

NATIONAL QUALITY FORUM
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PERINATAL AND REPRODUCTIVE HEALTHCARE
ENDORSEMENT MAINTENANCE STEERING COMMITTEE
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WEDNESDAY
NOVEMBER 30, 2011

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

PRESENT:

LAURA RILEY, MD, Co-Chair
CAROL SAKALA, PhD, MSPH, Co-Chair
JOANNE ARMSTRONG, MD, MPH, Aetna
JENNIFER BAILIT, MetroHealth Medical Center
SCOTT BERNS, MD, MPH, FAAP, March of Dimes
JENNIFER BRANDENBURG, RN, MSN, Decatur

Memorial Hospital
WILLIAM CALLAGHAN, MD, MPH, Centers for
Disease Control and Prevention
KATE CHENOK, MBA, Pacific Business Group on
Health
CHARLES DENK, PhD, New Jersey Department of
Health and Senior Services

ELIZABETH DRYE, MD, SM, Yale School of
Medicine
REBECCA GEE, MD, MPH, MS, Louisiana State
University School of Public Health
ANDREA GELZER, MD, MS, FACP, AmeriHealth Mercy
Family of Companies
CRAIG GILLIAM, BSMT, MT (ASCP), CIC, Arkansas

Children's Hospital
KIMBERLY GREGORY, MD, MPH, Cedars-Sinai
Medical Center

MAMBARAMBATH JALEEL, MD, University of Texas
Southwestern Medical Center

BARBARA KELLY, MD, A.F. Williams Family
Medicine Center

TERI KIEHN, MS, RNC, Intermountain Healthcare

MARYI SALGADY LESLIE, CNM, MSN, EdD(c),
The George Washington University

NANCY LOWE, CNM, PhD, FACNM, FAAN, University
of Colorado Denver

LEE PARTRIDGE, National Partnership for Women
& Families

JOCHEN PROFIT, MD, MPH, Baylor College of
Medicine

KATHLEEN RICE SIMPSON, PhD, RNC, FAAN,
St. John's Mercy Health Care

SHARON SUTHERLAND, MD, Cleveland Clinic

ROBERT WATSON, MD, MMM, CPE, Baylor Andrews
Women's Hospital

JANET YOUNG, MD, Carilion Health Systems

NQF STAFF:

HELEN BURSTIN, MD, MPH

JANET CORRIGAN

SHEILA CRAWFORD

EUGENE CUNNINGHAM

LAURA MILLER

SUZANNE THEBERGE

REVA WINKLER, MD, MPH

DONALD WASHINGTON

ALSO PRESENT:

JOSEPH CARPENTER, MS, Vermont Oxford Network

(via telephone)

SEAN CURRIGAN, MPH, American Congress of

Obstetricians and Gynecologists

MATT HOFFMAN, MD, Cristiana Care

JEFFREY HORBAR, MD, Vermont Oxford Network

(via telephone)

ELLIOT MAIN, MD, California Department of

Public Health

SUSAN MANN, MD, Beth Israel Deaconess Medical

Center (via telephone)

CELESTE MILTON, MPH, BSN, RN, The Joint

Commission

JANET MURI, The Joint Commission

STEPHEN PRATT, MD, Beth Israel Deaconess

Medical Center

PATRICK ROMANO, MD, University of California

- Davis

MICHAEL ROSS, MD, MPH, The Joint Commission

ANN WATT, MBA, RHIA, The Joint Commission

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

8:05 a.m.

DR. WINKLER: Okay, good morning everyone. We need to go ahead and get started. Our agenda this morning is fairly packed.

And we do, we're aware that lots of you have 5:00, 5:30, whatever, flights and will probably be leaving, you know, threeish. We've planned for that, that's a very normal thing. So if you feel that's your circumstance, you're not alone.

So we do want to get started. We've put up a slide of the summary of what you did yesterday of the 15 measures reviewed. You rated nine of them as meeting the criteria for endorsements.

With that, we have another day of measure evaluation. And so, Laura, Carol, whoever.

CO-CHAIR RILEY: All righty, so first on the agenda will be Jennifer, to do

1 Incidence of Episiotomy.

2 And do we know if there is someone
3 from Cristiana Care?

4 DR. WINKLER: Matt, you're here
5 from Cristiana, right? And did we get the
6 handheld mic for you?

7 CO-CHAIR RILEY: If not, you might
8 want to sit right here on the side, next to a
9 mic.

10 DR. BAILIT: So, this is the
11 Incidence of Episiotomy. Just to orient
12 everybody clinically, episiotomy is -- let me
13 start that again. Sorry about that.

14 So just to orient everybody
15 clinically to what a episiotomy is, to make
16 sure we're all on the same page.

17 Episiotomy is when the doctor cuts
18 the perineum right before delivery. Thought
19 to facilitate delivery in some schools. Can
20 also be used in an emergency situation, to try
21 to hasten delivery.

22 The evidence against using it is

1 fairly significant in that it increases the
2 chance of third and fourth degree tears.

3 Tears through the rectal sphincter
4 or rectal mucosa, which are, needless to say,
5 painful and can lead to incontinence of flatus
6 and stool later in a woman's life.

7 So, that's the scientific
8 background to this measure. This measure is
9 calculated off of administrative data. And it
10 is measured only in women who have a vaginal
11 delivery.

12 It is the procedure incidence in
13 women having a vaginal delivery over all
14 vaginal deliveries. The one exclusion is
15 shoulder dystocia. Generally considered an
16 emergency, and would be an appropriate time to
17 use an emergency procedure like an episiotomy.

18 In terms of what the work group
19 thought at our conference call, the importance
20 of measure was five high and four moderate.

21 Opportunities for improvement are
22 quite high. It was six high and three

1 moderate. The evidence shows that there's a
2 wide variety of rates in hospitals.

3 I don't have those numbers right
4 in front of me. But it was a ten or 20 point
5 spread between hospitals. And we also agreed,
6 with one exception, that it meets importance.

7 With that, why don't we open up to
8 the discussion of importance to measure?

9 CO-CHAIR RILEY: Any comments or
10 questions? If not, we should vote.

11 Screen's over here. Everybody is
12 trying to get oriented. The screen's over
13 here, it's going to be a yes/no. Just as
14 yesterday. Can't see when it opens up though.

15 CO-CHAIR RILEY: No. Can you
16 scoot over to Matt's other side, maybe? There
17 you go.

18 (Whereupon, the vote was taken,
19 with 19 yes and zero no.)

20 DR. BAILIT: Okay, so that was
21 pretty clear-cut. Move on to scientific --
22 so this is reliability and validity. In terms

1 of measuring, this is a procedure coded in
2 CPT codes. And generally charged pretty well.

3 Procedures in general are coded
4 well. Unlike other kinds of surgeries,
5 though, Global Care charging in pregnancy,
6 means they can't be charged for specifically.
7 But still, I think the general consensus is
8 that that coding is pretty reliable.

9 And there's been some work on
10 whether the medical record as the gold
11 standard, meets with the coding. That work is
12 quoted in this document.

13 And it shows there's a pretty high
14 fidelity. And that when there isn't fidelity
15 it's equally divided between under-coding and
16 over-coding. This is a random variation as
17 opposed to systematic error.

18 DR. ARMSTRONG: With the coding
19 issues, is it under- and over-coding the
20 degree of the episiotomy, or is it with the
21 laceration versus intentional?

22 DR. BAILIT: My understanding is,

1 because this is not an outcome, we're not
2 looking at the, it's not the diagnoses of the
3 degree. But it's actually the procedure.
4 It's yes or no.

5 Any thoughts or questions?

6 DR. KELLY: Jennifer, is that
7 captured as well in electronic coding?

8 DR. BAILIT: So this study, my
9 understanding is that the electronic coding or
10 the administrative billing data, which is what
11 this is built off of. And that's the study of
12 the electronic data.

13 It is -- what am I trying to say?
14 There's fidelity there, with the exception of
15 the few hospitals that don't, the few codes
16 that aren't, don't have high fidelity, are
17 equally distributed among over- and under-
18 coded.

19 And if you want, I can try to find
20 that number. I don't know if anybody else can
21 find the line and verse faster than I can.
22 Matt, do you remember off the top of your

1 head?

2 DR. HOFFMAN: So our validation
3 study was done against NPIC. We had chosen a
4 cohort of hospitals and looked at two separate
5 Epics. Once again, we do use UB-92 billing
6 information that compared it against the
7 medical record. We asked that a subset of
8 patients, both with and without episiotomy, be
9 compared.

10 DR. WINKLER: Matt, could you turn
11 your mic on?

12 DR. HOFFMAN: It is. I'm sorry,
13 I'm just not speaking close enough.

14 DR. WINKLER: It is? Okay.

15 DR. HOFFMAN: Just to repeat
16 myself. So the validation study that we did,
17 involved NPIC, we used a cohort of the larger
18 CWISH hospital, which is an entity underneath
19 NPIC.

20 It is predicated upon billing data
21 per se. But then we compared it to the
22 medical record. We looked at two separate

1 Epics and basically found very good
2 consistency between the medical record and the
3 coding data.

4 In the majority of hospitals,
5 where there was miscoding, it was a relatively
6 small percentage. And once again, and Jen had
7 mentioned, was equally divided, pretty much,
8 between those who under-coded and over-coded.

9 DR. BAILIT: Other thoughts or
10 concerns that you want to raise?

11 DR. DRYE: Question. Does coding
12 affect billing in this case? Because we, in
13 general, codes and claims data are more
14 reliable if they're related to billing and
15 audited.

16 DR. HOFFMAN: There is some
17 individuation with the insurance plans, but
18 for the majority of times it's captioned
19 underneath global codes.

20 The other part if it's recorded in
21 the medical record, is generally coders,
22 hospital-based coders, who are choosing to do

1 this. And then generally they're fairly
2 professional in their behavior.

3 DR. BAILIT: So global meaning
4 that there's one charge, no matter what you do
5 during the delivery?

6 DR. HOFFMAN: Right.

7 DR. SUTHERLAND: I can speak to
8 this a little bit in my institution, because
9 at the Cleveland Clinic, we started tracking
10 this a few years back. And we found that
11 there was a lot of documentation issue.

12 Many times this got documented in
13 the nurse record, rather than in the provider
14 record. So now that providers know it is
15 being tracked, are taking responsibility for
16 documenting more correctly. So that may help.

17 DR. WINKLER: I noted, Matt, on
18 this submission for maintenance, this measure
19 was previously endorsed three years ago. The
20 level of analysis is just facility.

21 And I know three years ago the
22 discussion was including clinician level as

1 the level of analysis. I'm wondering, was
2 that deliberately excluded or -- because that
3 is a change.

4 DR. HOFFMAN: So, from our
5 perspective, we think the starting of the
6 level of the facility is more appropriate in
7 what caused general change rather than
8 necessarily targeting providers.

9 I will say that I also participate
10 on the AMA PCPI, and they are looking at it as
11 an individual measure. So that may be
12 forthcoming.

13 DR. WINKLER: Though, frankly,
14 NQF's preference is to use a single measure
15 with broadest applicability, rather than
16 multiple little measures, as you'll see in our
17 discussion of relating and competing measures
18 later today.

19 DR. BAILIT: And just as a
20 researcher comment, I mean, I think the
21 confidence intervals around the individual
22 providers are so not reliable, that I'm not

1 sure you could even look at it.

2 For any given provider, they're
3 doing maybe handfuls. They're doing more than
4 handfuls. That's concerning, but they have to
5 have a lot of deliveries. So really the
6 hospital level is a more stable number to look
7 at, I think.

8 CO-CHAIR RILEY: Any further
9 questions, or can we vote on scientific
10 acceptability of the measure?

11 Nineteen yes, zero no.

12 DR. BAILIT: So is this
13 understandable by the public? I think yes,
14 and a lot of women going into labor,
15 understand what a cut is. Most of them don't
16 want it. Just the ick factor. It's
17 publically understandable.

18 And then, is this meaningful,
19 understandable and useful for quality
20 improvement? I think so. I think there's
21 fairly good consensus in the literature, that
22 this is not a desirable thing. It should be

1 used sparingly.

2 And there's wide variation and
3 performance gap, which would lead to the
4 potential for quality improvement.

5 DR. PROFIT: My question just
6 would be when the last three years, you know,
7 do you have evidence or data that people have
8 used this affect improvement, since it has
9 been out there for a while now? So can we see
10 some benefit of its use?

11 DR. HOFFMAN: So I can share, at
12 least within my own institution, we've gone
13 from a 16 percent rate to a four percent rate.
14 So by simply tracking and reporting, when we
15 do it on a physician level, because we have
16 the ability off of our EMR to do that. We've
17 been able to decrease our rates substantially.

18 I think California has had a like
19 experience. I can let Elliot comment to that.
20 But I know that it is being tracked in other
21 institutions and have shown improvements.

22 DR. BAILIT: Matt, I'm just

1 curious. But does this tends to be a sort of,
2 I may get myself in trouble here, but a
3 procedure used by older providers, that used
4 to be much more popular. As those folks are
5 retiring, do we have any evidence that it's
6 actually the measurement as apposed to just
7 the natural attrition of that generation of
8 OBs?

9 DR. WATSON: Since she just threw
10 me under the bus.

11 (Laughter.)

12 DR. WATSON: I mean, I was trained
13 to always do an episiotomy. You would much
14 rather do an episiotomy than then let the
15 pelvis shatter.

16 I'm still not convinced not doing
17 an episiotomy is the right thing. But I don't
18 do episiotomies any more.

19 But it's a big culture change.
20 It's a big practice change, for many of the
21 physicians, not just the older ones, but many
22 of the younger ones as well.

1 And we have been tracking this on
2 an individual basis in our hospital. We've
3 had a dramatic effect. So, from a quality
4 standpoint, it is, it has been very powerful.
5 We dropped our rate, well, ACOG's rate, I
6 think 2006, was 33 percent. It's gone down
7 and down and down.

8 As a system with 22,000
9 deliveries, we were at about 18 or 19 percent.
10 Now we're under ten percent, and going down.

11 So, there's a lot of change here.
12 But I think it's a very powerful measure for
13 quality improvement.

14 MS. BRANDENBURG: I'm curious,
15 with your decrease in episiotomies, have you
16 seen an increase in your tears?

17 DR. HOFFMAN: So, what one does
18 see is a slight increase in anterior
19 compartment tears. So, labial tears as a
20 tradeoff. Those are usually minor, usually
21 don't require stitching, fairly benign issues,
22 compared to the other of third and fourth

1 degrees.

2 DR. BAILIT: Anybody else?

3 CO-CHAIR RILEY: Other questions,
4 comments? We vote on --

5 DR. PROFIT: I guess this is
6 question for the OBs. So, where's the
7 tradeoff line between another? So one
8 catastrophic tear to, you know, like the
9 episiotomies. I don't know. What does it
10 mean for an individual mom to have a grade
11 four tear and incontinence? As opposed to
12 many moms having an episiotomy?

13 How do we make that cut-off? You
14 know, we can make the episiotomy rates go
15 down. But, you know, how do we make that?
16 Like maybe you can help us think about this.

17 DR. HOFFMAN: So let me clarify.
18 So the issue is, by cutting an episiotomy, you
19 in fact, weaken that tissue, predisposing a
20 woman to a third and fourth degree.

21 So if you will, an episiotomy is
22 on the pathway to raising the incidence of

1 third and fourth degree tears. So in fact
2 it's a preventive measure against third and
3 fourth degree lacerations.

4 DR. BAILIT: So, yes, lowering the
5 episiotomy rate should lower the fourth and
6 third degree tear rate.

7 DR. HOFFMAN: And that's been
8 actually shown. There is an article in the
9 French hospital, where they instituted a
10 policy, and they demonstrated as they lowered
11 their episiotomy rate, their third and fourth
12 rate incidence went down.

13 DR. BAILIT: Just anecdotally, at
14 our hospital, we almost never cut them. And
15 we are actually in trouble with our
16 residents, because they don't know how to
17 repair fourth degree any more. They just
18 don't see them anymore.

19 I don't want to throw my residents
20 under the bus either, but, it becomes, you
21 know, the senior resident case now, as opposed
22 to what use to be a lower level case.

1 MS. BRANDENBURG: I guess I
2 understand that. But I've also seen third and
3 fourth degrees occur because an episiotomy was
4 not done.

5 DR. HOFFMAN: So I think the
6 argument has been made, initially, is an
7 episiotomy easier to repair than a third and
8 fourth degree that spontaneously develops?
9 Yet if, you look at it, episiotomy clearly
10 leads to more third and fourths across the
11 incidence.

12 So, what you see is it's going to
13 occur, predicated upon factors that remain
14 beyond the obstetrician's control. The size
15 of the baby, the size of the mother. There
16 are actually ethnic differences as well.

17 So, no, we're not going to
18 eliminate third and fourth degrees, but we
19 will minimize them. And the one factor that
20 is underneath the obstetrician's control, is
21 the decision to cut an episiotomy.

22 DR. PROFIT: And wouldn't there be

1 a way for NPIC to track this more
2 systematically, like across multiple
3 institutions?

4 DR. HOFFMAN: So, in fact in our
5 submission, we did do that. And demonstrated
6 that, in fact, what we see is this wide
7 variation within hospitals. So one of our
8 hospitals had a 33 percent rate and another
9 one had, I believe it was a less than ten
10 percent rate.

11 So there is tremendous variation.
12 The answer to the earlier question, we are
13 seeing a decrease with time, as we're seeing
14 a cultural change. Yet it still remains a
15 significant percentage of women.

16 And particular hospitals that are
17 having high rates of episiotomy. As attention
18 has been focused on it, we're seeing decreases
19 in the overall rates. We're thinking that's
20 leading to improved outcomes.

21 CO-CHAIR RILEY: So can we go
22 ahead and vote on usability for this measure?

1 Remember here we are doing high, moderate,
2 low.

3 DR. DRYE: Can I just clarify?
4 So, someone said you didn't expect it to be
5 used in public reporting. But really, we're
6 voting on whether it is suitable for public
7 reporting across hospitals.

8 DR. BAILIT: I never -- at least
9 if you are referring to me. It wasn't that
10 hospital level, it was physician level I'm not
11 sure is ready for prime time. To the hospital
12 level, absolutely. In my mind at least.

13 CO-CHAIR RILEY: Can everybody
14 press it one more time, so that we don't get
15 the change?

16 (Whereupon, the vote was taken,
17 with 14 high, 4 moderate, and one low.)

18 CO-CHAIR RILEY: All right, so
19 moving on.

20 DR. LOWE: Yes. This is just a
21 request. Could I ask that we use more
22 inclusive language, acknowledging the fact

1 that not all births are attended by
2 physicians? Many of them are attended by
3 nurse midwives.

4 DR. BAILIT: The next slide up?
5 Can we have the next? Yes. So in terms of
6 feasibility, these are data generated during
7 care. It's routine administrative data. It
8 is electronically coded.

9 And we talked a little bit before
10 about the fidelity of the coding, compared to
11 the medical record. So I think, as Matt and
12 his group has shown, that this data is fairly
13 easy to use and manipulate across a wide group
14 of hospitals and able to make comparisons.

15 CO-CHAIR RILEY: Can we vote on
16 feasibility?

17 DR. WINKLER: Fifteen high, five
18 moderate, zero low. I don't know if anybody's
19 on the line or not.

20 CO-CHAIR RILEY: And moving on.
21 So overall suitability for endorsement, for
22 this measure. So 19 yes, 1 no. Thank you.

1 So our next measure is Exclusive Breastfeeding
2 at Hospital Discharge.

3 DR. ARMSTRONG: I have that one.

4 DR. WINKLER: Can I just say a few
5 words? The next measures we're going to be
6 introducing are from the Joint Commission.
7 These four measures were endorsed during NQF's
8 previous work. And they had different measure
9 developers.

10 Since that time the Joint
11 Commission has partnered with those original
12 measure developers to bring these measures
13 forward under the stewardship of the Joint
14 Commission. All right?

15 So they're expected to, you know,
16 they've made this a little bit of evolution
17 and transition.

18 DR. ARMSTRONG: Okay, right. So
19 this is exclusive breastfeeding during
20 hospitalization. It's for singleton term
21 infants. I think, unlike episiotomy, it's
22 pretty self-evident what exclusive

1 breastfeeding is.

2 You know, multiple recommendations
3 from multiple medical professional societies
4 and the Department of Health and Human
5 Services and the Healthy People 2010 and 2020
6 goals.

7 Lots of medical benefits for the
8 baby and the mom that have been described.
9 And significant gaps in performance, relative
10 to the Healthy People 2010 goals.

11 For exclusive breastfeeding at
12 discharge, the goal is 75 percent. Data from
13 the Joint Commission, looking at four quarters
14 of data reported in 2011, have a rate at 41.5
15 percent. So, little more than half of where
16 we're supposed to be.

17 The idea of exclusive
18 breastfeeding at discharge is that it
19 increases the likelihood of continued
20 breastfeeding at three months and six months.

21 Some data presented that for women
22 who exclusively breastfeed at discharge from

1 the hospital, they are seven times more likely
2 to be breastfeeding at one month, compared to
3 women who have some level of breastfeeding,
4 but it's not exclusive at discharge from the
5 hospital.

6 There's also data presented on
7 disparities by race and ethnicity. So from a
8 importance point of view, you know, our group
9 thought, obviously, it was very high. Both
10 the quantity, quality and consistency of the
11 data is high.

12 CO-CHAIR RILEY: Questions or
13 comments?

14 DR. BAILIT: I guess my concern
15 with this one is that it's very susceptible to
16 who your patients are, as opposed to what the
17 doctor is doing.

18 And I know that we talk about
19 racial disparities. We don't want to excuse
20 those, we don't want to excuse the economic
21 disparities that exist.

22 But, that, to a large degree those

1 are outside of the physician's purview and
2 ability to change.

3 If you've got a 15-year-old mom
4 with no breastfeeding support at home, you can
5 maybe convince her to do some things in the
6 hospital. But that chance of actually having
7 it go forward is little.

8 My other concern is that the
9 hospitals who are trying so hard do this go in
10 the other direction of patient autonomy.

11 So that they're forcing people to
12 breastfeed who -- there are, you know, moms
13 who are quite sick, who really just need to
14 rest, are being forced to breastfeed as well.

15 So, there's a tradeoff here, and I
16 just want to make sure that we're not
17 incentivizing people to go in the other
18 direction.

19 DR. LOWE: Yes, I think we're
20 little bit talking about apples and oranges.
21 Because, first of all, it's much more than the
22 provider who has an impact on whether the

1 mother goes home exclusively breastfeeding.

2 A lot of this has to do with
3 nursing care. And if we don't acknowledge the
4 fact that it's the whole system, that's what
5 healthy, or, excuse me, Baby-Friendly Hospital
6 Initiative is all about. Creating that
7 environment that truly supports breastfeeding
8 from the get-go.

9 One of my concerns about this
10 measure is that it's unrelated to intention.
11 The mother who comes in intending to
12 breastfeed is not in the equation anywhere.

13 Perhaps that might be another
14 measure that we could talk about. But, I
15 really believe, and I think there's ample data
16 to support, that if the environment supports
17 the mother who intends to breastfeed, she will
18 be successful.

19 And I really highly endorse this
20 measure. And one is to think beyond, it's not
21 about the provider. It's the whole
22 environment of the hospital or the site of the

1 birthing, of whether or not the mother goes
2 home exclusively breastfeeding.

3 DR. BAILIT: I would agree would
4 agree with that. I guess my concerns still
5 is" that's true for the mother who intends to
6 breastfeed. For the mother who's dead set
7 against it --

8 DR. LOWE: That's not what this
9 measure is about. It's about who goes home
10 exclusively breastfeeding.

11 DR. BAILIT: Right, but for the
12 mother who doesn't want to breastfeed, who --
13 the hospital is going to measure on the
14 quality. And that mother's going to be a
15 ding. She gets tremendous pressure to
16 breastfeed.

17 DR. LOWE: I would say there's
18 other evidence from the nursing literature,
19 that if even mothers who we consider a high
20 risk, who we consider unlikely to breastfeed,
21 if they're appropriately taught and brought to
22 understand the benefits of breastfeeding.

1 Any mother, regardless of
2 situation, wants to do the best thing for her
3 baby. And I've helped plenty of young mothers
4 breastfeed very successfully. I've helped
5 plenty of disadvantaged mothers.

6 And I think there's evidence in
7 the nursing literature, particularly from
8 Paula Meier at Rush University, that shows
9 that supporting, even in the NICU supporting
10 very disadvantaged mothers to breastfeed can
11 be highly successful. And often what they
12 will say is: nobody told me how important it
13 was for my baby that I breastfeed.

14 DR. BAILIT: I guess in my last
15 set of rebuttal, it would be that we're seeing
16 a tripling of our methadone moms. And our
17 moms in polypharmacy, and our pediatricians
18 don't want those moms breastfeeding.

19 For I think good reasons, and
20 there's no exclusion for that kind of thing.
21 So, you know, depending in the hospital, that
22 is very different than a private community

1 suburban hospital, when you have a lot of
2 methadone moms and a lot of poly-drug use.

3 So, I just think we need to build
4 some of those medical exceptions or at least
5 an acknowledgment of some of the extenuating
6 circumstances into this.

7 DR. GEE: Louisiana has, we're
8 50th in the nation in breastfeeding. We have
9 tremendous disparities. Our African-American
10 women initiate at much, much lower rates.

11 We're talking 20 percent, 30
12 percent in some settings. So let me just
13 start by saying, this measure, I think, is
14 fine. But it sets the bar extremely high.

15 And so my comments later today,
16 when we talk about new measures, we need new
17 measures for breastfeeding. I think this is,
18 if you're in a setting where breastfeeding
19 rates are high, exclusive breastfeeding is
20 fine to look at.

21 In Louisiana, our rates are
22 practically zero, of this rate. You look at

1 circumcision, there's some concern at Women's
2 Hospital, which is our largest birthing
3 hospital, if you give sugar water, is that,
4 then does that mean you didn't exclusively
5 breastfeed?

6 So there's confusion about the
7 measure. It's very difficult to measure,
8 because you have to -- it's every single
9 episode of care and feeding of that infant in
10 the hospital being exclusive.

11 Rather than looking at, what we're
12 thinking about putting in our report card is
13 breastfeeding at discharge. Because at least
14 you're then just looking at one day of data,
15 instead of the entire hospital stay.

16 And discharge, if you're
17 breastfeeding that day, that's a good
18 indication that you're intending to breastfeed
19 at home.

20 Another thing, I just looked at
21 our PRAMS data, our population-based data of
22 pregnant women. About disparities in hospital

1 experience, once women intend to breast feed,
2 we found that African-American women had much
3 less hospital support.

4 Even once they had initiated, so
5 they were more likely to get a gift bag. They
6 were less likely to get numbers in counseling
7 and lactation consultant referrals in
8 hospitals than white women, even if they had
9 both wanted to breastfeed.

10 So I think there are issues
11 associated with disparities here that needs to
12 be looked at in metrics.

13 But my issue with this measure
14 particularly, is that it's so labor-intensive
15 to collect it. Hospitals complain a lot about
16 it, because it's every single episode of
17 feeding.

18 And we're not looking at
19 disparities. And we are ought to maybe look,
20 if we want to do improvement, we ought to look
21 at something that we can improve easier,
22 because we are so lagging.

1 States that really need help, we
2 ought to be looking at a lower mark, maybe
3 breastfeeding at discharge. So this, maybe we
4 could we talk about that more later.

5 DR. ARMSTRONG: Yes, the question
6 there actually, it didn't come up in our
7 discussion group. But for hospitals that are
8 reporting on this, are they looking at every
9 episode of breastfeeding, whether that is
10 exclusive? Or is it intention, an early note
11 in the chart of intention to exclusively
12 breastfeed?

13 DR. GEE: In Louisiana, it's
14 measure every single episode. And so it's a
15 lot of work.

16 DR. WATSON: Just to echo what
17 Jennifer was saying, in our area we've had
18 some mothers complain to the hospital, or even
19 change hospitals to deliver their babies,
20 because they had no intention of
21 breastfeeding.

22 Perhaps they tried it last time

1 and it was unsuccessful. And they were so
2 belittled and intimidated by our nursing
3 staff, that was so focused on this measure to
4 be Baby-Friendly, that they did not want to
5 come back.

6 And so we're actually having some
7 of our patients that felt that way come to our
8 Baby-Friendly committee next month and talk
9 about their experiences.

10 So I think it, I think there can
11 be too much emphasis on the ones that don't
12 want to breastfeed, for one reason or another.

13 DR. WATSON: Hi, I'm sorry, did
14 you want to go?

15 CO-CHAIR RILEY: Kathleen, please.

16 DR. SIMPSON: I just wanted to say
17 this measure has been very helpful at our
18 hospital. We are a large community hospital,
19 so not like what you have, we're more like
20 Women's Hospital, I guess.

21 Our pediatricians were routinely
22 ordering sugar water after every birth,

1 supplementation in the hospital. And when
2 this came out, this was extremely helpful. It
3 changed practice right away.

4 And yes, it is labor-intensive.
5 But it has been very positive. We were able
6 to get more lactation consultants on staff
7 because of it.

8 We were able to change those
9 quirky practices that had not been able to be
10 changed for evidence, but they were changed by
11 now we were looking at this. And it's been
12 very helpful.

13 We do measure every feeding to
14 make sure that the baby didn't get any sugar
15 water or supplementation. So it does take a
16 lot of time, but it's been very positive.

17 DR. DENK: Hi. In New Jersey
18 we've, you know, we actually do risk adjust
19 for breastfeeding. We've been reporting
20 breastfeeding at discharge for, you know, 15
21 years in our hospitals.

22 And they weren't really paying

1 much attention, because they would always
2 argue that our, you know, populations differ
3 between hospitals serving Newark and hospitals
4 serving Princeton.

5 And there was just never going to
6 be any kind of, you know, dialogue on that
7 level.

8 So we started doing risk
9 adjustment. We also, you know, started
10 bringing out evidence which was, you know, I
11 mean, CDC did a great job. The developers, by
12 the way, did a great job summarizing the whole
13 literature on what is the hospital's piece of
14 all of this.

15 And that awareness has only come
16 around in the last four or five years, that
17 you have documentation that providers will pay
18 attention to, that say, you know, there's a
19 hospital piece.

20 PRAMS, we've used PRAMS to
21 actually demonstrate that women who start
22 breastfeeding, but then are not exclusively

1 breast-fed during the duration of hospital
2 stay have different outcomes, you know, eight
3 months, eight weeks post-partum.

4 So, you know, the face validity of
5 this with providers is tough, if there isn't
6 some kind of an acknowledgment that some moms
7 are different.

8 And, you know, our risk adjustment
9 is basically on the base of race and
10 educational attainment. And that's all, so
11 it's easy to do. But if you don't want to do
12 it, you could stratify by education and race
13 group. And maybe that, you know.

14 So that's something at least, at a
15 minimum to recommend sort of stratifying. So
16 to increase the usability of this with the
17 population you most need to talk to. Which is
18 the, well, one of the populations, which is
19 the provider population.

20 Oh, by the way, we did a study
21 that said that about 40 percent of the
22 variance in hospital to hospital,

1 breastfeeding rates came out via the risk
2 adjustment model.

3 So it's not at all insignificant,
4 although it isn't the whole story. And that's
5 the whole point, is that it's got two pieces.

6 CO-CHAIR RILEY: Yes.

7 DR. JALEEL: In terms of
8 Jennifer's last comment about the provider not
9 willing to do this. One of the denominator
10 exclusions is documented reason for not
11 exclusively breastfeeding. So there is a
12 documented reason then.

13 DR. BAILIT: Depending on where
14 you are, though, does HIV count, does
15 methadone count, does methadone with cocaine
16 count? I mean, it gets, how you parse that
17 gets tricky.

18 DR. ARMSTRONG: So it sort of
19 moves us to the next area of scientific
20 acceptability. So the exclusions are, again,
21 it's --

22 CO-CHAIR RILEY: Actually, are we

1 done with importance, like is everybody is on
2 board here? Because maybe we should vote on
3 this, and then move to the next thing.

4 Absolutely, feel free.

5 DR. MAIN: What we've learned is
6 that there's no such thing as an easy measure
7 here. No matter what you do, there all kinds
8 of what. Something as simple as breastfeeding
9 gets very complicated when you try to turn it
10 into a measure.

11 I think there's a couple of key
12 points here. First is: the disparity issue
13 was a big issue in California, because it's a
14 huge state with a lot of different ethnic
15 groups. This is an issue we've been working on
16 for five or six years in California. It has
17 shown that actually if you put a whole
18 community at work, you can actually change
19 ethnic acceptance of breastfeeding quite
20 successfully.

21 We have some counties that have
22 taken this on through their MCH programs very

1 aggressively. A lot of public outreach that
2 have markedly increased the exclusive
3 breastfeeding rates in hospitals in southern
4 California, where the rates are much lower.

5 Also, there are hospitals that
6 serve minority groups, in different parts of
7 the state that do much better than other parts
8 of the state.

9 In Oakland, for example, which has
10 a very high African-American population. They
11 have very good breastfeeding rates, whereas
12 other parts, other hospitals in other parts of
13 the states don't do as well.

14 So there are opportunities to
15 overcome the ethnic differences. But we're
16 not looking for 100 percent. That's really
17 the whole take-home thing.

18 And it gets to the point of over-
19 zealous nurses. Again, there has to be some
20 sensitivity training, that we're not looking
21 for every mom to do exclusive breastfeeding
22 for the whole stay.

1 We're looking for, you know, a
2 reasonable number, and if the mother is not
3 interested that should be very acceptable.
4 But that's a slippery slope, if you start
5 putting that into the measure definition,
6 though.

7 And, again, if you accept less
8 than 100 percent, that should come out. There
9 are a lot of documented reasons that would
10 exclude you from breastfeeding, including
11 methadone, including HIV. Those were all on
12 the Joint Commission list now.

13 Those end up not being a big
14 number, though. In most hospitals, you know.
15 Maybe Jen, at Metro it's a little higher
16 number. But in most hospitals it's still
17 five, ten percent, at the most.

18 There are ways of doing the
19 documentation that make it less onerous to
20 collect. Maybe you want to talk about that.

21 MS. MILTON: Actually, we're out
22 doing reliability visits right now on this

1 measure. And depending on how you have your
2 charts set up, if you go to the feeding record
3 you can get all of this data.

4 And most newborns that are healthy
5 aren't going to be in the hospital more than
6 a couple of days. So in my experience,
7 probably at seven or eight different
8 hospitals, it's probably been less than five
9 minutes per record, to take a look at that
10 information.

11 If they're admitted to a NICU,
12 they're immediately excluded, so you don't
13 look further in the record. And then you
14 strictly look at the feeding records.

15 If they've had strictly formula,
16 then you would have to look further to see if
17 there was an indicated reason that's
18 acceptable in our exclusions.

19 But if they're a combination, that
20 tells me that there wasn't a reason. You
21 wouldn't start breastfeeding if there was a
22 maternal reason to exclude.

1 So it really hasn't been too
2 difficult to find this information in the
3 records.

4 DR. MAIN: We looked for a number
5 of years, trying to compare women who
6 exclusively breast-fed versus women who breast
7 and bottle fed. Combined feeding.

8 And it was sort of interesting,
9 most hospitals claimed extraordinarily high
10 rates of breast and bottle, 90-plus percent.
11 But where you saw the biggest discrimination
12 between rates, or the biggest variance between
13 rates, was in the rates of exclusive
14 breastfeeding. And that's what's been
15 associated, in a number of pediatrics studies,
16 with long term success of breastfeeding at the
17 three and six month mark. Which is really --
18 what we're doing is a surrogate for three and
19 six month breastfeeding. Because that's
20 almost impossible to collect with current date
21 of collection systems.

22 So, we didn't feel that combined

1 breastfeeding was a reasonable target that
2 would show value. Because it could be just
3 a baby at a breast briefly and mostly bottle
4 feeding would qualify under that. And so, we
5 really wanted to shift toward exclusive,
6 knowing that it would not be a 100 percent,
7 though we have hospitals in California right
8 now, ranging from 40 to about 85 to 90
9 percent. And that's actually up about 20
10 percent from where it was a few years ago.
11 Both on the low end and the high end.

12 DR. GELZER: Our health plans
13 serve exclusively vulnerable populations. And
14 I just think that this measure is hugely
15 important to those populations.

16 And, sure, a safety net hospitals
17 may not score as well on this measure as is
18 other, you know, community hospitals and nice
19 suburbs. Having said that, Medicaid health
20 plans are measured prenatal, post-natal
21 visits, just as commercial plans are, and we
22 don't score as well, either. But that doesn't

1 mean we shouldn't measure the measure.

2 DR. DRYE: Have you thought about
3 stratifying for race? I'm over here. Because
4 I just think in this measure. I mean, we need
5 to always be really cautious about how we
6 think about disparities. And you don't want
7 to set different goals or benchmarks.

8 But it might be informative to
9 hospitals to see that some people are doing
10 very well -- some hospital systems are doing
11 well with some populations. And they may not
12 be able to make that direct comparison without
13 stratified results.

14 MS. MILTON: The issue of race is
15 very difficult, as far as defining it as a
16 reliable data element. And that's been the
17 problem. If it was strictly you had two
18 African Americans, well the baby would be
19 African American. But what if the mom's half
20 African American, half Hispanic, the father is
21 Chinese? I'm just throwing that out there.

22 Seriously, and that's been the

1 problem. We'd like to be able to do that.
2 But until we can find a reliable way of
3 measuring race it's almost impossible to do
4 that in a reliable manner. Where it would be
5 meaningful.

6 MS. PARTRIDGE: I really think
7 that particular argument ought to go away. I
8 live in the District of Columbia and we use to
9 have arguments about whether a baby was
10 Hispanic or African American, you know. We've
11 now got rules and I think most everybody
12 building measures follows them.

13 We haven't talked at all about the
14 benefit to the child, of the breastfeeding.
15 And this happens to be a measure that the
16 National Partnership and, I personally am very
17 supportive of.

18 As a working mom, many, many years
19 ago, my OB suggested that I try breastfeeding
20 for a month. Because four weeks was all I had
21 of leave. And, of course once you've done it
22 for a month, it's so easy, you're just keep

1 going. So in fact it was very, very helpful.
2 And we really hope that this will continue to
3 be in the measure set.

4 DR. PROFIT: I think what you said
5 there was really interesting and it strikes me
6 that it's almost like a social policy issue
7 that we're attacking at the wrong end.

8 So, it's like we're measuring the
9 providers with something that employers aren't
10 allowing, you know, mothers time for it. I'll
11 just put that out there.

12 MS. PARTRIDGE: That's actually
13 one of the goals that the Partnership hopes to
14 work on. Work place friendly for the nursing
15 mom.

16 DR. BAILIT: And I would just echo
17 that. I think this is a great population
18 health measure. I just don't think this is a
19 great health system measure.

20 I'm very intrigued by the fact
21 that you said you could raise it in the
22 community. If we wanted to collect this at

1 hospitals and report it at the community
2 level, that would be great. Because then
3 you're really bringing into play that bigger
4 support system, it's not just the hospital.

5 DR. MAIN: I think what we've
6 found, though, is that there's a huge amount
7 of impact that the nurses and the physicians
8 have in hospitals on the mother's actual
9 follow through in activity on this area.

10 So, it's -- it's really about
11 systems change. Both systems in the
12 communities as well as systems in the hospital
13 and the obstetric and pediatric community.

14 Yes, it needs some longer term
15 change in the employment. But this is really
16 focused on the parts that we can control in
17 the health care system.

18 DR. GREGORY: I would just echo
19 that. That because of this measure, hospitals
20 are now putting into place, lactation support.
21 And it's trickling down, you don't need just
22 a lactation specialist. All the nurses are

1 now being trained.

2 Where the big fall out is in the
3 middle of the night. That's when you need the
4 most support. And I have to say this is one
5 time where it's not the providers, but it's
6 the doctors that needed to be educated.
7 Because, even though we know it's a good
8 thing, you know, the doctors, the obstetricans
9 were saying, oh no, she needs her rest.

10 And so, it really took, you know,
11 looking at the evidence and bringing it
12 forward, and have pediatricians nagging the
13 obstetricans to really help make this system
14 change.

15 And I actually think sometimes the
16 education was a detriment that, you know, that
17 the more educated you are, the less you
18 thought it was a big deal. And so, bringing
19 this evidence out and sharing it with everyone
20 actually led to some pretty significant system
21 changes.

22 DR. ARMSTRONG: I would also

1 comment that some of the healthcare reform
2 legislation that's been enacted provides
3 access to lactation consultants and breast
4 pumps, which will help women, working women,
5 particularly continue longer term.

6 So, some of the system changes are
7 sort of moving in the direction of supporting
8 this more for more women.

9 DR. PROFIT: Just with the race
10 debate that we've had before. And I'd
11 appreciate our colleagues from California's
12 input on that.

13 We know that some of our Asian
14 population, they end up breastfeeding at home,
15 but for cultural reasons they do not want to
16 do it in the hospital. Even when we talk to
17 them, support them, said, you know, we really
18 would support you doing it. They just don't
19 want to do it in the hospital. But they will
20 breast feed as soon as they are at home.

21 I don't know if you've had any
22 experience with that, with the larger Asian

1 population in California.

2 DR. MAIN: My hospital delivers
3 6,000 babies a year, of which 40 percent are
4 Asians. Probably the largest Asian delivery
5 service in the country. That is a population
6 that has less exclusive breastfeeding in
7 general. But our hospitals as a whole still
8 has 75 percent overall exclusive breastfeeding
9 during hospital stay.

10 Again, it's a matter of
11 communications and working with the community
12 ahead of time. And you're looking for shifts
13 overtime.

14 There are, certainly, ethnic
15 variations to start with. California does
16 report this, both your hospital total
17 exclusive, and we do break it down by race.
18 Using birth certificate race categories. That
19 is a reason --

20 DR. ARMSTRONG: And the data in
21 this report suggest that for Asian women who
22 are exclusively breastfeeding at discharge,

1 about 60 -- 59 percent of those are
2 breastfeeding at one month, versus only 20
3 percent who leave the hospital not exclusively
4 breastfeeding.

