

NATIONAL QUALITY FORUM

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PEDIATRIC MEASURES STEERING COMMITTEE

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WEDNESDAY
DECEMBER 2, 2015

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The Steering Committee met at the National Quality Forum, 9th Floor Conference Room, 1030 15th Street, N.W., Washington, D.C., at 7:30 a.m., John Brookey and Jeffrey Susman, Co-Chairs, presiding.

PRESENT:

JOHN BROOKEY, MD, FAAP, Co-Chair
JEFFREY SUSMAN, MD, Co-Chair
LAUREN AGORATUS, MA, Family Voices NJ*
MARTHA BERGREN, DNS, RN, NCSN, APHN-BC, FNASN,
FASHA, FAAN, College of Nursing,
University of Illinois Chicago
JAMES BOST, MS, PhD, Children's Healthcare of
Atlanta
TARA BRISTOL-ROUSE, MA, Patient and Family
Centered Care Partners
KAREN DORSEY, MD, PhD, Yale University School of
Medicine
JAMES DUNCAN, MD, PhD, Washington University
School of Medicine
MAUREEN EDIGER, Children's Hospital Colorado
DAVID EINZIG, MD, Children's Hospital and
Clinics of Minnesota
DEBORAH FATTORI, MSN, RN, PPCNP-BC, Nemours
Alfred I DuPont Hospital for Children
KERRI FEI, MSN, RN, Blue Cross Blue Shield
Association
JONATHAN FINKELSTEIN, MD, MPH, Boston Children's
Hospital

KAREN HARPSTER, PhD, OTR/L, Cincinnati
Children's Hospital Medical Center

AMY HOUTROW, MD, PhD, MPH, University of
Pittsburgh, Children's Hospital of
Pittsburgh

DAVID KELLER, MD, University of Colorado School
of Medicine

KRAIG KNUDSEN, MD, Ohio Department of Mental
Health and Addiction Services

SUSAN KONEK, MA, RD, CSP, FAND, Academy of
Nutrition and Dietetics

MARLENE MILLER, MD, MSc, Johns Hopkins
Children's Center at JHHS

JILL MORROW-GORTON, MD, University of
Massachusetts Medical School

VIRGINIA MOYER, MD, MPH, American Board of
Pediatrics

RICARDO QUINONEZ, MD, FAAP, Children's Hospital
of San Antonio

JEFF SCHIFF, MD, MBA, Minnesota Department of
Human Services

KEVIN SLAVIN, MD, FAAP, Hackensack University
Hospital/Joseph M. Sanzari Children's
Hospital

CAROL STANLEY, MS, CPHQ, Commonwealth of
Virginia, Department of Medical Assistance
Services

JONATHAN THACKERAY, MA, FAAP, Ohio Department of
Medicaid

KEITH WHITE, MD, Intermountain Healthcare*

NQF STAFF:

HELEN BURSTIN, MD, MPH, Chief Scientific Officer

ELISA MUNTHALI, MPH, Vice President, Quality
Management

MARCIA WILSON, PhD, MBA, Senior Vice President,
Quality Measurement

NADINE ALLEN, MEd, Project Manager

SEVERA CHAVEZ, Project Analyst

KAREN JOHNSON, Senior Director

ROBYN NISHIMI, PhD, Senior Consultant

SUSAN THEBERGE, MPH, Senior Project Manager*

ALSO PRESENT:

MARY BARTON, MD, MPP, NCQA

SEPHEEN BYRON, MHS, NCQA

LARRY KLEINMAN, MD, MPH, CAPQuaM

MOLLY FINNERTY, MD,

KARISHMA KUMAR, MPH, University of California
San Francisco

CASEY LION, MD, MPH, Seattle Children's Research
Institute

MICHELLE MACY, MD, University of Michigan

RITA MANGIONE-SMITH MD, MPH, Seattle Children's
Research Institute

SARAH REEVES, PhD, Q-METRIC - University of
Michigan

EYAL SHEMESH, MD, CAPQuaM

SARAH HUDSON SCHOLLE, MPH, DRPH, NCQA

REBECCA SMITH-BINDMAN, MD, University of
California San Francisco

* present by teleconference

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

2 (7:31 a.m.)

3 CO-CHAIR BROOKEY: Good morning,
4 everybody. We have a quorum, so we're going to
5 go ahead and get started. Do we want our
6 developers to come up?

7 DR. NISHIMI: No, we first have to go
8 to Marcia. We have two new committee members.

9 CO-CHAIR BROOKEY: We have a few
10 things to do first. First of all, we have a
11 couple people here that weren't here yesterday,
12 and we have somebody here today that was on the
13 phone. Marcia, I'm going to turn it over to you
14 for disclosures.

15 DR. WILSON: Thank you so much, John.
16 We just have two committee members who have
17 joined us today, and we need to do our
18 disclosures of interest. Jim is here in the
19 room, and I believe on the phone, do we also have
20 our other committee person? Keith, are you on
21 the phone yet?

22 MEMBER WHITE: I am. Can you hear me?

1 DR. WILSON: Yes, I can. Thank you
2 very much. We're just going to do a brief oral
3 disclosure of interest. This is any work, paid
4 or unpaid, that is relevant to the measures
5 coming before the committee. It doesn't need to
6 be a complete summary of your experience, but any
7 relevant activities that you have to disclose,
8 and we do this in the spirit of transparency.
9 Jim, if I could go to you first, if you would
10 introduce yourself, tell us where you're from,
11 and if you have anything to disclose.

12 MEMBER DUNCAN: Sure. I'm Jim Duncan.
13 I'm a radiologist from Washington University in
14 St. Louis. I have a conflict of interest with
15 the measure submitted by UCSF. I believe it's
16 2820, CT Radiation Dose.

17 DR. WILSON: Thank you, Jim. Keith,
18 if you could introduce yourself and disclose if
19 you have anything.

20 MEMBER WHITE: My name is Keith White.
21 I'm a radiologist, medical imaging director for
22 Intermountain Healthcare, and I have no

1 disclosures.

2 DR. WILSON: Thank you very much,
3 Keith.

4 DR. NISHIMI: Then we have one new
5 member who was on the phone yesterday, who joined
6 us. Marlene, did you just want to -- you don't
7 have anything to disclose, but if you wanted to
8 just --

9 MEMBER MILLER: No, but I am the voice
10 on the phone.

11 CO-CHAIR BROOKEY: All right. We also
12 got out of here so quickly last night we failed
13 to allow for public input, so that's our bad, but
14 we will make up. What I would recommend doing,
15 because we're starting early, is to get through
16 -- to finish up the FECC measures, and then we
17 will have public input. We'll do that, Marcia,
18 if you can help us with that, to remind us. I
19 just want to say that I have been part of many
20 groups/committees over the years.

21 I should say this at the end of the
22 day, and not at the beginning, because I don't

1 know how you're going to be by 3:00, but I think
2 that this is a very well-functioning group. I
3 really appreciate working with all of you. The
4 comments were really very valuable. I think
5 everyone was respectful of each other, didn't
6 talk over each other. I think the group dynamics
7 have been very good, so I just wanted to say it's
8 been a real privilege working with you. We do
9 have a long day ahead of us, so we're going to
10 try to finish by 3:00. We had this existential
11 discussion yesterday about whether self-reported
12 outcome can be a process measure, vice versa. I
13 think we all struggled with this yesterday.

14 Quite honestly, I think that from what I
15 understand over the years, the committees have
16 approached this differently and not consistently.

17 We clearly had an inconsistency with
18 our approach yesterday, by no one's fault, but it
19 just turned out that I think people were thinking
20 one thing would flow down one pathway, and
21 something else would flow in a different pathway.
22 I don't think there's a right or wrong answer

1 here, quite honestly. I think we can argue that
2 patient-reported outcomes can be -- if you're
3 reporting a process -- I think that John said it
4 well. We do this in Kaiser.

5 If you say you've had a mammogram, we
6 will count that as a process measure for that
7 woman. I think it's a very good example of that.
8 But we're not going to debate that any further
9 because I think we do need to move on. The good
10 news is that I think that we could probably be
11 consistent with our approach and not completely
12 rehash every conversation from yesterday. What
13 the staff have proposed, and what I want to see
14 if you would agree to, is to take through the
15 FECC measures that did not completely pass --
16 those are the gray zone or the fails -- and just
17 revisit those and vote them up or down, going
18 along the top pathway. That would be FECC
19 Measures 7, 9, 14, and 17.

20 I will tell you that one that we had
21 a pretty clear pass on -- pretty close to pass,
22 58 percent, so it was very close to passing. The

1 other three were much less favorable. Many of
2 them were sort of felt to be insufficient. What
3 I would recommend that we do is to go through
4 those four. We'll go through how we voted on
5 them. We'll ask for any further comment, and we
6 will vote them up or down based on this being a
7 survey of patient-reported outcome. Any thoughts
8 about that process to get us moving forward?
9 Marlene?

10 MEMBER MILLER: I'm really kind of
11 confused why we would redo this, and then would
12 we judge all the rest of the FECC measures? It'd
13 be inconsistent to do half of them one way, half
14 another. I'm really confused why we did this.

15 CO-CHAIR BROOKEY: I think the
16 rationale is that if we pass them to begin with,
17 the likelihood is -- if they passed on the
18 vertical pathway, the chances are they would pass
19 on the horizontal pathway. That's just our
20 thinking about efficiency here. Any other
21 comments?

22 CO-CHAIR SUSMAN: I think the bottom

1 line is it seems more stringent when we've done
2 it down that vertical pathway and that the simple
3 yes/no, up/down vote was much less stringent and,
4 therefore, if things passed already, indeed they
5 should easily pass again. The only ones that
6 we'd reconsider are those that were on the
7 borderline.

8 CO-CHAIR BROOKEY: Jon?

9 MEMBER FINKELSTEIN: I think as a way
10 to move forward, that's fine with me, but I think
11 somewhere in the minutes, I think there's a
12 difference between outcome measures and process
13 measures. We can't call everything that's
14 patient reported a patient-reported outcome
15 measure. My example is if the question is did
16 you get a mammogram in the last 12 months, and
17 you ask the patient, that doesn't make it an
18 outcome measure. I don't disagree, but I think
19 we need to keep that straight in our thinking at
20 some point. Maybe that's feedback to NQF.

21 CO-CHAIR BROOKEY: I don't think we're
22 going to resolve this variation that we've had in

1 approaching these measures. We can't really
2 solve that today. I think the NQF staff need to
3 kind of go back and noodle on that a bit. But I
4 do want us to move forward so we can get to the
5 other measures this morning. David?

6 MEMBER KELLER: I don't want to hold
7 up that process, but just as an observation, what
8 I think the difference is is the more complex
9 pathway that involves reviewing evidence seems
10 fundamentally different from a pathway that, in
11 essence, is just asking us to propose a logic
12 model, that we could draw a Driver diagram.

13 That's a different standard of
14 evidence. We need to think through whether
15 there's a way of making that more -- I think
16 there's a way of making that more rigorous that
17 involves evidence to support the Driver diagram.

18 CO-CHAIR BROOKEY: I think that's why
19 we struggled so much with the adolescent measures
20 yesterday is we felt like we had a different
21 standard for that than we did for the FECC
22 measures. Amy?

1 MEMBER HOUTROW: I guess I'd just like
2 to echo that concern. It's not rigorous to say
3 is there a rationale? It's not also how they
4 were presented to us as measures. They were not
5 presented to us as patient-reported outcomes, so
6 I have a lot of discomfort with taking -- I
7 understand why we needed to do it with ADAPT
8 because that's how it was presented to us.

9 But taking out the ability to review
10 the evidence for why we would do something by
11 taking a pathway that wasn't the intended pathway
12 by the developers makes me very concerned that
13 we're doing something that undermines the basic
14 process of what we were asked to do, which was to
15 review the evidence for these things.

16 This up and down, is there a rationale
17 for the relationship by the patient saying I had
18 a mammogram in the process of them having a
19 mammogram, it's just circular. You can't skate
20 away from answering yes to that second question.
21 If we're going to say that a patient-reported
22 outcome is do you have a case manager, and they

1 say yes, that is circularly related to whether or
2 not they have a case manager.

3 The rationale is a one to one, as
4 Virginia was saying yesterday. So now we have to
5 ignore all of the evidence, and I don't think
6 that is appropriate for what we were tasked to
7 do. I was uncomfortable yesterday with that
8 process, and I'm even more uncomfortable with it
9 now.

10 CO-CHAIR BROOKEY: Marlene?

11 MEMBER MILLER: I was just going to
12 say the same thing. The developers didn't submit
13 them as outcomes measures, and I feel really
14 uncomfortable changing the rules midstream. I
15 think ADAPT should not have been reviewed as
16 outcomes because I think we have to rely on
17 evidence for all of these measures, but to
18 rejudge and change the way they were developed
19 just doesn't seem right to me.

20 CO-CHAIR BROOKEY: Go ahead, Karen.

21 MEMBER DORSEY: Just to reflect on
22 Helen's comments yesterday, I think that there's

1 a purposeful difference in the standard for an
2 outcome measure versus a process measure. It's
3 even more of a wrinkle to think about this as a
4 patient experience measure, which I think is
5 another bar.

6 I think when we talk about outcome
7 measures, just to use that as an example, we do
8 talk about the rationale or logic model. That's
9 the bar for outcome measures. But we also talk
10 about the importance, like why are we measuring
11 this outcome? I think that these have to be held
12 to that standard, even with respect to patient
13 experience.

14 Is there value in measuring this
15 aspect of patient experience? I felt yesterday
16 that the adolescent measure met that bar because
17 this is a structural fact of the healthcare
18 system. Everybody's going to go through this.
19 It's valuable to understand patients' experience
20 of this, and we think that the healthcare
21 processes can affect their experience.

22 All of those things, to me, made

1 sense, in terms of importance, but I think we
2 would have to apply that same standard to the
3 FECC group if we were going to say this is an
4 outcome measure. It's not just the logic model,
5 but it also is this valuable outcome or
6 experience for us to be measuring and reporting
7 on.

8 CO-CHAIR BROOKEY: Jeff.

9 CO-CHAIR SUSMAN: Just briefly, I
10 think we're doing more than just that one to one.
11 I think we're trying to assess whether the
12 patient-reported outcome is something that is
13 valued by the person who we're looking at and is
14 linked to -- hold on just a second -- and is
15 linked to a health outcome which is amenable to
16 -- as they say, influenced by structure, process,
17 blah, blah, blah.

18 Really, there is a tie between one,
19 this idea that it's of interest. There's going
20 to be some patient-reported outcomes that are of
21 no interest, that really they say, "I don't
22 care." There can also be patient-reported

1 outcomes that aren't really linked to any health
2 consequence, so there is that tie to evidence.

3 It has to be amenable to change
4 through any of those pathways. I think when you
5 start to deconstruct it there is a tie back to
6 the evidence. It's not as clear. It's not as
7 black and white. I understand all of our
8 confusing with this. I know Helen, when I talked
9 with her afterwards, understands this is a murky
10 area which needs cleaned up. I think we either
11 need to get on with it or decide we're not going
12 to rerate and move forward, just given the
13 pressure of time here today.

14 CO-CHAIR BROOKEY: I think that the
15 committee can decide what they want to do. I
16 don't think, at this point, it will make a
17 tremendous amount of difference if we leave it
18 the way we left it yesterday.

19 I think the outcome may not be very
20 different if we revote. I am comfortable with
21 the committee's decision. Jeff is comfortable
22 with the committee's decision with either

1 revoting or just letting it rest where we left
2 it.

3 Because we still have to go through
4 all the rest of the issues, which are gap and
5 reliability and so forth. Can we just sort of
6 get maybe a straw vote? How many people would be
7 comfortable leaving it where we left it yesterday
8 and moving forward with the discussion about gap
9 and liability and everything else?

10 So leaving it alone, how many would be
11 comfortable?

12 (No audible response.)

