBER KEATS: Hi. John Keats. I'm  
7 a general OB/GYN physician by training. My day  
8 job is with Cigna. I also do a lot of work with  
9 ACOG around safety and quality.

10 My only disclosure is I will be  
11 joining the ACOG executive board later this  
12 month, but nothing else to disclose. Thank you.

13 MEMBER FLANAGAN: Hi, my name is Tracy  
14 Flanagan. I am from Kaiser Permanente north,  
15 northern California, and my title is director of  
16 women's health. I have no disclosures.

17 MEMBER WESTHOFF: Hi, I'm Carolyn  
18 Westhoff. I'm trained as an OB/GYN. I'm at  
19 Columbia University.

20 And I also am an advisor to Planned  
21 Parenthood Federation which provided data to OPA  
22 on two of the contraceptive measures being

1 discussed today.

2 MEMBER JOLLES: Hi, I'm Diana Jolles.  
3 I'm a nurse midwife in Tucson and I have no  
4 disclosures.

5 MEMBER YOUNG: Hi, I'm Janet Young.  
6 I'm the square peg in the round hole of the room.  
7 I'm an emergency medicine physician. I work with  
8 medical forensics and the SANE team for our  
9 hospital.

10 And I have a training in OB/GYN before  
11 I switched to sanity and went into emergency  
12 medicine. I have no disclosures.

13 MEMBER SHEA: Good morning, I'm Karen  
14 Shea. I'm a corporate vice president with  
15 Anthem, Inc., and I lead maternal and child  
16 services for that entity. And I have no  
17 disclosures.

18 MEMBER NEVINS: Good morning. I am  
19 Juliet Nevins. I'm an OB/GYN by training. I'm a  
20 medical director for Aetna and in that capacity I  
21 serve on their preventative condition analysis  
22 team.



1 I just finished a workshop for the  
2 National Governors Association to reduce  
3 morbidity in patients, moms and babies in Jersey.

4 I'm also a laborist for NYU Lutheran  
5 in Brooklyn on the labor floor. I have nothing  
6 to disclose.

7 MEMBER MAMBARAMBATH: Good morning.  
8 I am Mambarambath Jaleel. You can call me  
9 Jaleel, that's my first name.

10 And I am a neonatologist from UT  
11 Southwestern Medical Center in Dallas. I'm also  
12 the medical director for the neonatal intensive  
13 care unit at Parkland Hospital.

14 I have nothing to disclose.

15 MEMBER MCNEIL: Good morning. I'm  
16 Sarah McNeil. I'm core faculty at the UCSF  
17 Contra Costa Family Medicine Residency.

18 I work at Planned Parenthood in labor  
19 and delivery. I have nothing to disclose.

20 MEMBER SPALDING: Good morning,  
21 everyone. My name is Mimi Spalding and I am a  
22 policy analyst at the National Health Law Program

1 which is here in Washington, D.C. And I have no  
2 disclosures.

3 MEMBER SCHAPIRO: Good morning,  
4 everyone. I'm Naomi Schapiro. I'm a pediatric  
5 nurse practitioner and a professor of nursing at  
6 the University of California San Francisco.

7 I'm a member of NAPNAP national, the  
8 pediatric nurse practitioner organization that  
9 nominated me.

10 And I practice in school-based health  
11 centers and work with Alameda County School-based  
12 health centers on quality measures.

13 MEMBER NELSON: I'm Kristi Nelson.  
14 I'm the women and newborn clinical program  
15 manager for Intermountain Healthcare. And I have  
16 no disclosures.

17 MS. WILSON: And I think, Greg, did  
18 you join us also, please?

19 MEMBER GOYERT: Greg Goyert, maternal-  
20 fetal medicine from Henry Ford Health System in  
21 Detroit.

22 MS. WILSON: All right. Is there

1 anyone who wasn't able to introduce themselves  
2 and disclose? Okay, thank you.

3 And I'd like to remind you all that if  
4 during the meeting you think you have a conflict  
5 please feel free to speak up. You can talk to  
6 the co-chairs of the NQF staff. You can approach  
7 anyone at NQF.

8 Or if you think a fellow committee  
9 member has a conflict please speak to the co-  
10 chairs or to the NQF staff.

11 What we don't want you to do is sit  
12 there and say I think there's something here that  
13 might be a conflict. So, please feel free to  
14 speak up and we will resolve this.

15 Based on what you've heard today do  
16 you have any questions for me or for any of your  
17 fellow committee persons? All right, thank you  
18 very much. And back to you.

19 MS. ALLEN: Hi, Nadine. Welcome again  
20 to our committee.

21 Moving to the next slide, please.

22 MS. WILSON: Here's the deal on the

1 microphones. They move. So what happens is  
2 you'll turn it on and then you'll sit back and  
3 you'll do this.

4 So please move the microphone close.  
5 We do record and then have a transcript of all  
6 these meetings. So please speak directly into  
7 your mike. Thank you.

8 MS. ALLEN: So, I know I've shared  
9 this slide with you originally at our orientation  
10 meeting so I'm not going to go into details about  
11 it.

12 But I know this project will be  
13 evaluating measures related to perinatal and  
14 reproductive health that's used for public  
15 reporting and accountability.

16 And some of the measures within the  
17 portfolio address reproductive health, pregnancy,  
18 labor and delivery in newborn and postpartum  
19 care.

20 We have 24 endorsed measures. These  
21 endorsed measures are up for maintenance review.  
22 So we will be discussing them more in detail

1 today.

2 We also have several new measures and  
3 we'll be looking at them again, the criteria.

4 Next slide, please.

5 So, for reproductive health we have  
6 four measures. One is up for maintenance review  
7 and three new measures around contraceptive care.

8 We have two pregnancy measures that  
9 address perinatal and postpartum care. Next  
10 slide, please.

11 So, as we think about the portfolio I  
12 know Diana Jolles mentioned to this during one of  
13 our workgroup calls about the labor and delivery  
14 measures and the caesarean measures.

15 And she mentioned what about the  
16 babies, and what about women that are of the  
17 child-bearing age that's not really under these  
18 categories. What about measures that address  
19 those types of care.

20 And so we'll discuss this later  
21 sometime tomorrow afternoon. We'll go into  
22 details about the gaps in the portfolio and what

1 measures you're looking at that needs to come  
2 into this portfolio to make it more  
3 comprehensive.

4 So as you can see, for labor and  
5 delivery we have a lot of measures around  
6 elective delivery and c-section, and a few high-  
7 risk measures around steroids and high-risk woman  
8 delivery. Next slide, please.

9 So, for newborn we have lots of  
10 measures, particularly around premature and low  
11 birth weight.

12 We have currently two new measures  
13 that's been submitted to us around the level 2 or  
14 higher nurseries, and then one around neonatal  
15 intensive care all-condition readmission.

16 For postpartum we have two measures.  
17 One is the paper measure and one is the eMeasure  
18 around breast milk feeding. Next slide, please.

19 So here in front of you are the  
20 measures that were submitted to us. So, we would  
21 like -- the measure steward is willing to  
22 transfer ownership.

1           So as we talk about these measures  
2 tomorrow afternoon we want to hear more from you  
3 do we really need to keep these measures alive,  
4 and if we do are there other measure stewards out  
5 there who is willing to take on these measures.

6           So, this is generally the roles for  
7 the standing committee. I'm not going to go into  
8 these because we discussed this during our  
9 orientation.

10           But what I want to take some time on  
11 is the next slides.

12           And this is about your roles as it  
13 pertains to the measure evaluation duties. So  
14 you're going to evaluate the measures against  
15 each criteria and then indicate the extent to  
16 which each criteria is met and rationale for  
17 rating the measure.

18           We want to also make recommendations  
19 to the NQF membership for endorsement.

20           And then as your role as the committee  
21 you need to review all the measures that's  
22 currently in front of you and make your

1 recommendation according to what is given in the  
2 criteria. Next slide, please.

3 So, we're fortunate to have the  
4 measure developers here with us today. Some are  
5 in the room, others are over the phone.

6 They have been given two to three  
7 minutes to introduce their measures to you, and  
8 then you're free to ask them questions as they  
9 arise as you're going through the criteria.

10 Developers have designated places at  
11 the main table. There's two reserved seats  
12 there. And they will come up as their measure is  
13 ready for discussion.

14 During the measure evaluation  
15 committee members often offer suggestions for  
16 improvement to the measures. These suggestions  
17 can be considered by the developer for future  
18 improvement. However, the committee is expected  
19 to evaluate and make recommendations on the  
20 measure per the submitted submissions and tested.  
21 Next slide, please.

22 Reva?



1 DR. WINKLER: Thanks. Good morning,  
2 everyone. I'm Reva Winkler. I'm the senior  
3 director here at NQF.

4 I think I've tried to introduce myself  
5 to all of you, but just by way of further  
6 introduction I've been at NQF now for 15 years,  
7 but prior to that I spent 20 years at Kaiser  
8 Permanente in their Los Angeles main hospital as  
9 an OB/GYN.

10 So I serve as the subject matter  
11 expert here at NQF for perinatal care.

12 And so we talked a bit about on our  
13 workgroup call so hopefully this isn't new  
14 information.

15 We do have both new measures, newly  
16 submitted that we've never seen before, but we  
17 also have a goodly number of measures that have  
18 been endorsed by NQF for awhile, some as many as  
19 eight years when we did our first perinatal  
20 project in 2008.

21 And so these measures are undergoing  
22 their periodic review to determine whether they

1 still meet NQF's evaluation criteria for ongoing  
2 endorsement.

3 And we call these maintenance  
4 measures. It's short for maintenance of  
5 endorsement review. So, just the shortcut  
6 terminology.

7 We this year as a result of feedback  
8 from committees are looking at our maintenance  
9 measures somewhat differently than new measures  
10 where for the new measures we run and go through  
11 all criteria because we've never looked at them  
12 before.

13 However, maintenance measures have  
14 been evaluated sometimes multiple times in the  
15 past. And many of the characteristics of a  
16 measure may not have changed a great deal, such  
17 as evidence or perhaps even the testing of a  
18 measure.

19 And so if there is no new information  
20 for this committee to consider one of the things  
21 that you will be able to do is kind of say, okay,  
22 been there, done that, we accept what's been done

1 before. We don't need to rehash it and rework it  
2 and do work that's already been done before and  
3 we can just accept it and move on without further  
4 spending a lot of time on it.

5 I will tell you that we have a very  
6 packed agenda. There are multiple measures that  
7 are likely to promote a great deal of discussion.  
8 And so we do need to keep to our agenda to get  
9 through all of the measures.

10 So the opportunity to kind of move  
11 quickly through measures that really don't need a  
12 lot of rework and re-discussion is going to  
13 benefit and give us time to talk about those that  
14 I think there may be further discussion.

15 So keep that in mind. We're all  
16 responsible for keeping us on track and getting  
17 the work done over two days.

18 So, in our maintenance measures the  
19 things we do want to care particularly and put  
20 greater focus on is what's happening. Current  
21 performance.

22 How has this measure been performing

1 as an NQF-endorsed measure over the last few  
2 years? What do we know about it? What's the  
3 experience of it? What's current performance and  
4 what's been happening? Is there an opportunity  
5 for improvement?

6 Also, how is it being used? How  
7 widespread is the use? What's been the impact?  
8 Did we have data and trends change over time?

9 And then any unexpected findings from  
10 use of that measure. What have we learned? Both  
11 positive and negative things.

12 Because again as we know anything that  
13 may have been tested well when it goes into  
14 widespread use all sorts of fun things can be  
15 learned and can occur.

16 So that's what we want to understand  
17 more about the maintenance measures is really  
18 what's happening with their use out in the field.

19 And for that many of you come from  
20 wonderful places all over the country out in the  
21 field.

22 And one of the things we really rely

1 on is you bringing that personal experience you  
2 may have in use of some of these measures.

3 And we really hope that you will offer  
4 and share that experience as part of the feedback  
5 on how NQF measures are working for you, or the  
6 problems you're having, or whatever that  
7 experience might be out in the field.

8 We had a lot of conversation in the  
9 workgroup calls about is it a structure or a  
10 process or an outcome measure.

11 There are implications for assigning  
12 the measure. Some of NQF's criteria depends on  
13 whether it's a structure or process versus a pure  
14 outcome measure.

15 I put this slide in for reference.  
16 The original source of the  
17 structure/process/outcome construct is from  
18 Donabedian and I've described it here.

19 We talked an awful lot about  
20 intermediate outcomes which Donabedian did not  
21 include, but I searched around and I kind of  
22 adopted and liked what the CDC describes as

1 intermediate outcomes which are interim results  
2 on the road to the ultimate health outcome of  
3 interest. So think of those in those terms.

4 So again, I just included this for  
5 reference and review.

6 So we do have some things that I want  
7 you to be aware of as we're evaluating measures.

8 There's been a lot of information  
9 during our orientation, our Q&A calls, our  
10 workgroup calls as you all recall they were  
11 pretty much packed and intense with information.

12 But there are a couple of other things  
13 that we want you to be aware of.

14 Because this whole world of  
15 measurement has been evolving, growing, becoming  
16 more complex. And so there are some things we do  
17 need to pay attention to, and I just want to  
18 point them out to you at this point.

19 You've probably heard us talking about  
20 the SDS trial. And what this refers to is the  
21 sociodemographic status trial that NQF is  
22 undergoing. We're smack in the middle of it,

1 actually.

2           There has been a longtime discussion  
3 on how to manage sociodemographic factors when it  
4 comes to creating measurement, and case mix  
5 adjustment, and adjusting for different patient-  
6 level factors.

7           Historically NQF has pretty much  
8 discouraged the use of patient-level factors in  
9 case mix adjustment. But there has been an  
10 ongoing conversation and really sort of two  
11 points of view on managing on how to deal with  
12 sociodemographic adjustment and factors.

13           One point of view is that by making  
14 those adjustments you will mask disparities in  
15 care and we really want to uncover disparities in  
16 care so that they can be addressed and attended  
17 to.

18           On the other hand there's another  
19 point of view that says that adjusting for  
20 sociodemographic factors is necessary to avoid  
21 making incorrect assumptions and conclusions  
22 about performance when comparing providers.

1           So those two points of view were  
2 hashed out by an SDS expert panel that NQF  
3 convened in 2014.

4           And again, there isn't one answer.  
5 There are perspectives. There are reasons. It  
6 becomes a very complex issue.

7           So the panel recommended to the NQF  
8 board which accepted and approved a two-year  
9 trial period during which we don't prohibit the  
10 use of the factors, but we want to know more  
11 about the thinking. What is the conceptual  
12 framework for including factors? Is there an  
13 empirical basis for it as opposed to, you know, I  
14 think they're harder.

15           So, there are some things that we want  
16 to attend to which I found in your workgroup  
17 discussions you all were naturally going there.

18           So, just to tell you that we'll be  
19 taking notes. And part of the output from this  
20 committee as part of this trial will be to look  
21 at the conversations you've had around outcome  
22 measures that are risk-adjusted and how they did



1 or did not address sociodemographic factors.

2 So, just to be clear what  
3 sociodemographic factors are, are patient factors  
4 present prior to treatment and known or suspected  
5 confounder of the treatment.

6 And that known or suspected is really  
7 the conceptual basis.

8 And so we look at socioeconomic  
9 status. We're looking at things like income,  
10 education, employment. Sociodemographic factors  
11 related to socioeconomic factors may be things  
12 like insurance status, homelessness, language,  
13 literacy, et cetera.

14 Generally race and ethnicity are not  
15 to be used as proxies for SES though reporting  
16 results stratified by race and ethnicity is  
17 encouraged to address disparities. So, again.  
18 Complex? Absolutely.

19 So we will look at the outcome  
20 measures and how they are or are not adjusted for  
21 case mix, and how the developers addressed  
22 potential sociodemographic factors. So just a

1 little add-on to everything else we need to think  
2 about.

3 So in terms of your evaluation for  
4 those we will ask you to look at things about a  
5 conceptual relationship. And I think all of you  
6 were doing that sort of naturally.

7 What variables were available to the  
8 developer when they were developing the measure,  
9 and does the empirical analysis show that the  
10 factor had a significant or unique effect on the  
11 outcome, and what measure ended up being  
12 specified as a result of the conceptual basis,  
13 the testing of the factors, and the testing of  
14 the models.

15 So that's naturally part of what  
16 you're going to be doing and you all were doing  
17 it anyway, but I just wanted to point out to you  
18 that we will be capturing this not just for this  
19 particular exercise, but also it will be  
20 contributing to NQF's trial period evaluation of  
21 this subject area.

22 MS. THEBERGE: Okay, before we talk

1 process we did have a committee member who came  
2 in late. If we could ask you to introduce  
3 yourself and whether you have anything to  
4 disclose.

5 MEMBER SRINIVAS: Hi, my name is  
6 Sindhu Srinivas. I'm from the University of  
7 Pennsylvania. I'm a maternal-fetal medicine  
8 specialist and the director of obstetrical  
9 services and the vice chair for quality and  
10 safety for our department. And I have no  
11 disclosures.

12 MS. THEBERGE: Thank you. Okay, next  
13 slide, please.

14 So, I just want to talk for a couple  
15 of minutes about the process, how this is all  
16 going to work today.

17 As mentioned we will have the  
18 developers give a very brief introduction of  
19 their measures.

20 And then we'll ask the lead  
21 discussants to begin the committee's discussion  
22 by providing a summary of the pre-meeting

1 comments and what was discussed in the workgroup  
2 call.

3 And really we're asking you to  
4 emphasize areas where there was concern or where  
5 there was differences of opinions on those calls  
6 and pre-meeting surveys.

7 The developers will be available to  
8 answer your questions. And we'll have the full  
9 committee discuss each of the criteria and then  
10 vote before moving onto the next criteria.

11 For both developers and committee  
12 members if you wish to speak during the  
13 discussion we ask you to just turn your table  
14 card up so that we -- like a raised hand so that  
15 we see that and we'll try to get to folks in the  
16 order that they've raised their cards.

17 We've gone over the criteria on the  
18 calls and we will be going through them in the  
19 order presented on the worksheet.

20 As we discussed evidence is must-pass  
21 meaning that if a measure does not pass evidence  
22 then the discussion stops there. And I'll get

1 into what does pass mean in a couple of minutes.

2 Performance gap, reliability and  
3 validity are all must-pass criteria.

4 After we vote on those we go through  
5 usability and use, feasibility and then overall  
6 suitability for endorsement.

7 So, now to talk about voting.  
8 Everybody should have a clicker that will allow  
9 you to vote.

10 And when we vote we're asking you to  
11 point to Kaitlynn over on the side of the room.  
12 She's got the computer that's collecting the  
13 votes. And we ask you to just point your clicker  
14 and click it once.

15 And your remote will show you're vote  
16 so that you can see what you voted. If you want  
17 to change your mind click it again. It will only  
18 record once. She is behind you, over by the  
19 windows.

20 So, I'll talk for a minute about what  
21 quorum is and our consensus not reached status.

22 Quorum is at least 66 percent of the

1 committee. We have definitely achieved that  
2 today since everybody's here.

3 And committee members who are recused  
4 are not included in that. So our numbers will  
5 drop up and down as we go through depending on  
6 whether or not somebody is recused from a  
7 measure.

8 To be considered recommended by the  
9 committee on any of the criteria -- so this is a  
10 pass as well -- measures must be greater than 60  
11 percent.

12 Votes between 40 percent and 60  
13 percent are considered consensus not reached, and  
14 that does include both 40 and 60. And anything  
15 less than 40 percent is not recommended.

16 If the vote is in this consensus not  
17 reached zone during one of the must-pass criteria  
18 we move on and continue to discuss and vote.

19 And if the measure does not achieve  
20 consensus on the overall recommendation then we  
21 put it forward for comment as consensus not  
22 reached.

1           We will ask the developers if you have  
2 a concern about, say, the reliability of the  
3 measure and you don't reach consensus the  
4 developers are invited to submit additional  
5 information during the comment period that you  
6 will be able to review and discuss on the post-  
7 comment call.

8           If the consensus not reached vote is  
9 on overall we'll ask for comment specifically on  
10 that. And again, you'll have the opportunity to  
11 re-vote after the call. All right. Next slide.

12           And finally just want to go over a  
13 couple of ground rules for the meeting.

14           We have worked really hard and are  
15 continuously striving to improve our meetings  
16 based on input from our stakeholders, from  
17 everybody that attends these meetings, committee  
18 members, developers and the public.

19           And we ask our committee members to  
20 act as a proxy for the NQF membership. So, as  
21 such this multi-stakeholder group has a lot of  
22 varied perspectives, varying values and

1 priorities. And you're all bringing that to the  
2 table. That's why you're here.

3 So of course we ask that you respect  
4 these differences of opinion and remain collegial  
5 with both each other and with the developers.

6 As has been mentioned a couple of  
7 times we have a very full agenda. So we do ask  
8 that you do your best to keep on time and help us  
9 get through everything today and tomorrow.

10 And with that I think we're ready to  
11 get started. I will just pause before we start  
12 and see if anybody has any questions at all.  
13 Process, logistics, criteria, anything?

14 MEMBER LOWE: I have a question about  
15 the consensus criteria and how the 60 percent was  
16 developed as the consensus mark.

17 Because frankly it seems fairly low to  
18 me for consensus.

19 DR. WINKLER: Well, actually, two  
20 years, maybe it's been three now, I don't know,  
21 the board established a consensus task force to  
22 address exactly that question - what is



1 consensus? Okay, good question.

2 Because actually up until recently, or  
3 I guess two or three years ago, actually 50  
4 percent, you know, a typical simple majority was  
5 what it would take.

6 And again, a very legitimate question  
7 was is that really consensus.

8 And so there is no absolute answer on  
9 this. And so we're probably still exploring.  
10 But 60 percent is more than 50 percent.

11 And so again, I think we will stop at  
12 one point that we've used that for awhile and  
13 see.

14 I think more the point of raising the  
15 issue of where consensus is not reached in the  
16 mid-range has become one of the sort of newer  
17 nuances to it.

18 Understanding that we definitely don't  
19 have consensus here, either yea or nay, and  
20 therefore we need to either gain more  
21 information, figure out what the issues are, and  
22 see if we can push it one way or another so that

1 there is a more definitive consensus.

2 But Nancy, you're right. The number  
3 at this point was the next step in trying to  
4 figure out what does consensus mean when you're  
5 doing a vote that's got to count the numbers.

6 Because in general the accepted  
7 definition of consensus is general agreement, but  
8 not necessarily unanimity. And if you can put a  
9 number on that, that would be lovely. So that's  
10 where the 60 percent has come from.

11 MEMBER FLANAGAN: A follow-up question  
12 on that. It's not really the same issue, but  
13 it's process.

14 Should a measure come into that  
15 category of 40 to 60, and there's a question and  
16 answer and resubmission, there's no change in the  
17 measure, correct? There's feedback, comment, and  
18 then it can be resubmitted a following year?  
19 Could you explain that a little bit?

20 DR. WINKLER: Yes. We are not part of  
21 the measure development team. We are reacting to  
22 the measure as is.

1           That doesn't mean the discussion does  
2 not provide very useful and valuable feedback to  
3 the developers.

4           Occasionally there will be something  
5 minor that can get tweaked that by mutual  
6 agreement on all parties but isn't a major change  
7 to a measure does occur.

8           But in general that is not the focus  
9 of the work we're doing.

10          And so we want to really realize that  
11 your discussion of gee, I wish the measure did  
12 this, I wish the measure did that, or I'd prefer  
13 it did this and that is simply feedback to the  
14 developer. And we are not looking to remake  
15 things here. Okay?

16          MS. THEBERGE: Any other questions?  
17 I thought I saw another hand.

18          Okay. I think we can go ahead and get  
19 started. But if you have questions throughout  
20 don't hesitate to ask one of the staff.

21          DR. WINKLER: And I think we'll turn  
22 it over to Carol and Kim as our co-chairs who

1 will lead you all through the discussion of the  
2 agenda.

3 CO-CHAIR SAKALA: Great, good morning.  
4 First of all, we have three new contraceptive  
5 measures to begin our work.

6 And the first one is 2903:  
7 Contraceptive Care - Most and Moderately  
8 Effective Methods.

9 And we are going to begin by asking  
10 the developer to come up and do a two- to three-  
11 minute introduction of that measure.

12 DR. GAVIN: Good morning. My name's  
13 Lorrie Gavin. I'm with the U.S. Office of  
14 Population Affairs. And I'm here with a  
15 colleague Phil Hastings who provided statistical  
16 consultation on the measures from a company  
17 called Far Harbor.

18 Thanks very much for considering our  
19 measure applications. We're very excited about  
20 the potential of these measures.

21 The first measure is the percentage of  
22 women at risk of unattended pregnancy that's

1 provided the most and moderately effective method  
2 of contraceptive.

3 We consider this an intermediate  
4 outcome measure because it reflects what happens  
5 at the end of the visit after an interactive  
6 discussion between the provider and client and  
7 because contraceptive method choice is so  
8 strongly associated with risk of unintended  
9 pregnancy.

10 We believe that a high percentage of  
11 women will choose one of the most or moderately  
12 effective methods, although it will likely not  
13 reach 100 percent because some women will choose  
14 a less effective or no method. And those choices  
15 need to be respected.

16 The second measure is focused on use  
17 of long-acting reversible contraceptive methods  
18 or LARC of IUDs and contraceptive implants.

19 This measure is used very differently  
20 than the first measure in that we'll use it to  
21 monitor access. We'll encourage health systems  
22 to look at reporting units with very low rates of

1 use -- or provision of LARC. For example, less  
2 than 1 to 2 percent, or looking at the median  
3 across a number of reporting units and looking at  
4 those that are well below the median.

5 The focus is on removing unnecessary  
6 barriers to LARC access. We do not think this  
7 would be an appropriate measure for setting a  
8 high benchmark, or for using a pay-for-  
9 performance approach due to potential concerns  
10 about coercion.

11 Contraceptive care is important  
12 because it prevents teen and unintended pregnancy  
13 and improves rates of birth spacing.

14 All of these are substantial public  
15 health concerns that have profound health, social  
16 and economic consequences for women, men, infants  
17 and society at large.

18 Recognizing this impact, several  
19 national bodies have noted the importance of  
20 efforts to prevent teen and unintended pregnancy.  
21 This includes Healthy People 2020, the National  
22 Prevention Strategy and most recently the

1 inclusion last year of unintended pregnancy in  
2 the Institute of Medicine's list of 15 core vital  
3 statistics that all health systems should  
4 monitor.

5 We also believe that the measure's  
6 focus on provision of more effective methods is  
7 consistent with women's own desires.

8 There's quite compelling evidence that  
9 when a client-centered approach is used, and by  
10 that we mean providers help women understand the  
11 sometimes complex pros and cons of the various  
12 methods, women have ready and affordable access  
13 to the method of their choice, and the provider  
14 respects a client's final decision, that a very  
15 high percentage of women will choose the more  
16 effective methods with high rates of decision-  
17 making autonomy and competence in their choice.

18 We've compiled on a two-page summary,  
19 and we're happy to share that with any of you  
20 some of the evidence that helps us be competent  
21 in those statements.

22 The first is a recently published

1 study just this year in which a large number,  
2 almost 1,500 women were surveyed in family  
3 planning abortion clinics about the various  
4 attributes of contraceptive methods that they  
5 thought were extremely important, somewhat  
6 important, important, or not at all important.

7 They were asked to rank the 18  
8 methods. And the most important one, the one  
9 that 89 percent of women reported as extremely  
10 important was method effectiveness.

11 This was consistent in terms of its  
12 relative importance even when stratified by  
13 different racial and ethnic groups.

14 The next higher factors were easy to  
15 get, affordability and easy to use.

16 These preferences were validated in  
17 several recent very rigorous studies that  
18 examined women's choice of methods after client-  
19 centered counseling was provided.

20 The first study was a cluster  
21 randomized trial that showed that when  
22 appropriately counseled one-third of participants



1 chose a LARC method. And there was no difference  
2 between groups in decision-making autonomy.

3 The second study, Project Choice,  
4 showed that again when counseled and the methods  
5 were provided at no cost 75 percent of all women  
6 chose a LARC method. And continuation rates were  
7 high at both 12 and 24 months.

8 A third study examined uptake of LARC  
9 among teens who were provided quality  
10 contraceptive counseling during prenatal care.  
11 Forty-three percent of these teens chose a LARC  
12 method, 86 percent were still using the method 12  
13 months later, and in a related study almost 90  
14 percent expressed strong confidence that she  
15 selected the right method for her.

16 These studies are in sharp contrast to  
17 data from the National Survey of Family Growth  
18 which showed that much lower rates of use of the  
19 most and moderately effective and LARC methods of  
20 contraception. Sixty-three percent for use of  
21 most and moderately effective, and 3 percent  
22 amongst teens, and 9 percent among adult women.

1                   This data has convinced us that  
2                   there's a huge unmet need for effective methods  
3                   and substantial room for improvement in the  
4                   measures.

5                   We think that we have all the  
6                   ingredients needed to scale up the results of  
7                   these studies in real life.

8                   There are CDC, OPA, ACOG and AAP  
9                   guidelines on how to provide contraception in a  
10                  safe and client-centered manner.

11                  The Affordable Care Act and recent  
12                  Medicaid actions have removed many of the cost  
13                  barriers to contraception.

14                  There's a need now to focus on  
15                  provider barriers. And we think use of the  
16                  proposed measures will go a long way towards  
17                  removing them.

18                  We expect that the use of the measures  
19                  will encourage more providers to first start  
20                  screening women who come for non-family planning  
21                  reasons about their pregnancy intention and  
22                  providing them contraceptive services as needed.

1                   And secondly, to start following  
2 federal and professional medical recommendations  
3 to inform women seeking contraception about the  
4 availability of a wide range of methods, for  
5 client-centered education about those methods  
6 that includes effectiveness as one piece of  
7 information, and take steps to ensure that those  
8 methods are available to the client, preferably  
9 on a same-day onsite basis.

10                   A last comment. The application  
11 described the current use of the measures by  
12 several health systems - Planned Parenthood,  
13 Medicaid and Title 10.

14                   But I want to take a moment to  
15 describe a very recent use of the measures that's  
16 emerged in response to the reproductive health  
17 threat posed by Zika.

18                   As we've worked at OPA to prepare our  
19 own network of 4,200 service sites across the  
20 country a first step has been to use the measures  
21 to identify the service sites that have little or  
22 no access to LARC.

1           We want to identify these service  
2 sites. We can quickly provide training and take  
3 other steps to address barriers so our clients  
4 have full access to the full range of methods.

5           We'll also be using these measures to  
6 monitor change over time.

7           Thank you for considering these  
8 measures and we look forward to the discussion.

9           CO-CHAIR SAKALA: Thank you. So, our  
10 two lead discussants today are Mimi and Sarah.  
11 And we'll ask you to begin with addressing the  
12 criteria for evidence.

13           MS. ALLEN: And before we get started  
14 we have one committee conflict, so just to note  
15 that. Carol? Thank you.

16           MEMBER SPALDING: So, the review of  
17 the evidence demonstrates strong support of both  
18 providing LARC and considering using a measure to  
19 support that clinics are providing greater access  
20 to a wide range of contraception options.

21           The other evidence that was not  
22 highlighted that is important is some of

1 Christine Dehlendorf's work out of UCSF that  
2 talks about when LARC is measured as a -- if  
3 we're looking at higher percentages of LARC  
4 uptake, rates of non-patient centered preferences  
5 can increase as well.

6 So, particularly with a history of  
7 coercion in contraceptive counseling there was a  
8 lot of discussion in our group about thinking  
9 about the history of that in terms of having this  
10 as a measure.

11 CO-CHAIR SAKALA: Okay, any difference  
12 of opinion or other comments from members of the  
13 committee? Matt?

14 MEMBER AUSTIN: It's more a process  
15 question. Are we considering both measures at  
16 the same time? Or is it 2903 that we're first  
17 considering?

18 CO-CHAIR SAKALA: So, I think it was  
19 helpful to get a little bit of the broader  
20 picture, but we will consider them consecutively.

21 MEMBER AUSTIN: Okay.

22 DR. WINKLER: So right now we're

1 discussing 2903, the contraceptive care most and  
2 moderately effective methods.

3 We will go through the same process  
4 for the other two as well.

5 MEMBER MCNEIL: So with this measure  
6 in particular the only patient-centered concern  
7 would be after discussion with a patient the  
8 patient walks away from the appointment after  
9 extensive counseling and decides on using  
10 condoms, or using family planning as her  
11 preferred method of choice.

12 And considering that that could be  
13 high-quality care not with provision of a most or  
14 moderately effective form of contraception, but  
15 rather what is patient-centered birth control  
16 option.

17 But we agree that after discussion,  
18 you know, even though this isn't an idea measure,  
19 the importance of measuring contraception uptake  
20 is important.

21 And, yes. There isn't an easy answer.

22 MEMBER BAILIT: Hi, two quick

1 questions. And I'm not sure if this is for the  
2 developer so much as for the group. And perhaps  
3 I just missed it.

4 CO-CHAIR SAKALA: Could you speak  
5 closer to the mike, Jennifer?

6 MEMBER BAILIT: Sure. How are women  
7 who depend on vasectomy as birth control  
8 encountered here? And how does this data capture  
9 women in same-sex relationships where birth  
10 control is not an issue?

11 DR. GAVIN: So, this version, we hope  
12 to do an eMeasure soon or a hybrid measure, but  
13 this version relies on claims data. So,  
14 vasectomy is one of several dimensions that we  
15 weren't able to capture.

16 But we will in future. So we proposed  
17 ways of using the National Survey of Family  
18 Growth to kind of adjust for these things like  
19 vasectomy, previous insertion of LARC, or  
20 previous sterilization.

21 Same thing. With claims data we  
22 cannot address those issues. We could in a

1 future hybrid measure that we're working on now.

2 CO-CHAIR SAKALA: Tracy?

3 MEMBER FLANAGAN: So, are we still  
4 talking about evidence? Are we going  
5 systematically through?

6 CO-CHAIR SAKALA: Yes. This is an  
7 opportunity for feedback before we need to vote  
8 on the evidence.

9 MEMBER FLANAGAN: So, question to the  
10 developers.

11 Has this measure or a proxy of the  
12 measure been tested anywhere? I heard the  
13 evidence that you presented, but exactly as it's  
14 laid out has that been tested?

15 DR. GAVIN: Yes, we've tested it at  
16 Planned Parenthood data, 800,000 some clients in  
17 Planned Parenthood across 25 affiliates, 3 state  
18 Medicaid programs, and then Title 10 also using a  
19 slightly variant because we don't use claims.

20 MEMBER FLANAGAN: Exactly as it's laid  
21 out.

22 DR. GAVIN: Yes, yes.



1                   MEMBER FLANAGAN: And in a larger  
2 population like a health plan?

3                   DR. GAVIN: What we were able to do is  
4 in the Wisconsin Medicaid and Louisiana  
5 Postpartum we were able to look at health plans  
6 for Medicaid managed care only, not commercial.

7                   MEMBER FLANAGAN: Thank you. Let me  
8 ask a follow-up question on that. Were there any  
9 -- was there feedback on it in any way that  
10 revealed problems?

11                  DR. GAVIN: No. I'm not sure what you  
12 -- I mean, there are some limitations clearly of  
13 using a strictly claims-based measure.

14                  MEMBER FLANAGAN: Yes.

15                  DR. GAVIN: That definitely is very  
16 apparent. But again, we think for a short 3- to  
17 5-year period while we're developing the eMeasure  
18 there's so much room for improvement we think it  
19 will serve the purposes even though there are all  
20 those limitations and you have to adjust.

21                  MEMBER FLANAGAN: Thank you.

22                  MEMBER GOYERT: I have two questions

1 or concerns neither of which I think are going to  
2 be adequately addressed. So, but they apply to  
3 all three.

4 First, the problem with this is that  
5 we're assessing providers on the basis of our  
6 patients' clinical decision-making.

7 And out in the field people are going  
8 to say foul. They're going to say I provided the  
9 best counseling in the world. The patient made a  
10 different decision. And yet we're getting as it  
11 were dinged.

12 The second concern is for, pick a  
13 number, 20, 25, 30 percent of the U.S. population  
14 contraception is against their moral compass.  
15 So, this measure is not going to look too good  
16 with the Catholic systems, the Sisters of  
17 whatever. So I'm not sure how you factor that  
18 into the decision-making. Thanks.

19 DR. GAVIN: These are great points.  
20 On the first point, the fact that a provider will  
21 be dinged because some of their clients did not  
22 choose a most or moderately effective method, we

1 think the evidence is pretty strong that when you  
2 counsel a woman about the range of factors that  
3 most of them will use those most or moderately  
4 effective methods.

5 I think there's eight methods in those  
6 top two tiers in that category. That's a lot of  
7 range. There's a lot of methods.

8 Because these other system barriers  
9 are removed we think the provider issue is the  
10 main thing driving choice.

11 The other aspect is we're not setting  
12 a benchmark of 100 percent. It's like many other  
13 measures where we never expected to reach 100  
14 percent for exactly that reason.

15 Some women will choose from looking at  
16 the Planned Parenthood data, Title 10 and some of  
17 these studies we haven't set a benchmark, but we  
18 will be consulting with experts over the coming  
19 years.

20 We think it's going to be about 85 to  
21 90 percent when you kind of look at the top  
22 amount that the dedicated family planning

1 providers and this Lancet study found, but we  
2 don't know that.

3 So it's not every client. There will  
4 be a benchmark. We're trying to move it up from  
5 63 percent. I mean, our goal is 15 percentage  
6 points in the next four to five years.

7 So it's not a matter of every woman  
8 being forced to use a most or moderately  
9 effective method.

10 The second thing, on the religious  
11 use, of course these are voluntary measures and  
12 it's very likely that Catholic hospitals will not  
13 use these measures.

14 However, I do want to point out that  
15 99 percent of women who identify within a  
16 religious affiliation including Catholic have  
17 ever used birth control, and that 89 percent of  
18 Catholics report currently using contraception if  
19 they're at risk.

20 Sixty-eight percent of Catholic women  
21 are using a highly effective method, and that's  
22 defined as sterilization, pill or other hormonal

1 method, or IUD.

2 Only 3 percent of Catholic women who  
3 are at risk of unintended pregnancy are using  
4 natural family planning.

5 So although their hospitals may not be  
6 monitoring it, we know that Catholic women are  
7 using those methods.

8 CO-CHAIR SAKALA: Cindy?

9 MEMBER PELLEGRINI: Thank you. I  
10 appreciated the comment that was made in the pre-  
11 evaluation comments about the choice between  
12 tying this measure to actual provision versus  
13 offering of the method.

14 And I wondered could you talk a little  
15 bit more about why you ended up deciding to go  
16 with actual provision of LARC or other methods?

17 DR. GAVIN: Well, we think that's  
18 closer to the outcome. Rather than offering.  
19 And it's measurable with claims data.

20 So, there's no way to measure whether  
21 the client was offered it unless you kind of  
22 collect new data elements.

1                   Claims data allows you to actually  
2 pretty precisely look at what methods were  
3 provided through an NDC code, a CPT, ICD-9 code,  
4 there's HCPCS code. There's pretty clear  
5 documentation what the methods were.

6                   That's different from what they  
7 actually use. We know that use is imperfect. So  
8 when you look at those estimates that we provided  
9 about contraceptive failure there are two  
10 estimates that Princeton comes up with. They  
11 publish the contraceptive failure rates.

12                   The two methods that they come up  
13 with, or two estimates, one is perfect use. And  
14 that's based off kind of FDA trial data. That's  
15 if you use the method correctly and consistently  
16 all the time.

17                   And then the typical use is the ones  
18 that we're using which is when you factor in the  
19 actual use and the fact that many women will not  
20 be able to use the method correctly and  
21 consistently.

22                   So we're relying on the typical use

1 method. So it's adjusting for some of that  
2 imperfection.

3 But again, we're focusing on what  
4 providers do. And I think there is a question  
5 and another part of the story, but as clinical  
6 performance measures we're interested in that  
7 providers are making sure women at least have  
8 access and can use them.

9 CO-CHAIR SAKALA: So, let's do Sindhu,  
10 and then Sarah, and this has been a great  
11 discussion that has a lot of background for all  
12 the dimensions of all three measures. But we do  
13 need to keep an eye on time. So after that let's  
14 plan to vote on evidence.

15 MEMBER SRINIVAS: I just had a quick  
16 question about the denominator of the measure  
17 that women who are recently postpartum are  
18 excluded. And I was wondering what the rationale  
19 for that is as those women are often the highest  
20 risk of repeat pregnancy.

21 DR. GAVIN: So, we had a whole measure  
22 that we'll talk about later because we agreed

1 they're an important population. So we developed  
2 a whole measure for them.

3 The reason we excluded them if they're  
4 within two months is strictly because we wanted  
5 to be as fair as possible to providers.

6 So the ACOG recommendation is provide  
7 contraception at the postpartum visit at six  
8 weeks. We added two weeks for lag time. So it's  
9 really just a fairness to provider issue so that  
10 -- we don't want to ding them for not having  
11 contraception before they came to the postpartum  
12 visit.

13 MEMBER MCNEIL: I work in a county  
14 healthcare system so I'm not the best on billing,  
15 but my understanding is that there's an ICD-9  
16 code for contraceptive counseling.

17 Did you consider -- that would kind of  
18 get at the offering versus provision of a method.

19 DR. GAVIN: We did not. We wanted to  
20 really focus on what was provided.

21 CO-CHAIR SAKALA: Okay. Do you want  
22 to give us any tips on use of these for voting on



1 evidence?

2 MS. THEBERGE: Well, point them --  
3 let's see, we'll have to pull up the voting  
4 slides. And just give us a moment.

5 MS. ROBINSON-ECTOR: Hi, everyone.  
6 So, just to go over really quickly. Make sure to  
7 point your clickers towards me.

8 And also, let's say you make a  
9 decision and you want to change it before the  
10 vote closes. Just simply pick the other option  
11 and push that button and it will cancel out your  
12 original vote. And you can revote without having  
13 to restart the whole vote.

14 So, voting is now open for evidence  
15 for measure 2903. And so if you just click your  
16 clicker at me the software will begin to capture  
17 your votes. And so each number on your clicker  
18 corresponds to the number on the slide.

19 CO-CHAIR SAKALA: So, the screens at  
20 the end of the room have the information. Yes is  
21 your agreement that the evidence meets the  
22 criteria for moving this measure forward.

1                   MEMBER MCNEIL: So can I ask a  
2 clarifying question? 1a responds to yes and 2b  
3 means no?

4                   CO-CHAIR SAKALA: Correct.

5                   MEMBER MCNEIL: Okay.

6                   MS. ALLEN: But, before we start our  
7 votes we may want to have a bigger discussion on  
8 the evidence itself.

9                   I know we were all over the place when  
10 we were having our discussion so we want to spend  
11 the time to discuss the evidence before voting.

12                   So, are you guys ready to vote?

13 Great.

14                   MS. THEBERGE: It looks like we are  
15 waiting for three more votes.

16                   MS. ALLEN: So we're voting on measure  
17 2903, evidence. Contraceptive care most and  
18 moderately effective methods. 1, yes, 2, no.  
19 Voting starts now.

20                   MS. ROBINSON-ECTOR: Okay, great. So,  
21 all the votes are in. Voting is now closed. It  
22 looks like we have 96 percent voted yes, 4

1 percent voted no and so the measure passes on  
2 evidence.

3 CO-CHAIR SAKALA: So, thank you. The  
4 next part of the discussion is regarding the  
5 opportunity for improvement. And let's ask our  
6 leads to start the conversation there.

7 MS. THEBERGE: Actually, just briefly  
8 before we do that we have one more committee  
9 member who came in. If we could just ask you to  
10 introduce yourself and whether you have anything  
11 to disclose. And then we'll move into the gap  
12 discussion.

13 MEMBER HIRAI: Hi, everyone. I'm  
14 sorry for the late arrival. I'm coming from the  
15 Pacific Coast.

16 My name's Ashley Hirai. I'm a health  
17 scientist at the Maternal and Child Health  
18 Bureau. And I have expertise in perinatal  
19 epidemiology and advanced research methods which  
20 I use to help to inform and evaluate bureau  
21 programs, most principally the Title 5 block  
22 grant program to states.

1 I have worked at the CDC and on the  
2 birth weight measure, and so I have been recused  
3 from that discussion.

4 CO-CHAIR SAKALA: Thank you. Okay.

5 MEMBER SPALDING: So, the next one if  
6 performance gap, right?

7 CO-CHAIR SAKALA: Yes.

8 MEMBER SPALDING: Okay.

9 CO-CHAIR SAKALA: And the  
10 opportunities.

11 MEMBER SPALDING: Opportunities, okay.  
12 So, this measure talked about the percentage of  
13 women of reproductive age who are at risk of  
14 unintended pregnancy which is -- so, 38 million  
15 women are at risk of unintended pregnancy and 51  
16 percent of 6.7 million pregnancies each year are  
17 unintended.

18 And also, the type of contraceptive  
19 method that is used is -- there's a strong  
20 relation between unintended pregnancy.

21 This measure indicated that there were  
22 differences in terms of age.

1           So, the population subgroups that the  
2           disparities were age. But there was no race or  
3           ethnicity, or socioeconomic status information  
4           data or differences.

5           I think -- but there's definitely gaps  
6           in unintended pregnancy especially for young  
7           folks and unmarried women as well.

8           CO-CHAIR SAKALA: I think the  
9           developer has one comment to make.

10          DR. GAVIN: Sorry. I just wanted to  
11          clarify that there are some racial ethnic -- some  
12          sociodemographic differences.

13          They're presented from NSFG and  
14          they're on page -- it's in section 2b4.2.

15          CO-CHAIR SAKALA: Okay. Committee  
16          discussion on the question of opportunity for  
17          improvement and performance gaps. Sarah?

18          MEMBER MCNEIL: The main thing for  
19          improvement that we talked about was thinking  
20          about how -- we appreciate that claims data is  
21          the easiest thing to look at right now. But  
22          thinking about kind of the future of this measure

1 and where to go.

2 A difference in offering birth control  
3 methods versus provision of birth control  
4 methods, and when we're really looking at  
5 patient-centered care and patient autonomy in  
6 terms of decision-making.

7 Highlighting that that is truly --  
8 that data support, that that's important and that  
9 we're not doing a good enough job of that. And  
10 that should really be kind of the move towards  
11 where we're going in terms of providing patient-  
12 centered care.

13 CO-CHAIR SAKALA: Jennifer?

14 MEMBER MOORE: I would agree on that  
15 comment, but I think that comment is also  
16 applicable for all the measures. And I'm not  
17 sure that we'll be able to capture that.

18 So I hear this comment being made, but  
19 I do think we need to put it within the context  
20 that all of maternity care we need to think about  
21 that. I'm not sure that we'll be able to capture  
22 that with all of the measures.

1 CO-CHAIR SAKALA: Other comments on  
2 opportunity to improve?

3 Great. So, I think if there are no  
4 more comments we can vote on whether -- Naomi has  
5 a comment.

6 MEMBER SCHAPIRO: So, my comment  
7 relates to in some ways measuring any of the  
8 methods for provision to adolescents under 18  
9 which is that there's a really wide variation  
10 across the country in access to birth control for  
11 adolescents.

12 There are only 25 states where teens  
13 can really fully consent to birth control under  
14 18.

15 So, I just have some concerns that we  
16 would be perhaps unfairly ding a clinic that's  
17 in a state where access is quite limited for  
18 access problems that have nothing to do with the  
19 clinic.