5 CO-CHAIR SAKALA: Several quick
6 comments to Lee's comment about benefits for
7 the baby. I'd like to say this is a great
8 measure for moms, as well. So I think that's
9 very valuable.

10 I'd like to echo the sentiment that
11 the fact of the disparities mean that we could
12 really benefit from really strong measures.

13 And finally I want to mention
14 mPINC survey from CDC, which shows phenomenal
15 variation in hospital practice, and around
16 practices around breastfeeding and tremendous
17 opportunities for improvement.

18 CO-CHAIR RILEY: Okay, so I think
19 we should move on. Can we vote on importance
20 to measure and report for this measure?

21 CO-CHAIR RILEY: Can you put your
22 phone on mute, please? If you're on the line?

1 Thank you.

2 DR. WINKLER: Twenty-one yes,
3 three no.

4 CO-CHAIR RILEY: So let's move on.

5 DR. ARMSTRONG: Okay. So
6 scientific acceptability, we discussed some of
7 these already, just the exclusions in the
8 measure are multiple births, babies admitted
9 to the NICU, and experience of death. A baby
10 enrolled in a clinical trial, or mother
11 enrolled in clinical trial length, stayed
12 greater than the 120 days. Transferred to
13 another hospital. Infants on TPN. And
14 documented reasons to not exclusively
15 breastfeed, which are specified in the
16 measure. They include HIV, illicit drug use,
17 mother taking other drugs, chemotherapy
18 agents, et cetera. TB, active breast herpes.
19 That's really it.

20 This question about whether there
21 other sort of reasons to breastfeed that are
22 being gamed in the chart. I think, Jennifer,

1 you sort of suggested maybe that's going on.
2 There's not really a discussion about that.

3 DR. BERNS: So, I have two
4 questions. One is general, because it comes
5 up in a number of different submissions. And
6 then the other is more specific, I think.

7 First, reliability testing, you
8 mentioned that you're going to be doing that,
9 you know, this year. And, I'm just wondering
10 in general how long it takes to do reliability
11 testing?

12 Because I noticed on a couple of
13 these measures that were approved in 2008 that
14 were about to do reliability testing. What's
15 the sort of time span on that? I've noticed
16 this in a couple of different measures that
17 we're viewing today.

18 MS. MILTON: We're actually doing
19 reliability site visits on all five of our
20 measures in the measures set. And we started
21 in October and we'll be finished in January,
22 as far as the site visits.

1 Our statistician selected 12 sites
2 randomly across the country. And we're
3 re-abstracting approximately 30 medical
4 records per site.

5 DR. BERNES: So, let me restate my
6 question. So, for a measure that's approved
7 in October 2008. Now, I assume because the
8 package wasn't implemented until 2010 -- I
9 mean, I'm making some assumptions, I'm just
10 trying to figure out what's the -- it just
11 seems like -- I wish we had the data now. Is
12 what I'm asking.

13 DR. ARMSTRONG: You do. So the
14 report says that, at least in four quarters
15 that they looked at, that the rate of
16 exclusive hospital breastfeeding changed from
17 39.7 percent to 42.9 percent. So some change
18 in a year.

19 MS. MILTON: It was a matter -- it
20 took time. Once they were endorsed for us to
21 actually specify them, to get our manual out,
22 to give everybody six months to embed the

1 measures. There are performance measurement
2 systems vendors, who acts as our intermediary
3 between the hospital and the Joint Commission.
4 We had to review all of their data collection
5 tools to make sure that they were, you know,
6 valid and reliable.

7 So there's a period of time, kind
8 of a set up time. And then actually after we
9 received the first couple of quarters of data,
10 we determined that there were additional
11 enhancements that were needed to the measure
12 specifications.

13 So we're actually doing
14 reliability visits on our second version of
15 the manual. It's not the first version. And
16 actually we're on the third version now.

17 There's always a lag time. You
18 just don't -- you'd like to go out sooner,
19 rather than later. But we had to really wait
20 until we felt we had something that would be
21 meaningful to review, as far as medical
22 records.

1 DR. BERNES: And just to follow up
2 on the validity testing, you do have, and this
3 is great, you know, the automatic, the
4 automated feedback system. And you had, at
5 least in this report, you had 130 submissions.
6 And you had some interesting comments here,
7 particularly regarding the denominator.

8 But -- so my question is, we heard
9 some anecdotal reports here regarding the
10 difficulty with the measure. I'm wondering if
11 any of those 130 submissions, if you've heard
12 similar responses, in terms of the challenges
13 of this measure?

14 MS. MILTON: Difficulty as far
15 collecting the information, or how it's
16 constructed? I'm not sure what your question
17 is.

18 DR. BERNES: Difficulty with
19 measuring. I mean, we heard from Louisiana
20 and -- I'm just curious.

21 CO-CHAIR RILEY: The fact that
22 you're collecting every single --

1 MS. MILTON: Okay. Well, actually
2 we really haven't in the automated system.
3 I'm just giving you my experience having gone
4 out to, probably, what I'd say, eight
5 different sites now. Each one with a
6 different type of a medical record. Some of
7 them are EMRs, some of them are paper-based,
8 some of them are hybrid, where they scan it
9 in.

10 And, really, the bottom line is,
11 especially for this measure, you go to the
12 feeding records. That's where you look. And
13 if the baby's there a day or two, you're
14 looking at a couple of days worth of feeding
15 records.

16 And if the flow sheets are well
17 constructed, it's pretty simple to see.
18 Because usually most of them will have a line
19 for breastfeeding, a line for formula feeding.
20 If they have a bottle, what was in the bottle.
21 Because sometimes we do allow -- they don't
22 have to actually be fed on the breast. It's

1 the breast milk that they received that we're
2 looking for.

3 So if they've clearly documented
4 in the flow sheet, I'm not spending more than
5 five minutes on a record, for the most part.
6 It's a pretty straight forward review of the
7 record. It's not like another project where
8 I looked at blood management, where if they
9 might have had a dozen transfusions, that's a
10 lot harder, more labor intensive. This is
11 fairly straight forward.

12 DR. BERNS: I think one of the key
13 systems changes to make it easy for hospitals
14 to collect this measure, is to actually to
15 tweak your forms, to make it real clear how
16 you're suppose to chart. And where to look
17 to find the data. Once you do that, things
18 fall into place.

19 CO-CHAIR RILEY: So --

20 MS. MILTON: We also do sample for
21 this measure, so we are not looking at every
22 single medical record, as well. So it's based

1 on the number of discharges that you have, or
2 deliveries per month. Then you would sample
3 accordingly.

4 CO-CHAIR RILEY: Okay, can we vote
5 then on scientific acceptability of this
6 measure? So reliability and validity.

7 DR. WINKLER: Twenty-two yes, two
8 no.

9 CO-CHAIR RILEY: Okay, so we can
10 move on.

11 DR. ARMSTRONG: Okay. Next, for
12 usability, our group thought that the measure
13 was very easy to understand. Good for public
14 reporting, good for quality improvement
15 efforts. Public could easily understand what
16 it is.

17 And there's some data presented
18 that it has actually made a small difference
19 in one year of reporting on the measure.
20 Comments?

21 CO-CHAIR RILEY: Okay, can we vote
22 on usability?

1 DR. WINKLER: Sixteen high, six
2 moderate and two low.

3 DR. ARMSTRONG: Okay, and then
4 from a feasibility point of view, we've
5 already discussed the ease of collecting the
6 data. I guess there's some, perhaps,
7 difference of opinion about it. But our group
8 thought generally that it was -- the measure
9 was rated high on feasibility. Four highs and
10 one moderate.

11 CO-CHAIR RILEY: For those of you
12 who weren't looking at the screen, I wasn't
13 either.

14 DR. WINKLER: High nine, moderate
15 12, low three.

16 CO-CHAIR RILEY: And then overall
17 suitability for endorsement.

18 DR. WINKLER: Twenty yes, four no.

19 DR. PROFIT: I would just mention
20 that maybe a similar measure could be
21 constructed for the NICU and is already in
22 use, you know, in many consortia. It

1 shouldn't be exclusive milk feeding, of
2 course, but maybe any human milk at discharge.
3 It was a very highly rated measure by many of
4 the expert panel that we conducted.

5 DR. JALEEL: Just want to comment
6 on the document itself. Having gone through
7 many of these documents, I think this has been
8 very well put together. And I just want to
9 comment the group. And this can be put as an
10 example of what the documents should be like.

11 DR. DENK: Hi, I just wanted to
12 make one comment if it's alright. As a person
13 who makes, who does report cards and other
14 kind of data reporting at a state level -- and
15 I don't have access to charts. I've got to
16 rely on instruments, like the electronic birth
17 registration system. I just like the Joint
18 Commission to think a little bit about how to
19 harmonize with that.

20 I mean, maybe there should be two
21 versions of the measure. Because, I'm not
22 sure, but I think the 2003 standard is

1 breastfeeding and -- exclusive breastfeeding
2 at discharge. Not exclusive breastfeeding
3 through out the hospitalization. I can't --
4 if anybody knows better, I'd appreciate that.
5 But, you know, not everybody who's doing these
6 measures and loves them, is doing them, you
7 know, has direct access to charts.

8 DR. GEE: I wanted to add to what
9 Chuck said. You're, Elliot, probably talking
10 about hospitals that are motivated to support
11 breastfeeding. When you're trying to change
12 behavior in hospitals that aren't motivated to
13 support breastfeeding. And you've got -- as
14 difficult as this is to collect, if you're not
15 setting your system up that way -- it's not --
16 and you can choose the measure or not.

17 We need to do measures that are
18 also more processed based. Looking at -- you
19 know, we have Baby-Friendly Hospitals, that
20 requires a certain architecture of your labor
21 floor.

22 In Louisiana we don't have a

1 single baby-Friendly hospital, for example.
2 And for some states that are trying to
3 improve, and you're looking at grading them,
4 we've had a heck of a time of what to put on
5 our report card.

6 We have something called the GIFT
7 Certification Program that varies by each
8 state, which is getting rid of the formula
9 bag. But I think we can talk about this
10 later, too, but Elliot, you may be leaving.

11 What other types of intermediate
12 process measures have you looked at? Because
13 from the state perspective, and the worst
14 performers' perspective, where you want to
15 change behavior quickly, we really just don't
16 have anything that's validated to grade them
17 on. And so we're creating our own as we go.

18 DR. MAIN: We started out years
19 ago using the data that was reported on the
20 newborn screening forms, which is a quick but
21 very dirty form of data, because it often
22 records what the intention was, rather than

1 what the reality was.

2 But that's a start, as a bridge to
3 get to a more refined measure. But, again, I
4 think the intent here is that this is
5 something that focuses attention on this issue
6 and makes the hospitals confront it, you know,
7 in a way that can be creative.

8 DR. GEE: If the measure were
9 required it would be a whole different ball
10 game. And then we could motivate behavior.
11 But for the non-motivated we are using newborn
12 screening for our report card. But it's just
13 a single time measure. And then discharge, it
14 sounds like New Jersey's using.

15 CO-CHAIR RILEY: Okay, so we're
16 going to move on. And our next measure is
17 Elective Delivery Prior to 39 Completed Weeks
18 Gestation.

19 DR. GREGORY: All right, is this
20 good to see that?

21 CO-CHAIR RILEY: Well, not behind
22 Elliot, you can't see it.

1 DR. GREGORY: Okay, so this is
2 elective delivery prior to 39 completed weeks,
3 which is 37 to 39 weeks. And this was a very
4 interesting discussion. Pretty much the group
5 felt this had high impact because of high
6 burden -- all right, yes, I will. Anyway,
7 I'll do it from memory.

8 We felt that this was high impact,
9 because of the high burden and the relatively
10 -- based on several publications, the
11 relatively high number of elective deliveries
12 that were occurring at this time period.

13 We felt that there was a high
14 opportunity for improvement. And so it met
15 the importance goal. There was pretty much
16 consensus around that. And the evidence to
17 support it was pretty good.

18 I think the biggest bugaboo in
19 this indicator was, one, there were very
20 generous exclusion criteria. But even in the
21 face of -- some of which may not necessarily
22 have been appropriate, but they were very

1 generous in their exclusion criteria. But,
2 then there were many criteria that should be
3 excluded, that aren't excluded, because there
4 are no codes for them.

5 And the one that comes in mind,
6 right away, is classical C-section. That is
7 a very good reason to have a delivery earlier
8 than 39 weeks. But there's no specific ICD-9
9 code for it.

10 But in general there was pretty
11 good consensus about that. So I'll open it up
12 for comments.

13 DR. DENK: Yes, I wanted to
14 comment just a little bit on the exclusions.
15 You know, New Jersey's been working on this
16 for about a year and a half. We've saw the 39
17 week thing as a low hanging fruit. And we got
18 half the hospital chairs in the state, you
19 know, OB chairs together to try to get them to
20 sort of jointly agree to a ban. It wound up
21 that hospitals had to do it, you know,
22 voluntarily and one on one.

1 And some hospitals have really
2 hard stops, where if you don't have medical
3 documentation you can't get scheduled, you
4 can't get admitted, you can't get nursing
5 staff to run the induction and so on.

6 But when a hospital puts a hard
7 stop in like that, then there's response from
8 physicians, OB physicians. One -- I was doing
9 CMEs and one deputy chair who was responsible
10 for screening all of these cases said that in
11 the week after they put a hard stop policy in
12 he had five recorded cases of oligo in the
13 38th week that had to be induced, right?

14 And oligo is here on the list and
15 I was just told, I'm not the provider, this
16 isn't my training, but I'm told that oligo is
17 a pretty unreliable measure. And if you do it
18 a couple of times over the course of two days
19 you can get any result you want, right?

20 CO-CHAIR RILEY: Or a dead baby if
21 you wait long enough.

22 DR. DENK: Okay. That's been the

1 New Jersey experience that, you know, that you
2 have to be really careful about these.

3 DR. BAILIT: We looked at the Ohio
4 Perinatal Quality Collaborative that brought
5 our rate down from around -- we decreased it
6 by 60 percent over a year. And we looked at
7 diagnosis creep and this data has been
8 published in abstract form but has not yet
9 been published in paper form.

10 The elective indications went
11 down, but the indicateds did not go up.
12 Suggesting that diagnosis creep is not a
13 significant player.

14 At some point you've got to trust
15 people to document the right thing. I'm not
16 saying that games don't get played, but I'm
17 just saying on a big picture it's not
18 happening. At least in Ohio where we looked
19 at it.

20 DR. GEE: Chuck -- we had a
21 similar process to what Chuck did in New
22 Jersey, where last year we challenged our

1 hospitals to be 39-week hospitals. We now
2 have 85 percent of our hospitals are 39-week
3 or above hospitals.

4 But our major problem has been
5 measurement. And this measure is difficult
6 and states -- in many states, Medicaid does
7 not require ICD-9 modifiers and so we only
8 have, let's say two per admission per billing.

9 And so we could not -- this would
10 require chart abstraction if we were for every
11 case or every single chart, for complicated
12 medical reasons the chart abstractors may not
13 understand.

14 And so the way we've gone is we're
15 revising our vital records system and creating
16 a check list for each physician delivering
17 that notes the indicative reason. And we've
18 created a consensus panel around what the
19 reasons are. And they were actually more
20 restrictive than these. Again, the classical
21 c-section is an important one that every one
22 agrees, that we've talked to, and I agree with

1 as a reason why you would deliver early.

2 But oligo and gestational,
3 depending on suspected macrosomia, some of
4 these are softer indications. But we've added
5 them, they're still on our checklist.

6 But it was important for us to go
7 through this process, I think ACOG needs to be
8 a bigger leader in terms of making stronger
9 statements on 39 weeks and helping providers
10 navigate these decisions.

11 But what about the issue of not
12 having the ICD-9 modifications that would
13 really clearly indicate what these are?
14 Elliot's actually worked with us trying to
15 help us. But we realized it would be
16 hopeless to try to do it from a billing
17 standpoint and we had to go to our vital
18 records system.

19 So it is a challenging measure in
20 that regard. And then people will always
21 question the classical -- the absence of that
22 modifier as a very important exception that's

1 missing.

2 DR. ARMSTRONG: I would comment
3 that we try to build in financial incentives
4 for both physicians and hospitals around this
5 measure but, again, you can't see it in the
6 code system. So you can't independently
7 verify it. So for 2000 ICD-10 is there
8 greater specificity in the coding?

9 MS. MILTON: Yes and no. There's
10 a lot more codes in ICD-10, but like the prior
11 classical cesarean section, it's not going to
12 be in the first iteration of ICD-10 codes but
13 I do understand it will be in the next
14 release.

15 So eventually that will be
16 something that can be coded, as will prior
17 myomectomy, that's another one that we hear
18 about as well. But that will be the iteration
19 after the second iteration, where we'll see
20 that.

21 So -- I'm trying to think of some
22 of the other things that we've heard. It's a

1 lot more specific, like if you're doing a
2 procedure, like the right side versus the left
3 side, versus lateral versus medial. There's
4 a lot of that when you're looking at
5 procedures but a lot the diagnosis codes, not
6 really.

7 DR. ARMSTRONG: So does this group
8 ever advocate to the AMA that there be
9 specific coding around elective deliveries and
10 gestational age of interest?

11 MS. MILTON: Gestational age is
12 another one, I believe, right, Sean? And
13 parity, correct? Okay, those two are coming
14 eventually. And then parity is in the next
15 iteration. So it's coming, but it's not here
16 yet.

17 DR. ARMSTRONG: Do you know what
18 year we're talking about?

19 (Off microphone comments.)

20 DR. GEE: And some states, the
21 state of Texas this year took the tack that
22 they would do Medicaid modifiers for billing

1 that indicated whether the delivery was
2 medically indicated or not.

3 My problem with that, obviously,
4 is there would be a lot of bias in the coding,
5 if you're voluntarily stating that you're not
6 going to be paid on your form.

7 But my understanding is that no
8 state has been able to get around the issue of
9 ICD-9 coders. Because you're not going to get
10 paid based on whether she -- you know, once
11 you go down a very long list of exclusions,
12 that you're not getting paid based on it,
13 there's very little motivation for coders to
14 put those codes in.

15 MS. KIEHN: I'm from Intermountain
16 Healthcare, for those of you that don't
17 understand them, we've been very well able to
18 put this into practice. Again, it is harder
19 if use ICD-9 codes. We have our own internal
20 system that we're able to pull it out.

21 As far as your question with oligo
22 and increase in stillbirths, I know there was

1 a recent article in ACOG and we have a
2 rebuttal to that that will be submitted.

3 We looked at our data last week,
4 looking at stillbirths and we have not seen an
5 increase since we have put this in. So just
6 so everyone is aware of that and that will be
7 out, if it gets accepted.

8 CO-CHAIR RILEY: Can we vote?

9 DR. WINKLER: Also, Kate Chenok is
10 on the phone. Kate, did you hear the
11 discussion and do want to enter a vote for
12 importance for the elective delivery part of
13 39 weeks?

14 MS. CHENOK: I would vote, yes, it
15 is important, thank you.

16 DR. GREGORY: Okay. We're going
17 to move to scientific acceptability. And
18 again, we had high on reliability, although
19 two people said it was moderate. And then we
20 were split on validity, four and four.

21 And, again, I think this comes
22 back to the coding. One of the other issues

1 that we didn't address is that another
2 exclusion is active labor or spontaneous
3 rupture. And active labor in particular is
4 not something that can very easily be detected
5 through coding, although there are some
6 algorithms for it.

7 But ultimately at some point after
8 you get your denominator there is some chart
9 abstractions that have to happen if you want
10 to be as accurate as possible. And so that's
11 where the issues come.

12 But, as a whole, we felt that it
13 was relatively reliable -- that is was very
14 reliable and relatively valid.

15 DR. BAILLIT: Can I just ask, in
16 my hospital too we're having the same
17 experience. We're going through by hand for
18 all of these and after we screen them by the
19 ICD-9s. Is it possible to build an exclusion
20 for a classical section for those who want to
21 do that?

22 Because we know that classical

1 sections are not equally distributed among
2 hospitals. They're much more concentrated in
3 the tertiary care centers. So is there a way
4 to say, if you choose to go through by hand
5 and pick those out, that we will accept that?

6 MS. MILTON: As a matter of fact,
7 we can create a debt element that would look
8 at prior classical cesarean and prior
9 myomectomy. So that could be accomplished by
10 chart abstraction.

11 DR. BAILIT: I would throw
12 cholestasis in there, too.

13 MS. MILTON: Actually, the code
14 has changed for that now. It used to be just
15 liver disorder, now it's and liver and biliary
16 disorder. So that has been addressed through
17 ICD-9 codes.

18 Also there's two new codes out, if
19 the coders are using it, that if the mother is
20 in spontaneous labor with a planned cesarean
21 section and they code for that then they no
22 longer need to look at the record to see if

1 they were in active labor prior to the
2 cesarean section.

3 So this is something that we're
4 looking to build into our algorithm as the
5 first check point. And if they don't code for
6 that we'll still have the original checkpoints
7 for cesarean section and then whether they
8 were in labor or had SROM prior to the
9 cesarean.

10 DR. BERNIS: Yes, just -- I support
11 this measure. I mean, I think this is a very
12 important measure. But just to echo something
13 that Kim said -- and Elliott, I think I know
14 you have a response to this. But the
15 denominator, the low risk women in collecting
16 that data, again, is challenging.

17 And we're actually -- we did a
18 pilot with 25 hospitals in partnership across
19 five states and it's very difficult to do,
20 certainly for all deliveries. And I
21 understand that, you know, you can get a
22 subset and that's I think the answer here.

1 But there are hospitals that do
2 want to, you know, input data and monitor not
3 just a handful of deliveries. So, you know,
4 I completely support this measure,
5 particularly the denominator, and having that
6 be a low risk denominator, as opposed to,
7 let's say, all early term deliveries or all
8 scheduled inductions and c-sections. It is a
9 challenge, for sure, I just wanted to make
10 that statement.

11 DR. WATSON: I'd just like to ask
12 a question. Again, I think this is a
13 wonderful measure, and I think it's been so
14 powerful that the country has changed its
15 practice over a short period of time. We've
16 seen dramatic improvement, and so I applaud
17 the developers.

18 My issue in trying to educate
19 physicians about this is, again, is the
20 glaring exclusion of the previous classical
21 and the previous myomectomy.

22 And so did I understand you to say

1 that we don't have to wait till ICD-10?
2 That's there's a work around? And what was
3 that work around and is that going to be
4 something soon?

5 MS. MILTON: You would have to
6 review the medical record. It would be chart
7 abstracted data element that we could create
8 and build into the algorithm as an exclusion
9 to the denominator population.

10 DR. MAIN: Perhaps if this group
11 recommended that, it might be considered more
12 strongly.

13 I think as we've tried to rule
14 this out over the last several years in
15 California statewide, we learned first of all
16 that there's no such thing as low hanging
17 fruit. This is hard. But it does change
18 practice dramatically. The biggest difficulty
19 here is clearly in data collection.

20 But I think what's happened is, as
21 this was recognized and supported by ACOG and
22 others, is that we've started to develop the

1 work around's that make it easier. To change
2 the ICD-9 codes. To add the classical c-
3 sections.

4 Actually, classical c-sections --
5 every hospital I talk to says that's an issue.
6 But the actual number of prior classical c-
7 sections is quite small. Even in a tertiary
8 center it is only a handful a year, when you
9 come right down to it.

10 With the other work, we're getting
11 around it in many parts of California by being
12 able to combine vital records and the ICD-9
13 codes, which gives you gestational age
14 imparities, so if that collection is done then
15 there's only about five percent of charts that
16 need to be looked at by hand to look at active
17 labor or ruptured membranes. If we change
18 those codes then it can be done even more
19 easily.

20 There is a problem with sampling,
21 though, Scott, in that the denominator gets
22 pretty small pretty quickly. If you have a

1 small denominator in a few cases you'll get
2 wide fluctuations, month to month or quarter
3 to quarter. So I have not been recommending
4 that we do a sampling, because we've seen big,
5 big fluctuations in our rates.

6 You know, as to whether the
7 denominator is all 37/38 weeks, versus just
8 the low risk members of 37/38 weeks. It's
9 harder to collect the denominator that way,
10 but it makes more sense if you're really only
11 looking at the cases from the low risk to
12 begin with. And I think that's why it got set
13 up that way to begin with.

14 DR. BERNIS: I know we're not on
15 usability yet, but I think it certainly gets
16 to an issue there, as well. Again, I support
17 the measure, but it is a challenge for some.

18 DR. GEE: Would you both be able
19 to speak to -- certainly there will be
20 fallouts with this measure, because of the
21 number of exclusions, patient population, et
22 cetera.

1 One of the things that Elliot and
2 I have talked about previously, is that five
3 percent would be the fallout rate that would
4 be acceptable. So you would expect that you
5 would have some of these that would come up in
6 the data.

7 Can you speak to -- and when
8 you're doing quality improvements, sometimes
9 that's a way to get around the prior classical
10 or your prior myomectomy, is just accepting
11 that if you're doing QI or payment reform
12 based on this that, there will be a fallout.

13 Can you speak to that in your
14 process in choosing that number and how that's
15 worked in California?

16 MS. MILTON: Actually, we do not
17 set benchmarks. We have not set a benchmark,
18 but for those hospitals that do report this
19 measure to the joint commission we set target
20 ranges.

21 Target ranges are based on all
22 hospitals from the previous quarter, how they

1 performed with this measure. So you have a
2 mean and you have a standard deviation above
3 and below. And that particular hospital's
4 rate would be plotted on that graph, so they
5 can see how they are performing relative to
6 other organizations that report the measure.

7 This will vary from quarter to
8 quarter, depending on how well the nation has
9 performed. So this is actually a moving
10 target range that we have set.

11 And the second quarter of this
12 year we were around 14 percent, for all
13 hospitals that reported.

14 DR. MAIN: The five percent came
15 from Leapfrog, that also uses the same
16 measure. In a big sampling in California
17 hospitals, and part of them in a March of
18 Dimes collaborative program, most of the
19 hospitals have been able to get down into the
20 under eight and many under five, to two
21 percent. And that's been the experience in
22 Intermountain Health. I think you're running

1 about 2.2 percent -- 1.9.

2 CO-CHAIR RILEY: Okay. In the
3 interest of time I think we should move on
4 here, and vote for scientific acceptability of
5 this measure.

6 DR. BAILLIT: This with acceptance
7 of the c-sections, prior classicals taken out
8 or no?

9 CO-CHAIR RILEY: With the
10 recommendation.

11 DR. GREGORY: We're measuring on
12 specifications as they stand.

13 DR. WINKLER: Kate, do you want to
14 vote on scientific acceptability of this
15 measure?

16 MS. CHENOK: Yes, I think it meets
17 acceptability. And if I get cut off, I'm
18 fully in support of this measure.

19 DR. WINKLER: Thank you. Okay, 25
20 yes, one no.

21 DR. GREGORY: We're now going to
22 talk about usability and feasibility, and,

1 again, it was rated highly usable, with two
2 people scoring moderate. And very feasible,
3 with one person scoring moderate, everyone
4 else scoring high.

5 There were some questions about
6 the risk adjustment. I thought, if I recall
7 the discussion, many people felt that it maybe
8 should not be risk adjusted. And that
9 especially the issue with race, sort of,
10 detracted from that, from the ability to see
11 disparities.

12 CO-CHAIR RILEY: Comments? None,
13 okay. So voting on usability.

14 DR. WINKLER: Kate, did you want
15 to vote on usability? High, moderate, low,
16 insufficient?

17 MS. CHENOK: Moderate.

18 DR. WINKLER: Thank you. Nine
19 high, 15 moderate, one low.

20 CO-CHAIR RILEY: Moving on.

21 DR. GREGORY: We talked about
22 feasibility. We felt that it's feasible. The

1 big issues we've already talked about, in
2 terms of parity, gestational age, labor. It's
3 a little intensive but it's feasible.

4 And so the overall rating was
5 pretty much mixed between high and moderate.

6 CO-CHAIR RILEY: So can we vote?

7 DR. WINKLER: Kate, your vote on
8 feasibility?

9 MS. CHENOK: Moderate.

10 DR. WINKLER: Thank you. Three
11 high, 21 moderate, one low.

12 CO-CHAIR RILEY: And then overall
13 suitability for endorsement?

14 DR. WINKLER: Kate, your overall?

15 MS. CHENOK: Yes.

16 DR. WINKLER: Thank you. Twenty-
17 five yes, zero noes.

18 DR. WATSON: Can we formally make
19 the recommendation to include previous
20 classical c-section and previous myomectomy?
21 Would that be appropriate at this time to make
22 that recommendation along with this?

1 DR. WINKLER: Is everyone in
2 agreement with that recommendation?

3 (Chorus of yeses.)

4 CO-CHAIR RILEY: And so we are
5 moving on to cesarean rate for low risk first
6 birth women.

7 DR. WATSON: Okay. This is my
8 metric, my measure. And I was actually quite
9 glad to see that the low-risk first birth
10 woman c-section rate has been changed.

11 I never quite understood that
12 metric. I think the NTSV is much clearer.
13 Obviously, getting our c-section rate down is
14 something that has plagued us for -- I think
15 the data said 20 years. It's been longer than
16 that.

17 I remember my first month in
18 private practice my division chief came up to
19 me and said I needed to get my c-section rate
20 down. And I said I have not done a c-section
21 yet. And he said it doesn't matter, you need
22 to get that rate down.

1 (Laughter.)

2 And obviously we have been
3 unsuccessful, the rate continues to climb.
4 And so any help that we can get in getting
5 that rate down I think would be greatly
6 appreciated.

7 Our workgroup thought that this
8 was a very important measure, had high impact.

9 And had high opportunity for improvement, and
10 was felt to be very, very important.

11 ACOG mentions that they feel that
12 this measure is probably the optimal measure
13 for cesarean section rate. More so than the
14 total c-section rate or the primary c-section
15 rate. And I think previously that's where
16 people have been trying to put their emphasis.

17 Early data shows that, currently,
18 nationwide we're at about 27.7 percent. And
19 I think that the rationale for this is that
20 this measure really kind of looks at the
21 process of labor or the management of labor.
22 And that's where we really need to put our

1 focus.

2 So I'll stop there and ask the
3 developers if they have any comments?

4 DR. MAIN: Just one comment, in
5 that this is a measure that really focuses on
6 the group of -- the sub-population cesarean
7 sections has seen the biggest rise in the also
8 15 years, besides repeat c-sections, but has
9 been -- labor c-sections has been the biggest
10 contributor to the rise of c-sections.

11 And it's also the biggest source
12 of variation among hospitals and among
13 providers. So this is where most of the
14 variation lies, is in this population of
15 women.

16 DR. GEE: I just want to say that
17 this is eminently usable, because it's looking
18 at the thing that we can modify most easily,
19 I mean, without getting into the VBAC argument
20 and complicated argument.

21 It's simple to measure. We're
22 putting it on our report card. It's useful,

1 I think, for both public reporting as well as
2 provider reporting. It's easy to do, you can
3 abstract it from vital records, which is a
4 godsend. In terms of hospitals wanting to
5 work with you, our hospital association is
6 very supportive of us collecting this measure,
7 supporting this measure because it does not
8 put a large burden on our providers. I think
9 it's a fantastic measure.

10 MS. PARTRIDGE: I would just add
11 that this is one of the core measures
12 recommended by Secretary Sebelius for use in
13 the Medicaid program. For those of you who
14 maybe don't realize it, the Medicaid programs
15 collectively pay for at least half, probably
16 now, clearly half, given the recession, of the
17 babies born in this country. In other words,
18 about two million a year.

19 And in the stakeholder group that
20 developed those recommendations for the
21 Secretary, there was wide representation of a
22 variety of perspectives, including states that

1 were concerned about data collection and
2 burden and so on. And it was overwhelmingly
3 endorsed. So it is certainly highly
4 recommended by the Medicaid programs.

5 DR. GELZER: This measure was
6 first endorsed in 2008, and maybe this is just
7 a silly question, but why -- it hasn't had
8 impact on the rate. Or has it decreased the
9 rate of increase? Can we make it required?

10 DR. MAIN: I think there's a
11 difference between endorsement and then being
12 used by, either insurance companies by linking
13 the payment, by people like the Joint
14 Commission that have picked it up, and other
15 groups. So it takes a few years to actually
16 get into play, is what we're seeing.

17 But I think you need an additional
18 incentive to go with the measure to make
19 change sometimes. I think this is one that's
20 going to need some incentives involved.

21 DR. ARMSTRONG: And for what it's
22 worth, we have about 200,000 deliveries a year

1 and the rate is stable. So there's been no
2 increase in it. Stable at a very high level.

3 DR. CALLAGHAN: Same with the
4 national data.

5 DR. GREGORY: I think this is one
6 where we not only need system issues, but we
7 need a lot of patient education about this
8 measure.

9 DR. BAILIT: I think the nice
10 thing about this, and along with the one we
11 just looked at, the 39 week, is that it's all
12 tied in with inductions. So there is
13 something that hospitals know that they can
14 look at if, they're found to be an outlier on
15 this, there's an obvious sort of place to look
16 to change practices.

17 DR. ARMSTRONG: We see huge
18 regional variation in this rate, around the
19 country. Lowest in the north central region.
20 Very high in the southwest and the southeast.
21 So there's something also about the culture of
22 how we talk to patients, how physicians train.

1 Maybe that has to be addressed as well.

2 CO-CHAIR RILEY: And how patients
3 accept what we say. So that's the other
4 thing, is that I don't think there's some
5 variation in what patients' expectations are.
6 You know, some demand what they demand and
7 others are willing to listen to reason.

8 CO-CHAIR RILEY: These regional
9 patterns match hysterectomy patterns around
10 the country so it's all tied in.

11 DR. WINKLER: Who has the handheld
12 mic? Guys, don't you have it back there?

13 DR. PRATT: Hi, I'm Steve Pratt,
14 I'm an anesthesiologist from Boston, and I
15 would offer one caution. Epidural's got
16 blamed for c-sections for a very long time.

17 When we all looked, when you all
18 looked at, what are the things that we know
19 that increase the risk for cesarean delivery.
20 Control for all these things and then said see
21 all that's left is the epidural, it must be
22 that.

1 As it turns out it, probably means
2 that pain was a marker for dysfunctional labor
3 and those woman ask for an epidural and that's
4 what the prospective randomized trials have
5 shown.

6 The concern that I would have is
7 that it means there's something that happens
8 in labor that we don't measure very well. And
9 can't understand very well and all those
10 things that we try to say are risk factors for
11 labor aren't the whole picture. And I'm just
12 wondering how you're going to deal with that?

13 CO-CHAIR RILEY: Okay. Any other
14 comments? Are we able to vote on at least the
15 first part of this measure? Importance to
16 measure and report.

17 DR. WINKLER: Kate, are you there?

18 MS. CHENOK: I'm here. It's
19 important.

20 DR. WINKLER: Great, okay, thanks.
21 Twenty-five yes, zero no's.

22 CO-CHAIR RILEY: Okay. Moving on

1 to reliability.

2 DR. WATSON: For reliability, our
3 workgroup felt this was a pretty clean
4 measure. The numerator is c-sections. The
5 denominator is basically defined by the
6 measure name with just a few exclusions.

7 There was some concern during our
8 discussions about the stratification of the
9 data by age. And if I heard correctly, during
10 our workgroup conversation, there was some
11 data to support that. And I would like to ask
12 whoever in the workgroup had that data.

13 DR. DENK: Actually, I brought it
14 up. A mild question about the risk adjustment
15 by age. And Elliot answered me and then I
16 went back looked at New Jersey data and he
17 was, I see exactly the same thing that he does
18 and I'm going to start risk adjusting as soon
19 as I get home, for age.

20 DR. MAIN: There's a very
21 dramatic, impressive straight line for
22 nulliparous c-sections, and actually c-

1 sections as a whole from age 18 to 40. It's
2 not something that begins at 30, 35 or 40.
3 It's straight line correlation coefficient of
4 about .96. It's pretty dramatically a
5 straight line.

6 So that women at 30 have seven or
7 eight percent higher rate than women at 24.
8 Women at 24 have higher rates than at 18, and
9 it's all the way up the line.

10 So it wasn't just women over 35 or
11 40 which is in California. Which is in San
12 Francisco, my issue, but it's a straight line
13 all the way from 18.

14 DR. BAILIT: Elliot is that true
15 for people in spontaneous labor or is that
16 really a reflection of the practices that the
17 older women have more complications, et
18 cetera, et cetera?

19 DR. MAIN: Well, we worried about
20 older, about it being a self full filling
21 prophesy about how you care for women over 35
22 or 40. That's why it was so dramatic to look

1 at women 18, 22, 24, 30. And it was a
2 straight line in that time period as well,
3 even up through the early 30's and 40's.

4 So we felt it was more biological
5 with some issues, you know, there's self full
6 filling prophesies and how we manage people
7 who are older or more obese or so forth that
8 that's hard to tease out in this.

9 But when you look at the earlier
10 ages and see the same thing happening, that's
11 when we thought it was real.

12 DR. ARMSTRONG: We did something
13 similar and then took the infertility
14 singleton patients which sort of our marker of
15 the premium births kind of thing. And they
16 just have higher rates that go up also with
17 age. So there's a bump that the premium baby
18 gets. But age, you see the same thing.

19 And did you also look at obesity,
20 stratify by that?

21 DR. MAIN: We've done -- obesity
22 gets blamed for a lot in this area. But the

1 big bump in obesity comes with morbid obesity.
2 But again, that was very hard to tease out
3 from what the physicians' intentions are from
4 what is biologically related.

5 They weren't necessarily that much
6 bigger babies. So we have not yet done a
7 correction, or a risk adjustment for obesity.
8 The one caveat I have would be morbid obesity
9 may be would be a different one.

10 And that is increasing, but it is
11 still a small proportion of all the obesity
12 and overweight that are seen in the U.S.

13 DR. DRYE: I'd just add that in
14 our outcomes measures morbid obesity is
15 showing up as important but not obesity in
16 general. Probably because obesity is so
17 common at this point.

18 CO-CHAIR RILEY: Okay. If there's
19 no further comment can we vote on the
20 reliability and validity of this measure?

21 Kate do you want to --

22 MS. CHENOK: Yes, I support.

1 CO-CHAIR RILEY: Thank you.

2 DR. WINKLER: Twenty-five yes,
3 zero no's.

4 CO-CHAIR RILEY: Moving on to
5 usability.

6 DR. WATSON: Well, the usability
7 for our workgroup that we had had some
8 discussion about the risk the adjustment that
9 we already talked about. But with that
10 exception we found it to be highly usable.

11 And I think to answer some of the
12 previous questions of why haven't we seen
13 improvement previously? And I think that
14 from a user's standpoint, I think it was
15 poorly understood at first. The low risk,
16 first birth. I think was a bit confusing.
17 And of course, we didn't know where the data
18 was.

19 Now we've had some time to collect
20 that and so hopefully the usability with
21 quality improvement going forward will be
22 demonstrated.

1 MS. BRANDENBURG: One comment I'd
2 like to make is we have been collecting the 39
3 weeks measure for about a year now for the
4 March of Dimes. And one thing we have seen is
5 we have dropped our c-section rate from about
6 39 percent to 32 percent.

7 And the only measure we've done is
8 the 39 weeks measure. So I'm wondering if
9 once the 39 weeks measure goes into place if
10 it won't affect this measure as well with the
11 c-section measure. Because we have seen that.

12 CO-CHAIR RILEY: Okay. So I think
13 we can vote on usability of this measure.

14 MS. CHENOK: Yes, it's usable.

15 CO-CHAIR RILEY: It's a high,
16 moderate, low, insufficient information.

17 MS. CHENOK: High.

18 CO-CHAIR RILEY: Okay. Awesome,
19 thanks.

20 (Off microphone comments)

21 DR. WINKLER: It's 23 high, two
22 moderate.

1 CO-CHAIR RILEY: And moving on to
2 feasibility, are there any other comments
3 about feasibility?

4 DR. DENK: Yes, I just want to
5 echo what Rebecca said before. From the point
6 of view of a state official or somebody
7 outside the health care system. This is
8 exactly what I'm talking about, a measure
9 that's harmonized with what we can do.

10 I can do this, I can't do the 39,
11 I can't do it in the way that it's endorsed
12 here. So, you know, I kind of wonder why one
13 measure has so many exclusions and the other
14 one doesn't. But that's for future thought.
15 But thank you.

16 DR. MAIN: We specifically
17 designed this measure to have two
18 specifications that are really pretty much the
19 same. One that's able to be used with vital
20 records and one that's done in a typical joint
21 commission manner. So it has a double set of
22 specifications you'll see in the application.

1 DR. ARMSTRONG: So this measure
2 has it's first births, right? So can you get
3 first births out of vital statistics data?

4 FEMALE PARTICIPANT: Yes, but you
5 can't get it out of claims data.

6 DR. GEE: Just to agree with
7 Chuck, we ought to be thinking more along the
8 lines from a public health standpoint in
9 population, improvements in population health.

10 Of how to use vital records more
11 effectively for measure creation, and whether
12 if we do need to modify them. How do we do
13 that regionally or nationally and create
14 technical assistance to states who are trying
15 to do this. Because it is very challenging.
16 But this a perfect example of how that works
17 very well.

18 DR. PROFIT: I guess what my
19 question would be is what the correlation is
20 between the two specifications that you
21 propose? And to some degree if the
22 correlation is really very high I wonder why

1 we'd need both.

2 If one of them can be done post
3 hoc without anybody having to go in an extract
4 data?

5 DR. MAIN: Not every state is
6 there yet, in terms of why not. A lot of
7 states haven't been able to release vital
8 stats data or use vital stats data for these
9 kinds of purposes. For many months to a year
10 or two after the fact. And so that degrades
11 it's value as quality metric.

12 There is some quality improvement
13 work that may need to be done on some state
14 birth certificates for presentation. In
15 California we had to work on that some. So
16 there is some work that you have to do as a
17 state. If you're going to take this on a
18 state to make certain your data is as clean as
19 possible.

20 In terms of head to head trials
21 we've not done a big assessment of that, but
22 it is a lot more time consuming to go through

1 the charts to do this. Which again, is why it
2 hasn't had wide acceptability in many states
3 yet.