13 CO-CHAIR BROOKEY: Does anybody want to
14 revote?

15 (No audible response.)

16 CO-CHAIR BROOKEY: I think that we
17 should just move forward and let it rest. We're
18 not going to go back and revisit adolescents,
19 even though I think some of us struggled with the
20 decision to take it through the horizontal
21 pathway. What I'd recommend we do is move
22 forward with gap. I believe that for the gap,

1 and correct me if I'm wrong, I believe we can
2 just vote on these in block.

3 DR. NISHIMI: You can decide to vote
4 on these in block.

5 CO-CHAIR BROOKEY: If anybody wants to
6 pull one out in particular, we can do it that
7 way, but those who have looked at this closely --
8 I'm going to ask those who were the experts on
9 this measure whether they would agree with that.
10 Which of you are the ones that were reviewing it?

11 You agree to take them in blocks? Any
12 disagreement to reviewing these in blocks? Who
13 would like to talk about the performance gaps
14 here? I can get my notes out. Who's on point
15 for this measure?

16 MEMBER MILLER: I'll start.

17 CO-CHAIR BROOKEY: Marlene, go ahead.

18 MEMBER MILLER: I struggled with this
19 one, in that there is a clear sense that there is
20 a gap here, but there was very little data --
21 none, really, that provided a lot of -- because
22 we don't have a lot of information on this, so

1 understanding the amount of the gap is really
2 unknown. I just didn't see any substantial data
3 attesting that there is a gap in this for kids
4 with special healthcare needs or however you want
5 to define medical complexity versus not. I think
6 we think it's there, but there's no proof.

7 MEMBER FEI: Overall, this is --
8 probably the reason we don't have data, it's a
9 low N overall. But while it's low occurrence,
10 it's high impact, high resolution, high risk
11 population. For me, that brings to the light
12 that it's something we should be.

13 CO-CHAIR BROOKEY: Any other comments?
14 Oh, sorry, Karen.

15 MEMBER HOUTROW: I just had a quick
16 question for the reviewer. There's a comment
17 that children with medical complexity comprise 13
18 percent of the pediatric population. I was
19 noting that number's markedly higher than
20 previous estimates of complexity and how that's
21 being used. It's on Page 9, I think.

22 DR. LION: The reference there was Jay

1 Berry's JAMA pediatrics paper in 2013 and Tamara
2 Simon's paper in Pediatrics.

3 MEMBER SLAVIN: I just wanted to
4 correct Nathan on his point, that the lack of
5 measurement in an area that we all come to
6 consensus on is important to measure, I think, is
7 enough of an assessment of gap, without breaking
8 out exactly the gap for the individual component
9 parts. I'm comfortable with the way the
10 developers rated it here.

11 CO-CHAIR BROOKEY: Jon.

12 MEMBER FINKELSTEIN: I think it's
13 reasonable to use the field test results as
14 evidence of gap. We have field test results on
15 all of those things, and some are higher and some
16 are lower, but they all, in my view, show some
17 gap.

18 CO-CHAIR SUSMAN: It seems to me this
19 is an area where there's sufficient evidence,
20 given where the scientific evidence has gone. We
21 have a field test. There may be some systematic
22 biases in that. I suspect not.

1 CO-CHAIR BROOKEY: There is some data
2 to support our intuition, I think, not a lot. Do
3 we have enough information to vote on gap?
4 Hearing no objections, we'll vote.

5 MS. CHAVEZ: We have 26, 24 in the
6 room, two over the phone.

7 MS. ALLEN: Keith and Lauren, if you
8 could please submit your vote via chat. Severa
9 will be reading the instructions.

10 MS. CHAVEZ: We are now voting on gap
11 for Measure 2770, family experiences with
12 coordination of care measure set. The answer
13 choices are 1 high, 2 moderate, 3 low, 4
14 insufficient. Voting's now open.

15 CO-CHAIR BROOKEY: I hope somebody is
16 videotaping us voting because it's really pretty
17 funny. From up here, it's hysterical. You
18 wonder if you squeezed out that last vote.

19 DR. NISHIMI: We need to do a show of
20 hands on this one. It's not just a plug it into
21 the wall issue, apparently, so that didn't work.
22 1 high, moderate, 25 moderate, low, and

1 insufficient. We need one more vote, and that
2 came in. Oh, Jeff is conflicted.

3 PARTICIPANT: He's always conflicted.

4 CO-CHAIR BROOKEY: We're going to move
5 on to reliability. Robyn, I think you are
6 recommending that we take these measure by
7 measure, or are there any of them that can be
8 lumped together, asking the reviewers if any can
9 be combined, or should we just take them one at a
10 time? Any recommendations?

11 DR. NISHIMI: During the workgroup's
12 review, you ended up wanting to break out a
13 little over half of them. That's why we went to,
14 at that point, measure by measure, but it really
15 would be up to the workgroup whether you want to
16 consolidate or not -- not the workgroup, the
17 committee; I'm sorry.

18 DR. BURSTIN: Robyn, in the past,
19 we've allowed committees to just agree to review
20 them all and then pull out by exception the ones
21 you want to discuss.

22 CO-CHAIR BROOKEY: Right, as we did

1 last time, we can do them en bloc. Remember,
2 this is a must pass. If we want to pull out any
3 of them for individual consideration, we can.
4 I'm going to recommend we do them en bloc. I'm
5 going to ask if anybody wants to pull any of them
6 out, if anybody has a preference to pull it out,
7 we'll approach them individually.

8 CO-CHAIR SUSMAN: I have sort of a
9 opposite thought here. Because I think the first
10 one around has care coordinator is most broad and
11 really the most evidence around it, probably the
12 most reliability, though I haven't read
13 extensively the detailed notes. I'm wondering if
14 that one should be voted first, and maybe the
15 rest of them en bloc, which are much more
16 particular.

17 CO-CHAIR BROOKEY: I'm okay with that.

18 (Simultaneous speaking.)

19 CO-CHAIR BROOKEY: Jim.

20 CO-CHAIR SUSMAN: I'm not wed to that.

21 MEMBER BOST: FECC-3 and 15 have no
22 reliability information presented, but as we

1 worked yesterday, if they provide valid data at
2 the element level, which they do provide, we
3 could use that as a substitute. If I was going
4 to block, I would use those two because we have
5 to evaluate them a little bit differently than
6 the rest, where they do have either
7 Spearman-Brown or internal consistency
8 reliability estimates.

9 CO-CHAIR BROOKEY: Okay, any other
10 requests? We'll just honor the individual
11 committee member requests to pull them out
12 individually. Let's go ahead and vote on one,
13 and then we'll vote on the others en bloc, except
14 for 3 and 15, is that correct? 1 is Marlene and
15 Jim. Any comments about reliability for No. 1?

16 MEMBER MILLER: I have a question for
17 the developers. When I look at this data, it
18 looks like they had about 1,200 surveys, and then
19 900 or so were picked for reliability. That
20 seems odd because if there's a giant sample, I
21 can respect taking 20 or 30 percent sample, but
22 if it takes 70 percent and not do all, but then

1 the back tables talk about the reliability, on
2 Pages 84 and 85. Then I see Ns of 30, 50 and
3 100. I'm very confused. Overall, it struck me
4 as a very small sample size, and why wasn't
5 everything included in reliability testing?

6 DR. LION: Great question. Because of
7 some limitations related to the IRB stipulations
8 with Washington State Medicaid, specifically --
9 we had two states, Washington and Minnesota.
10 With our Washington State data, we actually
11 didn't have practice-level information for some
12 of the participants.

13 While state is the level of intended
14 aggregation, for the purpose of reliability
15 testing, we looked at practice grouping, in order
16 to have -- because our field test only had two
17 states in it. Unfortunately, some of the sample
18 from Washington State was not actually
19 identifiable at the practice grouping level.

20 We did compare the characteristics of
21 the people who were included in the interclass
22 correlation coefficient calculations to the

1 overall participant -- the overall respondent
2 group in Table T-1, which I don't think my page
3 numbers match up with anyone else's, and overall,
4 the practice groupings look -- the demographic
5 characteristics of the groups looked very
6 similar.

7 In addition, we compared -- we
8 statistically compared the scores on the overall
9 respondent sample to the respondent sample that
10 we were able to use for the reliability testing.
11 There was actually only one score that different
12 significantly, and that was not actually one of
13 the measures that we submitted for endorsement
14 here today.

15 So we did -- although it is clearly a
16 limitation, we felt comfortable moving forward
17 with the analysis using the group for which we
18 have practice information. Regarding your second
19 question related to the sample sizes that we list
20 in the interclass correlation coefficient table,
21 those are actually the practice group numbers,
22 and then the number of patients.

1 So the first column, with the 92, 48,
2 59, is the number of practice groups, and then
3 the patients included in those. There were a
4 couple of practices for which we only had less
5 than five patients, so those, we weren't able to
6 use in the interclass correlation coefficients
7 either. Does that explain adequately for you the
8 difference in the sample sizes?

9 MEMBER MILLER: Sort of, although now
10 I'm more confused why, in Table T-3, the number
11 of patients varies dramatically for reliability
12 testing between each and every single question.

13 MEMBER BOST: I think I can answer
14 that. The Spearman-Brown formula basically takes
15 the interclass correlation coefficient and asks
16 you if this was your sample size, what would your
17 alpha be? The N equals 30, 50, 100 and 300 were
18 Ns that they chose to allow you to see what the
19 Spearman-Brown formula would then look like.

20 MEMBER MILLER: No, I'm thinking the
21 N is in two columns or so prior to that.

22 MEMBER BOST: The 626 patients?

1 MEMBER MILLER: Yes, but when you go
2 down -- this is, again, a global question against
3 all of them. You're right. For FECC-1, it's
4 626. Why for all the rest of them were such
5 variations in sample sizes of the patients when
6 it's one survey?

7 DR. LION: The eligibility for
8 individual items varied to some degree based on
9 the responses to previous questions. For FECC-3,
10 5, 7 and 8, for instance, you had to endorse that
11 you had a care coordinator in order to be
12 eligible for those questions regarding specific
13 functions of what your care coordinator did for
14 you. In addition, because we chose not to
15 include people for whom we had incomplete
16 information -- and we address this later in the
17 missingness section -- because we didn't feel
18 comfortable imputing responses, we only scored
19 measures for which we had complete information.

20 So for some of the measures,
21 especially ones that actually had multi-item
22 components, we have lower sample sizes because if

1 somebody didn't answer any of those, we didn't
2 want to unfairly -- for the measures for which we
3 rolled up the scores, we didn't want, in some
4 cases, for each item to have a weight of 33
5 percent, but then if someone only answered two of
6 them, for those to be weighted higher for those
7 people. So we only used people for whom we had
8 complete data for each individual item.

9 CO-CHAIR BROOKEY: Any other comments
10 about reliability for Measure 1?

11 MEMBER BOST: Basically, the values
12 are -- do demonstrate good reliability as
13 presented for FECC-1.

14 (Simultaneous speaking.)

15 CO-CHAIR BROOKEY: All right, thank
16 you very much. Are we ready to vote, just for
17 FECC-1?

18 MS. CHAVEZ: Okay, we're now getting
19 ready to vote on reliability for FECC-1. We have
20 27 votes, but one recusal, so we're expecting 26
21 votes, two over the phone. The options are 1
22 high, 2 moderate, 3 low, 4 insufficient.

1 Voting's open, 8, 24, two more, 24.

2 PARTICIPANT: Everybody vote.

3 MS. CHAVEZ: 25.

4 MEMBER WHITE: This is Keith White.

5 I'm going to defer the vote on this set because I
6 haven't been involved in the conversation. I'm
7 not familiar with the measures.

8 MS. CHAVEZ: Thank you, Dr. White.

9 That would give us 25 votes, so 5 voted high, 20
10 moderate, 0 for low, 0 insufficient. FECC-1
11 passes reliability.

12 CO-CHAIR BROOKEY: Okay, so the next
13 set of measures will be the rest, except for 3
14 and 15. Marlene, do you want to start off with
15 any comments about those?

16 DR. NISHIMI: I'm sorry. I just want
17 to clarify for the committee because 14 and 17
18 have already failed, they are not included in
19 your vote at all.

20 CO-CHAIR BROOKEY: Thank you, Robyn.
21 Would you please out the ones we're voting on,
22 then?

1 DR. NISHIMI: We're not voting on 3,
2 5, 14, and 17. You are voting on 7, which is --

3 PARTICIPANT: Care coordinator
4 assisted with specialist service referrals.

5 DR. NISHIMI: Right, 8, which is care
6 coordinator was knowledgeable, supportive, and
7 advocated for the child's needs, 9, which is
8 appropriate written visit summary content, 15,
9 which is related to the medical interpreter, and
10 16, which is shared care plan. Those are the
11 ones.

12 (Simultaneous speaking.)

13 MEMBER BOST: Did you yes, we're doing
14 5, or no? I couldn't --

15 DR. NISHIMI: No, we're not doing 3
16 and 5 because -- I'm sorry, 3 and 15. So you're
17 not voting yet on access to medical interpreter.

18 CO-CHAIR BROOKEY: So we're voting on
19 7, 8, 9, 15, and 16.

20 MEMBER BOST: And 5.

21 DR. NISHIMI: And 5, not 15.

22 CO-CHAIR BROOKEY: Not 15? We're

1 voting on 5, 7, 8, 9 and 16? Okay, 5, 7, 8, 9
2 and 16.

3 CO-CHAIR BROOKEY: Any comments about
4 these measures, in terms of reliability, from
5 those who reviewed them closely? Jim?

6 MEMBER BOST: So the reliability
7 estimates provided for 5, 8, and 9, because they
8 are multiple items, they did the within item set
9 alphas, which were actually very high, ranging
10 between .73 and .86. The rest of them, again,
11 were the same Spearman-Brown formula associated
12 with the interclass correlation coefficient.
13 Each one of those were fairly good.

14 Again, potentially the least good, if
15 you will, was FECC-9, but was still at .7, when
16 you had an N of 100. It was a little confusing
17 why some of these items did not have the ICC,
18 like Item 5, which seemed to have enough of a
19 sample size, but they did provide the within item
20 alpha, which was good. All of the data provided
21 on reliability, where it was provided for these
22 items, was good.

1 CO-CHAIR BROOKEY: Any other comments
2 about reliability of these measures? Okay,
3 should we vote for 5, 7, 8, 9, and 16?

4 MS. CHAVEZ: Okay, reliability for
5 FECC-5, 7, 8, 9, 16, 1 high, 2 moderate, 3 low, 4
6 insufficient. Voting's open -- 23, we're
7 expecting 25 votes, 24, 25 -- 2 voted high, 23
8 voted moderate, 0 for low, 0 insufficient. So
9 FECC-5, 7, 8, 9p, 16 pass reliability.

10 CO-CHAIR BROOKEY: Thank you. Moving
11 on to validity, I'll ask the same question. Jim,
12 Marlene, Kerri, others who reviewed it, are there
13 those that we would vote en bloc, or are those
14 that we should call out individually? Any
15 objection to -- go ahead, Jim.

16 MEMBER BOST: I think all of them
17 except 15 showed good validity, so I would,
18 again, probably consider 15 separate.

19 CO-CHAIR BROOKEY: Any disagreement
20 with that? So we'll be voting for all except for
21 15, but we also will not be voting on 14 and 17.
22 Let me just see if I can get this straight,

1 voting on --

2 MEMBER BOST: And we have to do the
3 validity or reliability.

4 CO-CHAIR BROOKEY: -- 1, 3, 5, 7, 8,
5 9 and 16.

6 DR. NISHIMI: We need to pull 3 out
7 separately, too, because you would want -- if
8 you're going to, you would want to use your
9 validity vote for the reliability vote.

10 CO-CHAIR BROOKEY: Okay, so we'll just
11 do it the way we did last time, then. We're
12 voting on -- but we're including 1 in the vote.
13 We're including 1, 5, 7, 8, 9 and 16, is that
14 correct? Jim is supporting the validity of these
15 measures. Any other conversation about validity?
16 Okay, we'll vote.