20 And I know sometimes the data is only  
21 collected for 15 to 21 so it may not really point  
22 that out enough, but that's my concern for

1 improvement measures.

2 DR. GAVIN: So, a couple of comments.  
3 That is true, there are more barriers to  
4 contraceptive care for many teens, although most  
5 states do allow confidential provision. But it  
6 is an issue.

7 In some programs it may not make sense  
8 to use the measure if there are serious access  
9 issues.

10 But the reason, I just want to clarify  
11 why we used and tested the measure using that age  
12 group. We did 15 through 20 and it was to align  
13 it with the Medicaid's, the way they stratify  
14 their age groups.

15 They wanted us to kind of align it  
16 with their kind of adult and child core measures.  
17 So that's the reason.

18 It could be stratified differently if  
19 you're interested in that particular  
20 subpopulation.

21 CO-CHAIR SAKALA: Yes, Karen.

22 MEMBER SHEA: Hi, I have a question



1 about opportunity for improvement with regard to  
2 setting a benchmark.

3 I know you mentioned in your opening  
4 comments the issue regarding coercion and making  
5 sure that every woman who's given the opportunity  
6 has the free choice given appropriate information  
7 to make that choice.

8 How will we demonstrate improvement  
9 and how will we avoid setting certain benchmarks  
10 for a measure like this once it gets out there in  
11 the Ethernet?

12 I can imagine that we'll be looking at  
13 one provider against another provider and wanting  
14 to say well look, you are much more effective  
15 with regard to counseling than perhaps another  
16 provider as evidenced by the fact that you are  
17 implanting more IUDs than another provider.

18 Don't get me wrong, I like the  
19 measure, but I worry about this type of  
20 benchmark-setting.

21 DR. GAVIN: I guess I can only look at  
22 it, the use perspective from where I sit at Title

1 10 and Medicaid. I don't sit at Medicaid, but  
2 we've worked closely with them.

3 And I am aware of how careful their  
4 quality people are in when they interpret it.  
5 We're with 14 state Medicaid programs right now.

6 And I think all of it depends on the  
7 responsibility of the program to interpret these.  
8 To be educated about their measures and to  
9 interpret them appropriately.

10 And making sure that there are kind of  
11 education about the value, education about what  
12 the benchmark should or should not be.

13 I know we're very careful about that  
14 within the Title 10 program.

15 Again, we're not -- we do intend to  
16 kind of look at more evidence that's being used.  
17 We have very good evidence now. I mean, it looks  
18 right now like 80-85 percent is kind of the --  
19 maybe 90 percent. But where that kind of tops  
20 off, it looks like where it is.

21 But we will be looking at that with  
22 expert panels over the next three years. We will

1 be having a discussion. And we will be very kind  
2 of from where we sit careful to make sure that we  
3 do not expect any program to ever expect 100  
4 percent.

5 So, then I think we just need to rely  
6 on the measure users to be educated and informed  
7 about the measures that they choose to use.

8 CO-CHAIR SAKALA: So, because of time  
9 considerations I think Tracy, why don't you make  
10 the last comment and then we should vote.

11 And I am allowing more time for this  
12 first of the three because a lot of the issues  
13 overlap. But we need to pay attention to the  
14 schedule as well.

15 MEMBER FLANAGAN: I'm going to respond  
16 to the last question and actually support the  
17 presenters on this in that I think that, speaking  
18 from a health plan or a large medical group  
19 perspective not everybody does everything.

20 And if we were, for example, in Kaiser  
21 Permanente to use this measure we would think  
22 along the lines of a whole group of physicians

1 providing this, and a population of women.

2 What we've found is that especially  
3 with LARC that in a particular setting of  
4 providers sometimes there's one that does it for  
5 everybody. So going down to the provider level  
6 is not really the way you're going to want to  
7 think about this.

8 DR. GAVIN: That's a really good  
9 point. When we tried to do the reliability  
10 testing we tried to go down to provider level.

11 But it was impossible. It's team-  
12 based care so you can't attribute a method to one  
13 specific provider the way claims at least is set  
14 up right now.

15 And it makes sense that provider-level  
16 measures for this would not work.

17 MEMBER SHEA: I was using the word  
18 "provider" synonymous with a health system or a  
19 tax ID number, not the individual provider.

20 CO-CHAIR SAKALA: Great. So, can we  
21 open the voting, please?

22 We will need to decide as a group

1 whether we feel that this measure does meet the  
2 opportunity for improvement criteria.

3 MS. ROBINSON-ECTOR: Okay, so voting  
4 is now open for performance gap for measure 2903.  
5 1 is high, 2 is moderate, 3 is low, and 4 is  
6 insufficient.

7 And please make sure to point your  
8 clickers directly at me. It looks like we're  
9 waiting on one more vote.

10 If all of you could resubmit. Yes,  
11 one person. Yes, it's still counted. We have 25  
12 voting on this measure.

13 MS. ALLEN: So, we're still missing a  
14 vote. Please point your clicker in the direction  
15 of Kaitlynn that's over here, please. Thank you.

16 MS. ROBINSON-ECTOR: We have 24 votes  
17 in. So, 54 percent voted high, 42 percent voted  
18 moderate, 4 percent voted low, and zero voted  
19 insufficient. So the measure passes on  
20 performance gap.

21 CO-CHAIR SAKALA: So, thank you. Next  
22 we separately address and vote on reliability and

1 validity. So, comments from the leads first on  
2 reliability, please.

3 MEMBER MCNEIL: We felt that in terms  
4 of looking at claims data this was both reliable  
5 and valid.

6 DR. WINKLER: This is when it would be  
7 appropriate to talk about anything in the  
8 specifications that you may have questions about  
9 as well.

10 CO-CHAIR SAKALA: Matt?

11 MEMBER AUSTIN: Thank you. One of the  
12 comments it looks like made by one of the  
13 committee reviewers was this idea of how you  
14 define "at risk."

15 Women who are at risk of pregnancy and  
16 to maybe Jennifer's point earlier, women in a  
17 same-sex relationship wouldn't necessarily  
18 technically be at risk.

19 Can you talk a little bit about how  
20 that's defined? Because it wasn't real clear in  
21 the measure specifications, at least in the  
22 denominator statements.

1 DR. GAVIN: Sure. Again, it's  
2 imperfect because of the nature of claims data.  
3 And we hope to improve with the eMeasure hybrid  
4 version in the next three to four years.

5 We defined "at risk" as having ever  
6 had sex, fecund, and not pregnant or seeking  
7 pregnancy. Fecund, able to become pregnant. So,  
8 we excluded, for example, a woman who had had an  
9 oophorectomy because of ovarian cancer or breast  
10 cancer.

11 Oh, should I repeat that? Sorry.

12 DR. WINKLER: No, everybody just needs  
13 to remember to talk up so we all can hear.

14 CO-CHAIR SAKALA: Okay, thanks.

15 Tracy? Oh, okay. Cindy?

16 MEMBER PELLEGRINI: Thank you. One of  
17 the things in looking at the three measures  
18 together that I was having a hard time with is  
19 figuring out do you expect clinics or plans,  
20 whatever, to choose one of these at a time? To  
21 use them all together?

22 Because some of them seem to have, of

1 course, a great deal of overlap. So, was this  
2 partly about providing degrees of -- degrees of  
3 difference to allow a setting to choose what was  
4 best for them? Or do you really think they  
5 should use a package?

6 DR. GAVIN: Well, if it was up to us  
7 everyone would measure all these measures all the  
8 time. Because I do think they're complementary.

9 The most or moderately effective among  
10 all women at risk tells you a certain amount  
11 about the mix of contraceptive methods,  
12 recognizing the importance that not everyone's  
13 going to choose a LARC. But still getting a  
14 sense that they're using those more effective  
15 methods. We think it's an important measure  
16 that's likely to predict health outcomes.

17 The LARC measure is strictly an  
18 access. I think it tells you something very  
19 different than the most or moderately effective  
20 method.

21 And we're looking at that left end of  
22 the distribution to make sure women who want



1 those expensive methods that there historically  
2 have been a lot of barriers to have access to  
3 them.

4 The postpartum measures are kind of a  
5 bundling of those things with a subpopulation.  
6 That's why we put it all into one application.

7 But we view the first two applications  
8 as kind of the broadest general populations and  
9 the broadest general measures, and then the  
10 postpartum is to us the most important, highest  
11 priority subpopulation to focus on.

12 Because they do -- this is 60 to 65  
13 percent of all births are to women who've had  
14 more than one child. So, there is this  
15 opportunity to kind of intervene in that time  
16 period.

17 You could develop this measure for  
18 other important subpopulations. For example,  
19 it's been suggested that we could look at this  
20 measure amongst women with a previous preterm  
21 birth which is another very high-risk population,  
22 or women with very poor pre-contraception health

1 status.

2 So, the concept was that you would  
3 kind of have these two measures, the most and  
4 moderately, and then the LARC to tell you about  
5 your program.

6 And then as time goes on depending on  
7 the population that you serve you might focus and  
8 look at different subpopulations more, in a more  
9 focused manner.

10 CO-CHAIR SAKALA: Thank you. Nancy?

11 MEMBER LOWE: Yes, my question is --  
12 I'm not an administrative claims person, so if  
13 you could just translate something for me.

14 When you say "who are provided" is it  
15 like the script for a pill? Or is it the woman's  
16 filling of the script for the pill? Which are  
17 two separate issues.

18 DR. GAVIN: So, for the pill we use  
19 the NDC code or a CPT code. So there's -- I'm  
20 not remembering my CPT codes. Brittni, if you  
21 remember offhand.

22 Some of the CPT codes were specific to

1 methods. Some of them were general. And I have  
2 to go back and look at the specs to remember  
3 which ones.

4 If the CPT code was not specific to  
5 the method then we said you had to then have an  
6 NDC code or HCPCS code which says they went and  
7 they filled the prescription because it's all  
8 claims-based.

9 MEMBER LOWE: Okay, thank you.

10 CO-CHAIR SAKALA: So, thank you.

11 Cindy, you're good, is that right? Great.

12 Karen.

13 MEMBER SHEA: Hi, I understand that  
14 oral contraception is going to be over the  
15 counter in California. So that may affect your  
16 measure.

17 I also have another comment about  
18 populations in terms of the Medicaid population,  
19 individuals and subpopulations with intellectual  
20 disabilities, and developmentally delayed, and  
21 long-term services and supports who are  
22 subpopulations of the Medicaid population who may

1 when you pull back the data really affect your  
2 outcome, or sway your outcome in a way that, you  
3 know, if you have a pretty large group within  
4 your denominator that this will affect your  
5 outcome. And the exclusion of those populations.

6 Not to say that they're not sexually  
7 active, but perhaps assumed less so.

8 CO-CHAIR SAKALA: Naomi?

9 MEMBER SCHAPIRO: So, I think that's  
10 a really interesting and important question. And  
11 I think it speaks to something that's really not  
12 discussed in the measure evidence which is that  
13 there's a lot of non-contraceptive benefits to  
14 contraception. And that may affect women's use.

15 So, women who are in a same-sex  
16 relationship might get oral contraceptives for  
17 their menstrual cramps, or many young people and  
18 parents of young people with developmental  
19 disabilities often use a contraceptive method to  
20 control menstruation because of hygiene issues.

21 So I think there's probably no way to  
22 really tease that out. Especially when we get

1 into looking at the next measure about LARC  
2 there's a lot of reasons people don't choose LARC  
3 because of the side effect profile, or because  
4 there was something they were really looking for  
5 like acne control that's in a mixed hormonal  
6 method that's not in a single hormonal method.

7 So, I think these are going to be  
8 imperfect measures, but it would be nice to sort  
9 of acknowledge that I think in the background  
10 literature for it.

11 The other thing I just wanted to say  
12 about same-sex relationships is that I don't have  
13 anything current, but I know in earlier years of  
14 the HIV epidemic when people were looking at HIV  
15 risk there were a lot of women who identified not  
16 just as being in a same-sex relationship, but  
17 identified as lesbians as opposed to bisexual who  
18 occasionally did have opposite sex relationships.  
19 And those tended to be not very well protected.

20 CO-CHAIR SAKALA: Thank you. So, I  
21 think Lorrie has a response and then we will vote  
22 on the reliability criteria.

1 DR. GAVIN: So, I just want to  
2 acknowledge that those are important  
3 considerations.

4 I think in the electronic or hybrid  
5 measure we'll be able to capture some of these  
6 things so we'll have a much better denominator.

7 But I also want to point out that we  
8 are adjusting for sexual activity. And we used  
9 it for the NSFG adjustment for kind of  
10 heterosexual.

11 So, it's an imperfect, and eMeasure,  
12 but we are trying to focus in on the sexually  
13 active population. But, point taken.

14 CO-CHAIR SAKALA: Thank you. Really  
15 interesting comments. Could we open the voting  
16 please for your thoughts and vote on whether the  
17 criteria for reliability are met for this  
18 measure?

19 MS. ROBINSON-ECTOR: Voting is now  
20 open for reliability of measure 2903. And just  
21 make sure to point your clickers directly at me.  
22 And if you vote you'll see your clicker light up.

1 You'll see a red light so that's how you'll know  
2 that your vote was sent towards me. And we're  
3 looking for 25 votes on this.

4 We still have one vote out. Okay, so  
5 all votes are in, thank you.

6 So, for reliability 33 percent voted  
7 high, 58 percent voted moderate, 8 percent voted  
8 low and zero voted insufficient. So, for  
9 reliability of measure 2903 the measure passes.

10 CO-CHAIR SAKALA: Thank you. So let's  
11 move on to validity please. And here we can give  
12 any thoughts about whether the specifications  
13 align with the evidence about the testing that is  
14 reported to date and other validity aspects. Do  
15 our leads want to start the conversation?

16 MEMBER SPALDING: So, validity testing  
17 was done using a panel that performed face  
18 validity assessment.

19 And the panel agreed and I think in  
20 our workgroup we also agreed that this measure  
21 would provide an accurate reflection of quality.

22 We did, of course, have some concerns

1 again about offering versus providing LARC or  
2 these moderate forms of contraception.

3 So, we thought that the validity -- we  
4 didn't have any concerns about validity of this.

5 CO-CHAIR SAKALA: Nancy, I presume  
6 your card is up from the last comment? Yes.  
7 Okay, so Jennifer.

8 MEMBER BAILIT: So, my question is a  
9 little bit about attribution.

10 So, if you are a 19-year-old and you  
11 go to the ENT at hospital A but your primary care  
12 doctor is at hospital B you're in both  
13 denominators.

14 Is hospital A where you get ENT care  
15 also going to get dinged for not providing you  
16 contraceptive care?

17 In other words, do you have to be  
18 seeing certain kinds of providers or in certain  
19 kinds of clinics? Because otherwise you're  
20 dinging the ENT for not giving birth control.

21 DR. GAVIN: So, I'm not sure. I think  
22 it depends on -- again, to me it goes to the use.



1                   What we were able to do is look at  
2 Medicaid systems and the Title 10 program and the  
3 Planned Parenthood program where the assumption  
4 is that most of those clients are receiving care  
5 from the same system.

6                   We didn't go down to the provider as  
7 we discussed earlier. So I'm not sure that you  
8 would use the measure in an ENT practice.

9                   MEMBER BAILIT: Let me try to clarify.  
10 So, people go to different systems for different  
11 things. They may have their primary care in one  
12 system and their specialty care in another.

13                   And so under claims data if she shows  
14 up in the denominator she's a claim in hospital  
15 system A, a claim in hospital system B. She's  
16 going to be in the denominator for both of those  
17 healthcare systems even though she really doesn't  
18 have an appropriate opportunity at one of those  
19 systems to get birth control.

20                   Concurrently, if she got birth control  
21 at hospital B, the primary care place, does the  
22 specialty system get credit for it?

1           So, this patient got birth control.  
2           It wasn't from them, but nevertheless she was  
3           covered.

4           So, can you just talk a little bit  
5           about who gets the carrots and who gets the  
6           dings?

7           DR. GAVIN: So, I guess we haven't  
8           thought about it that way. We thought about it  
9           at kind of a higher level above that.

10          It's like a Medicaid plan would be  
11          looking at their performance overall. And they  
12          might stratify within region or by group.

13          We haven't tested at that level so I  
14          just can't answer that because I think it depends  
15          on how the users of it decide to use it.

16          And if it doesn't make sense then --  
17          if there's no way to do the attribution then it  
18          doesn't seem like you'd use it in that setting.

19          Again, I think if you're looking at  
20          the levels that we tested people felt that was  
21          useful to do the kind of further exploration that  
22          they wanted to do to find out where the variation

1 was.

2 MEMBER BAILIT: Your point's well  
3 taken and I guess my question then reverts back  
4 to NQF.

5 My understanding of the measures here  
6 was that they were meant to compare hospitals or  
7 hospital systems. Or can it be at the health  
8 plan level or the population level?

9 DR. WINKLER: Absolutely. One of the  
10 things that's very critical about the  
11 specifications is looking at the level of  
12 analysis that's intended for the measure.

13 And so yes, we definitely have health  
14 plan measures and you're going to see several  
15 more this morning. So, it could be also at the  
16 individual clinician level depending on the  
17 measure.

18 So that is determined by how the  
19 measure is specified. And that's a critical  
20 aspect when you think about a measure and how  
21 it's going to be used, or how it's being used.

22 So no, it's not restricted to just

1 hospitals. So health plans, populations, medical  
2 groups, clinicians. It really depends on what  
3 the intention of the developer is for that  
4 specific measure.

5 And within our group that you're going  
6 to see over the next two days we have measures at  
7 all of those different levels.

8 MEMBER BAILIT: And so I guess my  
9 proviso would be this makes sense to me at an  
10 insurer level or a plan level, but we need a  
11 proviso that it is not appropriate then because  
12 it is not designed for nor does it capture well  
13 hospital-level or provider-level comparisons.

14 CO-CHAIR SAKALA: In the interest of  
15 time let's have Tracy, Ashley and Jaleel and then  
16 we'll need to vote on validity.

17 MEMBER FLANAGAN: I would agree with  
18 your point that I think it's really at a  
19 population level and a system level.

20 I do think you could get down to a  
21 medical group level. You didn't mention that in  
22 that.

1           For example, I'm thinking about this  
2 right now. We have an increasing number of adult  
3 family medicine folks who are working within our  
4 system.

5           And they're telling me that they're  
6 doing this kind of work whereas we as OB/GYNs  
7 feel that we are doing the work.

8           And so I could imagine in my large  
9 system of 4 million service pop that in fact I  
10 actually take this measure down to certain  
11 subpopulations of teams of doctors.

12           If adult family medicine feels that  
13 they're doing this as well and they are not using  
14 the OB/GYN group to do that what would their rate  
15 look like? Not at an individual provider level,  
16 but at the adult family medicine level. So I  
17 could see that as being very valuable, actually.

18           CO-CHAIR SAKALA: Ashley.

19           MEMBER HIRAI: I just have two  
20 questions. One was to follow up on Karen's point  
21 about California offering over-the-counter. And  
22 I live in Oregon now and they are also providing

1 it at the pharmacist.

2 Do you know -- this was piloted with  
3 Medicaid claims. Do you know if that for women  
4 enrolled in Medicaid, if they would have a claim  
5 at the point of a pharmacist, or how that would  
6 be affected?

7 DR. GAVIN: You're talking about like  
8 in Oregon or California?

9 MEMBER HIRAI: Yes.

10 DR. GAVIN: If they're billing, if  
11 they're getting it over the counter but it's  
12 being billed to Medicaid then yes, it should.

13 MEMBER HIRAI: It would only be if  
14 they happen to pay out of pocket.

15 DR. GAVIN: I mean, I'm not an expert  
16 in Medicaid claims in those two states but in  
17 principle it would. That's how we're getting the  
18 NDC codes. They're going through the pharmacy  
19 and then getting reported back up to Medicaid.

20 MEMBER HIRAI: Okay, great. And then  
21 secondly I brought this up on the workgroup call,  
22 but it does seem kind of inconsistent to I think

1 you're also subtracting women who had a LARC  
2 removal.

3 And that's not the case, you're not  
4 measuring discontinuation for other methods.

5 So, it just seems clearer to have a  
6 more pure provision measure, especially since  
7 you're not also accounting for the fact that  
8 women would have gotten LARCs in a previous  
9 measurement year.

10 DR. GAVIN: Yes, we could definitely  
11 consider that in the next iteration.

12 CO-CHAIR SAKALA: Jaleel.

13 MEMBER MAMBARAMBATH: I had a question  
14 about the face validity. Not being an expert in  
15 statistics or epidemiology it looks like they had  
16 nine experts whose consensus was taken.

17 Is that sufficient enough for  
18 validity?

19 DR. WINKLER: Essentially that's for  
20 you to determine. I mean, it's not like there  
21 are norms that say you have to do X number.

22 And so essentially they've provided

1 what they did, and from your perspective you want  
2 to know does this make sense. Does this make the  
3 case.

4 CO-CHAIR SAKALA: So, thank you, and  
5 that's a good lead-in because we have different  
6 levels that we can vote on. So, could we open  
7 the voting please for validity for 2903?

8 MS. ROBINSON-ECTOR: Voting is now  
9 open for validity of measure 2903. And 1 is  
10 moderate, 2 is low, and 3 is insufficient.

11 Looks like we're missing one vote.  
12 Great, all the votes are in. Seventy-one percent  
13 voted moderate, 25 percent voted low, 4 percent  
14 voted insufficient, so for validity of measure  
15 2903 the measure passes.

16 CO-CHAIR SAKALA: Okay, so we have  
17 three more votes to get through.

18 First of all, feasibility of use of  
19 this measure in the real world.

20 MEMBER SPALDING: So, this measure is  
21 based on administrative claims data from Medicaid  
22 programs. Two state Medicaid programs were



1       piloted here as well as Planned Parenthood  
2       claims.

3                   And so we thought that this was  
4       feasible. It didn't present an undue burden  
5       because collecting this data is routinely  
6       generated and it's not overly burdensome.

7                   MEMBER MCNEIL: So, as is it's very  
8       feasible, but another plug for it changing to  
9       what we're measuring in the future.

10                  CO-CHAIR SAKALA: Thank you. Comments  
11       from the committee on feasibility? Okay, let's  
12       open the voting.

13                  MS. ROBINSON-ECTOR: Voting is now  
14       open for feasibility of measure 2903. 1 is high,  
15       2 is moderate, 3 is low, and 4 is insufficient.

16                  Great, all the votes are in and voting  
17       is now closed. Eighty percent voted high, 20  
18       percent voted moderate, zero voted low and zero  
19       voted insufficient.

20                  So, for feasibility of measure 2903  
21       the measure passes.

22                  CO-CHAIR SAKALA: Thank you. So,

1 usability, please.

2 MEMBER MCNEIL: One of the concerns  
3 about usability is just how consumers and  
4 patients might view this measure.

5 So, in response to Jennifer's point I  
6 think particularly over the past five years  
7 there's been significant examples of coercion in  
8 contraception counseling, in the prison system in  
9 California about forced sterilization, for  
10 example.

11 And I think this sort of measure has  
12 the potential to have public backlash that we  
13 should consider just in terms of how  
14 contraception in particular is kind of rife with  
15 the possibility for patient concerns over  
16 autonomy.

17 I think in so many OB practices that's  
18 true, but contraception in particular.

19 And data recently that has come out  
20 specifically that has demonstrated true provider  
21 changes in contraceptive counseling based on  
22 socioeconomic factors. The patient who is

1 sitting in front of you, an implicit bias of  
2 everything that the provider brings into the  
3 room.

4 It's very clear that we change our  
5 contraceptive counseling based on how we think  
6 that the patients -- what we think is best for  
7 the patients rather than their own autonomous  
8 decisions.

9 CO-CHAIR SAKALA: Thank you. Comments  
10 from the committee on usability and use issues?  
11 Diana.

12 MEMBER RAMOS: Can you just clarify  
13 what your last statement was? It sounds like  
14 we're biased towards our counseling versus being  
15 non-biased and giving all the information.

16 MEMBER MCNEIL: One study in  
17 particular that was done out of UCSF in the past  
18 two years was a randomized controlled trial  
19 looking at how contraceptive counseling is  
20 different for women of different races and found  
21 that particularly for African-American patients  
22 providers are much more biased towards providing

1 LARC methods than to white patients.

2 CO-CHAIR SAKALA: Other comments on  
3 use and usability? Yes, Lorrie.

4 DR. GAVIN: I guess I just have two  
5 comments.

6 I feel like this is an issue, it's  
7 very possible that the public may misinterpret  
8 this. But again, I think it's our responsibility  
9 as users to make sure it's clearly described and  
10 that the intent is clearly articulated.

11 I think as measure users and  
12 developers that's a big priority for us.

13 And the second thing is I don't think  
14 that given the huge room for improvement this is  
15 going to be an issue right now. It could be, but  
16 it's unlikely I think given the room for  
17 improvement.

18 And if they're following CDC, ACOG and  
19 OPA and AAP recommendations. So, this is an  
20 assumption that people are providing care as  
21 defined by CDC, OPA and the professional medical  
22 associations which will not result in coercive

1 because there are standards for how to do client-  
2 centered counseling.

3 The third thing is we do take coercion  
4 very seriously in the whole client experience.

5 And we're just funding a study, we hope in three  
6 years to develop a patient-reported outcome  
7 measure looking at not just coercion, but  
8 coercion as one dimension of the entire client  
9 experience related to contraceptive care.

10 So hopefully again within three years  
11 we'll have a PRO-PM that we can use to kind of --  
12 when that is a particular concern we'll be able  
13 to look at that specifically.

14 CO-CHAIR SAKALA: Kim?

15 CO-CHAIR GREGORY: I was actually  
16 going to say to your point that by collecting the  
17 data you can also look at those rates.

18 And since it would be -- you can  
19 actually look at coupling it with the SDS  
20 variables if that's actually happening.

21 CO-CHAIR SAKALA: Okay, so let's do  
22 Naomi, and Nancy, and then plan to vote on this

1 final criteria.

2 MEMBER SCHAPIRO: Just to kind of  
3 speak to the point about people using  
4 recommendations, I don't think there's any way we  
5 can make an assumption that providers are using  
6 AAP, ACOG and OPA recommendations.

7 You know, just in terms of diffusion  
8 it takes a long time for recommendations to  
9 percolate down.

10 People may have a lot of -- if there's  
11 no health educator in the clinic and the provider  
12 has to do the counseling and the provision that  
13 may be more rushed and may be more coercive. Or  
14 not even coercive, but just perceived as less  
15 warm and friendly and client-centered. So, that  
16 can affect the decision in different ways.

17 So, I just don't think we can make  
18 that assumption. So, I would really applaud in  
19 the future that we have a better measure for  
20 that.

21 CO-CHAIR SAKALA: Nancy.

22 MEMBER LOWE: Yes, I think this is a

1 really, really important point. Because I don't  
2 think we can get away from the fact that it isn't  
3 always coercion. It's about limitation of the  
4 menu.

5 And what I mean by that is the  
6 provider says this is what I think is best for  
7 you, and it's one or two things out of that whole  
8 menu.

9 Rather than really doing comprehensive  
10 contraceptive counseling that exposes the women  
11 to all of her options and allows her to choose.

12 So, we know that from even different  
13 kinds of oral contraceptives it depends upon  
14 which drug rep has the best relationship with the  
15 office which particular oral contraceptive is the  
16 menu of the month, or the day, or the year.

17 And which do we have in the cabinet.  
18 You know. So, it's really interesting, all these  
19 social almost anthropological factors that go  
20 around this whole issue of contraceptive  
21 counseling.

22 So, I don't think any measure is going

1 to solve it, but I do think we need to be very  
2 respectful of the fact that contraceptive  
3 counseling for women is probably one of the most  
4 intimate things that providers do.

5 And there are lots of providers who  
6 are very unskilled at doing that well.  
7 Regardless of what guidelines they follow,  
8 they're very unskilled.

9 CO-CHAIR SAKALA: Thank you. So now  
10 could we open the voting please on whether you  
11 believe this measure meets the NQF criteria for  
12 usability and use.

13 MS. ROBINSON-ECTOR: Voting is now  
14 open for usability and use for measure 2903. 1  
15 is high, 2 is moderate, 3 is low and 4 is  
16 insufficient.

17 Great, so all the votes are in. So,  
18 40 percent voted high, 48 percent voted moderate,  
19 12 percent voted low and zero voted insufficient.  
20 So for usability and use measure 2903 passes.

21 CO-CHAIR SAKALA: Thank you. So,  
22 we've decided that this measure meets all the NQF



1 criteria. And the final vote is overall whether  
2 we wish to recommend endorsement of this measure.

3 Any final words from anyone before we  
4 vote on the overall endorsement? Matt?

5 MEMBER AUSTIN: So, I guess one maybe  
6 opportunity to sort of piggyback on Jennifer's  
7 earlier comment.

8 If there are concerns at doing this at  
9 the facility level is there any way to adjust the  
10 -- I'm trying to get the right term that you guys  
11 use here in the document.

12 CO-CHAIR SAKALA: The level.

13 MEMBER AUSTIN: The level of analysis  
14 to be plans and populations. Is that part of  
15 what we're endorsing is the level of analysis as  
16 well?

17 DR. WINKLER: The level of analysis is  
18 part of the measure specifications, and  
19 absolutely it is part of the endorsement. So  
20 that's all that NQF is endorsing is the use at  
21 the plan population level that has been specified  
22 and tested.

1           MEMBER AUSTIN: Okay. Because it said  
2 facility as well. Okay, just wanted to clarify.

3           CO-CHAIR SAKALA: Naomi?

4           MEMBER SCHAPIRO: Trying to save time  
5 for the next measure too because they're so  
6 similar.

7           But I think the question I have which  
8 relates to some people's concerns about coercion  
9 and individual patient uses.

10           If this measure passes how is it going  
11 to be worded for the clinics?

12           For example, when we get a measure  
13 about immunization rates we think they should be  
14 100 percent, or just as close to 100 percent as  
15 possible.

16           We're not saying that here. We're  
17 saying that we're looking at a bottom level to  
18 make sure that there's access and counseling  
19 about a method. But what is that level exactly?

20           I just have some concerns that if this  
21 passes and a clinic says oh, I better really  
22 provide this method because I'm going to be

1 dinged if I don't, but we're not saying that it  
2 should be 100 percent uptake.

3 So what is the number? Or how is it  
4 phrased?

5 DR. WINKLER: By and large most of the  
6 measures that come through NQF do not have the  
7 extension into specific uses or specific programs  
8 where the measure may be used.

9 Those program implementers tend to put  
10 the parameters around who's being measured and  
11 any benchmarks or any interpretation of the  
12 measure results.

13 Which is why for our maintenance  
14 measures we're particularly interested in what is  
15 going on in that realm because it isn't  
16 necessarily part of the specifications.

17 So, I think your questions are  
18 appropriate, but not answerable until we have  
19 more of a sense of the measure being used going  
20 forward.

21 DR. GAVIN: Just as the steward we  
22 would make sure that the webpage included that

1 information. We would make every effort to make  
2 that a clear part of anyone who's looking at the  
3 measures.

4 We don't have the benchmark. We will  
5 be convening advisory groups and we welcome you  
6 to join us over the time to kind of inform that.

7 It'll never be up for recommendation.  
8 It will just be some evidence findings. But we  
9 would make every effort on our part as a steward.

10 CO-CHAIR SAKALA: Thank you. I think  
11 now I need to stop the conversation because we  
12 have a lot of work to do in a short period of  
13 time on the next measure.

14 So, could we open the voting please  
15 for yes or no whether NQF should endorse this  
16 measure.

17 MS. ROBINSON-ECTOR: So, voting is now  
18 open for measure 2903 for the recommendation for  
19 overall suitability for endorsement.

20 Great, all the measures are in.  
21 Eighty percent voted yes, 20 percent voted no.  
22 So, for the recommendation for endorsement of

1 measure 2903 the measure passes.

2 CO-CHAIR SAKALA: Thank you. Now, I  
3 would like to ask everyone to reflect the fact  
4 that we've considered a lot of issues that relate  
5 to the next two measures that are being  
6 considered.

7 So we're going to move to 2904:  
8 Contraceptive Care - Access to LARC and begin  
9 with our lead.

10 And the leads are a little different  
11 for this measure. It's Mimi and Naomi, and  
12 Carolyn is recused.

13 MEMBER SCHAPIRO: So, this is a new  
14 measure. Do you have anything else to say about  
15 this? No? Okay.

16 So it's a new measure. It's kind of  
17 subsumed in a way under 2903, but there's a  
18 recommendation to kind of call it out on its own  
19 as a measure. And this is about the percentage  
20 of women at risk for unintended pregnancy who are  
21 provided implants/intrauterine devices. So long-  
22 acting reversible methods.

1           And it's an access measure. So, it's  
2           supposed to identify women who don't have access.  
3           So the concern would be if there is zero percent  
4           provision in a particular institution that either  
5           providers are not trained, or people are not  
6           counseling, or there's some reason around access  
7           that people can't get this. So again, we're  
8           looking at low numbers although they're not  
9           specified.

10           CO-CHAIR SAKALA: And specifically can  
11           you comment on the evidence? That will be the  
12           first thing we need to vote on.

13           MEMBER SCHAPIRO: Right.

14           CO-CHAIR SAKALA: Or feel free to say  
15           that it's -- if you feel that these various  
16           criteria are things we have already addressed in  
17           our voting.

18           MEMBER SPALDING: Yes. I actually  
19           think that the evidence was addressed in the  
20           discussion of 2903. So the evidence is the same  
21           here as it was with that one.

22           MEMBER SCHAPIRO: So, one thing I

1 would call out is just in terms of the study of  
2 teens, it was about postpartum teens. And I  
3 understand that in terms of the risk we're really  
4 looking at the risk of teens who are postpartum  
5 having another baby soon.

6 On the other hand that's not the  
7 majority of teenagers. And so most family  
8 planning providers are going to be dealing with  
9 teenagers who haven't had a baby.

10 So, it would be nice to see maybe in  
11 the future some more evidence about the  
12 adolescent population in general because I think  
13 it's being collected.

14 CO-CHAIR SAKALA: Thank you. Does  
15 anyone feel we need to vote on evidence as  
16 opposed to carrying over the previous vote?  
17 Cindy?

18 MEMBER PELLEGRINI: No, but I have a  
19 technical question I just want to make sure I  
20 understand beforehand. It goes back to actually  
21 I think some of the things on the last.

22 Are we -- is providing LARC being

1 defined as both prescribing and actually billing  
2 for implantation or insertion? Is it both of  
3 those things, or is it just one or the other?

4 DR. GAVIN: So, the claims codes,  
5 there are CPT, ICD-9, and NDC and HCPCS codes.

6 So the way we did it is for all of  
7 those. So you didn't have to have like CPT and a  
8 HCPCS code. We said any of those, we included  
9 that as provision.

10 CO-CHAIR SAKALA: Okay, we'll ask our  
11 leads then to comment on opportunity for  
12 improvement.

13 MEMBER SPALDING: This is the same as  
14 the previous one. There are certainly gaps in  
15 terms of unintended pregnancy rates among women  
16 of reproductive age. So, it's similar to the  
17 first one.

18 CO-CHAIR SAKALA: Yes. This is --  
19 LARC is one small piece of the more effective  
20 component of the first measure.

21 So, do you want to comment  
22 specifically on opportunity for LARC improvement?



1                   MEMBER SCHAPIRO: So, I would say in  
2 terms of this is where some of the issues around  
3 reasons why people would choose, you know, partly  
4 related to fear of having something inside your  
5 body, but also side effect profiles and non-  
6 contraceptive benefits would be particularly  
7 important because there are particularly  
8 bothersome side effects for some women around  
9 these methods.

10                   So I think it would be helpful in  
11 terms of the evidence to actually have some  
12 discussion of that in the future.

13                   CO-CHAIR SAKALA: Sarah.

14                   MEMBER MCNEIL: I think in terms of  
15 access a 1 percent cutoff is a great idea.

16                   CO-CHAIR SAKALA: Okay. Should we  
17 vote on this because it's different? Yes, I  
18 think we should vote on this one because it's  
19 such a small portion of the previous one.

20                   Could we open voting please on whether  
21 this LARC-specific measure meets the criteria for  
22 opportunity for improvement?

1 MS. ROBINSON-ECTOR: Okay, so for  
2 opportunity for improvement for measure 2904  
3 voting is now open. And 1 is high, 2 is  
4 moderate, 3 is low and 4 is insufficient.

5 All votes are in. Seventy-two percent  
6 voted high, 28 percent voted moderate, zero voted  
7 low, and zero voted insufficient.

8 So, for performance measure gap for  
9 measure 2904 the measure passes.

10 CO-CHAIR SAKALA: Thank you. So,  
11 next, comments please on reliability including  
12 whether you feel that this needs a new vote or  
13 not compared to the last one.

14 MEMBER SPALDING: I don't think it  
15 needs a new vote on reliability because it's the  
16 same kinds of claims measures being collected.

17 DR. WINKLER: Is there anything about  
18 the specifications of this measure? That's part  
19 of reliability.

20 MEMBER SPALDING: One second, sorry.

21 CO-CHAIR SAKALA: Kim?

22 CO-CHAIR GREGORY: I think sort of a

1 related question. When, and I'm sorry to go back  
2 to the previous measure, but in the previous  
3 measure you're actually measuring counts of the  
4 different methods.

5 So even though it's sort of like a  
6 composite measure you'd actually be able to know  
7 how many got LARC, how many got IUS, how many got  
8 pills, how many got each different kind. Okay?

9 CO-CHAIR SAKALA: So the answer is you  
10 could look at it that way from Lorrie. Tracy?

11 MEMBER FLANAGAN: I'm thinking about  
12 both of these measures from a standpoint of  
13 reliability, validity.

14 I was thinking that the denominator  
15 was visits or encounters. But when I reread it  
16 it's not, it's population.

17 And it's an interesting question of  
18 why you decided population versus encounters.

19 For example, you could imagine that  
20 somebody comes into let's just say a health plan  
21 with an IUD and up to date on their pap test and  
22 not need an encounter for two or three years.

1           Yet they -- you're not going to insert  
2 anything. They would count as a zero on both of  
3 these measures.

4           And so I'd love to hear a little  
5 discussion on the population denominator versus  
6 the encounters, thinking about that as the  
7 denominator.

8           Because I think it relates to  
9 reliability and validity as well.

10          DR. GAVIN: So let me -- I think I  
11 understand where you're going with this.

12          The reason we did the population is  
13 because we were -- if we were thinking about  
14 encounters, just when we tried to look at  
15 providers, I mean which provider do we look at.  
16 And which -- some of these measures, this measure  
17 doesn't attribute. You can't attribute it to  
18 just one encounter or one type of provider even  
19 because it's team-based care.

20          So I think we were looking at it again  
21 at a systems level, or kind of a higher level  
22 measure.

1           And the period of time, the population  
2           served by a system in a period of time seemed to  
3           make the most sense to us at that time because if  
4           you're looking at -- again, I know many people  
5           don't follow guidelines, but the CDC guidelines  
6           are to screen for reproductive life plan or  
7           pregnancy intention.

8           And so if you're doing that on an  
9           annual basis you would be capturing those women  
10          at least once a year. That was kind of how we  
11          were approaching it.

12                  MEMBER FLANAGAN: Let me just sort of  
13          add one question in that.

14                  Let's say that you did it per -- that  
15          you had a qualification for a person who was seen  
16          anywhere in this system. Let's just say a health  
17          plan system or a Medicaid system, anywhere, once.

18                  Because if they're not seen anywhere  
19          is that a barrier? Is that -- should that count  
20          against?

21                  But maybe the actual number, the  
22          percent will take that into account if you accept

1 a low enough number percent. Do you know what  
2 I'm saying?

3 DR. GAVIN: I think so. I mean, we  
4 were using paid claims. So everyone that we saw  
5 was enrolled either in Medicaid, or in Title 10,  
6 or in Planned Parenthood.

7 MEMBER FLANAGAN: But enrolled means  
8 something different than a paid claim.

9 DR. GAVIN: That's right.

10 MEMBER FLANAGAN: It's a system.

11 DR. GAVIN: We did have the enrolled  
12 people, and then we measured the numerator with  
13 the claims, yes.

14 And that was actually -- I mean, we  
15 can definitely consider that for the next  
16 version. But that was at the strong  
17 encouragement of our Medicaid colleagues because  
18 they felt, and we discussed this. I forgot, it  
19 was in the very beginning. They felt very  
20 strongly that -- the state Medicaid staff that  
21 were consulting with us, that there's an  
22 obligation, they felt an obligation to be doing

1 an outreach and providing the needs of clients  
2 that were enrolled.

3 MEMBER FLANAGAN: That there should be  
4 a paid claim.

5 DR. GAVIN: That there should be a  
6 paid claim, that's right.

7 MEMBER SCHAPIRO: Can I just ask one  
8 more question about this?

9 When I see people who are already on  
10 a method like the implant or IUD we bill -- there  
11 is a billing code that says that they're using  
12 the method that's maintenance.

13 So are you including a CPT for that,  
14 or is it just insertion?

15 DR. GAVIN: Yes, the surveillance.  
16 There's a surveillance. So we included those.

17 And not everyone does it. We know  
18 it's imperfect so we spend a lot of time doing  
19 lookbacks. And I will not -- I'll spare you the  
20 details why we did that.

21 We think we need an eMeasure to  
22 capture those aspects. But we did include the

1 surveillance codes.

2 CO-CHAIR SAKALA: So, we're going into  
3 our break time. I'm going to ask Diana, you were  
4 up for awhile and then we need to move on.

5 MEMBER RAMOS: I was just going to  
6 speak in support of a population denominator.  
7 Because in public health in Los Angeles County we  
8 do use that as our denominator.

9 It brings us the opportunity to  
10 develop a gap analysis as to who's receiving the  
11 care and who's not. So, I was just speaking in  
12 support of that population.

13 CO-CHAIR SAKALA: Thank you. Cindy?

14 MEMBER PELLEGRINI: To Tracy's point,  
15 is it possible that in the guidance around the  
16 measure or something that some women who had a  
17 previous method already implanted could be  
18 determined as not at risk for unintended  
19 pregnancy? And therefore would be removed.

20 MEMBER FLANAGAN: What they just said  
21 actually takes it into account in that you  
22 qualify in the numerator if you put -- and for



1 example, we have Epic Systems, presence of IUD,  
2 or maintenance, or -- they're codes that say, oh  
3 yes, I noted that she had an IUD.

4 So, it's six of one, half a dozen of  
5 another.

6 CO-CHAIR SAKALA: Thank you. So, we  
7 didn't hear any cases for needing to have a  
8 separate vote so I think we will carry over the  
9 vote on reliability from the previous measure and  
10 ask comments and the same question about need for  
11 a new vote on validity, please.

12 MEMBER SPALDING: So, the validity  
13 testing done here was similar as to the previous  
14 measure. It was face validity again as  
15 determined by a panel of nine experts.

16 And the panel indicated that this is  
17 strongly valid, or this measure has high  
18 validity.

19 One of the comments in our committee  
20 pre-evaluation was, again, that this measure  
21 provides a good metric for access, not  
22 necessarily quality. We've discussed that.

1 CO-CHAIR SAKALA: Do you think we need  
2 to vote? Anyone take the position that we do  
3 need to vote on this?

4 MEMBER SPALDING: We don't think we  
5 need a vote.

6 CO-CHAIR SAKALA: Okay, thank you.  
7 So, feasibility.

8 MEMBER SPALDING: Feasibility, it's  
9 the same. It's the claims data, Medicaid  
10 program. And so we think this is the same as  
11 well.

12 CO-CHAIR SAKALA: Other comments? Any  
13 objections to accepting the previous vote on this  
14 and previous discussion? Thank you.

15 Okay, last is usability. Same  
16 questions. Anything from the leads?

17 MEMBER SCHAPIRO: Well, I don't think  
18 it's very different, but I think because we're  
19 really pulling out a much more problematic  
20 measure to measure perhaps we should vote.

21 CO-CHAIR SAKALA: Thank you. Kim?

22 CO-CHAIR GREGORY: I wanted to go back

1 to the previous point of why couldn't there have  
2 just been a stipulation on your first measure to  
3 report by type. And then you would have had  
4 this.

5 DR. GAVIN: We could have. I think  
6 the reason we view it very differently is because  
7 of the issues so many people have been talking  
8 about with coercion.

9 We think it's so critically important  
10 that people not be looking for a high benchmark  
11 on this measure.

12 The interpretation is completely  
13 different. You look at the left end of the  
14 distribution. And we were worried if it got  
15 buried under there people would misinterpret no  
16 much how we tried to explain. So it was out of  
17 an abundance of caution because the  
18 interpretation is so different. But it could be  
19 viewed that way.

20 CO-CHAIR GREGORY: It could be  
21 interpreted the other way now too though.  
22 Because you're measuring it I'm supposed to be

1 pushing it. So, it's a catch-22.

2 CO-CHAIR SAKALA: I think we're going  
3 to vote now, please, on the question of usability  
4 and use for the LARC-specific contraceptive  
5 measure. Please open the voting.

6 MS. ROBINSON-ECTOR: Voting is now  
7 open for measure 2904 for usability and use. 1  
8 is high, 2 is moderate, 3 is low, and 4 is  
9 insufficient.

10 All the votes are in. Forty-eight  
11 percent voted high, 44 percent voted moderate, 8  
12 percent voted low and zero voted insufficient.  
13 So for usability and use of measure 2904 the  
14 measure passes.

15 CO-CHAIR SAKALA: Thank you. So,  
16 we've decided that this measure meets all the NQF  
17 criteria. And the final vote is overall whether  
18 we want to recommend that NQF endorse this  
19 measure.

20 And welcome any crucial parting  
21 comments before we vote. Seeing none because I  
22 think this is -- okay. So let's open the voting

1 for whether NQF should endorse this measure.

2 MS. ROBINSON-ECTOR: Voting is now  
3 open for a recommendation for overall suitability  
4 for endorsement for measure 2904. 1 is yes, 2 is  
5 no.

6 All the votes are in and voting is now  
7 closed. Eighty percent voted yes and 20 percent  
8 voted no. So, for recommendation for overall  
9 suitability for endorsement for measure 2904 the  
10 measure passes.

11 CO-CHAIR SAKALA: Thank you very much.  
12 So we are 10 minutes behind. And can we pick up  
13 5 of those, please, by reconvening in 10 minutes.

14 (Whereupon, the above-entitled matter  
15 went off the record at 10:40 a.m. and resumed at  
16 10:51 a.m.)

17 CO-CHAIR SAKALA: Let's start again,  
18 please.

19 CO-CHAIR GREGORY: If everyone could  
20 take their seats we'd like to get started,  
21 please.

22 We've had a new member join us and

1 we'd like her to introduce herself and give us  
2 any conflicts of interest. Sheila?

3 MEMBER OWENS-COLLINS: My name is  
4 Sheila Owens-Collins. I am medical director at  
5 Johns Hopkins University.

6 I'm a neonatologist by training and  
7 I'm happy to be here. And I have no conflict of  
8 interest, no financial conflicts.

9 CO-CHAIR GREGORY: Okay, so we are  
10 going to do the last new measure for this section  
11 which is 2902: Contraceptive Care Postpartum.