4 Because A, the joint commission is
5 not required. And B, you know, unless you use
6 vital stats you have to do chart review to do
7 this measure. And that's the difficulty.

8 DR. PROFIT: To some degree it
9 feels like we're shifting the burden, maybe
10 this should be a statewide burden but we're
11 shifting it to the hospital. I guess, I'm not
12 sure if it should be a statewide burden or a
13 hospital burden.

14 But maybe that's a worthwhile
15 discussion to have. Because I guess what
16 we're doing here then is shifting it squarely
17 onto the hospital, right?

18 Well, the state if they do the
19 vital statistics. But I guess the other
20 states, you could kind of say like well, if
21 they're not ready like go get ready.

22 CO-CHAIR RILEY: Okay. So if we

1 can vote on feasibility.

2 DR. WINKLER: Kate, is it high,
3 moderate or low for you?

4 MS. CHENOK: Moderate.

5 DR. WINKLER: Thanks. Sixteen
6 high, nine moderate, zero low.

7 CO-CHAIR RILEY: Moving on.
8 Overall suitability for endorsement for this
9 measure? Kate, yes, no.

10 MS. CHENOK: Yes.

11 CO-CHAIR RILEY: Okay.

12 DR. WINKLER: Twenty five yes,
13 zero no's.

14 CO-CHAIR RILEY: Okay. Next up is
15 appropriate use of antenatal steroids. This
16 is another joint commission measure. And this
17 measure, just to remind people was. the
18 numerator is a full course of antenatal
19 steroids prior to delivery. In that episode
20 of care, I should say.

21 And the denominator would be
22 babies between 24 and zero sevenths weeks up

1 to 32 and zero sevenths weeks. And in terms
2 of, this is sort of a no-brainer actually.

3 In terms of the data, there's lots
4 of it as well as clinic guidance from NIH,
5 from ACOG, from everyone you can imagine.
6 Suggest that the appropriate standard of care
7 for these babies is to get a dose of -- or get
8 a course, I should say. Of the antenatal
9 steroids if they fall between those
10 gestational ages with excellent evidence that
11 it will decrease the risk of RDS and NEC for
12 these babies.

13 So in terms of importance to
14 measure and report, everyone in the group felt
15 that it was high impact. In terms of
16 improvement, or whether or not there was a gap
17 in sort of what people are doing is that there
18 was clearly room for improvement based on the
19 data that was presented.

20 And although there's been some
21 improvement, which was good to see, to your
22 point Scott, there was clear data that it had

1 been tested and in some places it's seen some
2 improvement. They're still a ways to go in
3 this population.

4 And the workgroup also felt that
5 it obviously met importance. I don't know if
6 there was anything I left off that occurred on
7 the workgroup in terms of this. I can't
8 remember, honestly. Any comments or concerns?
9 Jennifer.

10 DR. BAILIT: Can JCo comment on
11 why it's a full course as opposed to a partial
12 course? One of the things we see is, we see
13 patients show up in late labor, we give them
14 a dose of steroids but you can't hold them off
15 for the full 48 hours.

16 MS. MILTON: I know originally
17 when the measure was endorsed they were
18 looking at just the initiation of it. But
19 when our technical advisory panel met to
20 review the measures they felt that we should
21 be looking at full course.

22 One thing that we have done in our

1 measure specifications, is that we would look
2 at patients, if they'd received, let's say,
3 one dose and then they deliver before the 24
4 hour period that would be an implied reason
5 why they didn't get the full course. So
6 therefore they would be removed from the
7 measure.

8 So that's forthcoming in
9 specifications beginning with January 1, 2011
10 discharges. Because we did hear that loud and
11 clear from the field.

12 DR. BAILIT: Okay. So just to
13 clarify, starting in January of next year that
14 if you deliver before the full course, that
15 excuses you.

16 MS. MILTON: Excludes.

17 DR. BAILIT: Excludes you, thank
18 you, from the measure?

19 MS. MILTON: That's correct. '12,
20 I'm sorry, got about a month to go.

21 DR. ARMSTRONG: So it excludes you
22 or it's a hit?

1 MS. MILTON: I'm sorry?

2 DR. ARMSTRONG: It excludes you?

3 MS. MILTON: It excludes you from
4 the measure. They would be taken out of the
5 measure.

6 CO-CHAIR RILEY: So just for the
7 non-clinicians in the room, I should have
8 mentioned this, I didn't. Full course means
9 that you get your first shot, and then 24
10 hours later you get your second and then
11 hopefully deliver 48 hours after the first
12 shot.

13 So it is not inconceivable that
14 women will come in, they'll get the first
15 shot. While you're waiting around to give the
16 second one they deliver.

17 So this is just for the non
18 clinicians in the room. I should have
19 mentioned that. And the other issue is that
20 if you use dexamethasone then it's Q 6 hours
21 and you're getting four doses.

22 DR. ARMSTRONG: It would just seem

1 that's appropriate care, so that you wouldn't
2 be excluded, you would count as a hit.

3 MS. MILTON: You get taken out of
4 the denominator.

5 CO-CHAIR RILEY: Right, so the
6 point is we are saying that you shouldn't get
7 penalized for something that you can't
8 control. Because tocolytics don't work, so
9 someone's going to deliver before your 48
10 hours.

11 DR. WINKLER: Question, Celeste,
12 does the specifications that you submitted to
13 us include that change?

14 MS. MILTON: Yes, it's in the data
15 element reason for not administering antenatal
16 steroids. It's spelled out in there, in the
17 notes for abstraction.

18 DR. GREGORY: Can you clarify, I
19 noticed that you went down to 32 weeks instead
20 of 34 weeks?

21 MS. MILTON: Right, when we worked
22 with this measure with the original measure

1 developer, I think that there's some evidence
2 that they haven't had, I might get this wrong,
3 premature rupture. That you could go up to
4 34.

5 So it wasn't as clear cut if you
6 were allowing if and or. So the decision was
7 made to simplify it and just look at that
8 discreet 24 to 32 week period. That was the
9 reason.

10 CO-CHAIR RILEY: So I think,
11 wasn't it to sort of mirror the NIH consensus
12 so that we wouldn't penalize people. Because
13 the NIH consensus, that was a lot of the
14 discussion was 32 to 34 and back and forth.

15 And no one could decide and think
16 they arbitrarily said okay, 32 weeks and so I
17 think this just sort of mirrors that.

18 DR. GREGORY: Well, the NIH said
19 24 to 32 for ruptured membranes, and then, I'm
20 sorry, 24 to 34 intact. And said, question
21 mark, ruptured 32 to 34.

22 So I'm just concerned that by

1 endorsing this measure then there's this 32 to
2 34 week group with intact membranes that -- I
3 want to make sure we're not sending the wrong
4 message.

5 DR. JALEEL: I'm Jaleel, from
6 Parkland Hospital. And over there the
7 constant held debate with the obstetricians
8 because of some of the controversies that you
9 have mentioned. One is hypertension and the
10 other one is diabetes.

11 And the previous old literature
12 which this was based on had clinical trials
13 which were done in hypertensive women where
14 there was an increase in fetal deaths, in
15 those hypertensive women.

16 And also there are multiple other
17 reasons why it might not be suitable for
18 mothers who have diabetes. So those are two
19 exclusions that our observations in our
20 hospital have for the antenatal steroids.

21 Do you want to comment on that?

22 MS. MILTON: This will be looking

1 at the evidence and I'm trying to remember if
2 I saw anything in the evidence that said that
3 there were any harms. I don't believe in the
4 evidence that we reviewed that we saw that.

5 So I guess I'm going to bring my
6 expert up here.

7 DR. ROSS: Can you repeat that
8 again?

9 DR. JALEEL: So in our hospital
10 two of the exclusion criteria for antenatal
11 steroids. One is hypertension and a second
12 one is diabetes. And so the reason that you
13 have given is that in the previous Cochrane
14 analysis which was done they had not
15 specifically looked into hypertensive women.

16 And one of the trials which had
17 looked into hypertensive women, there was an
18 increase in fetal death. And so there is a
19 concern for fetal death from that.

20 And then diabetes, one of the
21 concerns is yes, it can cause hyperglycemia,
22 it may inhibit surfactant action and all those

1 concerns. So I don't know what the recent
2 literature is, recent evidence is on that.

3 DR. ROSS: Yes, I think the
4 Cochrane had that response. Most of the
5 patients who are receiving this are on
6 constant monitoring. And so there's not
7 thought to be a very big concern about fetal
8 death and the glucocorticoids. I think that's
9 diminished in the literature.

10 As far as diabetics, certainly the
11 glucocorticoids can put that diabetic in poor
12 control, and that has to be dealt with. Never
13 the less the benefits are thought to far
14 outweigh the risks in that regard.

15 CO-CHAIR RILEY: So, Mike, do you
16 have a response in terms of this, what Kim's
17 bringing up terms of the 32 to 34 weeks
18 gestation. And sort of where does that leave
19 us with the intact membranes, I'm sorry, I
20 should clarify.

21 DR. ROSS: You know, I think the
22 reason we chose that, again, was to avoid

1 trying to break it out into whether the
2 membranes ruptured, and when did they rupture.
3 I haven't seen any trend that we're pushing
4 patients or pushing docs not to give the
5 steroids between 32 to 34 weeks.

6 So I would continue it at this 32
7 weeks for the simplification. I would perhaps
8 add one note for the future. And that is the
9 concern that we're overusing steroids. Which
10 is happening across the country. And people
11 are using it like water.

12 Every patient now in so many
13 community hospitals as well as the academic
14 hospitals are getting steroids the moment they
15 walk in with a contraction at 25 weeks. And
16 the vast, vast majority of those are not
17 delivering within the seven to 14 days.

18 I don't know, do we have any, we
19 noted that it's a seven day efficacy, but is
20 that counted in the?

21 MS. MILTON: We don't look at
22 that.

1 DR. ROSS: We don't look at that.
2 That might be something to long term consider
3 is the number of courses of the steroids as
4 well as whether you're giving it within an
5 appropriate time window of perhaps 14 days.
6 But for future discussion.

7 DR. PROFIT: So I'm a little bit
8 humored I think. In 2008, we a lot of
9 discussion about this measure. And a very
10 similar measure from Vermont Oxford.

11 And the main reason we ended up
12 endorsing this measure was that it included
13 the 32 to 34 weeks exclusion for women with
14 ruptured membranes, because the obstetricians
15 felt very, very strongly about this.

16 And, you know, on the other hand
17 we tried to make the arguments like, okay,
18 what's that we heard yesterday about 80
19 percent of VLBW infants already captured by
20 the VON and they're already collecting this
21 data.

22 But it was felt to be the more

1 scientifically pure and in line with NIH
2 guidelines to address the 32 to 34 week-ers.
3 So we had this big trade off between trying to
4 be perfect versus good enough.

5 And the perfect one out, and now
6 we're going back to good enough. Which, I'm
7 not against that but I would just kind of
8 caution about extra data collection again for
9 something that like 80 percent of the VLBW
10 patients already submitting somewhere.

11 I guess the other point that I
12 would make. And I understand we're in line
13 with the guidelines at 24 weeks, I can tell
14 you for a neonatologist how frustrating it is
15 to receive a 23 or 24 weeker from the
16 community that has not gotten steroids because
17 it didn't hit 24 weeks.

18 And I guess my last comment would
19 be that I feel like the evidence for antenatal
20 steroids on outcomes on babies is probably
21 stronger than anything else we have in
22 neonatology. So, you know, I'm fully

1 supportive of having some kind of antenatal
2 steroid measure.

3 CO-CHAIR RILEY: So are you
4 suggesting -- what exactly are you suggesting?

5 DR. PROFIT: So I'm not
6 suggesting, I know there's no Vermont Oxford
7 measure on here to harmonize and to think
8 about. It is probably because they didn't
9 want to resubmit after the last discussion we
10 had.

11 But I do think that we need to be
12 cautious, and I think for this round, you
13 know, I feel supportive of this measure. But
14 I feel like if there is another round in the
15 future where we would have, if you know, if
16 the VON would resubmit.

17 I'm just trying to be very
18 conscientious about hospitals not duplicating
19 work. And I think that's just wasted effort.
20 All of us who work hard on quality improvement
21 and trying to make things better are competing
22 for resources and hospitals to do anything on

1 the front lines.

2 And so if money flows into a
3 duplication of efforts, you know, on measures
4 that are very similar, you know, that money is
5 not available to do good things for our
6 patients. So I just want to be conscientious
7 about that.

8 I don't think we can do anything
9 about the 24 week-ers for this measure and
10 that's fine, but I would maybe this could be
11 brought to ACOG, I'm not sure.

12 But if you have representatives
13 from ACOG who could, you know, like leave it
14 the fact at what point it would be brought up
15 to extend, you know, to measure criteria.

16 Or maybe to investigate whether
17 this is going to be beneficial to babies that
18 are just below 24 weeks.

19 CO-CHAIR RILEY: So I think though
20 to speak to that last thing I think that we
21 would be looking for some clinical guidance?
22 Before you could measure whether or not people

1 are doing it?

2 I think we need some clinical
3 guidance that's very clear, with compelling
4 evidence, that says we should be ratcheting
5 down what we're doing and, because all you're
6 going to measure if you go to 23 and half or
7 whatever the number is. Is a huge variation
8 in opinion from neonatology as well as
9 obstetrics.

10 And that's going to be a mish mash
11 of who knows what it is. So I think if that's
12 an issue then we need to take that back to
13 both AAP and ACOG to take a look at that 23 to
14 24 week gestation and come up with some
15 guidelines that all of us can live with.

16 DR. PROFIT: Yes, I'm just
17 suggesting that maybe we can make a
18 recommendation as a committee that that should
19 be in an important thing to be looked at in
20 the future.

21 Because it's almost like when we
22 say, you know, when we enshrine it at 24 to

1 zero, you know, with this measure that, you
2 know, it will drive practice even more so.

3 And so I feel like at least we can
4 make a recommendations maybe that this is
5 something that should be investigated studied
6 or discussed at least. I'm not sure we're
7 able to get a trial on these babies together.

8 DR. WINKLER: I just want to make
9 a comment, this measure is up for it's
10 maintenance review and as Dr. Profit
11 mentioned, there has been a change. And so I
12 think that's something you need to factor in.

13 Because in the course of the prior
14 endorsement it had, you know, one set of
15 specifications that now have been modified as
16 you've commented on to a significant degree.

17 So that is an important aspect of
18 its, you know, sort of maintenance review is
19 how the measure evolves and changes.

20 CO-CHAIR RILEY: So can we vote on
21 importance to measure and report?

22 DR. WINKLER: Kate, are you still

1 with us?

2 DR. WINKLER: Twenty four yes,
3 zero no's.

4 CO-CHAIR RILEY: Okay. So moving
5 on to scientific acceptability, I think within
6 the workgroup we sort of talked about it
7 already. We felt that the reliability of the
8 measure was high. Five felt that and one
9 moderate.

10 And then in terms of the validity,
11 again, the vast majority of the work group
12 felt that it was highly valid. I don't know
13 that there was any other discussion, do people
14 feel there are other things that need to be
15 clarified? Feels that we can vote? Yes.

16 DR. DENK: There's a little corner
17 discussion going on over here. The issue of
18 excluding from the measure. Anybody who
19 starts a course but doesn't have a chance to
20 complete it before the baby is delivered. You
21 know, that means that you don't get credit for
22 starting a course, right?

1 And so while it's not a
2 denominator either, I mean, you don't get
3 credit for a lot of attempts at good health
4 care. So I'm just wondering if you thought
5 about the pros and cons of giving credit. I
6 know it's defined as full course. And that's
7 obviously a trade off. Do you want to
8 comment?

9 DR. ROSS: There's both ends of
10 that spectrum, one may be that the patient
11 comes in, the doc does a great job and can
12 only give a course, a half a course a few
13 hours before delivery.

14 The other is you wouldn't want to
15 just sort of allow that and say, "Oh, we
16 forgot to give this." So an hour before she's
17 about to deliver let's go give her a dose. So
18 I think excluding them is probably the wisest
19 for the present time.

20 DR. BERNES: So I kind of smiled at
21 that and I need some help from my OB
22 colleagues, you know the literature better.

1 But is it clear that a full course, two doses
2 is absolutely necessary?

3 My understanding is there's a
4 little bit of, that's not crystal clear in the
5 literature, that one dose even 48 hours and
6 beyond is, it can be beneficial. So I am
7 concerned. You know Chuck's point is an
8 important point. Plus, you know, this is
9 locking us into a full course, pretty much, of
10 two doses, right? I mean, if I'm reading this
11 correctly.

12 DR. ROSS: The literature, as most
13 of the OB studies is controversial. The vast
14 majority of studies that were originally done
15 through the report on the efficacy used
16 complete dosages.

17 And yet there are select studies,
18 that you are correct, show that independent of
19 the full dose or even the time to completion
20 may not have a difference of effect as
21 compared to the full dose. On certain outcome
22 parameters, particularly bronchopulmonary

1 dysplasia.

2 Nevertheless, I think the majority
3 of the literature and obstetricians would
4 believe that the full dose is what's really
5 most effective for the prevention of at least
6 the acute outcome of respiratory distress
7 syndrome.

8 CO-CHAIR RILEY: Also, I think
9 that we're at this point in practice where, I
10 don't know how you're actually going to get
11 the answer to your question.

12 I mean, I think it's a daily
13 debate on every unit. When you get that
14 person who comes in and you're like, she's not
15 going to make the 24 hours, should we do Q 12,
16 is there data to support that? I don't think
17 anybody knows, some people do it other people
18 don't.

19 And I feel as though you can see
20 studies which, you know, they are small, you
21 know, so I don't know that we're going to be
22 able to answer that question.

1 DR. WATSON: I'd like to ask our
2 perinatologists if you all, I mean you may
3 have just answered with no data. But at
4 national meetings this question has been
5 posed.

6 What's the latest time that you
7 can give steroids and the answer was just
8 before the ears come out. So just, nobody
9 really knows, and is it advantageous to give
10 it at that late date? So I just don't know.

11 DR. ARMSTRONG: Do you have a
12 sense in looking at the data for babies that
13 are appropriate for steroids but get only one
14 does. How often is it a quality issue versus
15 just a timing, no opportunity.

16 MS. MILTON: We really haven't
17 looked at that so I guess I couldn't answer
18 that. It seems though that when we do get
19 inquiries into the measure the majority of the
20 time, it's because they have delivered prior
21 to. You know, before they could get the
22 second dose.

1 That appears to be the issue for
2 the most part I would say. A couple of the
3 cases where there was a documented congenital
4 anomaly incompatible with life. So that would
5 have been the reason why they wouldn't have
6 needed the steroids as well.

7 DR. ARMSTRONG: Right, so by
8 excluding them you're leaving good behavior.
9 You're not accounting for some good behavior
10 that hospitals could get credit for.

11 CO-CHAIR RILEY: Other questions?

12 DR. ARMSTRONG: To answer your
13 question, I don't think anybody knows how
14 short a time. Kim's whispering in my ear, she
15 thinks she's heard four hours. I have no
16 idea, I haven't heard anything.

17 I just give it until I see,
18 literally the ears come out. I think the
19 reason that you get that answer is because we
20 cannot predict when someone's going to
21 deliver.

22 I think that that's the main

1 issue. Is that we don't have good predictors.
2 Fifty percent of the people won't, who come in
3 with contractions won't deliver, but I don't
4 know which 50 percent necessarily.

5 In which case that's how I think
6 we creep into that. Everybody gets it the
7 minute they have one contractions which I
8 agree with you is going to be, you know, in a
9 few years is going to be a real issue.

10 I'm not so sure that we can get at
11 that though. People getting too much
12 steroids, I think that we can get at people
13 getting too many repeated courses. The same
14 patient, getting repeated courses which we now
15 have data to suggests that that's a bad idea.

16 But I don't know how you would
17 ever be able to measure that people are giving
18 it with every contraction for every woman.

19 DR. ROSS: I guess there's
20 thinking in the future of the number of
21 patients who received it and then did not
22 deliver pre-term, or the number of patients

1 who have received one dose and then didn't
2 deliver at least for two weeks later.

3 And that's where we're sliding
4 into this overuse. Which has effects
5 potentially on fetal growth and neonatal
6 outcomes. Adverse effects.

7 CO-CHAIR RILEY: So if there are
8 no further questions or comments. Can we vote
9 on the reliability and the validity of the
10 measure? Kate, are you back on?

11 MS. CHENOK: I'm back, I'm going
12 through security.

13 CO-CHAIR RILEY: We're on
14 scientific acceptability of the antenatal
15 steroids measure.

16 MS. CHENOK: Right, it's one or
17 high, whatever the highest category is.

18 CO-CHAIR RILEY: That's how you
19 leave your license as you're going through.

20 DR. WINKLER: Twenty four yes, one
21 no.

22 CO-CHAIR RILEY: And then moving

1 on to usability. I think in the workgroup we
2 talked about, we talked a lot about the
3 augmentation. But most people felt it was
4 highly usable and were sort of split on
5 feasibility between high and moderate.

6 But for the most part we felt that
7 it was feasible. I mean, I do think that the
8 issue of chart review, and resources et
9 cetera, definitely came up. There's no easy
10 way of doing this currently. Lee.

11 MS. PARTRIDGE: I would just
12 volunteer that a process similar to that used
13 for developing the child and maternity care
14 related measurements set for Medicaid programs
15 took place over this past year with respect to
16 a set of measures for adults who are enrolled
17 in state Medicaid programs.

18 And this was one of the measures
19 that actually ended up being on the final list
20 that was sent to the secretary for her
21 consideration. And ultimate, we hope,
22 approval. But that process is still underway.

1 CO-CHAIR RILEY: Kate, this is a
2 high, moderate, low, insufficient information.

3 DR. WINKLER: Sixteen high, eight
4 moderate, zero low.

5 CO-CHAIR RILEY: And feasibility.
6 I already actually discussed it. But
7 feasibility can we vote on that?

8 DR. WINKLER: Six high, 16
9 moderate, two low.

10 CO-CHAIR RILEY: Okay. So
11 finally. Are there any other questions,
12 comments before we go on to the final?

13 Okay. So overall suitability for
14 endorsement for this measure. Kate, are you
15 back with us? She probably forgot to take
16 something off and so the poor thing is now
17 being searched.

18 DR. WINKLER: Push one more time,
19 everybody, please. Twenty four yes, zero no.

20 CO-CHAIR RILEY: We are moving on
21 to the final one of the morning.

22 Healthcare-Associated Bloodstream Infections

1 in Newborns. Scott, you're on.

2 DR. BERNS: Thanks, Laura. Okay.

3 This is Healthcare-Associated Bloodstream
4 Infections in Newborns. We discussed three
5 related measures yesterday.

6 This one assesses the number of
7 staphylococcal and gram negative septicemias
8 or bacteremias in high risk newborns. We went
9 through some of this data yesterday but for
10 some of those that weren't here, in terms of
11 impact.

12 This is a significant problem,
13 particularly for high risk infants. Very low
14 birth weight infants in particular. And
15 infections result in increased length of stay
16 as well as increased hospital costs and
17 charges.

18 And other risk factors include
19 central venous catheter use prolonged time
20 using parental nutrition. A prolonged time
21 with mechanical ventilation.

22 This is also very well written. I

1 want to add as well. There's a nice summary
2 here about effect preventive measures and
3 quite a bit of detail on that in this write
4 up.

5 In terms of opportunity for
6 improvement, there are a couple of notes in
7 here about how this rate varies widely across
8 different centers in terms of health care
9 associating infection rates.

10 They note between six percent and
11 33 percent and that educational interventions
12 in particular are noted here in terms of being
13 able to decrease catheter related blood stream
14 infections from, well, very significantly, as
15 noted here.

16 So in terms of the workgroup we
17 pretty much rated this in terms of importance
18 to measure with four high, with one being
19 moderate. We note that this measure is very
20 similar to Measure 478, and so we do have this
21 general agreement on the high impact.

22 And the issue did come up again

1 here in terms of when patients are transferred
2 from another hospital that it was what we want
3 to comment on. You'll also see, I think you
4 brought that up in our discussion, if I
5 remember correctly.

6 You don't have to comment on it,
7 you can if you want to.

8 In terms of evidence we rated in
9 terms of quantity, quality, consistency.
10 Moderate and high. So I'll just pause there
11 and see if there are any questions or comments
12 for the developers.

13 DR. DRYE: Sorry, can you just
14 remind us how you handled transfers?

15 MS. MILTON: For the larger birth
16 babies we're looking at those that are, I'm
17 blanking out. It's greater than fifteen
18 hundred grams, that's it.

19 We would take anybody that was
20 transferred in within two days of birth. They
21 would be considered high risk. Because that
22 typically would mean that the baby has

1 problems.

2 They're being moved from a smaller
3 facility to a tertiary facility so therefore
4 they would be part of the measure that we
5 would evaluate them just on the fact that they
6 were transferred in.

7 MR. GILLIAM: I wanted to ask, in
8 the brief description it talks about
9 staphylococcal and gram negative septicemia
10 and then under numerator it talks about
11 different ICD-9 codes not being familiar with
12 those. Do you, you would also include
13 enterococcal and fungal isolates as well?

14 MS. MILTON: I don't have it
15 memorized but I know some of those are in the
16 list, yes.

17 DR. DRYE: Sorry, just to go back
18 to the transfers for a minute. My brain
19 slowing down after all these measures. Can
20 you tell what the POA code was there was an
21 infection, I think that I remember that you
22 can. In which case that makes perfect sense

1 to me, what you're doing.

2 MS. MILTON: Whether it was
3 present on admission?

4 DR. DRYE: Right.

5 MS. MILTON: Right, yes. There is
6 a way of identifying that through ICD-9 codes
7 and we're working through that right now.
8 Taking a look at how this could be
9 facilitated.

10 DR. DRYE: Okay. I mean, in
11 general what we've tried to do in our hospital
12 based outcomes measures is we usually
13 attribute the outcome to the first admitting
14 hospital, which also takes responsibility for
15 the management of the patient going forward.

16 An in this case I think it's
17 tricky if the patient's coming from another
18 hospital to attribute the infection to the
19 second hospital unless you can be sure it
20 wasn't present on admission.

21 MS. MILTON: For a hospital
22 receiving a baby that's infected it would be

1 the principle diagnosis code so that's how you
2 would exclude them from that. In a hospital
3 that has the baby delivered there the
4 principle code will be a V30 code. That
5 occasions the reason for being admitted is
6 that they were born.

7 That's always going to be the
8 first code. Then we'd be looking at other
9 diagnosis codes that would be present on
10 admission to exclude them if they were born
11 with an infection at the reporting hospital.

12 DR. DRYE: And you probably just
13 can't know for sure, right? If that baby's
14 been at another hospital, where they acquired
15 the infection. I don't have a problem with it
16 because there's no perfect answer to it.

17 I did have a separate comment, one
18 of the things I thought it would be good for
19 you to talk about is the variation in the
20 measure.

21 So this is a risk adjusted
22 outcomes measure and the challenge we have

1 with risk adjusted outcomes measures, where we
2 go ahead and quantify the uncertainty
3 associated with the estimates is that if we
4 are careful to quantify uncertainties
5 sometimes we just can't see statistically
6 significant variation. So in 2B5.3 which is
7 on Page 20. You report, and I think this is
8 really helpful.

9 The range of scores and there is a
10 range in the 90 percentile score is 1.64
11 percent and the ten to zero, almost all the
12 way through this 70 percent is zero percent
13 but there aren't statistically significant
14 results from the target range. I assume
15 you're using the 95 percent confidence
16 interval there, but I'm not sure it's stated.

17 So I just, I don't personally have
18 a major issue with that for this measure but
19 I just think it's important to think about the
20 way the results look on the measure for other
21 people on the committee.

22 And options you can pursue that

1 are reasonable to me, they're not necessarily
2 to everyone. If you're using a really, really
3 tight confidence interval like 95, which you'd
4 want in a clinical trial you can back off of
5 that and you potentially will see outliers.

6 I don't need to know personally,
7 95 percent certainty that something
8 statistically different from a mean. If I'm
9 thinking about a quality measure. So anyway
10 there may be some ways that you can adjust the
11 reporting strategies so that you see more
12 variation even without adjusting you're
13 modeling.

14 DR. BERNS: Anyone else?

15 CO-CHAIR RILEY: Okay. So it
16 sounds like we're ready to vote.

17 DR. PROFIT: Can I ask one quick
18 question? Does that include early ons you're
19 including early ons and infections, right?
20 There's no, the baby doesn't have to be three
21 days old or 72 hours?

22 So you're just including those

1 because you're thought is that the incidence
2 is so low that it doesn't change the measure
3 overall?

4 MS. MILTON: We're looking at
5 newborns up to 120 days of hospitalization.

6 DR. PROFIT: You know
7 theoretically, if the number is very low and
8 you think it's insignificant that makes sense.
9 But quite clinically I find it a little hard
10 to attribute, like an early onset infection to
11 a hospital when that is something that has
12 already present.

13 When, essentially when the baby is
14 a fetus. So if an infection begins before
15 birth it's hard to attribute the outcome to
16 the hospital.

17 DR. ROSS: Yes, we discussed that
18 with cholio and Group B strep and E. coli as
19 the early onset infections. But I can't
20 recall the pediatricians' issues on this.

21 MS. MILTON: I'm trying to
22 remember how this went when our panel met to

1 discuss this. Because we did have
2 neonatologists addressing exactly what you
3 said.

4 And they looked over the list of
5 the codes that we're identifying here and they
6 felt that it would identify those that were
7 born with infections. And I don't have the
8 list in front of me right now, but that was
9 the consensus of the panel at that point in
10 time.

11 DR. PROFIT: The denominator
12 exclusions identified the babies that were
13 born with infections?

14 MS. MILTON: Right, yes, it's one
15 of the first ones for the ones that are born
16 with it. There's a couple of tables that
17 identify them, I think 11.11.2 or 11.10.2.

18 CO-CHAIR RILEY: Jochen, do you
19 want to look at that before we vote?

20 DR. PROFIT: I don't have all the
21 ICD-9 diagnosis codes on my head but I feel
22 like it would be important for acceptability

1 within a community to make sure that that is
2 the case.

3 Probably the overall rate of early
4 onset sepsis is going to be very low. So I
5 doubt if it will even make a difference. But
6 I think just in terms of general face validity
7 I think it's something I think that I'm sure
8 would have come up in your expert panel.

9 So I don't know if there's an easy
10 way to just look at it quickly, but I don't
11 want to hold up the committee for this because
12 I'm not sure how big the impact is. I
13 couldn't believe that you would not notice or
14 gotten feedback on that.

15 CO-CHAIR RILEY: Craig has some
16 help for us.

17 MR. GILLIAM: When I look at
18 denominator exclusions it does talk about
19 length of stay less than two days. So that
20 would catch most of the early onset Group B
21 strep and also probably the E. colis. I
22 assume that's what the pediatricians are

1 referring to.

2 (Off microphone comments.)

3 CO-CHAIR RILEY: Can you use your
4 mic please?

5 DR. GEE: Yes, I'm just saying
6 that was accurate. I think that the
7 exclusions are length of stay less than two
8 days. I think that's getting done. If
9 there's an infection in the first two days
10 that is not excluded. That's my understanding
11 of this measure, is that correct?

12 MS. MILTON: Only if they are
13 discharged within the first days are they
14 excluded. That's correct.

15 DR. PROFIT: So it does say in 2A
16 1.9, patients with ICD-9 principle diagnosis
17 code for sepsis are excluded. Is that what
18 you are referring to?

19 MS. MILTON: Yes, those would be
20 for the babies that are transferred in with
21 that infection. Because that would be the
22 reason for the admission.

1 Would be the principle code, that
2 would be the reason for the admission.

3 DR. GREGORY: But they do have POA
4 documentation now so, it should be coded as
5 present on it.

6 DR. DRYE: I think you're saying
7 the same thing. So any principle diagnosis
8 code is a reason for admission it's just
9 explicitly on there already on admission.

10 DR. BAILIT: But every newborn has
11 the primary diagnosis as newborn.

12 DR. DRYE: But this is a transfer
13 in, so the initial, the reason for admitting
14 the baby to the hospital is sepsis. So then
15 it has to be present on admission. If it's in
16 the primary diagnosis field. Because by
17 definition, in retrospect the reason for which
18 the baby is admitted.

19 DR. GREGORY: So that's great if
20 you're a transfer that doesn't address the
21 issue if you're an inborn baby who has GBS.

22 DR. PROFIT: I'm sorry I couldn't

1 remember those quite, but it does say
2 diagnosis codes for newborn septicemias are
3 excluded. So newborns septicemia what usually
4 covers early onset sepsis.

5 DR. ROSS: The newborn GBS or E.
6 coli, was excluded but again, I can't remember
7 which codes we use for that.

8 DR. PROFIT: I guess this goes
9 into the reliability of the extraction and how
10 the code is used. But newborn septicemia is
11 for early onset disease.

12 And there is like acquired,
13 there's a different code for acquired disease.
14 But I guess that would be a question about
15 reliability of the abstraction in that case.

16 CO-CHAIR RILEY: So are we all
17 okay, no.

18 DR. JALEEL: It seems like it's
19 important to know the differences, whether it
20 is there or not. The measure title itself
21 says health care of associated with
22 bloodstream infection. So if we don't know

1 that it is difficult to work one way or the
2 other.

3 CO-CHAIR RILEY: I think he's
4 saying that he sees it.

5 DR. JALEEL: Neonatal septicemia
6 is used for both early onset sepsis and later
7 onset sepsis. So newborn sepsis can be either
8 late or early. So we don't know that.

9 DR. DRYE: I don't know if you
10 have access to the table that's referred to at
11 that part of the, where the exclusion is.
12 It's table 11.1 because it doesn't seem to be
13 in our folder of appendixes. Oh, someone has
14 it, great.

15 DR. YOUNG: So I'll read it out to
16 the group that's here. Table 11.10, newborn
17 septicemia or bacteremia is septicemia or
18 sepsis of newborn. And bacteremia of newborn.

19 Table Number 11.11, is newborn
20 bacteremia, that includes Group D strep or
21 enterococcus, staphylococcus unspecified,
22 staphylococcus aureus, other staphylococcus.

1 Friedlander's bacillus, there's also
2 klebsiella pneumonia E. coli or pseudomonas.
3 That's Table 11.11.

4 Then Table 11.12, is that included
5 in this as well? Okay, sorry so Table 11.10
6 and 11.11.

7 (Off microphone comments.)

8 CO-CHAIR RILEY: Okay, so the
9 question is, we have to rely on our
10 neonatologist to help us figure this out. Is
11 that an answer to the question or no?

12 DR. JALEEL: We still don't know
13 the answer but I would assume that the
14 developers have gone through this and looked
15 at this carefully because, as the title itself
16 suggests, that it is health care associated
17 infection.

18 So early onset newborn sepsis
19 should be excluded from that. I would assume
20 that they would have done it, but we don't
21 know that for sure.

22 So I think it is, assuming that

1 they would have done it, it is probably okay
2 to go ahead and vote.

3 CO-CHAIR RILEY: So assuming that
4 that is an exclusion. Then we feel
5 comfortable voting on this?

6 DR. JALEEL: Yes.

7 DR. ROSS: And we'll double check
8 that.

9 CO-CHAIR RILEY: Okay, is
10 everybody okay with that?

11 DR. KELLY: Does the top of page
12 16 help you? The developers.

13 MS. MILTON: That's the
14 calculation algorithm. I'm actually looking
15 at the table right now.

16 Okay, it's Table 11.10.2 would be
17 the table when they come in with the principle
18 diagnosis of sepsis from another hospital.
19 And we're looking at streptococcal septicemia,
20 staphylococcal septicemia not specified,
21 MSRA, septicemia, staphylococcal septicemia,
22 pneumococcal septicemia.

1 CO-CHAIR RILEY: We're not
2 disagreeing with the bugs, we're disagreeing
3 with. We recognize that transfers, we're all
4 on board with that.

5 MS. MILTON: Okay.

6 CO-CHAIR RILEY: The question is
7 if you're born in that hospital and you got
8 infected in labor, and you now go to the
9 NICU's, the concern is if there isn't a code
10 that suggests that you were infected in utero
11 or you got infected in the first 24 hours.
12 It's not the NICU's fault, it's the uterus, or
13 I don't know.

14 (Simultaneous speaking.)

15 MS. MILTON: So for those babies
16 that are born there the first, the principle
17 code is the V30, then we'd be looking at
18 another diagnostic code that would be a sepsis
19 code from Table 11.10, and there's two codes.
20 Newborn bacteremia and newborn septicemia.

21 Those would be the two codes we're looking at.

22 However we have become aware that

1 it goes up to the first 28 days of age, that
2 you would code for that. So we're looking at
3 the present on admission flagging of the ICD-9
4 code to identify that.

5 CO-CHAIR RILEY: Does that work?

6 I don't know.

7 MS. MILTON: This is the
8 discussion we had with AHRQ as far as
9 harmonization of the measure.

10 DR. JALEEL: It kind of works but
11 doesn't really. Because when the newborn
12 comes in you don't know whether that baby is
13 septic. So you have, probably a diagnosis of
14 evaluation for sepsis, rather than neonatal
15 septicemia at that point. So you don't know
16 that at the beginning.

17 MS. MILTON: There's actually two
18 ways it can be flagged, where it's known or
19 unknown. And we'd only except if it's known.
20 So it would be the way that it's documented in
21 the medical record is my understanding of
22 that.

1 DR. JALEEL: Yes, the
2 documentation in the initial of 48 hours until
3 we get the cultures back will be evaluation of
4 sepsis and not neonatal sepsis.

5 DR. PROFIT: I guess one way
6 around that would just to look at day of life
7 three or 72 hours and just call it a late
8 onset sepsis measure. I think you're out of
9 the worry about the contamination then.

10 DR. JALEEL: For once the two
11 neonatologists agree.

12 CO-CHAIR RILEY: That means we've
13 been here too long.

14 DR. KELLY: Okay, I think I've got
15 it. I don't know for sure. But the bottom of
16 Page 15, 11.10, it says the stop processing so
17 I think that's the initial septicemia table.
18 So does that answer the question, I think.

19 To me it says if it's initial
20 septicemia and newborn septicemia you stop.

21 DR. DRYE: I think we're just
22 asking how clearly is that defined? Does that

1 have a time limit on it? Like it's in the
2 first two or three days, that code? Or if
3 it's on the first 30 days then you
4 potentially, babies get out of the measure who
5 actually had a hospital acquired infection.
6 If it's day 15, they get an infection and
7 that's coded as one of those codes.

8 CO-CHAIR RILEY: Can you turn the
9 mic on, or just like move up and just talk
10 into that. Because we can't hear you back
11 there. That's okay, scoot your chair up.

12 MS. WATT: Well, there are cords
13 here. And I hate to lean over everybody, but
14 I will.

15 I just want to make sure that I
16 understand what the issue is. And so please
17 refrain me if I'm incorrect. But if I'm
18 understanding correctly the question, is are
19 patients, are babies who are born already
20 infected eliminated from this measure?

21 And the answer is, maybe. And
22 it's not a fault of the measure, it's a fault

1 of the identification system of the coding
2 system. There is no way to identify somebody
3 using a code who was infected in utero.

4 We've done the best we could to
5 eliminate those people, the babies, with the
6 secondary diagnosis of septicemia or some sort
7 of an infection.

8 But if you all can share with us a
9 good reliable method of identifying those
10 patients who are born infected. That would be
11 a terrific help to us, because we can't do it
12 now. As far as we know.

13 CO-CHAIR RILEY: So, Jaleel, can
14 you repeat, I mean, I got the impression that
15 you were saying that if you just started at
16 day three of life, instead of day.

17 DR. MURI: It doesn't matter, an
18 infected person is an infected person and
19 there's no way to say okay, no easy way, to
20 say the infection occurred on day three of
21 life.

22 Using the codes, what you have is,

1 you've got the V30 code and you have that
2 secondary infection code and it's very, very
3 difficult to put time constraints on that.
4 Well like, impossibly difficult.

5 DR. ROSS: Do you feel that
6 delineating it by bacteria, you know, if you
7 avoided the E. coli and GBS would that give
8 you more of the hospital acquired infection?

9 DR. PROFIT: I think if you
10 avoided the GBS that would probably help. But
11 I think the instance is so low it's
12 meaningless.

13 MS. WATT: It's very low isn't it?

14 DR. PROFIT: Yes, it's like one in
15 a thousand.

16 DR. ROSS: And E. coli

17 DR. PROFIT: E. coli sepsis is
18 less prevalent, so you'd want to capture that
19 for sure.

20 DR. JALEEL: Listeria is the other
21 one, but again, the infection rate is so low,
22 it's mainly the E. coli.

1 But you would not be able to take
2 the E. coli out because E. coli can be late
3 onset infection as well. So I don't see an
4 easy way out. That's different from the
5 Vermont Oxford network measure which only
6 looks at late onset. And I'm not sure how
7 they do it.

8 DR. PROFIT: I think I would
9 assume that overall the correlation between
10 the measures would be very high. But, you
11 know, I feel like that is maybe work that
12 should be done.

13 MS. KIEHN: I guess the one other
14 question that I have is have you done a
15 crosswalk to ICD-10's?

16 MS. MILTON: Oh yes. We actually
17 sent it in to NQF, they have it if you're
18 wanting to look that over.

19 DR. WINKLER: It should be in your
20 files.

21 MS. MILTON: Right, the infection
22 codes, there really wasn't a lot of

1 difference. But boy, the surgical codes,
2 there's 42,000 now.

3 DR. PROFIT: I think just a
4 general, because our effect is for every
5 infection measured to is transfers out, so
6 it's like the exposure time the baby has in
7 the hospital. I think that's going to
8 introduce bias on all of the measures that we
9 have before us.

10 I don't know an easy way around
11 that. There probably isn't. But, you know,
12 it's just something to consider as we go along
13 here.

14 CO-CHAIR RILEY: So I guess the
15 question here is, giving it back to you, Dr.
16 Profit, I mean, this is going to be the
17 perfect versus good enough. Is sort of what
18 we're talking about.

19 I mean, and if the neonatal
20 infection read in the first couple of days
21 from the uterus, or wherever it comes from, is
22 really, really small, are you still going to

1 get meaningful data out of this measure, is
2 really what we're talking about.