17 MS. CHAVEZ: Okay, 1 high, 2 moderate,
18 3 low, 4 insufficient. Voting's now open, 23.

19 PARTICIPANT: One more.

20 MS. CHAVEZ: 24, 25.

21 CO-CHAIR BROOKEY: It sounds like we
22 need to vote on 3 and 15 separately. Let's vote

1 on 3, which Jim had recommended be part of the
2 other block, but we need to pull it out because
3 we pulled it out for reliability. So we're
4 voting only on 3. Any other comments about 3?

5 DR. NISHIMI: Before we start, Jim --
6 I'm sorry to cut you off -- Severa needs to read
7 the results out for the transcript.

8 CO-CHAIR BROOKEY: I'm sorry, go
9 ahead.

10 MS. CHAVEZ: Yes. For the record,
11 validity on FECC-1, 5, 7, 8, 9, 16, 2 voted high,
12 21 voted moderate, 1 low, 1 insufficient.

13 CO-CHAIR BROOKEY: Thank you. Any
14 other comments about validity for Measure 3?

15 MEMBER BOST: So the item level or
16 element level assessment that we're being asked
17 to review for 3 was done on the denominator,
18 where they looked at 700 children using the
19 algorithm associated with the measure and
20 compared whether the denominators were the same
21 using clinical chart review as the gold standard.
22 The results were very good, in terms of

1 sensitivity, specificity, at both Seattle
2 Children's and Washington Medicaid.

3 CO-CHAIR BROOKEY: Any other comments
4 about validity for Measure 3? Should we vote?

5 MEMBER HOUTROW: I have a question.

6 CO-CHAIR BROOKEY: Amy, go ahead.

7 MEMBER HOUTROW: For 3, it says it did
8 not achieve good reliability at the performance
9 score level, is that right, Jim?

10 MEMBER BOST: I'm sorry, I can't hear
11 the question.

12 MEMBER HOUTROW: On Page 14, Item 3
13 did not achieve good reliability at the
14 performance level, which the developer attributes
15 to small sample size.

16 MEMBER BOST: Right, that was the fact
17 that they had no reliability data and so were
18 using this element level one instead.

19 CO-CHAIR BROOKEY: Any objections to
20 voting? We're now voting on FECC-3 for validity.

21 MS. CHAVEZ: Yes, voting on FECC-3 for
22 validity, 1 high, 2 moderate, 3 low, 4

1 insufficient. Voting's open, 15, 24, 25. Okay,
2 1 voted high, 22 voted moderate, 2 voted low, 0
3 insufficient. FECC-3 passes validity.

4 CO-CHAIR BROOKEY: So moving forward
5 -- actually no, we need to vote on one more. We
6 need to vote on 15 for validity. Comments about
7 15?

8 MEMBER AGORATUS: This is Lauren.
9 There were some comments on validity, first in
10 specifications, the not accepting the sample size
11 as a reason for lack of reliability, not
12 reporting results, and then under validity
13 testing, again, small sample size. It should be
14 looked at separately.

15 Another comment, validity assessment
16 was good, unfair to deny high score due to lack
17 of convergent validity, difficulty with validity
18 testing due to small sample size, although there
19 was face validity, and finally, test sample was
20 inadequate. The result did not show validity.
21 That's it.

22 CO-CHAIR BROOKEY: Okay, Jim go ahead.

1 MEMBER BOST: That's exactly right.
2 The validity associated -- the convergent
3 validity was to look at an adult CAHPS measure
4 comparison, and for all the rest of the items,
5 the validity showed acceptable levels of
6 validity, except for FECC-15, which only showed
7 acceptable validity, I believe, in one of the
8 assessments. The thing to think about with
9 FECC-15 is that this is the did you have an
10 interpreter question.

11 I'm not surprised it had lower
12 validity because as we saw in earlier evidence
13 assessments, interpreters are used for everything
14 -- or every patient in need besides those with
15 complex kids. I think you have to decide whether
16 we should have expected them to do some other
17 kind of validity assessment for this question or
18 give it a pass because it wasn't as appropriate
19 for the items they chose for validity.

20 CO-CHAIR BROOKEY: But there was high
21 face validity.

22 MEMBER BOST: I'm sorry?

1 CO-CHAIR BROOKEY: There was high face
2 validity.

3 MEMBER BOST: Yes, their face validity
4 was good, the convergent validity not so good.

5 CO-CHAIR BROOKEY: So we could still
6 pass it based on face validity, but we can't give
7 it higher than a moderate.

8 PARTICIPANT: A moderate.

9 CO-CHAIR BROOKEY: Any other comments
10 before we vote? Okay, we're voting on FECC-15
11 for validity.

12 MS. CHAVEZ: 1 high, 2 moderate, 3
13 low, 4 insufficient. Voting's open, 20, 24, 25,
14 0 voted high, 18 voted moderate, 5 voted low, 2
15 voted insufficient. FECC-15 passes validity.

16 CO-CHAIR BROOKEY: Thank you. We're
17 moving on to feasibility. I suppose unless we're
18 sending out ten different surveys, which I hope
19 we don't do, that it should be the same for all
20 measures. I would recommend that we vote en
21 bloc. Any opposition to that? Any comments
22 about feasibility? It's a survey. It's probably

1 feasible. This is at a plan level or practice
2 level? I forget now. Plan level, it's at a plan
3 level survey, so not too challenging. Any
4 comments before we vote? Hearing none, we'll
5 vote for --

6 MS. CHAVEZ: Okay, voting on
7 feasibility for the whole FECC measure set,
8 except for FECC-14, correct?

9 CO-CHAIR BROOKEY: Actually --

10 PARTICIPANT: And 17.

11 MS. CHAVEZ: And 17.

12 CO-CHAIR BROOKEY: Correct, 14 and 17
13 will not move forward.

14 MS. CHAVEZ: Okay, voting on
15 feasibility, 1 high, 2 moderate, 3 low, 4
16 insufficient. Voting's open, 24, 25, 1 voted
17 high, 21 voted moderate, 3 voted low, 0 for
18 insufficient, so this passes feasibility.

19 CO-CHAIR BROOKEY: Thank you. We move
20 on to usability and use. Again, I would propose
21 that we vote en bloc, unless there's any
22 recommendations to vote for a measure

1 individually. Jon?

2 MEMBER FINKELSTEIN: I just have one
3 comment on one of the measures that's giving me
4 pause. If I'm the -- it's discharge instructions
5 visit by visit. What's giving me pause is not so
6 much the usability of the measure, but we're in
7 this meaningful use period, where the
8 requirements for discharge summaries have
9 entrained a whole bunch of non-productive gaming
10 and EHR things, so people get out the right
11 discharge instruction with the right elements.
12 I'm just a little concerned about doubling down
13 on that when I think we don't really know what
14 we're doing, as a field. I don't know if this is
15 exactly the right place to say that, but that one
16 is sticking out for me.

17 CO-CHAIR BROOKEY: Do you want to
18 provide that as input, or do you want to pull
19 that out for a separate vote?

20 MEMBER HOUTROW: Aren't we separate
21 voting all of them at the end?

22 CO-CHAIR BROOKEY: We can. You want

1 to do it that way?

2 MEMBER FINKELSTEIN: That might make
3 sense because -- yes.

4 CO-CHAIR BROOKEY: I'm okay with that.
5 Any objections to that? We will vote on
6 usability en bloc, but we'll have the opportunity
7 to do overall by measure for the two that didn't
8 move forward. Any other discussion? Otherwise,
9 we'll move to vote.

10 MS. CHAVEZ: Okay, now voting on
11 FECC-1, 3, 5, 7, 8, 9, 15, 16, usability and use.
12 1 high, 2 moderate, 3 low, 4 insufficient.
13 Voting's open.

14 MEMBER MILLER: Could I ask a
15 question, though, thinking about use and
16 usability? I was wondering if the developers --
17 because this is meant to be how would purchasers
18 and developers can comment to me -- what I see on
19 Page 102 is only three measures at a large state
20 level showed any differences, but I know there
21 was subsets and plans. Did any of these measures
22 show any differences? I think that affects

1 usability, that they can identify gaps. I'm just
2 trying to understand that only three of them
3 showed any difference.

4 DR. LION: We were limited by just
5 having a two state sample at this point. In our
6 field testing, we did four of the -- although, I
7 guess one of them was FECC-17, which is now out
8 -- so three of the remaining measures did show
9 differences at the state level. We also saw
10 differences by English proficiency and
11 race/ethnicity at -- in one, two, three, four,
12 five, six of the measures, which were not
13 necessarily the same ones that we saw differences
14 by state in, and we expect that with more states
15 and more points of comparison, we would likely
16 see more differences.

17 MEMBER MILLER: I'm just curious, did
18 you try looking at the health plan level, because
19 then you had hundreds of health plans, or you
20 didn't do that analysis?

21 DR. LION: We had Washington State
22 Medicaid, and we had Minnesota Medicaid, and that

1 was it.

2 CO-CHAIR BROOKEY: Any other comments
3 or questions? We'll go ahead and continue the
4 vote.

5 MS. CHAVEZ: Okay, voting on usability
6 and use for FECC-1, 3, 5, 7, 8, 9, 15, 16, 1
7 high, 2 moderate, 3 low, 4 insufficient.
8 Voting's open, 24, 25, 2 voted high, 18 voted
9 moderate, 5 voted low, 0 insufficient. This
10 group passes usability and use.

11 CO-CHAIR BROOKEY: Okay, so as
12 recommended, we're going to vote for overall, for
13 all of the measures except 14 and 17. Remember
14 this is a must pass, so this is your opportunity,
15 if you have reservations about one particular
16 measure, that you can vote yes or no. I'm going
17 to just go measure by measure, ask for comments,
18 and then we'll vote. FECC-1, has care
19 coordinator, any comments before voting?
20 Marlene?

21 MEMBER MILLER: Just a curiosity for
22 the developers I want to think about. It seems

1 to me if you grouped 1 and 8, where 8 says, "Was
2 the care coordinator knowledgeable and
3 supportive," you get at what you really want than
4 just the person being assigned to you.

5 CO-CHAIR BROOKEY: That came up
6 yesterday. We talked about not just having a
7 care coordinator, but having the care coordinator
8 actually do something for you, so comments for
9 the developer.

10 DR. MANGIONE-SMITH: Right.
11 Performance in FECC-1 was only 44 percent in the
12 two states among eligibles, so we felt pulling it
13 out as its own measure was important. We didn't
14 only want -- if you combine it with 8, then you
15 can only ask that measure of people who have a
16 care coordinator. That's why they're separate.
17 I know you want to double whammy them. You
18 mentioned that yesterday.

19 MEMBER FINKELSTEIN: It's just waiting
20 to come up -- is to use, in a sense, the
21 denominator for 1 with the numerator for 8.
22 That's just input. I understand that's not the

1 measure.

2 CO-CHAIR BROOKEY: Right, we talked
3 about that yesterday. Any other discussion about
4 overall for 1? Okay, we'll vote for 1 overall.

5 MS. CHAVEZ: Now voting on FECC-1,
6 overall suitability for endorsement, 1 for yes, 2
7 for no. Voting's open, 24, 25, 23 voted yes, 2
8 voted no, so FECC-1 has been recommended for
9 endorsement.

10 CO-CHAIR BROOKEY: Thank you. We're
11 going to FECC-3, care coordinator helped to
12 obtain community services overall. Any comments?
13 Hearing none, we'll go to a vote.

14 MS. CHAVEZ: Okay, voting on FECC-3,
15 overall suitability for endorsement, 1 yes, 2 no.
16 Voting's open, 25, 22 voted yes, 3 voted no.
17 FECC-3 has been recommended for endorsement.

18 CO-CHAIR BROOKEY: Thank you. We're
19 going to FECC-5, care coordinator asked about
20 concerns in health changes overall. Any
21 comments? Hearing none, we'll go to vote.

22 MS. CHAVEZ: Voting on FECC-5, overall

1 suitability for endorsement, 1 yes, 2 no.

2 Voting's open, 23, 24, 25, 21 voted yes, 4 voted
3 no. FECC-5 has been recommended for endorsement.

4 CO-CHAIR BROOKEY: Okay, moving on to
5 FECC-7, care coordinator assisted with special in
6 service referrals. Any comments about overall?
7 Okay, going to vote.

8 MS. CHAVEZ: Voting on FECC-7, 1 yes,
9 2 no. Voting is open, 24, 25, 19 voted yes, 6
10 voted no, FECC-7 has been recommended for
11 endorsement.

12 CO-CHAIR BROOKEY: Somebody yesterday
13 said that FECC-8 is what we really want, which is
14 a care coordinator was knowledgeable, supportive,
15 and advocated for child's needs, so any comments
16 about this measure? Okay, we'll go to vote.

17 MS. CHAVEZ: Okay, voting on FECC-8,
18 overall suitability for endorsement, 1 yes, 2 no.
19 Voting's open, 24, 25, 24 voted yes, 1 voted no.
20 FECC-8 has been recommended for endorsement.

21 CO-CHAIR BROOKEY: Thank you. FECC-9,
22 appropriate written visit summary content. Amy,

1 do you want to make a comment about this?

2 MEMBER HOUTROW: I have similar
3 concerns that John had about the expectation of
4 this measure, and also how it doesn't relate so
5 much to care coordination, but what an actual
6 physician does in the moment of providing care,
7 so conceptually, it seems a little bit different
8 than the rest of the ones that we just voted on.
9 In particular, upping the expectation past
10 meaningful use, I think, is going to be hard on
11 people, so I do have a couple of concerns about
12 this particular one.

13 CO-CHAIR BROOKEY: Rita.

14 DR. MANGIONE-SMITH: The only thing
15 I'd like to point out, in our validation
16 analyses, where we looked at the association
17 between increases in scores on that measure and
18 increases on four different CAHPS measures, that
19 one had the strongest validation results.

20 Just to give you a sense, there was
21 one validation metric that we looked at from
22 health plan CAHPS that asked about did you get

1 needed help coordinating your child's care, or
2 did you get all the help you felt you needed.
3 That's on a 0 to 100 scale, as is FECC-9. If you
4 were go from failing that measure being a 0 to
5 passing it being 100, you would move 36 points up
6 on the 0 to 100 scale on the CAHPS measure. That
7 was literally one of our strongest results in
8 validation. So although I hear what you're
9 saying about the meaningful use thing, it does
10 seem to matter, in terms of people feeling like
11 they got needed care coordination. That may have
12 to do with the fact that we pushed the envelope a
13 little bit on the NCQA criteria.

14 We were pushed by families, actually,
15 in our center to add the criteria that you would
16 put information about who to contact if problems
17 came up related to the visit. That extra content
18 you guys noted yesterday was actually very driven
19 by the families, so I would just ask you to keep
20 that in mind as you think about this.

21 CO-CHAIR BROOKEY: Any other comments?

22 Okay, we're going to vote on FECC-9.

1 MS. CHAVEZ: Now voting on FECC-9,
2 overall suitability for endorsement, 1 yes, 2 no.
3 Voting's open, 21, 24, 25, 18 voted yes, 7 voted
4 no. FECC-9 has been recommended for endorsement.

5 CO-CHAIR BROOKEY: Thank you. We're
6 going to go to FECC-15, caregiver has access to
7 medical interpreter when needed. Any comments?
8 Okay, let's go to the vote.

9 MS. CHAVEZ: Voting on FECC-15,
10 overall suitability for endorsement, 1 yes, 2 no.
11 Voting's open, 23, 25, 22 voted yes, 3 voted no,
12 FECC-15 has been recommended for endorsement.

13 CO-CHAIR BROOKEY: We're on the last
14 measure. It's FECC-16, child has shared care
15 plan. Any comments? Okay, move to vote.

16 MS. CHAVEZ: Okay, voting on FECC-16,
17 overall suitability for endorsement, 1 yes, 2 no.
18 Voting's open, 22, 25, 22 voted yes, 3 voted no.
19 FECC-16 has been recommended for endorsement.