12 And our discussants will be Ashley  
13 Hirai and John Keats. And there are no conflicts  
14 of interest.

15 Again, since a lot of this is similar  
16 to what we discussed this morning to the extent  
17 that we can we will carry over votes.

18 I'll ask the discussants to state if  
19 they think we should vote on the specific  
20 sections.

21 MEMBER KEATS: Okay, I'll just go  
22 ahead and get it kicked off.

1                   This was 2902 which was a smaller  
2 number than 2903 or 2904 so on the one hand I was  
3 disappointed at not going first, but relieved at  
4 going last because this is basically kind of a  
5 subset.

6                   I guess one of the exclusions for the  
7 other measures is not having had a baby in the  
8 last couple of months but for the measure period.  
9 And this is specifically then targeting that  
10 subset of the population that is immediately  
11 postpartum.

12                  But I think really all the evidence  
13 and all the other features are pretty similar  
14 unless I missed something. So I'll look to the  
15 measure developers to let me know if there's some  
16 different nuance here to this. Or Ashley, if you  
17 have something to say about it.

18                  MEMBER HIRAI: I think with that point  
19 I think we're still with the 60 days measure.  
20 Probably -- are you still excluding those who had  
21 a birth less than 60 days?

22                  DR. GAVIN: I'm sorry, are we

1 excluding which ones?

2 MEMBER HIRAI: So, there's a 3-day and  
3 a 60-day measure. Or two time periods.

4 DR. GAVIN: So, the first comment was  
5 about who's in the denominator and how this  
6 measure's denominator is different from the  
7 other.

8 This denominator is a subset of the  
9 earlier ones. These postpartum women are in kind  
10 of what we call the global measure sometimes  
11 because that's meant to be a broad sweep of all  
12 women of reproductive age.

13 But you're right in that we did  
14 exclude in both measures women who had given  
15 birth in the first two months.

16 I mean, they had to have been  
17 delivered and had two months -- we excluded. If  
18 they delivered and didn't have two months left in  
19 the measurement year we did not include them.

20 So women who gave birth like in -- we  
21 did January through December. If they gave birth  
22 in February we included them because we had 10



1 months of a postpartum period for those women to  
2 receive contraception.

3 If they gave birth in November we  
4 excluded them because we said they didn't have  
5 enough time.

6 So, that's consistent with both  
7 measures, it's just that this measure focused --  
8 used that same approach because we wanted to make  
9 sure women -- providers had time to reach women  
10 within two months after delivery.

11 So it's that subset, but we applied  
12 that two-month criteria to both measures. Does  
13 that help or further confuse things?

14 We wanted to make sure -- again, we  
15 wanted to make sure that providers had enough  
16 time after delivery to see the woman. And we  
17 were using as our benchmark the ACOG  
18 recommendation of a postpartum visit at six  
19 weeks. And then we added two weeks to that to  
20 kind of respect the fact there may be delays in  
21 care.

22 CO-CHAIR GREGORY: So, I'm asking the

1 discussants, do we think that the evidence that  
2 we've already voted on continues to support the  
3 evidence base for this measure?

4 MEMBER HIRAI: Yes, I think that it's  
5 very consistent. A large body of evidence  
6 demonstrating a relationship between  
7 contraception and reducing unintended pregnancy.  
8 And it's really no different for the postpartum  
9 period.

10 MEMBER KEATS: I agree with that. I  
11 guess what I would want to clarify, I mean, is  
12 this in fact two different measures? Within 3  
13 days and within 60 days? Or is the intent to  
14 roll that up into one result?

15 DR. GAVIN: So, the way we approached  
16 the application is you're viewing three.

17 The first two we pulled out because  
18 they're kind of all women at risk of unintended  
19 pregnancy is our concept. And because we wanted  
20 the abundance of caution we separated the LARC  
21 from most and moderate because the interpretation  
22 is so different.

1           The reason we bundled all this  
2 together is because we wanted to think about this  
3 as a subpopulation. We think all those measures  
4 apply to subpopulations.

5           So, I guess you could -- we are asking  
6 that you approve that bundled set of measures for  
7 the subpopulation.

8           We could have submitted it  
9 differently. This is what made sense to us, kind  
10 of the universal measures and then start looking  
11 at subpopulations.

12           You could imagine like I said earlier  
13 other subpopulations that you might want to  
14 really focus your look at contraceptive use or  
15 provision patterns among.

16           So, like I said earlier, women with a  
17 previous preterm birth, a subpopulation at high  
18 risk for subsequent preterm births. So you would  
19 want to make sure -- that might be another  
20 population we'd want to look at in the future as  
21 another example.

22           MEMBER KEATS: So is the idea that

1 they're going to be reported separately as two  
2 different numbers? Or are they going to be  
3 rolled together?

4 Because if they're going to be rolled  
5 together what's the point of specifying --

6 DR. GAVIN: So, of course we're  
7 assuming everyone -- these are all optional  
8 measures. So it would depend on your healthcare.

9 If you're looking at -- like Medicaid  
10 was very interested in their maternity care. So  
11 they would want to focus on this subpopulation in  
12 one state, for example.

13 If you're interested in the broader  
14 population, this is a subset of that broader. So  
15 it depends on what you want to look at.

16 If you want to zero in on the women  
17 who are providing 60 to 65 percent of your births  
18 every year then you'd look at that postpartum  
19 population.

20 If you are also interested in the  
21 broader population of women who are coming into  
22 primary care and not getting pregnant then you

1 could use that.

2 But yes, this is a sub-measure in  
3 terms of populations to the ones we just finished  
4 discussing.

5 MEMBER SHEA: So, this measure is  
6 within the time period of 3 days and 60 days, not  
7 immediate postpartum up to 3 days? If it doesn't  
8 include immediate postpartum I'm wondering why  
9 you didn't include that population.

10 DR. GAVIN: I'm sorry, I misunderstood  
11 your question. Yes, those are two measures.

12 We're looking at percent -- given the  
13 population what percent of them received it in  
14 that 3-day period. And we're considering that  
15 immediate postpartum.

16 And then also what percent received it  
17 within 60 days. As two kind of separate  
18 reportable measures.

19 DR. WINKLER: Just a question to  
20 clarify. Would you consider this a  
21 stratification of the one measure into two  
22 different time frames?

1 DR. GAVIN: Yes, although I think you  
2 asked that question on the call. We didn't put  
3 it in the stratification section. We proposed it  
4 as actual specifying the measure.

5 But conceptually, yes, that's exactly  
6 what it is.

7 MEMBER PELLEGRINI: This answer may be  
8 obvious to the providers in the room, but I'm  
9 just curious why the pregnancies that didn't end  
10 in a live birth were excluded.

11 DR. GAVIN: Because it's -- this is  
12 trying to capture that population that are  
13 receiving the postpartum care. That's where the  
14 visit is. So we were kind of focusing it on live  
15 births because that's a specific population, a  
16 specific group of providers. It just kind of  
17 made sense to us.

18 MEMBER PELLEGRINI: Is it partly like  
19 a feasibility of being able to measure that?

20 I mean, I assume that a lot of those  
21 women whose pregnancies don't end in live birth  
22 still need contraception. But they aren't going

1 to get a postpartum visit per se.

2 DR. GAVIN: Right. And those women  
3 would be captured in the measure we discussed  
4 earlier.

5 MEMBER OWENS-COLLINS: You may have  
6 already talked about this, but I was wondering if  
7 there's a way to harmonize this measure with the  
8 HEDIS measure of postpartum visits to widen that  
9 time frame. Because that's one of the measures  
10 that's hard to get, the timely prenatal care and  
11 postpartum visit.

12 DR. GAVIN: So, we could consider that  
13 for the next iteration.

14 The reason we didn't is because we  
15 wanted it harmonized with the measures we just  
16 discussed. But we could definitely revisit that  
17 for the next iteration because there's an  
18 inherent logic to that also.

19 MEMBER OWENS-COLLINS: Thank you.

20 CO-CHAIR GREGORY: Is there any  
21 objection to accepting the evidence that we've  
22 already accepted? Okay.

1           Then I'm going to ask the discussants  
2           to talk about the opportunities for improvement.

3           MEMBER KEATS: Well, there's certainly  
4           a lot of opportunity for improvement just like  
5           has been discussed with the others.

6           I mean, this whole concept of  
7           immediate postpartum long-acting reversible  
8           contraception is relatively new.

9           You know, back when I trained in the  
10          Dark Ages the evidence was read as specifically  
11          contraindicating things like inserting IUDs right  
12          after delivery. But the evidence has matured  
13          over time and now it's felt that that's an  
14          appropriate approach.

15          So, I really wonder how many  
16          practicing OB/GYN physicians are even thinking  
17          about offering immediate postpartum long-acting  
18          contraception. So this probably would serve some  
19          significant educational purpose if nothing else.

20          CO-CHAIR GREGORY: Any other comments?

21          MEMBER HIRAI: I think this kind of  
22          also speaks to the validity of the measure as



1 well.

2 But with this postpartum period we  
3 know that women really aren't planning to have  
4 another birth that soon after delivering. And  
5 it's not recommended for 18 months.

6 And so that performance gap is  
7 actually larger I would think for this  
8 population. And so if anything I think this is  
9 even a stronger measure than the previous ones  
10 we've discussed.

11 CO-CHAIR GREGORY: I think we can let  
12 that be reflected in the minutes that we don't  
13 need to vote on it.

14 DR. WINKLER: I think we should. It's  
15 different data and I think in that respect it  
16 would be good just to be sure that we're clear.

17 CO-CHAIR GREGORY: Okay, we'll be open  
18 for votes then if there are no further comments.  
19 Anyone else have any comments? Yes, Sarah.

20 MEMBER MCNEIL: I still think that the  
21 fact that if we all said that birth spacing  
22 should happen at at least 18 months and that has

1 better maternal and baby outcomes, if a patient  
2 still wants to have a baby, or still wants to get  
3 pregnant a month out that should still be a  
4 reasonable option.

5 So, a 100 percent LARC uptake even in  
6 the postpartum period shouldn't be the  
7 appropriate measure.

8 So, we still, even while it might be  
9 -- there might be stronger evidence, it doesn't  
10 necessarily mean that the quality that we're  
11 measuring should be a higher or an extremely high  
12 LARC -- that there should be a target.

13 MEMBER HIRAI: Well, this isn't just  
14 LARC. It's moderate to most effective. So I  
15 would agree if women are planning another  
16 pregnancy they may not want to jump on a LARC.

17 But it does seem to have more room for  
18 improvement, and less issues with the denominator  
19 of at risk of unintended pregnancy than the  
20 previous measures.

21 CO-CHAIR GREGORY: Tracy?

22 MEMBER FLANAGAN: Just another comment

1 in the same vein as the last comment.

2 Working in an integrated system we  
3 have 92 percent of our patients come back for  
4 postpartum visits.

5 And so putting an IUD in when 25  
6 percent of the time it expels is not a cost-  
7 effective thing to do. So we elect to do it at  
8 the postpartum visit.

9 So, one could imagine that if you had  
10 both of these measures that you might look, for  
11 example, not so great on the within three days,  
12 but much better at the six weeks.

13 So again, there needs to be  
14 explanation and some nuance here.

15 But overall I think that a health plan  
16 or a large system would look -- if they were  
17 doing due diligence either at the immediate or  
18 the long-term postpartum that there should be  
19 success or high rates eventually.

20 CO-CHAIR GREGORY: Any additional  
21 comments? Okay, then I think we'll be open for  
22 voting.

1 MS. ROBINSON-ECTOR: Voting is now  
2 open for performance gap for measure 2902. 1 is  
3 high, 2 is moderate, 3 is low and 4 is  
4 insufficient.

5 All the votes are in and voting is now  
6 closed. Seventy-eight percent voted high, 22  
7 percent voted moderate, zero voted low and zero  
8 voted insufficient.

9 So for performance gap of measure 2902  
10 the measure passes.

11 CO-CHAIR GREGORY: So, we're going to  
12 move on to the discussion about reliability and  
13 address measure specifications and reliability  
14 testing.

15 MEMBER HIRAI: I don't think there was  
16 much of a difference in terms of reliability for  
17 this measure compared to the previous ones. They  
18 all had high levels of the signal-to-noise test  
19 and the intraclass correlation coefficient.

20 CO-CHAIR GREGORY: So we'll let the  
21 previous vote stand and move to validity.  
22 Comments from our discussants?

1           MEMBER KEATS: Again, very similar.  
2           It's really identical I think to the previous  
3           discussion. I don't think there's anything I'd  
4           care to add.

5           MEMBER HIRAI: I think there was one  
6           difference with the face validity with the expert  
7           consultation, that there was an expert who was  
8           very concerned about the breastfeeding issue, I  
9           guess particularly related to hormonal methods.

10          CO-CHAIR GREGORY: Cindy?

11          MEMBER PELLEGRINI: I wonder if I'm  
12          asking this at the wrong point here, but I just  
13          had a question that under some of the reliability  
14          and validity there were numbers listed, numbers  
15          of cases recommended to have to maintain  
16          reliability.

17                 And I was wondering how those compared  
18          to other measures or other measures at least in  
19          this set. Because some of them did look kind of  
20          high. It was two, three, four thousand cases.  
21          And I wondered if there were going to be a lot of  
22          potential users of the measure that might not

1 make that threshold. I mean, plans would, but  
2 clinics or practices.

3 DR. HASTINGS: Can you say your  
4 question one more time so I understand it  
5 clearly?

6 MEMBER PELLEGRINI: Sure. And I'm on  
7 page 5, at the top of page 5 of the PDF of the  
8 measure worksheet.

9 And it was just saying for the  
10 measures there were listed numbers of cases that  
11 are recommended to have to maintain different  
12 levels of reliability.

13 And for the highest degree of  
14 reliability it was requiring some pretty high  
15 numbers of cases, over 3,000, over 2,000, over  
16 4,000.

17 So I was wondering is that going to  
18 limit the usability of this measure because a  
19 certain percentage of practices aren't going to  
20 be able to make that threshold.

21 DR. HASTINGS: In our reliability  
22 testing for all of the measures we did an

1 assessment of what's kind of the minimum  
2 threshold we would expect.

3 And for these measures in particular  
4 they were fairly high numbers required to achieve  
5 a high reliability of 0.9 or moderate level for a  
6 0.7 reliability which is acceptable or widely  
7 acceptable level of reliability.

8 We do recommend that for any user of  
9 the measure actually assess their own ICCs to  
10 determine what's the appropriate number of cases  
11 for their environment.

12 But for these data we found that we  
13 needed at least in the hundreds, generally close  
14 to 1,000 cases for adequate reliability.

15 And so, yes, when you push down to  
16 something like a hospital or health center you  
17 have to sort of be careful, or make sure that  
18 your measure is still appropriate in that  
19 population.

20 MEMBER PELLEGRINI: Thank you.

21 MEMBER GOYERT: Just to be consistent  
22 for 2902, 2903, 2904 the same argument applies in

1 terms of providers being on the hook for their  
2 patients' decision-making regardless of in any  
3 particular clinic the process, the counseling.

4 And so when you look under the  
5 validity the specific question is do you agree  
6 that the score from this measure as specified is  
7 an indicator of quality. I don't.

8 But by hearing it is working, and I  
9 understand that the level of analysis is at the  
10 population level, for the healthcare plan,  
11 whatever.

12 Okay, you can say that, but then what  
13 are you going to do about it? Where does the  
14 buck stop? Where does the accountability factor  
15 come in at any level if the results are -- then  
16 you have to say what's a good result, what's a  
17 bad result.

18 So it's about that attribution. It's  
19 about accountability and what you do with those  
20 results. Thank you.

21 MEMBER AUSTIN: Yes, thanks. I just  
22 wanted to offer a clarification for my fellow



1 committee members.

2 At least when I look at the  
3 documentation for this measure it looks like the  
4 level of analysis is the health plan and regional  
5 population. It doesn't list the facility which  
6 is different than 2903 and 2904 which we reviewed  
7 earlier.

8 Which perhaps raises issues around  
9 reliability and validity, and whether or not we  
10 feel like there might be a need to revote on  
11 those given that those are different populations.

12 DR. HASTINGS: I did hear your  
13 question on the prior measures about the health  
14 center for the Planned Parenthood data. We did  
15 analyze reliability down to the health center  
16 level.

17 For the state Medicaid data we did not  
18 go down to the health centers. We stayed at the  
19 plan or the region level.

20 However, even at the health center  
21 level the reliability for the prior measures was  
22 very high for -- we analyzed groups of

1 affiliates.

2 And so within each affiliate of  
3 Planned Parenthood there were a number of health  
4 centers. There may have been 8 to 10 health  
5 centers.

6 But even in the smallest health  
7 centers we had fairly high reliability.

8 We recommended though that the health  
9 centers see at least 450 patients per year for a  
10 very high reliability of 0.9 or above. And I  
11 think it was 125 patients per year for the 0.7  
12 level.

13 So it did -- on the prior measures we  
14 did see adequate evidence that reliability was  
15 high even for smaller areas.

16 MEMBER AUSTIN: If I can just quickly  
17 follow up on that. So why was the decision made  
18 not to use a facility-level as the level of  
19 analysis on this measure?

20 DR. GAVIN: We didn't do that because  
21 we didn't have access to the data, basically. We  
22 couldn't -- the Medicaid data we had we did not

1 feel like we could get down to the facility level  
2 with the codes that we had from the states that  
3 we had.

4 So, we were able to do that with the  
5 Planned Parenthood data, but Planned Parenthood  
6 doesn't see a lot of postpartum women so we  
7 didn't use that data to test this measure.

8 CO-CHAIR GREGORY: Greg, is that still  
9 up from before or you have another comment?

10 So, should we vote on this one? Does  
11 the group want to vote on this? I'll take that  
12 as a no. All right.

13 So then we should be on feasibility.

14 MEMBER HIRAI: I don't think there was  
15 any difference between this and the previous  
16 measures in terms of feasibility. Same data  
17 sources.

18 MEMBER KEATS: It's all the same,  
19 claims-based.

20 CO-CHAIR GREGORY: Are there any  
21 comments from the table? Okay, then we'll let  
22 that stand, the vote from before.

1                   And then we'll move to usability and  
2 use.

3                   MEMBER KEATS: Again, I think it's the  
4 same. In fact, for the reasons I stated maybe  
5 even more useful than the other measures.

6                   CO-CHAIR GREGORY: Okay. Then perhaps  
7 we should vote on this for the same reason?

8                   Okay, so we're open for voting.

9                   MS. ROBINSON-ECTOR: Voting is now  
10 open for usability and use for measure 2902. 1  
11 is high, 2 is moderate, 3 is low, and 4 is  
12 insufficient.

13                   All the votes are in and voting is now  
14 closed. Fifty-six percent voted high, 44 percent  
15 voted moderate, zero voted low, and zero voted  
16 insufficient.

17                   So for usability and use for measure  
18 2902 the measure passes.

19                   CO-CHAIR GREGORY: So now we'll vote  
20 on the recommendation for this as a measure for  
21 endorsement.

22                   MS. ROBINSON-ECTOR: Voting is now

1 open for recommendation for endorsement for  
2 measure 2902. 1 is yes and 2 is no.

3 All the votes are in and voting is now  
4 closed. Eighty-nine percent voted yes and 11  
5 percent voted no.

6 So for recommendation for overall  
7 suitability endorsement for measure 2902 the  
8 measure passes.

9 CO-CHAIR GREGORY: Okay, now we're  
10 going to talk about something different. And  
11 we'll also -- it's a slightly different process  
12 because this is a maintenance measure.

13 We're going to talk about measure  
14 0030: Chlamydia Screening in Women.

15 DR. WINKLER: Actually, it's 0033. We  
16 goofed on the agenda. The other documents are  
17 correct.

18 CO-CHAIR GREGORY: And our measure  
19 developers are the National Committee for Quality  
20 Assurance and they're going to give us a brief  
21 overview.

22 DR. BARTON: Hi, I'm Mary Barton from

1 the National Committee for Quality Assurance.

2 And my colleague Sepheen Byron is going to  
3 present 0033: Chlamydia Screening in Women.

4 MS. BYRON: Great. Hi. So, chlamydia  
5 screening in women, it's a longstanding HEDIS  
6 measure. So it's part of the HEDIS health plan  
7 measure set.

8 It's used in a wealth of programs.  
9 It's used within NCQA for health plan  
10 accreditation and it's also used in external  
11 programs including the Medicaid Child Core Sets  
12 for voluntary state reporting, and several other  
13 places, I think PQRS as well. It's all listed in  
14 the measure forms.

15 This looks at chlamydia screening in  
16 women 16 to 24 years of age. It aligns to a U.S.  
17 Preventative Services Task Force recommendation  
18 that has been around for awhile and that was  
19 recently updated in 2014. And so it continues to  
20 align with that evidence.

21 And it's a measure for which we still  
22 see some need for improvement. And we've heard

1 that it is very important to both commercial and  
2 Medicaid plans.

3 CO-CHAIR GREGORY: Are there any  
4 questions for the developers? Okay, then we'll  
5 move to our discussants, Ashley and Sarah. And  
6 there are no conflicts.

7 MEMBER MCNEIL: Can I just start with  
8 the evidence?

9 CO-CHAIR GREGORY: Sure, please.

10 MEMBER MCNEIL: So, the evidence is  
11 based on one randomized controlled trial that was  
12 large but did show mixed results and came up with  
13 good evidence for screening for patients at  
14 increased risk.

15 So, the evidence is for patients at  
16 increased risk, but the measure as I understand  
17 it is not for patients at increased risk.

18 MS. BYRON: Can I respond to that?  
19 So, the measure does focus on sexually active  
20 women. And I probably should have mentioned that  
21 in the description.

22 The U.S. Preventative Services Task

1 Force recommendation is for sexually active women  
2 24 or younger. And so the measure does align  
3 with that.

4 So sexually active I think is what  
5 captures the increased risk part of this. The  
6 Task Force did not make further recommendations  
7 around additional risk factors aside from  
8 sexually active.

9 CO-CHAIR GREGORY: So, are there --  
10 I'm sorry, go ahead.

11 MEMBER HIRAI: I think that the  
12 evidence -- there are many more RCTs. It was  
13 just updated to include one additional.

14 And it seemed a little bit suspect to  
15 me because the new study was really underpowered.  
16 It had a very high effect size, but because of  
17 the sample size it wasn't statistically  
18 significant.

19 And I think that the Task Force, it  
20 seemed like they initially had recommended the  
21 grade A, but after public comment downgraded it  
22 to a B.



1           So, I don't know if there's more  
2 history or detail about that, but I think there  
3 is strong evidence that screening can produce --  
4 and treatment can reduce chlamydia and sequelae.

5           CO-CHAIR GREGORY: So, since this is  
6 a maintenance measure and there's additional  
7 evidence that supports the prior evidence are  
8 there -- would anyone object to us just voting?  
9 Or not voting? Okay, accepting the evidence?

10           Okay, so we will accept the evidence  
11 and move on to gaps.

12           MEMBER MCNEIL: There are clear  
13 performance gaps in chlamydia testing. Only 38  
14 percent of the visits in one cohort in 2014 had  
15 appropriate testing. So, it seems pretty clear  
16 to me.

17           CO-CHAIR GREGORY: There was a gap  
18 before and there's still a gap. So we can  
19 probably accept this. No? Okay, we'll vote on  
20 this one. Everyone get their clickers ready.

21           DR. WINKLER: Just to explain. I  
22 mean, the performance gap and what current

1 performance is does change over time. So what  
2 happened before may not apply today. And that's  
3 why we want to be sure that your current  
4 assessment of the opportunity for improvement is  
5 based on the most recent data. So that's why  
6 it's important to focus in and get your input and  
7 vote on this one.

8 CO-CHAIR GREGORY: Jennifer.

9 MEMBER BAILIT: I'm not sure I'm in  
10 the right section, but let me just raise this.  
11 And I understand this is a maintenance measure  
12 and we don't necessarily need to recreate the  
13 wheel.

14 Why is this restricted to women? In  
15 other words, screening half the population seems  
16 to me to be a lot less effective than screening  
17 the whole population of sexually active 16- to  
18 24-year-olds.

19 MS. BYRON: Yes, this measure is  
20 really -- it's because we've aligned it to the  
21 Task Force recommendation which focuses only on  
22 women.

1           We did talk about that in our measure  
2 development meetings and you know, I think there  
3 can be a strong argument made to screen for  
4 males.

5           However, because the measure can be  
6 used for accountability we felt it was most  
7 important to stick to the U.S. Preventative  
8 Services Task Force guideline.

9           And so while we do hope males are  
10 being screened, the measure itself, it doesn't  
11 say don't screen males, but it does require  
12 screening for females.

13           CO-CHAIR GREGORY: Carolyn.

14           MEMBER WESTHOFF: Just to speak  
15 further to that. At the time the Task Force  
16 evaluated this before this measure was originally  
17 approved the evidence for a direct health benefit  
18 was limited to women.

19           And to my knowledge there's no  
20 evidence of a direct health benefit to men of  
21 screening men. And so that gets into some  
22 philosophical problems about screening that's

1 probably beyond our scope here.

2 CO-CHAIR GREGORY: Naomi.

3 MEMBER SCHAPIRO: So, just to further  
4 that point, one of the consequences of it only  
5 being limited to screening women is that in some  
6 counties you can't get paid for -- you can't get  
7 reimbursed for screening men. So in our county  
8 that's not true, but in many counties you cannot  
9 get paid because of the recommendations.

10 And so I would say -- I mean, there's  
11 some direct benefit to men, but primarily for men  
12 who have sex with women there's huge benefit to  
13 women if men act and come in to catching them.

14 And we often find, you know, in a  
15 school-based health center which is more limited  
16 that there are like pockets of kind of  
17 overlapping sexual partners where it could be  
18 incredibly helpful from a public health point of  
19 view to be screening the men.

20 So, that's just one of those  
21 unintended consequences I think of not including  
22 men in the measure is that people who want to do

1 it often can't get paid for it even if there's a  
2 good reason from the risk behavior.

3 CO-CHAIR GREGORY: Are there any  
4 additional comments from the committee? Yes.

5 MEMBER SRINIVAS: I guess one question  
6 that I have is that in the document it talks  
7 about how there's literature that we know of that  
8 demonstrates disparities in the disease and then  
9 screening, that you guys don't actually collect  
10 that information.

11 And as a maintenance measure it seems  
12 like one of our requirements is kind of to look  
13 at how effective it's been over time, and look at  
14 the data more longitudinally. And it doesn't  
15 seem like there's been much of a change when I  
16 look at the numbers. And maybe I'm interpreting  
17 them wrong.

18 But is there also sort of a move  
19 towards being able to collect that information to  
20 be able to really get more at the disparities  
21 issue?

22 DR. BARTON: I think -- we are very

1 interested in having data that would help propel  
2 the improvement and elimination of disparities.

3 And I think the release by CMS of  
4 Medicare Advantage data by race and ethnicity  
5 last week is a huge step forward and one that we  
6 are closely tracking so that we could figure out  
7 how we might be able to leverage that release  
8 into more and more opportunities for displaying  
9 data in stratified ways, or in ways that will  
10 help really push improvement.

11 But what we are presenting now as a  
12 maintenance measure is the measure as it has  
13 existed. And we're -- but I guess keep your eyes  
14 on this space.

15 MS. BYRON: And the other thing I'll  
16 just add to that is that we do hear from health  
17 plans because they have the data for race and  
18 ethnicity.

19 They are able to look at the measure  
20 as it's specified and just cut the data according  
21 to race/ethnicity or any other variable that  
22 they're interested in.

1           And then they can develop their  
2           quality improvement strategies around their  
3           results.

4           So we do see this measure used by  
5           plans in that way. So it's a good point.

6           MEMBER MOORE: I just want to clarify.  
7           I'm looking at the U.S. Preventative Services  
8           Task Force recommendation, and they do  
9           acknowledge the importance of men in this  
10          population but recognize the limitation of data.

11          They do cite extensively the CDC  
12          recommendations in screening and treating men.  
13          And they're also recommending expanding to look  
14          at subpopulations with LGBTQ community with men  
15          who have sex with men.

16          But based on -- I suspect that this is  
17          AHRQ data -- looking at the prevalence it's more  
18          prevalent in women over men, and also more costly  
19          for women than men. So that probably contributed  
20          to some of their analyses and recommendations.  
21          But I just wanted to clarify that.

22          MEMBER PELLEGRINI: So, there has been

1 a pretty respectable increase in the number of  
2 plans using this measure over time.

3 I was wondering if you have any sense  
4 whether the plans that have been using the  
5 measure longer are performing better and maybe  
6 the ones that have come in more recently are  
7 coming in at lower levels, and that's kind of  
8 keeping the mean from moving very much?

9 MS. BYRON: It's a good question and  
10 it's quite possible. We have not done that  
11 analysis today and I don't have those results in  
12 my head or anything like that, but it's a  
13 reasonable hypothesis.

14 We have looked at other measures and  
15 found that to be the case. And so yes, in some  
16 cases the mean can be a little deceiving and so  
17 we tend to also look at the ranges and the  
18 percentiles, and also a geographic distribution  
19 when we look at measures to see if there has been  
20 movement, or if there remains an opportunity for  
21 improvement.

22 And all of those signs seem to



1 indicate that there are opportunities for  
2 improvement.

3 CO-CHAIR GREGORY: And the last  
4 comment, Tracy.

5 MEMBER FLANAGAN: So, being in a  
6 system that's been working on this for awhile in  
7 an active capacity I will tell you that we had to  
8 create sub-reports for performance improvement  
9 that looked at where our missed opportunities  
10 were.

11 And what's interesting is our biggest  
12 missed opportunity is where somebody has a  
13 chlamydia test in the beginning of their  
14 pregnancy and then the missed opportunity is at  
15 the postpartum visit because they screen negative  
16 and it spans two calendar years. So that's our  
17 biggest opportunity for improvement.

18 Where we struggle, and this is not a  
19 criticism of the measure, but we find that our  
20 systems of care, if this could be split between  
21 up to 18 and beyond 18 it would really help us,  
22 if the original measure was split or there were

1 two subpopulations in it.

2 Because right now we have to create  
3 our own data to figure out who's the accountable  
4 entity. Because we have pediatrics for the most  
5 part with adult family medicine and OB/GYN with  
6 adult family medicine. And it really makes for a  
7 difficult stratification.

8 CO-CHAIR GREGORY: So, I see no  
9 further comments. We're going to open this up  
10 for vote to vote on the opportunities for  
11 improvement.

12 MS. ROBINSON-ECTOR: Voting is now  
13 open for performance gap for measure 0033. 1 is  
14 high, 2 is moderate, 3 is low, and 4 is  
15 insufficient.

16 All the votes are in and voting is now  
17 closed. Seventy-eight percent voted high, 22  
18 percent voted moderate, zero voted low, and zero  
19 voted insufficient.

20 So for performance gap for measure  
21 0033 the measure passes.

22 CO-CHAIR GREGORY: So we'll move to

1 comments related to reliability.

2 MEMBER HIRAI: I think the  
3 specification codes were updated to accommodate  
4 ICD-10 and other changes. And there were no  
5 updates for the reliability testing. So I'm not  
6 sure that I think we can skip the voting on this.

7 CO-CHAIR GREGORY: Juliet.

8 MEMBER NEVINS: Just a quick question  
9 with respect to the specifications.

10 It states a patient only needs to be  
11 identified in one method to be eligible for the  
12 measure, and the methods identified is either a  
13 claim or encounter, a pharmacy claim or encounter  
14 -- excuse me, a pharmacy, claim, or encounter  
15 indicating sexual activity.

16 So I was just curious as to how do you  
17 account for females between 16 and 24 who are  
18 using some type of contraception for a non-  
19 contraceptive benefit.

20 MS. BYRON: So, this would be an  
21 example of using oral birth control for non-birth  
22 control methods.

1           That has come up. The algorithm was  
2 tested originally to see if it's a reasonable  
3 proxy for sexual activity and did include oral  
4 contraceptives.

5           And during field testing the false  
6 negative rate was quite low. It was about 2 to 3  
7 percent across most of the plans, and up to 11  
8 percent I think for one of them.

9           The issue is you often have I think  
10 teenagers in that age group who say that they're  
11 using oral contraceptives for non-contraceptive  
12 reasons, but because of confidentiality and  
13 privacy issues they may be actually sexually  
14 active.

15           And so I think during testing we found  
16 that the algorithm was a reasonable proxy and  
17 that the false negative rates were quite low.

18           And so we feel confident that this  
19 administrative method for determining sexually  
20 active adolescents, while not perfect, is a good  
21 way to approximate the denominator and look for  
22 chlamydia screening.

1           MEMBER NEVINS: Okay. Well, I'll just  
2 add a comment that with the emergency of the  
3 transgender population this is usually their  
4 first method of controlling the menstrual cycle  
5 or trying to eliminate it.

6           And as that -- and I don't know how  
7 significant that cohort would be in terms of how  
8 it would impact the data. It may not be, right?  
9 But I just wanted to sort of throw that out there  
10 as something that we should kind of keep in mind.

11          MS. BYRON: Yes, that's a good point.  
12 I think we would believe that to be quite small.

13          And also, you know, probably similar  
14 across health plans. But it is a very good  
15 point.

16          CO-CHAIR GREGORY: Sindhu, did you  
17 want to have a comment?

18          So, if I heard you correctly the main  
19 change in the specifications was just the  
20 addition of the ICD-10. So, unless anyone  
21 objects I'm going to offer that we accept what's  
22 been previously accepted for this maintenance

1 measure and then move to the discussion on  
2 validity. And Matt has a comment.

3 MEMBER AUSTIN: So, have you had the  
4 opportunity to test it with the ICD-10 codes? It  
5 sounds like you've updated to them, but I was  
6 wondering if the testing --

7 MS. BYRON: Right. We have actually  
8 updated ICD-10 across all of the HEDIS measures.  
9 So we have not specifically tested it, but we did  
10 in doing so worked extensively with an external  
11 panel of coding experts to convert our HEDIS  
12 measures up to ICD-10.

13 And so we have done that sort of face  
14 validity testing, but not formally tested it.

15 MEMBER AUSTIN: Thanks.

16 CO-CHAIR GREGORY: Discussants'  
17 comment on validity. Is there any new data  
18 presented?

19 MEMBER HIRAI: I don't think there is  
20 an update. And it passed previously with the  
21 face validity test so the highest is moderate.

22 CO-CHAIR GREGORY: So, are there any

1 comments from the panel? Unless there are any  
2 objections I'm going to offer that we accept the  
3 validity as it was previously done.

4 Okay, then I am now moving to  
5 feasibility. Discussants?

6 MEMBER HIRAI: Administrative claims.  
7 It's feasible and considered to be low burden and  
8 there's no change there.

9 MEMBER MOORE: Ashley, can you speak  
10 into your microphone? I'm having a hard time  
11 hearing you. Thank you.

12 MEMBER HIRAI: It's based on claims  
13 data and that's considered to be feasible and low  
14 burden, and there's no change to that. So I  
15 don't think we need to revote on that.

16 CO-CHAIR GREGORY: Okay, are there any  
17 comments from the table?

18 All right, this one we're going to  
19 vote on. So, let's get our clickers ready.

20 DR. WINKLER: One of the issues around  
21 feasibility is now that the measure has been  
22 around for awhile and out in use is what are we

1 learning about how the measure is functioning.

2 So that's why feasibility continues to be a  
3 pertinent criterion for evaluation.

4 MEMBER MCNEIL: Isn't that more under  
5 usability and use than feasibility?

6 DR. WINKLER: It's both. Feasibility  
7 might be more around, you know, some aspects of  
8 data collection that may be unique to this  
9 measure that may have come up. Maybe issues  
10 around particular use of coding.

11 You're right, there's a lot of  
12 overlap.

13 MS. ROBINSON-ECTOR: So, voting is now  
14 open for feasibility for measure 0033. 1 is  
15 high, 2 is moderate, 3 is low, and 4 is  
16 insufficient.

17 All the votes are in and voting is now  
18 closed. Seventy-eight percent voted high, 19  
19 percent voted moderate, 4 percent voted low and  
20 zero voted insufficient.

21 So for feasibility of measure 0033 the  
22 measure passes.



1 CO-CHAIR GREGORY: And now we'll talk  
2 about usability and use.

3 MEMBER MCNEIL: So, I think Ashley's  
4 point is well taken that in terms of thinking  
5 about how this has been able to be implemented is  
6 concerning given the low rates of screening that  
7 we've had in the past.

8 But in terms of -- yes.

9 MEMBER HIRAI: Yes, I guess there's  
10 only been modest improvement over time.

11 And so one question I raised on the  
12 workgroup call was for those that have extra  
13 incentives like pay-for-performance which is in  
14 California have they seen greater improvements.  
15 Can the measure developers speak to that?

16 MS. BYRON: I don't have those data.  
17 It would be something we could look into.

18 But I will say that at the last  
19 measure re-evaluation we did look to see those  
20 sorts of things.

21 This measure over the past several  
22 years has been added to additional programs such

1 as the Medicaid Child Core Set. And so we would  
2 expect to see some movement among plans who are  
3 being required to report this.

4 CO-CHAIR GREGORY: Yes.

5 MEMBER SHEA: So, my concern is as we  
6 adopt the new standards around cervical cancer  
7 screening which are more on the every three years  
8 and every five years standpoint that this  
9 particular measure will suffer from those new  
10 standards.

11 And I hesitate to ask this question,  
12 but is there a measure around annual well woman  
13 exams? And how well would this particular  
14 measure dovetail with an annual well woman exam  
15 measure?

16 MS. BYRON: In terms of NQF-endorsed  
17 measures, no, there's not a measure for annual  
18 well woman exam. There is the HEDIS measure for  
19 cervical cancer screening, but not, as you say, a  
20 well woman exam.

21 MS. BYRON: Yes. And we don't have  
22 one in HEDIS that looks at well woman exams.

1           You know, we have measures that look  
2 at things like well child exams. And some of the  
3 criticisms we get around those is that why aren't  
4 you measuring the content of care that's going on  
5 within those exams.

6           And so I think for these measures  
7 cervical cancer screening and chlamydia  
8 screening, we're trying to get at the content of  
9 what should be happening.

10           One thing that would be good is that  
11 if both measures are watched to make sure that as  
12 rates for one increase you don't see decreasing  
13 rates in another.

14           We often have measures in a set that  
15 kind of serve that balancing purpose. And when  
16 you look at the HEDIS health plan measure set as  
17 a whole we look to see that we have measures that  
18 would balance out those sorts of unintended  
19 consequences.

20           So the cervical cancer screening  
21 measure in HEDIS does look to see if it's three  
22 to five years.

1           But that one is also in the core set  
2           for Medicaid. And so to the extent that programs  
3           continue to have all the measures that really  
4           address the spectrum of women's healthcare I  
5           think that's how we can watch for those sorts of  
6           issues. It is a good point.

7           MEMBER SCHAPIRO: There have been a  
8           number of studies of pediatricians, of pediatric  
9           practices showing that the chlamydia testing is  
10          really related to whether or not the teens even  
11          get a confidential discussion with their  
12          pediatrician. And that's actually quite low,  
13          that uptake.

14          So it would seem if we want to see  
15          some improvement on this measure in the future to  
16          really look at figuring out if there's a way to  
17          actually measure that, whether people are getting  
18          confidential discussion, which would be much  
19          harder because you wouldn't have a CPT code for  
20          it, or a billing code for it.

21          But that seems to be where the barrier  
22          is. The issue never comes up and there are

1       disparities. And so people who are publicly  
2       funded get more testing. Young women of color  
3       get more testing than white women because people  
4       make assumptions about whether they're sexually  
5       active or not, or need the testing.

6                So I think that's one area, if we  
7       don't really look at that we're never going to  
8       see this advance.

9                And it speaks to what the Kaiser  
10       contributor was saying about really needing to  
11       look at 15 to 18 in a different way from 18 or 19  
12       to 25.

13               CO-CHAIR GREGORY: The last comment  
14       will be from Tracy.

15               MEMBER FLANAGAN: Let me just  
16       elaborate a little bit on what we've done in this  
17       area.

18               Our pediatric colleagues actually have  
19       almost a different work set for the over-18.

20               In the under-18 they're working on  
21       coding -- a lot of the contraceptive use actually  
22       is for non-contraceptive reasons. And so we're

1 teaching to the code of that. That's one thing.

2 We also have a linked testing  
3 algorithm for when any teen gets a pregnancy test  
4 to actually make sure that they get some sort of  
5 a touch.

6 Many of these tests, I don't know --  
7 for the non-clinicians in the room don't really  
8 require necessarily an encounter. You can do it  
9 with a urine test. So it ends up being pretty  
10 low touch from the standpoint of face to face in  
11 some settings.

12 As far as the pap issue, pap testing  
13 isn't considered overdue until age 24 anyway so  
14 it's really not the same window as pap testing.

15 From the standpoint of what we've --  
16 we've increased 10 points from -- I think we were  
17 in the mid-fifties to the high sixties. And we  
18 can't seem to get beyond that.

19 I think our only other opportunity  
20 right now is adult family medicine. And the  
21 reason why we don't go to adult family medicine  
22 is because they have 120 measures they're

1 accountable to.

2 CO-CHAIR GREGORY: Assuming there are  
3 no further comments we'll vote on usability and  
4 use.

5 MS. ROBINSON-ECTOR: Voting is now  
6 open for usability and use of measure 0033. 1 is  
7 high, 2 is moderate, 3 is low, and 4 is  
8 insufficient.

9 Looks like we're missing one vote.  
10 All the votes are in and voting is now closed.  
11 Forty-eight percent voted high, 52 percent voted  
12 moderate, zero voted low and zero voted  
13 insufficient.

14 So for usability and use of measure  
15 0033 the measure passes.

16 CO-CHAIR GREGORY: Okay, so we're  
17 moving onto -- I'm sorry. We have to vote for  
18 continued endorsement. Thank you. We are open  
19 for votes.

20 MS. ROBINSON-ECTOR: Voting is now  
21 open for overall suitability for continued  
22 endorsement of measure 0033. 1 is yes and 2 is

1 no.

2 Looks like we are missing one vote.  
3 If everyone could just point their clickers at  
4 me. Thank you.

5 Great. All the votes are in and  
6 voting is now closed. For recommendation for  
7 continued endorsement of measure 0033 the measure  
8 passes with 100 percent voting yes.

9 CO-CHAIR GREGORY: That's consensus  
10 for you.

11 Okay, we have two measures left before  
12 lunch. And we definitely want to be available at  
13 12:15 for public comment because people are  
14 planning to call in.

15 So we will see how it goes, but we're  
16 going to start with measure 1391 frequency of  
17 ongoing prenatal care. It's a maintenance  
18 measure and it is also being supported by the  
19 National Committee for Quality Assurance.

20 It will be discussed by John and  
21 Sindhu. And Carol has a conflict so she will be  
22 recused.



1           We would like the developers to make  
2 a comment if you would like to.

3           MS. BYRON: So, these next two  
4 measures I'll actually talk about together,  
5 getting at similar issues.

6           The first is frequency of ongoing  
7 prenatal care. And this is a Medicaid measure  
8 that looks to see that you got the requisite  
9 number by percentage of prenatal visits that you  
10 should be getting according to the timelines that  
11 are put out by guidelines such as ACOG and the  
12 Institute for Clinical Systems Improvement.

13           The second measure is prenatal and  
14 postpartum care, and that one looks to see --  
15 it's really more getting at the timeliness issue.

16           So, did you get a prenatal visit  
17 within your first trimester, or very soon after  
18 enrolling with the plan. And then postpartum did  
19 you get a visit up to eight weeks after delivery  
20 which aligns, again, to the timelines that are  
21 put out there by the clinical guidelines.

22           Both measures also have been

1 longstanding HEDIS measures and are used in  
2 external programs. Both of these measures are  
3 also part of the Medicaid Child Core Set which  
4 addresses prenatal/perinatal care.

5 And the frequency of ongoing prenatal  
6 care has also been added to the AHIP CMS  
7 consensus core set as well, very recently.

8 So, we talked a little bit about  
9 basically visit-based measures. This is an area  
10 where particularly to Medicaid plans they find it  
11 very important to understand whether women are  
12 getting these visits. And so really it's a proxy  
13 for access. And they do appear in our access and  
14 availability of care domain.

15 CO-CHAIR GREGORY: Discussants.

16 MEMBER SRINIVAS: So now we're talking  
17 about the evidence first, correct?

18 CO-CHAIR GREGORY: Yes.

19 MEMBER SRINIVAS: Okay. So this is a  
20 current measure so we're sort of just assessing  
21 it from that perspective, I guess.

22 But the evidence for this measure is

1 pretty deficient in the sense that it's not  
2 really based on empiric evidence. It's based on  
3 just consensus, expert consensus in terms of  
4 frequency of visit.

5 And the stewards acknowledge the fact  
6 that there's not any real sort of true empiric  
7 evidence in terms of the visit schedule or the  
8 number of visits being truly associated with  
9 improvement in outcomes.

10 Although we know that limited prenatal  
11 care or fewer than a certain number of visits  
12 does seem to occur in disproportionate  
13 populations, and that is associated with some  
14 adverse pregnancy outcomes.

15 But the direct correlation of this  
16 measure with improvement in outcomes, that  
17 evidence is limited.

18 MEMBER KEATS: Yes, I think I  
19 expressed this on the call. I know this is a  
20 measure that's been endorsed previously. In  
21 fact, it's been around for a long time, but I  
22 just have a little trouble with it.

1           I mean, you talk about it being a  
2 proxy for access, but I don't know -- access as  
3 defined as what.

4           I mean, it seems to me attendance at  
5 prenatal visits particularly in a Medicaid  
6 population is going to be a proxy for ability to  
7 access transportation. It's a proxy for ability  
8 to get time off of work if you're a working  
9 mother.

10           I don't think it's necessarily a proxy  
11 for are there doctors available, or midwives, or  
12 mid-level practitioners available in your system  
13 to do these visits. It's are the patients  
14 motivated to show up and do they have the ability  
15 to show up.

16           So I don't know what we're really  
17 measuring with this.

18           DR. BARTON: I would just say isn't it  
19 the plan's concern that the patients get in. I'm  
20 not saying that health plans are currently  
21 constructed to provide door-to-door  
22 transportation. Of course they're not.

1           But when we're thinking about how to  
2 improve healthcare for vulnerable populations  
3 this is something that's been embraced by the  
4 Medicaid plans that they should be responsible  
5 for.

6           And so I think -- I don't disagree  
7 with you in the range of conditions that make it  
8 difficult for vulnerable populations to get care.

9           But I think the fact that accountable  
10 entities have sought to use this measure  
11 demonstrates its importance in its use.

12           CO-CHAIR GREGORY: I'm going to ask  
13 everyone to turn your name tags towards me,  
14 please. And then Juliet, do you have a comment?

15           MEMBER NEVINS: Just a quick comment  
16 with respect to the measure and the screening.

17           If we identify a type of care that's  
18 not being done it doesn't necessarily mean that  
19 there are not physicians or midwives that are  
20 available to do it.

21           But it may prompt us to do more  
22 aggressive outreach to patients with respect to

1 health literacy to develop their motivation.

2 They may not be aware of its importance.

3 So, finding out that this is not  
4 happening, that they're not coming in should  
5 prompt us as healthcare participants and  
6 providers to do more outreach, do more health  
7 education, to work on our health literacy  
8 programs.