3 DR. PROFIT: I think I would want
4 to say yes, but I'm not like, I think my
5 confidence is not terrible high about it. And
6 I think there will be substantial, there might
7 be at least. Substantial concern with the
8 neonatal community about this.

9 And I think you'll hear a lot of
10 feedback potentially about that. So, you
11 know, I think it's a valid concern that people
12 have.

13 I'm not sure if you actually
14 tested it how whether you'd truly find a big
15 difference. But I think that will be one of
16 those areas that people will try to, or will
17 at least note as a concern about the measure.

18 DR. JALEEL: If you look at, I'm
19 not an epidemiologist so I don't know what the
20 incidence of early onset sepsis is. But if
21 you look at he patients who are in the NICU,
22 many of those extremely low birth weight

1 babies will receive antibiotics for five to
2 seven days.

3 For either proven sepsis or
4 clinical sepsis. Suspected clinical sepsis.
5 So there are many babies who do get that and
6 if you're coding that, that will be coded as
7 neonatal sepsis.

8 CO-CHAIR RILEY: So maybe what we
9 should do is go ahead and vote, at least on
10 the first part of this and then I think some
11 of these concerns about how valid it is or how
12 reliable will come up? Is that fair? So
13 let's vote on the importance to measure and
14 report.

15 DR. WINKLER: Kate, did you rejoin
16 us? Twenty yes, four no.

17 DR. BERNS: Okay, should we keep
18 going?

19 CO-CHAIR RILEY: Let's forge
20 ahead.

21 DR. BERNS: Great, we're going to
22 forge ahead here. In terms of scientific

1 acceptability, we've talked a bit already
2 about the numerator and denominator.

3 But in terms of harmonization and
4 comparing to 478, the exclusions are a little
5 bit broader. Specifically around a length of
6 stay over 120 days, and being enrolled in a
7 clinical trial. That's my understanding
8 unless something has happened since I last
9 read this.

10 And then in terms of the group,
11 before I get to that. Just getting to
12 reliability, so further liability studies are
13 being done, I guess now. And I thought it was
14 interesting, of 26 contracted measurement
15 system vendors. I didn't realize that there
16 were that many.

17 CO-CHAIR RILEY: There are more
18 than that.

19 DR. BERNES: There are more, okay.
20 And the other thing that I noted in the
21 validity section here is that a couple of the
22 exclusions are not addressed in the

1 literature. But were included to harmonize
2 with other measures from I guess, CMS and
3 perhaps others.

4 And those were specifically length
5 of stay under 120, length of stay over two,
6 sorry, the other way. Length of stay under
7 two, length of stay over 120, and being
8 enrolled in clinical trials.

9 In terms of the group, and we
10 talked about some of this already. In terms
11 of the transfer piece and I guess in the
12 denominator statement. Experienced death,
13 there was some concern about hospitals that
14 have worse outcomes potentially looking better
15 in the measure.

16 So overall in terms of reliability
17 we were mostly in the moderate range as a
18 group. And our review of validity also on the
19 moderate range. Questions, comments?

20 DR. DRYE: I just have a general
21 comment. As a participant, as a measure
22 developer and other context. Putting measures

1 through NQF. So validity, I think NQF sort of
2 tightened up or been more explicit by what it
3 means by validity.

4 And in this very well written
5 application, the validity that's presented is
6 that JC takes feedback from users on a regular
7 basis about, sort of the accuracy of the data.
8 And I think data, the codes used to capture
9 what we're trying to capture. And that's
10 important.

11 But NQF is requiring now that face
12 validity, that expert panel assessment of
13 measures be quantified systematically. So we
14 take votes on our expert panels now and really
15 ask, you know, do you think this measure is
16 valid in the sense that it captures the
17 underlying quality construct that we think
18 it's trying to capture.

19 And it's interesting listening to
20 the dialogue here. I'm not sure that sort of
21 ad hoc feedback from hospitals is going to get
22 at that, right? We're hearing concerns from

1 neonatologists here that maybe this is
2 capturing, you know, what it really needs to
3 be capturing.

4 And I just wonder if any of you
5 can comment. Because I think these forms are
6 not the most current NQF forms and they don't
7 say if you're using face validity you need to
8 quantify that. Those are rally new forms that
9 we've been using.

10 DR. WINKLER: These are the new
11 forms, these are them.

12 DR. DRYE: So maybe you just don't
13 see. You see it when you're filling it out,
14 but it doesn't print out those criteria, okay.
15 But, I mean, do you have any thoughts on that
16 because I think we're kind of loosely using
17 the term validity in this committee.

18 DR. WINKLER: Yes, it's an
19 evolving concept because, you're right. The
20 attempt is to try and address validity, we try
21 not to be overly prescriptive about what that
22 means. Because there are many ways to assess

1 validity.

2 Certainly face validity done in an
3 organized systematic fashion but construct
4 validity and certain kinds of, you know, test
5 retest kinds of analysis assess validity.

6 So, you know, we're looking for
7 something more than, yes, it looks good to me.
8 And so but it's an evolving thing. And you're
9 absolutely right, I think there is a lot of
10 our membership in the audience who really want
11 to see things, you know, a little bit more
12 objective, and a little bit more quantified,
13 to the degree that that's possible in this
14 world.

15 DR. DRYE: And I think another
16 option listed on the NQF form now is comparing
17 outcomes with other measures. And we're going
18 to be talking about this set of newborn
19 infection measures.

20 And, you know, I think Dr. Profit
21 made a suggestion. Maybe they should be
22 arraigned against each other and see whether

1 they really truly are capturing similar
2 things. Because we're struggling with all of
3 them a little bit because they're so complex.

4 DR. WINKLER: That's your agenda
5 item for after lunch.

6 FEMALE PARTICIPANT: If we ever
7 get there, I couldn't resist.

8 (Laughter.)

9 CO-CHAIR RILEY: Okay. Are we
10 ready to now vote on reliability and validity
11 of this measure?

12 DR. WINKLER: Can everybody push
13 again, are we missing anybody? Thirteen yes,
14 11 no.

15 CO-CHAIR RILEY: Usability? Do
16 you want to talk about that, Scott?

17 DR. BERNIS: Okay, in terms of
18 usability. Let's see, there was a note in
19 here about consistent improvement in aggregate
20 performance measures. I guess between quarter
21 two in 2010 and quarter one in 2011.

22 There was some data presented in

1 here. And in terms of feasibility, let's see
2 in terms of the group, just to go back here.
3 Pretty much we were in the moderate to high
4 range in usability and feasibility split
5 between high and moderate. And a note about
6 needing to harmonize with 478.

7 MR. GILLIAM: If I could speak to
8 the usability. And since we're talking about
9 public reporting. The issues about public
10 reporting are not using necessarily this
11 measure, or even VON, they're using NHSN.
12 Which is slightly different and is more
13 specific and a narrower focus. And as these
14 efforts to decrease these events occur then
15 the numerator becomes more and more important.

16 And even though Group B strep or
17 maybe early onset E. coli maybe uncommon, if
18 you're talking about smaller and smaller
19 number of cases then using the codes. And I
20 accept what you say, that you can't
21 differentiate between true health care
22 associated and what's reported.

1 That may be more of an issue, and
2 I think neonatologists and infectious disease
3 people would have more of a concern about this
4 from a public reporting standpoint.

5 DR. PROFIT: Have you compared the
6 results of these measures to ones that are
7 based on like, blood cultures, you know, where
8 you're, because I just wonder how good the
9 coding is, you know, in relation to like some
10 sort of like former evidence on blood
11 cultures.

12 MS. MILTON: We haven't done any
13 comparisons to any other measures on this
14 particular measure.

15 DR. JALEEL: I have to reiterate
16 that the number of babies with less than 1500
17 gram, who get antibiotics in the first five to
18 seven days for sepsis is a significant number.

19 DR. PROFIT: I'd just want to
20 thank the non clinic folks who give some
21 perspective. I feel like there's a lot of
22 charting that goes on that's highly variable.

1 You know, a baby in a NICU may,
2 you know, have some minor symptoms, be started
3 on antibiotics, a new physician comes on.
4 Doesn't know the baby that well, say well,
5 let's just continue the antibiotics.

6 Like I don't know this baby so,
7 you know, not that that's necessarily good
8 quality but, you know, cultures may have all
9 of been negative. And so you know there's
10 different measures, like different measures
11 like the CDC has different criteria, and the
12 VON and your diagnosis.

13 So there is some uncertainty about
14 what truly constitutes and infection or not.
15 And I think once it goes to public reporting
16 everybody is going to asking like, well what's
17 this? Are these truly infected babies?

18 Or can we train our coders only to
19 be very specific about they're actually going
20 to abstract. Or are we going to train our
21 doctors to only specifically write down, you
22 know, X, Y and Z.

1 So I'm just wondering whether
2 some, you know, whether if it's only based on
3 coding whether there is going to be a lot of
4 gaming there in the system about, you know,
5 the rates are going to look better but are we
6 truly going to make a difference to the
7 patient?

8 DR. BERNS: Okay. Any other
9 comments?

10 (Off microphone comments.)

11 MS. BRANDENBURG: I have to agree
12 with im as well. I mean, if you're basing it
13 on coding, I would be concerned about coding
14 alone, because that's not always been proven
15 the most accurate.

16 DR. BERNS: Anyone else?

17 CO-CHAIR RILEY: So can we vote on
18 the usability of this measure? High,
19 moderate, low, insufficient?

20 DR. WINKLER: One high, ten
21 moderate, 13 low.

22 CO-CHAIR RILEY: Moving on to

1 feasibility, is there anything more we need to
2 say about that? Can we vote?

3 DR. WINKLER: Push again just for
4 good measure. one high, ten moderate, 13 low.

5 CO-CHAIR RILEY: Okay, moving on
6 to the overall suitability for endorsement.

7 DR. DENK: Sorry, quick question,
8 this is harmonized with another measure we did
9 yesterday? Did we approve that one?

10 DR. PROFIT: Yes.

11 CO-CHAIR RILEY: Okay, so now
12 we're voting again.

13 DR. WINKLER: Can everyone just
14 press one more time? Okay so that's where we
15 are on the first go around. And remember
16 we've talked about this. We've got multiple
17 similar measures that's our afternoon agenda
18 item. Is we're going to put these side by
19 side and take a look at them.

20 I think there's been an evolution
21 in discussion and thinking and consideration.
22 And this will give you an opportunity to

1 regroup on these measures, okay?

2 CO-CHAIR RILEY: So we're going to
3 take a 15 minute break.

4 (Whereupon, the above-entitled
5 matter went off the record at 10:58 a.m. and
6 resumed at 11:18 a.m.)

7 CO-CHAIR RILEY: Okay, we've got
8 we've got our work cut out for us. Dr. Gee,
9 let's go.

10 DR. WINKLER: We're still having
11 that echo.

12 (Off the record comments.)

13 DR. WINKLER: All right. The next
14 little bit is going to be a little bit of a
15 departure to what we've done. We're going to
16 be looking at a composite measure.

17 And just some history. There is a
18 growing interest in composite measures.

19 Because they do kind of bring summary
20 information together. Several years ago NQF
21 had looked at the measure evaluation criteria
22 as applied to composite measures.

1 Now admittedly, we haven't
2 reviewed that in a couple of years and there
3 have been a lot of new composites made. So
4 there are some challenges that we have yet to
5 confront.

6 But composite measures are
7 typically measures that are some way combined
8 of individual components to arrive at a single
9 score. So that's what we mean by a composite
10 measure.

11 And one of the sort of underlying
12 principles is that the component measures
13 should either be an endorsed measure or meet
14 the criteria for endorsement. The measure we
15 have in front of us is the measure 1769, an
16 adverse outcome index.

17 In this particular case there's no
18 indication or desire for the individual
19 components to be endorsed independently. They
20 are components of the overall composite
21 measure.

22 However we do want to be sure that

1 the components are appropriate. That they
2 are, you know, they contribute to the quality
3 construct. They are appropriately defining
4 coded or whatever the data collection
5 requirement is.

6 That within the context of the
7 composite they are usable and feasible. So
8 it's going to be, so it requires you to think
9 a little but differently.

10 Then the actual composite measure,
11 the overall, there are some additional
12 criteria to consider. Because the composite
13 methodology has additional elements to it. So
14 again, even if an individual component is not,
15 you know, super strong on it's own, as part of
16 a composite that may be perfectly fine.

17 The other issue is to think about
18 the construct for quality of the entire
19 composite. And is that well understood and do
20 all the components, are they consistent and
21 contribute to that quality construct, okay?

22 So that's what we're thinking of

1 when we're looking at the importance to
2 measure report criteria around composites.

3 Scientific acceptability, you
4 know, the specifications should be just as
5 good but you will need all the additional
6 specifications for standardizing scales, if
7 necessary. Scoring rules, weighting rules,
8 how you handle missing data of some of the
9 components.

10 You know, sampling issues if
11 necessary. So the criteria are not different
12 but you have to look at different elements
13 when you're looking at a composite measure,
14 because it has different characteristics.

15 We're still looking for
16 reliability and validity testing. We're still
17 looking at the resulting score, demonstrating
18 meaningful differences.

19 Ideally we'd like to see some
20 analysis of how the components contribute to
21 the overall score. And also that the scoring
22 and weighting rules are consistent with that

1 conceptual construct.

2 So these are the kinds of elements
3 that are additional evaluation criteria when
4 we're talking about a composite. In terms of,
5 I think usability and feasibility, there's not
6 a whole lot there.

7 The one key element is that the
8 data is collected and maintained such that you
9 can de-construct and go back to the component
10 measures to figure out what were the
11 contributions of various components to the
12 ultimate score. So somewhat different.

13 This particular measure I'm going
14 to ask Kathleen who's the lead to kind of
15 describe the measure conceptually in general.
16 And then what we're going to want to do is
17 quickly go through each of the components to
18 see how you feel about the contribution of
19 that. Are there any issues?

20 Thinking about all the usual
21 criteria but within the context of being a
22 component in a composite. And we'll vote,

1 just take a single vote on each of the
2 component elements to see how everyone feels
3 it is as a component.

4 And then we will wind up by
5 talking about all of the different evaluation
6 criteria for the composite measure. The usual
7 importance, scientific acceptability,
8 usability, with the additional criteria that
9 the composite evaluation criteria has.

10 So, complicated. We have a lot of
11 steps to go through. So with that I'm going
12 to go.

13 CO-CHAIR RILEY: Can I ask a
14 question first?

15 DR. WINKLER: Sure.

16 CO-CHAIR RILEY: As we sort of go
17 through these, I recognize we're going to look
18 one at a time. Is there the opportunity to
19 say no, to a particular component, yet the
20 whole rest of it looks okay? Or how does
21 that?

22 DR. WINKLER: I think that's going

1 to become one of your issues, because in all
2 honesty if you don't like one of the
3 components and feel that that's the fatal flaw
4 of the measure, and it's part of the whole,
5 then it's going to be very hard to justify
6 recommending the whole with a fatal flaw as
7 one of the components.

8 So I think you do need to think
9 about your evaluation of the component in the
10 context of being a contributor to the overall
11 composite score.

12 MS. PARTRIDGE: I was unclear, and
13 I think maybe it would be helpful at the
14 outset if this was clear for all of us.
15 Whether we're being ask to evaluate only the
16 adverse outcomes index or whether it's all
17 three components. Because in the submission,
18 sometimes I think they assume all three. The
19 AOI, the weighted one, and the severity index.

20 DR. SIMPSON: I think that
21 hopefully in the introduction that Kathleen's
22 going to do and then perhaps with some

1 comments from the developers we can get that
2 context before we launch into further
3 discussions.

4 DR. SIMPSON: Well, actually I
5 think that was a good question because in
6 reviewing the material I did not have a solid
7 answer to that question. So maybe you should
8 mention that right away before I proceed.

9 Are you intending to, does the
10 measure, the AOI, the weighted and the
11 severity index, is that what we're discussing?
12 It wasn't clear.

13 CO-CHAIR RILEY: Do you want to
14 come to the table?

15 DR. SIMPSON: Yes, why don't you,
16 that's very helpful to know because I did not
17 know that and did not glean that from the
18 materials.

19 DR. DRYE: And is that an all or
20 none? Or if we're, is the committee
21 considering each one? Because that's a little
22 different than unraveling the index. It's

1 just saying, you know, the AOI versus the
2 weighted for example. Or can we consider them
3 separately?

4 DR. SIMPSON: I think you can
5 discuss that, sure.

6 Okay, so the adverse outcome
7 index, just as a background was created in the
8 concept of a research study. And looking at
9 the potential impact of team training in labor
10 and delivery environments and their outcomes.

11 And this was a randomized trial,
12 that was done almost ten years ago and in the
13 context of this study. There were two
14 consensus groups of physicians and nurses who
15 came up with these ten indicators.

16 And then later on the indicators
17 were weighted, from my understanding, through
18 a ACOG quality improvement patient safety
19 committee. So you had your two consensus
20 panels and then it got weighted.

21 Now there are three then issues.
22 So there's the adverse outcome index, the

1 weighted adverse outcome score, and the
2 severity index. And they are all
3 interrelated.

4 Now, they include these ten
5 components. In hospital maternal death, and
6 interpartum neonatal death, they all have, I'm
7 not going to read into all them exclusions and
8 clarifications.

9 Uterine rupture and unplanned
10 maternal admission to the ICU. Birth trauma
11 and it's noted that it's not the same birth
12 trauma as the AHRQ measure, although we did
13 not approve that yesterday.

14 And then unanticipated operative
15 procedure, admission to the NICU of a baby
16 over 2500 grams. Apgar score less than seven
17 in five minutes. Maternal blood transfusion
18 and third or fourth degree laceration.

19 And the lastly behind this is that
20 most of things are very rare and so it you
21 combine them together you could be able to use
22 less of a sample and get an idea of what was

1 going on.

2 Now the philosophy is that each of
3 these things individually represent a aspect
4 of substandard care. And that was repeated
5 throughout the application. I'm not sure if
6 that is a true statement, if all these
7 represent substandard care.

8 Some of them actually might
9 represent quality care. So there's some
10 disagreement about that. The developer also
11 mentioned that there were several studies in
12 which this was used.

13 They said three studies, totaling
14 about 50,000 births. And then gave a list of
15 references. I was able to pull all those
16 references. And of course there's the
17 original randomized trial of team training.

18 And then there was a study of the
19 hospital, the Beth Israel Hospital that did
20 not participate in the team training but
21 coordinated the team training study. So that
22 was, first I thought that was the same data

1 but it wasn't. So those are separate data.

2 Then there was another study that
3 was done. Again a single hospital looking at
4 the active management of risk at term. With
5 the theory that if you induce a subset of
6 people who are at risk for a potentially
7 adverse outcome you might be in better shape.

8 And they used multiple things to
9 evaluate their intervention and adverse
10 outcome index was one of them.

11 Then there was the Yale study by
12 Petker in which they looked at interventions
13 over time. A comprehensive obstetrical team
14 training program, patient safety program,
15 multiple intervention. Fetal monitoring
16 certification, induction at the appropriate
17 time. The addition of a patient safety nurse.

18 I can't remember them all, and in
19 full disclosure, I was the one that
20 recommended they do all that. And I have to
21 say that I was part of that. I did not
22 participate in the study but I was one of the

1 consultants that went there and told them to
2 do all that stuff. That they eventually did
3 do.

4 So naturally I was thrilled when I
5 saw that study and saw that things were moving
6 in the right direction based on the AOI.

7 Then there were two additional
8 papers published. These papers their specific
9 intention was to evaluate the AOI, not to
10 evaluate any intervention measuring using the
11 AOI as a unit of measurement.

12 The one was Benedetti's group at
13 the UW in Seattle, they looked at just the one
14 hospital and they were going to see if the AOI
15 was handy could it be used to for the entire
16 state. So they spent quite a bit of time just
17 looking at their own hospital's data and going
18 back and forth looking at reliability and
19 validity and comparing medical record review
20 versus the algorithms put forth by the
21 National Perinatal Information Center, is my
22 understanding.

1 And so I actually emailed these
2 folks to see what the decision was because
3 they never said at the end of the article what
4 they had decided to do.

5 And they said that they had
6 decided not to go forward using the AOI
7 statewide adoption. So that was additional
8 information.

9 Then there was a recent paper
10 published by Hamilton. And they were looking
11 at how does the AOI perform? They used a four
12 hospital system, with about 7,000 births and
13 they were trying to figure out does the most
14 common thing that happens really lead the, I
15 guess, the trend of the AOI.

16 And their contention was that
17 third and fourth degree lacerations the Apgar
18 situation and maternal transfusion were
19 leading indicators. And in fact the third and
20 fourth degree lacerations being the most
21 common might obscure some other things that
22 were going on.

1 And also other people did find
2 that third and fourth degree lacerations in
3 admission to the NICU were the two most common
4 things. And so they then might obscure other
5 trends and other important things that are
6 going on with the other eight or nine
7 indicators.

8 There was also a couple of opinion
9 articles published that had some concerns
10 about use of the AOI. There was not anybody
11 that said, wow, this is a great thing, we
12 should do it. But they were measured in
13 their, you know, their enthusiasm.

14 Then there was another article
15 that was cited several times, however I could
16 not get it. And you might be able to comment
17 on that. It was something in Wyoming, and it
18 was cited on the A1 website I could not find
19 it.

20 But it was something about the
21 hospitals in Wyoming. I did spend quite a bit
22 of time trying to find it, so I don't know

1 what that was about.

2 So the main thing is that this is
3 the philosophy here is that one or more of
4 these things is a indicator of substandard
5 care which is, that's controversial. And that
6 together they can be handy because they don't
7 require as big of a sample.

8 Now I understand that the national
9 Perinatal Information Center has been using
10 this with a lot of their member hospitals.
11 And you did mention that several times here.
12 I didn't get, I mean, none of that data is
13 published. So I was unable to, you know, make
14 a big comment on that. So you might be
15 willing to say something about that.

16 So they include both process and
17 outcome measures as well. So that's, Reva
18 asked me to stop there and then we'll discuss
19 further once we talk about these individual
20 things.

21 So that's the state of the
22 evidence at this point.

1 CO-CHAIR SAKALA: Thanks,
2 Kathleen, that was a great summary. Would you
3 like to clarify now, the relationship of the
4 three different options and whether you're
5 putting forth one of them specifically for us
6 to consider?

7 DR. PRATT: Hi, I'm Steve Pratt,
8 I'm an obstetric anesthesiologist. I was lead
9 anesthesiologist on the original prospective
10 randomized trial. I'm sort of here for our
11 team. We have two or three other folks on the
12 phone as well. So they'll be asked to help as
13 we move along.

14 I actually think that all three
15 are important and here's why. The three
16 different components are, one the adverse
17 outcome index, and that's the percentage of
18 deliveries that is associated with one or more
19 of the ten events within the component.

20 So if you have all ten it still
21 counts as one on the numerator. The next,
22 each one of those adverse events has a weight

1 associated to it.

2 Ranging from five points for a
3 third or fourth degree laceration up to 750
4 points for a maternal death. The sum of
5 everything below maternal death is equal
6 actually to maternal death.

7 And that was one of the caveats we
8 said in weighting this is the worst thing that
9 can happen is to have a mom die. And even if
10 all the rest of it occurs it couldn't be worse
11 than a mom dying.

12 There are two ways to use those
13 weighted scores. One is to take the sum of
14 all of the points from all of the events that
15 occurred over a period of time and divide it
16 by the number of deliveries. That is the
17 weighted advert outcome score and it gives you
18 a sense of how much general bad things are
19 happening on the unit.

20 The second is called the severity
21 index, and you take that same numerator of
22 points, the sum of all of those points from

1 all the events from all deliveries, and divide
2 by the number of deliveries that had an event.

3 So in other words the numerator
4 from the AOI. And that speaks to how badly
5 the events are when they occur. And so an
6 example of why this is important is one could
7 get rid of third and fourth degree lacerations
8 by cesarean delivery on everybody.

9 One would expect that the adverse
10 outcome index would then go down. But lots of
11 other bad things might happen and the severity
12 index therefore should go up. Because the
13 adverse events that would occur would exclude
14 that bottom, the lowest scoring event.

15 And so we didn't want to allow
16 there to be policies and protocols that might
17 decrease the rate of events but worsen their
18 severity.

19 So I really think that all three,
20 and we've talked about this a length. That
21 really all three measures should be considered
22 here. And it's a way to measure quality in a

1 more aggregate way.

2 DR. SIMPSON: Can I ask a question
3 about that? I was looking at the Yale study
4 where they just counted the worst thing that
5 could have happened. So people have
6 operationalized it different ways.

7 What I couldn't understand is,
8 let's say I was looking at my own maternal
9 mortality data over the last ten years trying
10 to figure out how this would relate.

11 So if you have somebody that maybe
12 has four or five of these things but it's one
13 case. Are all of those things then added into
14 the, so you could have a couple of bad cases
15 and really all of a sudden have a very bad
16 score then, right?

17 Even if none of those cases
18 related in any way fault. Like an MBA comes,
19 well she's pregnant she gets a blood
20 transfusion, her baby dies, she goes to the
21 ICU. Now she dies.

22 And that's a lot of bad stuff

1 happening just for that one patient and it had
2 nothing to do with your so called substandard
3 care. That's a very concerning situation.

4 DR. PRATT: So again, it's the
5 reason to have both of, all three of these.
6 So you're right, the weighted scores would
7 move quite heavily with a couple of those
8 types of cases. Versus, now the adverse
9 outcome index in fact wouldn't. Because that
10 would count as one or two cases.

11 (Simultaneous speaking.)

12 DR. PRATT: One MVA would be one
13 case. And so it's a way to in fact to deal
14 with all of those issues. The Adverse Outcome
15 Index wouldn't change with that bad case.

16 The other part of it this is, as
17 you've already pointed out. Many of these bad
18 events are in fact probably not preventable.
19 And we know that, we accept that.

20 That's true of most adverse events
21 in medicine, and if we look at them
22 preventability is probably on the order of 50

1 percent for most of these terrible adverse
2 events.

3 We don't have a great way to try
4 to identify those that are preventable. But
5 we understand that if we can work on that 50
6 percent that is, we can still have significant
7 movement.

8 And the Yale study showed on the
9 order from the beginning of their study to the
10 end a 25 percent or better improvement. We
11 showed similar results. And that's worth
12 something.

13 DR. SIMPSON: Can you explain how
14 the weighting was done, you know, who decided
15 what weights per event, and how was that done?

16 DR. PRATT: Susan, are you on the
17 phone? Is there any way to figure out if we
18 have callers?

19 DR. MANN: Sorry, I was on mute.
20 I'm Susan Mann, I'm also an obstetrician
21 gynecologist at Beth Israel Deaconess Medical
22 Center and one of the authors of the

1 participant and the original team tracking
2 trial.

3 We ask the American College of
4 OB/GYN patient safety, quality improvement
5 patient safety committee. And I believe it
6 was a consensus process, I don't sit on that
7 committee so I wasn't privy to the results of
8 their voting and the process they did, but I
9 know it was also a consensus scale.

10 DR. PRATT: And like I said
11 earlier, the only role we gave them was the
12 sum of the first nine events could not be more
13 than maternal death. After that they came up
14 with the specific numbers.

15 DR. SIMPSON: Okay. And then in
16 your consensus panel, your two consensus
17 conferences, that's how you came up with the
18 ten. Where there, it doesn't mention in all
19 the articles, or at least maybe I skipped it.
20 How many did you start with and, you know,
21 what did you weed out to get to that ten?

22 DR. PRATT: Yes, so we actually

1 published that process a few years ago.

2 DR. SIMPSON: Yes, I got them all
3 right here.

4 DR. PRATT: We started with more
5 than fifty. And again, Susan, speak up
6 because you were the lead author on this.

7 But we started with more than 50.
8 We used six fairly specific criteria as we
9 went through each one of these. Many of them
10 overlapped. And the goal was, what we
11 ultimately wanted were events that we thought,
12 one were likely to be preventable.

13 To some extent we were looking at
14 things that were likely to be preventable by
15 broader aspects of care than a single policy.
16 So things that would change the overall
17 quality of care.

18 And so we were looking
19 specifically at teamwork. But overall other
20 protocols and broad guidelines have now been
21 demonstrated to be effective, as you've
22 mentioned the study at Penn.

1 Looking at management of risk in
2 late gestation. But we were, at the time,
3 looking largely for these that might.

4 DR. SIMPSON: For teamwork, right?
5 They were developed to test teamwork.

6 DR. PRATT: That was originally
7 the development.

8 DR. SIMPSON: Okay. That's what I
9 thought.

10 DR. MANN: And also for the ten
11 process measures.

12 DR. PRATT: Yes, those have not
13 been included here though. These are just the
14 ten outcome.

15 DR. SIMPSON: Does anybody else
16 have any questions about the actual measure?

17 DR. PRATT: If you'd like I can,
18 on the development you commented that some of
19 these might be actually measures of good care.
20 And the two that sort of jump out are maternal
21 transfusion and admission to the intensive
22 care unit.

1 We would never want to say, oh, it
2 is a bad idea to transfuse a mom with, you
3 know, with a hematocrit of 12, right? And we
4 understood that as we developed it. The issue
5 there is that many of the events on labor and
6 delivery that lead to either one of those are
7 associated with bad care.

8 And I'll use the ICU admission
9 for, the leading causes of maternal ICU
10 admission as you look from study to study, to
11 study, are maternal hemorrhage, eclampsia,
12 preeclampsia. Those tend to be the leading
13 causes.

14 The literature is very clear that
15 we don't manage any of those things very well.
16 Both in looking at what we know about actual
17 care but also when we look at the simulation
18 data. These are things that none of us do
19 very well. Or that are associated with a
20 relatively high rate of inadequate or
21 substandard care.

22 Rather than trying to have to go

1 through each one of these various reasons for
2 which a mom might get admitted to the
3 intensive care and measure each one of those.
4 Which would have become much more difficult.
5 We went with the concept that if these high
6 risk deliveries are managed effectively the
7 likelihood that mom will end up in the
8 intensive care unit goes down.

9 And so this was a way to sort of
10 grab all of that substandard care in these
11 high risk deliveries and identify when they've
12 gone badly and mom has ended up in the
13 intensive care unit.

14 Similar thinking went into the
15 went into the transfusion conversation. And,
16 you know, management of induction, for
17 instance. Would be a risk factor there
18 potentially. And that was the thinking behind
19 those two in particular.

20 DR. SIMPSON: Okay. Well I did
21 look at the references you provided as far as
22 ICU admissions and number one was hypertensive

1 disease. Then hemorrhage, then septic
2 abortion, and non obstetric sepsis.

3 And so those again, in my opinion,
4 are not all amenable to care. I mean, stuff
5 happens. So if those are the leading causes
6 of admission to the ICU for a mother and that
7 is an indicator then that would be something
8 controversial, I guess.

9 And then overall philosophy, is
10 that if you look at some of these things there
11 could be sort of gaming of the system if you
12 were sophisticated enough to say, well hey
13 maybe I'll just bring the people down to my
14 L&D unit rather than admitting them to the ICU
15 because I'll get a better score.

16 Or, you know, she's on the
17 borderline, let's not transfuse her because,
18 I mean I don't know if that would really
19 happen. But it does seem to kind of push
20 people towards doing things that might not be
21 in the best interest of mothers and babies.

22 Also with the avoidance of the

1 third and fourth degree laceration maybe
2 you're going to have more cesarean. You know
3 this is just a philosophical thing when you
4 look at the whole thing as a composite. So I
5 wanted to bring that up as well.

6 DR. PRATT: That is fair, and you
7 know, we worked on this very hard thinking
8 about, you know, god forbid we would ever try
9 to dissuade people from taking very sick moms
10 and putting them in the intensive care unit.

11 We had such a hard time believing
12 that anyone would actually do that. And, you
13 know, you speak to, yes, bad things happen
14 with severe preeclampsia and the hypertensive
15 disorders.

16 On the other hand up to 80 percent
17 of moms with severe preeclampsia do not have
18 their blood pressure managed well. And you
19 know, I think about my own specialty as an
20 anesthesiologist, this is something in which
21 we are absolute expert.

22 And my guess is that many of my

1 colleagues around the country are not as
2 involved in the management of those patients
3 as we might be. Again, now speaking to the
4 teamwork discussion.

5 Is it possible that, you know,
6 some moms are running around with an
7 hematocrit of 18 and feeling a little bit
8 fatigued and they didn't get transfused
9 because of the adverse outcome index. Would
10 that be possible? I suppose so it would.
11 But I would certainly hope that that would not
12 be big.

13 DR. SIMPSON: I'm not saying it's
14 legitimate, I'm just throwing it out there as
15 something that's in the literature, so I
16 wanted to bring that up in fair discussion
17 here. Others have mentioned that in the
18 literature.

19 DR. MANN: Similarly, the NICU
20 admissions. Boy I have a bad echo. Do you
21 want to talk about the NICU admission
22 commission?

1 DR. PRATT: Yes, this is a biggie,
2 in some places it is almost a primary driver
3 for their adverse outcome index and, you know,
4 Janet can probably speak to this better than
5 I.

6 When we look at the data for some
7 of these hospitals there's some folks who have
8 adverse outcome index rates of 20 or 25
9 percent. Now remember we are almost entirely
10 driven by NICU admissions. Now remember this
11 is at term, and greater than 2500 grams.

12 So these are good sized, term
13 babies, and they have to be there for more
14 than 24 hours. So this isn't they just went
15 and got some blood cultures for rule out
16 sepsis. These are generally real admissions
17 at term.

18 And there's such huge variation in
19 that that it's one of the, that's the one that
20 I think is going to be also difficult to deal
21 with. I frankly think that those hospitals
22 should have to own up to the fact that they're

1 sending 25 percent of their babies to the
2 NICU.

3 DR. SIMPSON: Don't you think that
4 there could be some financial incentive for
5 that?

6 DR. PRATT: Yes, I do, I
7 absolutely do.

8 (Simultaneous speaking.)

9 DR. PRATT: I think that that's a
10 good thing though to put that in the numerator
11 though, that these folks are making those
12 decisions for financial reasons.

13 DR. SIMPSON: It's possible, I
14 don't know.

15 DR. PROFIT: So I had the
16 privilege of training at the BIs so I know
17 the system very well. But the hospitals,
18 they're structured differently and some
19 hospitals babies will be sent to the level two
20 unit to receive two days of antibiotics. And
21 in other places they'll just have a work up
22 and they can go to the mother's room.

1 And so I wonder whether some of
2 your high rates actually derive from these
3 just different structural setups. You could
4 argue that well maybe they should change the
5 setup but I think, I wonder whether those are
6 two differences in neonatal outcomes or just
7 in the way the hospital is structured.

8 DR. MANN: It would still be a
9 neonatal outcome if the mother and baby aren't
10 bonding or breastfeeding because the baby's in
11 the NICU.

12 CO-CHAIR SAKALA: So maybe we
13 should save the discussion for the individual
14 components as we go through the measure.

15 MS. PARTRIDGE: In your submission
16 you mentioned that, and I'm not quite clear
17 what the it is. I think it's probably all
18 three measures. Are currently being used in
19 QI collaborative's, both in the state of
20 Maryland and the Premier System.

21 Now the Premier System we're all
22 pretty familiar with I think and Maryland's

1 one of the fairly progressive states in
2 improving maternal and child health quality.
3 Are they using them in the context of
4 reinforcing the team concept?

5 DR. MURI: Thank you Steve, I just
6 wanted to introduce myself. I'm Janet Muri,
7 president of the National Perinatal National
8 Information Center.

9 The Maryland patient safety
10 program used it in the context of team steps,
11 IHI, bundles, NICHD. So they did some
12 collection around those components as well as
13 some process. And then they used the AOI as
14 well.

15 That whole program has just
16 finished and they're in the process of
17 publishing. So they're working on some
18 articles on that. And they found really nice
19 improvement for many of the hospitals.

20 The hospitals that didn't improve,
21 seemed to have some issues around the team,
22 the leadership of the team and things like

1 that. Where they really couldn't really fully
2 engage the team concept.

3 The Premier is a subset of their
4 hospitals that are part of their excess risk
5 program. They have a patient safety program
6 that they've been involved with for about two
7 or three years.

8 And they too are beginning to
9 publish. They've just moved over to an AHRQ
10 Grant to do some research with a comparison
11 group of hospitals that are not doing the
12 interventions that they're doing.

13 CO-CHAIR SAKALA: Jennifer.

14 DR. BAILIT: My concern with this
15 measure in general, and I want to give you
16 some examples and just see what you say, is
17 the risk adjustment piece.

18 So for example if everybody had
19 the same mix of patients at all these
20 hospitals that would make sense to me that
21 this would be a good measure.

22 But given that we have trauma

1 centers, and given that especially now there's
2 a movement towards accreta centers where those
3 women are, we know that they're a high risk.
4 Some are going to die, they better get
5 transfusions. They should be in the ICU's.

6 And so these patients are not
7 equally distributed across America. I can
8 understand using AOI to look at your own
9 hospital year after year after year and see
10 how you're doing. Because your case mix
11 doesn't change that much from year to year.

12 I have grave concerns about
13 comparing hospitals using this with no risk
14 adjustment. Can you speak to that a little
15 bit?

16 DR. PRATT: I'll again, let Janet
17 speak to that because we've been able to this
18 not risk adjusting at the individual patient
19 level. But at the type of institutional level
20 a little bit. And comparing similar
21 institutions.

22 DR. MURI: Yes, one of the things

1 that we've looked at when we've looked at the
2 Maryland patients safety data as well as the
3 Premier data is to divide the hospitals by
4 level of care. One, two and three, and then
5 also by academic, non academic.

6 So that was, it's not really a
7 risk adjusting, we've talked about really risk
8 adjusting at the patient level and I think
9 that's the direction we'd like to go in. But
10 in terms of just looking at differences in
11 types of hospitals we can subset the data and
12 look at the metrics that way.

13 DR. BAILIT: So that makes sense
14 to me to some degree to stratify and look at
15 within the stratas. But all tertiary
16 hospitals are not alike. A tertiary care
17 hospital in the suburbs is different than in
18 the inner city. Is different than the two or
19 three accreta centers around the country.

20 So I just caution that we maybe
21 under risk adjusting or under stratifying
22 because you really need to know a lot about

1 those individual hospitals in a community
2 before you can say one is worse than the
3 other.

4 CO-CHAIR SAKALA: Nancy.

5 DR. LOWE: I have a question,
6 really which gets to one of our key criteria,
7 which is the public reporting aspect of this
8 thing.

9 You know indices that are
10 developed for use in research and are
11 composite measures are usually fairly
12 complicated for even the most sophisticated
13 among us to interpret. Because of the
14 complexity of the individual elements that go
15 into a composite.

16 And that was my reaction to this
17 whole thing. Is if we throw these out to the
18 public and I think Jennifer has brought up
19 some of the issues with it as a public
20 reporting measure.

21 But I have great difficulty with
22 understanding how, at the public level, this

1 could really be well understood. In the
2 context of the complexity of not only patient
3 mix but provider mix.

4 You know a rural hospital or a
5 frontier hospital in the middle of Oregon,
6 which has 49 babies a year. If they have one
7 maternal death and it gets reported. Which
8 may be a totally - or a non preventable
9 maternal death, an MVA off the highway, a bad
10 preeclampsic who is fulminates and comes in
11 and it is a tragedy. It just, I am really
12 struggling with the public reportability
13 aspect of it. And the understandability from
14 a public perspective of this complex of a
15 measure.

16 So if you could just speak to that
17 a little, why you think the public would be
18 able to resonate with this measure and really
19 understand it substantively. Rather than us
20 approaching it from the individual measure
21 standpoint.

22 DR. PRATT: For me, and, Susan

1 I'll let you go, and actually I think we
2 should all probably comment. My response to
3 that is I think it's going to be hard to
4 figure out what the public was going to be
5 able to understand.

6 I'm not sure that they can
7 necessarily understand even the component
8 measures. Within the context of the
9 complexity of health care.

10 I think having some idea of
11 stratification and we've done that with help,
12 number one. Number two the, again, that
13 single maternal death is not going to change
14 their complication rate very much. It's going
15 to change the severity score a lot.

16 But the complication rate is not
17 going to change any more than the third or
18 fourth degree laceration that they had last
19 week as well.

20 And then finally while we get very
21 concerned about those sorts of things the
22 likelihood that there's going to be a maternal

1 death in a place who's delivering, who know,
2 if the maternal mortality rate is 0.8 per
3 10,000.

4 The likelihood that if they're
5 doing 200 deliveries a year, that's 50 years
6 worth of deliveries. So the likelihood that
7 we're going to run into that particular
8 problem very much I think is quite small.

9 Yes, we should look at the
10 multiple deviation, standard deviations out in
11 the bell shaped curve of these events. But
12 you're probably now talking in that particular
13 example, you know, four or five, six standard
14 deviations out in terms of that rate.

15 The question is do you want this
16 to be something that works very well in the
17 middle and a couple standard deviations out or
18 does it need to work all the way out to the
19 very ends of those statistics?

20 CO-CHAIR SAKALA: Chuck.

21 DR. MURI: I'm sorry, I don't know
22 if I can really add too much to that except

1 that I appreciate that concern. And I think
2 that, you know, I think there are a lot of
3 measures out there that the public has
4 difficulty understanding.

5 And so, but I don't think, I think
6 part of the public is, you know, are payers
7 and other quality groups that are doing
8 assessments and reviews and things like that.

9 So I think if it's a measure that
10 maybe that need a little bit, or measures that
11 need a little bit more explanation I think you
12 can do it in language that makes it clear for
13 these three.

14 But will everybody understand it?
15 Will the whole general public understand it?
16 Probably not.

17 DR. SUTHERLAND: I guess I'd like
18 to go back to Kathleen's point about the issue
19 that we could bypass a lot of these parts of
20 the composite by doing cesareans.

21 And I'm going to go through the
22 list. Interpartum fetal death, uterine

1 rupture, birth trauma, unanticipated surgery.
2 Apgar less than seven and third and fourth
3 degree lacerations.

4 That's six out of your ten
5 composites. And there really aren't any
6 balancing things to look at the maternal
7 morbidity that we're seeing from all the
8 excess cesarean that we're doing.