20 CO-CHAIR BROOKEY: Great. We can all
21 take a sigh of relief now. We've gotten through
22 the FECC measures. Thank you to our developers.

1 This has been a great discussion. I know that
2 you'll take all these comments to heart, very
3 good discussion about the measurement set. Jim,
4 you want to --

5 MEMBER BOST: I just wanted to make
6 one closing comment, and that's about the fact
7 that we're doing these separately, as opposed to
8 in a group, for the developers to think about how
9 they would approach benchmarking for these items
10 if a health plan gets to choose which ones.
11 Perhaps that's fine for internal benchmarking,
12 but if they ever want to develop more national
13 benchmarking, you might want to consider that you
14 need to do them all in order to get your unbiased
15 benchmarks.

16 CO-CHAIR BROOKEY: Great feedback.
17 Kerri.

18 MEMBER FEI: One other closing
19 comment, as well, along those lines, that
20 regardless of what the measures are that come out
21 of the survey, keeping the survey together, as a
22 whole, and not just picking out the ones that

1 have measures associated with them.

2 CO-CHAIR BROOKEY: Agreed.

3 MEMBER FEI: I think that's important.
4 Otherwise, you're going to skew how people
5 respond.

6 CO-CHAIR BROOKEY: Agreed, thank you.
7 All right, thank you very much. Oh, one more
8 comment from Jeff.

9 MEMBER SCHIFF: I just want to
10 comment, now that voting's done, just to say that
11 -- just a couple things. One is I wanted to
12 compliment Rita and her staff for really keeping
13 this together in a good process. Some of the
14 interesting comments about Minnesota and
15 Washington are a lot alike, which is why there's
16 not a lot of variability, but I think that's a
17 challenge. The other thing I just really wanted
18 to point is from my point of view, in Medicaid --
19 I'm sure a lot of you who work with medical homes
20 and care coordination -- the whole movement to
21 care coordination happening at the practice level
22 in a measurable, identifiable way, this body of

1 measures moves that.

2 So as we think about this in a health
3 plan level, it helps the health plans be
4 accountable for something that's much more
5 meaningful going forward. I've just kind of been
6 sitting here all day. I just wanted to throw
7 that in.

8 CO-CHAIR BROOKEY: We want to make
9 sure we capture your comments, since you didn't
10 vote on anything, so thank you very much. Thank
11 you so much. We are going to now go to public
12 comment. You want to take --

13 DR. NISHIMI: Operator, can you
14 announce that it's public comment and see if
15 there's anyone who wishes to do so?

16 OPERATOR: At this time, if you would
17 like to make a public comment, please press star,
18 then the No. 1 on your telephone keypad. We have
19 no public comments at this time.

20 DR. NISHIMI: Is there anyone in the
21 audience who wishes to make public comment?
22 Okay.

1 CO-CHAIR BROOKEY: Thank you so much.
2 I'm going to pass the baton to Jeff now to pick
3 up on 2820, so take it away.

4 CO-CHAIR SUSMAN: All right, John. Go
5 get yourself a cup of coffee, a slug of whiskey.
6 You're off the hook for a bit. We're going to
7 turn to 2820, the pediatric CT radiation dose
8 measure, No. 2820. I believe we have developer
9 representatives dialing in. Are they there?

10 MS. KUMAR: Yes, Karishma Kumar from
11 UCSF is calling in.

12 DR. SMITH-BINDMAN: Hi, and this is
13 Rebecca Smith-Bindman from UCSF.

14 CO-CHAIR SUSMAN: Okay, and we have
15 one recusal in James Duncan. Any others who
16 recuse themselves? Okay, so for our measure
17 developer, I wonder if you could give us three to
18 five minutes, just brief overview of the measure
19 and the evidence and rationale gap.

20 DR. SMITH-BINDMAN: Yes, of course,
21 thank you. Good morning. The purpose of this
22 measure is to encourage facilities to assess the

1 radiation doses they use for CT, computed
2 tomography, in children, and to standardize and
3 lower these doses if they learn their doses are
4 higher than benchmarks.

5 Just a little background, most medical
6 imaging tests use ionizing radiation, and the
7 doses that are used for CT, which has become the
8 workhorse in radiology, are far higher than
9 conventional X-rays, many orders of magnitude
10 higher.

11 The doses that are typically used for
12 CT are in the range that they will cause cancer
13 in a small, but significant number of children.
14 These risks are particularly elevated in children
15 compared with adults. Thus, it's important to
16 keep these doses as low as possible.

17 Unfortunately, the doses that we typically use
18 for CT in process are far higher than needed for
19 diagnosis and are highly variable across
20 institutions. As an example, it's well known
21 that you should use a low dose -- 2, 3, 4
22 millisievert -- CT to diagnose kidney stones.

1 But we just completed a 15-center randomized
2 controlled trial comparing ultrasound versus CT
3 for kidney stones that we published in the New
4 England Journal last year, and we found that
5 fewer than 7 percent of patients actually
6 received low dose examinations.

7 The average dose was three times
8 higher, and the doses ranged up to 75
9 millisieverts for a single study, even though the
10 patient should have gotten a dose of 2. So the
11 variability is profound, and we've published
12 extensively on this. The work has shown, both
13 ours and others, that children have doses that
14 are even more highly variable. While higher
15 doses can lead to more detailed images, there's
16 no evidence at all that these lead to more
17 accurate diagnosis.

18 One of the primary reasons for the
19 variability is that institutions tend not to know
20 to dose that they routinely use. There's no one
21 who tends to look at, assess, or track their
22 dosage. This has changed dramatically in

1 California over the last two years, where state
2 law now requires reporting of dose in the medical
3 record, and this has really increased this
4 awareness across the state. This is also going
5 to change across the country in hospitals that
6 are covered by the Joint Commission because
7 they're beginning to require institutions to
8 begin assessing their typical doses.

9 However, this won't cover outpatient
10 facilities where most children are imaged. What
11 this measure does is provide a very simple
12 framework to allow facilities to assemble the
13 doses they use for CT and compare these doses to
14 typical benchmarks that are published. It calls
15 for facilities to look at their average doses, as
16 well as their high doses, and both of those will
17 contribute to the total dose that their patients
18 receive.

19 It asks them to assemble their doses,
20 and this can be done in various ways, both
21 automatic and using manual techniques, and we
22 have published comparing effort required using

1 automatic versus manual techniques, and it's
2 relatively modest, no matter what the approach.
3 Lastly, there have been several papers and
4 abstracts, including observational studies, as
5 well as a randomized control trial, that have
6 shown that assessment of doses, as described in
7 this measure, results in meaningful lowering of
8 doses, both average doses and typical doses. The
9 average institutional doses can be reduced 25
10 percent or more, and the outlier high doses above
11 the benchmark, in a paper we recently completed,
12 went down between 25 percent and 80 percent at
13 each individual institution after reviewing their
14 doses, as described in this measure.

15 I appreciate you considering this
16 measure. This measure was previously endorsed by
17 the NQF. It lost its endorsement because there
18 was concern that simply assessment of doses is
19 not enough to change the doses. I've resubmitted
20 the measure because now we have several
21 publications, and several more in press, that
22 show, in fact, looking at the doses using this

1 very simple framework does result in measurable
2 reduction. Thank you very much for considering
3 it.

4 CO-CHAIR SUSMAN: Thank you very much
5 for that succinct summary. Let me ask for
6 clarification up front about your intent. There
7 are essentially two parts to the measure, or
8 perhaps two measures, depending on how one is
9 thinking about this. The first is the mean dose,
10 and the second is the proportion of CT exams with
11 doses greater than the 75th percentile. Do you
12 mean this to be a composite, two separate
13 measures, or reporting just the latter or the
14 former? What is the intent?

15 DR. SMITH-BINDMAN: The intent was for
16 a facility to comply with this measure, they have
17 to collect data on their CT scans. They collect
18 data on 100 CT scans and they describe the
19 distribution. The benchmarks tend to be at two
20 points in that distribution.

21 The benchmarks tend to be published at
22 the 50th percentile, the average, and the 75th

1 percentile. So it's really just one measure.
2 Facilities can improve by comparing either or
3 both. They're not separate measures. They're
4 different points on a single distribution. So if
5 you know the 50th percentile, you also know every
6 other percentile, including the 75th.

7 It's just two points of comparison,
8 and those points are assembled because that's
9 where benchmarks are. As another example, you
10 could look at the 95th percentile or the 99th
11 percentile. There just tend not to be as many
12 benchmarks at those locations that you can
13 compare with.

14 CO-CHAIR SUSMAN: Maybe I'm not clear,
15 but let me try it again. In your reporting --
16 let's say I'm out there at a health plan or
17 integrated delivery system. What would I be
18 reporting, the percentage that are above the 75th
19 percentile, or both those measures, or something
20 else?

21 DR. SMITH-BINDMAN: You could report
22 both of those measures or either of those

1 measures.

2 CO-CHAIR SUSMAN: Okay. Joe.

3 MEMBER BOST: When you're talking
4 about 75th percentile of a benchmark, are you
5 just using the data collected at that time period
6 for your benchmark, or are you using all the
7 historical data from multiple time points, or are
8 you using national benchmarks from everybody that
9 does this measure?

10 DR. SMITH-BINDMAN: The benchmarks are
11 national benchmarks. The national benchmarks,
12 for example, these are within age strata -- we'll
13 say that the 50th percentile of a child's
14 abdominal CT is 5 millisieverts, and you'll
15 compare your 50th percentile to that benchmark,
16 or you'll look at the 75th percentile benchmark
17 created nationally, and say the 75th percentile
18 is -- by definition, you should have
19 approximately 25 percent of exams above the 75th
20 percentile benchmark if you're doing an average.

21 If the 75th percentile for children
22 nationally is 8 millisieverts, and in your data,

1 the 75th percentile you have 40 percent above
2 that benchmark, you're doing less good than
3 average. If you have 10 percent above that
4 benchmark, you have been doing better than
5 average.

6 MEMBER BOST: Do these benchmarks
7 already exist because you've been collecting this
8 historically, or will they be developed going
9 forward, based on who participates?

10 DR. SMITH-BINDMAN: There are several
11 existing publications on benchmarks in children,
12 including our own and internationally, but I
13 anticipate that as our group is publishing more
14 benchmarks, other groups will also publish
15 benchmarks. These benchmarks will, therefore, be
16 updated on a regular basis. For example, in
17 2015, hospitals might compare their data to
18 benchmarks published in 2014, and in 2016, you'd
19 compare your benchmarks to those of the year
20 prior.

21 CO-CHAIR SUSMAN: Okay, I'm going to
22 get Marlene, and then we'll turn to the

1 subcommittee that looked at this.

2 MEMBER MILLER: I'm wondering can you
3 just clarify for me again the denominator? What
4 I see is that it just says all these consecutive
5 CT scans, but can you clarify for me again three
6 specific populations of whether they're included
7 or not, the inpatient setting, the emergency
8 department setting, and then all other
9 ambulatory? I'm just confused from the document
10 of what is exactly in the denominator pool.

11 DR. SMITH-BINDMAN: The denominator is
12 every CT scan done within the organization that
13 chooses to participate in the measure. So if the
14 organization is an outpatient facility, it would
15 be every CT scan done at that facility. I
16 highlight the executive exams because the measure
17 doesn't call for looking at doses in typical
18 patients or subsets of patients. It calls for
19 looking at doses in all patients. An outpatient
20 facility would look at doses in every head CT,
21 every chest CT, every abdominal/pelvic CT. If
22 the institution participating is a health plan

1 that has both inpatient and outpatient and
2 hospital settings, it would assemble all of those
3 doses together and do the same with the
4 consecutive doses in every head, every chest,
5 every abdomen and pelvic CT. We have assessed
6 doses in a range of institutional size from very
7 tiny to very large, integrated healthcare
8 systems, with 3 million plus members, and have
9 shown --

10 CO-CHAIR SUSMAN: I'm sorry to break
11 in, but because we're really constrained on time,
12 I'm going to want to move us forward. I think
13 you nicely answered the question. I'd like to
14 turn to Keith and the members of the committee
15 who reviewed this, and then I will get your
16 comment. Yes? Good, okay, so please.

17 MEMBER FATTORI: I think the first
18 question that our workgroup wanted to clarify was
19 whether or not this should be evaluated as a
20 process measure or an outcome measure, so maybe
21 that's something that we can discuss at the
22 beginning, before we launch into the rest of the

1 conversation.

2 CO-CHAIR SUSMAN: Sounds good. I
3 invite the developer to discuss -- I think this
4 was presented as an intermediate clinical
5 outcome, and whether we determine or think of it
6 as such is going to influence which path -- the
7 infamous vertical or horizontal path we use
8 thereafter.

9 DR. SMITH-BINDMAN: I think we -- I
10 believe it's an intermediate outcome measure. In
11 order to assess the outcome of cancer, we'd have
12 to wait a very long time in these cohorts -- 5,
13 10, 20 years. There's a very strong relationship
14 between the radiation dose and cancer. Patients
15 and their parents care a great deal about the
16 radiation by itself as an outcome. So I believe
17 it's an intermediate outcome measure.

18 CO-CHAIR SUSMAN: Keith and others on
19 the subcommittee like to weigh in on that
20 particular issue?

21 MEMBER WHITE: I would agree with that
22 assessment. I think that if you believe the

1 science that links the administration of
2 radiation to the belt and cancer, even though,
3 for an individual patient, you can't actually
4 show a direct outcome or a direct impact on
5 cancer, on the population basis, you can infer a
6 direct outcome from amount of radiation given, so
7 I would agree that this would be an intermediate
8 outcome measure.

9 CO-CHAIR SUSMAN: If I'm following
10 correctly, if this is accepted as an intermediate
11 outcome measure, it would take us more on that
12 horizontal path of pass/no pass. Virginia?

13 MEMBER MOYER: As they were beginning
14 to talk about this, to me this is almost exactly
15 the same thing as immunization rates, which are
16 an intermediate clinical outcome.

17 CO-CHAIR SUSMAN: Okay, Keith or other
18 of the subgroup members want to comment
19 particularly, now, with regard to the
20 specifications and evidence and whether this is
21 an intermediate clinical outcome, as proposed?

22 MEMBER WHITE: Just on the

1 specifications, I don't know if this is the right
2 place to talk about this, but I'd like to maybe
3 ask a couple of questions about using the site
4 specific measure. The specifications were that
5 there would be measurements made of CT and BLT
6 and also the size specific. The size specific,
7 as was stated, I think, in the workup, it's going
8 to require either a lot more manual intervention,
9 or it's going to require systems that want to
10 employ this measure to have computer programs to
11 automatically do that modeling for them.

12 Could the developers comment on how
13 strongly they feel that the size-specific dosing
14 should be included, and if so, their belief as to
15 how that could best be operationalized?

16 DR. SMITH-BINDMAN: I think there's a
17 lot of attractiveness to the size-specific dose
18 estimate because it allows numbers to take into
19 account how large the patient is, a tiny infant
20 or a very large teenager. Once you've
21 established the age category, however, it becomes
22 far less important.

1 Quite honestly, in all of our work, we
2 have found no difference, whatsoever, in
3 identifying outliers, whether you use
4 size-specific dose estimates, or whether you use
5 the other metrics that it outlines. You get
6 exactly the same result. So there's a
7 theoretical attraction --

8 CO-CHAIR SUSMAN: Hello?

9 MEMBER WHITE: Hello?

10 CO-CHAIR SUSMAN: Our link to the sky.

11 MEMBER AGORATUS: Did Rebecca cut out?

12 CO-CHAIR SUSMAN: Yes.

13 DR. SMITH-BINDMAN: Can you hear me?

14 CO-CHAIR SUSMAN: Yes, we can hear
15 you. We can hear Keith.

16 (Simultaneous speaking.)