9 And maybe that should be the focus  
10 with respect to what we do with the data that we  
11 get from this measure.

12 CO-CHAIR GREGORY: Jennifer?

13 MEMBER MOORE: Yes, I would temper the  
14 assumption that Medicaid plans embrace this  
15 measure.

16 Working in this space there's a  
17 frequent discussion about the challenges of the  
18 frequency of ongoing prenatal care in the  
19 Medicaid population.

20 There are actually barriers that are  
21 not related to women or the plans that need to be  
22 overcome to ensure that they have access to

1 prenatal care and the appropriate number.

2 Some states require women to be  
3 enrolled in fee-for-service before they  
4 transition to managed care.

5 There are barriers within the states  
6 that for time constraints prevent them from  
7 getting enrolled into their plan within a  
8 sufficient time, recognizing that many of these  
9 women were not enrolled in a plan prior to  
10 pregnancy.

11 There's a lot of issues around churn  
12 and access to even having coverage that I think  
13 have to be addressed.

14 And so this measure actually comes up  
15 in discussion quite a bit because what we're  
16 trying to understand and how to figure out is how  
17 to improve access to coverage to address access  
18 to care.

19 So I'm not sure that this measure  
20 actually gets at the root of the issues centered  
21 around frequency of prenatal care at this time.

22 CO-CHAIR GREGORY: Jennifer?

1                   MEMBER BAILIT: So, appreciate your  
2                   comments, Jennifer, because I think they're very  
3                   good, I endorse this as a plan measure.

4                   The problem is it's being applied to  
5                   health centers. And the health centers really  
6                   don't have much control over when you get into  
7                   Medicaid and such.

8                   So to the extent that this keeps a  
9                   little back pressure on the Medicaid plans to  
10                  make sure that their enrollment and such for  
11                  pregnant women are as speedy as they can possibly  
12                  make it at the state system levels, I think we  
13                  need to have some sort of proviso to say this  
14                  should not be used at a facility level to get to  
15                  Dr. Keats' comments.

16                  This is about access at a population  
17                  level. This is not about whether the healthcare  
18                  center is doing a good job and they have enough  
19                  availability to get you in quickly.

20                  CO-CHAIR GREGORY: Nancy?

21                  MEMBER LOWE: Yes, I really respect  
22                  the Medicaid's interest in this measure.



1           But I think for me the fundamental  
2           problem is there's no science behind the number  
3           of prenatal visits. There's absolutely none.

4           And if you are as old as I am you  
5           remember a 1989 report from the U.S. Public  
6           Health Service called "Caring for Our Future: The  
7           Content of Prenatal Care." I just looked it up  
8           again last night.

9           And it's what happens in prenatal care  
10          that's important to outcome, not the number of  
11          times you see a provider.

12          So my objection to this measure is  
13          it's basically measuring the wrong thing. So I'm  
14          struggling with a very indirect measure that to  
15          me doesn't say anything about quality. It simply  
16          says how many times did somebody measure my belly  
17          and listen to the fetal heart rate, period.  
18          That's all it says.

19                   CO-CHAIR GREGORY: Tracy?

20                   MEMBER FLANAGAN: I want to endorse  
21          what Nancy just said. That was pretty much my  
22          comment.

1 I also want to say that there's new  
2 models that are coming out that would not adhere  
3 to this like centering which has perhaps promise  
4 for underserved women with respect to outcome.

5 And I think it has unintentional  
6 consequences. And I agree the evidence is not  
7 there.

8 CO-CHAIR GREGORY: Okay. If I've got  
9 this right we're going to have two more comments.  
10 Diana.

11 MEMBER RAMOS: Yes, I just want to  
12 echo that frequency does not equal quality.

13 And what oftentimes happens in Los  
14 Angeles County where 60 percent of the births are  
15 paid for by Medicaid is that the providers will  
16 bill all of the visits that they possibly can and  
17 use up the Medicaid visits, and then send the  
18 complicated patients to a university hospital  
19 that will take all of the patients.

20 So frequency does not equal quality,  
21 and I don't think this is measuring what we want.

22 CO-CHAIR GREGORY: Cindy?

1                   MEMBER PELLEGRINI: I won't re-say --  
2 I agree with a lot of the comments that have  
3 already been stated.

4                   But the other thing that I want to  
5 bring up is just that in looking at even, you  
6 know, while we want to think about it as plans  
7 using it to have some back pressure, there hasn't  
8 really been a lot of movement either since this  
9 is a measure that's been -- when you look at the  
10 data over time there hasn't been a lot of  
11 movement sort of suggesting that it's not really  
12 functioning in the way that it's intended to  
13 function, I guess.

14                   And I think in some ways probably  
15 inhibits kind of innovative strategies or people  
16 thinking about new ways to provide care that  
17 might improve the content that's delivered  
18 because the metric is so focused on the quantity.

19                   CO-CHAIR GREGORY: We have one more  
20 comment and that's Sheila.

21                   MEMBER OWENS-COLLINS: I want to just  
22 echo what everybody else has said.

1           On the managed care side it is very  
2           difficult to get the women in. And there are so  
3           many programmatic issues with the state in  
4           getting the women in and keeping them in for  
5           their pregnancy and beyond.

6           Also, there may be an advantage in  
7           picking up abnormalities in the fetus in terms of  
8           the prenatal visit in terms of the content.

9           But other than that I don't think  
10          there has been enough science to prove that it  
11          has improved neonatal outcomes significantly.

12          There's not a correlation of the  
13          content or the frequency of prenatal visits to  
14          move the needle and improve neonatal outcomes.

15          CO-CHAIR GREGORY: Okay. I think that  
16          -- okay, one more.

17          MEMBER SHEA: It doesn't seem like  
18          we're going to move beyond this particular aspect  
19          of the measure so I do want to get in that this  
20          measure is very difficult to measure given the  
21          tools that we have through claims in that there  
22          are bundled and global billing codes that don't

1 allow us to actually measure the number of  
2 prenatal visits that the woman attended.

3 So there's less than 3 that are billed  
4 with E&M codes, there are 4 to 6 that are billed  
5 in a bundle, and then there's 7 to 12 that are  
6 billed in a bundle.

7 So I'm not surprised that we haven't  
8 seen a lot of movement, incremental movement  
9 let's say between seven and eight visits because  
10 they're all billed in a bundle. We really have a  
11 hard time with this particular measure.

12 And our states don't tend to choose it  
13 as a measure that they hold us accountable to.

14 CO-CHAIR GREGORY: Well, on that note  
15 let's call for a vote on the evidence. Sure.

16 DR. BARTON: So, we appreciate this  
17 terrific discussion and I think that there's a  
18 lot of food for thought for us to go back and  
19 look at how -- as we do work on measures  
20 routinely how we would work on a measure like  
21 this to improve it.

22 I guess I just wanted to make two

1 points.

2 One is that as was said before the  
3 evidence for something to go right often does not  
4 extend into the details of a measure.

5 So, people who lack prenatal care do  
6 worse. We know that. So, the distance between  
7 that and saying, okay, we're going to make a  
8 measure that approximates what would need to  
9 happen to avoid that bad outcome.

10 And so this has been the measure that  
11 has worked for a number of years to be that  
12 approximation.

13 But I certainly take the point that  
14 there's no specific evidence that says you have  
15 to have a visit between 20 weeks and 22 weeks,  
16 and another one between 30, you know. That will  
17 never exist.

18 But that's the job of the measure  
19 developer is to take the evidence that is there  
20 and figure out how to put it into a measurement.

21 So that's one thing.

22 And I think the other thing is the

1 churn question. I have no doubt in my mind that  
2 this has been a tremendous challenge.

3 And it is certainly my hope, and I  
4 imagine a hope shared by many that the impact of  
5 the Affordable Care Act is to stabilize  
6 availability of health insurance for most  
7 Americans.

8 And so it would be my hope that as we  
9 continue to improve this measure that a measure  
10 or a measure like this is a valuable measure for  
11 vulnerable populations to assure access to  
12 prenatal care which we know is so important to  
13 improve outcomes. Thank you.

14 CO-CHAIR GREGORY: Okay. Let's get  
15 our clickers and vote on the evidence.

16 MS. ROBINSON-ECTOR: Voting is now  
17 open for evidence for measure 1391. 1 is high, 2  
18 is moderate, 3 is low and 4 is insufficient.

19 So we're missing one vote then. If  
20 everyone could revote, please. Great, thank you.

21 All the votes are in and voting is now  
22 closed. Four percent voted high, 12 percent

1 voted moderate, 27 percent voted low and 58  
2 percent voted insufficient.

3 So, for evidence of measure 1391 the  
4 measure does not pass.

5 DR. WINKLER: Just to understand the  
6 implications essentially to endorse this measure  
7 you would need to pass it on evidence either as  
8 it stands or via exception. And that would be  
9 through your vote on insufficient which not  
10 enough of you voted that one either.

11 So, I do want to be sure everybody  
12 understands that the results of this vote stops  
13 this measure right here. Okay? Just to be sure  
14 we're all comfortable with the result.

15 CO-CHAIR GREGORY: Okay. So, we're  
16 now going to discuss a similar measure but  
17 different. And that's measure 1517: Prenatal and  
18 Postpartum Care also sponsored by the National  
19 Committee for Quality Assurance.

20 We have the same committee conflicts  
21 with Carol. Would you guys like to address this  
22 measure, or do you think you had enough of an



1 overview?

2 Okay, then I'm going to ask Sindhu and  
3 Naomi as discussants to discuss the evidence.

4 MEMBER SRINIVAS: Actually can I ask  
5 a quick question just more for process?

6 So, when something -- when the last  
7 measure has insufficient evidence and then  
8 doesn't pass, it's not a separate discussion to  
9 determine whether it's granted the exception?

10 Not that I'm advocating for more  
11 discussion, I'm just asking the question.

12 DR. WINKLER: Enough of you have to  
13 vote for the insufficient for it to roll over to  
14 that potential question. And there weren't  
15 enough on that one. Sixty percent, that's sort  
16 of the magic number.

17 MEMBER SRINIVAS: I'm not sure that --  
18 I didn't realize that. I don't know if everybody  
19 else did.

20 CO-CHAIR GREGORY: Okay, someone has  
21 asked for a revote. Do we vote to revote? I  
22 think we probably should. And we should probably

1 do this by affirmation. By hand.

2 How many people would be in favor of  
3 revoting now that we understand that if it's  
4 insufficient evidence we can then make a decision  
5 about continuing to evaluate the measure based on  
6 exception.

7 So, how many people would like to  
8 revote?

9 DR. WINKLER: The NQF criteria for  
10 endorsement for evidence requires that it have  
11 empirical evidence that supports the relationship  
12 to outcomes.

13 If you determine that the evidence  
14 isn't there it's insufficient as opposed to low  
15 which means the evidence basically says the  
16 opposite.

17 But the evidence is insufficient,  
18 because there are instances where committees may  
19 feel that in spite of the evidence, or lack of  
20 evidence really, it's okay to hold providers  
21 accountable for a measure even though it lacks  
22 evidence.

1           You can then grant an exception to the  
2 evidence criteria. And that's the pathway you  
3 would go to keep this measure alive and moving  
4 forward.

5           CO-CHAIR GREGORY: So, we're now going  
6 to vote to determine if we want to have a revote.  
7 So, for everyone who wants to revote please raise  
8 your hand.

9           (Show of hands)

10          CO-CHAIR GREGORY: Okay. Everyone is  
11 shaking their head in power here so I'm assuming  
12 that we're revoting. Okay. So, can you put it  
13 up for us again, please?

14          MEMBER FLANAGAN: So, I think you need  
15 to clarify what a low versus insufficient.

16                 Low means it stops there.  
17 Insufficient means that we go forward with every  
18 part of the evaluation.

19          DR. WINKLER: Okay, remember you're  
20 judging against the presence of empirical  
21 evidence relating the measure to health outcomes.

22                 When you say the evidence is low it

1 means the evidence doesn't say there's a  
2 relationship to outcomes as opposed to  
3 insufficient where there is no empirical  
4 evidence.

5 One is no relationship. There is  
6 evidence, but there is no relationship. The  
7 other is there is nothing.

8 And yes, it can be a subtle  
9 difference, but it is an important one because  
10 the insufficient is where you're able to go the  
11 exception route.

12 MS. ROBINSON-ECTOR: Voting is now  
13 open for evidence of measure 1391. 1 is high, 2  
14 is moderate, 3 is low and 4 is insufficient.

15 All the votes are in and voting is now  
16 closed. Four percent voted high, 4 percent voted  
17 moderate, 35 percent voted low and 58 percent  
18 voted insufficient.

19 So, for evidence of measure 1391 the  
20 measure does not pass.

21 CO-CHAIR GREGORY: Okay, so we're  
22 going to open for public comment on the measures

1 that we've discussed so far.

2 If we have time after that we might  
3 try to do this last measure before lunch. But we  
4 want to make sure that we give people an  
5 opportunity for public comments.

6 OPERATOR: If you'd like to make a  
7 public comment please press \*1 on your telephone  
8 keypad.

9 DR. WINKLER: And then if there's  
10 anybody in the room we have a microphone over on  
11 the side.

12 CO-CHAIR GREGORY: So, I'm going to  
13 acknowledge someone in the room. Barbara Levy.

14 DR. LEVY: Hi, I'm Barbara Levy from  
15 ACOG. And I just wanted to --

16 MS. THEBERGE: If there are folks on  
17 the webinar who wish to make a comment who are  
18 not dialed into the phone please type your  
19 comment into the chat box and staff will read it  
20 out loud.

21 DR. LEVY: I think we've got it now.  
22 Okay, so I'm Barbara Levy from ACOG.

1           And I just wanted to reiterate our  
2 support for the contraceptive measures and our  
3 evaluation of these that they should be at the  
4 plan level, that they're not at the individual  
5 provider level.

6           That no way does anyone expect them to  
7 be at 80 percent, 90 percent, 100 percent. That  
8 it's critically important for access and for us  
9 to be able to measure that access.

10           It's also critically important that we  
11 understand that 49 percent of pregnancies are  
12 unintended in this country, and that we have a  
13 large population of women with chronic diseases,  
14 chronic conditions, and that we cannot impact  
15 perinatal morbidity and mortality if we can't  
16 plan those pregnancies in advance and optimize  
17 their care.

18           And we feel very strongly that these  
19 measures will help to support us in that work.

20           CO-CHAIR GREGORY: Any other comments?  
21 On the phone?

22           OPERATOR: There are no public

1 comments on the phone.

2 DR. MAIN: Elliott Main from -- I'm  
3 sorry, am I recognized? Elliott Main, CMQCC.

4 I would be in agreement with the  
5 difficulties regarding the number of visits for  
6 prenatal care.

7 But I think there may be a nugget  
8 there for the onset of prenatal care that might  
9 be worth exhuming at some point.

10 CO-CHAIR GREGORY: Are there any  
11 public comments on the phone?

12 OPERATOR: There are no comments at  
13 this time.

14 DR. BINGHAM: Hi, this is Debra  
15 Bingham from AWHONN and I wanted to also  
16 underscore AWHONN's support of the contraceptive  
17 measures. So thank you for all of your hard work  
18 on those measures.

19 In addition, I want to emphasize the  
20 need for some measures related to postpartum and  
21 prenatal care.

22 And so I think struggling with what

1 those right measures are is very, very critical.  
2 So I appreciate the conversation and the  
3 challenges related to that.

4 But if there -- it looks with this  
5 gap, this gap needs to be filled in this area.  
6 So thank you.

7 CO-CHAIR GREGORY: We're trying to  
8 negotiate our day. And I think what we're going  
9 to do is we're going to start the next measure  
10 and try to at least get through the evidence so  
11 that our developer can be a part of the  
12 discussion.

13 And so -- or we may be a little late  
14 to lunch. But let's go with prenatal and  
15 postpartum care. The National Committee for  
16 Quality Assurance is the measure developer.

17 Our discussants are Sindhu and Naomi.  
18 And Carol is still at conflict.

19 So developers, do you want to have any  
20 comments, or can we go straight to the  
21 discussants? Okay, discussants?

22 MEMBER SCHAPIRO: So this is Naomi.



1 So this was part of the ongoing discussion about  
2 evidence.

3 In the phone call we really felt that  
4 it was important that we women do have prenatal  
5 care and postpartum care for a variety of  
6 reasons.

7 But there were some issues about how  
8 soon that had to happen, and if somebody had  
9 postpartum care right away did they still have to  
10 have a six-week or so visit.

11 And so that's I think where we got  
12 kind of caught up because again there's not  
13 really particularly evidence about a particular  
14 time.

15 But we talked about a lot of reasons  
16 why it would be really important to have those  
17 visits.

18 CO-CHAIR GREGORY: Can I ask that we  
19 frame what the measure is for the two prenatal  
20 and postpartum so we all know what we're talking  
21 about?

22 MEMBER SRINIVAS: Sure. It's the

1       timeliness of prenatal care. So it's the  
2       percentage of deliveries that get prenatal care  
3       in the first trimester or within the first 42  
4       days of enrollment into the organization.

5                 And the second rate is postpartum  
6       care. And it's postpartum visit between 21 and  
7       56 days after delivery.

8                 And so I'll just add to Naomi's  
9       comment that I think sort of on face in terms of  
10      the need for prenatal care or initiation of care  
11      at some period and then postpartum care, I think  
12      people on the call felt like that was important.

13                I think one of the deficiencies is the  
14      timing of the postpartum care I think many people  
15      feel is not optimal in the sense that there's  
16      more and more in terms of some of the  
17      recommendations regarding follow-up for women  
18      with hypertension, or even postpartum depression  
19      screening that have the measures starting at  
20      three weeks after delivery versus a lot of people  
21      have started to move towards seeing patients in  
22      the first week or two after delivery to try to

1 address some of these more urgent issues.

2 And so in this metric right now, or in  
3 this measure that wouldn't count as a postpartum  
4 visit. And I think people have concerns about  
5 that.

6 MS. BYRON: Do you want me to address  
7 that? I can address the three-week time frame.

8 That was placed there to rule out  
9 women with c-section who might come in for wound  
10 care.

11 I think they felt like anything sooner  
12 than three weeks might not have been the right  
13 time point. And so they specified it at three to  
14 eight weeks which aligns to some of the  
15 guidelines that are out there.

16 MEMBER SRINIVAS: I think some of the  
17 newer guidelines related to hypertension and  
18 other things as well as just, you know, I  
19 understand the balance of not wanting to count a  
20 wound visit necessarily as a postpartum visit.

21 And at the same time it's a little bit  
22 late I think at this point to think about some of

1 the other concerns that people have.

2 People are wanting to move towards  
3 earlier visits, but having a metric that starts  
4 that late I think pushes care in potentially a  
5 wrong direction as well.

6 So I think, I don't know in the future  
7 if that could be considered in terms of changing  
8 the time frame.

9 CO-CHAIR GREGORY: Sheila.

10 MEMBER OWENS-COLLINS: I've worked  
11 with the chief medical officer for three health  
12 plans that found this measure to really just  
13 almost be impossible.

14 We could never get over the 55-56  
15 threshold. And a lot of it had to do with the  
16 timing. With a c-section mothers come in  
17 earlier, and if you get them back within two  
18 weeks it's hard to get them back again.

19 Also, the payment methodology with  
20 global deliveries makes that window too far out,  
21 especially for routine deliveries.

22 So, I agree that it's important but I

1 think that the window is too narrow. And it's  
2 very hard to again systematically comply with  
3 that at a high level.

4 CO-CHAIR GREGORY: Jennifer?

5 MEMBER MOORE: Can I ask a clarifying  
6 question, Sheila? Are you referring to prenatal  
7 or postnatal? Or postpartum, sorry.

8 MEMBER OWENS-COLLINS: For some reason  
9 the prenatal is easier. But the postpartum for  
10 sure.

11 CO-CHAIR GREGORY: Cindy.

12 MEMBER PELLEGRINI: Can I ask Reva to  
13 clarify for us, if these don't go forward and  
14 therefore can't be recommended -- if any measure  
15 can't be recommended or isn't recommended for  
16 endorsement what impact does that have on its  
17 ongoing use in programs?

18 I mean, these are in the Medicaid core  
19 sets.

20 DR. WINKLER: It actually depends on  
21 the measure developer. Again, what NQF's  
22 endorsement status does convey is meeting the

1 criteria as well as having gone through the  
2 consensus process.

3 We know that measurement is dynamic.  
4 A lot of things have changed around both  
5 measurement and care delivery over time. So we  
6 expect measures to come and go.

7 We do want to see new types of  
8 measures coming in and measures that may have  
9 outlived their usefulness move on. So it is a  
10 dynamic situation.

11 And that's sort of -- the endorsement  
12 is to provide that guidance to potential end  
13 users. But ultimately the decision of how  
14 measures are used is in those hands.

15 CO-CHAIR GREGORY: Tracy.

16 MEMBER FLANAGAN: So, from the  
17 standpoint of evidence it appears as if there's  
18 not very much evidence for either of these,  
19 looking at the summary, although I would say that  
20 in follow-up to Sheila's comment about the window  
21 I think it is possible to be successful, but it's  
22 kind of arbitrary to take out the one.

1                   Why is it three to eight? Why  
2                   couldn't it be one to eight? If there isn't  
3                   evidence against the one to three does it make  
4                   sense to put up an unnecessary barrier to both  
5                   health plans?

6                   And really what you end up doing is  
7                   saying well, you have to come back so that we get  
8                   that postpartum visit, when in fact in some cases  
9                   you can actually do everything in the one-week  
10                  postpartum visit.

11                  CO-CHAIR GREGORY: Karen.

12                  MEMBER SHEA: I believe both of these  
13                  measures are very important to evaluate our  
14                  programs, the first prenatal care visit and then  
15                  also the postpartum visit.

16                  What I'm having a problem with is the  
17                  codes or the specification for actually measuring  
18                  them.

19                  I would welcome the discussion of how  
20                  can we revise these measures to make them more  
21                  effective.

22                  So what I've heard in terms of the

1 first prenatal care visit that occurs within 42  
2 days of enrollment, again we suffer with the  
3 billing codes that are available to us and  
4 incentivize our providers to bill category 2 CPT  
5 codes so we can capture the encounter just to be  
6 able to measure this measure and be able to  
7 achieve the rating that our states are expecting  
8 of us.

9 So there's a tremendous amount of  
10 effort that's going into trying to meet this  
11 measure up against great headwinds, you know,  
12 given the billing system that's in front of us.

13 And in terms of the postpartum visit  
14 also, you know, that 21- to 56-day rule, I heard  
15 people say that there's that c-section that  
16 occurs, there's the post two-week surgical check  
17 that a lot of women believe is their postpartum  
18 visit. Providers have a hard time getting women  
19 back in.

20 I think we talked an awful lot about  
21 the importance of long-acting reversible  
22 contraception, birth spacing, depression



1 counseling. The CDC really sees this as a very  
2 important measure, the postpartum visit. I think  
3 we need to put some effort behind it.

4 I welcome a quality measure in  
5 accountability, but wondering really can we  
6 revise this measure so that we can see better  
7 achievement.

8 CO-CHAIR GREGORY: Greg?

9 MEMBER GOYERT: Again, I think this is  
10 an issue where you can't argue with the goal, but  
11 the provider, or the system, or the carrier is  
12 being held accountable for the patient's behavior  
13 and activities.

14 And when you look at both of these  
15 measures this really is a reflection of poverty,  
16 resources, transportation, social network, things  
17 like that.

18 But I think the primary thing is we're  
19 being held accountable for what our patients  
20 choose to do.

21 CO-CHAIR GREGORY: Naomi.

22 MEMBER SCHAPIRO: I have a procedural

1 question and then another question about how we  
2 measure pediatric visits around this.

3 But the procedural question is so if  
4 we really think this is an important measure to  
5 have in place, but we really don't like the  
6 parameters is there a way to do a provisional, or  
7 it has to come back, or is it just up or down?

8 You know, when we get accredited if  
9 our board doesn't like the way we're doing we can  
10 sometimes have a provisional but then they have  
11 to come back right away. But that doesn't happen  
12 here, it's up or down?

13 DR. WINKLER: At this point no. We're  
14 really asking you to evaluate the measure on the  
15 table.

16 Your feedback is certainly being heard  
17 and it can be taken into account. But we're  
18 asking you to provide your evaluation of this  
19 measure.

20 MEMBER SCHAPIRO: And the second part  
21 of that is you have a comprehensive health plan.  
22 So you have an FQHC that has birth to death, or

1 someplace like Kaiser that is very integrated.

2 And you have this mother coming back  
3 with her baby pretty early and pretty quick. And  
4 she gets screened for depression in the pediatric  
5 visit often, and she's having lactation problems.  
6 Those are often handled in pediatrics.

7 And so she may feel that she doesn't  
8 need to come back as much or as quickly to some  
9 other visit because she already got her needs  
10 met.

11 So I'm just kind of wondering how --  
12 but then instead of looking good because the  
13 health plan's really being kind of wraparound and  
14 holistic, the health plan could look bad because  
15 she didn't go to her own visit.

16 CO-CHAIR GREGORY: Okay, one more  
17 comment. Sindhu?

18 MEMBER SRINIVAS: I completely agree  
19 with that and I actually worry about this measure  
20 making people do things to try to really get the  
21 checkmark on that six-week and discouraging some  
22 of that earlier care that's actually probably

1 more important, and some of the later care that  
2 might actually not be totally necessary.

3 CO-CHAIR GREGORY: Carolyn.

4 MEMBER WESTHOFF: Yes, two process  
5 questions.

6 And one is really the consistency  
7 issue for this committee. In 2011 a previous  
8 committee decided the evidence was sufficient for  
9 this measure.

10 Does there need to be new evidence for  
11 the current committee to say we disagree with  
12 what they said four years ago?

13 DR. WINKLER: What they said four  
14 years ago wasn't that the evidence was there, but  
15 they accepted the lack of evidence as an  
16 exception.

17 We didn't have it as crisply laid out  
18 as we do now to see that two-step thing. The  
19 evidence was the same as you're looking at.  
20 There wasn't anything new.

21 But the committee accepted that as an  
22 exception to the evidence. And so passed it on

1 that basis.

2 MEMBER WESTHOFF: So, as quickly as I  
3 can, a backup. Does the sponsor who's going for  
4 continuation provide new evidence if there is  
5 any? And goes with that? Or any of the people  
6 commenting here believe there is new evidence to  
7 support a different interval?

8 DR. WINKLER: Yes. When we bring a  
9 measure in for a maintenance review the developer  
10 has the opportunity to go in and update all of  
11 the data, or all of the information as they wish  
12 in there.

13 Which is why you will see a mixture of  
14 some red things, that's the new stuff, but the  
15 old stuff is still there. So that's what's going  
16 on there.

17 CO-CHAIR GREGORY: So, I think I'm  
18 going to call this to a vote. And for  
19 clarification we are voting on the evidence. And  
20 if we want to consider this further we have to  
21 understand the criteria of high, moderate, low  
22 and insufficient.

1 MS. ROBINSON-ECTOR: So, voting is now  
2 open for evidence for measure 1517. 1 is high, 2  
3 is moderate, 3 is low and 4 is insufficient.

4 CO-CHAIR GREGORY: For prenatal onset  
5 and postpartum care.

6 MS. ROBINSON-ECTOR: All the votes are  
7 in and voting is now closed. Zero voted high, 12  
8 percent voted moderate, 8 percent voted low and  
9 81 percent voted insufficient. So we will be  
10 able to move forward with this measure.

11 DR. WINKLER: What this does is then  
12 prompt the question to you all is because you  
13 feel there's insufficient empirical evidence to  
14 support this measure it would otherwise go down  
15 unless the committee then votes that you are  
16 willing to grant an exception to the evidence  
17 criteria. And then that would keep the measure  
18 going forward.

19 Does that make sense to everybody?  
20 So, remember that our criteria is for a solid  
21 empirical evidence base. So if there isn't one  
22 you're going to have to give it an exception for

1 the measure to move forward.

2 Any questions about that?

3 MEMBER OWENS-COLLINS: We're voting on  
4 both the prenatal and the postpartum together?

5 DR. WINKLER: They are submitted as a  
6 single entity so yes, they go together.

7 CO-CHAIR GREGORY: And I'd like to  
8 call your attention to the slide so you  
9 understand what you would be voting for. 1 would  
10 be insufficient evidence with exception, and 2  
11 would be no exception in which case we would be  
12 done with this measure.

13 Tracy. Before you put it -- the  
14 developer wanted to say something?

15 MS. BYRON: Yes. So, this has been a  
16 really great discussion and I do appreciate  
17 what's been said here.

18 And I just wanted to mention that this  
19 measure was reevaluated by NCQA a few years ago.

20 And our measures development process  
21 is a consensus-based process that basically pulls  
22 together a group of experts, and clinicians, and

1 researchers, and consumers much like this one to  
2 think through these issues.

3 And many of the issues that you have  
4 raised here were discussed. So, just to let you  
5 know that we did think about it.

6 When you look at the ACOG 2012  
7 guidelines, and when you look at the Institute  
8 for Clinical Systems and Improvement guidelines  
9 that are also around 2012 the recommendation for  
10 a postpartum visit is for between four to six  
11 weeks.

12 For the Institute of Clinical Systems  
13 Improvement it's eight weeks.

14 Now, these are based on things such as  
15 what is the optimal time to be giving a cervical  
16 cancer screening so that you wouldn't get a false  
17 positive result. What's the optimal time to  
18 assess the woman.

19 And, yes, many things can be done at  
20 the pediatrics office, but I will say that in  
21 terms of someone who has given birth I would not  
22 have looked at that as a sufficient visit for my



1 care needs, especially physically speaking.

2 And it's great that it's being done at  
3 multiple points of care, but the guidelines say  
4 go back to your doctor and have a postpartum  
5 visit within this time frame.

6 We wanted to rule out wound care and  
7 that was the primary discussion around that.  
8 There may be newer guidelines coming out that say  
9 go sooner, but our committee was trying to  
10 balance those two intervals of time.

11 So we could say, you know, what is the  
12 empirical evidence behind six weeks versus seven  
13 versus eight and that is a fair question.

14 But when it comes to whether this  
15 measure is aligning to the current guidelines  
16 that are out there it does align. We have what  
17 we have.

18 In terms of access and availability to  
19 care we do believe that this measure is  
20 addressing some of that, especially for plans  
21 such as Medicaid plans.

22 And that is why this measure is in

1 things such as the Child Core Set, so that folks  
2 can look to see what are your rates.

3 Now, the frequency measure that you  
4 looked at previously was in our utilization  
5 domain meaning we're not necessarily saying  
6 higher is better. We're just looking to see what  
7 it is.

8 And this one though is looking at a  
9 timeliness factor. And we're trying to say get  
10 your prenatal visit within your first trimester  
11 or as soon as you can by the time you've gotten  
12 enrolled give or take some time for  
13 administrative issues. And get your postpartum  
14 visit according to what the guidelines are  
15 saying.

16 But I did want to say that I do  
17 appreciate these things because our advisory  
18 panel also thought through these issues and they  
19 are very important issues.

20 MEMBER LOWE: Yes, I think the  
21 fundamental issue that many of us are struggling  
22 with is the scientific standard versus expert

1 opinion.

2 And many of the guidelines are based  
3 on solely expert opinion. That's all it is.  
4 There is no data, empirical evidence behind it.

5 And I'm not willing to do that anymore  
6 because I think what we're endorsing is care  
7 that's based upon a certain philosophical  
8 assumption about what care is.

9 I'd encourage you to read the NICE  
10 guidelines from the UK where they base their  
11 recommendations on evidence. And if there is no  
12 evidence there is no recommendation.

13 So, it's not that anybody's perfect,  
14 but that's what I'm really struggling with is we  
15 continue to foster a system of care without  
16 evaluating whether or not we're improving  
17 outcomes by those things that we're doing and  
18 those things that we're measuring.

19 So, that's my struggle from a  
20 scientific perspective.

21 CO-CHAIR GREGORY: Okay, I see two  
22 comments. Tracy, are you up or down? Okay, so

1 two comments. Sheila.

2 MEMBER OWENS-COLLINS: So, I just want  
3 to comment on your comment about higher is not  
4 better, that you're not looking for higher  
5 numbers, when in fact in the State of Maryland  
6 the postpartum exam is part of the quality  
7 initiative for the state, for Medicaid plans.

8 And Hopkins has been penalized  
9 severely for not being able to meet that measure  
10 in spite of every effort that they have  
11 undertaken to get higher.

12 In Texas that was a part of the  
13 Quality Incentive Plan for Medicaid managed care,  
14 but there was just such a pushback because of all  
15 the issues that we've discussed here that they  
16 took it off. They took the postpartum and the  
17 prenatal out of the value-based program.

18 So there are plans, state governments  
19 that are linking that measure to monies in terms  
20 of incentive program payments, and it's caused a  
21 lot of heartache.

22 CO-CHAIR GREGORY: Naomi?

1                   MEMBER SCHAPIRO: Yes, I just wanted  
2 to say in what we had to work with is that there  
3 does seem to be some evidence, but it's sort of  
4 like not directly on the visit. It's more like  
5 the timing for the pap smear, the timing for  
6 certain kinds of birth control.

7                   And if that were in here then we would  
8 have something to work with. But it sort of kind  
9 of comes up in the conversation. So I think  
10 that's where we're having a problem with it as  
11 well.

12                  CO-CHAIR GREGORY: Last comment before  
13 lunch and a vote.

14                  MEMBER RAMOS: I just want to comment  
15 on the postpartum visit and really considering  
16 the changing of the timing.

17                  Because many providers are reluctant  
18 to see the patient at six weeks, eight weeks when  
19 they needed to see them seven days postpartum  
20 because they had preeclampsia, because they were  
21 transfused, because they had some kind of medical  
22 complication.

1                   And so this would really push to  
2                   increase the quality and the care for the  
3                   patient.

4                   And in terms of screening for  
5                   depression yes, it would be nice if the  
6                   pediatrician did it. But if you were in a system  
7                   where the patient was coming back because she was  
8                   at risk for depression why not get reimbursed for  
9                   that and get credit for that instead of having to  
10                  wait for six or eight weeks.

11                  CO-CHAIR GREGORY: Okay. Let us vote  
12                  on whether we want to say that this insufficient  
13                  evidence with exception, or no exception.

14                  MS. ROBINSON-ECTOR: For those who  
15                  have already voted you can revote if you so  
16                  choose just by clicking on 1 or 2.

17                  So voting is now open for measure  
18                  1517. 1 is insufficient evidence with exception,  
19                  and 2 is no exception.

20                  So I know we have one recusal. Okay,  
21                  great. So, all the votes are in and voting is  
22                  now closed.

1                   So, 62 percent voted insufficient  
2 evidence with exception and 38 percent voted no  
3 exception.

4                   So for measure 1517 the measure will  
5 move forward.

6                   CO-CHAIR GREGORY: So, on that note we  
7 are going to keep going. So we're going to keep  
8 going. And just remember that we stand between -  
9 - so we will now talk about opportunity for  
10 improvement. Discussants, please proceed.

11                   MEMBER SCHAPIRO: So, I'm not scrolled  
12 to the right page, but I remember from our  
13 previous discussion that there's a fairly low  
14 adherence to the measure. There seems to be a  
15 lot of missing care for women so we feel like  
16 there's a lot of room for improvement, although  
17 that's kind of couched in the previous discussion  
18 about the fact that they may be getting the care  
19 and it's not captured.

20                   CO-CHAIR GREGORY: And there's also  
21 disparities data that is very convincing.

22                   MEMBER SCHAPIRO: Yes.

1 CO-CHAIR GREGORY: Correct? So, are  
2 there any comments? Because I think we have to  
3 vote on this one.

4 All right, so I'm calling for a vote  
5 on opportunities for improvement.

6 MS. ROBINSON-ECTOR: Voting is now  
7 open for performance gap for measure 1517. 1 is  
8 high, 2 is moderate, 3 is low and 4 is  
9 insufficient.

10 It looks like we have one outstanding  
11 vote so if everyone could resubmit their vote,  
12 please. Oh, okay, so we have someone out.

13 Okay, great. All the votes are in and  
14 voting is now closed. Twenty-eight percent voted  
15 high, 60 percent voted moderate, 4 percent voted  
16 low and 8 percent voted insufficient.

17 So for performance gap for measure  
18 1517 the measure passes.

19 CO-CHAIR GREGORY: So we'd like to  
20 talk about reliability which would entail  
21 specifications and reliability testing. Sindhu  
22 and Naomi.



1           MEMBER SCHAPIRO: So, trying to not  
2 mix up reliability and validity and all the other  
3 questions we have, it seems that you could get  
4 this data from the data sources in terms of the  
5 codes.

6           CO-CHAIR GREGORY: It's administrative  
7 claims data is what it looks like.

8           MEMBER SCHAPIRO: Yes, it seems that  
9 it would be reliable.

10          MEMBER SRINIVAS: Yes, I agree. And  
11 there's no new information that was presented  
12 compared to the last time this measure was  
13 evaluated.

14          CO-CHAIR GREGORY: So, if there's no  
15 objections would we be willing to take it based  
16 on the prior approval? Okay.

17                 Then we're going to talk about  
18 validity. Is there any new data presented?

19          MEMBER SRINIVAS: So this, from a  
20 validity perspective it seems to meet -- I think  
21 from our previous discussion meet the sort of  
22 face validity aspect of measuring something that

1 people think is important.

2 Some of the specifics around the  
3 timing that we've brought up and other things  
4 might be in question, but in terms of should  
5 there be a metric for -- that measures initiation  
6 of care and then some postpartum care I think it  
7 seems to meet face validity for that.

8 CO-CHAIR GREGORY: Is everyone in  
9 agreement with that? Are there any comments?

10 MEMBER FLANAGAN: I'd like to make a  
11 comment on that.

12 I think one of the other speakers at  
13 the table mentioned that there's a limited number  
14 of codes that are accountable to meet the  
15 measure.

16 And so it doesn't really measure  
17 whether you had a postpartum visit in the  
18 interval in some instances.

19 So you have to teach your providers to  
20 code properly, or your coding people.

21 So is that -- not being a  
22 statistician, is that validity?

1 CO-CHAIR GREGORY: It's certainly a  
2 threat. There was another comment I heard over  
3 here? No?

4 Okay, do we need to vote on this one,  
5 or can we let the prior evaluation stand?

6 MEMBER SRINIVAS: One more comment.  
7 Obviously the measure also is specific about not  
8 what's the content of the visit, but that just  
9 there is a visit.

10 And again, I mean I agree with what  
11 you're saying that if you have to try to code to  
12 a measure to get it to work it does call into  
13 question whether it's valid.

14 I think the idea of it everyone agrees  
15 with, but maybe how it's measured I'm not sure.

16 CO-CHAIR GREGORY: That's sounding  
17 like we want to vote. Do we want to vote? Okay.  
18 So we want to vote.

19 MS. ROBINSON-ECTOR: Voting is now  
20 open for validity for measure 1517. 1 is  
21 moderate, 2 is low and 3 is insufficient.

22 All the votes are in and voting is now

1 closed. Fifty-four percent vote moderate, 38  
2 percent vote low and 8 percent votes  
3 insufficient.

4 DR. WINKLER: That does not pass.  
5 Because moderates need to be above 60 percent.  
6 And so this one in your estimation has failed the  
7 validity criterion and that is a must-pass  
8 criterion.

9 Any comments from anyone? Moderate  
10 has to be high enough.

11 Well, this is a consensus not reached  
12 for validity. So realize you've got some serious  
13 questions about the validity to this measure as  
14 you go forward.

15 MS. BYRON: Can I just state that this  
16 measure is hybrid. So it has -- I know because  
17 there was a comment about the number of codes  
18 available. But you can also look in the medical  
19 record to report it.

20 So, I just wanted to make sure that  
21 was understood before the vote.

22 CO-CHAIR GREGORY: Okay, so now we are

1 at feasibility.

2 MEMBER SCHAPIRO: So, it's both  
3 administrative data and chart audit.

4 CO-CHAIR GREGORY: Are there any  
5 feasibility concerns which have not already been  
6 verbalized?

7 MEMBER FLANAGAN: We're uncertain why  
8 we're going forward at this point.

9 DR. WINKLER: Because a consensus not  
10 reached is still in play. We need to be sure  
11 that that gets resolved.

12 When you have no consensus we need to  
13 continue further considering the issues. It will  
14 be put out that way for public comment for any  
15 feedback from the field and you will revisit.

16 But be very aware that you all have  
17 identified some serious validity concerns as you  
18 go forward.

19 MEMBER SCHAPIRO: So, just in terms of  
20 the feasibility since this is a hybrid measure if  
21 this had to be gleaned through chart review  
22 that's really problematic.

1                   And I've been working on a chart  
2 review. Even with medical records it's a lot.  
3 It's very time-intensive. The claims code  
4 billing is much easier to do.

5                   So I think if this had to be done in  
6 a hybrid way, and I think we don't maybe have  
7 enough information.

8                   CO-CHAIR GREGORY: She didn't say it  
9 had to. She said it was an option.

10                  MEMBER SCHAPIRO: Right, but if people  
11 are feeling that the codes are insufficient then  
12 it speaks to feasibility if you need to use  
13 something else.

14                  CO-CHAIR GREGORY: So, I think we  
15 should vote on this one. Okay? We'll put it up.

16                  MS. ROBINSON-ECTOR: Voting is now  
17 open for feasibility. 1 is high, 2 is moderate,  
18 3 is low and 4 is insufficient.

19                  All the votes are in and voting is now  
20 closed. For feasibility of measure 1517 15 voted  
21 high, 54 voted moderate, 27 percent voted low and  
22 4 percent voted insufficient.

1                   So for feasibility of measure 1517 the  
2                   measure passes.

3                   CO-CHAIR GREGORY: Usability and use.  
4                   Comments from our discussants?

5                   MEMBER SRINIVAS: So, this is how does  
6                   the measure -- sort of the extent to which public  
7                   or other audiences, policymakers could use this,  
8                   both for accountability and performance  
9                   improvement activities.

10                  And I think we've sort of talked at  
11                  length about the limitations and the deficiencies  
12                  of the measure.

13                  In the way that it's used now it is  
14                  publicly reported and available, and it is used  
15                  to try to improve the things that we've discussed  
16                  and its limitations. I don't want to repeat what  
17                  we've already talked about.

18                  CO-CHAIR GREGORY: So, are there  
19                  comments from the panel, or should we vote?

20                  MEMBER MCNEIL: Question. So, just  
21                  because I think we're having some confusion. I'm  
22                  a first-time participant so it's a little

1 confusing to me too.

2 But so I'm wondering like, okay, are  
3 we just voting on the fact that lots of people  
4 use it? So even if we think it's an imperfect  
5 measure are we voting on the fact that it's been  
6 usable?

7 Like what does that mean? It just  
8 means that lots of people are using it? Because  
9 we've got a lot of evidence around the table that  
10 people are using it. So, all we're voting on is  
11 whether it's really used a lot.

12 DR. WINKLER: The use and usability  
13 criteria around -- there are multiple  
14 subcriteria.

15 So, the extent to which the measure is  
16 used is certainly one of them.

17 But things like what's the impact of  
18 the measure. What do we know about performance  
19 over time? What have we learned? Any potential  
20 unintended findings or consequences, or  
21 unexpected positive findings?

22 So, it's not just how many people are



1 using it, but what have we learned from the use  
2 of the measure? So, to understand its potential  
3 pros and cons.

4 So it's more complex than just how  
5 many people are using it. The usability criteria  
6 really gets to the is this a usable measure for  
7 the variety of purposes that measurement is often  
8 used by the variety of stakeholders. Is the  
9 measure information usable for a variety of  
10 stakeholder audiences?

11 CO-CHAIR GREGORY: Diana.

12 MEMBER JOLLES: I just wanted to  
13 comment on the usability with regard to the  
14 measure's potential for improvement which is  
15 included in here.

16 As we sit around the table it would be  
17 quite depressing for all of us to acknowledge  
18 that prenatal care and postpartum care don't have  
19 impact and don't have value, and that there's not  
20 research to support it.

21 Yet I could argue with the evidence  
22 that's been put here and talk about studies that

1 have been done that have demonstrated just that,  
2 that we aren't effective.

3 And so if our goal with the big  
4 picture of the National Quality Strategy, of  
5 endorsing measures through NQF is to effect  
6 change in quality in this country we have to stop  
7 and think about what Dr. Owens-Collins just said  
8 about how her head is stuck and they can't get  
9 past, they can't move this measure anywhere.  
10 They can't get above 56 percent.

11 And I would argue that, well, this is  
12 radical healthcare redesign now. Because when  
13 you bring women and babies in for dyad care and  
14 you have the appropriate provider there who can  
15 provide care for mother and baby you now move the  
16 measure because women do come.

17 When you effect change in how their  
18 experience of care, they do come.

19 And so we can do better. And I would  
20 just say that this measure, while it has multiple  
21 issues, in a very different way it offers us  
22 something that isn't offered by much of what we

1 have on the table.

2 CO-CHAIR GREGORY: Diana Ramos? Okay.  
3 Tracy?

4 MEMBER FLANAGAN: I would underline  
5 what you just said, Diana. I think that having  
6 used both of these measures within our system we  
7 really believe that early prenatal care is a good  
8 time for risk assessment, and postnatal care is  
9 really important for peripartum depression  
10 screening as well as contraception as well as  
11 life planning.

12 Neither of these measures measure that  
13 and they're flawed for those reasons.

14 I do think that we did improve both  
15 measures with concerted effort because we  
16 believed that by having those touches we have the  
17 opportunity to do something that has an outcome.

18 We've been hovering between 89 and 91  
19 percent for our postpartum visit with  
20 considerable effort, considerable effort because  
21 we started in the seventies. So, from a use and  
22 usability standpoint I think we got behind it

1 because of all the reasons I just said.

2 But I still want to echo that I think  
3 we need to go where outcomes are. And I  
4 completely agree with what everybody said in the  
5 room.

6 MEMBER LOWE: Yes, my comment really  
7 dovetails on what Diana said.

8 And I was struck by the developer's  
9 comments under improvement results that  
10 performance results show that the rates have been  
11 steady over the past three years among commercial  
12 and Medicaid plans. It's not clear why  
13 improvement has not occurred.

14 So, that for me begs the question of  
15 if it's being done but the needle isn't moving is  
16 the measure helping us improve quality.

17 So, I really, I'm with Diana. I think  
18 what we need is a revolution in how we provide  
19 care. Not to keep measuring the same problematic  
20 measures that really don't get to outcome.

21 And Jennifer and I were having a  
22 little sidebar which I know we shouldn't do, but

1 at the same time postpartum depression screening  
2 is an important thing that needs to happen.

3 It can be done in the pediatric  
4 office. It can be done in the obstetrical  
5 office. It can be done in family planning. It  
6 can be done by a nurse making a home visit.

7 So, shouldn't we be more thinking  
8 about things that really get to quality of care?  
9 And postpartum depression screening certainly has  
10 a lot of evidence behind it as I understand that  
11 evidence. Rather than a gestalt measure that  
12 doesn't seem to want to move and doesn't really  
13 get to the outcomes.

14 CO-CHAIR GREGORY: Sheila? No, you're  
15 not up.

16 MEMBER OWENS-COLLINS: I'll take  
17 advantage of this. I just had a question about  
18 what we're voting on.

19 So, if we are -- are we voting to keep  
20 the measure as it is?

21 CO-CHAIR GREGORY: Usability and use  
22 as it is, yes.

1 MEMBER OWENS-COLLINS: All right.

2 Okay, thank you.

3 CO-CHAIR GREGORY: Cindy?

4 MEMBER PELLEGRINI: I'd like to  
5 associate myself with all the comments that have  
6 been made about the need for better measures that  
7 measure the content of care.