9 A lot of us, I think, understand
10 that some of the complications we're seeing in
11 obstetrics are higher in the last 20 years
12 because of our interventional attitudes.

13 And I know there are folks around
14 the table that really support natural
15 childbirth, so I guess I would like to bring
16 that up to kind of think about.

17 What the individual things in the
18 composite are and are they really balanced?
19 As far as what our public health goals are for
20 women's health. So I'd just like to hear some
21 comments.

22 DR. PRATT: Susan, do you want to

1 take some of that?

2 DR. MANN: That's why we have a,
3 I'm sorry, the echo is bad. That's why we
4 have the weighting, is to look at that. And
5 furthermore the experience at our own
6 institution collecting this data, actually our
7 cesarean section rate has decreased in the
8 last several years.

9 So I think that it's not a
10 necessarily, people don't make an individual
11 decisions to do a cesarean section based on
12 their rate of - on the average outcomes index
13 score.

14 It's a very complex decision of
15 why you do a cesarean section, so I am a
16 proponent of natural childbirth as well and
17 vaginal deliveries and I don't think that
18 these aren't necessarily in concert with one
19 another.

20 I still think it's information
21 that been useful for hospitals. We certainly
22 see hospitals drill down and do quality

1 improvement projects such as hemorrhage
2 protocols, shoulder dystocia drills based on
3 their experience with the staff.

4 DR. PRATT: Just one thing to
5 clarify as well. I thought that we had made
6 the language clear that the neonatal death is
7 actually in hospital neonatal death, not
8 interpartum.

9 And if it says that I'm sorry. I
10 thought we had changed all that. It is not
11 just interpartum, it is during the delivery
12 hospitalization. So that changes that outcome
13 significantly.

14 Because babies can die after
15 cesarean delivery or due to events related to
16 a cesarean delivery. But obviously if they
17 have an elective cesarean delivery they cannot
18 die of an interpartum death. So that one
19 would be changed at least a little bit.

20 CO-CHAIR SAKALA: Thank you.
21 Chuck.

22 MALE PARTICIPANT: Do I have time

1 for one additional comment?

2 CO-CHAIR SAKALA: Yes.

3 MALE PARTICIPANT: (telephonic
4 interference, unintelligible)

5 DR. PRATT: The other part of this
6 is, I think we're all in favor of having
7 normal vaginal deliveries, and as an
8 anesthesiologist I'm not willing to use
9 natural childbirth. Although my wife had
10 both of her babies with no medications, thank
11 you very much.

12 But, on the other hand, if we can
13 demonstrate that the cesareans that we're
14 doing are in fact changing adverse events. If
15 the complication rates are changing because of
16 the cesarean deliveries, or at least in
17 association with those, then those are the
18 ones we want to be doing.

19 And I'm not convinced that doing
20 cesarean delivery to save a third or fourth
21 degree laceration is necessarily the right
22 thing to do.

1 But if one is doing the c-sections
2 and it's improving the rest of these scores,
3 those are the ones we want to do. That is the
4 kind of medicine, at least I think, that we
5 likely want to do.

6 And as Susan said, our cesarean
7 section, that rate went down at the same time
8 that our adverse event rate went down. And
9 our severity index went down. So it all moved
10 in a good direction.

11 CO-CHAIR SAKALA: And are you
12 attributing that to this program
13 implementation in particular, or other things
14 going on at the time?

15 DR. PRATT: We really believe that
16 this was, that the teamwork was a big chunk of
17 this. Now as Susan alluded the teamwork
18 actually ended up leading to many, many, many,
19 other changes. As you sit there and work as
20 a team you realize all the other issues that
21 come up on the unit.

22 And so the development of

1 communication protocols with the attending
2 anaesthesiologist came out of this. So if
3 there is a vacuum delivery now on our unit, I
4 get called.

5 So if there is a stat section for
6 that failed vacuum I am already in the
7 operating room. Ninety percent of the time or
8 more the vacuum works and I go back to bed at
9 3 0'clock in the morning.

10 Those are all things that are not
11 specific to teamwork but came out of all of
12 this. Hemorrhage protocol, shoulder dystocia
13 protocols. Drills to help practice all of
14 these things grew out of all that.

15 So I won't say just the team steps
16 based teamwork training did it.

17 DR. BAILIT: I think there's a
18 difference between, you know, if we measure
19 health care and we put a lot of sunshine on it
20 you have impetuous to get better and things
21 are going to get better.

22 But I think the NQF has purview to

1 hold measures to a higher standard. Which is
2 public reporting of inter hospital
3 comparisons.

4 And that's a different kind,
5 potentially a different kind of measure. Even
6 if this is very good at what you're talking
7 about quality improvement.

8 It doesn't necessarily mean it's
9 ready for the big stage of we're going
10 identify hospital X as being a not so good
11 hospital and Aetna won't cover it and Medicaid
12 won't favor it.

13 And they have big implications,
14 and so that quality improvement work and
15 something that's useful in an individual
16 hospital quality improvement work is not the
17 same as what we need to hold the measure to.

18 CO-CHAIR SAKALA: Chuck, please go
19 ahead.

20 DR. DENK: Well I can think of a
21 couple positive things to say about this. I
22 agree with a lot of the comments about there

1 is a public reporting measure of hospital
2 quality it sort of has a lack of transparency.

3 And part of that is, I think,
4 because, you know, I think you're overdoing
5 the link. I mean, we all want to have our
6 indexes relate strongly to a single construct.

7 And your construct that you've
8 named is quality care. But I don't think, I
9 think this thing can have value without going
10 that far. And it's sort of an intermediate
11 thing.

12 What's striking me about this is
13 that it solves some problems that I've been
14 thinking about for the last two days. We have
15 problems with sort of defining what are good
16 validation strategies for a lot of the
17 measures that we've been talking about. The
18 process measures that we've been talking about
19 today.

20 We have also been talking about
21 the fact that a lot of the outcomes we'd like
22 to prevent happen very rarely and don't

1 aggregate well to individual hospitals and
2 things like that.

3 And so this is a sort of, I think
4 of this as more of a utility measure. Where
5 it's not necessarily for public reporting at
6 all. And it's not necessarily labeled as a
7 quality of care thing.

8 But the constructed measures I
9 adversity, and that it can be used exactly in
10 the way that it's been used in the literature
11 described. You know, to assess the
12 generalized impacts of multifaceted things.

13 Everything, you know, from
14 improving teamwork in hospitals. In
15 communication in hospitals to what's the
16 impact of delayed prenatal care or low quality
17 prenatal care.

18 Or you know a mom moving from one
19 state to another in the middle of her
20 pregnancy. I mean, you know, there's a lot of
21 issues like that. And so this could,
22 something like this could become a good sort

1 of standard.

2 And I don't know if that means we
3 would endorse it. But it could become a good
4 standard for, you know, use this to validate
5 generalized measures to prove a broad impact
6 across a lot of outcomes.

7 And let me just close with another
8 example. I'm sure a lot of you saw the same
9 article I did a year or two ago. I think it
10 was called an index of near miss, near miss
11 mortality or something like that.

12 Where a whole bunch of different
13 adverse events were added together and the
14 scale was, or the weights were basically as
15 far as I remember, how likely each event was
16 likely to result in a mortality. I think it
17 was all maternal mortality.

18 So you know, a laceration would
19 have a very low weight because it's unlikely
20 to by itself to lead to it, right? And you
21 know a lot of things, and there are a lot of
22 things in a near miss that aren't in here.

1 What's nice about this is that it,
2 you know, it's kind of randomly poking at
3 different parts of the system and so it would
4 be a good first pass way to look at systemic
5 improvements.

6 And it would be a good sort of
7 generalized way as a first pass for
8 validations, maybe. So those are comments I
9 have.

10 I think this thing could have a
11 place in the firmament of measures but maybe
12 not, it doesn't have that linkage to direct
13 patient quality improvement that we've been
14 using as a standard for the last two days.

15 DR. WINKLER: Just to clarify, you
16 know, public reporting is one type of
17 accountability. And while that may not be the
18 only it's certainly something of an area we
19 see a lot of.

20 But other accountabilities around
21 the payment accreditation, blah, blah, kind of
22 things are also included. So it isn't

1 absolutely public reporting but that
2 accountability realm.

3 DR. DRYE: When you say that,
4 Reva, I just want to clarify, because I think
5 this is really important. I totally agree
6 with Jennifer's point.

7 And if you move into the payment
8 realm I think you're in the realm of comparing
9 hospitals in this case. And so that's really
10 what we're asking.

11 Even if you don't use the word
12 public reporting. You're saying should this
13 be used to compare and either publicly report
14 or quantitatively reward or penalize hospitals
15 even with this measure. Would that be fair?
16 So it has to meet that standard.

17 DR. ARMSTRONG: Yes, and I would
18 say as the payer in room, or one of the payers
19 in the room. That from an absolute count
20 perspective here. The number of complications
21 per delivery, you know, it's interesting, it
22 says something.

1 I think when you put the weighted
2 averages on it, you know, you really have to
3 dive into whether that's the right weighting
4 and then the risk adjustment piece is huge.

5 Because you can't compare
6 hospitals, it's a non starter in a discussion
7 about hospitals until you can risk adjust it.

8 CO-CHAIR SAKALA: Kathleen, did
9 you?

10 DR. SIMPSON: I just wanted to
11 make a comment that to respond to what you
12 said about it is a measure of adversity. But
13 the one thing I think that can't be overlooked
14 is that there's an underlying assumption that
15 this adversity is related to substandard care.

16 And that is not the case in each
17 one of these things. If that were the case,
18 if there were somehow, because I really like
19 this concept, you know, I'm not opposed at
20 all.

21 I like the whole thing, it's just
22 that if there's some way to do a preventable

1 versus non preventable for each one of these
2 ten things, and I know there's not. It would
3 be great, but there isn't a way.

4 And again, the way this is put
5 together is you're making an assumption that
6 there is a direct link between one of these
7 ten things and substandard care.

8 And it's repeated throughout all
9 of the things that you've submitted. And I
10 don't think that is true. You know, so that's
11 the problem I have with that. The adversity
12 is not all related to substandard care.

13 CO-CHAIR SAKALA: Kathleen, I just
14 wanted to mention, one of those examples I
15 think is the incidence of episiotomy versus
16 tear. And so episiotomy being the direct
17 clinical intervention where we're wanting to
18 avoid third and fourth degree lacerations.

19 If you have a shoulder dystocia
20 you need to get the kid out that's not a
21 clinical mistake. Whereas episiotomy ought to
22 be used rarely and with caution.

1 So why, how did you choose third
2 and fourth degree lacs, and some of these
3 things. What were your considerations in
4 thinking towards that?

5 CO-CHAIR SAKALA: I think we need
6 to save the specific questions for later.
7 Because two of the three versions are so
8 influenced by the weighting process, I wanted
9 to ask Sean Currigan if you could comment on
10 that? About how that worked.

11 MR. CURRIGAN: I was not present
12 for the weighting because that happened before
13 my time. But my understanding was that it was
14 how measures were developed in those days. A
15 bunch of guys around a table, and they
16 discussed.

17 I think at that time, I mean it
18 wasn't that long ago. Everybody, they
19 discussed it and deliberated it over, like
20 half of a committee meeting, about the
21 weighting. And I don't know that they used
22 any numbers to come up with those weighted

1 scores.

2 CO-CHAIR SAKALA: Okay. Thank
3 you, that was helpful. So I think we're going
4 now ask our lead discussants to very briefly
5 present each of the components.

6 Can we try to stick to five
7 minutes for presentation and quick discussion
8 and a vote. And my understanding is that it
9 would be possible to vote no on some subset
10 and then revisit this at the end. Looking at
11 the whole and say is it a deal breaker?

12 So it's not as if we vote no we
13 stop. So we'll go through them all then we'll
14 come back again to the total. So the first
15 one is Bill Callaghan for in-hospital maternal
16 deaths.

17 DR. CALLAGHAN: Hi, I think this
18 will be brief, a lot of what has been
19 discussed already pertains to this particular
20 measure.

21 So the measure is all pregnant
22 women who died during the hospital. They come

1 in for delivery and the denominator is all
2 pregnant women who delivered during whatever
3 time you're measuring this in.

4 As somebody who has spent the last
5 ten years writing and talking around the
6 country about pregnancy related mortality and
7 severe morbidity. This is something that's
8 near and dear to my heart.

9 I view maternal deaths as a true
10 sentinel event that demands that the reasons
11 for death, that the factors associated with
12 the death be identified, reviewed and that
13 that information be used to take action for
14 preventability.

15 That being said, I share the same
16 issue that has been brought up over and over
17 again in terms of how that relates to
18 accountability.

19 We view, we do surveillance of
20 maternal mortality in the division of
21 reproductive health. It's a little bit
22 different from National Center for Health

1 Statistics.

2 We identify about 600 deaths per
3 year, probably about 400 of them are during
4 the delivery hospitalization. So these are
5 extraordinarily rare.

6 And that being said, we think that
7 at the same time that fact that one women died
8 likely resulted from processes and system
9 problems that occur over and over and over
10 again all over the place. And in fact don't
11 result in death.

12 Perhaps because of the sheer
13 tenacity of young women who can survive a lot.
14 But that doesn't mean that those processes
15 shouldn't be addressed. So our take, my take,
16 I guess is personal on maternal deaths.

17 These should be reviewed in
18 aggregate. Perhaps at the facility but even
19 better at state where these systematic errors,
20 if there are systematic errors. And again, we
21 think that about 50 percent are preventable by
22 changes in health care behaviors, or system

1 problems.

2 And that those, the factors
3 associated with them, once they are
4 identified, those are shotgunned out to
5 everybody. You don't assume that it's that
6 hospital that made the mistake, and it only
7 happened there. It happens everywhere all the
8 time.

9 And the system needs to be
10 improved over and over again everywhere. So
11 from that standpoint, these are incredibly
12 important events to review but I don't know
13 that they should be, we should, as everybody,
14 as many people have said, being used for
15 accountability and public reporting.

16 I have some real problems with
17 that, the review of maternal deaths being used
18 in that way I think they should be reviewed
19 but not just not counted and ticked off.

20 CO-CHAIR SAKALA: Okay. Thank
21 you.

22 DR. CALLAGHAN: Counting and

1 ticking them off the information gets lost,
2 there's nothing that can be learned from it
3 except perhaps maybe in the one instance that
4 it occurred. Perhaps a public health
5 perspective as opposed to an individual
6 facility perspective.

7 CO-CHAIR SAKALA: Okay, a quick
8 comment please from the developer perspective,
9 and then we'll hear from our other.

10 DR. PRATT: I would just say that
11 these are not, we in no way would suggest that
12 these are mutually exclusive. We are no way
13 suggesting that this is the only way that
14 maternal deaths should be reviewed.

15 And I agree with you that they are
16 such high sentinel events absolutely every one
17 needs to be reviewed. That doesn't mean that
18 they couldn't be also part of a numerator
19 process for adverse events.

20 So that would be my only comment
21 back to you was that our intent was never to
22 try to undermine the case review for this.

1 CO-CHAIR SAKALA: Comments from
2 other members of the committee on maternal
3 mortality as a component?

4 Okay. Wow, we made our five
5 minutes, almost. So let's have a vote then
6 about this particular component.

7 Okay, great. So next we move on
8 to Rob, for uterine rupture

9 DR. WATSON: Well, my component's
10 uterine rupture and I'm not sure exactly how
11 I feel about this, so let me just sort of
12 summerize.

13 It's a very rare event, it occurs
14 in about 0.06 percent to 0.55 percent in the
15 general population. It occurs in a greater
16 frequency for VBAC's at about 1.5 percent.

17 The developers feel that uterine
18 rupture could be associated with substandard
19 care, being especially reflective of
20 management decisions during labor, induction
21 of labor or augmentation of labor.

22 And they feel that the rate of

1 rupture is an indirect measure of clinical
2 decision making. ACOG rates this third out of
3 the ten measures on their weighting list.

4 I had some concerns originally
5 about the feasibility and maybe confusion of
6 data collection between a true uterine rupture
7 and a dehiscence, which we see quite
8 frequently. But I think you all have worked
9 that out.

10 So it's something that happens
11 very, very rarely, you know, it can happen in
12 spontaneous labors as well. Which would not
13 be any kind of substandard care necessarily.
14 And it could be prevented by a c-section.

15 CO-CHAIR SAKALA: Thank you.
16 Comments on uterine rupture as a component of
17 this measure?

18 CO-CHAIR RILEY: So I think this
19 is one of those that, this could drive us
20 exactly where we don't want to go. I mean, I
21 feel like this is one measure where you put
22 this out to the public, and not even the

1 public.

2 I'm thinking myself, okay, if I'm
3 going to dinged for a uterine rupture because
4 I allowed someone to labor because that's what
5 she wanted and I had everything in my
6 institution to support that.

7 I'm not going, I mean, it's not
8 going to be that long before I get smart and
9 say you know what there's no benefit to this
10 hospital to do VBAC's and we'll be done.

11 So if we want to close that door,
12 which I understand there's a lot of people
13 that want to close that door and make that
14 access. Then I really think that putting this
15 out will get us, we're getting there anyway.
16 But I really feel strongly that this will
17 probably close the door on it.

18 DR. DENK: Just really briefly to
19 that I agree with the logic of that but when
20 he said it I thought, okay the cesarean you
21 want to prevent is the primary one. And that
22 way you don't have uterine ruptures. I mean,

1 that's a good way to prevent uterine ruptures,
2 is not to do the primary.

3 CO-CHAIR RILEY: That makes great
4 sense, but the reality is that, and we're
5 working on that, we have a measure. But the
6 reality is that this will also take away any
7 patient who feels that she wants to give it a
8 go. She's not going to have any access.

9 CO-CHAIR SAKALA: And 20 percent
10 of child-bearing -- of pregnant women now have
11 a history of cesarean.

12 DR. WATSON: I don't think,
13 furthermore, from a quality standpoint, this
14 is a rare event, and each one of these would
15 be scrutinized at the quality committee at the
16 local hospital. So it's not like these things
17 are going to happen and no one's ever going to
18 pay any attention.

19 They'll be looked at and if there
20 has been misuse of Pitocin or mismanagement of
21 labor that would be addressed at that local
22 level.

1 CO-CHAIR SAKALA: Other comments
2 about uterine rupture as a component?

3 DR. GEE: Would it be appropriate
4 to speak to why would it be before maternal
5 admission to the ICU, it seems like uterine
6 rupture is weighted too much.

7 Can we speak to the weighting, it
8 seems like it's too heavily weighted. Because
9 it's somebody's, and often it's not avoidable.
10 If you want to let someone do a VBAC you may
11 have a uterine rupture.

12 And we discuss that with patients.
13 That's somewhat predictable as an outcome with
14 VBAC. So I think it's weighted too heavily.

15 CO-CHAIR SAKALA: So we could go
16 on record as saying that, that we can't
17 negotiate to change the terms of what we're
18 considering. Are we ready to vote, 37
19 seconds, you're good. Vote.

20 So on that we have four yes, and
21 20 no. And I think we didn't report to the
22 people on the phone the first measure was

1 evenly divided, 12 and 12.

2 So now we're going to go to
3 Elizabeth for unplanned maternal ICU
4 admission.

5 DR. DRYE: Okay. So this isn't my
6 area of expertise, but I'm going to both this
7 one and the NICU admissions. And I do develop
8 outcomes measures for a living. And I just
9 wanted to in 30 seconds comment on this as a
10 outcomes measure going through NQF, it isn't
11 risk adjusted, we've talked about why.

12 If you think 50 percent are
13 preventable and 50 percent are not it's really
14 hard to understand why the measure is not risk
15 adjusted. There's a requirement at NQF, if
16 you're not going to risk adjust an outcome
17 that you show that risk adjustment is not
18 needed.

19 And there is no data in the
20 application that I saw anywhere where risk
21 adjustment, for example, for patient factors
22 like age even were tested and dismissed.

1 So that's a huge thing and another
2 thing is that usually for outcomes measures we
3 try to characterize the amount of uncertainty
4 around our estimates because outcomes are
5 affected by quality and by chance and by
6 patient factors and we like to try to at least
7 capture the, quantify the amount of variation
8 that's probably due to chance so that we are
9 comparing providers fairly and not by chance
10 calling some providers worse than others. So
11 that's just as a preface.

12 And then finally when we're moving
13 from a QI measure, and it sounds like there's
14 a lot of expense with this as a constructive
15 QM measure towards, a measure for comparing,
16 and then we have to pay attention to how the
17 outcomes are defined and whether those
18 outcomes are coded, as we talked about a lot
19 in this group I think in the last two days,
20 systematically across institutions.

21 So I'm going to be speaking to
22 that as I look at this measure and then the

1 NICU admission measure.

2 And so briefly this component is
3 unplanned maternal admission to the ICU.
4 Which has a frequency as reported here of 0.1
5 to 0.4 of deliveries.

6 And the rationale is that the
7 causes are typically preventable including
8 hemorrhage sepsis, hypertension, pulmonary
9 edema. The numerator, I think one thing Reva
10 encouraged me to look at since I was looking
11 at two of these last night, was how
12 specifically the numerator and denominator
13 defined for these components of the outcome
14 and they are specified as DRG's or MS-DRG's
15 and the data source is multiple potential data
16 sources. So you could use claims, medical
17 records, et cetera.

18 And DRG's and MS-DRG's are
19 deliveries essentially, either vaginal or c-
20 section. But there's also an or statement and
21 I wasn't sure I could follow it completely
22 that identified women who were treated with

1 ventilatory support I think in a positive way
2 defined to include not just intubation but
3 positive pressure or et cetera. And so I
4 think that the NICU stay component of this may
5 be NICU or, and I just need to clarify with
6 you all, NICU or use of respiratory support.

7 And I don't know if that's true or
8 if it's just admission to a NICU's, maybe you
9 can quickly clarify. I'm sorry, I have NICU
10 on the brain. ICU.

11 DR. MURI: No, I think it's an or
12 statement because some of the hospitals you
13 can get at the unplanned admission, through
14 billing data. And with the exceptions it has
15 to be a postpartum complication.

16 But if the hospital does not have,
17 per se an ICU or do they do not code ICU
18 charges, the clinical conditions were added to
19 capture those women that may be in some other
20 defined area. But have a very serious
21 unplanned complication.

22 DR. DRYE: So I couldn't totally

1 follow that. I'm going to sum up and then you
2 can speak to the overall thing. Because
3 there's also in 2A 1.8 there's under
4 denominator details, there's an allowed
5 exclusion for planned ICU admissions for
6 things like placenta accreta, given as an
7 example.

8 And yet it says under 2B.3.1,
9 which are threats to validity that the planned
10 postpartum admissions to the ICU can be
11 excluded but must be identified by chart
12 review.

13 So I think there's some, to me it
14 wasn't completely able to discern from the
15 written specifications what is allowed and not
16 allowed to try to pull out planned admissions.

17 I think it's always good in an
18 outcome measure to try to pull out planned
19 procedures, which those, by definition, are
20 not things, or planned outcomes, these are
21 not, in this case an admission to an ICU.
22 Those are not things that we're trying to

1 measure or prevent.

2 But it wasn't clear that the
3 mechanism is really well defined here to do
4 that. Or that medically we could anticipate
5 clearly, and I just don't know enough about
6 OB. What was planned or unplanned and
7 differentiate.

8 So why don't I sum up and then you
9 guys, if you want to speak, because I know
10 we're running out of time.

11 So I just in summary, these are
12 ICU admissions, I see days, but it sounds like
13 in hospitals without ICU type care would be
14 captured, the rate is pretty low in this
15 population, 0.1 to 0.4 percent.

16 You're trying to develop a
17 mechanism to pull out unplanned, I mean,
18 pulled planned out and only capture unplanned.
19 But for me the overwhelming.

20 So there's a concern for me about
21 the uniformity of that outcome, whether or not
22 someone is admitted or not to ICU given the

1 way the measure is specified. Have you, you
2 know, really saying ICU admission at the IDMC
3 is the same as an ICU admission in a local
4 community hospital.

5 You know is there really the same
6 group of patients that you're, it's the same
7 outcome that you're capturing there and I
8 think given out discussion about NICUs and the
9 variation and how they're defined there.

10 I don't know as much about adult
11 ICUs but I would be concerned if that outcome
12 would be capturing very different things
13 across hospitals. And then just overall the
14 measure is not risk adjusted and I assume that
15 maternal factors are fact a risk in ICU
16 admission.

17 CO-CHAIR SAKALA: Did you want to
18 comment on that?

19 DR. MURI: Sure, I think in terms
20 of the definition of the patients, if you have
21 coded data. You can look at antepartum
22 conditions and an ICU admission, which is an

1 appropriate admission to an ICU.

2 Versus a postpartum complication,
3 so that's part of the distinction is to look
4 at the fifth digit for the ICD-9 codes. To
5 indicate that this is a postpartum
6 complication, within the range of OB
7 complications.

8 The other issue is if the hospital
9 does not have an adult ICU, or does not code
10 their financial data that way, charge for that
11 activity. That you have to get at the other
12 level of complications using the ICD-9 codes
13 or procedures. The procedures for intubation,
14 et cetera, et cetera.

15 The other issue is if a hospital
16 does not have the capability to put the woman
17 in an ICU and needs to transfer that woman out
18 immediately. That's where you get into the
19 transfer issue. Both on the neonatal side and
20 on the adult side.

21 That the woman or the baby is
22 transferred out immediately, and on the adult

1 side has a postpartum complication. So the
2 assumption it's not perfect. But the
3 assumption is that they're going out because
4 that hospital cannot accommodate that woman.

5 DR. DRYE: I apologize, I forgot,
6 I didn't define the numerator. I forgot to
7 say admission to the ICU or transfer to
8 another hospital for ICU admission.

9 DR. PRATT: I'll just comment
10 quickly on the issue of trying to deal with a
11 plan. You've already heard that in theory
12 there should be a postpartum event, and Janet
13 can get that from the fifth digit.

14 We tried, we looked very long and
15 hard at whether there were any conditions that
16 might have a high enough planned ICU rate that
17 we would say, let's exclude those. And the
18 fact is there are very few of those.

19 And we couldn't come up with, you
20 know, mom comes in with an uncorrected tet and
21 happens to be pregnant, it's probably a good
22 idea to put her into an intensive care unit

1 around the time of her delivery.

2 Extraordinarily rare cause of an intensive
3 care unit admission.

4 So there weren't any that were a,
5 it's true a procrasto, many of them are going
6 to go. But not all of them and not even maybe
7 many of them. And so the ability to sort of
8 identify that through coding was pretty tough
9 or to exclude specific pre existing
10 conditions. Actually we did not think we
11 could do.

12 CO-CHAIR SAKALA: Thank you, other
13 members of the committee?

14 CO-CHAIR RILEY: So I think that
15 this is one of those areas as where you
16 alluded to comparing ICU definitions would be
17 difficult.

18 Because, I mean, I think, you
19 know, I'm at Mass General and I can watch
20 things on the labor floor. Because I have
21 awesome anesthesiologists looking over my
22 shoulder for a lot longer than necessarily

1 somebody might do a another hospital.

2 And I sort of feel like, you know,
3 another bad care would be keeping on your unit
4 to long and not going to the ICU, and not
5 going to the ICU and sort of not recognizing
6 that you got someone who's in shock.

7 Which I think we hear all the
8 time, so I don't know how to sort of grapple
9 with that. I sort of recognize that the
10 benefit of looking at ICU admissions.

11 But I just wonder about, sort of,
12 another area where the risk stratification or
13 somehow separating these hospitals, you know,
14 I'm sure that, you know, on Jennifer's unit
15 she can hold on to things a long time too.

16 And even tertiary care centers are
17 vastly different.

18 DR. PRATT: We certainly can do
19 the stratification, and that's already been
20 done. And we could do this by, you know,
21 number of deliveries. We don't have the data
22 on things like 24/7 OB trained

1 anesthesiologists, right?

2 So that would be more difficult
3 although in theory one could stratify for that
4 if one had those data. The issue of, and this
5 gets, to the previous question of whether
6 people are actually going to keep people out
7 of the ICU in order to avoid this numerator.

8 We were having such a hard time
9 believing it. Although you also commented on
10 the idea that not, failure to recognize that
11 this patient, where it's not an on purpose
12 decision. You're not saying, oh I don't want
13 to take that hit. But they just aren't
14 realizing it.

15 Those folks are going to end up in
16 the ICU, or dead, or one of these other events
17 anyway, right? I mean, if they're that sick
18 they're going to get there one way or another.
19 So I'm no worried very much about missing
20 those folks.

21 CO-CHAIR SAKALA: Other urgent
22 comments? Yes, Kim.

1 DR. GREGORY: Well, I just, first
2 of all, I guess it goes back to the tenor of
3 the purpose, and that is that it represents
4 bad care.

5 And I agree that it's important to
6 do case finding, for patients going to the
7 ICU. And the same way that we're looking at
8 maternal events for, maternal deaths as
9 sentinel events.

10 And the possibility of review
11 systems of care that can be improved, but I
12 would argue that, you know, I would argue
13 especially after reviewing some of the
14 maternal deaths in California that the
15 majority of patients who ended up in the ICU,
16 it was actually a good thing that they were
17 there.

18 And I'm just sort of I'm concerned
19 that we're sending the wrong message.

20 DR. PRATT: There's no question
21 that in general going to the intensive care
22 unit is the right thing to do. The fact is

1 most of the diagnosis that lead to this are
2 associated with bad care. And therefore
3 potentially that ICU could have been.

4 DR. GREGORY: I would say, for
5 example, preeclampsia is probably is probably
6 one of the leading causes. And that's not
7 preventable. We have yet to be able to
8 prevent it.

9 DR. PRATT: Not preeclampsia, but
10 the ICU admission might be.

11 DR. GREGORY: The health, most of
12 them are going because of health, or some TTP
13 variant, or some variation thereof.

14 DR. PRATT: Those ones you're not
15 going to prevent. The hypertensive crisis you
16 might. They bleed because of the hypertensive
17 crisis. You might. There are lots of, and
18 there's very compelling data that's
19 demonstrating that blood pressure control is
20 done poorly in the severe preeclamptics a very
21 large percent of the time.

22 Now when I say there's often

1 substandard care, let me quantify, I'm saying
2 on the order of 50 percent of these cases. So
3 you're absolutely right, and we've talked
4 about this. And this is going to be your
5 problem without come measures forever.

6 DR. GREGORY: Right.

7 DR. PRATT: That all of them that
8 I've ever looked at they've got about a 50
9 percent preventability rate. And many, many,
10 many of those are not able to be risk adjusted
11 at this point. Or identified which ones are
12 in fact preventable.

13 And you all are going to have to
14 deal with that over and over again, whether
15 that's good enough to help you want to measure
16 it.

17 CO-CHAIR SAKALA: Last comment
18 please, then we need to take a vote.

19 DR. DRYE: Thanks, I actually,
20 what's great about outcomes measures from my
21 stand point, is you don't have to know which
22 ones are preventable. You don't, you have to

1 risk adjust out the patients factors. You
2 have to account for chance variations.

3 And then you can compare how
4 hospitals do on them and some are going to do
5 better than others. And if there's a lot of
6 variation then we know some are preventable.

7 And in fact when we think about
8 outcomes measures we try, in my group we don't
9 like, you know, to try to find the preventable
10 thing. You do want to find something you can
11 affect, but the concept isn't can you prevent
12 this and get it down to zero.

13 It's can you lower the risk
14 environment the patient is in and lower the
15 rate, so that the risk performers start to
16 look more like the best performers.

17 So I don't think it's an issue
18 whether something's preventable, you know,
19 identifying for any individual patient whether
20 something's preventable or not.

21 Planned is a different concept,
22 and, you know, it would be wonderful if we

1 could always tell what was planned and what
2 was not. But the data doesn't support it
3 always.

4 CO-CHAIR SAKALA: Okay, let's take
5 a vote.

6 DR. BAILIT: This is a process,
7 not an outcome. ICU admission is a process,
8 it's not a patient outcome.

9 DR. DRYE: Yes, I think it's on
10 the border, I don't know it's some
11 intermediate. It's not a process in the sense
12 that's it's clinically, you know, it's the
13 standard of care like giving an aspirin at
14 arrival for MI.

15 It's not that kind of process
16 measure but it's, I'd really call it like an
17 intermediate outcome. I think is what we
18 would call it. It's not necessarily something
19 that's bad for the patient but it's maybe on
20 the pathway to something bad?

21 CO-CHAIR SAKALA: Okay, can we
22 take a vote please? On unplanned ICU

1 admission of mothers. Okay, so we have eight
2 yes, and 16 no.

3 And we'll move on to Maryi for
4 third and fourth degree lacerations.

5 MS. LESLIE: Okay. So third and
6 fourth degree lacerations, this is not a
7 previously endorsed measure. The numerator is
8 the number of women who suffer third or fourth
9 degree laceration of the perineum during
10 vaginal delivery.

11 The denominator is all women who
12 deliver. Not all women who deliver vaginally,
13 but all women who deliver.

14 And with regard to having a high
15 impact it is a national priority partnership
16 goal so it meets that criteria, via that
17 mechanism.

18 It happens in as high as 30
19 percent of operational vaginal deliveries and
20 in 2009 that was 3.7 percent of the births in
21 this country.

22 In terms of there being a gap,

1 there's several OB management modes such
2 episiotomy and upper vaginal delivery that can
3 be modified that would effect the number of
4 third and fourth degree tears.

5 And there's some patient risk
6 factors that theoretically could be modified.
7 So it is something that we could have an
8 impact on.

9 A lot of the evidence presented in
10 the form was really about the AOI, and not so
11 much about third and fourth degree tear but I
12 would say that there's a moderate amount of
13 evidence.

14 And in terms of reliability,
15 testing at Beth Israel, they commented that
16 there was a strong match in terms of their
17 reliability testing. But they also commented
18 that when there was not a strong match, and
19 they described what they did about it.

20 So it suggested that maybe there
21 was some problems in terms of the match during
22 the reliability testing.

1 And I think one of the things with
2 third and fourth degree tears is that it's
3 been documented in several studies that
4 there's a lot of variation between provider
5 diagnosis and also coding. There's problems
6 with coding.

7 And it's mentioned even in the
8 form that like a second degree tear with an
9 extension is coded as a third degree tear.
10 And a third degree tear with an extension is
11 coded as a fourth degree tear.

12 And there's some variability in
13 how it's coded. So reliability might be not
14 as good as it could be.

15 Validity testing based on what's
16 said in the form I think is high. And it has
17 been used for public reporting both by JCo and
18 by AHRQ and I think it appears to be easily
19 collectable data. I'll open it up.

20 DR. BAILIT: I wish Bill Grobman
21 were here, but he's got a beautiful study from
22 2006 in the Gray Journal that talks about why

1 this measure has to be risk adjusted and is
2 not a great quality measure. So I refer the
3 Committee to that paper.

4 CO-CHAIR SAKALA: Comments from
5 anyone? Kathleen.

6 DR. SIMPSON: I just wanted to
7 mention that the joint commission decided not,
8 that that measure was retired. So it's not
9 something that is ongoing, that was retired
10 from the first. And then the incidence of
11 episiotomy was decided would be a better thing
12 than a third and fourth degree. That's not
13 current.

14 DR. WATSON: What's substandard
15 about getting a third degree midline
16 laceration on a vaginal delivery of a nine
17 pound baby? What's substandard about that?

18 DR. PRATT: I'll let the
19 obstetricians speak to that so, Susan?

20 DR. MANN: One of the adverse
21 outcome is that, I apologize for the echo, was
22 created it was at a time when both joint

1 commission and AHRQ were collecting this data.

2 And it was felt that obviously it
3 was important to bodies higher up than the
4 consensus panel with the results that it
5 needed to be included.

6 And that was the thinking then
7 because the literature has been, or
8 measurement has been done historically with it
9 that has remained in the adverse argument
10 there.

11 DR. WATSON: But that's now been
12 retired and we're just looking at episiotomy
13 rates. So the emphasis has changed.

14 DR. PRATT: To answer your
15 question, probably nothing. Although again,
16 I'm an anesthesiologist. The second question
17 though is why are we looking at episiotomy
18 rates? Or why are you all looking at
19 episiotomy rates? And my assumption is
20 because it's associated with an increased risk
21 for third and fourth degree tears.

22 You're right, so what we're

1 getting at is, if you do an episiotomy and
2 nothing bad happens and the provider gets
3 dinged, and it speaks to now, are we looking
4 at measures, that are process measures and as
5 provider, I love that.

6 Because I can give my antibiotics
7 within 60 minutes of incision, and I've done
8 a good job and our hospital looks great on our
9 SCIP measures, and off we go.

10 But if the patient gets a wound
11 infection despite that the patient does care
12 how well I did. The patient got a wound
13 infection. And if we look at care from the
14 patients stand point, rather from the
15 providers stand point.

16 They don't care whether or not you
17 cut an episiotomy they care whether or not
18 they got a fourth degree tear and now have a
19 fecal incontinence for the rest of their life.
20 right? That's what they care about.

21 And so that's why the outcome.
22 Now it is true that we've kept this largely

1 for historic reasons and we've thought about
2 it over and over again. And it's entirely
3 possible that we'll end up retiring this as
4 well.

5 But still, philosophically, you
6 all are saying let's change this so that we
7 measure what the clinicians are doing and I'm
8 saying I care more about the moms perineum
9 than the decisions made by the clinicians.

10 DR. WATSON: But I think the point
11 is --

12 DR. MANN: The performance of
13 episiotomy would not be a third and fourth
14 degree, you know, when it's coded, it's coded
15 as an extension to the third or fourth degree.

16 CO-CHAIR SAKALA: Nancy, did you
17 have a comment?

18 DR. LOWE: Yes, I guess we have to
19 remember though that for a huge two, three
20 generations of women. They regularly had
21 their perineums incised. And I can tell you
22 it was not pleasant. And I can also tell you

1 that when you had an extension of one of those
2 it was not pleasant.

3 And what we do know from the
4 literature and from the data is that
5 episiotomy is the precursor to the third or
6 the fourth degree extension. That's so clear.
7 That that's the precursor event.

8 And so that's why we've already
9 adopted that as a measure. And so to look at
10 simply third and fourth degrees does not, to
11 me, does not get at the sentinel event. If we
12 want to use that terminology. Which is the
13 episiotomy itself.

14 And once you've done that, like
15 someone said, I don't know if it was Laura
16 that said this, someone said. You know, if
17 you're, if it's a difficult delivery because
18 it's a large fetus. And we've done the
19 episiotomy we've already set up the situation
20 in which the woman is likely to have a third
21 or a fourth degree lac.

22 So, you know, I don't buy your

1 logic that the episiotomy is not the
2 appropriate thing to measure. Which is very
3 easy to measure off the chart.

4 DR. PRATT: From a measurement
5 stand point, you're absolutely right, it's
6 easier. And we're in agreement that that the
7 way that the third and the fourth degree tears
8 would be influenced is by creating practice
9 improvement around episiotomy.

10 Also probably around operative
11 vaginal deliveries. The OB anesthesia
12 literature demonstrates that there are many
13 obstetricians who do operable vaginal
14 deliveries because moms got an epidural in.
15 Not because she necessarily needs it but
16 because she happens to have one in.

17 Or this is the one they teach
18 their residents on because she's got one in.
19 So there are lots of places in both of those
20 where there could be quality improvement
21 efforts to decrease the rate of this outcome.

22 As I said, it's a question of

1 whether you want to get at measuring the risks
2 and the process level or the actual outcome.
3 And that's somewhat philosophical.

4 CO-CHAIR SAKALA: So, Kathleen,
5 and then we'll have a vote.

6 DR. SIMPSON: I just wanted to
7 mention that if you did go from episiotomy to,
8 I mean from third and fourth degree to
9 episiotomy, right now third and fourth degree
10 laceration already drives this measure.

11 When it's the most common thing,
12 is my understanding. So if you went to
13 episiotomy then the whole thing, AOI, would be
14 about episiotomies because then you would have
15 a higher number of those.

16 Rather than, you know, it would
17 totally screw up the whole thing. I mean,
18 that's all it would be about is episiotomy, I
19 agree with you that episiotomy is the bad
20 event.

21 But I'm just, you know, from the
22 purpose of what they're trying to do is that

1 would be pretty much, it would all be about
2 episiotomy.

3 DR. LOWE: I was objecting to the
4 idea that women don't care. If they have an
5 episiotomy. That's what was said. Trust me,
6 we care.

7 (Simultaneous speaking)

8 DR. PRATT: Given my gender I will
9 do better about trying to presume what women
10 do and do not care about. Fair enough.

11 CO-CHAIR SAKALA: Thank you. Let's
12 take a vote. So we have seven yes and 17 no.

13 Now we've just made an executive
14 decision that the way we're going to pick up
15 some time here is to have a working lunch. So
16 I'm going to ask you, it's sandwiches, easy to
17 do, to five of to be back, okay? So don't get
18 sidetracked with conversations, et cetera,
19 phone. Thank you.

20 (Whereupon, the above-entitled
21 matter went off the record at 12:52 p.m. and
22 resumed at 1:05 p.m.)

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1:05 P.M.

CO-CHAIR SAKALA: Okay. So we're going to move ahead with Lee, on Unintended Operative Procedure.

MS. PARTRIDGE: This component addresses so-called Unintended Operative Procedures. The numerator is the number of women who, during their delivery/hospitalization, which for me turned out to be important, have an unanticipated operative procedure. Basically D&Cs or repair or control of hemorrhage.

There are a few more codes in there but that's sort of the broad categories. The question that I had as I read this through was, and again, an awful lot of the material that was submitted related to the whole AOI and not necessarily specifically to this component.

The fact that you're tracking this only during the actual admission for the

1 delivery suggests to me that you might miss a
2 significant number of cases in which there
3 was, somehow the case was not handled as well
4 as it might have been. And the woman has gone
5 home.

6 And then the hemorrhage develops
7 or the need for the D&C or et cetera. So I
8 was just curious as to whether or not you all
9 felt comfortable that this was adequate as a
10 measure of what were perhaps inappropriate
11 care.