17 DR. SMITH-BINDMAN: I thought I cut
18 out. I got back. Okay, so if you use these data
19 automatically -- if you collect them
20 automatically, it's very easy to do SSDEs. If
21 you have to do them manually, it's an enormous
22 amount of work and not practical at all. It

1 requires calculations. That's just not feasible
2 for most people to do. It's not impossible.

3 So the bottom line is I don't think it
4 adds that much, but I think it will enhance
5 radiologists and medical physicists' adoption of
6 this measure because they like it very much. I
7 think it is equivalent. It takes extra work if
8 you have to do it manually, but if you do it
9 automatically, it's the same. In terms of how
10 well the measure will work, though, it doesn't
11 change whether you're using the SSDE or the other
12 metrics that I outlined.

13 MS. KUMAR: Don't most modern CT
14 machines calculate it automatically?

15 DR. SMITH-BINDMAN: That's a great
16 question. It calculates all the other measures
17 that I specified, and that's why the other ones
18 are easier to get. You get direct output of
19 CTDIvol or DLP from the machine SSDE is not
20 calculated automatically. It's basically the
21 CTDIvol divided by the abdominal circumference,
22 but you have to measure the abdominal

1 circumference. If you're doing it automatically,
2 it's a piece of cake. If you're doing it by
3 hand, it will take time.

4 CO-CHAIR SUSMAN: David, do you have
5 a question?

6 MEMBER EINZIG: It's just a general
7 question. Is there any risk for other clinical
8 times where a higher dose of radiation is
9 warranted, or is there a risk that something will
10 be missed? Are there times where something could
11 be missed because of using a lower dose?

12 DR. SMITH-BINDMAN: This is looking at
13 institutional averages. If there are some
14 patients who get higher doses and some patients
15 who get lower doses, that will average at the
16 institutional level. This measure does not
17 require every patient to be below the benchmark.
18 It requires the averages.

19 There's a lot of variability in dose
20 depending on clinical indications, but that
21 variability is dwarfed compared to the
22 variability based on institutional preference. A

1 concrete example is that some facilities use
2 single-phase settings going for an area once for
3 a clinical question, others use multiple phase.

4 If you use multiple phase, your dose
5 is about twice as high. So in general, if an
6 institution uses multiple phase on all their
7 patients, their doses will be twice as high.
8 It's not to say that if you usually use single
9 phase, you can't use double phase in some
10 patients for some clinical institutions.

11 CO-CHAIR SUSMAN: Okay, going up the
12 line, Martha.

13 MEMBER BERGREN: I didn't understand
14 that last explanation, so I'm going to ask the
15 question that I need to understand. Would the
16 requirement or the motivation to the lower the
17 doses lead to an unintended consequence of having
18 to repeat scans?

19 DR. SMITH-BINDMAN: If an institution
20 has doses that are, in general, very, very high,
21 and to lower those doses they make a concerted
22 effort to bring the doses down in all patients,

1 there could be examples where for an individual
2 patient, those images are no longer diagnostic
3 because the dose is too low, and they'll have to
4 repeat an individual case.

5 I don't think that is an ongoing
6 problem because if they realize they have to
7 start repeating cases, they will raise the doses
8 up. The strategy that most institutions use for
9 getting the right dose is they lower them as low
10 as they can until they start seeing that they
11 can't make good diagnoses, and then the
12 radiologist will you you've got to bring the dose
13 back up because we're starting to get
14 non-diagnostic scans.

15 MEMBER BERGREN: Thank you.

16 DR. SMITH-BINDMAN: That's the typical
17 approach that facilities use to get the right
18 dosage.

19 MEMBER WHITE: This is Keith. I would
20 concur. That's a very common approach. That's
21 basically the hard reality of dose reduction is
22 that at least at one level, there's a subjective

1 acceptability of the image noise that
2 radiologists have.

3 What is clearly true, based on
4 published evidence and also by practical
5 experience of institutions that are trying to
6 manage actively their radiation dose, is that
7 there's a tension in the dynamic between the dose
8 that's administered and the acceptability of the
9 images to the radiologists.

10 It's clear that by measuring -- for an
11 institution measuring their dose and contrasting
12 it to national benchmarks and coming back and
13 saying we're using high dose, that will force
14 that organization to address that tension, and
15 experience shows that they will decrease
16 radiation exposure to children.

17 The other thing I would point out is
18 that the data clearly shows, as well, that on the
19 average, the doses that are being administered
20 across the board in the country for children are
21 higher than are really, truthfully needed to make
22 diagnoses. I would echo that there's potential

1 for unintended consequences from doing this, but
2 I agree that it would be more on an individual
3 level, and that the overall benefit to the
4 population, as a whole, would far exceed any
5 compromise that's being extended for the care of
6 an individual.

7 MEMBER BERGREN: Thank you.

8 CO-CHAIR SUSMAN: Okay, there are a
9 number of questions over here. I'm going to
10 start with Jeff, who is one of our subcommittee
11 members.

12 MEMBER SCHIFF: I just wanted to ask
13 the developer to talk a little bit about -- this
14 states modern CTs. I think the number we got
15 from your information was that's 90 percent. I'm
16 curious if you have any data in the amount of CT
17 scanning that's done by the other 10 percent? I
18 guess what I'm really asking is are we looking
19 for the keys under the streetlight here, where
20 the other 10 percent may be the ones we should be
21 most concerned about with regard to this, and if
22 you have any data on those?

1 DR. SMITH-BINDMAN: Are you asking how
2 many facilities have CT scanners that don't
3 report these measures?

4 MEMBER SCHIFF: Or don't have the
5 ability to report them, and what the pediatric
6 population in those, if you have any information
7 on the pediatric population in those sites?

8 DR. SMITH-BINDMAN: The only number
9 that's available for how many facilities don't
10 have these measures automatically recorded was a
11 survey done in 2005, so ten years ago, by the
12 FDA. That number, at the time, was 95 percent.
13 I believe that number is closer to 99 percent.
14 Really, these numbers -- any new scanner, and any
15 scanner within the last ten years, reports these
16 data.

17 The number of facilities that don't
18 have the capacity to do this -- there are no
19 data, but it should be in the ballpark of 1
20 percent, so very, very few facilities. There's
21 no way to really get a handle on it. Truth be
22 told, those facilities could still do this. It

1 just would require using a free computer software
2 program, where they put in --

3 (Simultaneous speaking.)

4 CO-CHAIR SUSMAN: This sounds more
5 like a feasibility issue, and I think you've well
6 described it. Thank you very much. Jon.

7 MEMBER FINKELSTEIN: Mine is actually
8 just a very quick follow on to that. I just want
9 to make sure, for the record, that places don't
10 need a particular brand of CT, that machines from
11 all the different companies do this the same way,
12 that we won't be pushing people toward something
13 proprietary that there's a conflict here. I
14 doubt it, but I think we should ask that
15 question.

16 DR. SMITH-BINDMAN: Absolutely not.
17 You can get these data from every vendor's CT
18 scanner, and there are a half dozen dose software
19 products out there. You can get these data from
20 any of those products.

21 CO-CHAIR SUSMAN: Ricardo.

22 MEMBER QUINONEZ: My question relates

1 to access of care if this were to pass. Contrary
2 to popular belief, most children are not taken
3 care of in children's hospitals or children's
4 ERs. Most are seen in community settings and
5 community ERs, where there's no pediatric
6 radiologist. I would imagine that lowering the
7 dose to its most minimal need would make the need
8 for pediatric radiologists reading studies a
9 little bit higher, since they would be more
10 comfortable with the lower-dose results. Did you
11 consider whether doing that would limit access to
12 care for children, since most of them are
13 actually seen in outlying ERs?

14 DR. SMITH-BINDMAN: I think your
15 question is an excellent one. I think most of
16 the reason the small, non-academic, non-pediatric
17 hospitals use higher doses is they don't tailor
18 the doses they're using for children. This
19 measure would encourage them to tailor their
20 doses to children, but at some point, they may
21 not have the expertise to read those studies.

22 I would say the way the access issue

1 can be addressed is these studies can easily and
2 electronically be sent to other facilities,
3 larger academic facilities or pediatric
4 facilities. But it's certainly possible, at a
5 facility that has no trained pediatric
6 radiologist or no radiologist who's experienced
7 with using these doses that they could have
8 difficulty using them.

9 CO-CHAIR SUSMAN: Okay, thank you.

10 MEMBER WHITE: Can I make one other
11 comment there on that question?

12 CO-CHAIR SUSMAN: Yes.

13 MEMBER WHITE: That is that if you
14 really think about this, if you have a child in
15 an adult facility and that child has a scan done
16 at an adult protocol, so the adult amount of
17 radiation administered, those images on that
18 child are going to be extremely sharp and really
19 very, very high detailed, more high detail than
20 what would be a comparable scan done with that
21 same protocol in an adult.

22 Those radiologists would have been

1 used to looking at those more noisy images on the
2 adult, so if they were to tailor and to decrease
3 the radiation exposure on the child, such that
4 the quality of the images was the same as what
5 they were generating on the adult, it would
6 reduce the dose for the child, and they would
7 still be looking at studies that are basically of
8 the same quality as what they're reading daily
9 for the adults.

10 CO-CHAIR SUSMAN: Marlene.

11 MEMBER MILLER: I just wanted to make
12 three points. In the State of Maryland, our
13 state considers an amoxicillin radiation dose
14 error just like a medication error. I often
15 train our residents that you have to think of
16 X-ray dose or radiation dose just like
17 amoxicillin dose. If you put that lens on and
18 think about it, we would never want a child going
19 to a community ED and be given an adult
20 amoxicillin. This is one of those rare
21 opportunities we have to move that field to the
22 right thing for kids.

1 You've heard it from the developers.
2 The scans can do this. We know the right doses.
3 It won't impede the reading, and we would not
4 want children exposed to these unnecessary doses,
5 just like a medication wouldn't be acceptable at
6 a community hospital. Maybe they shouldn't be
7 seeing the children if they can only do adult
8 amoxicillin.

9 CO-CHAIR SUSMAN: Okay, one final
10 question, at least, that I have is you say that
11 the actual measurement provokes changes in
12 behavior, but from the studies that I've seen
13 that you provided, it looked like it was always
14 associated with some educational or quality
15 improvement process. In much of quality
16 improvement work, just measuring something
17 doesn't always evoke behavioral change. I just
18 wonder if you could comment briefly on that as
19 the developer?

20 DR. SMITH-BINDMAN: I think facilities
21 are starting, largely, with no knowledge of how
22 they're doing. So giving them a framework, which

1 is what this measure does, for looking at their
2 dose and comparing it, I think, is a strong
3 motivator.

4 The intensity of our educational
5 intervention has been very modest, to say the
6 least. It's been basically encouraging people to
7 speak on the phone and share best practices, so
8 we have not made extensive materials available to
9 optimize dose. That being said, as part of two
10 large federal NIH grants that I have, we'll be
11 making a lot of materials available online, for
12 example, optimized pediatric protocols.

13 Those don't currently exist very
14 often. There are very few protocols out there,
15 basically instructions, so we will provide those
16 in the next few months. They'll be available
17 freely for anyone to download, which I think
18 should help. But our several projects that lower
19 doses, there was no gauge it was basically
20 encouraging calls to share best practices, and
21 that led to lowering doses dramatically in some
22 settings.

1 CO-CHAIR SUSMAN: Okay, thank you. As
2 we come to a vote, really, there's two or three
3 paths we can take. One is to consider this as a
4 single measure, if you would, and vote on both
5 components, mean dose and proportionate CTs
6 greater than 75th percentile of benchmark
7 together, or we could separate those out and vote
8 for each. Obviously, you need to have a mean
9 dose before you can benchmark it. Just like the
10 committee's input about how we consider that.
11 Yes, Dave.

12 MEMBER KELLER: I'd suggest that we
13 consider these two together. As I hear the two
14 measures, what it reminds me the most of is how
15 you look at a distribution and you're really
16 doing is identifying what would be the standard
17 deviation. While one of them is identifying sort
18 of your general level, and the other is
19 identifying the degree of variation within your
20 practice, I think they're really all of a piece
21 when you're trying to look at how this material
22 is used. I'd suggest we look at them together.

1 CO-CHAIR SUSMAN: Ricardo.

2 MEMBER QUINONEZ: The only caveat to
3 this is that I'm not convinced, from hearing the
4 developers are looking at this measure, that
5 there are general accepted national benchmarks.
6 It seems like there are a few. There's some
7 national ones. There's some being developed.
8 There's some that might come out of this measure,
9 but having it together when there are no
10 nationally accepted benchmarks that everybody
11 agrees on would be -- how do you implement this
12 if there are none?

13 CO-CHAIR SUSMAN: Keith, maybe you
14 could comment from a radiologist's perspective on
15 are there nationally accepted benchmarks? How
16 would radiologists who are actually doing this
17 work look at this?

18 MEMBER WHITE: I'm going to go back to
19 the statement I made earlier that what they say
20 what is acceptable imaging quality is in truth,
21 in all honesty, is a subjective assessment.
22 There is really very little objective data

1 evidence that directly correlates, for example,
2 radiation dose for a specific indication what the
3 diagnostic accuracy of that study. So to a
4 certain degree, these are surveys of educated and
5 dedicated teams that are working in this area.
6 But, for example, the work that Dr. Goske did has
7 been referred to. I know that particular study,
8 where they were establishing some national
9 benchmarks for CT dose, involved a number of
10 different children's facilities, all of them
11 coming together.

12 It included not just an assessment of
13 the doses that were used, but an assessment of
14 some observer studies looking at the sharpness
15 and detail of certain anatomic structures to try
16 to put some objectivity into whether or not the
17 images were of adequate diagnostic accuracy. I
18 don't believe these benchmark studies are devoid
19 of any objective assessment of image sharpness or
20 image quality.

21 The truth is that they're the best
22 we've got and I'd like to improve and mature over

1 time. But I think it would be a shame to not
2 have the measure pass simply because we don't
3 have really rigorous measures of image quality,
4 which I think is extremely difficult to do and
5 will take a lot of effort to put together.

6 CO-CHAIR SUSMAN: Okay, thank you very
7 much, Keith. We have two more comments, and then
8 we'll see if we can vote here. Virginia.

9 MEMBER AGORATUS: This is Lauren. I
10 have a question.

11 CO-CHAIR SUSMAN: Sure, please.

12 MEMBER AGORATUS: I'm just wondering
13 if -- first of all, if there's any difference
14 between CT scans with and without contrast, and
15 also if anyone is looking at -- and this may be
16 beyond the scope of this measure -- in terms of
17 reducing dose length and frequency of scans
18 medically complex children who have multi-system
19 involvement and may be receiving multiple scans
20 within days, or even the same day?

21 CO-CHAIR SUSMAN: Keith, maybe you
22 could comment on the first part.

1 MEMBER WHITE: Because she asked two
2 questions, and due to time, I may have to answer
3 first question only.

4 CO-CHAIR SUSMAN: You can answer both
5 if you like.

6 MEMBER WHITE: Restate the first
7 question.

8 MEMBER AGORATUS: If there's any
9 difference in outcomes between CT scans that are
10 used with and without contrast?

11 MEMBER WHITE: In terms of radiation
12 dose, typically, hospitals do not have distinct
13 radiation profiles for with or without contrast.
14 They don't differentiate at that level.
15 Generally, there's not going to be a difference
16 in the radiation administered, whether contrast
17 was given or not. I'm sure there are exceptions
18 to that, but as a general rule, that's not done.
19 Second question, repeat that one.

20 CO-CHAIR SUSMAN: It's about medically
21 complex children who might be getting multiple
22 scans, even on the same day.

1 MEMBER WHITE: The question is risk in
2 those patients? The right way to think of -- the
3 whole theory behind radiation dose here is -- I
4 think the best analogy, it's like flying in an
5 airplane. Every time you get on an airplane,
6 there is a risk that something bad's going to
7 happen.