8 But I find myself very reluctant to  
9 kind of throw this measure overboard without  
10 anything to replace it.

11 CO-CHAIR GREGORY: So, if there are no  
12 further comments I'm going to call this for a  
13 vote. Diana.

14 MEMBER RAMOS: I just have a question  
15 to the developers.

16 So, say that this was voted down.  
17 Taking all of the feedback that you've heard  
18 would you then incorporate this information and  
19 move on to develop a measure that would be  
20 reflective of the feedback? Or would you just  
21 drop it? What happens to it?

22 DR. BARTON: So, NCQA stewards over 80

1 measures that are currently in the NQF pipeline.

2 So that being said, yes, in theory we  
3 will go back, but I can't say that we're going to  
4 go back tomorrow and make a new measure because  
5 our timelines don't work like that. Sepheen has  
6 already referred to our own consensus development  
7 process which includes a set of expert panels and  
8 other public comment sequences that are time-  
9 consuming.

10 And so in spirit I would want to  
11 answer your question affirmatively. And being  
12 realistic I would have to say it would take time.

13 MS. BYRON: And I'll just add that as  
14 noted most of these issues did come up during a  
15 pretty fairly recent re-evaluation.

16 Our panels also agreed that we need  
17 better measures. Our panels also agreed that  
18 this is a feasible measure today and it's still  
19 important, particularly for Medicaid.

20 In terms of what we wrote, yes, the  
21 rates have been steady, that is true. But when  
22 you look at the variation between the low-

1 performing plans and the high-performing plans  
2 there's actually quite a bit of difference.  
3 There's like a 28 percentage point difference  
4 between low and high in some cases. So we do  
5 think that there is room for improvement here.

6 That said, we are always looking at  
7 better measures. And we take input through this  
8 process and other processes because we hear about  
9 use of these measures in many different venues,  
10 and we do think about that in terms of an overall  
11 strategy and when we look at the HEDIS measure  
12 set as a whole to say, okay, where can we get  
13 better measures.

14 Depression screening is addressed in  
15 HEDIS and it includes pregnant women so we agree  
16 that we want to get at important content. But  
17 when it comes to access to care, you know, I  
18 definitely feel the push/pull here. You want to  
19 have a measure that looks at access and says are  
20 women getting prenatal and postpartum care when  
21 they should. We also want to look at content.

22 So we'll continue to look at that as



1 we look at all HEDIS measures in the future. So  
2 we do appreciate the comments that are raised  
3 here.

4 CO-CHAIR GREGORY: Okay, thank you,  
5 everyone. This has been a very healthy and  
6 robust discussion. But now we're going to vote  
7 on usability and use.

8 MS. ROBINSON-ECTOR: Voting is now  
9 open for usability and use of measure 1517. 1 is  
10 high, 2 is moderate, 3 is low and 4 is  
11 insufficient.

12 It looks like we have one outstanding  
13 vote so if you all could resubmit your votes,  
14 please.

15 Great, all the votes are in and voting  
16 is now closed. Eight percent voted high, 54  
17 percent voted moderate, 31 percent voted low and  
18 38 percent voted insufficient. So the measure  
19 passes.

20 CO-CHAIR GREGORY: Okay, so now we  
21 have the fun part of the final vote which is  
22 should we -- suitability for ongoing endorsement.

1 DR. WINKLER: Just one thing I want to  
2 tell you. When we take the results of your  
3 evaluation and we put it out in the draft report  
4 and final comment we will very strongly emphasize  
5 all of the discussion points.

6 And this one's sort of -- particularly  
7 your concerns around validity and evidence will  
8 have a bit of a, you know, take it under  
9 advisement because of all the concerns. So we  
10 will make a point of putting all these out.

11 But realizing as you are evaluating it  
12 you're supposed to be bringing together in  
13 aggregate all of the criteria. And you do have a  
14 consensus not reached situation around validity.

15 MS. ROBINSON-ECTOR: So, voting is now  
16 open for recommendation for overall suitability  
17 for continued endorsement of measure 1517. 1 is  
18 yes and 2 is no.

19 All the votes are in and voting is now  
20 closed. Forty-six percent voted yes and 54  
21 percent voted no.

22 DR. WINKLER: Well, what it is is

1 you've now got a consensus not reached situation  
2 which is exactly sort of not unexpected.

3 And so again, as we go out for public  
4 comment we will be relaying this and looking for  
5 feedback that you will then revisit after the  
6 public comment and we will ask you to revote on  
7 it based on -- so we're looking, again, raise  
8 your concerns. Make those well known. Get as  
9 much feedback that we can during public comment  
10 for you to consider. And then you'll have a  
11 final revote.

12 MEMBER SHEA: Excuse me, but doesn't  
13 this also give the author the opportunity to make  
14 some revisions to the measure before, or no?

15 DR. WINKLER: No.

16 MEMBER SHEA: It's just as is.

17 DR. WINKLER: As is. Because as they  
18 told you, particularly in this case, but it's  
19 true for all developers, you don't make changes  
20 to measures on the dime. Not within what we're  
21 doing right now.

22 Well, I'm sure everybody's hungry and

1 lunch is ready. We're a little bit behind time.  
2 Frankly this is not totally unusual.

3 So what I would suggest is if the  
4 committee could take your break, grab lunch.  
5 Maybe we'll try and shorten it to 15 minutes so  
6 that we can get rolling.

7 Well, the problem is 15 minutes I say  
8 turns into 20 anyway. So, we really do need to  
9 keep going because our afternoon is fairly full  
10 as well.

11 But lunch is ready for you in the back  
12 of the room.

13 MS. THEBERGE: And while you're all  
14 getting up I have a couple of brief  
15 announcements.

16 We will be drawing numbers for your  
17 two-year or three-year terms. Because this is a  
18 new committee we have to decide who's going to be  
19 on a three-year term and who a two-year term. So  
20 we'll be having you draw numbers out of a hat  
21 throughout lunch.

22 And we also would like to do a very

1 quick hand count to confirm the dinner  
2 reservation. Please raise your hand if you would  
3 like to have dinner with us tonight. Okay, 14.  
4 Thanks very much.

5 CO-CHAIR GREGORY: If you could be  
6 back at 1:25 that's -- to start at 1:25. That  
7 gives you your 15 minutes.

8 (Whereupon, the above-entitled matter  
9 went off the record at 1:06 p.m. and resumed at  
10 1:25 p.m.)

11 DR. WINKLER: All right, if I could  
12 ask the committee members to kind of make your  
13 way back to the table. Bring your lunch with  
14 you. Could we have the measure developer for the  
15 next measure join us at the table please?

16 CO-CHAIR SAKALA: Okay, thank you  
17 everyone. We're going to begin our afternoon  
18 session. We have one new measure followed by a  
19 series of maintenance measures in the next block  
20 of time.

21 The next measure is 2896: Structural  
22 Attributes of Facility in which High Risk Women

1 Deliver Newborns. And our discussants will be  
2 Amy Bell, and Sheila Owens-Collins, and recusing  
3 themselves from this measure are Kim Gregory and  
4 Jennifer Bailit.

5 So let's start with an opportunity to  
6 learn about this measure from the developers.

7 Thank you.

8 DR. KLEINMAN: Thank you. Good  
9 afternoon. I'm Larry Kleinman. This is Suzanne  
10 Lo. We are here officially as representatives of  
11 University Hospitals of Cleveland, the proposed  
12 steward, but actually this work was a part of the  
13 CAPQuaM, the Collaboration for Advancing  
14 Pediatric Quality Measures, which was one of the  
15 seven CHIPRA Centers of Excellence AHRQ-CMS  
16 Centers of Excellence.

17 I want to acknowledge your service and  
18 appreciate, or appreciate you for your service  
19 and acknowledge how hard this work is.

20 I thought I'd share with you a little  
21 bit of the context in which this measure was  
22 developed. And I'm going to go through this in

1 about two minutes total.

2 PQMP, the Pediatric Quality Measures  
3 Program was a part of the Child Health Insurance  
4 Program Reauthorization Act test to improve in  
5 strength in children's health quality measures,  
6 expand on existing quality measures, and increase  
7 the portfolio of quality measures available to  
8 public and private insurers.

9 And we use this as our guidance in  
10 thinking about quality. The degree to which, the  
11 IOM definition, which is the degree to which  
12 health services for individuals in populations  
13 increase the likelihood of desired health  
14 outcomes, and are consistent with current  
15 professional knowledge. And one of the things  
16 you noted on the call was this measure looks a  
17 bit different.

18 It does in part because we're viewing  
19 quality as a continuum and not simply a dichotomy  
20 of good and bad.

21 Our consortium consisted of the Child  
22 and Adolescent Health Measurement Initiative,

1       formerly in Portland, now at Johns Hopkins, NCQA,  
2       the American Academy of Pediatrics, the American  
3       Academy of Family Physicians, the American  
4       Congress of Obstetrics and Gynecology, the  
5       Institute for Patient and Family-Centered Care,  
6       the National Institute for Health Quality  
7       Improvement, of Children's Health Quality  
8       Improvement, New York State Medicaid.

9               Other stakeholders ranged from Empire  
10       Blue Cross Blue Shield to practices, hospitals,  
11       the Northeast Business Group on Health and  
12       Consumer Reports.

13               We had a wide variety of doing, of  
14       perspectives. We used the peer-reviewed process  
15       that we developed, we call the 360 degree  
16       process, which is grounded initially in a scoping  
17       review with interviews of front line  
18       practitioners, and then a formal RAND-style  
19       expert panel leading to, leading us towards the  
20       measure.

21               This current measure, I know there was  
22       some confusion on the call. It is not about the



1 hospitals themselves, but it's the proportion of  
2 women who deliver in hospitals that have four key  
3 structural attributes.

4 A 24/7 physician in-house capable of  
5 doing an emergency C-section on the Labor and  
6 Delivery floor, a 24/7 anesthesiologist skilled  
7 in OB anesthesia, in-house and available to L&D,  
8 24/7 blood banking services. We define them in  
9 our questionnaire, but it's basically the  
10 capacity to type, cross, and transfuse.

11 And a 24/7 open level 3 or higher  
12 NICU, using either the American Academy of  
13 Pediatrics standards, or if there is a local, a  
14 state health department standard.

15 We will accept the local standard  
16 rather than the AAP's. And I'm happy to engage  
17 in discussion and dialogue as will be helpful.

18 CO-CHAIR SAKALA: Thank you. So we  
19 will need to go through all elements of these  
20 criteria and vote on all of them. Amy or Sheila,  
21 who wants to begin?

22 MEMBER BELL: I'll go ahead and start.

1 Looking at the, you want to start with the  
2 evidence?

3 CO-CHAIR SAKALA: Yes, please.

4 MEMBER BELL: So with the evidence for  
5 this measure, it's mostly on expert consent says  
6 there's no systematic review for those. The  
7 other thing I would ask, just in general, about  
8 your on-site blood banking services.

9 DR. KLEINMAN: What was that?

10 MEMBER BELL: On the on-site blood  
11 banking services.

12 DR. KLEINMAN: Yes.

13 MEMBER BELL: Is there a reason why  
14 platelets was excluded from, or the ability to  
15 give platelets excluded from that? If you look  
16 at the massive transfusion protocol, you know,  
17 that's one of the elements for that.

18 DR. KLEINMAN: Yes. The reason was we  
19 actually borrowed it from New York State, what  
20 they used. But I don't think it's fundamental to  
21 our thinking about this, and if it were important  
22 to the committee, that actually would be a very

1 easy fix.

2 MEMBER BELL: Okay.

3 CO-CHAIR SAKALA: Can you turn on your  
4 microphone please?

5 MEMBER OWENS-COLLINS: Okay, so I  
6 agree with Amy. It's not evidence-based. It is  
7 more process, and there was a lot of discussion  
8 on the telephone call that this is not parleyed  
9 into an accountable, accountability issue for the  
10 providers or the facility, that this is a  
11 population-based measure.

12 And I just wanted to also say that  
13 Texas is working on a similar initiative.  
14 They're regionalizing maternal care to be aligned  
15 with neonatal care, which has been regionalized  
16 and doubles with care, have been well described  
17 for several years now.

18 The only thing that I would add to  
19 what you already have is that, and there was  
20 also, as I mentioned, a pharmacy availability,  
21 which I don't know if you consider that 24 hour  
22 for consultation, as well as identifying women

1 that are high risk, not only for their  
2 conditions, but having a high risk newborn.

3 I'm saying with congenital anomalies  
4 or something that would place them at high risk,  
5 the mother and the baby at high risk, as needing  
6 to be delivered at specialized facilities.

7 DR. KLEINMAN: I honestly don't  
8 remember the answer to whether the issue of  
9 pharmacy was discussed. And I'm actually, I  
10 won't look to your chair who was a member of the  
11 panel to see if she remembers.

12 But what I can tell you is these  
13 attributes were the ones that were rated at eight  
14 or nine on a median score from one to nine. I  
15 think they were actually all rated nine by the  
16 panel.

17 And that issue, if it wasn't, if it  
18 was brought up and discussed, it was rated more  
19 low, it was rated lower, or it wasn't brought up  
20 in a, in a situation where the panel had the  
21 opportunity to bring it up. And I'm sorry, the  
22 other question you asked was --

1 MEMBER OWENS-COLLINS: Oh, about  
2 conditions of the fetus that would place the mom  
3 at high risk.

4 DR. KLEINMAN: Oh, conditions, so --

5 MEMBER OWENS-COLLINS: The pregnancy  
6 at high risk.

7 DR. KLEINMAN: If it would appear on  
8 the mother's record, there actually, I believe,  
9 are some codes, but because we were trying to  
10 make this more feasible, we wanted to have the  
11 high risk diagnoses and definitions either  
12 noticed at the time of deliver, or things that  
13 were of the mother, because we thought otherwise  
14 it might be difficult to identify that with  
15 available data.

16 So we did our best that we could to  
17 try to get to those ideas. It is, I will say at  
18 the outset, it is clearly an imperfect measure.  
19 It is intended to be an index.

20 It is not supposed to be 100 percent  
21 by any imagination, any stretch of the  
22 imagination. It is intended to be a systematic

1 way that the system can learn about how important  
2 these things are by standardizing how we measure,  
3 and then linking that in the future with  
4 outcomes, which can't happen without the use of  
5 the measure.

6 MEMBER OWENS-COLLINS: Right. So the  
7 lasting, the last topic that came up was the  
8 impact of women that live in rural areas, and how  
9 that impacts their care and getting the delivery.

10 Because I think that's, that is what  
11 makes this important because those women, in  
12 general, can do worse, just because of their,  
13 with their geography. So could you address that?

14 DR. KLEINMAN: Sure. Well, we  
15 actually, as a part of our early process of data  
16 gathering, we spoke with both obstetricians and  
17 family physicians who did deliveries in both  
18 urban and rural areas. And what we heard, and we  
19 heard this from of the panel members too.

20 Aaron Caughey who, from Oregon in  
21 particular, that there are any number of  
22 communities where the right thing is to get the

1 mother in a car or on a bus sufficiently in  
2 advance of when she's likely to deliver so that  
3 she can get to a more distant hospital when she  
4 is at risk.

5 We also, in designing the measure, it  
6 was intended to show a gradient, and the Oregon  
7 example, it was that Portland would be different  
8 from Salem, which would be different from Bend,  
9 which had, I think, one or two MFM, which would  
10 be different than the other side of the mountains  
11 in which it was all happening in a family  
12 practice environment.

13 And so, it wouldn't have validity if  
14 it didn't differ. This is why, this, the  
15 normative would be expected to be different in  
16 each of these. We have for New York State, by  
17 county, and can give some of that data.

18 We've looked statewide at, I think, 14  
19 states, and that data was presented. But it is  
20 true, the standardization and use that we'll  
21 begin to understand what is a well-resourced  
22 rural community versus a not as well-resourced

1 rural community, taking in mind both the local  
2 resources and the capacity to transport pre-  
3 delivery.

4 CO-CHAIR SAKALA: So, thank you. We  
5 have quite a few people with questions or  
6 comments. Can we move on to the panel now? So  
7 next is John.

8 MEMBER KEATS: Thanks. The question  
9 I have is, I was trying to look this up and  
10 figure this out. I know about a year or so ago  
11 ACOG came out with a sort of a consensus  
12 statement about levels of maternity care, trying  
13 to match up to NICU levels, which are well-  
14 established levels of maternity care or not well-  
15 established. How does this map to that? Do you  
16 know? Oh, I have to turn mine off. Sorry.

17 DR. KLEINMAN: We developed ours, this  
18 development actually occurred and was submitted  
19 to the Pediatric Quality and Measures Program in  
20 advance of that. It's close, and when we're  
21 looking at evidence, there were a lot of  
22 similarities, but I don't believe it was



1 identical.

2 And I will say that ACOG designated  
3 Liz Howell as a representative to this process,  
4 and she was a co-lead of the development of it.  
5 So they were a part of this, and they also were  
6 invited to and attended some steering committee  
7 meetings.

8 CO-CHAIR SAKALA: Raj?

9 MEMBER WADHAWAN: I see there's an  
10 obstetrician in-house 24/7 available for C-  
11 section, anesthesia. As far as NICU, and this is  
12 just a clarification, it says 24/7 availability  
13 of level 3 NICU. No mention of in-house  
14 neonatology. Was that the intent here, or was  
15 that, and if not, why not? If anesthesia and OB?

16 MEMBER OWENS-COLLINS: I assume that  
17 this level 3 is in-house neonatology.

18 DR. KLEINMAN: If you give me a  
19 second, we have it actually in our appendix. We  
20 have the AAP guides. I believe 24/7 was in, but  
21 the reason for doing this was this was the only  
22 published standard that we had, and we were

1 trying to, where we can be harmonized with other  
2 things.

3 I think, give me just a second, I can  
4 answer that question. The words in here are  
5 prompt and available access with a neonatologist.  
6 So I think that it probably does leave a little  
7 wiggle room, but I think if that was, again, that  
8 to my mind that would be a relatively easy fix.

9 It's just harder from a measurement  
10 point of view because things are often reported  
11 into terms of the levels that the AAP uses. So  
12 it's a feasibility versus a validity issue. I'm  
13 comfortable on either side of that.

14 CO-CHAIR SAKALA: Jennifer?

15 MEMBER MOORE: Yes. So this measure  
16 actually was the source of --

17 CO-CHAIR SAKALA: I think it's not on.

18 MEMBER MOORE: Oh, sorry. This  
19 measure was actually the source of a lot of  
20 discussion and debate as part of our work group,  
21 but I think that that is important to mention as  
22 part of today's meeting.

1           And I can't remember who on the call  
2           made this comment, but it's really stuck with me,  
3           and I haven't been able to move past this. And  
4           my colleague, who I can't remember the name,  
5           indicated that this is a designation, not a  
6           measure of quality.

7           And I've been really processing that.  
8           I reread this again. The lack of evidence for a  
9           lot of these pieces. I really am struggling with  
10          this one.

11          DR. KLEINMAN: Thank you. I believe  
12          that that colleague actually had mischaracterized  
13          what we were measuring because as I recall, that  
14          it's the same comment, the comment was it wasn't,  
15          it was measure of the hospitals and not the care.

16          That's actually, that would be true if  
17          we just surveyed the hospitals and gave you a  
18          distribution of them. But we're looking at where  
19          the women deliver.

20          This isn't in the classic Donabedian  
21          framework. This is a structural, these are  
22          structural attributes. The process aspect is,

1 did the women get there.

2 So this is sort of the structure  
3 process measure that looks at the entire  
4 population of women as defined by a health plan  
5 or accountee or a community or a state or however  
6 we wanted to cut it.

7 But because it is actually where they  
8 delivered, as opposed to the nature of the  
9 institutions, specifically where they reside, I  
10 think it moves from characterizing the  
11 institutions to that care.

12 CO-CHAIR SAKALA: Okay. Ashley,  
13 please.

14 MEMBER HIRAI: Just on your numerator  
15 specification, I'm just curious why you're  
16 allowing a health department designation? I  
17 mean, there are professional standards. Those  
18 are the AAP guidelines. And what we want to get  
19 away from is a lot of the interstate variation in  
20 these standards.

21 And it is a really important concept  
22 of regionalized care that can reduce

1 significantly mortality and morbidity and very  
2 low birth weight events.

3 And then I didn't read further, but I  
4 know that Elliot, since he's here, has a similar  
5 measure in California. So just about  
6 harmonization with that and what this is  
7 capturing beyond that.

8 DR. KLEINMAN: Thank you. And the  
9 harmonization part, again I think we actually  
10 talked to Elliot in the very early phase of doing  
11 this work.

12 But this measure came through a peer-  
13 reviewed, defined process. And so some of the  
14 things, like some of the definitional issues  
15 we've talked about, I think are open for  
16 discussion.

17 But I think that some of the things  
18 like how to identify the woman, we at least, or  
19 given categories that it had to be in a level of  
20 severity it had to meet.

21 So, I don't know Elliot's measure. I  
22 wasn't aware of it specifically. Okay. Okay.

1 Thank you. In regard to the AAP, the answer to  
2 that is quite simple.

3 Part of this had, part of the purpose  
4 of this was for measurement in Medicaid, and our  
5 partner Medicaid program and others whom we  
6 talked to told us that for acceptance at the  
7 Medicaid and use at the Medicaid level, a few  
8 states might need this leeway.

9 We did not anticipate that it was  
10 actually going to make a large difference,  
11 because when we looked at some state guidelines  
12 for defining, they were actually very similar to  
13 the Academy guidelines.

14 So it was, but that's where that came  
15 from. It wasn't about the, and I share, I share  
16 your desire for standardization.

17 CO-CHAIR SAKALA: Okay. So we're  
18 initially talking about evidence, but I think  
19 it's really important to get the big picture  
20 here. So let's continue the discussion. I'm  
21 sorry? Yes.

22 DR. WINKLER: I just want to mention

1 that this is a composite measure, which adds a  
2 little bit of another layer onto measurement in  
3 general, and so you essentially have four  
4 components.

5 And so we do want to look at the  
6 components in terms of the evidence. But there  
7 also will be additional questions around measure  
8 construct.

9 Why did you put these four things  
10 together, and what's the rationale behind that  
11 and that, does that make sense?

12 So realize that this is a composite  
13 measure. It has a few other nuances to it  
14 compared to some of the other measures. So just  
15 be aware.

16 CO-CHAIR SAKALA: Thank you. Nancy?

17 MEMBER LOWE: I'm struggling with the  
18 various components of how these, particularly the  
19 numerator, for how many -- and when I look at the  
20 specifications and forgive me for not being able  
21 to be more articulate about this, but when things  
22 happen, not everything that happens is

1       predictable.

2                   And so how can that, is that  
3       reflected? You know, the things that intrapartum  
4       events that we cannot or should not transfer a  
5       woman? She is where she is and we do the best  
6       that we can under the circumstances.

7                   And I'm thinking of what we do in  
8       Colorado, which is our annual morbidity review,  
9       mortality review.

10                   And living in a very rural state, that  
11       there are large pieces of geography between a  
12       level 1 and a level 2 or a level 3, including  
13       high mountains and all kinds of stuff.

14                   You know, we, transfer is not always  
15       the right thing to do. So how do, I'm struggling  
16       with that piece of this, and can you help?

17                   DR. KLEINMAN: I thought that was very  
18       articulate, and here's what I would say. We  
19       explicitly, and in the panel, this was a part of  
20       the conversation, decided to de-link this measure  
21       from the quality of care for any given woman.

22                   So this is why it is a population



1 index, because it is not the right thing to  
2 transfer for every woman. Every woman who has  
3 the conditions that would be captured in the  
4 denominator is not at high risk. Not every woman  
5 at high risk is captured in this.

6 The key question was, can we  
7 distinguish the availability of care from one  
8 population to another.

9 And we felt that given the state of  
10 knowledge and the state of information, if we  
11 tried to do that on an individual level for an  
12 individual person or an individual clinician's  
13 practice, it was folly. The evidence and the  
14 state of the art did not support it.

15 So given we had this assignment, we  
16 spent a lot of time and a lot of conversation on  
17 this. How could we resolve that uncertainty in a  
18 way in which there still was meaning that was  
19 grounded in evidence? And this notion of an  
20 index is what we came up with. But thank you for  
21 the question.

22 MEMBER JOLLES: I know we're speaking

1 about evidence, but, and this is going to cross  
2 over topics a tiny bit, but briefly, I feel  
3 compelled to discuss the fact that 85 percent of  
4 child bearing women in our country are healthy  
5 and low risk, and there is known supply-sensitive  
6 variation that's occurring, harming that  
7 population of people.

8 I have a lot of concern about the way  
9 this measure is drafted, specifically with regard  
10 to its inclusion of what qualifies as high risk  
11 as among the 2,000th line of indicators.

12 Things like anemia in pregnancy,  
13 substance abuse, cannabis, smoking, and first  
14 trimester placental previa without bleeding.  
15 That could be resolved.

16 So just looking at the strong start  
17 data out of Medicaid, this, these, and various  
18 other studies, the TIOP III, the research out of  
19 Doctor Howell, and now let me speak to the fact  
20 that I'm a nurse-midwife out in Tuba City,  
21 Arizona.

22 If every patient of mine with a

1 narcotic addiction was sent to Phoenix, we need  
2 mental health providers on the reservation.

3 DR. KLEINMAN: Thank you. Thank you.

4 And let me say, we did have a nurse-midwife on  
5 this panel as a part of it. We, the panel felt  
6 very strongly about substance abuse.

7 So what I would say is I think there  
8 are always varieties of opinion, and again, I  
9 would speak to the notion of this as an index  
10 that is not designed to define whether any  
11 individual person was at risk or should have  
12 delivered in those hospitals.

13 It is designed to describe practices  
14 and availability of care for a population. And  
15 we tried in going through the, we spent quite a  
16 lot of time in trying to remove things that we  
17 thought were trivial diagnoses in categories that  
18 weren't likely to have impact.

19 For those where there was a diversity,  
20 and there wasn't the level of detail, then we  
21 tried to, we erred probably on the side of  
22 including, except for things that were very

1 prevalent.

2           Some of the mitral valve things, for  
3 example. Now, it's also possible, and I would  
4 need to review, that during the mapping for ICD-9  
5 to ICD-10, something slipped back in.

6           We tried to make sure that that didn't  
7 happen. But this work was done initially in ICD-  
8 9 because of the time when the work was done.  
9 But thank you.

10           CO-CHAIR SAKALA: So, these are all  
11 great questions, but a lot of them relate to  
12 later steps in our process, so I think what I'd  
13 like to do is understand that you all probably  
14 have great things to say, and we haven't been  
15 hearing more on the evidence.

16           So if we could vote for that and then  
17 offer you the opportunity as we move on to  
18 comment. Could we open it up for evidence? A  
19 question of whether the evidence presented in  
20 this documentation meets the NQF criteria.

21           MS. ROBINSON-ECTOR: So voting is now  
22 open for evidence for measure 2896. One is high,

1 two is moderate, three is low, and four is  
2 insufficient.

3 Okay. All the votes are in, and voting is  
4 now closed. Four percent voted high, 24 percent  
5 voted moderate, 12 percent voted low, and 60  
6 percent voted insufficient.

7 DR. WINKLER: Yes. This is, we've  
8 been down this road before. So we're back to  
9 insufficient.

10 So the secondary question is, would  
11 you wish to grant an exception to NQF's evidence  
12 criteria to allow this measure to continue on  
13 being evaluated?

14 CO-CHAIR SAKALA: So comments specific  
15 to that. Nancy, are you? Oh. Okay. So shall  
16 we re-vote on that question? So, a one would be  
17 there's insufficient evidence, but we think this  
18 is important and want to continue to discuss  
19 this, or two would be, no exception, in which  
20 case this would stop the process.

21 MS. ROBINSON-ECTOR: Voting is now  
22 open for potential exception to empirical

1 evidence for measure 2896. One is insufficient  
2 evidence with exception, and two is no exception.

3 Like all the votes are in. So 44  
4 percent voted insufficient evidence with  
5 exception, and 56 percent voted no exception.

6 DR. WINKLER: Yes, this went obvious,  
7 obviously the, more people said no exception  
8 versus the other, and so we really don't have the  
9 committee's support for going forward with an  
10 exception. So we'll close it down right there.

11 CO-CHAIR SAKALA: And I guess I'd like  
12 to offer that there's a lot of interest in this  
13 and a lot of other comments if you have the  
14 opportunity to move it forward, I'm sure people  
15 would be happy to continue to comment on that.

16 DR. KLEINMAN: Thank you. And I  
17 welcome folk's comments and thoughts. This is an  
18 important part of measurement and I think frankly  
19 the linking of, excuse me, this sort of  
20 obstetrical measurement to child health is  
21 actually a critical point in moving both of our  
22 fields forward. Thank you.

1 CO-CHAIR SAKALA: Okay. So could we  
2 ask for the developer for 1382: Percentage of  
3 low birth weight births? This is a maintenance  
4 measure. It's a maintenance measure, and Ashley  
5 is recused from this, and we have three leads on  
6 it, Carolyn, Kristi, and Cindy.

7 DR. WINKLER: Do we, do we have our  
8 measure -- no? This is CDC. Yes. Yes. Is  
9 anybody on the phone with the developer for  
10 measure, wait a minute, let me read the number  
11 from here, 1382: Percentage of low birth weight  
12 births?

13 This comes to us from CDC. Okay.  
14 Perhaps not. Essentially this is a measure that  
15 is collected as part of vital statistics. It is  
16 a population-based measure. It is an outcome  
17 measure. So why don't we give our leads.

18 CO-CHAIR SAKALA: Okay. So who wants  
19 to kick us off with evidence?

20 MEMBER WESTHOFF: So the evidence on  
21 this was established with the original submission  
22 in 2011 showing, in essence, that everything bad

1 happens much more often to low birth weight  
2 infants, and that therefore the percent low birth  
3 weight taken together is a global indicator of  
4 quality.

5 And that there is not just a huge  
6 amount of variability at any moment in time, but  
7 that in the United States there have been secular  
8 trends in the incidence of low birth weight,  
9 suggesting that it is in fact modifiable, as well  
10 as the fact that our levels are very different  
11 from those seen in other countries. And that  
12 evidence has not changed since the original that,  
13 original endorsement.

14 DR. WINKLER: Just as a reminder, when  
15 a true outcome measure like this, the evidence  
16 that is required is really, is there some  
17 structure or process or activity that can be done  
18 that could potentially influence the outcome?

19 In other words, is there an  
20 actionability aspect about it, rather than the  
21 more intensive look at systematic review of the  
22 evidence, that you, is required for a process or



1 intermediate outcome measure.

2 MEMBER WESTHOFF: Yes. And speaking  
3 to that, somewhat indirectly, the secular changes  
4 over time in this country absolutely support  
5 that.

6 CO-CHAIR SAKALA: And also for these  
7 measures in general, with your comments, if you  
8 could clarify whether you think there's any  
9 reason to re-vote, and you did mention you don't  
10 think there's new evidence. Thank you. Others  
11 who are commenting on this? Anything? Okay.

12 So any comments from the panel or  
13 reasons why, and objections to not re-voting,  
14 let's say, as well. Did, yes, Sheila? Can you  
15 turn on your mic please?

16 MEMBER OWENS-COLLINS: I just had a  
17 clarifying question. I agree that birth weight  
18 is a barometer of the health status of a nation,  
19 also gestational age. And so I was wondering if  
20 you considered looking also at gestational age?

21 DR. WINKLER: We don't have the  
22 developer with us, but again, this particular

1 measure is strictly around low birth weight. And  
2 I'm not aware that gestational age is part of the  
3 measure.

4 MEMBER OWENS-COLLINS: Right. Okay.

5 CO-CHAIR SAKALA: Okay. So there  
6 being no objection, yes, we will move onto  
7 opportunity for improvement, and any comments  
8 from the discussants to get that discussion off.

9 MEMBER PELLEGRINI: There's  
10 substantial opportunity still for improvement in  
11 this measure while rates have sort of edged down  
12 ever so slightly over the last few years, they've  
13 been fairly close to flat, and they also include  
14 some pretty substantial variations in race and  
15 ethnicity.

16 So there's certainly a lot of room  
17 here for this measure to be used to inform  
18 efforts that both target those disparities as  
19 well as the rates overall.

20 CO-CHAIR SAKALA: I can't see. I  
21 can't read that card from here. Oh, it's Tracy.  
22 Yes.

1                   MEMBER FLANAGAN: We skipped over  
2 evidence. I'm really struggling with this. The  
3 subcommittee put a pass on this. This seems to  
4 be a descriptive measure, and based on the  
5 comment that you made, we have about, whether  
6 this is actionable.

7                   Was there evidence presented that  
8 prenatal care was what did this, that the  
9 provision of prenatal care is what reduced the,  
10 you know, this, or improved this measure? I'm  
11 still struggling with the evidence because there  
12 are so many things that can affect this.

13                  DR. WINKLER: Well, I think that's  
14 exactly the issue around the evidence criteria  
15 for outcome measures is because there are so many  
16 multi-factorial things that can, you know, feed  
17 into the ultimate outcome. But it's the outcome  
18 we care about.

19                  And so that's why the evidence  
20 criterion is different for a pure outcome measure  
21 compared to a process or intermediate outcome  
22 measure. And it isn't specific to any particular

1 process.

2 But the question is, you know, are  
3 there anything? Whether it's prenatal care or  
4 change in maternal smoking, or you know,  
5 whatever. Things that can affect the outcome.

6 So there is a difference in the  
7 evidence criterion requirements for a pure  
8 outcome measure versus a process or intermediate  
9 outcome measure. And this isn't, this isn't a  
10 pure outcome measure.

11 MEMBER FLANAGAN: Yes, I'll just put  
12 one more comment on this. I think we know that  
13 there are lots of variables that are associated  
14 with this, but whether or not you can absolutely  
15 do a performance improvement project around this,  
16 I'm struggling to figure out what that would be.

17 This variation could be that people  
18 couldn't afford IVF. I mean, it could be that  
19 for the last five years, because of the economic  
20 downturn.

21 So I'm just struggling a little bit  
22 with the evidence here, even though I think it's

1 a very important descriptive measure.

2 DR. WINKLER: Realize also that the  
3 level of analysis for this measure is at the  
4 state level for the nation.

5 MEMBER PELLEGRINI: So this is, this  
6 is about getting a signal in a community,  
7 right? It doesn't tell you why that signal is  
8 happening or what to do about it.

9 That's where you have to, let's say  
10 partner with the March of Dimes to do a deep dive  
11 into your data and figure out what's going on  
12 there and what sorts of things you might be able  
13 to impact.

14 So this is just purely a number. It's  
15 not going to point you in a specific direction of  
16 action.

17 CO-CHAIR SAKALA: Okay. Is that okay  
18 with you, Tracy, that we can move past evidence  
19 and it sounds like there's no reason to re-vote  
20 on opportunity -- Oh, we will vote on opportunity  
21 for improvement if there are no further comments  
22 here.

1 MS. ROBINSON-ECTOR: Okay. Voting is  
2 now open for performance gap for measure 1382.  
3 Option one is high, two is moderate, three is  
4 low, and four is insufficient.

5 It looks like we are missing one vote.  
6 I know we have one recusal. So if everyone  
7 could, oh, someone's out. Okay, great. Thank  
8 you.

9 So voting is now closed. Sixty  
10 percent voted high, 36 percent voted moderate,  
11 four percent voted low, and zero voted  
12 insufficient. So for performance gap, the  
13 measure passes.

14 CO-CHAIR SAKALA: So comments from the  
15 discussants on reliability? We need not vote on  
16 this if there is no news, new information  
17 presented.

18 MEMBER NELSON: I don't believe  
19 there's any new information on this. It's pretty  
20 easy to obtain from vital statistics, and the  
21 validity testing was done on that also.

22 CO-CHAIR SAKALA: Okay. And Tracy,

1 your, is your card up, or, okay. All right. So  
2 there being no objections, let's move on to  
3 validity comments on that. And now we want to  
4 look at how, whether there's new testing data  
5 presented by the developer.

6 MEMBER NELSON: There was no new  
7 testing from the developer.

8 CO-CHAIR SAKALA: Any objections to  
9 accepting the previous support for validity?  
10 Okay. So now we're on feasibility, which we do  
11 need to vote on. And now we can share any  
12 information that we have from observing that this  
13 measure has been in use over a period of time.

14 MEMBER PELLEGRINI: The developer  
15 hasn't noted any difficulties that have been  
16 encountered in using this measure.

17 MEMBER WESTHOFF: I mean, it is data  
18 collected by law that's universally available.  
19 So that has implications for all of these  
20 questions.

21 CO-CHAIR SAKALA: Great. Can still be  
22 voted on I guess. Okay. Reva says we do vote on

1 it, even under those circumstances. So I see no  
2 other cards up. Let us open the voting for  
3 feasibility.

4 MS. ROBINSON-ECTOR: Voting is now  
5 open --

6 CO-CHAIR SAKALA: Yes.

7 MS. ROBINSON-ECTOR: -- for  
8 feasibility for measure 1382. One is high, two  
9 is moderate, three is low, and four is  
10 insufficient.

11 Okay. All of the votes are in and  
12 voting is now closed. Ninety-six percent voted  
13 high, four percent voted moderate, zero voted  
14 low, and zero voted insufficient, so for  
15 feasibility, measure 1382 passes.

16 CO-CHAIR SAKALA: Okay. Thank you.  
17 And for usability, any comments on the use of  
18 this in public programs or for quality  
19 improvement? Okay.

20 MEMBER GOYERT: I think I got stuck  
21 the same place Tracy did, and it falls into the -  
22 -



1 CO-CHAIR SAKALA: Could you speak a  
2 little closer?

3 MEMBER GOYERT: -- falls into the  
4 usability in that this is not a reflection in any  
5 direct way of quality of care, but rather it's a  
6 reflection of society.

7 It's like saying what's the percentage  
8 of patients with diabetes? Or what's the  
9 percentage of patients that smoke? Yes, there is  
10 lot of interventions that can go to influence  
11 that.

12 So it's more a vital statistic than a  
13 quality, than a metric for quality, albeit it's  
14 still very important somehow to track.

15 CO-CHAIR SAKALA: Thank you. Naomi?

16 MEMBER SCHAPIRO: I agree. I just  
17 think from a public health and planning point of  
18 view, it's helpful to know how many babies are  
19 going to need NICU follow up, you know, and are  
20 going to need some kind of support service as  
21 they get down the road. So it's useful to be  
22 able to predict that I think.

1 CO-CHAIR SAKALA: Thank you. Diana.

2 MEMBER JOLLES: Well, I just wanted to  
3 comment on its relationship to elective induction  
4 of labor, and I'm not sure if we're ready to  
5 retire that measure yet, and if so, if not, then  
6 we still do have iatrogenic causes of low birth  
7 weight.

8 CO-CHAIR SAKALA: Thank you. Sheila.

9 MEMBER OWENS-COLLINS: I just wanted  
10 to comment that birth weight is one of the  
11 barometers for the status of the health of a  
12 nation, and we do compare, and it's more directed  
13 to infant mortality, and that's why I brought up  
14 the case of gestational age, because as the  
15 United States ranks very low in, among industrial  
16 countries in terms of their infant mortality rate  
17 and their maternal mortality rate.

18 So this is a link to that, getting to  
19 that public health metric, which makes it  
20 important, relevant.

21 CO-CHAIR SAKALA: Thank you. Any  
22 other comments? I don't see any so let's have a

1 usability and use vote. Oh, sorry. Amy.

2 MEMBER BELL: Sorry. I just wanted to  
3 kind of just make focus aware about the birth  
4 certificate data and how it is not all that  
5 reliable, especially, I know from North Carolina,  
6 we are actually going to launch a project through  
7 our Quality Collaborative about really making  
8 sure we have valid, reliable data, because we  
9 know statewide it is not there. And I think  
10 other states probably are in the same boat with  
11 that.

12 CO-CHAIR SAKALA: Jennifer?

13 MEMBER BAILIT: Just to address that  
14 point, that's true for a lot of the maternal  
15 indicators, and for indications and stuff. But  
16 birth weight and gestational age are pretty rock  
17 solid on the birth certificate. If you're going  
18 to pick anything on the birth certificate, those  
19 are the ones to pick.

20 CO-CHAIR SAKALA: Okay. Not seeing  
21 any other comments. Let's open up voting for  
22 usability and use.

1 MS. ROBINSON-ECTOR: Voting is now  
2 open for usability and use for measure 1382. One  
3 is high, two is moderate, three is low, and four  
4 is insufficient.

5 Okay. So all the votes are in and  
6 voting is now closed. Sixty-nine percent voted  
7 high, 27 percent voted moderate, four percent  
8 voted low, and zero voted insufficient. So for  
9 usability and use, measure 1382 passes.

10 CO-CHAIR SAKALA: Thank you. So  
11 before we vote on whether to, for NQF to  
12 recommend that NQF re-endorse this measure, are  
13 there any crucial big picture comments? Jaleel?

14 MEMBER MAMBARAMBATH: I'm confused  
15 about this now. Now this is a widely scattered  
16 stakes, why are we considering this as a, as a  
17 measure, as a quality measure?

18 Yes, it has implications for quality,  
19 but is it really a quality measure, because as  
20 Greg mentioned, diabetes or incidence of heart  
21 attacks or myocardial infarction, or whatever is  
22 true. Everything is vital statistics, and

1 everything has quality measures that you can put  
2 in place to improve the quality, but is it really  
3 a quality measure? I'm not sure.

4 CO-CHAIR SAKALA: So I can't speak for  
5 the developer, but I will say that there is a  
6 move afoot to get out of our silos, to be working  
7 together on shared priority goals. So that might  
8 be one way to think of this. Naomi?

9 MEMBER SCHAPIRO: I'm just reflecting  
10 about the discussion and, you know, we did point  
11 to a few things that may raise the incidence of  
12 low birth weight that are more attributable to  
13 middle class women, such as IVF and maybe early  
14 elective labor, but this is a huge health  
15 inequity, especially for African American women  
16 of every social and economic status, and I think,  
17 you know, and that way it's the way to call out  
18 the fact that we haven't fixed this problem.

19 Even if it's going down our lower  
20 stable, so just, I think that's important in  
21 terms of the quality and speaks to working  
22 together.

1 CO-CHAIR SAKALA: Thank you.  
2 Jennifer. Is that, oh, sorry. All right. Okay.  
3 All right. So let's turn to a vote of whether  
4 you recommend that the endorsement be continued  
5 for this measure.

6 MS. ROBINSON-ECTOR: Voting is now  
7 open for recommendation of overall suitability  
8 for continued endorsement of Measure 1382. Yes  
9 is one and two is no.

10 Looks like we, okay, great. All the  
11 votes are in and voting is now closed. One  
12 hundred percent votes yes, zero votes no. So for  
13 recommendation for --

14 CO-CHAIR SAKALA: Again, there's --

15 MS. ROBINSON-ECTOR: -- continued  
16 endorsement. Measure 1382 passes.

17 CO-CHAIR SAKALA: All right. Okay.  
18 So could we get our developer up here, and Kim  
19 and I are both recused from this, so Reva's going  
20 to jump in.

21 DR. WINKLER: Lucky me. Okay. The  
22 next measure that we have is measure 716:

1 Unexpected Complications in Term Newborns from  
2 the California Maternal Quality Care  
3 Collaborative.

4 Elliot Main is here with us. Just to  
5 point out, this measure was originally endorsed  
6 four years ago as a measure that looked a little  
7 bit different.

8 It was healthy term newborn, where it  
9 was flipped so that the results were in the high  
10 90's, and Elliot can tell you perhaps why they  
11 revised it. And so just to have that  
12 understanding that even though it was previously  
13 endorsed, it was previously endorsed know, on its  
14 head.

15 And now we're looking at it somewhat  
16 differently, but it will carry the same number,  
17 and essentially is measuring the same thing,  
18 albeit somewhat differently. So Elliot, brief  
19 introduction to the measure before we go to our  
20 lead discussants.

21 DR. MAIN: Thank you very much. I  
22 should apologize to Ashley Hirai, there was a

1 measure that we did develop in California  
2 previously, which was a, somewhat remained the  
3 last conversation, which was under 1,500 gram  
4 babies not delivered at a level 3 center.

5 So it was about regionalization of  
6 care that was endorsed previously. We decided  
7 not to re-endorse it this time because we  
8 struggled like we did last time with, is this a  
9 public health indicator or quality indicator.  
10 Went back and forth and decided it was more of a  
11 public health indicator.

12 And so it's not brought forth as a  
13 quality measure, thought it could well have been.  
14 So this measure though on the table now is, I  
15 think, important in one's portfolio to have a  
16 measure of, excuse me, of what is the most  
17 important outcome of labor and deliver, which is  
18 having a healthy baby at the end of the day.

19 And when we talk about, we'll talk  
20 tomorrow about other indicators that the Joint  
21 Commission has, but at the end of the day you  
22 want to have a healthy baby, and this is a



1 measure that identifies those babies who come to  
2 labor and delivery in their mother without any  
3 major pre-existing conditions.

4 They have no birth defects, they have  
5 no, they're at term, they're a singleton, they  
6 have no underlying medical conditions such as  
7 isoimmunization or so forth, so the expectation  
8 is that they would have a normal outcome. They  
9 would not need to go to the NICU.

10 And so the numerator then is babies  
11 that did have a diagnosis or procedure that would  
12 be characteristic of being in the NICU, since  
13 there is no measure administratively of NICU  
14 admission that is easily attainable through the  
15 country.

16 So it is, it does rely on coding. And  
17 therein gets into some tricky business because  
18 coding is coding as we all know, and so we went  
19 through great lengths to try and build in  
20 features that would protect against over-coding  
21 and under-coding, both of which can be issues in  
22 the newborn period.

1 Over-coding would be, or added on  
2 diagnoses, perhaps expanding the severity of the  
3 diagnoses, which, and perhaps to get more  
4 reimbursement for the hospital.

5 An example of this is a baby, the  
6 chart says rule out sepsis and it gets coded as  
7 sepsis. Fairly common actually. And so as an  
8 example, we put length of stay modifiers on most  
9 of these so that you cannot have a length of stay  
10 of two days and have a diagnosis of sepsis and  
11 have it count. It has to be at least four days,  
12 which would be the minimum course of antibiotics  
13 required for a diagnosis of sepsis.

14 So we went through and did all those.  
15 We spent a couple of years actually seeing how  
16 these played out in real life coding, in real  
17 life practice, because it's one thing to get a  
18 group of experts together to come up with great  
19 ideas about what coding should go into a bucket,  
20 but then you really have to see how, in our  
21 state, in our setting of 250 maternity hospitals  
22 in California, how the coding is actually done.

1           And we found some peaks and valleys  
2 around the state that were really indicative of  
3 some of these coding anomalies I spoke of.

4           So we actually ended up adding and  
5 tweaking the measure to account for coding  
6 variation, including in some, in my hospital, we  
7 found that babies who got bagging as part of  
8 resuscitation in the delivery room got coded as  
9 CPAP, and that had definite continuous positive  
10 airway pressure.

11           That got definite upgrading on their,  
12 on their, what they could charge for. But it was  
13 a clearly inappropriate billing. And we spread  
14 that through the state, and that brought down  
15 some of the outliers.