12 DR. PRATT: Dr. Mann.

13 CO-CHAIR SAKALA: If you're on
14 mute we can't hear you.

15 DR. PRATT: I can speak to that a
16 little bit. The issue, of course, there is
17 the capture of those who have gone home. We
18 can of course capture them if they came back
19 to the admitting hospital.

20 But if they went somewhere else we
21 would be unable completely to identify those
22 folks. And that's why this decision was made,

1 primarily.

2 MS. PARTRIDGE: But as I read the
3 description, even if they returned, if it
4 wasn't within the original hospitalization it
5 wouldn't be in your numerator. Am I wrong?

6 DR. PRATT: Correct. The reason
7 to exclude those is you end up now speaking to
8 different practice areas. You know, I'm in
9 Boston you throw a stone, you hit four
10 hospitals. Right?

11 Whereas you're someplace that has
12 only one hospital for four miles they are
13 going to get all of those returns. And I'm
14 likely to get none.

15 And so it wasn't reasonable to
16 have those come back and count in the
17 numerator when the practice patterns would be
18 so different from one location to another.

19 MS. PARTRIDGE: In essence the
20 damage could have been created at Hospital A
21 and the person was admitted to Hospital B for
22 the correction?

1 DR. PRATT: Right.

2 MS. PARTRIDGE: Okay.

3 CO-CHAIR SAKALA: Other comments?

4 DR. DRYE: So a downside of that
5 strategy, because I think that's a good
6 example where you thought about differences in
7 systems in defining the outcome.

8 But the downside is that hospitals
9 with shorter lengths of stay, who send their
10 patients home earlier, which may put them at
11 risk for the outcome they're going to get let
12 off the hook for that or be held even less
13 accountable.

14 MS. PARTRIDGE: Well I would
15 probably also add that sometimes it's not the
16 hospital that determines whether you stay a
17 short time, it's the patient herself in this
18 instance.

19 CO-CHAIR SAKALA: Other comments
20 on unanticipated operative procedure? Okay.
21 So let's take a vote then. Okay. So we have
22 15 yes and 9 no.

1 DR. PRATT: You're just happier
2 now that you have food.

3 (Laughter)

4 CO-CHAIR SAKALA: Okay. So Sarah
5 Brown's not here.

6 DR. WINKLER: The next one is
7 Measure 750, which is Maternal Blood
8 Transfusion. And we do have the DRG and the
9 MSDRG codes for blood transfusion, again, as
10 a part of the component.

11 I think there's been some
12 conversation earlier about appropriateness of
13 blood transfusion at times. But I think blood
14 transfusion in and of itself is fairly
15 straightforward.

16 CO-CHAIR SAKALA: Any comments
17 about Maternal Blood Transfusion as a
18 component of this composite measure? Okay.
19 So let's vote. So we have 17 yes and 7 no on
20 that one.

21 And we're turning to Five Minute
22 Apgar Less Than 7. Angelio.

1 DR. JALEEL: So I had difficulty
2 navigating through the submitted document.
3 Partly it's because it does not address the
4 specific component.

5 CO-CHAIR SAKALA: Could you speak a
6 little closer to the mic? Thanks.

7 DR. JALEEL: I have my plate up
8 here. So I had difficulty navigating through
9 the submitted document. Partly it's because
10 it does not specifically address the specific
11 component. It addresses the general measure.

12 And partly it is because the
13 questions are not specifically answered in
14 multiple places and things like that.

15 So anyway, the measure is Five
16 Minute Apgar of Less Than 7. And my thought
17 is that, is a low Apgar a measure of
18 substandard care or a preventable
19 complication? So that's the issue here. So
20 one of the references that has been mentioned
21 is the citation for evidence of high impact is
22 the policy statement by the American Academy

1 of Pediatrics.

2 Actually when you read the AAP
3 statement it actually focuses on being more
4 cautious about the use of Apgar score, because
5 a number of factors may influence the Apgar
6 score.

7 It is not appropriate to use Apgar
8 score alone to establish the diagnosis of
9 asphyxia, because there are so many other
10 components.

11 Maybe a better measure would be
12 checking of cord blood gas for fetal acidemia
13 so that would probably be more appropriate.

14 And an Apgar score at five
15 minutes, in term infants, correlates poorly if
16 you are looking at the neonatal outcomes, it
17 correlates poorly with the neurological
18 outcome.

19 So that doesn't help either. And
20 can it be used for monitoring the delivery
21 service? Yes it does say that it can be
22 useful.

1 But with the caveat it says
2 specifically in that document that individual
3 case reviews are more, can identify these
4 issues and it probably doesn't help as a
5 quality measure for, what's the word, I
6 forget. For disclosure.

7 Yes, public reporting that was the
8 word I was looking for. So I'm not sure
9 whether this is a good measure or not because
10 there are multiple factors which do factor in.

11 And one of the citations for data
12 on the performance gap that they have
13 mentioned are three citations, which
14 specifically again, do not address Apgar score
15 but address the index or such.

16 So it doesn't help in that. And
17 then there's one more citation which looks at
18 a Swedish registry and looking at low Apgar
19 score at five minutes.

20 And I went back and looked at that
21 article and it's a Swedish registry. And what
22 weighs in more is the birth weight and the

1 gestation.

2 And there are several observed
3 risk factors which are associated with the low
4 five minute Apgar score in term infants. But
5 many of them are preeclampsia and things like
6 that, which we don't have control on. So I'm
7 not sure whether it helps either.

8 Maybe as a composite measure it
9 might help. But individually is this outcome
10 measure an important one which can be reported
11 publicly? I don't think so.

12 DR. PRATT: Just quickly, we do
13 restrict this to term babies at 2,500 grams,
14 so we're dealing with much of the prematurity
15 issue. And yes, as is true with all of these,
16 there are many factors that can influence it.
17 But certainly does include obstetric
18 management and obstetric decisions.

19 And we also exclude many
20 congenital anomalies to try to look at
21 basically healthy term babies who now come out
22 with a pretty low Apgar score that is

1 maintained.

2 It's not just the baby that has a
3 vacuum or assisted delivery and comes out and
4 is a little stunned and by five minutes it's
5 pink and screaming.

6 These are babies that carry on to
7 have a fairly low score. So we tried to
8 narrow this down to babies that really should
9 be good, you know, good babies by five
10 minutes.

11 This isn't trying to measure
12 whether they're going to have high grade HIE,
13 it's not going to assess whether or not
14 they're going to get into Harvard when they're
15 18.

16 But we tried to, as best we could,
17 find just those babies that really should be
18 doing well.

19 CO-CHAIR SAKALA: Other comments?
20 Kathleen?

21 DR. SIMPSON: I just had a
22 question on the references. You said that

1 about 50 percent of the low Apgars at five
2 minutes are related to intrapartum events.
3 But there's not reference cited for that.

4 And so I, like Jaleel, was looking
5 for citations specifically related to the low
6 Apgar. And that one really was interesting
7 because that does give you some idea as to
8 maybe it could be prevented or not.

9 But I didn't see the reference.
10 So could you provide, or do you know where
11 that's from?

12 DR. PRATT: Dr. Mann wrote this
13 up, wrote this particular one. We all sign
14 off on all of them. But she was the one
15 getting those references. Susan, are you
16 there still?

17 CO-CHAIR SAKALA: Okay.

18 DR. JALEEL: Yes, that's a concern
19 with many of the statements which have made.
20 There are no references or the references are
21 in different places, which don't actually,
22 it's not well documented.

1 MS. PARTRIDGE: I found that a
2 challenge, I must say, in reviewing all of
3 this. Some of the references are incorrectly
4 cited too. They have like the wrong volume or
5 the wrong year. I mean I eventually found
6 most of them, but that was frustrating.

7 And then the just broad range
8 comments that this is related to substandard
9 care, no reference. I think it could have
10 been better prepared I think.

11 DR. PROFIT: I'll tell you when I
12 was putting references I cut and paste them
13 from PubMed, so if there was an issue with
14 which volume we can talk to them. So the ones
15 that --

16 MS. PARTRIDGE: Okay.

17 CO-CHAIR SAKALA: Any other urgent
18 comments on 5 Minute Apgar less than 7?

19 DR. PROFIT: I guess I was just
20 wondering why you didn't use Apgar at one
21 minute rather than Apgar at five, because most
22 of the index seems to relate to kind of like

1 prenatal, like obstetric care.

2 And generally lest we kind of
3 conceive of the personal doctor's score
4 consistent with maybe prenatal care versus
5 five minute Apgar scores also then dependent
6 on resuscitation and technique of
7 resuscitation.

8 DR. PRATT: Certainly that is
9 true. But there's so many babies who, for
10 various reasons, are born and have a
11 relatively low one-minute Apgar. You know,
12 precipitous delivery can cause a low one
13 minute Apgar.

14 And we certainly wouldn't want to
15 put that into the numerator. And the other
16 part of that is, yes, again remember this is
17 looking at the overall quality of care, not
18 just the issues related to obstetric
19 management.

20 And so, you know, who's in the
21 room. Are there obstetric nurses doing all
22 that resuscitation? That speaks to the

1 overall labor and delivery care.

2 Just quickly speaking to using
3 cord gases. It may well be a better measure.
4 It certainly is a better measure of acute acid
5 base. One of the issues there is remember the
6 obstetrician is in charge of whether or not
7 that gets sent.

8 And there certainly is the
9 potential for some bias there in terms of
10 whether or not they send it. My guess is that
11 most are sending it to be defensive and
12 over-send. But you could certainly imagine
13 them not wanting to know what that pH is.

14 Versus most of these Apgars are
15 being measured by people other than the
16 delivering obstetrician. Pediatricians,
17 nurses, et cetera. And so it is a measure
18 that is by somebody who is not as invested in
19 that delivery.

20 DR. PROFIT: Apgar score, as we
21 know, it is a very subjective measure. And
22 there have been multiple studies looking at

1 multiple providers, neonatal providers and
2 pediatric providers doing this and having
3 variable results. So it's not a very good
4 measure.

5 And you can probably mandate and
6 say if you have these risk factors then you
7 should get a cord gas. Is that something that
8 you can do? I'm not sure, but I --

9 CO-CHAIR SAKALA: Okay.

10 CO-CHAIR RILEY: That is actually
11 in guidelines for perinatal care. With Apgars
12 less than X you need to get cord gases. And
13 you know, we're at CRICO institutions, if you
14 don't get it they're not helping you out when
15 you have to sit in the big room. So I don't
16 see that, actually, as an impediment.

17 I think the time that people are
18 should I send them, should I not send them,
19 the Apgar is good but the tracing was bad or
20 something else was going on.

21 And you're thinking do I really
22 want to hang myself them. I don't thing

1 people game that system in the wrong direction
2 actually.

3 I think if anything people are
4 getting more information. And it may be
5 medical/legally motivated. But nonetheless I
6 think that they get the information.

7 CO-CHAIR SAKALA: Okay. Could we
8 please take a vote now? Suitability of 5
9 Minute Apgar Less than 7 as a component of
10 this measure.

11 So we have 10 yes and 14 no. And
12 we'll turn to Nancy for Birth Trauma.

13 DR. LOWE: the Birth Trauma
14 Measure, if you remember from our discussion
15 yesterday, it is very similar to 474 that we
16 talked about yesterday, that we did not
17 endorse.

18 There is one primary difference
19 between 474 and this measure, in that in this
20 measure brachial plexus injury is included.
21 So I'm not sure we need to revisit all that
22 stuff, because it's the same measure.

1 The weights are the same. The
2 ICD-9 codes are the same, except for brachial
3 plexus injury, which is included in this
4 measure.

5 MS. WATT: I just wanted to
6 mention, there is one other code that is
7 different from the PSI 17. 767.8 is not
8 included in this measure, in this metric.
9 767.8 is Other Specified Birth Trauma.

10 The other difference is that the
11 denominator here is deliveries, obviously
12 because it's part of the AOI.

13 CO-CHAIR SAKALA: Are you done,
14 Nancy?

15 DR. LOWE: I mean, I just don't
16 think there's a need based upon the long
17 discussion we had yesterday about this.

18 CO-CHAIR SAKALA: Okay. Anyone
19 else? Okay. Let's take a vote on this.
20 Birth Trauma as a Component of the Index.

21 Yes, others who haven't weighed
22 in. Okay. So we have 8 yes and 15 no. So

1 we'll turn to Bill Callaghan for In-Hospital
2 Neonatal Death.

3 DR. CALLAGHAN: Thanks. I have to
4 admit I was a little confused by this measure
5 as specified. In the numerator it specified
6 as any in-born, discharged disposition of died
7 within seven days of birth (perinatal death),
8 which really isn't a perinatal death.

9 A perinatal death is an early
10 neonatal death. So perinatal death would
11 include still fetal deaths. And then in the
12 AOI papers they specify intrapartum and
13 neonatal death.

14 And more specifically these are
15 greater than 2,500 grams and more than 37
16 weeks term. So I took this on face value to
17 be early neonatal deaths. That is born alive
18 and died within seven days of birth.

19 Okay. Obviously, again, this is
20 another rare and sentinel event. There are
21 data that were published in the Journal of
22 Pediatrics in 2007 that actually looked at

1 this, in a different context, to compare late
2 pre-term births with termed births.

3 And if, as specified in this
4 definition, you eliminate congenital
5 malformations as a cause of death that would
6 limit this to about 750 deaths a year.

7 About one in five of those deaths
8 would have been assigned a cause of death as
9 birth asphyxia or intrauterine hypoxia and
10 then the rest various and sundry causes of
11 death.

12 So this represents a fairly
13 heterogenous and rare group of deaths. It's
14 difficult to understand for me, where sort of
15 the, again from an accountability standpoint,
16 who is accountable for what.

17 If the intent was that this was
18 about intrapartum management then I think it
19 gets even sketchier, because again this is
20 about 750 deaths per year in this group of
21 non-anomalous term fetuses. One in five of
22 which would have been assigned intrauterine

1 hypoxia and birth asphyxia.

2 And it still remains unclear, I
3 think, in this day and age how much of that is
4 really and truly intrapartum management, how
5 much of it isn't.

6 From a citation standpoint,
7 there's some citations from some international
8 articles that have more of an international
9 focus where intrapartum death certainly is a
10 very different phenomenon that it is in the
11 U.S., as well as asphyxia.

12 Some references to infant
13 mortality and neonatal mortality and
14 post-neonatal mortality in general. But not
15 specifically addressing the issue of early
16 term neonatal mortality.

17 So I think, again, at the end of
18 the day, from my perspective, this represents
19 a group that is pretty hard to hold out again
20 for accountability or preventability.

21 CO-CHAIR SAKALA: Comments,
22 questions, from anyone around the table?

1 DR. PROFIT: I guess for me it's
2 interesting it took a group of obstetricians
3 to give the neonatal death only about half the
4 weight of maternal death, but a point well
5 taken.

6 DR. CALLAGHAN: Was the intent
7 basically based around intrapartum management?
8 Because the focus of this, although it's been
9 unstated I think explicitly, is that this
10 relates to intrapartum care.

11 DR. PRATT: Yes, absolutely. This
12 was designed to be around intrapartum
13 management. There have been several other
14 studies looking at entire pregnancy management
15 and various outcome measures associated with
16 managing the entire pregnancy.

17 But the entire AOI has been about
18 measuring quality of care in labor.

19 DR. CALLAGHAN: But not, for this
20 measure specifically, not care after delivery?

21 DR. PRATT: Not, so correct. So
22 one of your points may be --

1 DR. CALLAGHAN: And if it dies
2 before seven days of life may have been of the
3 Apgars.

4 DR. PRATT: Yes, might be his
5 fault.

6 DR. CALLAGHAN: Probably was.

7 DR. PRATT: Fair enough. And
8 you're right. We did not include this as a
9 measure of nursery or NICU care.

10 DR. PROFIT: I'd like one more
11 comment, I think goes back to the
12 stratification by kind of hospital. And maybe
13 I missed this in here but in a lot of smaller
14 hospitals a baby may be admitted to a NICU or
15 Level 2 nursery or something that you would
16 define as a NICU but then get shipped out to
17 a tertiary care center.

18 And so I couldn't really see how,
19 or didn't quite understand how this would be
20 captured in your index. So they may not die
21 in your hospital. There's some hospitals that
22 pretty much don't want kids to die there and

1 they'll end up dying somewhere else.

2 DR. MURI: Yes, I think that's a
3 real problem with any measure at any hospital
4 that has the opportunity to transfer out the
5 problem. You know, you're not going to pick
6 that up unless the receiving hospital gets
7 dinged for it you're just not going to get it.

8 But you're not going to get it
9 from the hospital that's doing the
10 transferring, unfortunately. Better linked
11 data.

12 DR. PRATT: Yes, although we do,
13 for the neonatal ICU admission, we do get
14 those transfers. So we would still identify
15 it as a case. We likely would miss the death.
16 And I think that that's going to be true for,
17 it was also true for the unplanned procedure,
18 right.

19 But at least we would still get
20 this as an event because it would have been
21 transferred out, likely to go a NICU and we do
22 capture those.

1 CO-CHAIR SAKALA: Okay. Can we
2 have a vote then on In-Hospital Neonatal Death
3 as a component of this measure? Okay. So we
4 have 8 yes and 16 no. And Elizabeth, we turn
5 back to you for the final component.
6 Admission to NICU at Term.

7 DR. DRYE: Okay. So this is our
8 last component of our last measure, I think,
9 until we go to the harmonization discussion.

10 The measure is for babies who are
11 at least 2,500 grams and 37 weeks who are
12 admitted to the NICU within one day of birth
13 and who stay greater than or equal to one day
14 in the NICU.

15 Or who are transferred within one
16 day, which is parallel to the maternal ICU
17 admits. The challenge with this measure is,
18 well the baseline rate reported in the
19 application is six to eight percent. So it's
20 much higher than a lot of the other things
21 we're looking at.

22 And the challenge is that, again,

1 the two big challenges are are that there's
2 not risk adjustment and I'm sure that both
3 maternal and infant factors contribute to
4 their NICU admission risk.

5 And then thinking about that as a
6 threshold, admission to a NICU or transfer,
7 there is, as we've talked about already so we
8 don't need to go over it again, a lot of
9 variability of the rates of admissions to
10 NICUs. Some of which may be a quality signal.

11 Some of which may be a structural
12 or inefficiency signal that, you know, if
13 hospitals are admitting 25 percent of their
14 babies to NICU that may be a different kind of
15 signal that we would be getting out of this
16 count that would be feeding into the composite
17 score.

18 The information on this specific
19 form for this sub-component is pretty brief
20 and I don't blame the metric developers, it's
21 a lot to fill out ten different forms for all
22 these outcomes is challenging.

1 But there's very little on the
2 validity of the measure. The studies cited
3 are really back to the index, not this
4 individual component.

5 There is some look at the data
6 validity and there's subjective words like,
7 you know, there was a strong match or
8 whatever.

9 But there's not quantification in
10 the application about how well the different
11 data sources lined up in determining who was
12 admitted to the NICU or not. So I think those
13 are the main points.

14 CO-CHAIR SAKALA: Other comments,
15 questions?

16 DR. MURI: I just wanted to
17 mentioned that one of the ways that we try and
18 do discriminate in terms of the processes at
19 a hospital is that the baby actually has to be
20 in the highest level bed.

21 So many hospitals will have
22 intermediate level beds. They'll have

1 step-down beds, they'll have observation beds.
2 So these babies in this 2,500 gram, 37 week
3 can be taken care of for a couple of days in
4 those types of beds. But if you're putting a
5 baby, without the exclusions, if you're
6 putting a baby in a NICU level bed then there
7 are other drivers potentially that are causing
8 that. So, I think, that's why we're trying to
9 discriminate that the baby can't be just in a
10 special care bed, but it has to be in a NICU
11 bed. And so that's why you get those very
12 large numbers of cases.

13 So when hospitals begin to look at
14 their data they start saying, oh, they really
15 shouldn't be at that level. They could be in
16 an observation bed for rule out sepsis and
17 those types of things, so is it really
18 appropriate care.

19 DR. DRYE: So let me just clarify
20 one thing, which I forget to mention. This
21 two out of two numerator statements I've
22 incompletely presented to you. So I

1 apologize. But this one does have an
2 exclusion for babies with congenital
3 anomalies, fetal hydrops, dwarfism or neonatal
4 abstinence syndrome. And codes are provided
5 for those.

6 I'm not sure what you just
7 discussed about level of bed addresses the
8 observation we were making earlier that some
9 NICUs, say in a community hospital, there may
10 be a Level 2 NICU. And it's really the only
11 place where there are nurses and potentially
12 a on-call resident, for example, this is my
13 experience in a small community New Haven
14 hospital, really able to care for babies where
15 there's any concern. And so the threshold for
16 admission is very low versus say at a tertiary
17 care center like Yale. So I think that's a
18 difference that we're all acknowledging.

19 And the issue is in a composite
20 measure like this, what would the signal be
21 giving you. You'd be capturing potentially
22 two very different things. One is sort of an

1 inefficiency in the system or a management
2 choice that we don't think makes sense versus
3 a quality signal that was poor perinatal care
4 during the delivery.

5 DR. MURI: I think for that type
6 of hospital if the baby really needed the NICU
7 level bed that baby would not be picked up on
8 this measure. But if the baby really needed
9 the NICU level they would be transferred out
10 and they would be covered under that transfer
11 scenario.

12 DR. DRYE: So let me just clarify
13 then, because I'm confused. If the hospital,
14 the highest level is a Level 2 NICU bed, say
15 a six-bed NICU, would you count that? That
16 would be a NICU admission I think documented
17 in the charges.

18 DR. MURI: A Level 2 bed NICU is
19 driven by the revenue codes, the UB-04 revenue
20 codes. So a Level 2 bed is coded at 172 or
21 173, the only ones that we're picking up are
22 174s. So it has to be truly charged at the

1 NICU level. They may call it a NICU.

2 DR. PRATT: At the Level 3 NICU
3 level.

4 DR. DRYE: Okay. Well that's a
5 clarification. I think it's not really
6 specified in the form. And again, these forms
7 are kind of endless and they're hard to do.

8 And let me just say reviewing it,
9 it would have, I think, it would be helpful
10 just to have those kinds details there and
11 also even just the DRGs listed so that you
12 don't have to look them up as -- just a
13 description of the DRG not just the number so
14 you don't have to look them up to understand
15 the basic things like numerator and
16 denominator statements.

17 CO-CHAIR SAKALA: Are we ready to
18 vote? Thank you. Admission to NICU at Term
19 as a component of the composite measure.
20 Okay. So we have 11 yes and 13 no on that.

21 So Suzanne has prepared a summary
22 slide of our votes. She's just putting in the

1 last one and then we'll put it up. We had a
2 tie, a no, a no, a no. A yes, a yes. A no,
3 a no, a no and a no in terms of the simple
4 majority votes. But now we're going to ask
5 you with no further discussion? Yes. Okay.

6 So we're going to go through all
7 of the four major NQF criteria, thinking of
8 this composite measure as a whole. So the
9 first question is importance to measure and
10 report. Opening it up for comments.

11 DR. GEE: I just wanted to ask,
12 and Scott and I were just talking and we both
13 had the same question. On a national level
14 certainly the maternity field is very
15 premature in terms of our measurement science.

16 A measure like ths is extremely
17 complex, certainly now with, we don't know I
18 think now, four of the ten are still in there.
19 How do we vote on something like that where we
20 don't know -- understand -- okay, if you redid
21 it with only a few measures and you want to
22 weigh it a certain way, how could you think

1 about it?

2 Then on a national level who else
3 are using composite measures? Are they well
4 validated elsewhere? Are there other
5 professions that use these, and what are
6 examples of those?

7 DR. WINKLER: Yes. Two questions.
8 First one is you need to vote on what's
9 presented. So there's no tweaking, you've
10 given a lot of feedback, but that's not what
11 you're voting on. You're voting on what's
12 right here in front of you. Okay?

13 So the second. Are other
14 composite measures used? Yes, they are.
15 There are two basic measure kinds of composite
16 measures that we've endorsed. We've endorsed,
17 several now, what are known as all or none
18 composites where there will be multiple
19 components.

20 Often process measures, but they
21 can be outcome measures. Where it's, for
22 instance, good diabetes care means your

1 hemoglobin A1c is less than whatever your
2 number is. Blood pressure is less than. And,
3 you know, the LDL is less than.

4 And the patient, in order to get
5 credit for the measure, you have to hit all
6 four. Okay? So that's a kind of measure
7 we're seeing a lot more of. And we've
8 endorsed any number of those and they are
9 being used nationally.

10 The other kind are the kind that
11 Elizabeth's worked on. And these are more
12 traditional composites where there's weighting
13 and risk adjustment of the components and
14 factor analysis and, you know, they all get
15 kind of put together a little bit odd.

16 (Off microphone comments.)

17 DR. WINKLER: Microphone, please.

18 DR. DRYE: Both are outcomes
19 measures that we've -- one's just finishing up
20 the NQF process and one's approved. They are
21 risk adjusted but they are specified in the
22 way that these are. It's one or more of six

1 or seven outcomes. And so we didn't treat
2 them as a component per se. We looked at each
3 of those clinically and at the coding
4 variation and asked a lot of the questions
5 that we talked about today, but they weren't
6 true composites.

7 And I think, you know, everything
8 is evolving.

9 DR. WINKLER: Yes, that's one of
10 the evolving issues, is when is a composite
11 composite and when is it something that there
12 are just multiple criteria to meet for the
13 numerator. And at this point it's sort of
14 arbitrary and we're still trying to find our
15 way through that.

16 But there are those kinds of
17 measures endorsed and being used.

18 CO-CHAIR RILEY: Getting back to
19 that, that two. One of the main questions
20 that's been brought up all morning is how
21 would the public use this. Like it's
22 complicated. So how would the public use

1 this? So I guess my question is --

2 CO-CHAIR SAKALA: Are you at
3 usability or -- ?

4 CO-CHAIR RILEY: Oh, okay. All
5 right I won't ask the question that I was
6 going to, shoot it back to Elizabeth.

7 (Off microphone comments.)

8 CO-CHAIR RILEY: So she told me to
9 stop talking because --

10 CO-CHAIR SAKALA: Other comments
11 on importance to measure and report?

12 CO-CHAIR RILEY: For the
13 composite?

14 CO-CHAIR SAKALA: Yes, for the
15 overall composite of all ten components.
16 Okay. Please vote. Okay, so the vote is 7
17 yes and 17 no. And now we do stop according
18 to the process, because the first two criteria
19 are must-pass criteria. But we thank you for
20 your work and your time.

21 CO-CHAIR RILEY: So now I do get
22 to talk? So one of the major issues,

1 obviously, that we're having with this is if
2 you were to put this out to the public and
3 they're going to compare hospital to hospital,
4 you know, we're getting really, you know,
5 having chest pain thinking about it.

6 So with those composite measures,
7 or whatever you call the measures that you're
8 doing, how is the complexity of those rolled
9 out to the public. Like, what does that look
10 like? I'm just trying to understand.

11 DR. DRYE: On the two that we've
12 done they're not publicly reported yet. But
13 I will just tell you I think the way we'd
14 handle it would be the same as the other
15 outcomes measures. So there are one or more
16 of five or six complications following ICD
17 implantation and the other one is similarly.

18 I can't remember off the top, I
19 think it's six or seven different
20 complications following elective hip/knee
21 replacement. So what would show up is that
22 there are one or more complications.

1 The drill down data would get to
2 providers so they could have that. And it's
3 supported with a risk adjusted rate, but also
4 with an uncertainty estimate around that rate,
5 which is challenging enough to communicate to
6 consumers.

7 Let me just make one point I
8 thought about earlier with respect to the
9 usability of this measure. You know, it's
10 just worth thinking about when do patients
11 have a lot of choice.

12 So for example, we developed CMS
13 reports AMI mortality and AMI readmission risk
14 adjusted rates on the website Hospital
15 Compare. And we don't think of people really
16 choosing their hospitals by looking up, you
17 know, that data online when they're having
18 chest pain, speaking of chest pain.

19 But it's, I would think a little
20 bit more and you all can tell me more. I know
21 there are payment and provider arrangements
22 with specific hospitals. But the patients

1 might be more sensitive to using this kind of
2 measure to make choice.

3 And so in that sense I think we
4 have to be judicious about putting, you know,
5 we want them to have more information but this
6 is one that's more likely to get used for
7 patient choice.

8 DR. WINKLER: I'll take the
9 prerogative, I'd like to introduce the Senior
10 Vice-President of Performance Measures here at
11 NQF, Dr. Helen Burstin, who snuck in earlier
12 today and she'd like to make a comment.

13 (Off microphone comments.)

14 CO-CHAIR RILEY: So I just wonder
15 if, and that makes complete sense to me, but
16 as I think about it people are coming in all
17 with one thing.

18 So you had a hip replacement, so
19 everybody had a hip replacement, and then
20 you're going to stratify based on, you know,
21 sort of how you are as a patient or your age
22 or whatever it is or how sick you are.

1 And that to me is straight
2 forward, like we're all talking about the same
3 thing. And a little bit of this is that we're
4 talking about vaginal delivery, we're talking
5 C-Section.

6 And it's not as homogeneous. Like
7 I don't know whether it would be easier to
8 understand if we were talking about everyone
9 having a vaginal delivery and then, you know,
10 sort of composite measures or whatever versus
11 -- No?

12 (Off microphone comments.)

13 CO-CHAIR RILEY: Okay. Their
14 expectations are very different.

15 (Off microphone comments.)

16 MS. PARTRIDGE: When I first saw
17 this measure I was very excited. And I don't
18 want you developers to go away feeling, I'm
19 sure you're going to get a little discouraged
20 at this reaction.

21 But I was excited for exactly what
22 Helen was talking about. This is one of the

1 situations in which a woman, or a family, as
2 sometime's it's a joint decision, can get to
3 choose which facility she goes to.

4 And I'm one of those people who
5 does read Hospital Compare. And when my
6 husband was contemplating a hip replacement I
7 read all of the stuff that I could find about
8 the Washington D.C. hospitals and I think it
9 considerably narrowed his choice of both
10 surgeon and facility.

11 As we've worked our way through
12 this measure today, as you can see, there were
13 a number of concerns about a number of the
14 components.

15 And I think part of it is the
16 problem that we're used to dealing with
17 measures individually. Judging each
18 particular measure on its own bottom.

19 Here we're trying to do a market
20 basket and that's a little harder to get your
21 head around. But please come back at some
22 point when there are opportunities to do that.

1 Composites are something that we do welcome.

2 And I do think they can be
3 explained very easily to the patient. And I
4 think, frankly, it's the kind of information
5 that you're attending, your docs and nurse
6 midwives too, because in Washington we have
7 both, in Washington like to know.

8 If you've got a sloppy hospital
9 you'd like to know it. You don't want to be
10 associated with it, or you'd like to see it
11 get better.

12 DR. ARMSTRONG: You know, I would
13 say again echoing the payer perspective, sort
14 of the first introduction of this is very
15 attractive.

16 A huge interest on the part of
17 payers, an enormous interest on the part of
18 planned sponsors, companies that are paying
19 the bill.

20 But it puts a great responsibility
21 on the developers to make sure that these are
22 really the markers of adverse care.

1 And that the weight attributed to
2 each of these things really reflects quality
3 and the opportunity to change it, because as
4 soon as it goes out into the marketplace the
5 plans, the companies, the plan sponsor's
6 employers will say, ah, this system has a 450
7 score and this one has a 320.

8 I want all of my employees to go
9 here. And I want you to create financial
10 incentives to make sure that happens. So
11 obviously that's how it's used.

12 DR. DRYE: I just want to
13 follow-up on Laura's point because you made
14 the point and we just want to distinguish
15 between how we define the cohort of patients
16 we're measuring and then how we define the
17 outcome or a set of composite outcomes.

18 And so for hip and knee surgery,
19 for example, those are elective procedures.
20 We clunked them together because they're done
21 by the same surgeons in the same parts of the
22 facility with the same support team.

1 And then we looked at a set of
2 outcomes that we could combine together as,
3 you know, consistent with your strategy to get
4 enough volume to really be able to risk adjust
5 for patient differences and still get some
6 variation that wasn't just due to chance.
7 That could be attributed to quality.

8 So the dilemma you might be able
9 to take, you need to have a sum coherence in
10 the cohort you're measuring. If you're
11 throwing in sort of high-risk OB patients, and
12 you know who they are in advance. And they
13 know who they are.

14 You know you might stratify some
15 OB patients and look at them with a composite
16 outcome and then have sort of younger, healthy
17 patients without any comorbidities in another
18 group and look at a composite outcome for
19 them.

20 And what you do by doing that is
21 you get more out of your risk adjustment. I
22 mean, technically, it's what you want to do.

1 You want to have clean cohorts. That's part
2 of the sort of standards for outcomes,
3 measures and risk adjustments.

4 So it's not an either/or. What
5 we're talking about that consumers like is the
6 composite of sort of events at the end. It
7 doesn't mean that you have to smush all the
8 patients together who are different, you know,
9 in order to do those composites. I'm not sure
10 I'm being clear.

11 CO-CHAIR RILEY: Yes, that was
12 incredibly helpful, because it's sort of, it's
13 not that you would think, oh yes, I'm going to
14 have a C-Section and I want to be in this box,
15 because obviously you're thinking I'm going in
16 to have a baby.

17 But I do think patients are pretty
18 sharp, they know when they're high risk. I
19 mean sometimes they know better than we do.

20 But, I mean, I think that's an
21 easier way for me to think about it in terms
22 of if you're a low risk person you're thinking

1 man why does that hospital have so many people
2 that are getting blood transfusions. What the
3 heck is going on there?

4 And I would be very suspicious if
5 you saw that a lot of those low risk women
6 were getting blood transfusions. So maybe
7 that's another thing to consider. That I can
8 understand.

9 DR. BAILIT: So I think this
10 measure's still got life. Here's what I would
11 suggest, because I think this needs to be risk
12 adjusted. I think there are a couple of ways
13 to do it.

14 There are a sophisticated risk
15 adjustment models. As we've seen with
16 C-Section they've kind of fallen by the
17 wayside. I would do AOIs only in the same
18 population you're doing the nulliparous term
19 singleton vertex rate.

20 And by narrowing the population,
21 and if you stick with the same population the
22 NTSV rate's already doing, the hospitals have

1 already figured out who those people are,
2 every hospital has low-risk women. Don't hold
3 them responsible for the high-risk.

4 But what's happening in that
5 low-risk population. I think that would be an
6 easy way to resurrect this.

7 DR. PRATT: First I want to say
8 thank you all, this has been very interesting,
9 very fun for me. I'm an anesthesiologist so
10 I like getting beat up. Surgeons do this
11 routinely.

12 The questions I was going to ask
13 were, sounds like risk adjustment. And it
14 sounds likes perhaps even you'd be happy with
15 risk adjustment into some rather large
16 categories.

17 So low-risk/high-risk women,
18 perhaps. And maybe even, I'm not sure about
19 cesarean delivery versus vaginal delivery.
20 Yes. But certainly even if we were to say
21 low-risk/high-risk, even that would make you
22 happier with this. That's one.

1 Second, potentially, is
2 stratifying by levels of care and getting some
3 of that more clearly delineated. We've done
4 some of it but present some of those data and
5 make that more clear.

6 I know you guys had some questions
7 about the weighting of each of the, and we
8 could certainly go back and, you know, this
9 was done by consensus and we're all going to,
10 you know, if we asked all of us around the
11 table my guess is we'd get 43 different
12 answers and there are only 40 of us in the
13 room kind of thing.

14 And then finally, there were a
15 couple of them, while it seemed to me like
16 most of these ten you had issues with you
17 thought there was a reasonable measure
18 potentially, but wanted risk adjustment with
19 it.

20 There were several that you had
21 real concerns about and I would say that
22 that's third and fourth degree tear or

1 lacerations. And Five Minute Apgar were the
2 two that it sounds like just basically you had
3 issues with at a basic level of the measure
4 itself.

5 CO-CHAIR RILEY: I think that
6 certainly for Apgar it was the science, I
7 think, was the sort of really measuring the --

8 DR. PRATT: Right. That subject
9 and the third and fourth degree tear, I'm
10 still going to internally push back to do we
11 do this. This measure is about to be about to
12 be about patients rather than processes of
13 care. So we'd have to have that conversation
14 ongoing.

15 MS. PARTRIDGE: I think that the
16 third measure that got an overwhelming number
17 of no's was uterine rupture.

18 (Off microphone comments.)

19 DR. PRATT: Oh yes, right if we
20 did lower at risk versus birth, I mean, there
21 wouldn't be very many. It would likely go
22 away. The vast majority of those either get,

1 if we care about them, they get a transfusion
2 or go to the unit anyway so we're likely to
3 find them in other ways.

4 CO-CHAIR RILEY: And if you've got
5 a uterine rupture in that situation you ought
6 to look at that. It really is rare, rare,
7 rare, rare. It does happen, but it's rare.

8 (Off microphone comments.)

9 DR. SIMPSON: I just wanted to say
10 one thing. I like the way that you mentioned
11 that it was sort of a one subject. And you
12 said hey, this is really all about labor care.
13 And maybe you could repackage this and the
14 concept and say that it's about care during
15 labor. I never heard that until you said it.

16 I read all the stuff about it and
17 I seen this thing and that thing and all over
18 the map. And yet, when you said we're really
19 looking at care during labor. How safe is it
20 during labor.

21 Maybe if you somehow focus that
22 and that was your message, and maybe even

1 change the name of it, you know, you might be
2 in better shape.

3 Well, because if that's what
4 you're trying to measure, is safe care during
5 labor, that makes a lot more sense than all
6 the rest of this.

7 DR. PRATT: I have one more
8 question, I know you guys have lots of work to
9 do. There was one sort of opinion piece on
10 this that suggested that we turn it on its
11 head and do one minus the AOI in essence.
12 Suggesting that what consumers might want is
13 what percentage of moms go in and have a good
14 healthy delivery.

15 And therefore you would say, here
16 we go, 93 percent of these moms came in and
17 had nothing bad happen to them. As opposed to
18 here's the percent that had something bad
19 happen to them, if you will.

20 DR. GREGORY: I can refer you to a
21 paper, where I'm the first author, called the
22 Ideal Birth Outcome. And so that has been

1 done and maybe we could work together.

2 DR. PROFIT: One more thought
3 about perinatal outcomes. It was like the
4 neonatal death is so rare probably, but what
5 you're really interested in is some kind of
6 asphyxic event presumably, right, HIE. So
7 brain cooling really is becoming standard of
8 care.

9 You know, if you could somehow
10 figure whether an infant gets cooled at this
11 point, then --

12 DR. PRATT: Most of those get
13 transferred out. So we probably, we would get
14 the transfer but we wouldn't know the
15 management.

16 CO-CHAIR SAKALA: Nancy had a --

17 DR. LOWE: Yes, thank you. Just
18 another comment. And it came through a few
19 minutes ago and I'm not sure you guys heard
20 down there because of some other things that
21 were going on.

22 But is the issue to think about

1 whether or not a concentration might be the
2 nulliparous women at term, one baby, head
3 down.

4 You know, the same one we've got
5 the suction measure for. And because, you
6 know, we all know very practically if we do a
7 good job with that birth chances are the rest
8 of her obstetrical history will be good.

9 I mean not always, but it's a
10 pretty good predictor that she will labor well
11 in the future or that she will, you know,
12 we're more successful messing with her in
13 causing things that we really don't want to
14 happen than we are with a subsequent mother.

15 So I would suggest that that might
16 be another place to concentrate. And it would
17 partner well with some of the other measures
18 that we voted to endorse.

19 And the second thing is, if you
20 look on the American College of Nurse Midwives
21 website there's a whole webpage about the
22 Optimality Index, which comes from Europe.

1 But it's the idea of optimal
2 outcomes. And what does that mean in birth.
3 And so it is that idea of turning it upside
4 down and saying, what we're trying to do is
5 promote healthy moms, healthy babies,
6 optimally.

7 DR. PRATT: I definitely did hear
8 that. And actually the other thing that we
9 may do, is then go to the other extreme and
10 take the very high-risk. Leave the middle,
11 the middle's muddy. And so leave the middle
12 out.

13 Go to the pointy end of the stick
14 with the high-risk and define it somehow,
15 figure out what that looks like. Go to the
16 high volume stuff with all those low risks and
17 leave that messy stuff in the middle out of
18 it.

19 DR. WINKLER: Okay. You've
20 actually evaluated all the measures put forth
21 to you. However, as we've discussed and you
22 all have raised, we've got several measures

1 that are all about hospital acquired
2 infections in newborns.

3 And I think the question has been
4 raised multiple times is what do we do with so
5 many similar measures. And this is a huge and
6 growing issue in NQF. Our members and,
7 frankly, it's a major issue with the board of
8 directors.

9 We're really hearing and sensitive
10 to all of the frustrations and logistical
11 challenges out there, because we want things
12 being measured.

13 But if the demands are such that
14 we're asking to measure the same thing, or
15 very similar things, in multiple different
16 ways resources are wasted and people don't do
17 it.

18 So there's just all the reason in
19 the world to try and be sure that we're not
20 trying to put out there multiple measures that
21 are measuring the same thing differently. But
22 rather than a library trying to help people

1 pick the one that seems to work the best.

2 So the real challenge over the
3 last couple of years has been trying to help
4 committees look at measures side-by-side. So
5 I'd like you to take a look at the memo you
6 were provided, whether electronically or on
7 paper, on the evaluation of related or
8 competing measures.

9 And what we've done is the staff
10 has identified, in this particular set of
11 measures that you all have looked at, four
12 measures that are very similar.

13 Measure 478, which is the AHRQ
14 measure on nosocomial bloodstream infection.
15 1731, which is the healthcare associated
16 bloodstream infection in newborns from the
17 Joint Commission.

18 And realize that those two were
19 intentionally harmonized. Their differences
20 are more about their data source and very
21 little about their construct. So they're
22 essentially very much the same measure.

1 And then the two measures from the
2 Vermont Oxford, the late sepsis for meningitis
3 in neonates, either for all of them, or the
4 second measure for the very low birth weight.

5 So when it comes to looking at
6 measures side-by-side, you know, how do you
7 pick. I mean what are the principles or what
8 are the values we use to kind of say what
9 should get maybe more support compared to
10 others.