8 The fact that you have flown 1,000
9 times doesn't change the risk that on the next
10 flight, you could have an event. Patients that
11 had repeated examinations cumulatively over time
12 have an increase of developing cancer, but the
13 increase in the risk of cancer that occurs from
14 any single CT event is the equivalent for them as
15 it would be for any patient.

16 CO-CHAIR SUSMAN: I appreciate your
17 insight, since we're all flying home. Virginia.

18 MEMBER MOYER: I had has to do with
19 the benchmarking issue. As I understand this
20 measure, the measure is are you measuring? It
21 isn't are you meeting a particular benchmark
22 because the benchmarks are currently not really

1 out there. I think that -- and the documentation
2 provided, I thought, by the developers that
3 simply measuring is associated with decrease in
4 dose, and at this point in history, that probably
5 is where we are with this. Maybe ten years from
6 now we will be there, our benchmarks --

7 (Simultaneous speaking.)

8 CO-CHAIR SUSMAN: As I understand
9 this, there are really two components. One is
10 indeed the mean dose, and the other is the
11 proportion of CT scans with doses greater than
12 75th percentile.

13 MEMBER MOYER: Right. The question
14 still is are you measuring? It's two different
15 measures. It's essentially the mean and standard
16 deviation. The question is not how many patients
17 are and we're going to judge you on that; the
18 question is did you measure? Because just
19 measuring alone seems to result in improved in
20 dosage.

21 CO-CHAIR SUSMAN: Again, I'm fine, and
22 if the will of the group -- let's hear Jim -- is

1 to just consider this as a single measure that's
2 closely tied, obviously as more and more data are
3 accumulated, that'll allow us to establish more
4 rigorous, nationally accepted benchmarks. Jim?

5 DR. SMITH-BINDMAN: Can I say just one
6 thing about the last comment? It's exactly right
7 that just measuring is useful, and even in the
8 absence of any external benchmark, institutions
9 can compare their doses on a monthly or quarterly
10 basis to their own doses from the same prior
11 period, and then encourage doses to go down.
12 That's what we happened to do at our institution.
13 Our doses are quite lower than national averages,
14 and yet we keep trying to achieve lower doses for
15 our patients by having our doses be compared
16 monthly, over time.

17 CO-CHAIR SUSMAN: Okay, I'm going to
18 get Jim and John, and then see if there are any
19 final questions.

20 MEMBER BOST: For the second measure,
21 I'm just not sure how you can collect this
22 measure unless the developer provides or endorses

1 a value that is considered the 75th percentile,
2 so that everybody who does this measure can
3 report it consistently.

4 CO-CHAIR SUSMAN: Thank you. John.

5 CO-CHAIR BROOKEY: Yes, I just had a
6 question. Just measuring this and reporting it
7 out publicly, it could be reported out
8 comparatively with percentiles and have really
9 the same effect as comparing it to benchmarks
10 which have not really yet be established.

11 So to me, the first measure can really
12 effectively fulfill the intent of both, depending
13 on the way it's reported and how it's displayed,
14 so people could compare themselves to other
15 institutions. I'm not sure if that was the
16 intent or not, but I'm just looking at it and
17 thinking that would sort of solve the issue.
18 That's a question for the developer.

19 DR. SMITH-BINDMAN: I'm sorry, can you
20 repeat the question part of it? Sorry.

21 CO-CHAIR BROOKEY: If the first
22 measure is to measure, and then to report, it

1 could be reported comparatively, institution to
2 institution, and even reported by percentile,
3 irrespective of whether there's a benchmark or
4 not. It can just be comparative data. I don't
5 know if that was your intention or not.

6 DR. SMITH-BINDMAN: No, that's
7 absolutely true. This provides data that
8 currently don't exist.

9 CO-CHAIR SUSMAN: Okay, I would
10 suggest we move to a vote on evidence,
11 considering the whole discussion that we've had.
12 Is there any comment? Robyn, you --

13 DR. NISHIMI: I just need to clarify
14 for folks the submission set outcome, the
15 developer said today intermediate outcome, and
16 what I just heard now was the measure is did you
17 measure, which is a process. So just putting it
18 out there that we need a little bit of clarity
19 here.

20 CO-CHAIR SUSMAN: I heard earlier in
21 the discussion that this was an intermediate
22 clinical outcome of interest from many of you,

1 whether I personally agree with that or not -- if
2 that's the committee's wisdom, it's going to send
3 us down one path. If it's a process, it's going
4 to send us down something else and so forth, so
5 we need to be really clear.

6 MEMBER FINKELSTEIN: I'm very
7 comfortable with this as an intermediate outcome,
8 and I think the benchmark -- I think it's did you
9 measure, but I think the benchmarking is part of
10 it. It's implicit in it, and I would go across
11 the top pathway on this. That's my two cents.

12 DR. NISHIMI: Actually, an
13 intermediate outcome sends you down anyway.

14 CO-CHAIR SUSMAN: Yes, it sends you
15 down.

16 DR. NISHIMI: But we like to
17 characterize our measures to our members
18 correctly. That's why I'm pressing it.

19 CO-CHAIR SUSMAN: Virginia, or did you
20 have another comment, Jim? Okay, anybody else --
21 yes, please.

22 MEMBER MORROW-GORTON: I just want to

1 sort of echo what you said. I think this is not
2 did you measure, it's what was the measurement,
3 which is an outcome, not a process.

4 CO-CHAIR SUSMAN: Let's consider this,
5 then, an intermediate outcome measure, which is
6 going to send us down the blue boxes in our
7 typical fashion here for evidence. That will
8 allow us to be clear for anyone using this
9 measure, as well as for all of you in voting on
10 it. We have evidence and high, moderate, low, or
11 insufficient. We're going to vote for this en
12 bloc, the two parts of this, if you will,
13 measurement.

14 MS. CHAVEZ: We're now voting for
15 Measure 2820, pediatric CT radiation dose, 1
16 high, 2 moderate, 3 low, 4 insufficient. Voting
17 is open, 20, we are expecting 26 votes, 23, 26, 7
18 voted high, 16 voted moderate, 1 voted low, 2
19 voted insufficient. This measure passes
20 evidence.

21 CO-CHAIR SUSMAN: With regard to gap,
22 then, opportunity for improvement. Deb, you're

1 one of our subcommittee members.

2 MEMBER FATTORI: Our discussion at the
3 subcommittee really was around that the gap was
4 illustrated by the variability in radiation
5 doses. We also discussed -- the developer
6 provided some of their data through their work --
7 that there was -- in their work, they found a
8 bigger gap, if you will, higher radiation in
9 county hospitals as compared to more academic
10 hospitals. We felt that was significant and
11 further illustrated the gap.

12 CO-CHAIR SUSMAN: So we've had one
13 member who looked at this closely concur that
14 there is a gap here. Other comments before we
15 vote? Okay, let's move to vote on the
16 performance gap, 1 is high, 2 moderate, 3 low,
17 and 4 insufficient.

18 MS. CHAVEZ: Voting on gap 2820.
19 Voting is open, 24, 26, 11 voted high, 14 voted
20 moderate, 0 voted low, 1 voted insufficient.
21 This measure passes gap.

22 CO-CHAIR SUSMAN: Let's move on to

1 reliability. Keith, you want to talk to
2 reliability of this measure, perhaps?

3 MEMBER WHITE: I thought there were
4 questions -- I think they've already been
5 discussed -- about the clarity on the data
6 elements that needed to be defined. I think that
7 I would agree with what was said earlier, that it
8 would really be helpful if, as a part of the
9 measure, there was at least some attempt to put a
10 benchmark standard that could be used in the
11 measure. I think that I agree with what was
12 stated earlier that if there's not an accepted
13 benchmark that putting in the measure the
14 requirement to compare with a benchmark is not
15 very useful.

16 CO-CHAIR SUSMAN: And the Kappa scores
17 on a limited number of locations, I think, were
18 certainly adequate. Any other comments on
19 reliability? Let's go ahead, then, and vote, 1
20 high, 2 moderate, 3 low, 4 insufficient.

21 MS. CHAVEZ: Now voting on
22 reliability. Voting's open, 21, 24, 26, 5 voted

1 high, 17 voted moderate, 1 voted low, 3
2 insufficient. This measure passes reliability.

3 CO-CHAIR SUSMAN: And that brings us
4 to validity. Keith, any comments on validity?

5 MEMBER WHITE: Nothing that hasn't
6 been discussed already.

7 CO-CHAIR SUSMAN: Deb, any further
8 comments on validity?

9 MEMBER FATTORI: The only question
10 that came up was in regards to exclusions. There
11 was one area in the measure summary that said
12 there were no exclusions, and then there was
13 another area that listed the exclusions out, so
14 if the developer would just clarify that.

15 DR. SMITH-BINDMAN: I think that was
16 my error in how I described it. The measure
17 looks at consecutive exams in the specified
18 anatomic areas, head, chest, abdomen, pelvis. It
19 does not look at exams in other anatomic areas.
20 It does not look at radiation oncology-guided CT
21 scans, and it does not look at procedure-related
22 CT scans. Those are not really exclusions, as

1 much as areas that are not covered by this
2 measure.

3 CO-CHAIR SUSMAN: Thank you. Kevin.

4 MEMBER SLAVIN: Just a question about
5 the indications for scanning and if there's a
6 particular facility or area that has a specialty
7 where there's a high volume of patients with a
8 particular indication, how would that affect
9 where they score on a benchmarking compared to
10 other facilities, and would that then sort of be
11 problematic for the validity of it as a quality
12 measure?

13 DR. SMITH-BINDMAN: I think that is a
14 theoretical concern, but not a practical concern
15 because there are no such indications that would
16 be expected to have such a profound effect on the
17 average doses. If a facility did, however, have,
18 let's say, only obese children -- if it was a
19 facility dedicated to studying obese children,
20 then their doses would be higher than the
21 averages, and they probably should not compare to
22 those benchmarks.

1 But other than that example, I can't
2 come up with any other indication that should
3 lead to such a profound shift in typical doses.
4 We have a large paper coming out in radiology
5 that looks at 800,000 exams. In fact, the
6 indication for imaging is much less important
7 predictor of dose than just institutional
8 preferences and variations.

9 CO-CHAIR SUSMAN: Thank you. Any
10 other questions on validity? Hearing none,
11 seeing none, let's go ahead and vote on validity,
12 1 high, 2 moderate, 3 low, 4 insufficient.

13 MS. CHAVEZ: Voting is now open, 5,
14 21, 24, 25, 26, thank you.

15 CO-CHAIR SUSMAN: Robyn has a comment.

16 DR. NISHIMI: I can do it at the end.

17 CO-CHAIR SUSMAN: Okay, at the end.

18 MS. CHAVEZ: Okay, 6 voted high, 16
19 voted moderate, 0 for low, 4 insufficient. This
20 measure passes validity.

21 CO-CHAIR SUSMAN: Okay, I think we've
22 talked about the feasibility of this in some

1 detail. Kerri, you have a question?

2 MEMBER FEI: I do have a question. I
3 was trying to think of the right time to bring
4 this one up. I noticed that in the documentation
5 it says the measure could be used at the health
6 plan level. It has not been -- it doesn't appear
7 that it's been tested at the health plan level.

8 The other problem is most health plans
9 right now are not going to have access to any of
10 this data. They're going to have to go to
11 providers to get it, either through contracting
12 with a service or getting direct access to EMR or
13 having providers report data to them and the
14 labor intensive and burdensome at a health plan
15 level right now, in our current state, to be able
16 to even get this measure.

17 CO-CHAIR SUSMAN: So you'll be happy
18 to know that Robyn was right on this issue, and
19 that was the concern she had, so the NQF is
20 working for you.

21 MEMBER FEI: Yes, I think in the long
22 term, this is something health plans would like

1 to be able to have access to, but it's just not
2 -- we're not there yet.

3 DR. SMITH-BINDMAN: Can I make a
4 comment about that?

5 CO-CHAIR SUSMAN: Sure.

6 DR. SMITH-BINDMAN: We actually have
7 assessed these doses at many health plan levels.
8 If an HMO is considered a health plan, we've
9 assessed these doses across six large integrated
10 health plans. We've included those data in two
11 JAMA papers. I currently have a project that's
12 collecting similar data across 100 hospitals
13 across the country, including several very large
14 health plans. So I agree these data take some
15 work to assemble. It's relatively modest, and we
16 have assembled them across many small and large
17 health plans.

18 CO-CHAIR SUSMAN: Thank you. Kerri?

19 MEMBER FEI: There's a difference
20 between a large integrated health system that has
21 a health plan associated with it, so your Kaisers
22 or Intermountains or Geisingers that yes, they

1 can do this. Your run-of-the-mill private health
2 insurer right now cannot.

3 CO-CHAIR SUSMAN: I think the point is
4 well made. Thank you. Other questions about
5 feasibility?

6 DR. NISHIMI: I just want to make the
7 point, though, that under the NQF rubric, we will
8 be asking the developer to remove that checkbox.

9 CO-CHAIR SUSMAN: Certainly, that's
10 work I think we'd all like to be able to see in
11 the future, but let's go ahead, then, and vote on
12 feasibility.

13 MS. CHAVEZ: Voting on feasibility, 1
14 high, 2 moderate, 3 low, 4 insufficient. Voting
15 is open, 9, 23, 25, 25, 26, thank you, 9 voted
16 high, 12 voted moderate, 3 voted low, 2
17 insufficient. This measure passes feasibility.

18 CO-CHAIR SUSMAN: Okay, now let's go
19 to usability. I think again, we've discussed
20 this broadly. Are there any other new comments?
21 Seeing and hearing none, let's move to vote on
22 usability.

1 MS. CHAVEZ: Voting on usability, 1
2 high, 2 moderate, 3 low, 4 insufficient.
3 Voting's open, 18, 24, 25, 26, 10 voted high, 14
4 voted moderate, 1 voted low, 1 voted
5 insufficient. This measure passes usability and
6 use.

7 CO-CHAIR SUSMAN: Finally, the overall
8 voting on this measure, overall suitability for
9 endorsement, 1 yes and 2 no. Are there any final
10 comments? Seeing none, let's vote.

11 MS. CHAVEZ: We're now voting on
12 measure --

13 CO-CHAIR SUSMAN: Wait a minute,
14 excuse me. Maureen, you did have a comment.

15 MEMBER EDIGER: Sorry. I have a kid
16 who this totally applies to. He has Spina
17 Bifida, so gets CT and MRI scans very frequently.
18 You had asked about changes in behavior. Just
19 the more transparent this information is, it
20 absolutely will change behavior. It's been great
21 being part of this process.

22 CO-CHAIR SUSMAN: Thank you very much

1 for that comment. Any other final comments?

2 Okay, let's vote, 1 yes, 2 no on overall
3 suitability for endorsement.

4 MS. CHAVEZ: Thank you.

5 CO-CHAIR SUSMAN: Thank you.

6 MS. CHAVEZ: Voting on Measure 2820,
7 overall suitability for endorsement. Voting is
8 open, 24, 25, 26, 24 voted yes, 2 voted no. This
9 measure, 2820, pediatric CT radiation dose, has
10 been recommended for endorsement.

11 CO-CHAIR SUSMAN: Okay, thank you very
12 much. That was good work, smoothly done. We're
13 going to plow ahead, trying to keep us on
14 schedule here.

15 PARTICIPANT: Thank you.

16 CO-CHAIR SUSMAN: Thank you so much,
17 appreciate all the effort on this.

18 DR. SMITH-BINDMAN: Thank you very
19 much.

20 CO-CHAIR SUSMAN: So we're going to
21 move to the overuse element. If you need to take
22 a break for coffee, the restroom, please feel

1 free, but in an effort to keep us on schedule,
2 I'm going to plow further. This is overuse of
3 imaging for the evaluation of children with
4 post-traumatic headache, a Q-METRIC proposal from
5 the University of Michigan. We should have, on
6 the line, either Gary Freed or Julie McCormick or
7 both. Are you there?