16           But there are lessons to be learned  
17 actually if you look at coding, and you really  
18 have to delve into each hospital's rates and  
19 drill down to see why their indicators are high.

20           So that's what's built into it now.  
21 We flipped it, the measure, from being a healthy  
22 term baby into an unexpected complication.

1           The rate of healthy babies is high on  
2 this. Somewhere around 94 to 97 percent, and  
3 that sounds like a great grade if you're going to  
4 do an exam. You know, sort of psychologically.

5           But it's very different if you are  
6 looking at a three to six percent of unexpected  
7 complications. That's more attention-getting and  
8 provides more of an opportunity to improve than  
9 we're trying to move from 95 to 96 percent at the  
10 other end of the scale.

11           So that was a frame shift in how the  
12 measure was looked at. And so those are the two  
13 main differences between prior endorsement and  
14 now, is that frame shift and the addition of more  
15 codes and ways of combating over-coding and we  
16 actually looked for under-coding too.

17           If the mom has a length of, the baby  
18 has a long length to stay, for example, without  
19 the diagnosis. That's picked up as well. So I  
20 can certainly --

21           DR. WINKLER: Thank you, Elliot. So  
22 let's move onto our discussants. Again, this is

1 another outcome measure, so for evidence, we are  
2 just looking for, you know, the sort of  
3 actionability question.

4 And we got a team on this measure, and  
5 I don't know who wants to volunteer to comment,  
6 whether it's Diana, Juliet, Carolyn or Cindy, but  
7 who wants to go first?

8 MEMBER RAMOS: I'm going first.

9 DR. WINKLER: Go ahead.

10 MEMBER RAMOS: So I'm commenting on  
11 the evidence, and because this is a maintenance  
12 measure, and as Elliot explained, really looking  
13 at the evidence of the coding variation, there  
14 really is a support here that the evidence is  
15 here.

16 This really is a structure process  
17 activity that does influence the outcome. As he  
18 explained, we really are reframing the way that  
19 we are looking at our outcomes.

20 We're not just focusing on the good,  
21 but really focusing on the opportunities for  
22 improvement. And so that was the highlight from

1 our group, the recommendation for support.

2 DR. WINKLER: Comments from anybody  
3 else? Again, Sindhu?

4 MEMBER SRINIVAS: I think that this  
5 measure is really a great, a great opportunity to  
6 improve the, or reduce or eliminate adverse  
7 outcomes for term babies who come into the  
8 hospital "healthy."

9 Just as an anecdotal comment, we have  
10 been looking at like some version of this for the  
11 last couple of years at our hospital in  
12 Pennsylvania and have, you know, been able to  
13 dive into some particular opportunities that can  
14 improve care. And I've definitely seen  
15 significant improvement, even though the number  
16 is small. The number you could argue should be  
17 zero. So, even though we never like to put a  
18 specific bar on something, but I definitely think  
19 it's very much linked to opportunities for  
20 improvement that really relate directly to this  
21 outcome.

22 DR. WINKLER: Since this is a

1 maintenance measure and there really doesn't  
2 appear to be any, you know, new evidence, you all  
3 seem to be -- does anybody object if we just  
4 accept the prior meaning of this criteria and  
5 then move on to gap?

6 Seeing no objections -- Ah, there we  
7 go. Karen?

8 MEMBER SHEA: So I have one question  
9 about how we're defining a sick newborn here. Is  
10 it based on actual NICU admission with a revenue  
11 code or is it based on DRG and diagnosis code?

12 DR. MAIN: No, there is -- most states  
13 do not have an easy way to capture NICU  
14 admission. And, indeed, NICU admission is an  
15 ephemeral thing if you get right down to it  
16 because it means different things in different  
17 hospitals. So we looked at the diagnosis and  
18 procedure codes, so things like sepsis, things  
19 like seizures, so the whole spectrum of pretty  
20 serious conditions and then some moderate  
21 conditions that had length of stay modifiers on  
22 them.

1           So we did not look at revenue codes  
2 specifically for that use.

3           DR. WINKLER: Okay. If there are no  
4 objections to accepting the evidence as  
5 previously, then let's go on to the opportunity  
6 for improvement and looking at current data.

7           And, also, I will note that the  
8 workgroup asked Elliott for more recent data for  
9 this measure. And, indeed, if you go into your  
10 SharePoint folder for this measure, Elliott did  
11 send us additional data from 2013 and 2014, so it  
12 is available to you in your document set.

13           And so, with that, we can go back to  
14 our lead discussants, Diana, Juliet, Carolyn,  
15 Cindy. Who wants to go first?

16           Microphone, please.

17           MEMBER NEVINS: Before I make my  
18 comment on the gap I just wanted to second  
19 Sindhu's statements with respect to this measure.  
20 I was so excited to see it because, you know, we  
21 never focus on the healthy mom who walks into  
22 triage and leaves without a baby. So this was



1 very exciting to sort of delve into some of those  
2 variables that are happening on the labor floor.

3 But certainly, I mean I have not had  
4 a chance to look at the more recent data, but  
5 certainly just looking at 2012, there is  
6 certainly room to push some of these numbers  
7 closer to the ideal zero.

8 DR. WINKLER: All right.

9 MEMBER NEVINS: So I would say that  
10 there is definitely an opportunity to use this  
11 measure till we've made some more changes.

12 DR. WINKLER: Comments from anyone else  
13 on the committee about this measure?

14 Sarah?

15 MEMBER McNEIL: The ideal number might  
16 not be zero though; right? Because if, if I have  
17 a woman who comes in who has a shoulder dystocia  
18 and baby has a clavicular fracture, it might be  
19 appropriate that the baby has a clavicular  
20 fracture over worse outcomes. And I just worry  
21 that if the goal is zero, then we might be doing  
22 other interventions that would be worse to avoid,

1       you know, a 1 percent or 2 percent.

2                   MEMBER NEVINS: Well, certainly we have  
3       lots of measures and work flows in place to  
4       prevent shoulder dystocias and to sort of guide  
5       practitioners in terms of not going to maneuvers  
6       that would lead to a clavicular fracture.

7                   So, yes, I agree with you. But  
8       certainly we want to make sure that physicians  
9       are adhering to those policies with respect to  
10      either taking the person for a primary C-section  
11      or doing an induction. That issue is there. Or  
12      using a vacuum when you shouldn't use a vacuum,  
13      or using a vacuum inappropriately.

14                   So even in that sense, you know, it  
15      allows us to look at, you know, events that could  
16      have led up to that fracture.

17                   DR. MAIN: We're certainly not  
18      proposing that this be driven down to zero.  
19      Because as with most outcome measures, it's very  
20      hard to get anywhere near a zero rate.

21                   But there are some histograms in your  
22      packet that show that there is significant

1 variation among facilities, both Level 1, 2 and 3  
2 level. NICU-level facilities have significant  
3 variation.

4 One of the big sources of variation  
5 was how you handled neonatal sepsis, which is a  
6 big area now being evaluated. And some of the  
7 hospitals we've worked with have adjusted how  
8 they handle neonatal sepsis and have had much  
9 better neonatal outcomes because of that, being  
10 less aggressive in how they diagnose and treat  
11 it. So that's babies that are -- don't have a  
12 long course in the NICU, being separated by their  
13 mother and for other, other secondary effects as  
14 well.

15 Obstetrics is kind of a tricky  
16 business because you're weighing two things. If  
17 you push one way you're going to get something  
18 than another way, for example, for episiotomy  
19 versus C-section, or third and fourth degree  
20 lacerations versus C-section. Because if you  
21 have no third and fourth degree lacerations by  
22 doing a lot of C-sections and sort of vice versa.

1           So there's always that trying to find  
2           that middle ground. And this would be one, one  
3           of those type of measures.

4           DR. WINKLER: Okay. Sindhu, did you  
5           have another comment?

6           MEMBER SRINIVAS: I didn't mean to  
7           suggest earlier, because I think I am the one  
8           that sort of threw that out there about the  
9           trying to drive it down, but I do think that  
10          taking notice in your own hospital that you had a  
11          high, higher than expected rate of clavicular  
12          fractures on shoulder, that might suggest that,  
13          you know, you need some simulation or other  
14          things that help with improvement in the actual  
15          maneuvers and other things.

16          So definitely while you might not be  
17          able to eliminate them totally, there's certainly  
18          an opportunity for improvement. And this measure  
19          I think definitely helps with that.

20          DR. WINKLER: Okay. Mimi?

21          MEMBER SPALDING: Yeah. So the initial  
22          endorsement evaluation said that it doesn't

1 account for disadvantaged populations. And I  
2 know Reva mentioned that you have new data. I  
3 didn't see that anywhere. Is that --

4 DR. MAIN: There is race, race and  
5 ethnicity data showing modest differences, not  
6 huge differences, that African-American women do  
7 have slightly higher rates. But they're not  
8 nearly as high as infant mortality, neonatal  
9 mortality, and the term mortality for that matter  
10 are.

11 So this is being shown as the  
12 histogram of the distribution. There's a table  
13 in here as well that shows the race data. That's  
14 by level of care. I think here it is, and you  
15 can see African-American women are a little  
16 higher, but not as high as I might have expected  
17 given some of the other disadvantages they have.  
18 Most of the disadvantages I think with African-  
19 American women -- or African-American infants is  
20 in pre-term birth and low birth rate.

21 SGA infants or pre-existing condition  
22 are not in this, in this cohort.

1 DR. WINKLER: Any other comments from  
2 anybody on the committee or are we ready to vote  
3 on opportunity for improvement?

4 (No response.)

5 DR. WINKLER: Okay, let's go ahead and  
6 vote.

7 MS. ROBINSON-ECTOR: Voting is now open  
8 for performance gap for Measure 0716. One is  
9 high; two is moderate; three is low; and four is  
10 insufficient.

11 (Vote.)

12 MS. ROBINSON-ECTOR: So all the votes  
13 are in and voting is now closed. 67 percent  
14 voted high, 33 percent voted moderate, 0 voted  
15 low and 0 voted insufficient.

16 So for performance gap of Measure  
17 0716, the measure passes.

18 DR. WINKLER: Thank you.

19 All right, to our lead discussants,  
20 let's move on to reliability, which includes the  
21 specifications and testing for reliability.

22 Ladies, who wants to comment?

1                   MEMBER NEVINS: So I'll comment. And  
2 I have a -- well, I'll start by saying you  
3 already answered the question I had prepared with  
4 respect to the numerator. Because I looked at  
5 the descriptions and I thought to myself, well,  
6 that's pretty broad, you know, nerve injury. But  
7 you've already described the things that you've  
8 put in place to sort of counter that. Right?

9                   I do have a question, however, about  
10 the denominator. And given the list that's here,  
11 I just wanted to know specifically if gestational  
12 diabetics and hypertensive, pre-gestational or  
13 gestational hypertensive disease was left out of  
14 this inclusion list on purpose?

15                  DR. MAIN: They were not excluded on  
16 purpose, in that that is a source of potential  
17 new meta morbidities that is pretty wide -- it's  
18 some pretty common populations, 5, 6, 7 percent  
19 depending on your ethnic mix have gestational  
20 diabetes. So we did include those in the  
21 population that we're looking at.

22                  MEMBER NEVINS: So the reason I thought

1 of this and I asked this question, in my mind --  
2 and I'm going to try to be sure to articulate my  
3 question clearly -- you know, some of the outcome  
4 is not necessarily related to the work flow or  
5 maneuvers or the number of drills you have on the  
6 labor floor, but to the condition of the patient  
7 when she walks in the door.

8 And so, certainly, if you have someone  
9 who has gestational diabetes and gestational  
10 hypertension, at baseline they're already at risk  
11 for some of the outcomes that are -- that we're  
12 looking for.

13 DR. MAIN: We actually have done some  
14 serious attempts at further risk adjustment,  
15 looking at adjusting for hypertension, diabetes,  
16 birth weight, and a variety of other factors.

17 And found that the population that was at  
18 greatest risk was not gestational diabetics but  
19 really insulin pre-gestational diabetics, which  
20 is not very many. That is probably why the  
21 tertiary centers, or one of the contributors why  
22 the tertiary centers have slightly higher rates.



1           Though there is big variation within  
2           tertiary centers on this measure. It's really  
3           kind of interesting that they could learn from  
4           each other.

5           It's one of the most important uses of  
6           this measure though, I failed to mention earlier,  
7           is not so much saying you have a 5 percent, you  
8           have a 4 percent rate, you know, that makes you  
9           better or worse. It's following the hospital  
10          over time as we introduce other measures that are  
11          going to change obstetric practice, such as  
12          efforts to reduce cesarean rate.

13          The question every obstetrician has  
14          is, is that going to increase my rate of injured  
15          babies or dead babies in some way or the other?  
16          We need to have a measure to balance that out.  
17          So this is a balancing measure in many respects  
18          to other obstetric interventions.

19                 DR. WINKLER: Cindy, do you have a  
20                 comment?

21                 MEMBER PELLEGRINI: A question actually  
22                 for Dr. Main.

1 I really appreciated the new, the  
2 reliability testing that you provided that was  
3 hospital by hospital. And saw that you had  
4 recommended that this should be used, the measure  
5 should be used primarily by hospitals with more  
6 than 200 births.

7 And in the chart, I'm sure you know,  
8 there were a number of places, number of  
9 facilities where the reliability did drop below  
10 the benchmark of 0.7, and they tended to be the  
11 ones who had more than 200 births but like less  
12 than 500.

13 So I was curious about how you chose  
14 those, those cutoffs?

15 DR. MAIN: This is going back a ways.

16 I think that was based on a -- we  
17 considered 200 to 500 births as sort of a gray  
18 zone. Under 200 is clearly not a good place to  
19 be; there just aren't enough sample size for  
20 that. And 500 is barely there. But I think it  
21 still has value, particularly as you look at it  
22 over time within your facility.

1                   So we consider that a gray zone.

2                   DR. WINKLER: Okay. Any comments from  
3 anyone else before we vote on reliability? Or  
4 does everyone feel comfortable with this measure?  
5 It was previously endorsed. Do you feel  
6 comfortable enough to maybe object if we accept  
7 the prior evaluation of meeting the reliability  
8 criterion?

9                   No objections?

10                   (No response.)

11                   DR. WINKLER: Okay. Let's talk about  
12 validity.

13                   MEMBER NEVINS: I didn't have any  
14 additional questions or concerns with respect to  
15 validity. I mean certainly, you know, what  
16 they're testing does show I would say causation,  
17 if not association, with the outcomes that we're  
18 looking for.

19                   DR. WINKLER: Okay. Comments from  
20 anyone else?

21                   I mean this is new testing that we did  
22 not see before that is testing the validity of

1 the measure's score. So we will vote on this one  
2 because it is new data.

3 Any further comment? Carolyn, you're  
4 looking --

5 MEMBER WESTHOFF: Only that it's  
6 exactly I think the sort of data that I would  
7 hope to see because there's clearly a lot of  
8 attention to the performance, the statistical  
9 performance and the performance of the data over  
10 time and the flipping it, and adding the birth  
11 certificate data to make sure they are term  
12 infants and so on.

13 So I was -- I would love to see this  
14 much detail and attention for any of the measures  
15 with their, you know, experience over several  
16 years of use. That was very encouraging.

17 DR. WINKLER: Nancy, did you have  
18 comments?

19 MEMBER LOWE: Elliott, I just had a  
20 real minor question.

21 Is PROM controlled for?

22 DR. MAIN: I'm sorry, premature rupture

1 of membranes?

2 MEMBER LOWE: Yeah, yeah. In the  
3 sepsis.

4 DR. MAIN: No.

5 MEMBER LOWE: Okay.

6 DR. WINKLER: Any other comments? Oh,  
7 there you are. Thank you.

8 MEMBER RAMOS: Yes, I just wanted to  
9 remind us, and just picking up on someone else's  
10 comment about the hospitals with the low number  
11 of births and so the validity could really be  
12 skewed depending upon, you know, the outcomes.  
13 Because they have a low number of births, then  
14 they may not be so adept at dealing with the  
15 complications.

16 And so that's just something to keep  
17 in mind. And, unfortunately, there's nothing  
18 that we can really do to control but it's good to  
19 get the data so that we can then act on, on those  
20 initiatives.

21 DR. MAIN: We're encouraged that it did  
22 well for hospitals over 500 births, 500 to 1,000,

1 because that's a lot of facilities. In very  
2 small facilities we look at this as a case  
3 finding tool rather than a measure, that all  
4 these cases should be drilled down to in those  
5 settings.

6 DR. WINKLER: Okay. Any other comments  
7 from anybody on validity?

8 (No response.)

9 DR. WINKLER: So let's go ahead and  
10 vote.

11 MS. ROBINSON-ECTOR: Voting is now open  
12 for validity of Measure 0716. One is high; two  
13 is moderate; three is low; and four is  
14 insufficient.

15 (Vote.)

16 MS. ROBINSON-ECTOR: It looks like we  
17 are missing one vote.

18 (Vote.)

19 MS. ROBINSON-ECTOR: Great; thank you.

20 All the votes are in and voting is now  
21 closed. 72 percent voted high; 28 percent voted  
22 moderate; 0 voted low; and 0 voted insufficient.

1           So for validity, Measure 0716 passes.

2           DR. WINKLER: Okay. Our next criteria  
3 is feasibility. Again, for our lead discussants,  
4 your thoughts on feasibility?

5           MEMBER WESTHOFF: It is impressive to  
6 me how complicated it is to define the numerators  
7 and define the denominators over time. And I  
8 think the developer has presented really, you  
9 know, detailed information over time  
10 substantiating the feasibility.

11          DR. WINKLER: Okay. Thoughts from  
12 anyone else? Are you ready to vote on  
13 feasibility?

14          Oh, question. Sarah?

15          MEMBER McNEIL: I just have a quick  
16 question.

17          I work in a small county hospital.  
18 How does this actually get instituted at a place?  
19 Like is it -- yeah, maybe I don't know if that's  
20 relevant, but.

21          DR. MAIN: It was designed to really be  
22 developed by someone who has the state data sets

1       rather than a hospital themselves. I think you can  
2       use some of the markers to case finding. But in  
3       terms of it -- the struggle here and the reason  
4       for the complexity is we were trying to make it  
5       as perfect as we could, which sometimes perfect  
6       is the enemy of. But if you're comparing good  
7       baby outcomes you want to be, you know, as close  
8       to possible, because it's certainly very sad of  
9       course if you include cases you shouldn't have.

10                So, you know, it is with this big  
11       state data set that makes it easiest to do.

12                DR. WINKLER: Elliott, you might just  
13       mention --

14                DR. MAIN: So then reduces, there's no  
15       burden when you do it that way.

16                DR. WINKLER: Yes. Elliott, you might  
17       mention, I got a red -- I know you're certainly  
18       working on this in California. Are any other  
19       states using this measure?

20                DR. MAIN: NPIC is using it for all its  
21       hospitals as well, which is another I think  
22       380,000 births. The others have 500,000 births a



1 year.

2 DR. WINKLER: Okay, great.

3 MEMBER GOYERT: We have used this for  
4 the last five years linked up with Kim's and your  
5 ideal delivery rate, for the last five years, and  
6 found it to be really quite helpful across a four  
7 obstetric site system in Southeastern Michigan.

8 The only negative that I would have  
9 is, you know, it's a lot easier to go to the  
10 Board of Trustees with a 95, 96, 97 percent good  
11 stuff, instead of red marks again. So I was kind  
12 of disappointed to see it brought back. But it's  
13 not that hard to set up if you have some  
14 dedicated help.

15 DR. WINKLER: Okay. We can go ahead  
16 and vote on feasibility.

17 MS. ROBINSON-ECTOR: Voting for  
18 feasibility for Measure 0716 is now open. One is  
19 high; two is moderate; three is low; and four is  
20 insufficient.

21 (Vote.)

22 MS. ROBINSON-ECTOR: Voting is now

1 closed. 67 percent voted high; 33 percent voted  
2 moderate; 0 voted low; and 0 voted insufficient.

3 So for feasibility, Measure 0716  
4 passes.

5 DR. WINKLER: Okay. Moving on to the  
6 last criteria, usability and use. I mean a lot  
7 of the conversation we've had has been -- does  
8 address usability and use. But for our lead  
9 discussants, could you just make any last  
10 comments perhaps?

11 MEMBER NEVINS: Certainly the addition  
12 of the birth certificate data allows for more  
13 accuracy with respect to the collection. But I  
14 think overall this would be usable.

15 I mean I do worry about, you know,  
16 hospitals or hospital systems that are not as  
17 efficient in terms of their electronic medical  
18 records. But, you know, overall I would say that  
19 this is certainly usable.

20 DR. WINKLER: Comments from anyone  
21 else? Cindy?

22 MEMBER PELLEGRINI: It's been good to

1 see that this has been used more. As the  
2 document states here, it was originally only used  
3 in California. Has now been used in Washington,  
4 Oregon, Alaska, Montana, et cetera.

5 And I think this would be attractive  
6 for increasing use, partly because of the  
7 reframing, that this is I think now framed to the  
8 way that's even more kind of consumer-friendly in  
9 that it addresses that issue of the otherwise --  
10 the woman who goes in thinking she's healthy and  
11 her baby is healthy and then ends up having a  
12 very different outcome, which is something we, we  
13 all want to prevent.

14 DR. WINKLER: Any other comments?

15 (No response.)

16 DR. WINKLER: All right, should we go  
17 ahead and vote for usability and use?

18 MS. ROBINSON-ECTOR: Voting is now open  
19 for usability and use for Measure 0716.

20 (Vote.)

21 MS. ROBINSON-ECTOR: All the votes are  
22 in and voting is now closed. 84 percent voted

1 high; 16 percent voted moderate; 0 voted low; and  
2 0 voted insufficient.

3 So for usability and use, Measure 0716  
4 passes.

5 DR. WINKLER: Okay. Any last comments  
6 before we do the overall vote on suitability for  
7 continued endorsement?

8 (No response.)

9 DR. WINKLER: I don't see any, so let's  
10 go ahead and vote.

11 MS. ROBINSON-ECTOR: Voting is now open  
12 for recommendation for continued overall  
13 suitability for endorsement of Measure 0716. One  
14 is yes; and two is no.

15 (Vote.)

16 MS. ROBINSON-ECTOR: All the votes are  
17 in and voting is now closed. And 100 percent  
18 voted yes; and 0 voted no.

19 So for recommendation for continued  
20 endorsement, Measure 0716 passes.

21 DR. WINKLER: Okay. I will turn it  
22 back over to Carol I think. Our next measure is

1 Measure 0470: Incidence of Episiotomy.

2 I know Janet Muri is on the line.

3 And, Matt, are you here? There you go. Good. I  
4 see Matt every three years to tell us about  
5 episiotomy.

6 DR. HOFFMAN: So I'm Matt Hoffman. I'm  
7 the Chair of OB/GYN at Christiana Care in concert  
8 with NPIC. We developed the episiotomy measure.

9 As mentioned, this is a maintenance  
10 measure. Episiotomy has long been known a cause  
11 of pain, infection, bleeding, as well as third  
12 and fourth degree lacerations. So with that in  
13 mind, it was intended as an over-use measure.

14 Since the last time that we have met  
15 with have done the crosswalk with ICD-10. We  
16 have also looked at data internally within NPIC.  
17 And although the general trend has been to lower  
18 rates of episiotomy, what one sees is continued,  
19 even tenfold variation between hospital systems.

20 And so with that I'll stop.

21 CO-CHAIR SAKALA: Thank you.

22 So our discussants are Nancy and

1 Jennifer. And we'll begin with Nancy.

2 MEMBER LOWE: In terms of the evidence,  
3 this is a measure that was originally endorsed in  
4 2008. And it's a process measure. It was re-  
5 endorsed in 2012. And the developer has attested  
6 that the underlying evidence has not changed  
7 since the last endorsement review. The last  
8 Cochrane Review indeed is 2009, which was cited.  
9 And I verified that. And the ACOG related  
10 bulletin is 2006.

11 There were restricted use of  
12 episiotomy is directly linked to lower rates of  
13 perinatal injury. And I validated that there is  
14 no new evidence for a revised Cochrane Review on  
15 the topic. So I think we're set.

16 CO-CHAIR SAKALA: Great. Any  
17 objections to not voting for evidence and going  
18 with the previous evidence?

19 (No response.)

20 CO-CHAIR SAKALA: Okay. So next would  
21 be opportunity for improvement.

22 MEMBER LOWE: Shoot. I'm missing my

1 thing that I so carefully filled out, I've lost  
2 my way.

3 MEMBER BAILIT: I'll hum a few bars  
4 while she looks for her song.

5 MEMBER LOWE: I don't know where I was.

6 MEMBER BAILIT: So I think the bottom  
7 line here is that there is still great variation.  
8 And whether it's generational, whether it's  
9 training, but there is still great variation  
10 between hospitals. We think that there is still  
11 room for improvement here.

12 MEMBER LOWE: Yes. And as I remember  
13 from the data, there was roughly a 33 percent  
14 overall decline. But the issue is this  
15 tremendous variation from institution to  
16 institution which remains persistent and is, I  
17 think is as high as 20 percent variation from  
18 institution to institution, as recall.

19 DR. HOFFMAN: Yeah, that is correct as  
20 stated. You know, there has been a significant  
21 trend line down with this measure, fortunately,  
22 which reflects modernization of practices, using

1 best practice. Nonetheless, if one looks at  
2 institutions there's tremendous variation between  
3 center to center.

4 CO-CHAIR SAKALA: Great. So we will  
5 need to vote on this because of the changes in  
6 practice. And I think there are no other  
7 comments on opportunity for improvement.

8 So could we open the voting, please?

9 MS. ROBINSON-ECTOR: Voting is now open  
10 for measure performance gap for Measure 0470.  
11 One is high; two is moderate; three is low; and  
12 four is insufficient.

13 (Vote.)

14 MS. ROBINSON-ECTOR: So we have all of  
15 the votes. 83 percent voted high; 17 percent  
16 voted moderate; 0 voted low; and 0 voted  
17 insufficient.

18 So for Measure 0470, measure passes on  
19 performance gap.

20 CO-CHAIR SAKALA: Thank you.

21 Now reliability, please. And we do  
22 not need to re-vote if there is no new -- there



1 are no new data on reliability testing.

2 Anybody have any objection to that?

3 Yeah. And the specs haven't changed Reva says.

4 Okay, so -- Oh, Cindy. Yes?

5 MEMBER PELLEGRINI: I actually have one  
6 question. We were saying over here that despite  
7 sort of the decline, I'm actually surprised, a  
8 little bit surprised that there's still so much  
9 variation in the practice. And so is there -- do  
10 you have any data on sort of the percentage of  
11 these cases, of episiotomy that are happening in  
12 the setting of an operative delivery or some  
13 other sort of reason that even though there's a  
14 decline that there's still kind of so much  
15 variation?

16 Because we know that from our risk  
17 stratification, which I think we know we're not  
18 controlling for different confounders, that may  
19 be certain hospitals have higher operative  
20 delivery rates, maybe that's one of the driving -  
21 - not that that's an excuse. I'm just more  
22 asking for an explanation because I'm surprised.

1 DR. HOFFMAN: I'm equally as  
2 unenlightened as you on this question.

3 CO-CHAIR SAKALA: Deb?

4 MEMBER KILDAY: There we go. I visit  
5 hundreds and hundreds of hospitals in helping  
6 them with their quality improvement. And this  
7 was one of the easiest measures for me to go to  
8 hospitals and work directly with providers. And  
9 the variation is incredible when you walk into a  
10 hospital from providers understanding the  
11 practice standpoint.

12 So when I do an assessment, I  
13 literally watch the deliveries happen. And you  
14 would be floored at how I could go within one  
15 system, one hospital would operate and one weigh-  
16 based on provider presence and practice, and  
17 you'll go and within the same system it will be  
18 completely different.

19 So there is tremendous opportunity for  
20 improvement with this measure. I personally love  
21 working with it because having witnessed within  
22 our hospitals the amazing amount of decrease in

1 third and fourth degree lacerations,  
2 notwithstanding the pain and harm, I personally  
3 am very encouraged by this measure. And I love  
4 it. It's endorsable, it's easy, and there is  
5 variation, and it's provider generally.

6 CO-CHAIR SAKALA: Thank you.

7 Tracy?

8 MEMBER FLANAGAN: So when we started  
9 working on this we had to get down to the  
10 provider level. And we actually published  
11 provider-level data. Because this is one of the  
12 few measures where you actually can really make a  
13 difference when you use provider levels.

14 We had one hospital that had very high  
15 rates. We brought it down in three months,  
16 literally that fast.

17 In answer to your question about  
18 instrumented deliveries, we actually have a  
19 pretty high rate of instrumented deliveries. We  
20 also have a high rate of third and fourth degree  
21 relative to other statistics. So we have low  
22 episiotomy, high third and fourth degree, higher

1 than the average of vacuum, and then also low C-  
2 sections. So they do all kind of go together.

3 But in answer to your question about  
4 episiotomy being done for vacuum, no. That, they  
5 don't have to travel together.

6 CO-CHAIR SAKALA: Yes. Amy?

7 MEMBER BELL: I personally like this  
8 measure as well. And I think we have a huge  
9 opportunity to make a difference in the health of  
10 our moms.

11 Question though for the group: is  
12 there chance that this could be a Joint  
13 Commission measure where it could be publicly  
14 reported as a mandatory public reporting measure?  
15 And I think if that happened we will really see  
16 performance improve, hopefully within our  
17 lifetime.

18 DR. WINKLER: Again, as I mentioned  
19 earlier, the adoption measures is, tends to be  
20 determined by whoever is doing the  
21 implementation. So certainly this measure has  
22 been out there.

1 I will mention, and I was just going  
2 to go to Matt who is reaching for his card, to  
3 tell us a little bit about how this is being used  
4 with Leapfrog.

5 MEMBER AUSTIN: So as I mentioned  
6 earlier, I have a contract with The Leapfrog  
7 Group to provide them with guidance around  
8 measurement. And so this is actually a measure  
9 The Leapfrog Group has been using I think now for  
10 probably five years. It has been publicly  
11 reporting hospital performance.

12 I think there's close to a thousand  
13 hospitals that report on this measure. And to  
14 reflect what others have said, we see significant  
15 variation across hospitals.

16 I can think of one hospital in  
17 particular that called and they had a rate up in  
18 the 30 percent range and were convinced that all  
19 the other hospitals were being untruthful, that  
20 they carried -- cared for much more significant  
21 high risk patients than other hospitals across  
22 the country, even though some of the biggest

1 birthing centers have rates in the 1 percent, 2  
2 percent range.

3 So it's been, it's been useful. There  
4 are data that are out there. I think Leapfrog  
5 would be happy to share those data. So let me  
6 know if that somehow would be helpful or useful.

7 CO-CHAIR SAKALA: Thank you.

8 Sindhu, are you up again with the  
9 card? No. Okay.

10 Tracy, Nancy, I think we're probably  
11 good here. Yeah, so if there's no objection,  
12 we'll accept the previous reliability measure.

13 And can we do validity as well? Any  
14 comments on validity before we?

15 (No response.)

16 All right, so moving on to  
17 feasibility. Comments from the field or based on  
18 what you saw in the documentation?

19 MEMBER BAILIT: you said because this  
20 is a procedure they're easily coded, very easily  
21 detectable. It's binary. There's no sort of you  
22 did half an episiotomy. So it's very

1 straightforward in terms of feasibility and use.  
2 It's in the discharge sets, and it's in the  
3 administrative data sets. So it's fairly  
4 straightforward.

5 DR. HOFFMAN: The ICD-10 led some  
6 clarity here, too. So there were some coding  
7 issues in the past, but ICD-10 has eliminated  
8 those.

9 CO-CHAIR SAKALA: Good to know.

10 Any other comments on feasibility?

11 (No response.)

12 CO-CHAIR SAKALA: Okay. I think we  
13 need to vote on this one. So could we open the  
14 vote, please, for episiotomy feasibility?

15 MS. ROBINSON-ECTOR: Voting for  
16 feasibility of Measure 0470 is now open.

17 (Vote.)

18 MS. ROBINSON-ECTOR: All the votes are  
19 in and voting is now closed. 96 percent voted  
20 high; 4 percent voted moderate; 0 voted low; and  
21 0 voted insufficient.

22 So for feasibility of Measure 0470,

1 the measure passes.

2 CO-CHAIR SAKALA: Thank you.

3 So the last criteria area is usability  
4 and use. Do we have comments on how it's working  
5 for accountability and quality improvement?

6 Greg?

7 MEMBER GOYERT: We've used a variation  
8 on it, very similar to this measure, the last two  
9 or three years. And it's very easy when you have  
10 outliers.

11 And I would echo what everybody else  
12 has said, our X is three to four X within a unit  
13 across units, things like that. And at the  
14 request of the various CMOs across the system  
15 they say sit down with those guys and win them.  
16 And you just say, here's the average. Here's the  
17 average for your hospital. Here's you. And  
18 here's the ACOG episiotomy practice bulletin  
19 evidence, too.

20 That follow chart, they swear at me  
21 and they slash my tires, but it, it works.

22 (Laughter.)



1 DR. HOFFMAN: I had a very similar  
2 speech and very similar tires.

3 (Laughter.)

4 CO-CHAIR SAKALA: Thank you. So that's  
5 the power story.

6 Who's got a comment?

7 MEMBER LOWE: Yes. I just have a  
8 comment in response to Greg's comment. And that  
9 is one of the things that does concern me is who  
10 actually helps those providers learn how to  
11 attend birth without cutting?

12 MEMBER GOYERT: "Greg, it's the way  
13 I've always done it."

14 "Well, stop doing it."

15 I mean it's just an ingrained, we all  
16 know it's just an ingrained practice. Got to get  
17 there and cut the episiotomy before the baby  
18 falls out, you know. No, you don't need to do  
19 that.

20 And it's a process of education and  
21 saying this is contemporary practice, what you  
22 were doing before isn't. Doesn't make you a bad

1 person. It really has to be peer to peer; that's  
2 what works.

3 MEMBER NEVINS: So, if I may.

4 CO-CHAIR SAKALA: Juliet.

5 MEMBER NEVINS: Just a very brief  
6 comment. You know, I was curious as to whether  
7 the variation could be matched with the average  
8 age of the provider in different -- no, you know,  
9 I'm a young doctor. Sorry.

10 (Laughter.)

11 But I, and also whether or not, if  
12 we're talking about an academic institution, if  
13 it's one where residents have access to  
14 urogynecologists. Because they really counter,  
15 you know, the cutting of the episiotomy when they  
16 bring you into the OR and they make you repair,  
17 you know, a perineum that's, you know, gone to  
18 hell.

19 But don't record that.

20 But, you know, those two factors, I  
21 just wondered if, if we could measure that, if  
22 that would help us kind of figure out, you know,

1 where the variation is coming from. Education  
2 and just sort of a realization of what will  
3 happen to this woman's body, you know, 10, 20  
4 years down the line. And certainly kind of re-  
5 training people who have older methods of doing  
6 the delivery.

7 CO-CHAIR SAKALA: Deb.

8 MEMBER KILDAY: I just want to comment,  
9 I have no statistical sort of basis for backing  
10 this up, but again having worked with hundreds  
11 and hundreds of providers and hospitals, you'd be  
12 amazed at the age range. I would say the  
13 preponderance may be in that bucket of being a  
14 little older. But there are a wide number of  
15 younger physicians who have been taught to  
16 practice that way. And then they begin to  
17 practice in environments that are similar.

18 And I find myself really educating  
19 physicians and teams of all ages.

20 CO-CHAIR SAKALA: Thank you.

21 Diana?

22 MEMBER RAMOS: Yes. You know, along

1 the lines of Dr. Nevins and looking at what's  
2 happening in your hospitals, also looking to see  
3 how many -- and I would be curious -- providers,  
4 M.D.s work with the midwives. Because oftentimes  
5 there's a big influence in the midwives and the  
6 providers. And it is surely a see one, do one,  
7 teach one.

8 And, you know, I've walked in and with  
9 a midwife and I go, What are you doing? You  
10 know, I'm just learning from her. And so that  
11 would be something that just see if there was an  
12 influence there in the rates of episiotomy.

13 CO-CHAIR SAKALA: Thank you.

14 Naomi?

15 MEMBER SCHAPIRO: My granddaughter was  
16 born this summer in a Kaiser hospital. And  
17 although there was no midwife on duty during the  
18 time my daughter was in active labor, you know, I  
19 walk in to find this whole team of OB/GYN folks  
20 massaging her perineum all along. I thought, Oh  
21 my God, what happened? And, you know, hadn't  
22 done an episiotomy but they were like constantly

1 massaging her perineum. Okay.

2 And I think that was actually from  
3 having midwives helping in the training. But it  
4 was so wonderful to see, so. Varying ages, so I  
5 think it can be done.

6 CO-CHAIR SAKALA: Thank you.

7 So, Tracy, and then maybe we can move  
8 on with our voting.

9 MEMBER FLANAGAN: I'm certainly into  
10 this measure. I have to say, I wish we had seen  
11 our third and fourth degree rates go down as a  
12 result of this. You know, we're pretty much zero  
13 episiotomy. Because that was actually the intent  
14 of this measure is to reduce third and fourth  
15 degree lacerations, and we have not.

16 I know that's what the data says based  
17 on the '80s study. But we don't know whether our  
18 high rate is due to coding or more willingness to  
19 code, whether there's, you know, the third and  
20 fourth -- we won't go there here because I think  
21 everybody in this room knows the issue of the  
22 third and fourth degree measures. But I wish we

1 had seen a difference.

2 CO-CHAIR SAKALA: Thank you.

3 Okay, Juliet, last comment?

4 MEMBER NEVINS: I just wanted to sort  
5 of add to that in the sense that I think there  
6 are other variables with respect to the third and  
7 fourth degree lacerations, like the size of the  
8 baby. And because everyone is now afraid to do a  
9 C-section because they're going to get dinged;  
10 right? There's certainly more operative vaginal  
11 deliveries that lead to these kind of injuries.

12 CO-CHAIR SAKALA: Thank you.

13 Okay, could we vote, please on  
14 usability and use for the episiotomy measure.

15 MS. ROBINSON-ECTOR: Voting is now open  
16 for usability and use of Measure 0470.

17 (Vote.)

18 MS. ROBINSON-ECTOR: All the votes are  
19 in and the voting is now closed. 93 percent  
20 voted high; 7 percent voted moderate; 0 voted  
21 low; and 0 voted insufficient.

22 So for usability and use, Measure 0470

1 passes.

2 CO-CHAIR SAKALA: Thank you. And I  
3 think I'm going to just decide in the interests  
4 of time that we have pretty good consensus, and  
5 there have been few, if any, outlier comments, so  
6 can we move to the overall voting for whether we  
7 are going to recommend -- I'm sorry, did you?

8 PARTICIPANT: No, no.

9 CO-CHAIR SAKALA: Oh, okay. Whether we  
10 recommend that NQF endorse, continue the  
11 endorsement of this measure.

12 MS. ROBINSON-ECTOR: Voting is now open  
13 for recommendation of overall suitability for a  
14 continued endorsement of Measure 0470.

15 (Vote.)

16 MS. ROBINSON-ECTOR: Looks like all the  
17 votes are in and voting is now closed. 100  
18 percent voted yes; and 0 voted no.

19 So for --

20 CO-CHAIR SAKALA: Great.

21 MS. ROBINSON-ECTOR: -- recommendation  
22 for overall endorsement for Measure 0470, the

1 measure passes.

2 CO-CHAIR SAKALA: So lunch wasn't too  
3 far back. Are we okay with doing this last  
4 measure before we take a break? Yes, promise.

5 Okay, so do we have someone from CDC  
6 for the Hepatitis B vaccine measure?

7 MS. ROBINSON-ECTOR: I think they're on  
8 the line.

9 DR. SCHILLIE: Yes. This is Sarah  
10 Schillie from CDC.

11 CO-CHAIR SAKALA: Okay, thank you,  
12 Sarah.

13 So we're going to move to 0475, no  
14 recusals, and we do have three discussants:  
15 Karen, Diana J. and Kim after we hear from CDC.  
16 Thank you.

17 DR. SCHILLIE: So this is for  
18 maintenance of Measure 0475, Hepatitis B  
19 vaccination before hospital discharge.

20 There's considerable room for  
21 improvement still in the rates of newborn  
22 Hepatitis B coverage. For example, the most



1 recent data showed about 72 percent of newborns  
2 received the Hepatitis B vaccine before hospital  
3 discharge. And it's universally recommended.

4 There is an enormous amount of  
5 evidence pointing to the efficacy of Hepatitis B  
6 vaccine, and also related to that, to the  
7 prevention of Hepatitis B infection. About 90  
8 percent of infants who are infected perinatally  
9 with Hepatitis B virus will develop chronic  
10 infections, which carries about a 25 percent risk  
11 for premature death from liver failure or liver  
12 cancer.

13 One thing we are asking with this  
14 measure is in the past, parent refusals were  
15 excluded from the denominator. But when you look  
16 at some of our data there is a huge amount of  
17 variation in parent refusals.

18 For example, there are some hospitals  
19 that for their NQF measure report well over a 90  
20 percent newborn Hepatitis B vaccine coverage  
21 rate. But when you look at it a little more  
22 closely, for example, some of these hospitals

1 have over half, over 50 percent of parents  
2 refusing. So in actuality the rate might only be  
3 40 percent or something.

4 Whereas other hospitals have  
5 essentially no parent refusals.

6 So we were wondering if NQF could  
7 consider removing the exclusion for parent  
8 refusals from the denominator.

9 DR. WINKLER: Yes, essentially what we  
10 can do is consider this as a revision to the  
11 measure that Sarah has presented to us by  
12 removing that exclusion. As part of the  
13 maintenance update, that's how they want to  
14 change the measure. And that can be the way you  
15 can approach it and discuss it.

16 CO-CHAIR SAKALA: Thank you. Are you  
17 finished with your introduction, Sarah?

18 DR. SCHILLIE: Yes.

19 CO-CHAIR SAKALA: Great. So can we  
20 have our discussants comment on the evidence?

21 MEMBER SHEA: So thank you, Sarah, for  
22 your introduction to the measure. So, again,

1 this is a revision of the maintenance measure.  
2 And data is collected through electronic means,  
3 through paper medical records. And should we  
4 just move on to the importance of the measure?

5 CO-CHAIR SAKALA: If there is no  
6 objection, we can do that.

7 (No response.)

8 CO-CHAIR SAKALA: Okay. So importance  
9 of the measure.

10 MEMBER SHEA: So the measure, it's an  
11 important measure and it's shown to have high  
12 validity and that infants who receive the  
13 medication have a lower incidence of contracting  
14 Hepatitis B after delivery and have better  
15 outcomes.

16 And there were four systematic reviews  
17 that agreed and demonstrated that Hepatitis B  
18 vaccine administered shortly after, effectively  
19 prevents Hepatitis B transmission.

20 And I wonder if there's any further  
21 discussion on this? I think that the major issue  
22 for discussion is the exclusion that's being

1 presented, and that should we exclude from this  
2 measure parental refusal?

3 CO-CHAIR SAKALA: So given the changes  
4 in use of the measure, we need to vote on  
5 opportunity for improvement, or changes in  
6 performance.

7 Any -- Yes, sorry.

8 MEMBER OWENS-COLLINS: I'm concerned  
9 about the exclusion when the parent refused  
10 because in the nursery you don't have much  
11 recourse when they do. It, you know, depends on  
12 how hard you want to fight. And depending on  
13 where you're located that can be a large number.

14 And so it's a factor that, you know,  
15 may not be as much under our control so,  
16 therefore, it may not be as much of a measure of  
17 access or quality. Because that can be a large  
18 factor, the parental refusal.

19 MEMBER SHEA: I believe what we've seen  
20 in the data, though, is that the reliability of  
21 the measure is improved when parental refusal is  
22 excluded from the exclusion criteria.

1 CO-CHAIR SAKALA: Diana?

2 MEMBER JOLLES: I think that this issue  
3 of preference-sensitive variables continues to  
4 come up. And I like the way Cindy put it in one  
5 of the previous measures in that you may be  
6 working with a population, let's say you're  
7 serving Mennonite or Amish people who chose not  
8 to vaccinate, and so your rates will affect --  
9 and I'm making an assumption there. I've not  
10 worked with the population. But, sure, you may  
11 have a different performance on that. But it's  
12 your signal to evaluate what's happening.

13 And the fact is that research shows  
14 that providers drive preferences when it comes to  
15 measurement of quality outcomes more than  
16 patients are driving preferences. So among the  
17 same population you'll see Hepatitis B  
18 vaccination uptake. The variability and  
19 performance isn't related to preferencing, it's  
20 related to our lack of shared decision making and  
21 our lack of effective communication.

22 So I'm in favor of the new exclusion.

1 Yeah, the decision to exclude.

2 CO-CHAIR SAKALA: Kim, did you want to?

3 Okay.

4 Jaleel?

5 MEMBER MAMBARAMBATH: I'm in favor of  
6 taking out the exclusion. But I also wanted to  
7 mention that it is not only the reason for not --  
8 not consenting for the vaccine in the hospital is  
9 sometimes that the parents want the vaccination  
10 to be done by the pediatrician.

11 So it is not only because of not  
12 consenting.

13 CO-CHAIR SAKALA: Thank you.

14 DR. SCHILLIE: This is Sarah from CDC.  
15 If I may, we've actually heard anecdotal evidence  
16 of, for example, pediatric care providers  
17 encouraging the mothers to decline Hepatitis B  
18 vaccine in the hospital so that it can be given  
19 in the pediatric care provider's office shortly  
20 after birth. And in that way the pediatric care  
21 provider can bill for that vaccination.

22 CO-CHAIR SAKALA: Thank you.

1 Other comments before we vote on  
2 opportunity for improvement?

3 (No response.)

4 CO-CHAIR SAKALA: Okay. Can we open  
5 the voting, please?

6 MS. ROBINSON-ECTOR: Voting is now open  
7 for performance gap for Measure 0475. One is  
8 high; two is moderate; three is low; and four is  
9 insufficient.

10 MS. ROBINSON-ECTOR: Great. All the  
11 votes are in and voting is now closed. 69  
12 percent voted high; 31 percent voted moderate; 0  
13 voted low; and 0 voted insufficient.

14 So for performance gap for Measure  
15 0475, the measure passes.

16 CO-CHAIR SAKALA: Okay. So since we  
17 have a little bit of an important change in the  
18 specifications, we will be voting on reliability  
19 for this maintenance measure. And opening it up  
20 for comments from discussants and others.

21 Jennifer?

22 MEMBER BAILIT: I think this improves

1 the reliability. I think documenting refusals is  
2 a little shaky, but yes/no is much simpler.

3 CO-CHAIR SAKALA: Kim?

4 CO-CHAIR GREGORY: I was going to agree  
5 with that and make sure that everyone understood  
6 that it was a facility-level measure and that  
7 most of this would be done by either electronic  
8 data or pharmacy.

9 CO-CHAIR SAKALA: Okay, Diana, are you  
10 up again? Okay.

11 If there are no other comments, we can  
12 open it up for voting on reliability.

13 MS. ROBINSON-ECTOR: Voting is now open  
14 for reliability of Measure 0475. One is high;  
15 two is moderate; three is low; and four is  
16 insufficient.

17 (Vote.)

18 MS. ROBINSON-ECTOR: All the votes are  
19 in and voting is now closed. 96 percent voted  
20 high; 4 percent voted moderate; 0 voted low; and  
21 0 voted insufficient.