11 And NQF has developed sort of a
12 selection criteria. I'm not sure we've used
13 the term "Best in Class" I'm not sure that's
14 the right term to use. But essentially those
15 principles are around we want to try and avoid
16 endorsement of multiple measures unless
17 there's a very good justification.

18 So that's not to say you cannot
19 recommend, you know, several measures.
20 However, we've got to be crystal clear as to
21 why we're doing that, realizing the impact
22 it's going to have out in the field for people

1 actually doing these measures.

2 NQF has a couple of preferences
3 when it comes to looking at similar measures.
4 There's a preference for broad target
5 populations. Measures that capture the
6 largest number of patients. You just get more
7 bang for your measurement buck out of a
8 measure that does that.

9 Also measures that have the
10 broadest levels of analysis. A measure that
11 can be applied at the facility level, the plan
12 level, the system level, wherever. You know,
13 has broader applicability and greater utility
14 than a measure that's only for a clinician.
15 Only for a hospital. Only for this.

16 And you end up with multiple
17 measures that are very related but they're
18 taking just a tiny slice. We're really
19 looking to not have multiple measures. People
20 are calling it measure clutter.

21 And so we really would like to see
22 measures developed more robustly to be able to

1 capture a large segment of the healthcare
2 system. Harmonization of related measures is
3 absolutely essential.

4 And I think you can understand
5 why. And some of the issues we've got to look
6 at are definitional, because that's the one
7 that kind of drives everybody nuts. You know,
8 defining different data elements differently.

9 And then, of course, the
10 corresponding codes, not the code list being
11 off by one or two. And also because this is
12 an evolutionary process, what we don't have
13 that everybody wants when we do these
14 discussions is, okay, did you run it both ways
15 and how did it compare.

16 Well that hasn't been done,
17 typically. So we're left sort of ignorant of
18 what that really means in terms of what the
19 results are going to look like one way versus
20 another. But recommending that those analysis
21 be done is a real important aspect of what
22 we're going to do.

1 So, you know, again this is a
2 very, very challenging exercise. It's a very,
3 you know, steering committees have tried to
4 walk through this with the four, difficult
5 times. So I get it when you're going to
6 struggle, I'll be there with you.

7 So what I tried to do is these
8 four measures in the memo, I didn't make
9 slides because it just got too much. I put in
10 the side-by-side.

11 Now, just one other thing which
12 always complicates it is there is another
13 measure out in one of NQF's other projects and
14 this is one, I think, that Craig has referred
15 to and that is the measure for CLABSI, a
16 central line associated blood stream infection
17 that is for everybody.

18 But it's stratified and high-risk
19 nurseries or NICUs are one of the strata,
20 okay. So that measure is, you know, I'm sort
21 of close to endorsement if not absolutely. It
22 depends on whether all the emails are in or

1 not.

2 And so that is a measure that we
3 also have to realize is in the portfolio, so
4 that's there. So when you look at these
5 measures, what I did was in the first column
6 is that measure, the CLABSI measure. And I
7 pulled out the elements of it that relate to
8 NICUs.

9 The second column are the
10 harmonized AHRQ and Joint Commission measures.
11 Now, we've heard from them both that they've
12 spent a lot of time harmonizing them. There
13 are some intrinsic differences. But, in
14 general, they're harmonized to the extent
15 possible.

16 And then again, similarly, the two
17 measures from Vermont Oxford, 303 and 304, the
18 constructs are essentially the same. The risk
19 models are slightly different, because one is
20 all of them and the other is the very low
21 birth weight. So I left them kind of in their
22 same columns.

1 And so that's how the side-by-side
2 is laid out for you. I've presented
3 committees with side-by-sides where the table
4 goes on for ten pages and that really makes my
5 eyes spin too.

6 So I tried to break it up to make
7 it just a tad more readable. And if anybody's
8 got additional suggestions on how to present
9 these side-by-sides I'm all ears.

10 So if we look at just the first
11 row we're talking about just the description
12 of what these things measure. The first
13 question is, how alike, how similar and how
14 different are they? What do each of them
15 really measure? How much overlap is there?

16 And then so in the first group,
17 the CLABSI measure, you're talking about
18 central line, or in case umbilical line
19 associated. So if you don't have a line in
20 you're not in the measure.

21 The middle group, the AHRQ, Joint
22 Commission Measure, are blood stream

1 infections. And then the third is the VON
2 measures are both blood stream and meningitis.

3 So there's a little bit of
4 difference. And I'm going to ask all of you,
5 particularly all of our neonatal colleagues,
6 how much overlap. I mean how similar and how
7 different are these measures?

8 DR. BERNS: Can I ask a question?

9 DR. WINKLER: Sure.

10 DR. BERNS: You can stop me right
11 in my tracks if you want. But I just can't
12 seem to get past something here. I can't
13 figure out what happened in the past day in
14 terms of us voting yes for 478 and then no for
15 1731, so if you want me to hold and we can go
16 through this.

17 But my mind is still sort of stuck
18 on that. So if folks here can help me with
19 that I'd appreciate it.

20 DR. WINKLER: Yes. I think that's
21 a discussion you need to have when you look
22 at, particularly, how you evaluated the AHRQ

1 measure and the Joint Commission measure,
2 because given that the construct's the same
3 and they're intended to be totally aligned
4 with some minor differences that are more
5 related to the data source.

6 Actually, I've got, Suzanne just
7 has to enter it, I actually have a table with
8 how you voted on all of them. And we just
9 have to put this morning's one in. And she's
10 going to do that right now.

11 So if you'd like to do that first
12 that's fine, because I do think that in order
13 to explain your decision making I think we do
14 have to revisit the discussion we had this
15 morning versus the discussion on the AHRQ
16 measure, because you did come up quite
17 differently.

18 And the measures are really
19 extremely similar in construct. Now part of
20 this is, I think, we have to ask ourselves is
21 were we using the same value system in our
22 minds when we were evaluating the measures.

1 The conversation this morning was
2 a little different than the one yesterday.
3 And did we bring in new thinking that may
4 change how we want to think about our ratings
5 from yesterday.

6 So optimally it probably would
7 have been nice to be able to discuss them,
8 sort of temporally in the same time frame but
9 that just didn't work out with our measure
10 developers.

11 So, Scott, you know, it's fine
12 with me if you want to try and tackle that
13 issue first.

14 CO-CHAIR RILEY: But one of the
15 remarkable things is, is if you look at, if
16 you scan this. If you look at feasibility,
17 seems like it may have been a pretty big
18 driver at least for -- Do you see where I'm
19 looking like in that second column. In 1731,
20 Scott?

21 For 1731 versus 478. As well as
22 usability so those seem to be --

1 DR. WINKLER: Well I think wasn't
2 the issue with coding this morning? I mean
3 the issue you talked about this morning was
4 the coding and more the scientific
5 acceptability. That seemed to be the big
6 issue this morning.

7 Yet that didn't get picked up in
8 the conversation yesterday. Did we just kind
9 of overlook it? Or is that a true difference
10 between the measures?

11 MS. KIEHN: I went back and went
12 through my ICD-9 codes to see if we could
13 really, truly pick up what was related in the
14 first few days and afterwards. And that's
15 what made me different on this one today. I
16 don't know if anyone else had that same
17 thought process.

18 As I was looking back through my
19 notes to myself I realized that the big
20 differences in the one we discussed today more
21 of the aspect of could I define which ones
22 were present on admission and which weren't

1 for in-born infants.

2 And that's what drove my thoughts
3 and then the ah-ha that that didn't come into
4 my thinking yesterday.

5 DR. WINKLER: If you had to go
6 back to yesterday's conversation, would that
7 impact your assessment there? Who had --

8 MR. GILLIAM: I think we'd have to
9 pull it up, because I thought the issue was
10 731 versus 478 is definitional. It's that you
11 can't exclude by coding those that were
12 present on admission, even though they may not
13 be great. But I think you can with the AHRQ.
14 I may be wrong.

15 DR. WINKLER: Is the developer on
16 the line? Patrick, are you on the line?
17 Patrick, who was here yesterday, was supposed
18 to call in. But the data source for the AHRQ
19 measure is also administrative data.

20 MS. WATT: Hi. You know,
21 honestly, the code tables are exactly the same
22 for the two measures. We have worked very

1 closely with AHRQ, with Patrick, to do that.

2 And actually they have always been very, very
3 close except for one or two differences.

4 And we have resolved those so that
5 there should be no differences at all. And I
6 think, and this is sort of a self-serving
7 comment so forgive me.

8 But the Joint Commission is quite
9 often criticized, and rightly so sometimes, I
10 guess, that we require, generally speaking
11 chart abstraction of medical records.

12 And we don't do measures based on
13 administrative data. I just think it is so
14 ironic that we're getting gigged here because
15 we're using coded data as opposed to requiring
16 chart abstraction.

17 And frankly, I'm having a hard
18 time bringing those two things together too.
19 And if you could help me I'd appreciated that.

20 CO-CHAIR RILEY: Okay. So here my
21 ignorance is going to show up. So if you go
22 back to 478 from yesterday, it says in 2A1.8,

1 denominator exclusions. And this was the
2 thing that I think we were all stuck on.

3 It says, "With principle diagnosis
4 code of sepsis or secondary diagnosis code
5 present on admission." So does that work or
6 it doesn't work to exclude those, because this
7 is what it comes down to is, and this doesn't
8 say anything about transfer.

9 So what we were trying to exclude
10 were babies that were in-born who got septic
11 during the delivery. So does this not exclude
12 that?

13 DR. LOWE: Laura, though the
14 denominator does include all newborns and
15 out-borns in 478. But then with those
16 exclusions.

17 CO-CHAIR RILEY: It says
18 denominator exclusions.

19 DR. LOWE: Right, but it does
20 include the out-borns though. And I thought
21 I just heard you say it was only the in-borns.

22 CO-CHAIR RILEY: These guys, when

1 we were trying to figure out how to make the
2 JCo one work, we kept getting stuck on this
3 sort of transfer thing. And the transfer
4 works, because that made sense.

5 So I'm just wondering if, the way
6 this is written, the denominator exclusions
7 exclude cases with a principal diagnosis code
8 of sepsis. Or a secondary diagnosis code
9 present on admission.

10 DR. ARMSTRONG: I think Jaleel led
11 this discussion and he said that when the baby
12 is admitted to the NICU that present on
13 admission is not yet confirmed. It's
14 suspected but not confirmed, so it's not going
15 to come in with the code. And hence you can't
16 --

17 CO-CHAIR RILEY: So then this
18 should look the same as the other one the. So
19 this has the same fault or same flaw, I
20 shouldn't say fault, flaw as the other one.
21 Is that right?

22 DR. GREGORY: But there is a teeny

1 bit of a distinction and it would be great if
2 we had a coder here to confirm I'm telling you
3 the truth.

4 But a newborn that is the
5 principle diagnosis. A baby born in your
6 hospital, a newborn, is the principle
7 diagnosis.

8 Then they could be admitted from
9 labor and delivery with sepsis, okay. That
10 would be excluded from this. New
11 conversation. A baby transferred with sepsis
12 has present on admission.

13 And it's present on admission is
14 new within the last, actually ever since we
15 started coding for DVT and all these diagnosis
16 that are hospital acquired, they've been
17 extremely vigilant about applying the present
18 on admission diagnosis to get those
19 exclusions.

20 So the present on admission is to
21 capture your transfers and to exclude them.
22 And then the principle diagnosis for newborn

1 baby is newborn baby. And sepsis would be a
2 diagnosis that the neonatologist would have
3 had to given that baby from labor and
4 delivery.

5 FEMALE PARTICIPANT: So if that's
6 the case then that flaw is the same.

7 DR. BAILIT: Well no, because part
8 of the problem is, and tell me if I'm telling
9 tales out of school, is that you can have a
10 newborn baby that looks fine on admission and
11 two days later becomes septic and that's
12 still an early neonatal sepsis.

13 And that would not be in your
14 present on admission or even in the admission
15 codes. But it still counts against the OBs
16 and not the pediatricians.

17 DR. JALEEL: I agree. I think
18 what we want to have a dichotomus is early
19 onset sepsis versus late onset sepsis. That's
20 what we want to know.

21 And what struck me when we did
22 this discussion today, in the morning, was the

1 title of the Joint Commission measure, which
2 said, "Health Related Blood Stream Infection"
3 or something like that, I don't have it up
4 here. Healthcare Associated, which means it
5 should not include early onset infections.

6 And over here the 478, which we
7 did not, probably it was one of our, we all
8 looked at and partly the reason it might be
9 because it says neonatal blood stream
10 infections and not health care associated.

11 MS. PARTRIDGE: It sounds as
12 though we're revisiting our decision on 478.
13 Is that an option? I mean we might say no to
14 both of them?

15 DR. WINKLER: I think that it's
16 going to be very hard for me to explain to the
17 audiences out there for two measures that are
18 as close as these are to have two different
19 decisions. So I would like you to reconcile
20 it. I think that's an important conversation
21 for you to have right now.

22 You know, whichever way you go.

1 But if they're not the same it needs to be
2 based on the differences of the measures. And
3 they are very much alike.

4 DR. PROFIT: I think what struck
5 me today -- I'm sorry. Just one second. So
6 first I think I really want to recognize that
7 both the Joint Commission and AHRQ I think
8 have done a really excellent job at putting
9 this together and risk adjustment and getting
10 expert input and all this.

11 I think it's a really thorough
12 process. What struck me today that didn't
13 really strike me as much as yesterday and
14 probably led me to at least mention it, even
15 though I didn't change my final vote, was that
16 I was concerned that there is really no- sort
17 of, and we talked about this a little bit-
18 like criteria on validation being done.

19 So we know, we have coding that is
20 probably is done as well as you can do it.
21 But have we really compared those against a
22 gold standard? Or at least tested it.

1 So my hesitation is a little bit
2 about making this a measure for public
3 reporting and comparing hospitals when we just
4 have very little information about how much
5 this actually reflects the truth as close as
6 can get it at least.

7 And so that would be my concern
8 with regard to putting this out to the wider
9 community and that we'd want to see some kind
10 of information like that.

11 FEMALE PARTICIPANT: Reva, we
12 missed the public comment period. And I know
13 you have a very rich discussion going, but I
14 had comment that's related to this discussion.
15 I am here representing the Association of
16 Women's Health, Obstetric and Neonatal Nurses,
17 which it represents the interest of over
18 350,000 nurses, as you all know.

19 And I'm very concerned that we
20 have the Joint Commission measure has been
21 well adopted, a lot of hospitals may not have
22 been reporting it yet publicly, but they are

1 working on it.

2 And very concerned not to have
3 that measure go away. And also, especially
4 since they are so similar, it's so similar to
5 the other measure unless there was some
6 extremely good reason not to continue to
7 continue to measure this, I think, it would be
8 important to have this for the country.

9 The issue of the patient's having
10 infection or the locus of the infection I
11 think would probably be more compelling to me
12 if the rates of these infections were higher
13 than they are.

14 So the total rate of these
15 infections for the hospitals, the 164
16 hospitals who have publicly reported, is only
17 0.3 percent. So I think we might be
18 nitpicking here a little on something that may
19 not be having a huge impact.

20 I don't know, but that would be
21 something I think for future discussion, for
22 getting other data on that. And without the

1 measure I don't know if we'll be able to get
2 those data.

3 MS. WATT: You know, this is
4 something that we have talked about with AHRQ,
5 believe it or not, in terms of identifying
6 these patients. Whether or not we should be
7 adopting the present on admission, which is
8 not generally in the medical record. It's a
9 billing designation required by CMS.

10 And that's part of our issue,
11 because our data source is the medical record,
12 it's not the bill. And that is the big
13 difference actually between this, our, the
14 Joint Commission measure and the AHRQ measure.

15 But based on the discussion I hear
16 you, we hear you, in terms of where you're
17 coming from. And I think that what we can do
18 -- excuse me, is to evaluate.

19 And actually we sort of have a
20 golden opportunity to do it right now, because
21 as you know we are in the middle of the
22 reliability test of this measure.

1 We can actually look at patients
2 in the next, I think we have six more
3 hospitals to go to, you know, we can look at
4 those patients who meet the numerator for this
5 measure and look to see what proportion of
6 that group had positive cultures within the
7 first three days of birth, or whatever, to see
8 if that is a big proportion.

9 And if, therefore, skewing the
10 measure rates. You know, we can do that,
11 we're willing to do that. And we can
12 certainly, of course I'm saying this like yes,
13 it's like that.

14 But we could, I suppose, add a
15 data element that would have to be manually
16 chosen, picked out of the medical record that
17 says this is a intrauterine infection.

18 Now that would be pretty hard, I
19 think, to define that data element for a
20 non-clinical data abstractor. But, I mean,
21 we're certainly anxious to make this the best
22 measure that it can be.

1 DR. PROFIT: So I think my general
2 concern is even lesser about those first three
3 days, because I think it would be important to
4 look at what you said during the reliability
5 testing.

6 But I guess my personal feeling,
7 which I don't know would reflect the wider
8 general population, would be that those
9 numbers are probably relatively small overall.

10 But then I think what I would be a
11 little more concerned on is like later on.
12 How reliable is an identification of an
13 infection in the NICU. How correlated is
14 that, like you know, whatever.

15 Maybe CDC or other places have
16 defined what they think is sort of the gold
17 standard where whether something is truly and
18 infection, like -- things like positive blood
19 cultures.

20 You should have a couple of
21 algorithms to define whether or not, but I
22 think as you said, you could do this now if

1 you did reliability testing. You could look
2 at the charts and determine against a gold
3 standard how valid this is.

4 DR. JALEEL: I think that's a good
5 point. But there are two components to the
6 early onset septicemia. So one is these are
7 vulnerable babies who are on extremely
8 critical nursing care. And stopping
9 antibiotics on these babies is something which
10 gives jitters to everybody.

11 So many of these babies are
12 continued on antibiotics just because they are
13 sick. They don't want to, a provider, does
14 not want to stop the antibiotics. So that
15 will also be coded. If it is coded it is
16 coded as neonatal sepsis.

17 So that is one group. And the
18 second group is a group which is positive
19 blood cultures. So that's confirmed early
20 onset sepsis.

21 So if we can get both of these
22 together, and that's a big group when you say

1 the number of babies who just receive
2 antibiotics for presumed sepsis, that's a big
3 number of babies.

4 So if you can identify both of
5 those from the reliability testing that will
6 be good.

7 MS. WATT: You know, maybe this is
8 sort of a moot discussion anyway, because
9 let's face it, by 2015 they say, or even if by
10 2018 or whatever, these measures are all going
11 to be specified for retrieval from the
12 electronic health record.

13 And what we can't do now, with the
14 existing ICD-9 and 10 codes, in terms of
15 identifying positive blood cultures those
16 kinds of things, we will be able to do with
17 the electronic specifications because that
18 will be a LOINC, you know it will be defined
19 in LOINC.

20 And so I don't know, maybe this
21 measure has been in place now for, well a
22 year. And it seems to have good resonance

1 with the country. And we know that it's going
2 to be transitioned into an electronic measure
3 sometime in the foreseeable future.

4 Is it, and I'm asking you this,
5 this is not a rhetorical question. Well this
6 is what we say at the Joint all the time. Is
7 the juice worth the squeeze to try and do this
8 at this point?

9 DR. GEE: I just wanted to add
10 from a state perspective that there is such a
11 dearth of measures that can be arrived at
12 without direct chart abstraction. And we are
13 hungry for those types of measures.

14 Those are the kinds of things
15 we're hoping to put on report cards to drive
16 change faster. And I don't want the perfect
17 to be the enemy of the good here where we're
18 not, I applaud the efforts that you have made
19 to make this ICD-9ish.

20 And so I just wanted to put that
21 out there. We need more measures like that.

22 DR. BERNES: I'm trying to go

1 through these four measures again in my mind,
2 it's getting jumbled here. But the
3 criticisms, the points that you guys are
4 making today, I'm looking at the
5 neonatologists here, you know, I'm a
6 pediatrician.

7 So don't they apply to 303 and 304
8 too? I mean, how's that --

9 (Off microphone discussion.)

10 DR. BERNS: But isn't this based
11 on. I mean help me here, I'm really being
12 dense. So this is based on septicemia or
13 bacteremia as well. But it's --

14 DR. GEE: Rule out sepsis, right?
15 Isn't that what this is all about? Put the
16 baby on antibiotics just in case it's septic.

17 DR. JALEEL: This is coded as
18 neonatal sepsis. But without a positive
19 culture. So if you're 303 and 4 that is with
20 a positive culture. Either from the mother or
21 from the --

22 DR. BERNS: So it's suspected

1 bacteremia is that what?

2 MS. WATT: I think just to talk
3 about it in developerese, I think the issue is
4 really you're looking at can we trust that
5 what the physician writes in the medical
6 record as an infection, and therefore is coded
7 as an infection, because I don't think coders
8 just code stuff willy nilly, is that right.

9 And you know what? That's really
10 not what this measure is intended to look at.
11 I understand what you're saying and that there
12 might be a problem here. But I think that as
13 far as these measures themselves are
14 concerned, they just reflect what the
15 documentation is in the medical record.

16 And they don't intend or try to
17 identify whether or not that documentation is
18 correct. I think you're making, I think
19 you're not looking at the measure as a measure
20 itself.

21 MR. GILLIAM: Just for
22 clarification, and I do want to ask one

1 question. With VON it's clinical people that
2 are doing the data collection if I understand
3 that correctly. It's not --

4 FEMALE PARTICIPANT: No.

5 MR. GILLIAM: Not necessarily? I
6 know in my facility it's --

7 DR. JALEEL: When you say
8 clinical?

9 MR. GILLIAM: I mean RNs that are
10 collecting it.

11 DR. JALEEL: In our institution it
12 a research nurse, but I don't know in all
13 other places what the code personnel.

14 MR. GILLIAM: But then my question
15 is, is 1731 and, as far as that goes, 478 are
16 those blood stream infections that you're
17 asking about. Are they blood stream
18 infections related to the hospitalization?
19 Because VON, in my opinion, is looking at
20 those related to care in the hospital.

21 Something that we can do something
22 about and improve performance. With, as I

1 said, maybe 900 facilities, even though it's
2 a subset of facilities. Whereas this, I'm not
3 sure, it's just looking at the global blood
4 stream infection, if I understand it.

5 DR. MURI: No, that's not entirely
6 true. What we are attempting to do, what AHRQ
7 is attempting to do, is to eliminate those
8 patients who are admitted to our hospital
9 already infected, whether that means they are
10 coming out of the uterus already infected or
11 they're coming from another hospital already
12 infected.

13 And the problem is there is no way
14 to differentiate. There is people who are
15 transferred in and I think both of these
16 measures do a good job of that. And I think
17 what the concern has been this morning is that
18 there is not a good way of identifying
19 patients who are infected intrauterinely. And
20 VON can't do it either.

21 CO-CHAIR RILEY: But actually, I
22 mean, I think --

1 DR. HORBAR: Can I just say that
2 that's not quite accurate. We collect
3 information about early sepsis separately from
4 late infections.

5 DR. JALEEL: I would like to
6 mention two things about the measure title of
7 the Joint Commission measure. One is it
8 healthcare associated. If you are deriving
9 this information from coding then it is a
10 combination of both early onset sepsis and
11 late onset sepsis. And this presumed sepsis.

12 So that is not clearly, purely
13 healthcare associated. And the second thing
14 is blood stream. If you're deriving this from
15 coding it is not a blood stream infection
16 because it is not a documented blood stream
17 infection.

18 The code just says neonatal
19 sepsis. So it's not a blood stream infection
20 either. So the measure title itself is not
21 accurate.

22 MS. WATT: Well we can certainly

1 change the title of the measure.

2 DR. PROFIT: I don't think it's
3 just the title of the measure, I wouldn't be
4 so nit pick, personally I don't feel that nit
5 picky about that.

6 But I feel for national quality
7 benchmarking, public benchmarking, I don't
8 really feel like I'm being extravagant in
9 asking that coded data be validated against
10 like a gold standard.

11 You know, especially if you have
12 the opportunity to do it, like right with the
13 charge that you're reviewing right now.

14 CO-CHAIR RILEY: I have a question
15 about that.

16 DR. PROFIT: Go ahead.

17 CO-CHAIR RILEY: Because initially
18 what got us off to sort of a different tangent
19 on 1731 was the sense that what you would try
20 and change, if you had a high rate at your
21 hospital, what you would try to change would
22 be whatever practice is happening in your NICU

1 that's giving your babies infections.

2 And so what you wanted to do was
3 carve out those babies who actually got
4 infected in the NICU and not include the
5 babies who got infected in the uterus. So
6 that's how we started the conversation down
7 this path.

8 It's not clear to me how the
9 validation is going to get to that. And I
10 actually don't even think you can get there,
11 because if you think about it clinically we
12 can't figure out who's even infected in utero.

13 If the mother's even infected, or
14 the baby's infected and then the baby comes
15 out and it takes, you know, you'll never be
16 able to sort of even clinically answer the
17 question who got infected in the uterus and
18 who was really the baby who happened to be
19 there and on day four the kid's sick.

20 Most of those kids are on
21 antibiotics anyway, right? Just because
22 they're pronged or because they're pre-term

1 labor everybody says they must have been
2 infected.

3 So they're already on antibiotics.
4 So I'm not sure that the issues with the
5 measure --

6 DR. PROFIT: I think we're talking
7 about two different issues. So I think
8 there's two different issues. I think there's
9 one, there's the early onset differentiation
10 for treatment of suspected sepsis during the
11 first maybe 48/72 hours of life.

12 And then there is an issue, to me,
13 about the data validity much later on during
14 the course of the hospitalization, where you
15 have, and maybe you can educated me how the
16 coders usually handle that data. You know, we
17 have a resident or a nurse practitioner,
18 attending, multiple people charting on the
19 same patient.

20 If the baby has rule out NEC, you
21 know, the baby got started on antibiotics.
22 Somebody writes, like, rule out sepsis at the

1 same time because we don't know if the baby
2 has NEC or sepsis, you know, what it is.

3 Low bowel sounds, so it gets
4 started for like a 48-hour watch. Not really
5 sure, you know, Stage 1 NEC is essentially
6 defined as a hodgepodge of it could be almost
7 anything.

8 And then the attending may not
9 feel like that this baby really has an
10 infection but somebody else has coded it as an
11 infection. The cultures are negative, you get
12 five days, six days, seven days of antibiotics
13 and it may permutate to the coder extracting
14 it as an infection when the baby never really
15 had a positive culture or an infection.

16 And so I just feel like there may
17 be issues along extracting, typical for coder
18 data,, I guess, just extracting whatever the
19 truth is from the chart.

20 CO-CHAIR RILEY: So are you saying
21 that if that part of the study was done, if
22 they went back and validated the fact that the

1 coding, wherever they got it from, actually
2 reflected some positive blood cultures that
3 you would be fine with it?

4 DR. PROFIT: Yes. Yes and I think
5 I would need --

6 CO-CHAIR RILEY: How, then, do you
7 answer the first part of the issue. Is that
8 a big deal or no?

9 DR. PROFIT: I mean, that's what
10 I've tried to say before, is that I think the
11 actual incidence of early onset sepsis is
12 probably very low. I think Joe Carpenter is
13 on the phone from VON and he may be able to
14 give us numbers.

15 I'm not sure what -- but the times
16 we truly see positive blood cultures at birth
17 are probably not that terribly high. So I
18 don't know, compared to the overall infection
19 rates, whether that makes much of a
20 difference.

21 So my real concern is mostly about
22 just the validation of the -- and I think

1 Jaleel has more concerns about the early onset
2 infection maybe than I do. And I understand
3 his reasoning.

4 So I feel like -- I think these
5 are two separate questions, slightly, but I
6 think both of these questions could be
7 answered during the chart review.

8 DR. SUTHERLAND: But if you don't
9 mind, I just want to bring up the issue about
10 UHC. And I don't know if anybody here
11 participates in UHC. But the problem is that
12 what we're seeing within institutions is using
13 administrative data, because we may have
14 coders who are very talented and they've been
15 told to capture every single piece of
16 information and code it.

17 For example, accidental punctures
18 and lacerations. I don't know how many of you
19 are following that. But we're finding in our
20 institution is doing a laparoscopy and
21 "rupturing an ovarian cyst" is coded as an
22 accidental puncture/laceration. Or cutting

1 the uterus when you're actually taking it out.
2 So we're doing a big documentation project at
3 the Cleveland Clinic to try to have
4 communication with our coders to understand
5 what's a technical error that really needs to
6 be coded as an accidental puncture or
7 laceration versus something that's a normal
8 course.

9 For example, the normal course in
10 a very pre-term baby is to put them on
11 antibiotics. That would be read out, though,
12 by your coder as probably a sepsis diagnosis.
13 So I think that's really the concern here. I
14 think when you get down to it our coding data
15 doesn't really reflect on the truth.

16 CO-CHAIR RILEY: I mean our you
17 saying we don't whether or not the coding data
18 reflects --

19 DR. SUTHERLAND: Right, until you
20 really get to the level of the chart review.

21 CO-CHAIR RILEY: So then the only
22 thing I would bring up --

1 DR. SUTHERLAND: -- many of them
2 fall out.

3 CO-CHAIR RILEY: -- is that we
4 have the same issue then, 478 and 1731, suffer
5 from the same -- if that's the real concern,
6 both measures suffer from the same issue.

7 So we probably need to go one way
8 or the -- I mean, it makes no sense to have --
9 And the title is not the reason. Do you know
10 what I'm saying? So I think if we --

11 DR. JALEEL: That was -- I just
12 mentioned about the title because that was the
13 prompt for me. But, yes, I agree. If the
14 coding is the same in both these places, then
15 I think both need to be weighed the same or
16 valued the same.

17 CO-CHAIR RILEY: Can I just ask --

18 DR. ROMANO: Hello? Can I speak?

19 CO-CHAIR RILEY: Yes. We're
20 listening.

21 DR. ROMANO: Oh, hi, this is
22 Patrick Romano. I'm not sure -- I just joined

1 about 20 minutes ago. I'm on the phone from
2 California today, again representing AHRQ.
3 Can people hear me?

4 CO-CHAIR RILEY: Yes, we can hear
5 you.

6 DR. ROMANO: Oh, thank you. Well,
7 I just wanted to point out one thing that I
8 think may not be apparent in this discussion,
9 which is that the logic of this indicator, in
10 both of our harmonized specifications,
11 requires a specific organism to be identified.

12 So I don't think the concern about
13 culture negative infections applies. If you
14 look at the architecture of the numerator
15 specification, it requires the identification
16 of staphylococcus, either
17 methicillin-resistant or
18 methicillin-sensitive, a gram negative
19 pathogen, such as E. coli pseudomonas or
20 serratia, or disseminated candidiasis. So
21 there's no way that this could be triggered
22 unless there's a code for a specific pathogen.

1 And, of course, a coder would have
2 no basis for applying such a code without a
3 positive culture result. Obviously, we look
4 forward to the opportunity to validate this in
5 collaboration with the Joint Commission.

6 But I don't think that people
7 would be sort of inventing organisms as they
8 code the record. Logic does require that if
9 the hospital reports the diagnosis of neonatal
10 sepsis they must also report a separate code
11 documenting the pathogen that was identified.
12 Does that make sense?

13 CO-CHAIR RILEY: Yes.

14 DR. PROFIT: That's very helpful,
15 thank you.

16 CO-CHAIR RILEY: That is extremely
17 helpful and answers your question, does it
18 not?

19 DR. JALEEL: Is that true for the
20 Joint Commission measure as well?

21 MS. WATT: We have the same codes.

22 CO-CHAIR RILEY: It's the same.

1 DR. ROMANO: We've harmonized
2 ICD-9s specifications. The only difference,
3 as Celeste has mentioned, is that in the
4 reporting to the Joint Commission the hospital
5 would have the opportunity to override what's
6 in the administrative data if it felt that
7 there was an error. Am I saying that
8 correctly, Celeste?

9 MS. WATT: This is Ann, Patrick.
10 And actually not entirely. But generally
11 speaking we don't give abstractors the
12 capability to say, oh no, that's not the right
13 code, therefore I'm not going to use it.

14 The intent of our measure is that
15 the codes, as they exist, are the codes that
16 are used.

17 DR. JALEEL: I think that was --
18 I think that was not clear when we discussed
19 this with the Joint Commission measure, that
20 the concern I had, which I clearly voiced out,
21 was that there will be a significant number of
22 babies who will be culture negative and will

1 be coded as neonatal sepsis. So it was not
2 clear when we did the Joint Commission
3 measure.

4 CO-CHAIR RILEY: So can we
5 re-vote?

6 MR. GILLIAM: Can I ask one
7 question? Since you said they were the same,
8 in the document that was submitted where is
9 that? I found it clearly in 478, but I can't
10 find it in 1731.

11 MS. WATT: Where is what?

12 MR. GILLIAM: That -- as Patrick
13 was saying that you have --

14 MS. WATT: It's that -- excuse me
15 for interrupting. It's those tables that we
16 reeled off this morning. They are exactly
17 what Patrick just reeled off. So 11-10 to
18 11-11.

19 MS. KIEHN: Yes, 11-11 is the one,
20 exact same thing.

21 MS. WATT: Streptococcus Group D,
22 enterococcus, staphylococcus unspecified,

1 staphylococcus aureus, other staphylococcus,
2 Friedlander's bacillus, klebsiella pneumoniae,
3 E. coli and pseudomonas. They're all there.

4 MR. GILLIAM: But it's in a
5 separate document, it's not in this
6 submission?

7 MS. WATT: Yes, it is in this
8 submission. It is in a table that is referred
9 to in this submission and was included.

10 DR. ROMANO: And I might hope to
11 clarify that what we tried to do with our
12 expert panels, and I think the Joint
13 Commission had this discussion as well, was to
14 specifically exclude some infections, such as
15 Group B strep or listeria, that are
16 overwhelmingly perinatally acquired.

17 Now, of course, thanks to
18 antibiotic treatment, we don't see nearly as
19 much Group B strep as we did when I was in
20 training. But, still, those organisms that
21 are specifically perinatally acquired are
22 excluded from this list.

1 DR. BERNS: Yes, 478 had the list
2 in it. Whereas this was -- you had a link to
3 it to get online to the table.

4 CO-CHAIR RILEY: Can we go back
5 and now vote on 1731? Are people okay? Have
6 we discussed this to death now?

7 We go through the whole thing
8 right?

9 (Off-microphone discussion.)

10 CO-CHAIR RILEY: So this one we
11 all loved. Let's go on to the next ones.
12 Scientific acceptability. Right, because
13 that's where it started to go in the wrong
14 direction. Okay. So now we're re-voting on
15 1731 for Scientific Acceptability. Yes.

16 Everybody press your button again.
17 I don't even know how many people are still
18 here though. We are 21? Okay. Perfect. So
19 it's 21 yes and noes.

20 Can we move on? And now we'll do
21 Usability. 9 high, 12 moderate.

22 And then we'll go on to

1 Feasibility. We're there, 7 high, 14
2 moderate.

3 And now overall suitability for
4 endorsement. Here we go, 21 yes, no noes. So
5 then it looks a little bit closer. Okay.

6 MS. PARTRIDGE: So we've now voted
7 yes on both? I'm sorry, on all four. And
8 we're now trying to narrow that?

9 DR. WINKLER: Well, you've
10 recommended four measures, which you have
11 identified as being similar. And you've
12 already brought up the issue that that can
13 cause issues out in the field. Implementation,
14 you know, demands on hospitals.

15 I think you need to have a further
16 discussion about the implications and the
17 impact of the recommendations you're making on
18 these very similar measures.

19 I think one of the first questions
20 I wanted to know, because I really am not
21 totally clear, is how much overlap? Are these
22 really that similar? Is there something

1 really different about some of them, maybe?

2 Because it really is the 478, 731
3 we've already just determined they're the
4 same. And 304 and 303 are pretty much the
5 same. It's just one's a subset of the other
6 for very low birth weight.

7 So the constructs are pretty much
8 the same. The question is are they measuring
9 the same thing? Or are they measuring
10 something different?

11 DR. SUTHERLAND: And before we get
12 too far, how does CLABSI factor into this?

13 DR. WINKLER: Well, realize that
14 there is a measure also that includes NICUs
15 for CLABSI. So that's just another one that's
16 out there.

17 You can't act on it, but to know
18 that it exists in NQF's endorsed measure
19 portfolio is -- again, is related.

20 DR. DENK: My understanding was,
21 from yesterday's conversation, was that one of
22 the things that was unique about VON is that

1 it's sort of run more like a registry than
2 anything else.

3 And that there's additional
4 criteria for patients in the VON network to
5 sort of be sort of counted towards all kinds
6 of data collection.

7 So if we asked if that's true, and
8 we ask VON to harmonize with these others,
9 then they're going to de-harmonize with a lot
10 of other things within the VON measurement
11 system. And that seems to me to be a
12 reasonable excuse to let it be slightly
13 different.

14 DR. GEE: Another difference is
15 VON has a number of modifications for gram
16 negative bacteria, which we've mentioned are
17 very common. Often it's unclear as to the
18 severity of those infections.

19 And so VON has spent more time
20 thinking about how risky are those and which
21 ones are meaningful versus this measure which
22 doesn't. So that is -- you're measuring two

1 slightly different things.

2 DR. PROFIT: So I would say I
3 think the CLABSI measure is a little bit
4 different. I mean, maybe you could argue that
5 the underlying processes are still rather
6 similar, but CLABSI is used like in large
7 state collaboratives. Now there are specific
8 bundles for it. So I think because it's
9 restricted just to line infections it's a
10 little bit different.

11 I think the other measures -- I
12 would say, a large degree of overlap overall
13 between the other measures, personally.

14 I do. I mean there might be
15 slight differences. But overall I think
16 they're all measuring blood stream infection.
17 A pretty large number of at-risk babies.

18 I don't think I can like easily
19 say, based on the scientific merits of these
20 measures, whether any would be more superior
21 than the other.

22 I think it kind of comes -- to me

1 personally, it would come down to issues such
2 as feasibility and what's already being done.

3 So the easier it is to get or the
4 larger number of places already doing some
5 collection would, to me, trump my ordering in
6 my head for this. But I don't think we need
7 all four measures for all four hospitals.

8 DR. BERNS: Yes, I think, Chuck,
9 you actually had a question for the VON folks,
10 right?

11 DR. DENK: Yes. Okay. So that
12 should have been in the form of a question,
13 yes. Is there definitional issues about how
14 patients are counted in the VON network and
15 excluded from both numerators and denominators
16 as general things that would make it hard to
17 harmonize with these other two measures?

18 DR. HORBAR: Well, I'm not exactly
19 sure how to answer that question when you say
20 are there definitional issues. I mean, are
21 you asking what are the criteria of
22 eligibility for the VON?

1 DR. DENK: Yes, I think that's
2 kind of what I mean.

3 DR. HORBAR: Well, basically it's
4 any infant that's born in the hospital that's
5 within 401 to 1,500 grams or 22 to 29 weeks,
6 or who's admitted to that hospital within 28
7 days of life. That's the very low birth
8 weight measure.

9 We've reported for all the very
10 low birth weight infants, as well as for
11 infants 501 to 1,500 grams, for example.

12 Now the other measure, 303,
13 includes any infant that's admitted to a NICU
14 within 28 days of life at the reporting
15 hospital. Or who dies at the hospital on or
16 before day 28. As well as the very low birth
17 weight population I mentioned.

18 DR. WINKLER: Now, one of the
19 things I think is difficult about this whole
20 issue is the fact that all of these measures
21 are -- they're slightly different data
22 platforms, which means they're likely to be

1 somewhat different users.

2 The AHRQ measures are clearly used
3 often the state level and, I don't know,
4 purchasers use them. And so, because they're
5 purely administrative data based -- Rebecca
6 mentioned that.

7 The Joint Commission's are
8 administrative plus. So there's some,
9 perhaps, some extra chart review in using
10 their specific methodology. But we've already
11 determined that the two of them are aligned as
12 much as possible.

13 The VON measures are just
14 completely different data source. And, you
15 know, it's a registry. We don't have any
16 head-to-head comparisons. I guess, you know,
17 does that mean they have different users?

18 DR. PROFIT: I don't mean to speak
19 for, I would ask VON to respond. You're
20 looking at me but --

21 DR. WINKLER: I'm looking at you
22 because your hospital is -- how many of these

1 does your hospital do?

2 DR. PROFIT: I assume we do all of
3 them currently, probably. I mean, I'm not in
4 the measurement department of my hospital.
5 But I know we do the CLABSI ones that go to
6 the CDC for sure. You know, we code all these
7 things so I'm sure AHRQ could -- they take,
8 I'm sure, probably part of the Joint
9 Commission also.

10 So we're probably doing that
11 effort as well. But I'm just -- like, I guess
12 as a value -- what I'm trying to think about
13 is as a value to the frontline provider who's
14 trying to reduce healthcare infections, is
15 like I don't need four of these.

16 That's like -- maybe CLABSI plus
17 one of the others. You know, I think like the
18 VLBW measures, maybe -- like before I said
19 they all can overlap. But maybe like there's
20 a VLBW measure from VONs a little different
21 because all the other measures cover larger
22 baby also.

1 But otherwise, you know, I think
2 the general gist of this is that the other
3 users, like the VON, are largely going to be
4 the NICUs directly. And maybe in extension to
5 the NICUs the hospitals that ask, you know,
6 the board of the hospitals to ask the NICU
7 director to present that data.

8 And then through VON there's also
9 families in a lot of NICUs have access to that
10 data. But that's dependent on the NICUs' use.

11 DR. SUTHERLAND: I guess my issue
12 is are we really targeting the line use,
13 because when we look at the part 1A-3 on 1731
14 there are five citations. And it says that
15 the risk factors are decreasing birth weight,
16 central venous catheter use, prolonged
17 perineal nutrition and prolonged ventilation.

18 So is the point really to target
19 careful use of central lines and reducing
20 central line infection? I guess that's really
21 my question, even to Joint Commission.

22 DR. PROFIT: Yes, I think we know

1 that the overall infection rates, if you look
2 at just CLABSI rates versus overall infection
3 rates, there are substantial differences. And
4 I think CLABSI is also now being used as part
5 of U.S. News World and Health Report. It is,
6 right?