8 DR. MACY: Hi, this is Michelle Macy.
9 I'm a pediatric emergency physician at the
10 University of Michigan and the Q-METRIC topic
11 lead for this measure. We appreciate the
12 opportunity to provide opening remarks on behalf
13 of the entire Q-METRIC team, who's here with me.

14 CO-CHAIR SUSMAN: Okay, any recusals
15 on behalf of the committee? Seeing none, we'll
16 go ahead and hear from our measure developer for
17 a brief description.

18 DR. MACY: The measurement of imaging
19 overuse for headache and seizures was determined
20 by CMS processes to be of high national priority,
21 especially for Medicaid patients. This topic was
22 assigned by CMS to Q-METRIC for measure

1 development and testing. Reduction in overuse
2 can benefit children by lowering immediate risks
3 associated with sedation and anesthesia and
4 lifetime risks associated with radiation
5 exposure, which include leukemia, brain tumors,
6 and other malignancies. Reduction in cost is an
7 additional benefit.

8 Our proposed measure is crucial, in
9 light of the strong evidence for the existence of
10 imaging overuse in the evaluation of children
11 with head injury, as demonstrated by the
12 Pediatric Emergency Care Applied Research Network
13 or PECARN studies that led to the development of
14 two age-stratified clinical decision rules for
15 the identification of children at very low risk
16 for clinically important traumatic brain injury.
17 As this measure is discussed, it's essential to
18 keep in mind a few important points. First, our
19 assignment from CMS was specified to children
20 with headache. Children with post-traumatic
21 headache are a subset of a broader group of
22 children who have experienced a head injury.

1 Children 2 years and older were
2 selected as the initial population of focus for
3 this measure because we were not assigned the
4 task of -- because we were assigned the tasks of
5 measuring imaging overuse for headache. Younger,
6 pre-verbal children cannot reliably report this
7 symptom. Future measure enhancements can broaden
8 the eligible population. Second, the sole focus
9 of this measure is overuse. Overuse is distinct
10 from use, under use, and inappropriate use.

11 Overuse is defined as any patient who
12 undergoes a test or procedure without an
13 appropriate indication. Overuse calculations are
14 therefore derived from the population of patients
15 who have undergone the test of interest.

16 Specifically for this measure, the denominator
17 consists of children who underwent neuro-imaging
18 for the evaluation of post-traumatic headache in
19 the emergency department within 24 hours of
20 injury. The numerator includes a subset of
21 children from the denominator who received the
22 neuro-imaging test without an appropriate

1 indication. Our measure inclusion criteria are
2 aligned with the PECARN study.

3 We also relied on the PECARN study to
4 determine indications for neuro-imaging that
5 exclude cases from the numerator. Children with
6 an indication for neuro-imaging documented in the
7 medical record were excluded from the numerator,
8 leaving behind children without an indication for
9 imaging. Through testing, we found that
10 administrative claims can be used reliably and
11 feasibly to narrow the population eligible for
12 chart review.

13 At the present time, chart review is
14 necessary for the calculation of this measure
15 because there are no ICD-9-CM or ICD-10-CM codes
16 for key measure inclusion criteria, specifically
17 neuro-imaging obtained within 24 hours of injury
18 among children with normal mental status. More
19 than half of the 200 charts sampled for testing
20 were excluded due to lack of documentation of
21 injury occurring within 24 hours prior to the ED
22 visit in which imaging was obtained. We did

1 include ICD-9-CM codes for concussion without
2 loss of consciousness in the population eligible
3 for the chart-review sampling. Based on comments
4 from the workgroup call, we have recalculated
5 overuse in our test sample, including children
6 with concussion and no documentation of headache
7 in chart review.

8 The inclusion of these children
9 resulted in higher overuse at 18 percent, and
10 just for reference, overuse in the PECARN study
11 was around 20 percent. In closing, we believe
12 that this evidence-based measure is highly
13 important and has potential to make substantial
14 positive impact on the quality of care for
15 children.

16 Our measure focuses on the overuse of
17 imaging, which is a national concern and priority
18 for CMS. Our testing found this measure to be
19 valid, reliable, and feasible through chart
20 review. Efforts to enhance this measure and
21 expand on its utility can be pursued in the
22 future. We look forward to addressing any

1 questions or concerns you may have, and thank you
2 for your time and consideration.

3 CO-CHAIR SUSMAN: Thank you for that
4 very succinct and thorough presentation. One of
5 the things to orient us here, this is an overuse
6 measure, and it looks a little different because
7 the denominator is those who have undergone
8 neuro-imaging, and the numerators are those with
9 no appropriate indication, as opposed to -- I
10 think it's the PECARN study was laid out kids
11 come in, they have a variety of concussion, blah,
12 blah, blah, and measuring how many have an
13 appropriate indication.

14 It's a different denominator. It gets
15 a little bit fuzzy when you start thinking about
16 that, so just keep that in mind as we discuss
17 this measure. We're looking at overuse, and the
18 denominator is those who have undergone
19 neuro-imaging. Did I get that right, developer?

20 DR. MACY: That's correct.

21 CO-CHAIR SUSMAN: We have a lot of
22 questions here. Let's have these four questions,

1 and then probably it would be useful to have
2 those who reviewed this most thoroughly -- maybe
3 I'll start with Jeff, since you were on the
4 subcommittee that did that.

5 MEMBER SCHIFF: I was on the
6 subcommittee. I think the developer already
7 talked about one of the concerns we had about the
8 limitation around headache and addressed that, so
9 I think that's been addressed. I think that the
10 -- I have one major comment and one smaller one.

11 The major one I'm concerned about is
12 the numerator exclusion for absence of documented
13 neurologic examination because I just feel that
14 would mean that -- and I need the developer to
15 help with that because unless I'm missing a
16 double negative, that seems illogical to me.
17 Then the other one I just want to talk about is
18 I'd like to hear about why that is not a
19 hospital-level measure.

20 CO-CHAIR SUSMAN: Why don't we get
21 responses from the developer on those issues
22 while they're fresh at hand.

1 DR. MACY: With regard to a chart
2 where there is no documented neurologic exam, we
3 didn't feel that was a chart that was appropriate
4 for inclusion in the measure. I think that ends
5 up being a rare occurrence for kids who are
6 undergoing neuro-imaging events. It might be a
7 point that we could look at specifically in our
8 chart review elements and get back to you as to
9 the number of cases that we had that occur. Then
10 the second question?

11 MEMBER SCHIFF: Was about health plan
12 level.

13 DR. MACY: And why we went with a
14 health plan level? We went through the health
15 plan level because that was the Medicaid focus
16 for the CMS measures, and our approach for
17 testing was designed to be in line with that. We
18 think that future enhancements of the measure
19 could be looked at at the hospital level, but we
20 do not have testing results at this time for
21 that.

22 MEMBER SCHIFF: Can I just ask a

1 follow-up question?

2 CO-CHAIR SUSMAN: Please.

3 MEMBER SCHIFF: Do you have numbers on
4 the -- you mentioned that it was a rare
5 occurrence to have an undocumented neurologic
6 examination. My concern was that obviously would
7 mean that there was absolutely no indication
8 documented. What was the rate on your review
9 without a documented neurologic examination, do
10 you know, or did I miss it?

11 DR. MACY: About 7 of the 200 cases
12 that we did chart review on had no documented
13 neurologic exam.

14 CO-CHAIR SUSMAN: Thank you. Let me
15 turn to Jim, who is our expert in this area. We
16 want to make sure he has a chance to say wise
17 words.

18 MEMBER DUNCAN: I don't know if I'm an
19 expert. I would actually think Jeff, in the
20 emergency room, probably sees these children on a
21 regular basis. I have personal experience with
22 my son going through this process. I guess I'm

1 guilty of carrying a slightly different
2 nomenclature for overuse in my head. It sort of
3 goes to antibiotics. Antibiotics for viral
4 symptoms are often cited as an example of overuse
5 of antibiotics.

6 So, therefore, my mental model was
7 looking for a measure that was looking for head
8 CTs, much like PECARN, in children presenting
9 with head trauma, and not with the exclusion of
10 headaches, which I also think begins to sort of
11 pull apart the strong linkages back to a
12 considerable amount of data, which I think no one
13 will argue with. That was part of what we
14 discussed as a subgroup before is part of my
15 concerns.

16 CO-CHAIR SUSMAN: I think, again,
17 getting our heads around, so to speak, that we're
18 starting out with neuro-imaging in the
19 denominator is a different mental setup than,
20 say, how PECARN study was set up, so an important
21 point. I'm going to go back to Carol, and then
22 we'll get the rest of the comments in order.

1 MEMBER STANLEY: I'm just curious why
2 children who are suspected of neglect are going
3 to be excluded? With the Medicaid population, I
4 would think that the exclusion, if you tested it
5 with any Medicaid health plan specifically, if
6 you would have had some different results?

7 DR. MACY: In our committee meeting
8 within the Q-METRIC group to design this with the
9 national panel, it was strongly expressed among
10 the emergency providers that CT imaging of the
11 head is an important step in the evaluation of
12 children with suspected child abuse and neglect
13 and, therefore, we felt that being in a situation
14 where providers could be doing that appropriate
15 evaluation of children with that clinical concern
16 should be excluded from this measure.

17 CO-CHAIR SUSMAN: Okay, Deb?

18 MEMBER FATTORI: I'm a little
19 reluctant to bring this up, but I'm just a little
20 confused as to why this is categorized as a
21 process measure, where our last imaging measure
22 was an intermediate outcome measure, so I'm

1 trying to get my head around that and appreciate
2 any input.

3 CO-CHAIR SUSMAN: I think the process
4 is obtaining the image, and as everybody sitting
5 on this panel knows, the classification of these
6 measures remains something that troubles us. I'm
7 not sure there's much more to say about that,
8 unless the staff wanted to weigh in on it. As
9 Helen said, it's up to us, guys and gals.

10 MEMBER FEI: I could offer one thing.
11 It's a process of whether or not something was
12 done. It's not the outcome or the report or the
13 result. It's yes or no. It's a yes or no
14 answer.

15 CO-CHAIR SUSMAN: This, to me, is a
16 pretty classic process measure, but I understand
17 the discomfort. Did you have anything else,
18 Kerri?

19 MEMBER FEI: I did, actually, I just
20 --

21 (Simultaneous speaking.)

22 CO-CHAIR SUSMAN: Go ahead.

1 MEMBER FEI: -- just for the fun of
2 it. Understanding that this is a health plan
3 measure and it was tested Medicaid data and had
4 chart abstraction that's part of it, again,
5 generalizing to health plans across the board can
6 be done, but would incur expense and, in the
7 present time, is difficult.

8 CO-CHAIR SUSMAN: Thank you. Ricardo.

9 MEMBER QUINONEZ: I was part of the
10 subcommittee that looked at this measure. My
11 only -- for sure, there's no question that the
12 evidence strongly supports this, except that as
13 has been discussed before, but I'd like a little
14 bit more clarification from the developers, by
15 including imaging in both the numerator and the
16 denominator, you're excluding most of the kids
17 that would benefit from this measure.

18 Most kids who show up to the ER after
19 a minor head injury don't have a post-traumatic
20 headache. I'm just a little bit confused and
21 concerned that if we pass this measure, this will
22 be seen as the measure of overuse for minor head

1 injury when the numerator could be all children
2 presenting to the ER with minor head injuries,
3 which would actually capture the spirit of what
4 overuse is. This is looking at a subset of a
5 subset, and it would capture a minority of the
6 children who have had imaging done improperly.

7 CO-CHAIR SUSMAN: I think that's a
8 tremendously important point, but probably goes
9 in our usability and, ultimately, to our vote on
10 this measure. I'm going to suggest we sort of
11 stay on the point of evidence. Recognizing that
12 this may not be the best measure we could think
13 of, we still have to vote on the measure that's
14 before us. Thank you for those comments. Yes?

15 MEMBER MORROW-GORTON: I just want to
16 go back to the question about children who've
17 been abused. I think they have to be excluded.
18 One, you can't rely on the history from the
19 family or whoever brings them in. Two, you don't
20 know whether they had a head injury or not.

21 There are a lot of legal things you
22 have to do. I just think they're a completely

1 different -- it's a completely different work up,
2 a completely different way to think about it.
3 You're not thinking overuse. In that population,
4 you're really not thinking overuse.

5 CO-CHAIR SUSMAN: So essentially, the
6 pretest probability of a positive test is going
7 to be much higher. There's a much higher
8 prevalence of bad things. Go ahead, John.

9 MEMBER MORROW-GORTON: I absolutely --

10 (Simultaneous speaking.)

11 MEMBER STANLEY: I was specifically
12 thinking about neglected children, not
13 necessarily abuse.

14 MEMBER THACKERAY: That's what I was
15 going to say. I absolutely agree with Jill that
16 if there's a consideration of physical abuse,
17 none of this should apply. It doesn't apply for
18 PECARN, and I'm glad to see it doesn't apply
19 here. But I do think saying child abuse or
20 neglect is different, there's very few
21 indications to be doing head CTs when you have a
22 concern for neglect. So it might be just more

1 clear to specify suspected child physical abuse
2 and not say abuse or neglect.

3 CO-CHAIR SUSMAN: It's a good comment,
4 and maybe, if you will, sloppiness in our
5 language or documentation that drives some of
6 that, but we'll certainly make sure that's taken
7 into consideration. Jim.

8 MEMBER AGORATUS: This is Lauren. I
9 have a question.

10 CO-CHAIR SUSMAN: Go ahead.

11 MEMBER AGORATUS: I'm a little
12 concerned because it says in the absence of
13 neurological symptoms, yet prolonged headache is
14 listed as a neurological symptom, so I'm not
15 sure, again, if we're going to be not testing
16 people that should be tested.

17 CO-CHAIR SUSMAN: Does the developer
18 want to respond?

19 DR. MACY: It's the absence of
20 neurologic symptoms that would be indicative of
21 clinically important traumatic brain injury, as
22 outlined by the PECARN studies, so not acting

1 like themselves, persistent vomiting, those sets
2 of symptoms that were identified in the PECARN
3 study were the ones that we were including in
4 that statement.

5 CO-CHAIR SUSMAN: So that did not
6 include prolonged headache?

7 DR. MACY: I think headache was one of
8 our sets of symptoms, and because we're looking
9 at within 24 hours of injury, I don't think you
10 would cross that threshold of prolonged,
11 necessarily.

12 CO-CHAIR SUSMAN: Fair enough, thank
13 you. Jim.

14 MEMBER DUNCAN: It might be best left
15 to the validity discussion, but I think this idea
16 of when the denominator gets small, rather than
17 all the children with head trauma, you start
18 introducing that the abuse case can sort of tweak
19 the numbers, and that's the advantage of having a
20 large denominator is it's going to improve the
21 validity. I think the developer found no cases
22 that needed the child abuse exclusion in their

1 test set. So I would think that, again, if you
2 expand the denominator, again, it's going to have
3 a very small impact.

4 I also think -- and it's part of the
5 usability discussion -- the more exclusions --
6 trying to calculate these within our department,
7 it makes it really tough because you have to get
8 the data, and then you have to run the algorithm.
9 The simpler the measure, the more it fits -- I
10 think we're trying to impact the decision making
11 in the ER, by the physician, about whether this
12 child needs a head CT. You want to be getting
13 credit for making a good decision which is,
14 again, outside this measure.

15 CO-CHAIR SUSMAN: So I think again,
16 good points, probably more apropos to usability.
17 Any discussions further on evidence here? Seeing
18 none, let's go ahead and vote on evidence, which
19 is 1 high, 2 moderate, 3 low, and 4 insufficient.

20 MS. CHAVEZ: Now voting on evidence
21 for Measure 2802. Voting's open, we are
22 expecting 27 votes, 19, 23, 25, 26, okay, 26

1 votes, 8 voted high, 15 voted moderate, 2 voted
2 low, 1 voted insufficient. This measure passes
3 evidence.

4 CO-CHAIR SUSMAN: So opportunity for
5 improvement or gap? Is there a gap here? Keith,
6 any members of the subcommittee? Jim?