22 So for reliability of Measure 0475,



1 the measure passes.

2 CO-CHAIR SAKALA: Thank you.

3 So moving on to validity, this is a  
4 maintenance measure. So is there new testing  
5 data? And if not, do we need to do anything  
6 relative to the past reports of the validity of  
7 this measure?

8 DR. WINKLER: There was no new testing.

9 MEMBER SHEA: So I believe that the  
10 developers did test the measure using the  
11 exclusion and found that it had high, very high  
12 reliability with the exclusions.

13 CO-CHAIR SAKALA: Any other comments on  
14 validity?

15 (Off-microphone comment.)

16 CO-CHAIR SAKALA: We can do that.

17 PARTICIPANT: We're not voting on new  
18 data.

19 MEMBER AUSTIN: Because they didn't re-  
20 specify it?

21 DR. WINKLER: I believe the original  
22 testing was at the data element which removing

1 the data element really doesn't change the  
2 results of the prior validity testing. And also  
3 -- oh, wait a minute, this stays validity only.  
4 Sorry. I'm thinking of a different measure.

5 It's your call.

6 CO-CHAIR SAKALA: Does anyone object if  
7 we do not vote for validity testing again?

8 (No response.)

9 CO-CHAIR SAKALA: Thank you.

10 Okay. So moving on to feasibility.

11 Any other? We've had some comments from the  
12 field about how this is working. Comments from  
13 discussants or others at this point in time?

14 Kim?

15 CO-CHAIR GREGORY: I just think that  
16 it's sort of important that with the exclusion  
17 being removed that we understand that we're not  
18 going to get to 100 percent, and that that's  
19 okay. But try to get as close as we can.

20 CO-CHAIR SAKALA: Sarah, do you have  
21 any comments on that, the issue of benchmarking  
22 here and what you --

1 DR. SCHILLIE: Oh.

2 CO-CHAIR SAKALA: -- would be  
3 communicating?

4 DR. SCHILLIE: No. I mean, you know,  
5 certainly we, like someone just said, we can't  
6 expect to get to 100 percent. But, you know, the  
7 higher, the better.

8 Certain hospitals that we looked at  
9 had, you know, well into the 90s with no, with no  
10 parent refusal. So I think it's completely  
11 realistic to get into the 90s.

12 CO-CHAIR SAKALA: Thank you.

13 Other comments anyone wishes to make  
14 on feasibility?

15 (No response.)

16 CO-CHAIR SAKALA: If not, we can open  
17 it up for a vote.

18 MS. ROBINSON-ECTOR: Voting is now open  
19 for feasibility of Measure 0475. One is high;  
20 two is moderate; three is low; and four is  
21 insufficient.

22 We have two outstanding votes.

1 (Vote.)

2 MS. ROBINSON-ECTOR: Great. All the  
3 votes are in and voting is now closed. 74  
4 percent voted high; 26 percent voted moderate; 0  
5 voted low; and 0 voted insufficient.

6 So for feasibility of Measure 0475,  
7 the measure passes.

8 CO-CHAIR SAKALA: Thank you.

9 So, finally, usability and use.  
10 Comments from either discussants or other members  
11 of the committee?

12 You're ready for a break; right?

13 MEMBER SHEA: Well, as a discussant I  
14 will say that it is being publicly reported and  
15 that it is also being used in accountability  
16 programs. So and I know that certainly at our  
17 institution we're actually working very hard to  
18 influence those who have different opinions.

19 CO-CHAIR SAKALA: Thank you.

20 Seeing no other comments, I will be  
21 happy to open this up for a vote, please, on  
22 usability and use.

1 MS. ROBINSON-ECTOR: Voting is now open  
2 for usability and use of Measure 0475. One is  
3 high; two is moderate; three is low; and four is  
4 insufficient.

5 (Vote.)

6 MS. ROBINSON-ECTOR: All the votes are  
7 in and voting is now closed. 89 percent voted  
8 high; 11 percent voted moderate; 0 voted low; and  
9 0 voted insufficient.

10 So for usability and use of Measure  
11 0475, the measure passes.

12 CO-CHAIR SAKALA: Thank you.

13 So this meets all of the NQF criteria.  
14 And our final vote is on whether we recommend  
15 that NQF continue to endorse this measure.

16 MS. ROBINSON-ECTOR: Voting is now open  
17 for recommendation of overall suitability for  
18 continued endorsement of Measure 0475. One is  
19 yes; and two is no.

20 (Vote.)

21 MS. ROBINSON-ECTOR: Looks like we have  
22 -- we're still missing one vote. If everyone

1 could resubmit their vote, please. Thank you.

2 (Vote.)

3 MS. ROBINSON-ECTOR: Great. All the  
4 votes are in and voting is now closed. 100  
5 percent voted yes, and 0 percent voted no.

6 So for recommendation of overall  
7 suitability for continued endorsement, Measure  
8 0475 passes.

9 CO-CHAIR SAKALA: Thank you.

10 So let us be back, please at 20 of to  
11 start work on our final session of the day.

12 (Whereupon, the above-entitled matter  
13 went off the record at 3:25 p.m. and resumed at  
14 3:46 p.m.)

15 MS. THEBERGE: Okay, folks, please  
16 take your seats so that we can go ahead and get  
17 started again.

18 CO-CHAIR GREGORY: Okay. We are on  
19 the homestretch here for the afternoon. We have  
20 four more measures to discuss today. One is a  
21 new measure and three are maintenance measures.

22 So our first measure for the afternoon

1 is 2895: Thermal Condition of Low Birthweight  
2 Neonates Admitted to Level 2 or Higher Nurseries  
3 in the First 24 Hours of Life.

4 This is being put forth by the  
5 Collaboration for Pediatric Quality Measures.

6 Our discussants will be -- Raj?

7 MEMBER WADHAWAN: Raj.

8 CO-CHAIR GREGORY: Raj, thank you,  
9 Matt, and Diana, and we have one committee  
10 conflict, and that's Jennifer Bailit. We'll  
11 start with our developers giving us an overview.

12 DR. KLEINMAN: Thank you very much.  
13 So this was developed using the same process I  
14 described earlier but a different expert panel.  
15 So I won't go over that, except to say it was  
16 very highly engaged, and in this area there is a  
17 plethora of literature. It has been known since  
18 the 19th century that children -- that infants,  
19 small infants, getting cool die, and that has  
20 been confirmed and validated in much research.

21 Yesterday, I attended the Williams  
22 Silverman lecture at the American Academy of

1 Pediatrics, and Dr. Silverman, for whom it is  
2 named, is a neonatologist who described his  
3 greatest achievement as identifying and  
4 quantifying the impact of low temperature on  
5 birth outcomes.

6 So I have a handout. I don't know if  
7 I'm allowed to give it. But one of the things  
8 that was raised on the call was concern about how  
9 does one differentiate -- how does one use  
10 distributions as a method of comparison.

11 So I just sort of created a little  
12 simulated data actually in a narrower-than-data-  
13 usually-are-expanded band. Is it okay that I  
14 pass it -- okay. Thank you.

15 So, in any case, this is a PQMP  
16 measure. It was developed when we set up the  
17 measurement process with an awareness of certain  
18 measures that had been considered and not moved  
19 forward by NQF, by VON, the Vermont Oxford  
20 Network some years ago related to hypothermia.

21 So one of the things we wanted to  
22 avoid was the controversy regarding what is



1       hypothermia and what is not because there is real  
2       disagreement in the field if you're going to use  
3       that word. But one of the things we discovered  
4       was both in the literature and then in our own  
5       data that it really is a continuous and not  
6       threshold construct, that below 37 degrees each  
7       degree temperature loss is about equivalent in  
8       inpatient mortality to about 100 grams of  
9       additional birthweight or less birthweight.

10               So it is actually pretty meaningful,  
11       and maybe I'll just leave it there. And I am  
12       happy to respond and answer to questions. But I  
13       -- and so we presented data in two ways. One is  
14       this distribution, and another is with some  
15       family-friendly terms that came up actually out  
16       of our engagement with families and family  
17       organizations, the about right, too cold, very  
18       cold. I mean, that all came from our process.

19               Thank you.

20               CO-CHAIR GREGORY: Okay. Our measure  
21       discussants?

22               MEMBER WADHAWAN: I can start, if

1 that's okay. So just going through the first  
2 piece of -- this is an intermediate outcome  
3 measure. And discussing the evidence, I think  
4 there is strong evidence, as is pointed out, that  
5 hypothermia is related to adverse outcomes in the  
6 neonatal period.

7 The strongest evidence, though, exists  
8 in the very low birthweight infants. That has  
9 been well-published, although there is data  
10 provided on LBW infants using a data set from  
11 three hospitals, as I understand, that even in  
12 that category, hypothermia does increase  
13 mortality, although if you look at literature,  
14 the strongest correlation is with intracranial  
15 hemorrhage and those kind of things. It is  
16 really defined for VLBW infants and not so well  
17 for LBW infants, because they are not the kids  
18 who are at extreme high risk of intracranial  
19 hemorrhage and those kind of things.

20 But there is definitely a higher risk  
21 of mortality, even in this database. So I think  
22 the -- I was quite convinced that there was

1 substantial evidence for this to be used.

2 CO-CHAIR GREGORY: Are there any other  
3 comments from the panel? Hearing none, I guess  
4 we'll vote then, about the evidence. So how  
5 would you -- you said it was very strong, is that  
6 right? Yes. Okay. We will vote.

7 MS. ROBINSON-ECTOR: Voting is now  
8 open for evidence for Measure --

9 CO-CHAIR GREGORY: One comment. I'm  
10 sorry. Jaleel has a comment. Okay.

11 MS. ROBINSON-ECTOR: All right.  
12 Voting is now open for Measure 2895 for evidence.  
13 One is yes, and two is no.

14 (Voting.)

15 MEMBER OWENS-COLLINS: So can I vote  
16 or -- this is Sheila Owens-Collins. Or do I need  
17 to email?

18 CO-CHAIR GREGORY: Whatever you feel  
19 comfortable with.

20 MEMBER OWENS-COLLINS: Okay. So I  
21 vote yes.

22 CO-CHAIR GREGORY: Okay.

1 MS. ROBINSON-ECTOR: Thank you. All  
2 the votes are in, and voting is now closed. One  
3 hundred percent voted yes, and zero voted no. So  
4 for evidence for Measure 2895, the measure  
5 passes.

6 DR. WINKLER: Kaitlynn, what's the  
7 number on this, the number of votes?

8 MS. ROBINSON-ECTOR: What?

9 DR. WINKLER: What's the number of  
10 votes?

11 MS. ROBINSON-ECTOR: 25.

12 CO-CHAIR GREGORY: So we're now going  
13 to talk about the gap, opportunities for  
14 improvement, and any issues related to disparity.

15 MEMBER WADHAWAN: I can take that one  
16 as well. There is substantial variation in the  
17 percentage of infants that has been reported in  
18 different temperature categories. It is  
19 certainly a significant problem in this  
20 birthweight category, and there is a variation  
21 within units that also has been reported that  
22 they have shown as well.

1           Of the percentage of infants who are  
2 either in the low 34.5 category are 34.5 or 35.5  
3 and other categories, there is also racial  
4 disparities that have been reported, with a  
5 higher incidence being reported in some of the  
6 infants in some races. So there is a substantial  
7 gap from a care point of view. At least that's  
8 what my interpretation was.

9           CO-CHAIR GREGORY: Comments from the  
10 committee? Okay. Hearing none, we will vote.  
11 Oh, wait, I hear one. Tracy.

12           MEMBER FLANAGAN: I'm looking for it  
13 in the specs. Does any other major organization  
14 use this measure or something similar to this  
15 that could comment on gap? I'm asking it at  
16 large. Is this a VON measure?

17           DR. KLEINMAN: So I believe VON has  
18 their own measures that did not make it through  
19 this process some time ago. There are any number  
20 of places that are using different thermal  
21 measures as means for improvement within their  
22 units, but this is an attempt to create a

1 standard national measure.

2 MEMBER FLANAGAN: Thank you.

3 MEMBER OWENS-COLLINS: I had a  
4 question, because there will be a difference in  
5 the ability to implement this protocol, depending  
6 on if you're in a tertiary center or a community  
7 hospital. So is that taken into consideration?

8 DR. KLEINMAN: What I would say is the  
9 management of these infants, we saw in our three  
10 hospital study, which included -- I mean, it was  
11 all New York City hospitals. They are all New  
12 York City hospitals, but some were community and  
13 some were academic and some were public and  
14 private. We saw a substantial variation at all  
15 levels of complexity in all three hospitals.

16 I will also just inform the committee  
17 that there is an Epic implementation that is  
18 going on right now, but there was -- it was  
19 supposed to have happened a year ago, but there  
20 was a delay completely unrelated to the measure  
21 but related to the facility. And we also have  
22 developed a portal where someone -- that would be

1 for data collection that would not have to be  
2 tied to an EMR but just to the internet.

3 So there are a number of ways to do  
4 this ranging from chart audit to prospective  
5 collection.

6 MEMBER OWENS-COLLINS: Hi. This is  
7 Sheila Owens-Collins again. I'm still not quite  
8 clear on how usable it is across different  
9 nurseries with different levels of care. I  
10 understand it is very useful in Level 3 and Level  
11 4, but in the Level 2 and special care nursery,  
12 could you get credit for at least starting the  
13 protocol until it is transferred to a tertiary  
14 center?

15 DR. KLEINMAN: This doesn't require  
16 specific protocol. It actually looks at the  
17 outcome as to whether the infant gets cool or not  
18 between the delivery room and either the Level 2,  
19 3, or 4 nursery. I guess it's not either since  
20 there's three, but any of the Level 2, 3, or 4  
21 nurseries.

22 So it doesn't require specific

1 protocols. Each institution can do what meets  
2 its -- what it feels meets its children's needs  
3 the best.

4 CO-CHAIR GREGORY: Jaleel?

5 MEMBER OWENS-COLLINS: Thank you.

6 MEMBER MAMBARAMBATH: There is a --  
7 where the baby gets admitted is different in  
8 different hospitals, so there are hospitals where  
9 they have a Level 3 NICU, but they also have a  
10 newborn nursery. And many of these babies were  
11 more than 2,100 grams or more than 1,800 grams in  
12 some of the institutions, admitted to the newborn  
13 nursery. So they are not a Level 2 unit.

14 DR. KLEINMAN: We actually have a  
15 distinct measure in the measure set that wasn't  
16 submitted here because there were only a limited  
17 number that looks as to whether or not those  
18 children got a temperature taken and recorded  
19 within the first hour. But this measure  
20 specifically is for that subset of children who  
21 are recognized as needing special care services  
22 within the first day of life. But I agree that's



1 an important opportunity for measurement as well.

2 CO-CHAIR GREGORY: Raj?

3 MEMBER WADHAWAN: I have significant  
4 concerns in the same regard as well, because I  
5 think the numerator is a problem here, although I  
6 was going to discuss it in the next session. But  
7 since we brought it up, I just wanted to share my  
8 thoughts as well.

9 The numerator is going to be infants  
10 who are admitted to a Level 2 facility within the  
11 first 24 hours of life, and your hospital policy  
12 may dictate what your numerator is. There is  
13 substantial variation in how people take care of  
14 these low birthweight infants. Some people would  
15 bring anybody under 1,800 grams into the NICU,  
16 regardless of their gestation weight or how  
17 they're doing, and they let them prove themselves  
18 before they send them out.

19 Other places would start with -- at  
20 2,000 grams and some below 1,800 grams, although  
21 unusual though. But certainly I have seen  
22 practices where 1,600 or 1,700 grams may be the

1 cutoff, and you leave those kids in the nursery.  
2 And if they do fine, they are fine. If they  
3 fail, they come to the NICU.

4 So your denominator is a big problem  
5 based on where you are. And you also have a  
6 lower incidence of hypothermia in bigger kids.  
7 So if you are, by policy, admitting all of the,  
8 quote/unquote, "healthy low birthweight infants"  
9 in that birthweight category into the NICU, you  
10 falsely inflate the denominator, and you may  
11 actually have a problem and be -- it will be hard  
12 to interpret the data when the denominator is not  
13 a level playing field is what I am worried about.

14 DR. KLEINMAN: We do request that  
15 stratifications occur by birthweight. I think  
16 what you are describing is real. We are trying  
17 to develop a measure that has salience and  
18 relevance, and we felt that those -- so our  
19 measure set included whether or not the  
20 temperature is taken in the first hour.

21 So thinking about the golden hour,  
22 because there is a great risk for those children

1 who go to the newborn nursery to never have a  
2 temperature taken, get cold, become shocky, and  
3 be in deep trouble. Those are really safety  
4 failures.

5 The second relates to the timing of  
6 the temperature taken once they have arrived at  
7 the nursery, because otherwise that is an  
8 opportunity for gaming, and what we do here is we  
9 build a stratification for those for delay.

10 The third and fourth measures, which  
11 are categorical and continuous, were combined  
12 into this measure. Our attempt is to provide  
13 rational specifications for measurement so that  
14 we can be consistent and learn, and it's -- you  
15 know, I'll say, as I said in my other measure,  
16 it's imperfect. I think it really does a very  
17 good job, and we saw that it would have been  
18 helpful using the New York State database, which  
19 is an all-payer, virtually all-hospital database  
20 at Level 2 and 3 nurseries.

21 There will be variation, but I think  
22 that the substantive variation, the signal

1 relative to the noise, is much greater.

2 MEMBER WADHAWAN: I just have a  
3 question in that regard. Did you look at the  
4 data in New York hospitals, specifically for  
5 babies who are between 1,501 grams to 2,500  
6 grams, and showed that there was -- if their  
7 hypothermia incidence, number one, was different;  
8 number two, if it was different, they would also  
9 correlate to adverse mortality, because I worry  
10 that it may be diluted by the smaller kids.

11 If you just look at all of the LBWs,  
12 including the VLBW infants, the difference in  
13 mortality that you are seeing may purely be  
14 reflective of what is going on in the VLBW  
15 infants and not so much in the bigger kids. Did  
16 you look at that specifically?

17 DR. KLEINMAN: We did. We found it,  
18 and I just don't remember the details. But I  
19 could dig up what we were able to look at. We  
20 certainly found that there was significant  
21 variation in those -- in that group as well, so  
22 it did capture some what appeared to be real

1 signal in the group. But I just don't have it in  
2 my head.

3 CO-CHAIR GREGORY: Cindy?

4 MEMBER PELLEGRINI: So just a couple  
5 questions here about the fact that the structure  
6 here of the four different categories of  
7 temperature from a consumer perspective feels  
8 kind of academic, that there is a -- I understand  
9 you are trying to give a granularity to the data,  
10 but from a parental perspective, a layperson  
11 perspective, I think the question would be, well,  
12 why isn't it just, are you doing the right thing,  
13 or are you doing the wrong thing?

14 Is the baby warm enough or not?

15 Whether they are a little bit too cool, a lot --  
16 I mean, does that actually change, for example,  
17 the way you would treat the baby or the  
18 intervention? I understand that it does have an  
19 impact on outcomes and mortality, but it almost  
20 feels like things are perhaps unnecessarily  
21 complicated.

22 DR. KLEINMAN: I feel -- I am just --

1 I find it interesting sometimes the way things  
2 come about. Those terms and those categories  
3 actually came from parent organizations using our  
4 process.

5 So this was actually very much  
6 responsive to what we heard from parents and  
7 parent organizations. We -- actually, it was  
8 patient organizations is better said than parent,  
9 specifically. One is parent, and one was more  
10 patient.

11 I think what -- one of the things we  
12 learned in our work as a center was that there is  
13 a tendency to dumb this down below what people  
14 actually want. And so we decided that we would  
15 try to find both a sweet spot and to not obscure  
16 with detail.

17 So, in some ways, we thought the  
18 categorical portion of this spoke more to  
19 consumers, to families, to people who need bright  
20 lines between things; that the continuous would  
21 allow those who are the accountability entities  
22 to identify which aspect they cared most about

1 and use that for the accountable entities while  
2 having standard specifications for while these  
3 things were -- how these things were identified  
4 and calculated.

5 Maybe we didn't achieve it. I thought  
6 we did a nice job, but I'm interested in the  
7 feedback.

8 MEMBER PELLEGRINI: I'll just offer  
9 you one other thought, then, which is March of  
10 Dimes works with a lot of parent and patient  
11 organizations, and what we find is that there  
12 tend to be those groups that are populated with  
13 parents who have had an outcome who have a very  
14 vested interest and who, in the interest of their  
15 child's health, have essentially become medical  
16 experts themselves. And then there's everybody  
17 else, right?

18 So when you're dealing with a patient  
19 and parent organization, it's great to have that  
20 voice, but sometimes it's not necessarily  
21 representative of the general population.

22 DR. KLEINMAN: I agree with that. I

1 would say less involved in the direct development  
2 of this but very involved in the shaping and the  
3 decision was also consumer reports. So we really  
4 try to get at that. Again, one is never -- it's  
5 never perfect.

6 And I know we emailed your  
7 organization, as well, as we were doing this and  
8 invited comments.

9 CO-CHAIR GREGORY: Tracy, is your  
10 thing up?

11 MEMBER FLANAGAN: You know, in hearing  
12 this conversation -- I wasn't involved in the  
13 earlier discussions -- it seems to me you could  
14 correct this by -- based on the comments so far,  
15 by admitting to a nursery within a hospital that  
16 has a well-baby and Level 2 nursery.

17 Since everybody is saying that the  
18 care here is going to be -- you know, you're  
19 still going to evaluate a small baby in a well-  
20 baby nursery, and you should. That is the  
21 standard of care. So just a small correction in  
22 that could solve it.



1 DR. KLEINMAN: I mean, we would be  
2 open to -- if that were important to the  
3 committee, I think that would be within the kind  
4 of latitude that our expert panel gave us.

5 CO-CHAIR GREGORY: Jaleel?

6 MEMBER MAMBARAMBATH: I have two  
7 comments and one question. So I was under the  
8 impression that these different stratifications  
9 that you have are based on WHO's definition of  
10 mild, moderate, and severe hypothermia. So if it  
11 is not, I'm not sure why this was taken then.

12 So the other -- in answer to Cindy's  
13 question, why the stratification is important, it  
14 comes from a study from Dr. Abbot Laptook, which  
15 you have mentioned in your literature review, and  
16 it is on babies who are extremely -- very low  
17 birthweight infants, who are less than 1,500  
18 grams. And for every reduction, decrease in  
19 temperature by one degree Celsius, there was an  
20 increase in mortality by 28 percent.

21 So that's probably where that is  
22 coming from. And so, again, it emphasizes the

1 fact that it is more often a problem in the very  
2 low birthweight infants, as Raj mentioned, and  
3 probably focusing on that very low birthweight  
4 infant might be a better way of doing this.

5 DR. KLEINMAN: Thank you. It's  
6 helpful to hear this. I will say that our expert  
7 panel had very explicit and extensive discussion  
8 about whether to only include the very low  
9 birthweight infants. Their feeling was that it  
10 was meaningful and common enough in the larger  
11 infants to measure it. They felt if we wanted to  
12 have an impact in terms of focus that the ones  
13 who were admitted to the Level 2 nursery were the  
14 most likely to be hypothermic because of clinical  
15 circumstances, and, therefore, they could  
16 increase -- they could make it more efficient by  
17 doing that.

18 And then, to balance that was this  
19 requirement of a temperature within an hour. As  
20 I said, it's a separate measure that has been  
21 accepted through the PQMP, but it has not been  
22 submitted here. Actually, it was rejected by NQF

1 some years ago because it was felt that  
2 hypothermia was not common enough in the general  
3 population.

4 But this is specifically for the low  
5 birthweight population, that there was a -- would  
6 be a temperature within the first hour, so that  
7 if any of those children made it into the well  
8 nursery and, in fact, were hypothermic and not  
9 recognized clinically that they would have the  
10 measurement and the opportunity to be transferred  
11 in.

12 CO-CHAIR GREGORY: So, Raj, this is  
13 about the gap, right, your comment?

14 MEMBER WADHAWAN: It's related to the  
15 data that I was going to go into in --

16 CO-CHAIR GREGORY: Okay. So we are  
17 going to vote on the gap, unless anyone has any  
18 objections. So we've just voted on the evidence,  
19 so now we're voting on the gap to say that it's  
20 important.

21 MEMBER OWENS-COLLINS: Sheila Owens-  
22 Collins. I vote aye.

1 MS. THEBERGE: Thank you.

2 MS. ROBINSON-ECTOR: Okay. So voting  
3 is now open for performance gap for Measure 2895.  
4 One is high, two is moderate, three is low, and  
5 four is insufficient.

6 (Voting.)

7 MS. ROBINSON-ECTOR: All the votes are  
8 in, and voting is now closed. Fifty-four percent  
9 voted high, 38 percent voted moderate, eight  
10 percent voted zero, and zero voted insufficient.  
11 So for performance gap for Measure 2895, the  
12 measure passes.

13 CO-CHAIR GREGORY: So we've already  
14 had a considerable amount of discussion about the  
15 reliability, but Raj had something to add, so I  
16 will open the --

17 MEMBER WADHAWAN: Yes, thank you.  
18 Again, coming back to the same comments, Tracy's  
19 comments, I think there's two ways to make this  
20 clean in my mind. One is restrict VLBWs, which  
21 again I am not sure what the data is for outcomes  
22 between 1,500 and 2,500 grams as we just

1 discussed. Maybe there is enough data that shows  
2 that if you get high cold in that birthweight  
3 category, you also have adverse outcomes.

4 In that case, it won't make sense to  
5 restrict VLBW. Otherwise, leveling the playing  
6 field way to do that would be 2,000 grams or  
7 2,500 grams, all-comers, but recognizing that  
8 there is a huge amount of data burden in that  
9 because there are so many more kids who go to the  
10 newborn nursery, who never come to the NICU. And  
11 if you admitted 30,000 kids for every hospital,  
12 so that's an excessive data burden.

13 I still have little concerns about the  
14 temperature categories. I'm not sure if they are  
15 really based on anything. Is it just based on an  
16 expert panel that came up with these categories?  
17 I'm not familiar with any literature that  
18 proposes these categories.

19 And just one last comment about  
20 reliability from my point of view is that I think  
21 looking at hypothermia alone, without a balancing  
22 measure, is a problem because you could have a

1 situation where you have too many babies who are  
2 being too warm in an overzealous attempt to  
3 prevent hypothermia, and that institution may  
4 look great because the hypothermia is very low,  
5 while on the other hand kids are getting burns,  
6 and they are being heated up to 39 degrees.

7 So you have to have a counterbalancing  
8 measure in there. Just looking at too cold  
9 category, which is one of the proposals on the  
10 table, just look at Category 1, 2, 3, and look at  
11 that and ignore everything else is probably not  
12 the right way either because then you don't have  
13 a balancing measure.

14 DR. KLEINMAN: Thank you. So to  
15 answer the second comment first, as I think is  
16 apparent, we tried to include the balancing  
17 measure in here. We shared your concerns.

18 With regard to the categories, with  
19 the literature review which includes information  
20 about the WHO categories, the expert panel  
21 specifically identified levels, what they felt  
22 were rational levels to cut off, understanding

1 that all of us in the development process  
2 preferred the distribution measure because it  
3 didn't require artificial distinctions.

4 Clearly, a difference of .01 degree  
5 temperature is not clinically significant, and  
6 yet it can push you from one category into  
7 another. So that's a limitation of having  
8 categories, basically putting a handle on the  
9 elephant.

10 But it was explicit, it was a RAND --  
11 it was a national expert panel,  
12 multidisciplinary, with a formal RAND modified  
13 Delphi process. It is I think as good as it gets  
14 with regard to the expert panel process.

15 Dr. Gregory participated in another  
16 one of these. Maybe she -- I don't know if you'd  
17 want to comment on your sense of it, but we tried  
18 to do it in a very rigorous way.

19 CO-CHAIR GREGORY: Okay. Any other  
20 comments from the panel? Okay. Are you ready to  
21 vote on reliability?

22 MS. ROBINSON-ECTOR: Voting is now

1 open for reliability for Measure 2895. One is  
2 moderate, two is low, and three is insufficient.

3 MS. THEBERGE: Sheila, would you like  
4 to submit your vote?

5 (Voting.)

6 MS. ROBINSON-ECTOR: All the votes are  
7 in, and voting is now closed. Fifty-two percent  
8 voted moderate, 32 percent voted low, 16 percent  
9 voted insufficient. So for reliability of  
10 Measure 2895, the measure passes. Well,  
11 actually, it's gray zone.

12 DR. WINKLER: Consensus is not  
13 reached. Remember, in this particular case, you  
14 didn't have a high category because it was only  
15 data outline validity that was tested. And so  
16 only the moderates feed into it, so at 52 percent  
17 you're in the gray zone.

18 CO-CHAIR GREGORY: But that means we  
19 still continue. So can we talk about validity?

20 MEMBER AUSTIN: Yes. So based on the  
21 data that the measure developer provided, it  
22 looks like they provided data around actually a



1 sort of variant on the measure itself where they  
2 looked at the proportion of babies that were  
3 categorized as cold and very cold in relationship  
4 to mortality.

5 So I think one of the questions for  
6 the bigger committee is, are we comfortable with  
7 -- in providing data for not exactly the measure  
8 that's being put forth but sort of a variation on  
9 that measure, or do we feel like we do need data  
10 for the measure as it is exactly specified.

11 DR. KLEINMAN: May I make a comment?

12 MEMBER AUSTIN: Yes.

13 DR. KLEINMAN: Yes, I think the other  
14 thing that we did, I hope it was clear -- may not  
15 have been -- was that for our study of the three  
16 hospitals, we actually demonstrated this as a  
17 continuous function. So that, in point of fact,  
18 one could in theory have put the cut points  
19 anywhere sufficiently apart, and you would have  
20 meaningful voltage drop in terms of survival  
21 rate.

22 It gets complicated because some of

1 the data we didn't own to be able to fully  
2 categorize, and that was -- so some of that New  
3 York State did, we were dealing with things that  
4 New York State was doing for us. And after a  
5 period of time, they got tired of having us say,  
6 "Well, can you just cut it this way?" So we  
7 tried to present it the best we can. I'm sorry  
8 if it didn't come through as clearly as it needed  
9 to have.

10 CO-CHAIR GREGORY: So based on the  
11 data you have, would you say that it's valid or  
12 not? Or what are your concerns?

13 MEMBER AUSTIN: Well, and I think this  
14 sort of speaks to maybe a bigger question that we  
15 have as a committee, which is, do we want to  
16 propose some variant on the distribution? So, I  
17 mean, one possible idea is to have the measure be  
18 percentage of babies that were cold or very cold.

19 Another opportunity would be for that  
20 measure to be the percentage of babies that were  
21 just right, and whether they were too cold or too  
22 warm is a failure. And so I think that's -- and

1 I know that's sort of in contradiction to the  
2 feedback that the VON measure had sort of run  
3 into, so I think there's a little bit of a  
4 tension there.

5 So I think it sort of depends on where  
6 we are falling in terms of the measure itself to  
7 whether or not the testing supports that.

8 DR. WINKLER: Recall that you are  
9 asked to evaluate the measure as specified. Go  
10 ahead, please.

11 DR. KLEINMAN: This is where I might  
12 make reference to what I sent around before to  
13 demonstrate that something that -- now, I set it  
14 up so they all had the same mean and median  
15 within a -- we did a simulation, so it doesn't  
16 come out exactly.

17 But it points out that aspects of the  
18 distribution actually can inform very different  
19 practices with things that have different  
20 implications, both in terms of how you want to  
21 improve it and how well you are doing. And so I  
22 do think there is additional information by

1 looking at dispersion and spread, but I  
2 appreciate the comments.

3 I think this is attention that the  
4 committee -- our expert committee spent a lot of  
5 time on. This is what they came up with, and  
6 they actually recommended all of the -- those  
7 moments specifically and rejected other moments  
8 for the measure.

9 CO-CHAIR GREGORY: So I'm going to  
10 call the question, if there are no further  
11 comments from the committee, and we'll be voting  
12 on the validity.

13 MS. ROBINSON-ECTOR: Voting is now  
14 open for validity of Measure 2895. One is high,  
15 two is moderate, three is low, and four is  
16 insufficient.

17 (Voting.)

18 MS. ROBINSON-ECTOR: All the votes are  
19 in, and voting is now closed. Twelve percent  
20 voted high, 32 percent voted moderate, 16 percent  
21 voted low, and 40 percent voted insufficient. So  
22 for validity the measure does not pass.

1 MS. THEBERGE: That's consensus not  
2 reached.

3 DR. WINKLER: Consensus not reached,  
4 so we keep going.

5 CO-CHAIR GREGORY: Okay. So I am now  
6 moving to feasibility.

7 MEMBER RAMOS: So in terms of  
8 feasibility based upon what is presented, the  
9 data elements are temperature to first decimal  
10 place, units of temperature Celsius or  
11 Fahrenheit, time temperature was measured, and  
12 time of arrival to the nursery.

13 So all of these are actually feasible,  
14 and there is a data -- what would you call it? A  
15 web data entry portal that supports the  
16 collection of this. So in terms of feasibility,  
17 it -- you know, it does seem that it is supported  
18 and doable.

19 CO-CHAIR GREGORY: And for  
20 clarification, the web data is -- like there's an  
21 FTE who puts it in at the hospital site?

22 MEMBER RAMOS: And even if there

1 wasn't, if the data is to be collected  
2 separately, it could be acquired from the birth  
3 certificate.

4 CO-CHAIR GREGORY: Okay. Questions  
5 from the panel? Okay. Then I'll call for --  
6 yes, ma'am?

7 MEMBER SHEA: I heard someone say that  
8 temperature is on the birth certificate?

9 MEMBER RAMOS: I'm sorry. Birth  
10 certificate or the nursing notes.

11 MEMBER SHEA: Oh, okay.

12 CO-CHAIR GREGORY: All right.

13 MEMBER SHEA: I do have some questions  
14 about the feasibility of data collection. I'm  
15 thinking that it's easy enough to identify the  
16 admissions to the Level 2 and 3 nursery but  
17 actually collecting the temperature information  
18 is not something that we are going to get off an  
19 administrative claim. And it's solely going to  
20 be dependent on a chart audit and maybe  
21 electronic medical record. So it seems like  
22 you've got a ready answer.

1 DR. KLEINMAN: It's an imperfect  
2 answer because, of course, it is more granular  
3 data. What I would say is that the EMR could be  
4 readily constructed to collect this data. And  
5 the way we designed the web portal was it would  
6 be contemporaneously as a part of the admission  
7 process, so that it -- the intention was, if it  
8 wasn't completed within 24 hours of admission to  
9 the NICU, someone could get an alert that that  
10 was the case and it can be added as a part of  
11 routine work. So the idea was to try to build it  
12 into workflow for the unit secretary or whatever  
13 the -- that's the old term. I'm blanking on what  
14 the current term for that person is, but that was  
15 the intention.

16 It is clinically granular data. It is  
17 also very readily available and typically fairly  
18 obvious in the chart, and something that would be  
19 accessible both during the admission and  
20 subsequently.

21 CO-CHAIR GREGORY: Okay. Naomi?

22 MEMBER SCHAPIRO: So I have a question

1 about this, thinking about it as a national  
2 measure, because any time you have to get it from  
3 a chart as opposed to the claims data, somebody  
4 has to do it, and that somebody is pretty busy.

5 And also, if you're looking at, say,  
6 300 hospitals, there could be five or six  
7 different kinds of medical records, and they all,  
8 I've been learning, have their own idiosyncrasies  
9 for construction, so it's not the same procedure  
10 to extract it from all of them.

11 So then this -- and I don't know  
12 because I haven't really collected non-research  
13 data in a NICU, but it seems to me that this  
14 might not be so easy to collect, even if it's  
15 very important, which speaks to feasibility. And  
16 I would actually like to hear people who are more  
17 experts in this area discuss or respond.

18 MEMBER WADHAWAN: I can certainly  
19 comment to that. This is data that is collected  
20 always. The question is extraction of the data,  
21 and that may need to be some sort of -- either  
22 you build something into EMR or its manual



1 extraction. More than likely manual extraction,  
2 again, because EMR is not easy to work with when  
3 it comes to data extraction.

4 MEMBER SHEA: I agree. On admission  
5 to the unit, you're going to have a temperature  
6 that is very fundamental. You're going to see it  
7 in the chart. But how does it take this measure  
8 from a local quality improvement initiative that  
9 pertains to a particular facility to a national  
10 measure where we have consistency in the way in  
11 which this data element is collected across  
12 different hospitals and health systems  
13 nationally.

14 CO-CHAIR GREGORY: Go ahead.

15 DR. KLEINMAN: Thank you. My answer  
16 would be that I would like to see this become  
17 ultimately an eMeasure. But at the moment, what  
18 we can do is provide a consistent portal that can  
19 be used either for review, to make review more  
20 simple, or contemporaneously it is something of  
21 high importance.

22 What wasn't mentioned earlier is that

1 study that Laptook did which found a huge gap was  
2 done in the NICHD, the National Institute for  
3 Children's Health and Development Research  
4 Network. So these were the elite NICUs in the  
5 country who were killing babies because they got  
6 cold. I think the juice is worth a squeeze.

7 CO-CHAIR GREGORY: Okay. Let's call  
8 for a question on feasibility, unless we want to  
9 make --

10 MS. ROBINSON-ECTOR: Voting is now  
11 open for feasibility of Measure 2895. One is  
12 high, two is moderate, three is low, and four is  
13 insufficient.

14 (Voting.)

15 MS. ROBINSON-ECTOR: It looks like  
16 we're missing one vote. Okay. We have 25 now.  
17 Thank you. So 12 percent is high, 60 percent is  
18 moderate, 20 percent is low, and eight percent is  
19 insufficient. So for feasibility of Measure  
20 2895, the measure passes.

21 CO-CHAIR GREGORY: Okay. And the  
22 final consideration is usability.

1                   MEMBER WADHAWAN: I'm still unclear  
2                   how we -- I know we have these graphs in hand,  
3                   because this is a question that came up on our  
4                   call as well. I think this is one of the biggest  
5                   concerns I had was interpretability of -- how do  
6                   you interpret this data if you show it in a --  
7                   but I think it makes sense to have it in  
8                   continuous fashion because it's hard to devise  
9                   categories. And, you know, if you are off by .1,  
10                  36.4 or 36.5, is really not that much different,  
11                  but it puts you in a whole different category.

12                  So categorization by using a  
13                  continuous variable, and having it divided by one  
14                  degree Centigrade certainly makes sense. But I'm  
15                  not sure about the interpretation when it comes  
16                  to a consumer, or how would you do that even with  
17                  these graphs? I think it's really complicated  
18                  having all of those.

19                  The other measures that have been  
20                  proposed, I already shared my concerns about  
21                  that. If you just took too cold category, then  
22                  you are leaving out the too warm category. Not

1       sure quite how to deal with that, so I think  
2       those are real practical challenges with using  
3       the data as presented or the measure as  
4       presented.

5                   CO-CHAIR GREGORY: Any other comments  
6       from the committee? All right. Well, then let's  
7       vote.

8                   DR. KLEINMAN: May I say something?

9                   CO-CHAIR GREGORY: Sure.

10                  DR. KLEINMAN: What I would like to  
11       suggest is that this measure was designed to give  
12       users options. And one doesn't lose anything by  
13       -- and the work of actually developing a  
14       distribution is literally one line of SAS code.

15                  And so by having it and the -- the pie  
16       chart or the categories, one has an opportunity  
17       to use it as it works in a local context, and  
18       that also, by virtue of having the distribution,  
19       would allow for -- it supports improvement as  
20       well as accountability in a much more granular  
21       fashion.

22                  Thank you.

1 MS. ROBINSON-ECTOR: Voting is now  
2 open for usability and use for Measure 2895. One  
3 is high, two is moderate, three is low, and four  
4 is insufficient. And we are looking for 25 votes  
5 on this measure.

6 (Voting.)

7 MS. ROBINSON-ECTOR: It looks like we  
8 are missing one measure -- or one vote, sorry.

9 MS. THEBERGE: Can everyone vote  
10 again, please?

11 MS. ROBINSON-ECTOR: Great. Thank  
12 you. We now have 25 votes, and voting is now  
13 closed. Eight percent voted high, 52 percent  
14 voted moderate, 36 percent voted low, and four  
15 percent voted insufficient. So for usability and  
16 use of Measure 2895, the measure passes.

17 DR. WINKLER: It's actually in the  
18 gray zone.

19 MS. ROBINSON-ECTOR: Is it?

20 DR. WINKLER: Sixty percent. It's got  
21 to be greater than that.

22 MS. ROBINSON-ECTOR: Oh, sorry.

1 CO-CHAIR GREGORY: All right. So we  
2 will still vote for whether it's endorsed or not?

3 DR. WINKLER: Yes. I mean, because  
4 that's what we have been doing, but be aware that  
5 you've had serious issues both with reliability,  
6 validity, and usability and use.

7 CO-CHAIR GREGORY: Okay. So we are  
8 now going to call for question whether -- the  
9 overall suitability for endorsement. This is a  
10 yes or no vote. Yes, please.

11 MEMBER WADHAWAN: Another way to look  
12 at it, although I fully recognize we are voting  
13 on measure as it is, but just a thought that I  
14 want to share with the developer. Another way to  
15 do this would be coming up with a propensity  
16 score where you attach a weight age to how much  
17 below you are below 36.5 category. And if you  
18 are 20 percent below 34.5, those babies get the  
19 highest weight in that score that you are coming  
20 up with, and then you have a score for 34.5 and  
21 35.5, and a lower score for 35.5 and 36.5.

22 That will be one way, and creating a

1 composite score that people can compare across  
2 institutions and have a better idea rather than  
3 looking at percentage categories. Just a  
4 thought.

5 DR. KLEINMAN: Thank you. I  
6 appreciate it. I think it's very interesting. I  
7 would say that's not something we can do with  
8 this, because this was -- we went through a peer  
9 reviewed process endorsed by AHRQ and CMS, and  
10 are restricted to listening to our expert panel.

11 So in a future process, one might  
12 think about that. But at this point, that's not  
13 some -- that's not a path we can go down. But  
14 thank you.

15 CO-CHAIR GREGORY: So I'm going to  
16 call for a question.

17 MS. ROBINSON-ECTOR: Voting is now  
18 open for recommendation for overall suitability  
19 of endorsement for Measure 2895.

20 (Voting.)

21 MS. ROBINSON-ECTOR: All the votes are  
22 in, and voting is now closed. So 28 percent

1 voted yes, and 72 percent voted no. So the  
2 measure does not pass.

3 CO-CHAIR GREGORY: Okay. We're going  
4 to now move to -- thank you -- proportion of  
5 infants 22 to 29 weeks gestation screened for  
6 retinopathy of prematurity. This is a  
7 maintenance vote. It is -- the developers are  
8 Vermont Oxford Network, and the discussants are  
9 Juliet, Deborah, and Kristi. Are the developers  
10 on board? Hi. Would you like to give us a two  
11 minute overview?

12 DR. EDWARDS: Sure. Would love to.  
13 So we would like to thank you for considering  
14 this for endorsement.

15 So I just want to clarify something  
16 that we talked about on the phone rather  
17 extensively, and I appreciate that some of you in  
18 the room are VON members and look at your  
19 reports, so you have a sense of what I'm talking  
20 about. And if I -- this doesn't make sense, just  
21 raise your hand.

22 We ask hospitals to tell us for every



1 infant, was your infant -- did your infant  
2 receive a retinal exam, yes or no? We don't ask  
3 for the date or the age at which they received an  
4 exam. We just ask, did they get an exam?

5 We then use -- we calculate the post-  
6 menstrual age, the proportion of infants that  
7 were in the hospital at the recommended post-  
8 menstrual age, the range, as designated by the  
9 American Academy of Pediatrics, and we say, okay,  
10 well, out of the proportion of infants that were  
11 at your hospital at that time, what percent got a  
12 retinal exam? And that is what we report to  
13 hospitals, and that has always been the measure  
14 because we don't know the exact date.

15 Now, as someone said, it's important  
16 to know when they got the exam, and we agree  
17 completely. And some day when we are in an  
18 electronic world, you know, this fancy electronic  
19 world that we all dream of, maybe we will be able  
20 to do that. Maybe we will at least be able to  
21 get a date, but right now we don't collect any  
22 dates because we would consider that to be PHI.

1           So right now we are following the big  
2 dot of, what proportion of infants were in your  
3 hospital at that recommended post-menstrual age?  
4 And of those, what percent received an eye exam?

5           CO-CHAIR GREGORY: Would the  
6 discussants please share information about the  
7 evidence? Or can we assume that since this is  
8 not a new measure -- go ahead, please.

9           MEMBER NEVINS: I was -- just a brief  
10 two sentence comment, just to say that additional  
11 studies were added, but they serve to support  
12 information that we already had about this  
13 measure. And I will just further elaborate to  
14 say that based on the available studies we don't  
15 know exactly when this testing should be done,  
16 only that it should be done and that it has been  
17 supported by clinical guidelines in this  
18 discipline.

19           CO-CHAIR GREGORY: Okay. Given the  
20 fact that there is new evidence that supports the  
21 old evidence, is it okay that we let the prior  
22 evaluation stand and move to a discussion about

1 opportunities for improvement? Which we have to  
2 vote on. So discussants?

3 MEMBER NEVINS: Based on the  
4 information provided, with the initial sweep of  
5 this study there was certainly an improvement in  
6 the number of babies screened during the  
7 appropriate time period or the time period set by  
8 the developer. And certainly there is room for  
9 improvement in that number, so certainly this is  
10 a measure that can be used to get at that  
11 information.

12 CO-CHAIR GREGORY: And was there any  
13 data on disparities or --

14 MEMBER KILDAY: There was. There is  
15 no gap in race and ethnicity identified. And, as  
16 mentioned, there was an obvious improvement. The  
17 only question we had in that particular category  
18 was it came up that for those infants that did  
19 not receive their retinal exam, a question came  
20 up during the subgroup meeting that for low  
21 resource areas when a pediatric ophthalmologist  
22 was not available. Didn't know if you could

1 speak to that.

2 DR. EDWARDS: It's my understanding  
3 actually that a pediatric ophthalmologist -- say  
4 that 10 times fast -- is not necessarily needed,  
5 given that there are mechanisms that non-  
6 ophthalmologists can use, neonatologists and  
7 others can use to measure the retina. And I'm  
8 looking at the neonatologists to confirm, because  
9 I'm not one.

10 CO-CHAIR GREGORY: Okay. You want to  
11 confirm that, and then I'll go to Matt.

12 MEMBER WADHAWAN: The RetCam is what  
13 you are referring to, which is a retinal camera.  
14 The usage has not really been adopted very well.  
15 It was thought to be the solution for remote  
16 areas. There are very few ophthalmologists who  
17 actually want to deal with ROP screening just  
18 because it's a high liability area, and one wrong  
19 diagnosis can mean the difference between a child  
20 who can see versus who can't see.

21 But RetCam really has not taken off,  
22 and most neonatologists are not really

1 comfortable using the RetCam. Again, still, not  
2 a reason not to have the services because, again,  
3 if it's a quality measure, I mean, it's a useful  
4 quality unit, any unit that takes care of a  
5 preterm infant's needs should have a mechanism to  
6 do this. Otherwise, you shouldn't take care of  
7 preterm babies. I think that's pretty simple  
8 from a -- from that point of view. But RetCam is  
9 really not the solution. I think solution is  
10 finding ophthalmology practice that will support  
11 you.