7 So we haven't talked about CLABSI
8 but when you talk to IUD specialists within
9 each hospital there's some leeway to decide on
10 what are we going to call a CLABSI, what are
11 not going to call the CLABSI. So there's
12 going to be some wiggle room around those
13 things where you may not have perfect data
14 from each hospital either.

15 So it comes back, I think, to the
16 philosophical idea about what are we trying to
17 do. And I don't know if I have a perfect
18 solution to this.

19 I think all of these measures are
20 reasonable measures and they're well -- you
21 know, obviously all of them have a lot of
22 input from a lot of people and they're well

1 developed.

2 I would just, if I was a hospital
3 CEO, I'd want to go ahead and shoot myself
4 over having to report four different measures.

5 DR. WINKLER: So how about Teri or
6 Jenny, you guys --

7 DR. PROFIT: Maybe not shoot
8 myself, but --

9 DR. WINKLER: -- are often on the
10 front line for this stuff.

11 MS. KIEHN: I know that we do
12 provide the CDC measures and we do do VON
13 also. So having to do -- we have chosen not
14 to do the Joint Commission just for that fact
15 that we know we have to do the CDC.

16 VON we use internally for data,
17 because we're already collecting a lot of
18 other measures with it. So that's my take on
19 that side.

20 DR. JALEEL: So I agree with Dr.
21 Profit, the CLABSI is sort of kind of
22 different measure. And it would probably be

1 useful to have that as a separate measure.

2 But these four, there is a
3 significant amount of overlap, if you have a
4 Venn diagram, most of them will be covered by
5 all of these four measures.

6 So then it comes to me as to if I
7 had to pick one, which one would I pick? If
8 I just had one choice. Then I would say 304,
9 which is late sepsis and meningitis in very
10 low birth weight infants. So that's my
11 preference, but again --

12 DR. GEE: You also have to think
13 about real world application. I would argue
14 five years from now we don't need different
15 ones, but now we do. In Louisiana, I just
16 paid to aggregate all of VON data. We have 17
17 NICUs who report. It's an excellent measure.

18 But for the half of our NICUs it's
19 just not approachable, we can't get -- so are
20 we going to make a decision that will exclude
21 other metrics that use ICD-9 or -10 coding?
22 Because VON is slightly better?

1 And then make a decision that we're not going
2 to get data from our hospitals that don't
3 participate in VON, which is associated with
4 a cost.

5 Or do we just say right now, in
6 our real world healthcare measurement world,
7 we have different ways of collecting data.
8 And also, hospitals are not required to report
9 JCo measures now. They ought to be, I think,
10 on a lot of these required, but they're not
11 now.

12 And so if they want to make a
13 decision to report VON they'll do that. If
14 they don't report VON they'll do what's
15 convenient for them. But at least it will
16 give us some data that we can use for quality
17 improvement.

18 DR. JALEEL: I completely agree
19 with you.

20 DR. DRYE: Yes, I do too. And I
21 would just add this comes up in the measures
22 that my group works on as well, because they

1 are registry measures and they're claims based
2 measures.

3 And sometimes actually we're
4 intentionally developing them in parallel
5 because usually only a certain portion of
6 hospitals are going to participate in
7 registries.

8 We don't want to undermine what
9 they're doing because sometimes, and
10 oftentimes, those are the very best measures.
11 But we don't wait or require every hospital to
12 join a private registry.

13 So I think the marginal costs to
14 the hospital -- I think it's difficult to look
15 at four different -- it's really three
16 different measures results because the AHRQ
17 and the JC measure are the same.

18 But I would just say right now I'm
19 not hearing that it's a lot of a marginal
20 burden. If you're in VON then you get this
21 measure result. And then the other ones are
22 claims-based, so it's not a burden on the

1 hospital.

2 So I don't think we're generating
3 an excessive burden by allowing all these
4 measures to stand at this point.

5 MS. BRANDENBURG: I think the
6 Level 3 centers in our area -- we've already
7 gone to VON so that's what they would choose.
8 But the Level 2 centers they're most likely
9 going to choose AHRQ or Joint Commission, so
10 it just depends on the facility.

11 DR. JALEEL: Yes, and that was the
12 reason for approving both yesterday. That was
13 the discussion that we had.

14 CO-CHAIR RILEY: So it sounds like
15 everybody's saying we need at least two,
16 right? So at least 303, 304 and one of 478
17 and 1731, am I hearing that reasonably?

18 MR. GILLIAM: Just to confuse it
19 slightly. As Reva said, CLABSIs are required
20 in many states. And in fact, beginning first
21 of the year most hospitals in the United
22 States will have to collect CLABSI data, and

1 whether their state requires it or not for CMS
2 they're going to have to collect that data.

3 And most pediatric hospitals do
4 VON, or they're in VON and so they're also
5 doing the CLABSI because they're required.
6 And so we're in the same situation, we chose
7 not to do AHRQ or the Joint Commission because
8 we're doing the NHSN system.

9 And it's separate groups, so even
10 though it's a third measure -- and my concern
11 with all of this is you will get slightly
12 different rates or percentages of infections
13 depending on which one.

14 VON, which is very good, they have
15 definitional problems that the CDC does not
16 like, as far as goes with staph epi. AHRQ and
17 the Joint Commission, using coding data, you
18 only have to have one positive culture. In
19 NHSN, depending on the pathogen, you have to
20 have more than one positive.

21 So whatever is recommended, it
22 depends upon whose ox is going to get gored,

1 so to speak, when it's presented at a board,
2 because your numbers may look good with one
3 system and not so good with another.

4 CO-CHAIR RILEY: So at the end of
5 the day, we can't really control what people
6 do with the data, who gets gored. But we can
7 at least make sure that the measures are
8 available so that they at least have a menu
9 and they can choose. Would that be fair?

10 MS. PARTRIDGE: I don't want to
11 lose Rebecca's comment, because I'm sitting
12 here wearing my old purchaser hat. I don't
13 have access to VON data if I'm a state
14 Medicaid administrator. I don't necessarily
15 have access to J Commission data, but I'm more
16 likely to.

17 DR. GEE: And with VON it's
18 totally -- it's blinded. So even though I
19 paid for the data I can't report which
20 hospital it is. That is the mantra of VON.

21 And so for a public reporting --
22 and it's fine. That's good for quality

1 improvement, but for public reporting it's
2 useless. Unless -- I mean, you can see
3 trends, but you're not going to be able to see
4 which hospital can I go to for better care?

5 MS. PARTRIDGE: What I wanted to
6 say is as this goes forward, if we end up
7 recommending all three measures, I think the
8 record should be very clear that there are
9 considerations for hospitals, which are
10 entirely reasonable, you know, I'm not going
11 to do Joint Commission because I'm doing VON.

12 But at the same time what we're
13 hoping is that this is accessible to
14 purchasers, public and private. And therefore
15 we don't want to discourage the adoption of a
16 very similar measure that could be publicly
17 available, such as the Commission's.

18 DR. WINKLER: I guess the question
19 I would put to you at this point is, do you
20 feel strongly enough that you really need to
21 make a selection among the four? Can you live
22 with the push back you're going to get by

1 recommending four?

2 DR. GREGORY: This is Kim. Am I
3 really recommending four or I've endorsed
4 four, I mean, they can do whatever they want.

5 DR. WINKLER: Yes, right. And
6 that's a philosophical issue around NQF, it's
7 been there since the very beginning. Do we
8 create a library or are we trying to be more
9 directive.

10 And that comes and goes. But I
11 can tell you that -- to standardize so that
12 everybody's doing the same thing. It fosters
13 comparability, fosters standardization. So
14 this is a tension that's very real.

15 MS. PARTRIDGE: Right, and that's
16 why I said what I said about making sure the
17 record is clear as to why, if we go forward
18 with four, we are going forward with four or
19 are we going forward with three, because as it
20 goes up to CSAC and as it goes to the Board
21 there will be questions raised as to why all
22 four or all three.

1 DR. WINKLER: It's not that these
2 issues aren't valid. I mean, with
3 justification. Now not everybody is going to
4 agree with your justification.

5 But as long as we can clearly
6 articulate the reasoning, and that's what
7 you've done over the last hour. And so I
8 think we're there. I just need it to be your
9 decision.

10 DR. PROFIT: I have a question.

11 CO-CHAIR RILEY: Is there any way
12 to choose between 303 and 304? No?

13 DR. PROFIT: It depends on what
14 you want to measure.

15 DR. SUTHERLAND: I guess my
16 concern with leaving all four on the table is
17 you're leaving the opportunity to game the
18 system. Okay?

19 And I know that sounds very
20 negative, but I'm in a situation where we're
21 bringing together a lot of hospitals who have
22 different backgrounds as far as how they track

1 things.

2 And they may choose, they say
3 we've always done this, therefore we do this.
4 And we're going to look unfavorable if we
5 switch to that. So this isn't something that
6 I directly am involved in.

7 But when we talk about, even within internal
8 hospital systems, you know, leaving so many
9 options out there I think makes it harder to
10 align care and to really compare.

11 You know, we really should be
12 comparing apples to apples. I guess that
13 would be my concern.

14 DR. BERNS: Yes, I think I get
15 what you're saying, Sharon. I don't know if
16 I totally agree. What I'm struggling with are
17 the criteria that you put out here for us,
18 Reva, which I'm specifically thinking about
19 how to reach as many possible individuals and
20 entities.

21 And if that's what we really want
22 to do then I feel sort of stuck. Because I

1 really want one. I really want one. I want
2 one.

3 But you have however many number
4 of hospitals, 900 or whatever it is, that are
5 already reporting into VON. That's huge. I
6 mean, you know, that is just huge.

7 At the same time that's not public
8 data. Right? So where's the accountability
9 piece, it's up to the hospital. So that's
10 where I get torn, because it's like -- I would
11 like one.

12 I'm thinking, okay, do we make it
13 just one topic and then you could have a
14 couple of choices underneath? That's going to
15 upset people too I'm sure, or confuse people.

16 So that's why, I mean, the fact
17 that we're harmonized with AHRQ and Joint
18 Commission, I think, of that, Laura, as one
19 just like you. And I would love to see a
20 choice between 303 and 304 if we could.
21 I hear that that's not as helpful from a
22 practical standpoint. But we are going to get

1 push back if we approve three.

2 And we do have to decide, Reva, if
3 we can live with it. And, for me, I think I
4 can live with it with the rationale I'd like
5 to as well, but with the rationale of we're
6 reaching as many possible individuals and
7 entities as possible. But it's that public
8 reporting piece that we just don't have
9 through VON, which is -- yes.

10 DR. GEE: My understanding was
11 it's not four measures. We're talking about
12 three that we then harmonized, right, Patrick?
13 And that has already happened. So when you
14 say four, let's at least make it it's only
15 three.

16 DR. WINKLER: Unfortunately, that
17 doesn't fly, because two is two. They need to
18 be harmonized, but for those folks who count
19 the 700 measures in our portfolio and wonder
20 why in the world we have so many, it's two.

21 DR. ROMANO: This is Patrick. I
22 mean, I think -- I don't know if the 700

1 number is some automatically evil number. But
2 the point I think is to have measures that can
3 be applied by a variety of different users and
4 stakeholders.

5 And what we tried to do is set
6 things up so that if a hospital chooses to
7 participate in the Joint Commission perinatal
8 measure set, they have a measure that they can
9 use.

10 If they chose not to do that, if
11 an insurance company or a researcher or some
12 other organization that has access to
13 administrative data, all payer administrative
14 data, wishes to look at the same phenomenon,
15 they have a measure that they can use. And
16 those measures have been harmonized.

17 So I don't -- in a world where we
18 have different data streams that are under the
19 control of different organizations following
20 different paths, I don't quite see a way to
21 get around this problem. At least until we
22 reach the nirvana of the electronic health

1 record where all of this information can be
2 accessed by anyone.

3 DR. GREGORY: The point that keeps
4 coming up about VON not being publicly
5 disclosed, isn't the whole point of them
6 having brought it here is so that it
7 ultimately would be publicly disclosed?

8 DR. WINKLER: A couple of avenues.
9 A measure that's endorsed by NQF, we make
10 those measure specifications available. They
11 could be adopted by non-VON folks to be
12 implemented in their facility and used and
13 adopted in some other way.

14 So we aren't endorsing the VON
15 registry per se. And then each of those
16 potential users determines, you know, how they
17 will use in public reporting.

18 Now, certainly one of the things
19 we encourage, and we're looking for measures
20 to become more publicly available, and that
21 would be one of the things we really want to
22 encourage. But it's not absolutely required.

1 DR. PROFIT: So that was kind of
2 my question. So if Medicaid, you know, so VON
3 is proprietary but if Medicaid said, well, we
4 want from all hospitals data specified just as
5 the VON does, or like the Joint Commission
6 does. What keeps them from theoretically
7 doing that?

8 Is it really our role to say we
9 want to measure for X, Y and Z so that every
10 stakeholder can get at it? Or is it a role
11 for us to say, okay, we think X, Y, this does
12 seem to be the measure that makes the most
13 sense, as it currently is.

14 Now it is up to the policy makers
15 to take it further. You know, I guess I'm not
16 quite clear where the overlap or the frontier
17 there is.

18 MS. PARTRIDGE: Unfortunately,
19 Jochen, it's not quite that simple. If I said
20 I want all the hospitals to use the VON specs
21 and submit the following data to me, I
22 wouldn't have any way to gather it, aggregate

1 it, sort it, analyze it or spit it back out.

2 It's not just the specs that
3 you're buying in essence. What I would like
4 to have is: let there be an agreement between
5 VON and X that you'll send the data to VON
6 then VON will share it with whomever I, the
7 hospital, have agreed can have it.

8 That would be the nice way to do
9 it. But presently that's not the way it
10 usually works.

11 DR. JALEEL: Can I make a
12 suggestion? So I like the 304 measure and VR
13 part of VON as well, and we appreciate the
14 work they are doing. But for simplicity's
15 sake, can we do this that, since all these
16 four measures almost measure the same,
17 harmonize 478 and 173 and pick that? What's
18 the downside of doing that?

19 CO-CHAIR RILEY: So you're saying
20 what Scott and I were sort of motioning to,
21 right?

22 DR. JALEEL: No, just one.

1 CO-CHAIR RILEY: Oh, just one.

2 DR. JALEEL: Harmonize 478 and
3 1731, which they are.

4 CO-CHAIR RILEY: So that's one.

5 DR. JALEEL: So that's one.

6 CO-CHAIR RILEY: And so just pick
7 that?

8 DR. JALEEL: And pick that.

9 CO-CHAIR RILEY: To select one of
10 them.

11 DR. JALEEL: Since the theme is
12 public reporting and VON's data is not
13 available to everybody, it might make sense to
14 harmonize 478 and 1731, which is already done,
15 and pick that.

16 CO-CHAIR RILEY: So pick the Joint
17 Commission's?

18 DR. DENK: I also wanted to --

19 DR. JALEEL: Is there any
20 objection to that? Are there any downsides to
21 that? I don't know.

22 DR. DENK: Yes, I also would vote

1 to decertify or whatever it is the VON,
2 because they don't speak for public
3 disclosure. So why should they be the
4 custodian of the measure?

5 And I don't care whether it's AHRQ
6 or the Joint Commission, but I don't see why
7 we can't get rid of one of them and just have
8 one measure.

9 And if VON wants to go and enter
10 into negotiations with the other two parties
11 who figured out how to do it, right, how to
12 harmonize, and if they want to enter into
13 negotiations and harmonize all of them I think
14 that would be great. But I think the burden
15 should be on VON.

16 MR. CARPENTER: So if I could just
17 say a word. This is Joe Carpenter at VON.

18 The concerns about extracting
19 ICD-9 data at this point are that we want to
20 be able to differentiate infections reliably.
21 So we have identified specific pathogens that
22 constitute infections as well as a clear

1 definition of coag negative staph that we
2 consider reliable data.

3 And the issue that was brought
4 before about the reliability of the ICD-9 data
5 are important to us. We're certainly
6 considering using administrative data in the
7 future and ways that we might do that
8 reliably.

9 But it may be some time. So I
10 would just say that you're right, we are
11 pointing it toward quality improvement.

12 And we don't, as an organization,
13 publicly report data but we do encourage
14 transparency. We leave it up to the
15 hospitals. So I just want to make that point.
16 Thank you.

17 CO-CHAIR RILEY: Thank you.

18 DR. GREGORY: Yes, I want to make
19 that point too. I think really very strongly
20 as a developer, or someone who believes in
21 quality and someone who does performance
22 improvement, that we need both of them.

1 So if we're going to reduce it, we
2 should reduce it to two. And I think the
3 reason, you know, being able to do it from
4 both administrative data and from chart audit,
5 it's the same as sort of the randomized
6 control trial, where there's the effectiveness
7 studies and then the real life efficacy
8 studies.

9 And the data registries will be
10 the effectiveness. And the administrative
11 data are your efficacy. And I think having
12 the opportunity to do it both ways is
13 important.

14 DR. PROFIT: Yes, I don't
15 necessarily object to that myself.

16 CO-CHAIR SAKALA: Could we vote,
17 because we'll be here all day?

18 DR. PROFIT: But could we get a
19 sense of what is it so far? So for AHRQ, we
20 heard yesterday that essentially no extra work
21 is required for the hospital to collect it,
22 right? So I'm trying to still think, there's

1 no hospital representative, maybe Teri's a
2 hospital representative.

3 But so for Joint Commission, could
4 you tell us, like what does the hospital have
5 to pay, essentially, for each data point? Or
6 anything, maybe they have to pay nothing and
7 then I think we're all very happy and we can
8 just endorse it.

9 MS. WATT: The Joint Commission
10 measures can be used by -- go to the website,
11 all of our specifications are publicly
12 available free of charge.

13 If hospitals choose to collect the
14 Perinatal Care Measure set, and remember this
15 is just one measure in a set of five, and they
16 want that to be reported to the Joint
17 Commission then they contract with a
18 performance measurement system vendor who
19 actually, the vendor provides the data
20 collection tool, which we validate, and all of
21 those good things that you read in this stuff.

22 And then the hospital collects the

1 data using that vendor's tool. The vendor, we
2 have a zillion different quality checks that
3 these data are required to be cleaned through,
4 and then the data come from the vendor to the
5 Joint Commission.

6 There is a charge to the hospital
7 from the vendor, not from the Joint
8 Commission. And that's up to the vendor.

9 MS. KIEHN: The charge would be
10 the initial setting up of the query. Pulling
11 all of the information, then after that it's
12 really a push of the button. And it goes once
13 we've validated it. So it's not a manual
14 extraction at all.

15 And I am comfortable with the fact
16 -- because we're going to collect VON no
17 matter what. We'll collect NHSN no matter
18 what. So moving forward with that, I'm fine
19 if we do not recommend this.

20 CO-CHAIR RILEY: Nancy.

21 DR. LOWE: Yes, I was just, to
22 move us along, willing to make a motion. That

1 we keep harmonized 748 and 731, so that's one
2 measure. And that we keep 304, was that the
3 one. Or was it 303?

4 DR. JALEEL: Take off both, I
5 would say.

6 DR. LOWE: Take off both?

7 DR. JALEEL: Essentially.

8 DR. LOWE: 304?

9 CO-CHAIR RILEY: Two is a
10 compromise, I think.

11 DR. LOWE: Two is a compromise.
12 So our harmonized one and 304. So that's a
13 motion.

14 DR. SIMPSON: But we really have
15 to get rid of one of those two, because there
16 will always be two unless we decide which one
17 we're going to chose and which one we're not,
18 right?

19 CO-CHAIR RILEY: You said 478 or
20 1731, we have to pick one. And then 304 or
21 303, got to pick one of those.

22 DR. WINKLER: I mean, it's your

1 decision that you have to pick one. Okay?

2 That's the whole point is, you have to decide.

3 But certainly, we've heard all the
4 arguments why four is not highly desirable.

5 And there are real issues around coming down
6 to one. As long as you can explain and
7 justify you can pick one, two, three or four.

8 CO-CHAIR RILEY: It sounds like we
9 have a justification for why you might want to
10 have something other than VON because it's not
11 publicly reported. So that's a reasonable
12 differentiation there.

13 But then beyond that, we've got to
14 come up and decide -- okay. That's fine. But
15 then beyond that we need to decide whether we
16 feel comfortable having three, which would be
17 478, 1731 and whichever one, 303 or 304. Or
18 whether we really just want two. And you had
19 a comment?

20 DR. MURI: Just to state, maybe,
21 the obvious. If 1731, the determination were
22 made to not endorse that measure. Then if

1 that measure went away from the Joint
2 Commission's stable of measures, that
3 eliminates a whole data pathway.

4 You know, this is an established
5 method for hospitals to collect these data and
6 to get them publicly reported. And if that
7 goes away, I don't know that there is a
8 similar infrastructure developed for
9 collection of the 478 measure.

10 DR. BERNS: Or you'd have to start
11 all over. Meaning you'd have to, I mean you
12 could potentially then consider the AHRQ
13 measure. And I'm not quite sure how we got
14 here, but if we chose one and for some reason
15 we chose the AHRQ one --

16 DR. MURI: Yes. Can I give you a
17 little bit of history here? When we, the
18 Joint Commission, decided to develop or put
19 forward this perinatal care measure set, we
20 chose from the already endorsed, and it was
21 just right after the endorsement, already
22 endorsed perinatal care measures.

1 Our measure is the AHRQ measure.
2 But here's the thing, and I don't want to say
3 anything to denigrate AHRQ or the AHRQ
4 measures or anything else. We maintain this
5 measure. We update it every six months. It's
6 published, those kinds of things. And that
7 would go away because we would no longer be
8 the measure steward. AHRQ would do whatever
9 it is that AHRQ does, and they do it very
10 well, but the Joint Commission would not be
11 maintaining a measure that we are not the
12 steward for. That's the bottom line, to be
13 blunt.

14 DR. BERNS: Before we -- I just
15 want to -- we went a little bit past a very
16 bold suggestion that came from two people,
17 Jaleel and Chuck, basically. It would be a
18 bold step for this committee to recommend one
19 measure.

20 And I feel like we're --

21 DR. JALEEL: I'm still not clear
22 on why we need two. If you can explain it,

1 somebody who is opposed to having just one, if
2 they can explain it to me why we need two?

3 DR. BERNS: You're saying, I
4 think, because from the VON perspective that
5 they're going to collect this, I heard, I
6 think, Dr. Profit say, they're going to do it
7 anyway. You're a member of VON you're going
8 to collect.

9 It's a great measure and it's 900
10 hospitals and --

11 DR. JALEEL: It's a great measure,
12 we have it. And all the hospitals who are the
13 members of VON will get that information
14 anyway. So why do we need a second one for
15 the whole community?

16 MS. BRANDENBURG: One thing I'd
17 like to remember too. When we originally did
18 this, you know, the difference between the
19 AHRQ and the Joint Commission. The AHRQ one
20 we all passed unanimously right out of the
21 gate, really not much question about it.

22 The Joint Commission one we

1 debated for quite a long time. And maybe it's
2 just the way it's written, because we've
3 determined they are very well the same thing.
4 But the AHRQ one seemed to be pretty well cut
5 and dried, easy decision. Where the Joint
6 Commission one, we debated quite awhile about.

7 DR. ROMANO: This is Patrick.
8 Again, I would emphasize that the difference
9 here is really a difference of two data
10 streams and two co-stewards that are working
11 together.

12 You know, AHRQ and the Joint
13 Commission have been working together to
14 harmonize this measure. Under NQF policy, we
15 were asked to submit them as two separate
16 measures, even though they've been harmonized,
17 because there are some differences related to
18 the data flow that feeds the measures.

19 But it would be difficult, I
20 think, to say well, drop one because then, as
21 Ann has pointed out, then you lose a way of
22 accessing that information. Whichever one you

1 drop, you lose the other method of accessing
2 that information.

3 DR. BERNES: So I'm confused. Why
4 do you lose that route? It could still be
5 reported. Let's just say the Joint
6 Commission, I'm just -- unless I am
7 misunderstanding it.

8 Let's say the Joint Commission
9 measure is the one that goes forward, can't
10 the AHRQ measure still be used by whoever
11 wants to use it? What am I missing here? I
12 mean, the measure's out there.

13 DR. WINKLER: There is a benefit
14 to having it endorsed by NQF. And that's
15 essentially the decision you're making. It's
16 because people, users, will very commonly,
17 something we strongly encourage, that they
18 will select the measures they use in their
19 programs among the NQF-endorsed measures,
20 because it's gone through all of this angst.

21 DR. JALEEL: Is it possible to
22 have a joint stewardship?

1 DR. ROMANO: Yes, that forces us
2 to harmonize our measures, which we probably
3 wouldn't do absent this process.

4 DR. PROFIT: So I find it
5 impossible to chose between the two if the
6 economic effect of both of them is the same as
7 having either one of them, I find it
8 impossible to choose. Like if there's no
9 disadvantage.

10 DR. WINKLER: I don't think you
11 have to. As long as you have the reasoning.
12 As long as it's not arbitrary or I like red
13 better than blue. I mean, I need something
14 concrete. And you've given it. If you're
15 comfortable --

16 DR. PROFIT: I mean, for me
17 primarily, you know, if there's no additional
18 work, economic expense for the hospitals.
19 Like who the data flows to is pretty
20 inconsequential to me personally.

21 DR. GREGORY: Can I just clarify
22 that? It might actually be cheaper, right?

1 Because you don't need the vendor to use AHRQ,
2 right? You could calculate and report it and
3 not have to go through a third party?

4 DR. DENK: AHRQ supplies software.
5 This is part of the patient safety indicator
6 thing. And they provide SAS programs, and I
7 don't know what other platforms, for anybody
8 to do this. So yes, and it's free.

9 CO-CHAIR SAKALA: Can we vote and
10 --

11 DR. MURI: What you don't have
12 though is the data cleaning that you have with
13 the Joint Commission processes, that's the
14 difference. You have self-reported data being
15 reported. You don't have anybody looking at
16 the quality of those data.

17 DR. GEE: Reva, can you outline
18 for us, because at this point I think some of
19 us are confused about what we're discussing.
20 Could we just decide what we need to discuss
21 and decide and --

22 DR. WINKLER: Part of your

1 discussion is making that decision.

2 DR. GEE: So my understanding is
3 that we have these two measures, they're very
4 similar. We really can't substantively
5 determine, they've already said they'll
6 harmonize. So I guess who decides, is it AHRQ
7 or, I mean, who decides?

8 DR. WINKLER: You do.

9 DR. GEE: Okay. So we have to
10 decide that. So maybe we should vote on that.
11 Or do we have to decide today?

12 DR. WINKLER: I would appreciate
13 it, because, I mean, is there anything that's
14 going to change if we wait until tomorrow?

15 CO-CHAIR RILEY: So let's do this.
16 So here's the question. How many people want
17 to keep all four, as they are, on that board
18 and give people the choice?

19 MS. LESLIE: Can we just do two at
20 a time? There's like two different issues.
21 Can we do the first two and then the second
22 two?

1 CO-CHAIR RILEY: As long as we can
2 articulate it at the end of this, yes that's
3 great. Okay. Should we have 478 and 1731?
4 Should we have both 478 and 1731, recognizing
5 that they both measure the same thing?

6 Just raise your hand. Oh, we have
7 this thing. Okay, this is fun, I love this
8 thing.

9 DR. DRYE: This is Elizabeth Drye
10 on the phone. Can I vote?

11 CO-CHAIR RILEY: Awesome. You can
12 vote. Hang on one quick second. Jaleel?

13 DR. JALEEL: If we say yes to this
14 one, then we are going to discuss whether to
15 keep 478 or 1731, is that how it is going to
16 be next?

17 CO-CHAIR RILEY: No, the question
18 on the table is: do we want to keep 478 and
19 1731? Do we want both measures on the table?
20 That's the question. Did you get that,
21 Elizabeth?

22 DR. DRYE: Yes.

1 CO-CHAIR RILEY: Okay.

2 DR. PROFIT: So it seemed like the
3 Joint Commission was implying that the AHRQ
4 measure would be lower quality over time? I
5 mean, that's what I heard on the last
6 statement.

7 You know, that it would be
8 self-reported and not cleaned. And I think
9 that's an important piece, I mean, I think
10 that's not an inconsequential statement,
11 personally, to me.

12 DR. DENK: I'm sorry. When you
13 said cleaned, you mean that the hospitals'
14 reports will be somehow reprocessed and then
15 they will be published, something other than
16 what they reported?

17 Or by cleaned you really just mean
18 the kind of analysis you presented here?

19 DR. MURI: What I mean is that
20 there are 32 quality checks that our vendors
21 put every piece of data that is submitted to
22 them through. For missing data. For, does

1 this seem like this is aberrant in terms of
2 the volumes that we've seen before and the
3 patient populations?

4 There's just a number of these
5 things. As well as review for inter-rater
6 reliability of the data and that kind of a
7 thing. That is work that is done by the
8 vendors and then the data are reported to the
9 Joint Commission.

10 If the vendor finds problems with
11 the hospital's data, they will send it back
12 and ask them to clarify and correct.

13 There's nothing that goes from the
14 hospital to the Joint Commission that the
15 hospital doesn't know about. I mean, there's
16 not some magic box there.

17 DR. BERNIS: Just a quick question.
18 Patrick, can you remind me how many report
19 this measure to AHRQ? I'm sure it's in this
20 submission, I just --

21 DR. ROMANO: Well, in general it
22 happens through data sets that are being

1 collected by state health data organizations
2 or through insurance companies or others, in
3 some cases regional collaboratives that
4 collect this data.

5 So overall, there are 44 states
6 that collect data of this type from all
7 non-federal hospitals within their states. So
8 there are six states that would not currently
9 have a reporting structure for the AHRQ
10 indicator.

11 DR. DRYE: What you just mean is
12 that they collect claims data and run the AHRQ
13 stats back on them. The hospitals don't, they
14 just submit their data to the state and this
15 is part of what the states do with it?

16 DR. ROMANO: Right, I mean
17 technically we don't call it claims data
18 because the state health data organizations
19 are not collecting it for the purpose of
20 processing claims.

21 But they are generated by the
22 hospitals with the ICD-9 CM codes and they're

1 submitted to the state health data
2 organizations.

3 Now, different state health data
4 organizations have different mechanisms for
5 cleaning and validating the data.

6 So this is where our data stream
7 is a bit different from the Joint
8 Commission's, because the Joint Commission has
9 certain requirements on its vendors that it
10 requires all of its vendors to process the
11 data in a certain way and to validate it in a
12 certain way.

13 Unfortunately, AHRQ doesn't have
14 the mechanism for doing that. So we are
15 perhaps more dependent on the different data
16 streams that follow in different states. But,
17 that reflects the real world.

18 As somebody said earlier, there's
19 diversity of different data streams out there
20 in the world.

21 If a hospital chooses to follow
22 the Joint Commission data stream and to

1 contract with one of their vendors then that
2 does provide some assurance about the data
3 quality.

4 DR. DRYE: And if a hospital did
5 that, can they generate the results and give
6 it to their state if the state requires it?
7 I mean, what we're trying to avoid is a
8 hospital having to work to produce the results
9 for two measures.

10 I'm just trying to figure out. Is
11 that our job to say, well, geez, the State of
12 California shouldn't be requiring this because
13 the Joint Commission is requiring it? It's
14 the same measure.

15 So I just don't know whether our
16 vote to approve one, you know, if we approve
17 one and not the other we're cutting off
18 opportunities for some kinds of reporting. We
19 just are.

20 But why should we be -- the
21 measures are harmonized, so if you generate it
22 for JC or Joint Commission aren't you

1 generating it for the state at the same time?

2 That was the goal of
3 harmonization, right, you wouldn't have to
4 generate the results twice?

5 DR. ROMANO: Right. But hospitals
6 are not reporting the AHRQ measure in and of
7 itself. It's a product of applying the
8 software to data that the hospitals are
9 already reporting to state health data
10 agencies.

11 So that's why it's a different
12 data flow. There's no additional work
13 associated with a hospital using the AHRQ
14 measure.

15 But there's also, you lose the
16 benefit of the Joint Commission's program for
17 ensuring, or for assessing and evaluating and
18 assuring the quality of the data as it comes
19 into the Joint Commission, because the Joint
20 Commission is directly collecting all of that
21 data through its vendors.

22 DR. DRYE: Right, and if you

1 eliminate the AHRQ measure you would eliminate
2 the burdenless way of reporting this measure
3 and you would just have the Joint Commission
4 approach which requires contracting with a
5 vendor more or less, right?

6 DR. GEE: Could we move to vote on
7 keeping the Joint Commission measure as the
8 single measure? Could we take a vote on that?
9 Are we ready to?

10 CO-CHAIR RILEY: The vote that's
11 on the table is that we're going to keep both
12 478 and 1731, recognizing that there are
13 advantages and disadvantages to that.

14 So everyone can go ahead and vote.
15 So you're voting yes if in fact you believe
16 both should be available.

17 DR. WINKLER: Elizabeth, you want
18 to vote?

19 DR. DRYE: Yes, I vote yes.

20 CO-CHAIR RILEY: How many people
21 should that be? It is what it is, so we keep
22 both. Ten and eight, okay. So then we have

1 to vote 303 and 304, is that right? Yes.

2

3 So the result of that last vote to
4 keep both 478 and 1731 was 10 yes, 8 noes. So
5 now we're moving on to decide, if you vote yes
6 here you're saying you want 303 and 304, so
7 both VON measures in addition to the other
8 two.

9 DR. ROMANO: Can I ask a question?

10 My understanding from previous NQF processes
11 is that stratified versions of a measure are
12 usually considered part of the same measure.

13 So we have a number of AHRQ
14 measures that are stratified, where those are
15 sub-measures within a single measures. Would
16 this fall into that classification or not?

17 DR. WINKLER: Actually, Patrick,
18 this is Reva, you know what, I'm not seeing
19 that in this particular measure. And that's
20 not the way you kind of presented it.

21 DR. WINKLER: Well, I didn't --

22 DR. ROMANO: Oh, you're talking

1 about the VON measure. Well, that was one of
2 the questions we asked, but they are different
3 because the risk models are different.

4 DR. WINKLER: Okay. Well, I will
5 say, we do have AHRQ measures where there are
6 stratum-specific risk models that are still
7 labeled under the same measure number. So
8 it's just a issue for consistency. Not
9 directly relevant to this panel.

10 MR. CARPENTER: If I may just say,
11 Joe Carpenter at VON again. Yes, we
12 originally presented two measures because the
13 populations are quite different.

14 You know, you see an average
15 infection rate in the very low birth weight,
16 it's around 15 percent versus three percent.

17 But if it's more convenient to
18 include these as separate populations within
19 a single measure, I mean, that could certainly
20 be done.

21 (Simultaneous speaking.)

22 MR. CARPENTER: Essentially what

1 that would mean is that you would still have
2 two separate models, they would just be
3 addressed separately within the measure.

4 DR. WINKLER: Right. I mean
5 that's something that we could do. It would
6 reduce the measure clutter and the numbers.
7 And if that's something that appeals to you
8 all we can certainly work with VON to do that.
9 Yes, the CLABSI's there too.

10 CO-CHAIR RILEY: So now we're
11 voting whether we want to keep 303 and 304.

12 DR. WINKLER: Elizabeth, did you
13 want to vote?

14 DR. DRYE: Yes, I'm going to vote
15 yes.

16 CO-CHAIR RILEY: Okay. The vote
17 is 13 no, 5 yes.

18 DR. WINKLER: You haven't really
19 changed anything. It's more paper. So the
20 reality hasn't changed. We could probably put
21 all the information under one number. The
22 question is it's still two measures,

1 operationally. So that's the question.

2 MS. LESLIE: Also you could also
3 vote no on this, meaning, no, you don't want
4 either measure. Or no, you want one measure.

5 CO-CHAIR RILEY: So the majority
6 voted that they do not want both 303 and 304.
7 So now there's a measure of do we want to keep
8 a VON measure.

9 DR. WATSON: Did VON, didn't they
10 offer to put them on --

11 DR. WINKLER: We can. That hasn't
12 changed the measures by putting them under one
13 number. That's something I can do. That's
14 not a really huge deal.

15 The question is: do you want two
16 measures, because they do have separate risk
17 models. You're talking about two measure
18 results.

19 CO-CHAIR RILEY: So I think we
20 need to ask the question. Do we want a VON
21 measure at all, is what I'm hearing. A
22 combined VON measure or a VON measure at all,

1 right? Do we want to combine 303 and 304?

2 That's the question. So if you vote yes then
3 you want the combination, 303 and 304.

4 DR. WINKLER: Elizabeth, are you
5 still here?

6 (No response.)

7 DR. WINKLER: 303 is the measure
8 for all the babies. 304 is the very low birth
9 weight babies.

10 CO-CHAIR RILEY: But they told us
11 that, and you guys told us that the very low
12 birth weight baby is the one that is at higher
13 risk and the prevalence is higher, that's 304.

14 Yes, 303, which is the whole
15 population. It's just a yes/no at this point.

16 DR. WINKLER: So it's 3 yes and 14
17 no. I think you should take the vote on 304,
18 just to be sure that it's clear.

19 CO-CHAIR RILEY: Okay. So now
20 we're voting on 304, which is the smallest
21 babies, highest prevalence. Can everybody
22 press their button one more time, because

1 we're missing one?

2 DR: WINKLER: I think, you know, we
3 could keep repeating and doing this. The next
4 steps, I think, are important. You guys have
5 made decisions and recommendations on all of
6 the measures that we can capture and, in fact,
7 are in the process of capturing.

8 And essentially our next step is
9 to bundle it all up and post it for public
10 comment. You're going to get a chance to see
11 what that feedback is. And at that point you
12 may need to rethink some of the issues based
13 on the feedback you get.

14 It'll be an opportunity to take
15 one more look at it. And the fact that some
16 of these are close, yes, these are tough.
17 These are not easy issues and that's kind of
18 the reality of the world we're working in.

19 So what we'd like to do, as
20 everybody is leaving, just a couple of
21 followup things. We'll have a summary out to
22 you shortly, probably early next week for you

1 to take a look at.

2 One area we didn't get to on the
3 agenda, although it came up a couple of times.
4 If your thoughts about the kinds of measures
5 that aren't currently in the portfolio, the
6 gaps, the kinds of things you'd like to see
7 developed, shoot me an email.

8 Send this in, we'll include them,
9 because it's a nice paragraph to provide
10 guidance to the world about the kinds of
11 things that, you know, we looked at these and
12 it's okay but gee, we wish we had measures of
13 this, this and this as well. So that's an
14 important thing.

15 You can send it to everybody, yes.
16 I mean, it won't go anywhere in NQF if you
17 don't include me. So you can talk among
18 yourselves all you want to, but if you want us
19 to put in the report it's got to come to me.

20 So I think that's really all the
21 business we had. Thank you all for -- we need
22 to do public comment --

1 MR. CARPENTER: Can I just ask
2 what the vote was on 304?

3 DR. WINKLER: It was yes 9. No 8.

4 MR. CARPENTER: Okay. Thank you.

5 CO-CHAIR RILEY: Sure. So is
6 there anybody on the phone, nobody's still in
7 the room, who wanted to say anything? There's
8 somebody there behind the pillar, I'm sorry.

9 MS. JOHNSTON: I'm Tina Johnston,
10 I'm from the American College of Nurse
11 Midwives. And I want to thank you all for all
12 of your hard work.

13 And I just wanted to call to your
14 attention a landmark, unprecedented document
15 that was just released today, that just came
16 across our emails, that involves the American
17 Academy of Family Physicians, AAP Pediatrics,
18 ACNN, ACOG, A1, SMFM and the osteopath
19 OB/GYNs.

20 And that document is entitled,
21 "Leading Healthcare Organizations Issue
22 Recommendations for Quality Patient Care in

1 Labor and Delivery. An unprecedented
2 collaboration creates a joint call to action."

3 And basically, I will forward this
4 to anybody that wants it, but it's going to be
5 on all of our organizational websites.

6 We recommend, for healthcare
7 providers and administrators, that we ensure
8 patient-centered care and safety. That our
9 organizational priorities, guiding decisions
10 for policies, fostering a culture of openness
11 by promoting active communication of good
12 outcomes and opportunities for improvement.

13 Developing forums to facilitate
14 communication and track issues of concern.
15 Providing resources for clinicians.

16 And this is the one that I think
17 is key and most relevant here. Providing
18 resources for clinicians to be trained in the
19 principles of teamwork, safety and shared
20 decision-making.

21 Develop methods to systematically
22 track and evaluate care processes and

1 outcomes. Facilitate cross-departmental
2 sharing of resources and expertise. Ensure
3 that quality obstetric care is a priority that
4 guides individual and team decisions.

5 Identify and communicate safety
6 concerns and work together to mitigate safety
7 risks. To disseminate and use the best
8 available evidence, including individual and
9 hospital-level data to guide practice
10 patterns.

11 And so as we're all discussing
12 this today, this is coming out. I think that
13 one of the major gaps we have here is a way to
14 really track the processes that are going on.

15 And I think that maybe moving
16 forward, if you think about this in terms of
17 systems and in terms of teamwork,
18 communication, and those processes that we
19 know produce good outcomes.

20 Moving forward, I think that there
21 are major quality gaps in that arena that
22 these documents address. So thank you for

1 listening.

2 DR. WINKLER: I look forward to
3 seeing the document. Anybody else? Anybody
4 on the phone? Casey, is there anybody? Are
5 the lines open? Okay.

6 OPERATOR: I can open the lines
7 now.

8 DR. WINKLER: Okay. Please do.

9 OPERATOR: The lines are open.

10 DR. WINKLER: Any comments or
11 questions from anybody on the phone? Another
12 comment?

13 PARTICIPANT: Yes, I might have
14 missed it. Did you talk about research
15 recommendations for the future for measure
16 developers?

17 DR. WINKLER: We just did. There
18 wasn't time for the conversation but during
19 the course of conversation, things have picked
20 up and I've asked everyone to send me their
21 thoughts and ideas.

22 PARTICIPANT: Okay, good. Can you

1 say when you need that by?

2 DR. WINKLER: Within the next
3 week.

4 (Whereupon, the above-entitled
5 matter was concluded at 3:57 p.m.)

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In the matter of: Perinatal and Reproductive Health

Before: NQF

Date: 11-30-11

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