12 CO-CHAIR GREGORY: Matt?

13 MEMBER AUSTIN: So this is an issue  
14 that maybe comes up for multiple of your measures  
15 from VON. Based on the call, it sounded like  
16 some of your participants are centers from other  
17 countries. Is that correct? Are the data you  
18 shared in terms of a gap, is that just U.S. data,  
19 or does that reflect the U.S. and other sites?

20 DR. EDWARDS: That's such a great  
21 question because it -- I believe that it actually  
22 includes everyone. We looked at U.S. only, and

1 it's really not that different, because our  
2 international members generally are high resource  
3 NICUs or NICUs that really don't necessarily take  
4 care of this population, so their population  
5 wouldn't be included here, the public hospitals  
6 in South Africa, for example. So I looked at  
7 that, and I was kind of shocked.

8 CO-CHAIR GREGORY: Okay. If there are  
9 no further comments from the committee, then I  
10 think we can vote on opportunities for  
11 improvement.

12 MS. ROBINSON-ECTOR: Voting is now  
13 open for performance gap for Measure 0483. One  
14 is high, two is moderate, three is low, and four  
15 is insufficient.

16 (Voting.)

17 MS. ROBINSON-ECTOR: Great. All the  
18 votes are in, and voting is now closed. Forty-  
19 six percent voted high, 46 percent voted  
20 moderate, eight percent voted low, and zero voted  
21 insufficient. So for performance gap of Measure  
22 0483, the measure passes.

1 CO-CHAIR GREGORY: So with regard to  
2 reliability, are there any new testing?

3 DR. WINKLER: There's new measure  
4 score testing for this measure.

5 DR. EDWARDS: Reva knows because she  
6 talked me through it. We did a split-half  
7 analysis, so we took the -- all of the hospitals,  
8 divided the infants in half, looked at the rates  
9 of screening in both halves, compared the  
10 correlations across all of the hospitals, and we  
11 did this for 100 random samples.

12 And the -- I believe the overall  
13 correlation was over 0.7, which -- and it gets --  
14 like with anything, it gets better as the  
15 hospitals get bigger, because you have more  
16 sample.

17 So we were -- I was a little  
18 surprised, but -- that I would like it to be  
19 higher, and I think it's something that we can  
20 always work on, but it wasn't that bad and it was  
21 -- didn't really differ that much, again, U.S.  
22 versus international.

1                   MEMBER MAMBARAMBATH: The AAP  
2                   recommendation is to -- is for babies who are  
3                   less than 1,500 grams or less than -- 30 weeks or  
4                   less, and one network measure is up to 29 weeks.  
5                   AAP also recommends if there are more than 30  
6                   weeks, even after 32 weeks, if they are higher  
7                   risk, then, yes, we should be doing the  
8                   screening. Can you explain that, why that is cut  
9                   off at 29 weeks?

10                  DR. EDWARDS: So we have -- Vermont  
11                  Oxford Network maintains two databases. One is  
12                  very low birthweight infants, about -- and one is  
13                  all infants admitted to the neonatal intensive  
14                  care unit at a hospital, including the very low  
15                  birthweight infants.

16                  About half of our members are in this  
17                  larger database, about half due to very low  
18                  birthweight only. The eligibility for the very  
19                  low birthweight database is 401 to 1,500 grams or  
20                  22 to 29 weeks, 29 and six.

21                  So we report this measure to our  
22                  members for all infants, both the very low



1 birthweight and the expanded, so that you -- the  
2 centers that are in the expanded database can see  
3 the 30, 31, 32 weekers, and whether they were  
4 screened. But we restricted it here because we  
5 know the full denominator on all of the infants  
6 in that 22 to 29 week gestational age.

7 So we agree, this came up I think the  
8 last time that we came up for endorsement, we  
9 agree and we reported it that way, if you are  
10 collecting data on all centers, on all of your  
11 hospitals, all of your infants in your hospital  
12 that are in your NICU.

13 And just for point of reference, we  
14 are estimating that we are collecting data on  
15 over 85 percent of the very low birthweight  
16 infants born in the United States right now.

17 CO-CHAIR GREGORY: Any other comments?

18 Yes.

19 MEMBER SRINIVAS: In the reliability  
20 section, I think it is mentioned that the  
21 definition may not be applied in the same manner  
22 across infants at all hospitals, and that was one

1 of the explanations for maybe the -- like sort of  
2 moderate correlation. How is the definition sort  
3 of in question?

4 DR. EDWARDS: I don't know. I mean  
5 when I was trying to interpret the results, I  
6 think for this one it should be pretty easy.  
7 It's did you have a retinal exam? Yes or no. So  
8 I was trying to figure out why it would be  
9 different other than simply due to measurement  
10 error. But this is not a measure that I get a  
11 lot of questions about. Most everybody is  
12 comfortable answering this question.

13 MEMBER SRINIVAS: I guess -- sorry,  
14 one quick follow up. I guess as a follow up to  
15 that, in the past when you presumably have --  
16 hospitals are not doing as well as they should in  
17 terms of the screening exam, so how does this  
18 data get used in terms of like drilling down into  
19 those hospitals and it just -- it's reported back  
20 to them and they are asked to look at their  
21 practice, basically?

22 DR. EDWARDS: We -- so yes, we report

1 the measure of any retinal exam to hospitals in  
2 their annual report that is printed. We also  
3 report this measure on our internet site as well  
4 as this specific recommended post-menstrual age  
5 measure.

6 We do not prescribe, so -- and at this  
7 point we do not give any narrative or  
8 recommendations to our members, so we would not  
9 necessarily say anything to them about having a  
10 low rate of screening.

11 It is something that is addressed in  
12 our quality improvement collaboratives, the idea  
13 of screening for retinopathy, and we have centers  
14 that elect to work on the sort of greater issue  
15 of process measures and improving process  
16 measures. But we do not prescribe or give  
17 recommendations to hospitals.

18 CO-CHAIR GREGORY: Okay. Go ahead,  
19 Raj.

20 MEMBER WADHAWAN: Thank you. I have  
21 a question about the exclusions. One of the  
22 exclusions is that if a child was transferred

1 before the age for exam, retinal exam, before  
2 that patient has achieved the age of retinal exam  
3 which is appropriate, but the second part says if  
4 they have the exam but at the wrong time, they  
5 were excluded.

6 I do not believe they should be  
7 excluded. That is a miss on the part of the  
8 unit, and it should not be excluded from the  
9 denominator. That should stay in the denominator  
10 and that's inappropriate or a missed screening  
11 opportunity, and it should count like as if that  
12 patient was not screened.

13 Because timing is so critical. It's  
14 not just if you screen or not. It is also when  
15 you screen, because if you screen too late you  
16 already have retinopathy and, could be, retinal  
17 detachment and blindness has already ensued.

18 DR. EDWARDS: I think that that's a  
19 really great point and a great recommendation,  
20 and it's something that I can actually do  
21 something about because I can change how we  
22 report it. So I will go back and take a look at

1 that.

2 CO-CHAIR GREGORY: Okay. Shall we  
3 vote, if there are no objections?

4 MS. ROBINSON-ECTOR: Voting for  
5 reliability of Measure 0483 is now open. One is  
6 high, two is moderate, three is low, and four is  
7 insufficient.

8 (Voting.)

9 MS. ROBINSON-ECTOR: All the votes are  
10 in, and voting is now closed. Thirty-one percent  
11 voted high, 62 percent voted moderate, eight  
12 percent voted low, and zero voted insufficient,  
13 so for reliability of Measure 0483, the measure  
14 passes.

15 CO-CHAIR GREGORY: Are there  
16 additional comments about validity or additional  
17 testing, new information? Okay. Hearing none,  
18 then can we accept what has been previously  
19 accepted for this measure? We then move to  
20 feasibility.

21 MEMBER NELSON: I just have one  
22 comment on feasibility. This needs to be a

1 manual chart abstraction, so just --

2 DR. EDWARDS: Yes, that's correct.

3 Nearly all of our measures are manually  
4 abstracted right now but we're working hard to  
5 address that.

6 CO-CHAIR GREGORY: So do we have to  
7 vote on the feasibility or -- okay. So I'm going  
8 to call for a question on feasibility.

9 MS. ROBINSON-ECTOR: Voting is now  
10 open for feasibility of Measure --

11 CO-CHAIR GREGORY: Oh, wait. Sorry.  
12 Did I miss comments? Please.

13 MEMBER NEVINS: No I was just going to  
14 say that even though it's a manual abstraction  
15 and we always recoil from that, I mean, given the  
16 severity and the finality of the outcome when  
17 this is missed, I think it is certainly something  
18 that is worth doing.

19 CO-CHAIR GREGORY: Nancy? I mean,  
20 Naomi? Sorry.

21 MEMBER SCHAPIRO: Yes, I think -- my  
22 question is just even if it's manual, is it

1 something you have to report or that people are  
2 going to report? I just have a lot of experience  
3 in the outpatient level of people not reporting  
4 the things that aren't actually connected to  
5 billing.

6 So I'm just wondering, is that -- it  
7 seems like it's really important, but is your  
8 experience that people do report this or that  
9 it's -- you know, that you can collect it even  
10 though it's manual?

11 DR. EDWARDS: So my experience at  
12 Vermont Oxford Network, we have over 1,000  
13 hospitals that report this to us on an infant-by-  
14 infant basis. So I'm assuming that it's tied to  
15 billing somehow but, you know, all of our  
16 measures are chart abstractions, they're all from  
17 clinical data, so, yes.

18 MEMBER WADHAWAN: I would say the same  
19 thing. Almost every hospital reports this  
20 measure, but just based on VON, this is a VON  
21 requirement. If you're in the database, you're  
22 going to report it.

1           The question is, how I can really  
2 report it? Do they capture everybody, or did  
3 they miss somebody? That's certainly possible.  
4 It is always reported, and it is -- all Level 1  
5 isometric database data is manual extraction,  
6 including this and other elements. That's all  
7 the collected data.

8           MEMBER KILDAY: I can say having  
9 helped NICUs develop some reliable processes to  
10 abstract this measure, it really wasn't very  
11 difficult to set up and make it so your  
12 physicians would have some success with  
13 reporting.

14           CO-CHAIR GREGORY: Okay. Let's have  
15 a vote.

16           MS. ROBINSON-ECTOR: Voting is now  
17 open for feasibility of Measure 0483.

18           (Voting.)

19           MS. ROBINSON-ECTOR: It looks like we  
20 are missing one measure minus -- because we are  
21 looking for 26 votes for this measure.

22           (Voting.)



1 MS. ROBINSON-ECTOR: Okay. We're at  
2 25, looks like we're still missing one voting in  
3 the room.

4 DR. WINKLER: Okay, one more time.  
5 Third time's the charm.

6 MS. ROBINSON-ECTOR: Great. Thank  
7 you.

8 (Voting.)

9 DR. WINKLER: Is somebody out of a  
10 battery or something? How do we know? Let's try  
11 one more time. Last time.

12 MS. ROBINSON-ECTOR: Yes, great.  
13 Thanks.

14 DR. WINKLER: You got it?

15 MS. ROBINSON-ECTOR: We still have 25.  
16 Oh, wait, maybe she went to the -- is that it?  
17 No.

18 Great, okay. Twenty-six votes, and  
19 the vote's now closed. We've got 15 percent  
20 voted high, 77 percent voted moderate, eight  
21 percent voted low, and zero voted insufficient.  
22 So for feasibility of Measure 0483, the measure

1 passes.

2 CO-CHAIR GREGORY: Let's do usability  
3 and use. Discussants?

4 MEMBER NEVINS: I think we've had many  
5 comments around this type of measure to attest  
6 that I think the majority of us believe that this  
7 is a usable test. I don't mean to speak for the  
8 rest of the committee, but certainly that's the  
9 way I feel.

10 CO-CHAIR GREGORY: So let's vote,  
11 unless anyone objects.

12 I have a comment from Cindy.

13 MEMBER PELLEGRINI: Thanks. I wanted  
14 to put a comment out there for consideration that  
15 looking at the usability section, this is -- it  
16 says it's not publicly reported, although I think  
17 you do some of that on your website, is that  
18 correct? Or is it -- or do you only report to  
19 your members?

20 DR. EDWARDS: Only to members.

21 MEMBER PELLEGRINI: Okay.

22 DR. EDWARDS: Except for that we do

1 report in publications, so this was in a paper  
2 that we did that was published in Pediatrics, for  
3 example.

4 MEMBER PELLEGRINI: So that's sort of  
5 a gray area on public reporting. But it's not  
6 used in any of the accountability programs and it  
7 can't really be used in any of the accountability  
8 programs because it's in a closed system that you  
9 have to pay to be a part of, and that it seems  
10 like it's functionally impossible to use if you  
11 aren't part of that network.

12 So I am -- I guess I'm a little  
13 confused about why this comes to NQF almost at  
14 all, except to be able to say good job, VON,  
15 using this -- developing this measure that can't  
16 be used by anybody else. Well, I'm sorry --

17 DR. EDWARDS: I mean, I think that  
18 that's a really good point. I mean, we do have  
19 over 700 members in the U.S. and more -- I mean,  
20 literally one a day joining right now including  
21 the Level 2s, 3s, and 4s, so from that  
22 perspective, we have measures in the -- in

1 Leapfrog as well. And we have members that --  
2 people that join, centers that join, because of  
3 Leapfrog, so they want to be able to report our  
4 measures in Leapfrog.

5 So I understand the point and it's not  
6 like we're out to get new membership. We're a  
7 nonprofit organization, but we do have a pretty  
8 wide distribution right now and a hospital that  
9 isn't a member of VON could still report this  
10 measure fairly easily.

11 MEMBER PELLEGRINI: Right. I think it  
12 makes perfect sense for you all to bring the  
13 measure here. I'm not as sure it makes as much  
14 sense for us to endorse the measure in such a way  
15 that it goes into the NQF database and is kind of  
16 viewable to the rest of the world but can't  
17 actually be used by them. So --

18 DR. WINKLER: Actually, in terms --  
19 from NQF's perspective, we have a fair number of  
20 measures which were developed within, say, a  
21 system of registry, which is essentially what  
22 this is, and that is very common. And so what we

1 are looking to see about the measure is, could it  
2 be done outside the registry in terms of  
3 specifications?

4 So as long as that's possible, you  
5 know, it doesn't make it -- it's okay. All  
6 right?

7 But I think you're raising some of the  
8 usability issues because there certainly is a  
9 significant desire at NQF to see measures  
10 publicly reported, to see comparative data, and  
11 things like that. So, yes, you're raising some  
12 of the big issues around, you know, measurement  
13 and public reporting of measurement.

14 MEMBER SHEA: And doesn't that also  
15 get to the issue of feasibility? We were talking  
16 about the ability to collect this data, perhaps  
17 solely because of the VON database and membership  
18 and the strict definition for the way in which  
19 the data is collected.

20 But outside of that database and that  
21 membership, the feasibility of data collection  
22 perhaps would not nearly be as strong. So it

1 goes to feasibility, but it also goes to the  
2 issue of public reporting. But we still think  
3 it's a great measure.

4 CO-CHAIR GREGORY: All right.

5 MEMBER MOORE: I don't think we should  
6 deem organizations who collect funds to do this,  
7 because it's a tremendous amount of work to even  
8 bring a measure to this point, to this committee,  
9 and there is no guarantee that anyone would take  
10 up a measure like this if they didn't have the  
11 funds behind it to support it.

12 And I'm just speaking from my hat at  
13 AHRQ, you know, how many times has staff said  
14 God, we wish we could do this measure, but  
15 there's no funds behind it, and yet it would be  
16 so great if we could move it forward. So, you  
17 know, I'm real sensitive to that. I know that  
18 you have to -- what is that, no margin no  
19 mission. So I just want to talk about it.

20 CO-CHAIR GREGORY: Raj?

21 MEMBER WADHAWAN: I just wanted to add  
22 to that. I believe there is nothing in this

1 measure that cannot be adapted outside of VON.  
2 It is not specific to VON. There is nothing  
3 proprietary about it. Anybody can collect and  
4 report this data if they use the right  
5 definition. So I think it's a very important  
6 measure, even though it's a VON-specific measure.

7 CO-CHAIR GREGORY: Matt?

8 MEMBER AUSTIN: And this is maybe more  
9 a question for Reva. So in the guidance around  
10 usability, it says that the goal should be within  
11 six years of a measure being endorsed that it's  
12 publicly reported. Many of these VON measures  
13 are now past that six-year mark, so I think this  
14 applies to other measures we'll talk about this  
15 afternoon.

16 What is considered public reporting?

17 Is that -- so The Leapfrog Group does have some  
18 VON measures that those who participate in VON  
19 can report to Leapfrog to Leapfrog publishes  
20 those results? Obviously, hospitals themselves  
21 could put it out on their own website if they  
22 were interested. Does that all count as public

1 reporting, or what do you guys see as that  
2 definition?

3 DR. WINKLER: You know, we're not that  
4 specific, Matt, but it -- you know, to understand  
5 how these are used and potentially public  
6 reported in various places -- in fact, I wasn't  
7 aware that Leapfrog did this measure. Not this  
8 one, but the other VON measures. I mean, so  
9 there are potentials.

10 Again, I'll let you weigh that. Use  
11 and usability is not a must-pass criteria. Okay?  
12 But certainly it is one of NQF's sort of mission  
13 priorities to see measures broadly used and  
14 publicly reported to provide information to  
15 various stakeholders. I'll leave it at that.

16 CO-CHAIR GREGORY: Sindhu, is your  
17 card up? Tracy?

18 MEMBER FLANAGAN: Not being a  
19 pediatrician, I may be a little bit off base on  
20 saying this, but in talking to my pediatric  
21 colleagues, VON is a database that is very  
22 difficult to understand unless you are a



1 neonatologist.

2 I have looked at some of the measures  
3 myself as an obstetrician/gynecologist, and I am  
4 glad that a lot of it is not put out to the  
5 public because sometimes I've had difficulty  
6 understanding it.

7 I think the ones that are -- like this  
8 is very straightforward. This has high impact,  
9 and misses have high impact on babies. So I  
10 think this -- I think we're being judicious about  
11 what of VON gets into this database and -- I  
12 mean, this portfolio of recommendations.

13 So I would just say that just to  
14 comment -- and maybe VON wouldn't even  
15 characterize themselves this way, but I find it a  
16 very different sort of set of measures than some  
17 of the others that have been publicly reported or  
18 intended to be publicly reported from the very  
19 beginning.

20 CO-CHAIR GREGORY: Okay. This was  
21 pretty thought-provoking. Let's vote on  
22 usability.

1 MS. ROBINSON-ECTOR: Voting is now  
2 open for usability and use of Measure 0483. One  
3 is high, two is moderate, three is low, and four  
4 is insufficient.

5 (Voting.)

6 MS. ROBINSON-ECTOR: Looks like we're  
7 missing one measure -- or one vote. If you all  
8 could revote, please.

9 (Voting.)

10 MS. ROBINSON-ECTOR: Great. Thank  
11 you. We have 26 votes. All the votes are in.  
12 Nineteen percent voted high, 58 percent voted  
13 moderate, 23 percent voted low, and zero voted  
14 insufficient. So for usability and use of  
15 Measure 0483, the measure passes.

16 CO-CHAIR GREGORY: And then lastly we  
17 are going to vote to -- whether or not it's  
18 suitable for continued endorsement, and it's a  
19 yes or no vote.

20 MS. ROBINSON-ECTOR: Voting is now  
21 open for recommendation for overall suitable  
22 endorsement for Measure 0483.

1 (Voting.)

2 MS. ROBINSON-ECTOR: Great. All the  
3 votes are in, and voting is now closed. Ninety-  
4 two percent voted yes, and eight percent voted  
5 no, so for recommendation for overall suitability  
6 for endorsement, Measure 0483 passes.

7 CO-CHAIR GREGORY: Okay. We're going  
8 to go to another maintenance measure, which is  
9 also supported by -- or developed by Vermont  
10 Oxford Network, and that's late -- Measure 0304,  
11 late sepsis or meningitis in very low birthweight  
12 neonates.

13 We will start this discussion. I want  
14 to keep everyone aware of the fact that at 5:15  
15 we will take a break to make sure that there are  
16 -- if there are any public comments available,  
17 whereupon we will continue and get through our  
18 agenda. Okay?

19 So would our developer like to give us  
20 an overlay?

21 DR. EDWARDS: So this measure is for  
22 bacterial infections in blood or cerebral spinal

1 fluid, making it slightly different from the  
2 other two infection measures on the table. It's  
3 also clinically based, not claims based.

4 It is risk-adjusted for hospital case  
5 mix and hospital volume, and it helps hospitals  
6 understand their performance versus what we would  
7 expect -- how we would expect them to perform.

8 Members of the Vermont Oxford Network  
9 have made tremendous progress in infection, and  
10 we're getting so close to zero percent. Still,  
11 we still have hospitals that have more than 10  
12 percent of their infants with late-onset sepsis  
13 or meningitis. So as a concept, we feel like  
14 this is an important thing to measure.

15 I will let you know that we have been  
16 working quite closely with the Centers for  
17 Disease Control and Prevention on including a  
18 measure like this in the National Healthcare  
19 Safety Network, but we are dropping the signs of  
20 generalized infection. I think that, Dr. Austin,  
21 that was your comment on the phone, I believe.

22 So a measure like this is currently

1 under development, and it will be developed as an  
2 electronic measure. Again, this measure is  
3 clinically based and generally hand-abstracted by  
4 members.

5 CO-CHAIR GREGORY: All right.

6 Discussants?

7 MEMBER AUSTIN: Okay. I'll jump in to  
8 talk a little bit about the evidence. So the  
9 measure -- Stuart has actually provided an update  
10 with 11 observational and quasi-experimental  
11 studies and one clinical guideline further  
12 supporting the evidence of this measure.

13 And they have identified that there  
14 are specific process and structures that can be  
15 performed to improve performance on the  
16 intermediate outcome, things like hand hygiene,  
17 prevention of central line-associated bloodstream  
18 infections, skin care, et cetera.

19 And so the recommendation would be to  
20 pass on the evidence.

21 CO-CHAIR GREGORY: Okay.

22 MEMBER AUSTIN: And that seems to

1 further support what they have already  
2 identified.

3 CO-CHAIR GREGORY: That means we are  
4 going to accept prior evidence. Is that correct?

5 MEMBER AUSTIN: Correct.

6 CO-CHAIR GREGORY: Okay. Then we are  
7 going to talk about the opportunity for  
8 improvement and any issues related to gaps and  
9 disparity.

10 MEMBER AUSTIN: Yes. So VON provided  
11 data on the -- for the last nine years, their  
12 centers, and how they have done the mean  
13 performance, the minimum, and the maximum. They  
14 actually have seen a reduction in the mean, which  
15 is terrific, but there continues to be variation  
16 between the min and max.

17 In terms of disparities, once again,  
18 they provided nine years' worth of data  
19 stratified by race and ethnicity, and while the  
20 disparities seem to be closing, which is a  
21 positive, there still remain disparities amongst  
22 different subgroups.

1           So there appears to be still some  
2 opportunities for improvement for this measure.

3           CO-CHAIR GREGORY: So this is one that  
4 we have to vote on. Are there any other comments  
5 before we vote from the committee?

6           MEMBER MOORE: I would just like to  
7 mention that I need to recuse myself from this  
8 one.

9           CO-CHAIR GREGORY: Oh, I'm sorry.

10          MEMBER MOORE: Yes, that's okay. Last  
11 minute addition. It wasn't on the agenda. I  
12 just decided.

13          CO-CHAIR GREGORY: Thank you. So we  
14 are going to vote.

15          MS. ROBINSON-ECTOR: Okay. Voting is  
16 now open for performance gap of Measure 0304.  
17 One is high, two is moderate, three is low, and  
18 four is insufficient.

19                   (Voting.)

20          MS. ROBINSON-ECTOR: All the votes are  
21 in, and voting is now closed. Sixty percent  
22 voted moderate, 36 -- 60 percent voted high, 36

1 percent voted moderate, four percent voted low,  
2 and zero voted insufficient. So for performance  
3 gap of Measure 0304, the measure passes.

4 CO-CHAIR GREGORY: So we'd like to  
5 talk about reliability. Are there any -- was  
6 there any new testing provided?

7 DR. EDWARDS: Yes, we did the same  
8 process and in this case that I described before,  
9 in this case I believe -- right. So in this case  
10 the correlation was 0.63 in that split-half  
11 analysis, and it again was different actually  
12 this time -- I'm not going to say in which way --  
13 between U.S. and international, which actually  
14 really surprised me.

15 I think that the -- part of the  
16 challenge of this definition is the part two of  
17 one or more signs of generalized infection, which  
18 is one of the reasons why it is under review at a  
19 -- in the organization and with outside  
20 organizations to update this definition to maybe  
21 think about removing that. I think that that is  
22 creating confusion.



1 CO-CHAIR GREGORY: Comments from the  
2 committee? Raj?

3 MEMBER WADHAWAN: I'm curious about  
4 the definition. The way the definition stands  
5 right now, it is somewhat in line with the NHSN  
6 definition for neonatal sepsis or central line-  
7 associated bloodstream infection, because the  
8 trouble is, if you have a pathogen that's easy,  
9 if you have staphylococcal sepsis and you've got  
10 one culture, what do you do with it?

11 Unless you define it as two separate  
12 cultures drawn from two different sites within 24  
13 hours of each other, as NHSN defines it, then  
14 it's easy. If it is not that, then they -- using  
15 clinical science, although imperfect, is one way  
16 to do it. If you drop that, I am concerned that  
17 -- I guess it's not dropping here because this is  
18 staying the same, so it's less of a concern here.

19 But in that situation, if that is to  
20 be dropped, something else needs to be added into  
21 it to make it more robust. Because if you have  
22 one culture that is staph-B positive, and you'd

1 be calling it infection, I think that is the  
2 wrong thing to do, because you're not sure. It  
3 could be, but it may very well not be because  
4 it's a common cell.

5 The second question that I have in  
6 regards to reliability, which we discussed on the  
7 call as well and that's a significant concern of  
8 mine, has been the model that is being used here  
9 has been tested for kids between 500 and 1,500  
10 grams, whereas we are applying it for babies  
11 between 400 and 1,500 grams.

12 So I'm not quite sure how the model  
13 would fit, and it's not been tested. That's what  
14 was shared with us. It has not been tested for  
15 this birthweight category, so although it is only  
16 slightly different, but that's a totally  
17 different category of babies between 400 and 500  
18 grams as compared to bigger kids.

19 CO-CHAIR GREGORY: Any other comments?  
20 Okay. Then let's vote on reliability.

21 MS. ROBINSON-ECTOR: Voting for  
22 reliability for Measure 0304 is now open.

1 (Voting.)

2 CO-CHAIR GREGORY: Are we good?

3 MS. ROBINSON-ECTOR: Yes. So all of  
4 the votes are in, and voting is now closed.  
5 Eight percent is high, 84 percent is moderate,  
6 eight percent is low, and zero voted  
7 insufficient. So for reliability of Measure  
8 0304, the measure passes.

9 CO-CHAIR GREGORY: Validity? Any new  
10 issues related to validity that the discussants  
11 would like to share? Can we accept the validity  
12 -- I apologize, Jaleel. I missed that.

13 MEMBER MAMBARAMBATH: Just a quick  
14 question about the addition of meningitis into  
15 this mix. What prompted the addition of  
16 meningitis to the mix, and how much does it  
17 contribute? Because when I look at the  
18 references that you have quoted, most of the  
19 references are geared towards catheter-related  
20 infections or bloodstream infections. There is  
21 not much about meningitis anywhere in those  
22 references.

1 DR. EDWARDS: The measure -- the  
2 definition of the measure is a positive blood  
3 culture in blood or CSF. So we don't  
4 distinguish.

5 MEMBER MAMBARAMBATH: Positive blood  
6 culture and positive CSF?

7 DR. EDWARDS: Or positive CSF. Thank  
8 you. So we don't distinguish one from the other,  
9 so I can't tell you how much it contributes. I  
10 have no idea.

11 CO-CHAIR GREGORY: Jaleel?

12 MEMBER WADHAWAN: May I clarify that?

13 CO-CHAIR GREGORY: Raj?

14 MEMBER WADHAWAN: I'm sorry. There is  
15 vital source data from NICHD that shows that you  
16 can have positive CSF cultures without positive  
17 blood cultures. So I think it's to capture that  
18 nuance where the blood culture may be negative  
19 but there is meningitis. So I think when it's  
20 all-comers sepsis, some way of capturing CSF  
21 cultures that are positive without a blood  
22 culture positivity needs to be in there. So I

1 think it's probably appropriate and valid.

2 MEMBER MAMBARAMBATH: The reason I'm  
3 asking that question is that that's the only  
4 thing which -- there are two other measures which  
5 we will be talking about which talk about  
6 bloodstream infections. And this measure has  
7 meningitis as well. So that's the only thing  
8 that differentiates this from the other -- that's  
9 one of the major things that differentiates it.

10 CO-CHAIR GREGORY: So with no further  
11 comments, I'm going to call for a vote on  
12 validity.

13 MS. ROBINSON-ECTOR: Voting is now  
14 open for validity of Measure 0304.

15 (Voting.)

16 MS. ROBINSON-ECTOR: It looks like we  
17 are missing two votes, so if everybody could  
18 resubmit their vote, please. Oh, we lost you.  
19 Okay.

20 (Voting.)

21 MS. ROBINSON-ECTOR: Great. Okay, so  
22 all the votes are in, and voting is now closed.

1 CO-CHAIR GREGORY: So advice?

2 MS. ROBINSON-ECTOR: So 83 percent  
3 voted moderate, 17 percent voted low, and zero  
4 voted insufficient. So for validity testing for  
5 Measure 0304, the measure passes.

6 CO-CHAIR GREGORY: So I just want to  
7 make a comment to anyone on the phone for public  
8 comments that we will be doing them, but we are  
9 going to finish these last two voting before  
10 opening up the phone lines.

11 So for the discussant, any comments  
12 related to feasibility? Anything different from  
13 prior? Can we accept -- well, we have to vote.  
14 Are you okay with carrying on the vote related to  
15 feasibility from the prior VON measure?

16 MEMBER AUSTIN: Yes. I mean, it would  
17 be the same issues as we've already discussed.

18 CO-CHAIR GREGORY: Okay. And then  
19 with regard to usability and use, there's greater  
20 emphasis for maintenance measures, so let's talk  
21 about -- has it been used? Or, actually, we know  
22 it's been used, but the same measures, it's not

1 publicly reported.

2 So I think we should vote on this one.  
3 Raj has his card up, do you want to say  
4 something?

5 MEMBER WADHAWAN: So this one is a  
6 little different in my mind, because this is  
7 really VON proprietary as compared to the ROP  
8 data, because there you cannot calculate these  
9 SMRs, unless you have all of the VON data. That  
10 is one issue with generalized usability.

11 The second problem is that, yes, VON  
12 does capture 85 percent of birth hospital NICUs,  
13 but 25 percent of neonatal care is provided by  
14 children's hospitals, freestanding children's  
15 hospitals. Many of them are not part of Vermont  
16 Oxford Network, and what happens is although  
17 these kids are born at a center that is a VON  
18 center, they get transferred out to these  
19 specialized children's hospitals for further  
20 care.

21 So there is actually a substantial  
22 proportion of the population that will not be

1 picked up using this, so that's one caveat. And,  
2 really, if you're not part of VON, you really  
3 can't use this.

4 CO-CHAIR GREGORY: So I guess I have  
5 a question. Given the fact that there -- you  
6 have 85 percent of the population, what's the  
7 likelihood that you will either get the other 15  
8 percent or you'll make it more publicly  
9 available?

10 DR. EDWARDS: We are at -- so there  
11 are a fair number of freestanding children's  
12 hospitals in Vermont Oxford Network, not all, and  
13 so that's certainly a gap and that's something  
14 that we're -- that's an active area of concern at  
15 my organization.

16 That being said, we have talked a lot  
17 about producing a public panel, a publicly  
18 reported panel that a hospital -- that we would  
19 provide to a hospital that a hospital could  
20 choose to put on its website if it wanted to.  
21 And it would include the ROP measure, and it  
22 would include this measure as well as others.



1           And we -- there is a likelihood that  
2 we would at least provide that information to  
3 hospitals. We will never publicly report on  
4 behalf of our members, but we will certainly make  
5 it easier for them to publicly report, should  
6 they choose to do so.

7           CO-CHAIR GREGORY: Any other questions  
8 or comments? All right, so -- yes?

9           MEMBER WADHAWAN: I just have one  
10 additional clarification question. It says that  
11 the patients have to be -- or the infants have to  
12 be in the hospital by day three of life. What  
13 happens to those infants that are transferred  
14 into a tertiary level children's hospital at,  
15 let's say, 21 days of life? They are a part of  
16 Vermont Oxford Network. Would they be counted  
17 here, although they got in there late? And where  
18 do you count them? Do you count them at the  
19 referring hospital, or do you count them at the  
20 receiving hospital?

21           DR. EDWARDS: They are counted,  
22 because we count all admissions before day 28,

1 and we ask the hospitals to tell us where the  
2 infant developed the infection, and we have  
3 specific rules about if -- at what point the  
4 infant came to you with the infection.

5 So and then it will be either at  
6 Hospital A, where the infant started, or at  
7 Hospital B, where the infant ended up. So we  
8 report all of that, whether it happened at your  
9 hospital or at the original hospital or -- and  
10 then we also report all.

11 So we -- that's one of the  
12 differentiators that we have here, and we report  
13 those separately in both unadjusted and risk-  
14 adjusted.

15 CO-CHAIR GREGORY: Greg?

16 MEMBER GOYERT: At the risk of  
17 prolonging this, the developer said VON is  
18 committed to working with accredited bodies that  
19 are developing public -- or publicly reported  
20 quality measures, blah, blah, blah. Yet you just  
21 said we will never report our members.

22 So I'm -- is this just verbiage, or

1 what does this mean?

2 DR. EDWARDS: No. We are actively  
3 working with the American Academy of Pediatrics  
4 and with the Centers for Disease Control and  
5 other -- the National Quality Forum and other  
6 organizations, Leapfrog, but I can't tell this  
7 panel Raj's hospital's data, or your hospital's  
8 data.

9 That is not in our member contract,  
10 and it -- or actually it's the other way around.  
11 It is specifically in our member contract that we  
12 won't do that. So I will report it to Raj, and  
13 then Raj can say, this is a great panel, and I'm  
14 going to post this on our website, because I want  
15 the world to know how we are doing compared to  
16 the Vermont Oxford Network.

17 CO-CHAIR GREGORY: Okay. So I'm going  
18 to call for a question on usability.

19 MS. ROBINSON-ECTOR: Voting is now  
20 open for usability and use of Measure 0304.

21 (Voting.)

22 MS. ROBINSON-ECTOR: Okay. All the

1 votes are in, and voting is now closed. Eight  
2 percent voted high, 50 percent voted moderate, 42  
3 percent voted low, and zero voted insufficient.

4 CO-CHAIR GREGORY: So what was -- 50,  
5 so --

6 DR. WINKLER: This is in the consensus  
7 not reached land, but this is -- usability and  
8 use is not a must-pass criteria, so just factor  
9 it into the rest of your evaluation.

10 CO-CHAIR GREGORY: So that's great,  
11 because the rest of our evaluation is whether or  
12 not we are going to recommend endorsement of this  
13 measure. So it's a yes or no vote, and I'm  
14 calling for a question.

15 MS. ROBINSON-ECTOR: Voting is now  
16 open for overall suitability for continued  
17 endorsement of Measure 0304. One is yes, and two  
18 is no.

19 (Voting.)

20 MS. ROBINSON-ECTOR: It looks like  
21 we're still missing two votes.

22 DR. WINKLER: Okay. Everybody vote

1 again.

2 (Voting.)

3 MS. ROBINSON-ECTOR: Sorry. We're  
4 still missing one vote.

5 DR. WINKLER: How many are there?

6 MS. ROBINSON-ECTOR: Twenty -- okay.

7 DR. WINKLER: It's 24 people, right?

8 MS. ROBINSON-ECTOR: Okay.

9 So we have -- all the votes are in, and voting is  
10 now closed. Eighty-eight percent voted yes, and  
11 13 percent voted no. So for recommendation of  
12 continued suitability for endorsement of Measure  
13 0304, the measure passes.

14 CO-CHAIR GREGORY: So I'm going to go  
15 to the operator and ask if there is anyone online  
16 who would like to make public comments, and also  
17 in the room. Operator?

18 OPERATOR: To make a public comment,  
19 please press star one.

20 And there are no public comments.

21 CO-CHAIR GREGORY: Okay. So the good  
22 news is we're almost done. The bad news is we

1 plan to finish.

2 So we're going to do 0478, which is  
3 neonatal bloodstream infection rate. It is a  
4 maintenance measure, so a lot of what has gone on  
5 before perhaps could carry.

6 AHRQ is the developer, and the  
7 discussants are Jaleel, Greg, and Florencia. Is  
8 Florencia here?

9 DR. WINKLER: No.

10 CO-CHAIR GREGORY: Okay.

11 DR. WINKLER: Is someone on the phone  
12 from AHRQ?

13 DR. OWENS: Yes, I'm here. This is  
14 Pam Owens.

15 DR. WINKLER: Great. Thanks, Pam.

16 CO-CHAIR GREGORY: So, Pam, you get  
17 the privilege of a two-minute overview, if you'd  
18 like, on this particular indicator?

19 DR. OWENS: Excellent. Thank you very  
20 much for giving me this opportunity and I  
21 apologize that I am not there in person, and I  
22 appreciate your patience doing this on the phone.

1                   NQI 03, is what AHRQ calls it, is  
2                   constructed to capture all hospital-acquired  
3                   sepsis in high-risk neonates, regardless of  
4                   precipitating infection. It is not focused  
5                   solely on perinatal-acquired sepsis. It is a  
6                   measure that is based on administrative data, and  
7                   I think this is important in the context of the  
8                   next measure that will be talked about tomorrow  
9                   in terms of harmonization and, you know, what  
10                  sort of the role of each measure might be and in  
11                  what context.

12                  So this is an administrative data  
13                  measure. It is collected -- the data is  
14                  collected using the Healthcare Cost and  
15                  Utilization Project, which collects the universal  
16                  discharges from all community, non-rehab, short-  
17                  term acute care hospitals in 48 states. For the  
18                  purposes of this analysis, we have subset it down  
19                  to 34 states, the discharges from 34 states,  
20                  because those states were deemed to have adequate  
21                  present-on-admission data in 2013.

22                  The administrative data, of course, is

1 quickly available. We use billing data, you  
2 could use claims data for this. It is nationally  
3 representative, and there are a lot of national  
4 guidelines and standards that dictate the way in  
5 which billing data is done and is submitted for  
6 reimbursement. And so you wouldn't submit  
7 something for reimbursement unless it occurred.  
8 We can talk about that, of course, in more  
9 detail.

10 Because our measure is based on  
11 administrative data, we only include neonatal  
12 sepsis codes with specific organism codes or  
13 sepsis codes for specific organisms that are  
14 unlikely to be perinatally acquired, such as  
15 staph aureus. I didn't say that correctly. I  
16 apologize.

17 We exclude organisms that are most  
18 likely to be perinatally acquired, most common  
19 being the Group B strep. Our denominator  
20 captures only the babies at the highest risk of  
21 sepsis, namely very low birthweights, those  
22 undergoing major procedures, or those transferred



1 in the first day of life, indicating the need for  
2 a higher level of care.

3 Our exclusions are really around  
4 length of stay and transfer. They are meant to  
5 exclude babies that are quickly transferred to  
6 another facility or have such a short length of  
7 stay, discharged to home, that they are unlikely  
8 to be at risk for hospital-acquired sepsis.

9 I think that pretty much captures it.  
10 There are a couple of people on the phone. Our  
11 contractor is Stanford, with support from UC  
12 Davis and Schruben, and I am not a clinician by  
13 the way. Consequently, I can't say medical terms  
14 off the cuff too quickly. I'm an epidemiologist,  
15 so I apologize, but we do actually have a lead  
16 clinician on the phone to answer some additional  
17 questions as well.

18 Thank you.

19 CO-CHAIR GREGORY: Okay. Discussants,  
20 with regard to the evidence, is there any new  
21 evidence?

22 MEMBER MAMBARAMBATH: So with regard

1 to the evidence, there is no new evidence  
2 fostered by the measure developer. There are 11  
3 studies from the past which have been presented  
4 which are all non-randomized studies, and these  
5 are quasi-experimental studies. Some of them are  
6 using historical data compared to current data or  
7 concurrent control units. One unit does a bundle  
8 of things to improve care, and the other unit  
9 does not.

10 So one of the examples that they have  
11 is Vermont Oxford Network's NICUs that compared  
12 different hospitals. One of the groups had  
13 implemented a quality improvement model versus  
14 other NICUs which had not, and so they had seen  
15 significant difference in there.

16 So, yes, there are 12 studies, and  
17 they are reasonably -- reasonable studies.

18 CO-CHAIR GREGORY: Okay. Is it okay  
19 with the committee if we accept the prior  
20 evidence and move forward with usability -- I  
21 mean, opportunities for improvement? Okay.  
22 Opportunities for improvement.

1           MEMBER GOYERT: When you look at the  
2 information that the developer provided, there  
3 were significant performance gaps. There were  
4 significant disparity gaps, and there was a high  
5 opportunity for improvement.

6           CO-CHAIR GREGORY: So any comments  
7 from the committee, or can we vote on  
8 opportunities for improvement? Let's vote.

9           MS. ROBINSON-ECTOR: Voting is now  
10 open for performance gap of Measure 0478.

11           (Voting.)

12           MS. ROBINSON-ECTOR: And all the votes  
13 are in, and voting is now closed. Sixty-one  
14 percent voted high, 39 percent voted moderate,  
15 zero voted low, and zero voted insufficient. So  
16 for performance gap of Measure 0478, the measure  
17 passes.

18           CO-CHAIR GREGORY: Okay. With regard  
19 to reliability, can our discussants comment if  
20 there was any new measurement or testing done for  
21 reliability?

22           MEMBER GOYERT: The elements were

1 clearly defined. They were converted to ICD-10  
2 codes. The calculations I thought were clear,  
3 and the signal-to-noise ratio they calculated was  
4 .63.

5 CO-CHAIR GREGORY: Can I make a  
6 suggestion that we accept that as based on prior  
7 evidence and move forward with validity?  
8 Comments on validity, discussants? We get real  
9 efficient around dinnertime.

10 (Laughter.)

11 CO-CHAIR GREGORY: Are there any new  
12 issues related to validity, or can we accept the  
13 prior vote?

14 MEMBER GOYERT: Accept the prior  
15 endorsement.

16 CO-CHAIR GREGORY: Okay. So we have  
17 to talk about this one a little bit, and that is  
18 feasibility.

19 The data source -- I think we can  
20 accept this one from before. I think it's the  
21 usability we have to vote for. Is everyone  
22 comfortable with accepting feasibility from

1 before, the prior vote, the original endorsement?

2 And then usability, we need to comment  
3 about whether it is currently being used?

4 MEMBER GOYERT: And it is.

5 CO-CHAIR GREGORY: And as a measure  
6 for performance and accountability? Yes, it is?  
7 So let's vote on that, vote on usability and use.

8 MS. ROBINSON-ECTOR: Voting is now  
9 open for usability and use for Measure 0478.

10 (Voting.)

11 MS. ROBINSON-ECTOR: I think we're  
12 missing one vote.

13 (Voting.)

14 MS. ROBINSON-ECTOR: Okay. We had 23  
15 in the last vote. There we go. Okay. So all  
16 the votes are in, and voting is now closed.  
17 Seventy percent voted high, 30 percent voted  
18 moderate, zero voted low, and zero voted  
19 insufficient. So for usability and use of  
20 Measure 0478, the measure passes.

21 CO-CHAIR GREGORY: Okay. So last but  
22 not least, on today is whether we would like to

1 vote to move this measure for consideration for  
2 ongoing endorsement, and it's a one/two vote.

3 MS. ROBINSON-ECTOR: Voting is now  
4 open for overall suitability of endorsement for  
5 Measure 0478.

6 CO-CHAIR GREGORY: Oh, I'm sorry.  
7 There was a comment. Greg, please.

8 MEMBER GOYERT: That's fine. The  
9 question is when we're going to have the bar  
10 fight about harmonization.

11 CO-CHAIR GREGORY: That's tomorrow.

12 MEMBER GOYERT: So we're going to have  
13 the bar fight tomorrow. Perfect.

14 CO-CHAIR GREGORY: Tomorrow.

15 MEMBER GOYERT: Perfect.

16 CO-CHAIR GREGORY: Or tonight at the  
17 bar.

18 (Laughter.)

19 CO-CHAIR GREGORY: Okay. We're  
20 voting.

21 (Voting.)

22 MS. ROBINSON-ECTOR: And it looks like

1 we're missing one vote.

2 MS. ALLEN: Would everyone please vote  
3 one more time?

4 (Voting.)

5 MS. ROBINSON-ECTOR: All the votes are  
6 in, and voting is now closed. Ninety-six percent  
7 voted yes, and four percent voted no. So for  
8 recommendation of continued endorsement for  
9 Measure 0478, the measure passes.

10 CO-CHAIR GREGORY: Yes, please.

11 DR. WINKLER: Just before we all  
12 decompress completely, I just wanted to let you  
13 know there will be one more of these infection  
14 measures that we start off the morning with, and  
15 then there was time to have the relating  
16 competing discussion.

17 I just want to make you aware that in  
18 your document sets there are two additional  
19 documents that I want you to be aware of. One is  
20 the side by side of the three infection measures  
21 with, you know, how they look in terms of their  
22 specifications.

1           And then at the request of -- I forget  
2           which workgroup it was, three or something -- we  
3           wanted to look at comparison between the Joint  
4           Commission's extracted measure and AHRQ's -- and  
5           the CLINS-based measure. And the Joint  
6           Commission did submit an analysis and that  
7           information has also been put in your document  
8           set so be aware that it's there. Okay?

9           DR. OWENS: Can I make one comment?  
10          This is Pam again. Thank you very much. The one  
11          thing I did forget to mention, and it does  
12          directly relate to that harmonization discussion  
13          for tomorrow, AHRQ and the Joint Commission did  
14          work this past six months together to try to  
15          harmonize as much as possible, taking into  
16          consideration the different purposes and the  
17          different data streams.

18          So I had forgot to mention that at the  
19          very beginning. Which you'll see differences, as  
20          you can see from the papers you guys already got  
21          tonight and in the morning.

22          DR. WINKLER: Okay. Thank you, Janet.



1       Apparently, the document set that it's in is in  
2       Measure 1731. It got dropped, and we should have  
3       dropped it in all three of them, but apparently  
4       didn't happen.

5                   MS. THEBERGE: Okay. Thank you,  
6       everyone. Yes, you can leave your table tent and  
7       your name card here for tomorrow. We do have  
8       dinner reservations for 6:15 at McCormick &  
9       Schmick's. It is on K Street, 1652 K Street, so  
10      that is on K Street between 16th and 17th. It's  
11      about a half a block from the hotel, and we'll be  
12      convening there at 6:15.

13                   Thank you very much.

14                   (Whereupon, the above-entitled matter  
15      went off the record at 5:37 p.m.)

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