7 MEMBER DUNCAN: Again, it goes back to
8 how they calculated their measure, the other
9 examples that I've seen calculated using
10 different -- clearly shows overuse of head CTs,
11 but it's, again, hard to say that this measure
12 would parallel what's been seen by other
13 calculations.

14 MEMBER QUINONEZ: I agree. I don't
15 think there's a gap that has been shown by the
16 developers because of the inclusion of the
17 denominator of only kids with headache. So the
18 gap is in all children who present to the ER with
19 minor head injury. I don't think they have
20 proven that for their specific measure there's a
21 gap.

22 CO-CHAIR SUSMAN: Does the developer

1 want to respond or have any further input? Then
2 I'll get Jeff.

3 DR. MACY: It has been shown that CT
4 utilization ranges widely across emergency
5 departments and free-standing children's
6 hospitals from about 20 to 60 or 70 percent of
7 kids are imaged, and we have no reason to believe
8 that imaging inappropriate or overuse measurement
9 would not also have a similar spread.

10 CO-CHAIR SUSMAN: Jeff, and then John.

11 MEMBER SCHIFF: In Minnesota Medicaid,
12 we looked at CT scans by Level 1 and 2 trauma
13 centers and found a range from 27 percent to 80
14 percent for head injury. This is probably seven
15 or eight years ago. So there was a big
16 variation, but I think the concern that Ricardo
17 brought up is really the relevant one, is are we
18 going to identify a significant gap in a subset
19 of kids just with headache? I guess what I'd
20 like to know from the developer is is there any
21 -- can you tell us any larger numerator and how
22 many kids, of all the kids that were looked at,

1 had -- what percent of kids had headache?

2 Because we, in my ER, almost never would code

3 headache.

4 CO-CHAIR SUSMAN: Developer?

5 DR. MACY: One moment please.

6 CO-CHAIR SUSMAN: Okay, maybe in the
7 meantime, Jon you want to comment?

8 MEMBER FINKELSTEIN: Yes, as I'm
9 thinking of this, there are two separate issues
10 here. One is is the patient population that the
11 measure addresses too narrow, and is it either
12 unimportant -- that's not the evidence part -- or
13 there isn't enough evidence in this subgroup of a
14 subgroup, if you will.

15 The second is the way the measure's
16 specified, which I think is a separate issue, it
17 is -- and the developer's laid this out pretty
18 well. The way it's specified is as a fraction of
19 scans, inappropriate scans as a fraction of
20 scans. The other way you can think of it is as a
21 fraction of people. I agree that it's more
22 natural to think of it as a fraction of people.

1 It's what they call an inappropriate use measure.
2 They're calling this an overuse measure. In both
3 cases, the target should be zero, but that's a
4 separate issue. That's how they've specified it.
5 I don't think that's the evidence or gap.

6 CO-CHAIR SUSMAN: I think it boils
7 down to we know there's a lot of overuse of
8 scans, but we're looking at this as an overuse
9 measurement and is there a gap there? Questions
10 of whether that exists. Developer, do you have
11 an answer for Jeff?

12 DR. MACY: Yes. First I'd like to
13 note that this was a determined priority of CMS
14 for the nation. We have a denominator of
15 children with post-traumatic headache of 5,912,
16 based on ICD-9 codes that include the specific
17 code for post-traumatic headache, as well as
18 concussion without loss of consciousness.

19 CO-CHAIR SUSMAN: Okay, Jim?

20 MEMBER DUNCAN: I don't think we've
21 yet seen a performance gap at the health plan
22 level. Most of us will quote data showing

1 hospital-to-hospital variation or
2 physician-to-physician ordering variation. I
3 don't know if I've yet seen evidence that there's
4 performance gaps at the health plan level, nor
5 did, I think, in the submitted materials did we
6 see that.

7 CO-CHAIR SUSMAN: Yes, so there's, I
8 think, some important issues that have been
9 raised. Is there any other further comment? If
10 not, I'd suggest we vote on gap.

11 MS. CHAVEZ: Now voting on gap for
12 Measure 2802, 1 high, 2 moderate, 3 low, 4
13 insufficient. Voting's open, 25, 27, 2 voted
14 high, 9 voted moderate, 11 voted low, 5 voted
15 insufficient.

16 CO-CHAIR SUSMAN: My reckoning of this
17 is it does not pass on this, is that correct?

18 MS. CHAVEZ: This puts us in the gray
19 zone.

20 DR. NISHIMI: No, we have 27 votes now,
21 though, so it's --

22 CO-CHAIR SUSMAN: Please.

1 DR. NISHIMI: You need 17 to pass.

2 (Simultaneous speaking.)

3 CO-CHAIR SUSMAN: Do you want us to
4 continue, I guess, is the operative question?

5 It's right on the border. It's gray
6 zone. We will continue and let NQF staff sort
7 out how they treat this. Moving right along,
8 we've considered gaps, and now we get to
9 reliability. Any comments on scientific
10 reliability? Jim?

11 MEMBER WHITE: This is Keith. One of
12 the concerns I have, because this relies on chart
13 review, and because -- and maybe the developers
14 could clarify a little bit more, when it talks
15 about identifying the neurologic findings that
16 would warrant the testing, there's, I think, a
17 great deal of subjectivity there. I think
18 there's a question about how reliably the data
19 could be collected with chart reviews, especially
20 where the measure is somewhat vague on what
21 constitutes the specific neurologic indications
22 for concern.

1 CO-CHAIR SUSMAN: Does the developer
2 want to comment?

3 DR. MACY: Yes, we had a high degree
4 of reliability between the chart review elements
5 across our data abstractors. It was 99 percent,
6 with a Kappa of .98.

7 CO-CHAIR SUSMAN: I'm going to go to
8 Jim.

9 MEMBER DUNCAN: I always worry about
10 very, very high values in agreement on something
11 that I think is going to be very subjective in
12 reviewing charts. Also, especially when you blow
13 this up to try and review charts across the
14 country, and with a pretty low number of charts
15 being reviewed at any particular site or with any
16 particular health plan, you're probably going to
17 get different reviewers and abstractors. I don't
18 know if that reliability would hold.

19 CO-CHAIR SUSMAN: Okay, Jeff.

20 MEMBER SCHIFF: The numerator
21 exclusions are on the top of Page 28, and they
22 are abnormal neurologic signs and symptoms of

1 intracranial pressure increased, intracranial
2 pressure, e.g. decreased alertness, altered
3 mental status, GCS less than 14, gait
4 disturbance.

5 I have to tell you that my concern is
6 that if this becomes a health plan level measure
7 by which ER docs are somehow held accountable to
8 health plans, we already document these things
9 when I want to do a CAT scan, and if I know I
10 have to meet the criteria, they will always meet
11 these. So it may or may not be that the Kappa
12 will be variable depending on how well documented
13 it is. My concern is that we're going to create
14 a market or a process by which people will
15 document well, rather than get to an exclusion,
16 if that makes sense.

17 CO-CHAIR SUSMAN: Probably use your
18 microphone if you're going to make comments. I'm
19 sorry.

20 MEMBER SCHIFF: We never imagine
21 otitis in the emergency room, Dr. Moyer.

22 MEMBER MOYER: Got it.

1 CO-CHAIR SUSMAN: Okay, that's all off
2 the record, thank you. Any other comments about
3 the reliability? I think if we go -- yes, Kevin?

4 MEMBER SLAVIN: Maybe I missed this in
5 what Jeff had just said, but is there a list or a
6 tool to identify the history of the other medical
7 conditions that would warrant neuro-imaging? I'm
8 specifically thinking of things like genetic
9 collagen disorders that prone vessels to rupture,
10 or other types of medical conditions where
11 neuro-imaging might be indicated, even in the
12 absence of specific findings.

13 DR. MACY: We do have an extensive
14 list based on ICD-9-CM codes that were translated
15 over to ICD-10-CM codes that are included in our
16 documentation.

17 CO-CHAIR SUSMAN: And the testing here
18 was also at the element level for validity, which
19 I think will reflect back to the reliability
20 testing that we've discussed in prior measures
21 here, and not just the inter-rater reliability.
22 David, did you have a comment?

1 MEMBER KELLER: Yes, just a question,
2 based on what you just said. So the exclusions
3 are applied at the coding level, not by the chart
4 abstractor? I would have thought you'd also want
5 to have a list of diagnoses or trigger words that
6 you'd be looking for in chart abstraction that
7 were not code based, or at least most of us don't
8 write codes in our notes.

9 DR. MACY: We used the ICD-9-CM codes
10 to screen the administrative data for the
11 presence of those conditions, and then with the
12 chart review, those different kind of categories,
13 like sickle cell disease and blood dyscrasias
14 were included. Brain tumors were included for
15 things that people were looking for in the chart.

16 CO-CHAIR SUSMAN: Thank you. Any
17 other discussion of reliability? Okay, let's
18 move to vote, 1 high, 2 moderate, 3 low, 4
19 insufficient on reliability. I think Robyn has a
20 comment.

21 DR. NISHIMI: Yes, I just wanted -- a
22 reminder that this is at the performance element

1 level, so the highest eligible score is moderate.

2 CO-CHAIR SUSMAN: Is moderate, yes.

3 Thank you.

4 MS. CHAVEZ: Now voting on
5 reliability. Voting is open, 20, 26, 27, 0 voted
6 high, 12 voted moderate, 13 voted low, 2 voted
7 insufficient, and this takes us in the gray zone.

8 CO-CHAIR SUSMAN: Another measure in
9 the gray zone. Let us press on to validity.
10 Comments on validity, Jim or Keith, others?
11 There was empirical validity testing done at the
12 element level, for what that is worth.

13 MEMBER DUNCAN: The validity testing,
14 as I read through the measure, was not on the
15 data level. It's really the expert panel face
16 validity, is that correct?

17 CO-CHAIR SUSMAN: Measure developer,
18 please clarify. I thought there was element
19 validity.

20 DR. MACY: We do have element
21 validity.

22 CO-CHAIR SUSMAN: Thanks. Ricardo.

1 MEMBER QUINONEZ: My biggest concern
2 with validity here is that it -- to me, again, it
3 just fails to pass that this measure would
4 adequately measure quality of care provided,
5 again, because of the numerator, the way it's
6 written. That, to me, would make it not valid
7 for the spirit and the intent of the measure.

8 CO-CHAIR SUSMAN: It's going to be
9 difficult, I think, for some of us to separate
10 out how we view this and where we vote our
11 conscience on this, so thank you. Any other
12 comments about validity? If not, I'd suggest we
13 go ahead and vote, 1 high, 2 moderate, 3 low, 4
14 insufficient.

15 MS. CHAVEZ: Now voting on validity.
16 Voting is open, 18, 25, 27, 1 voted high, 8 voted
17 moderate, 17 voted low, 1 voted insufficient.
18 This measure does not pass validity.

19 CO-CHAIR SUSMAN: I think we actually
20 have gone beyond the gray zone to the death zone.
21 This measure didn't make it. I think everybody
22 agrees that overuse of imaging is an important

1 concern. What I've heard is that by limiting it
2 to those with headache who have neuro-imaging,
3 the definition, whether it be by CMS, at least
4 those of us in the field feel like we have
5 rarefied the sample so much that it will have
6 much less impact, will be much more prone to
7 error, and have some problems.

8 While we recognize when you're given
9 a task order from CMS you have to follow their
10 instructions, there might be some feedback from
11 us that would be useful. Let me go ahead and get
12 further comment first from Jim, then Jeff.

13 MEMBER DUNCAN: As I said before,
14 personal experience, when I was a radiology
15 resident, my 2-year-old son fell, hit the floor,
16 loud thunk in the other room, screaming. Scoop
17 him up, drive --

18 Yes, ludicrous levels to the emergency
19 room. Luckily I went to a children's hospital,
20 where they looked at them, calmed me down,
21 recognized that he was calming down, and gave me
22 the list of instructions and sent me home. My

1 son is now fine. I guess the thought was that I
2 want to thank the people that made a good
3 decision at that point and recognize that they
4 just wouldn't have gotten credit for that good
5 decision in this algorithm. Again, if we're
6 trying to improve best practice, that's, I guess,
7 the tweak that I was thinking.

8 CO-CHAIR SUSMAN: Thank you. Jeff.

9 MEMBER SCHIFF: This is both to the
10 committee and to the developer. I think that
11 there's a little bit of a message that I think we
12 need to have the ability to say to CMS, which is
13 along those lines. One is that we need to look
14 at a broader message, as Jim said, that doesn't
15 cut that denominator so small that it becomes not
16 relevant. That's not the developer's fault.
17 It's the task order they were given.

18 Then the second thing is that
19 measuring this at the health plan, in many states
20 where the health plans overlap, especially of
21 children's institutions, is gigantic seems to be
22 an inappropriate level of accountability. I

1 think those are two messages that I just wanted
2 -- more for the fact that I think the developer
3 tried hard to get a peg to fit into a certain
4 sized hole.

5 CO-CHAIR SUSMAN: Yes, I think to make
6 it clear to the developer, the data, the
7 information, the forms were very well filled out,
8 clear. You were given a thankless task, if you
9 will. I'm going to go around the room, get the
10 final comments. John.

11 CO-CHAIR BROOKEY: Yes, I just want to
12 kind of restate the obvious, but I deal with peer
13 review across all disciplines where I work. I
14 continually challenge our ED physicians and our
15 family practice doctors to provide the same level
16 of care that a pediatrician would provide.
17 Pediatricians do exactly what you just described
18 every single day.

19 Every single day they're in clinic
20 they have a kid that bumps their head. But if
21 the kid shows up in a pedes clinic, they're going
22 to get a different recommendation, often, than if

1 they show up in urgent care or family practice or
2 the ED. So the one aspiration that I have is to
3 try to have the same care for the children
4 wherever they go. So for developers, I hope they
5 keep that in mind because that really would be my
6 goal.

7 CO-CHAIR SUSMAN: A laudable one.

8 Finally?

9 MEMBER MORROW-GORTON: I wanted to
10 echo what Jeff said about doing this at a health
11 plan level, as opposed to a hospital or provider
12 level. But the other thing I wanted to say was
13 that I think in -- while your numbers ended up
14 being very small, having a concentration on a
15 single reason actually makes it easier to
16 remediate -- and sorry to use CMS language -- to
17 improve, in the end, because you have a single
18 reason -- a single way to address it, rather than
19 having multiple causes all lumped together. So
20 for whatever that's worth, I think there was some
21 value in thinking about it from that vantage
22 point.

1 CO-CHAIR SUSMAN: Thank you very much.
2 I think these were very useful comments and
3 appreciate the committee's hard work. We're
4 making the executive decision here to take a
5 break. I can see people squirming in their
6 seats. Let's try to be back by 25 after, so that
7 we can continue to get through this large dose of
8 measures. Thank you.

9 (Whereupon, the above-entitled meeting
10 went off the record at 10:11 a.m. and resumed at
11 10:22 a.m.)

12 CO-CHAIR SUSMAN: Okay, we're going to
13 go ahead and get started. The next measure we're
14 going to be considering is transcranial Doppler
15 ultrasonography screening among children with
16 sickle cell anemia. This is another Q-METRIC
17 measure from the University of Michigan, No.
18 2797. Gary Freed, Julie McCormick, or whoever,
19 are you on the phone?

20 DR. REEVES: Hi, this is Sarah Reeves.
21 I'm an epidemiologist on the Q-METRIC team. I'll
22 be the developer for this measure.

1 CO-CHAIR SUSMAN: Thank you, Sarah.
2 Are there any people who asked to recuse
3 themselves? I saw Jonathan Finkelstein.

4 No, forget that. It's wrong here.
5 Developer, would you please give us an overview
6 of the measure and the information behind it?
7 Thank you.

8 DR. REEVES: Absolutely, thank you.
9 This measure assesses the percentage of children
10 ages 2 through 15 that have sickle cell anemia
11 who received at least one transcranial Doppler
12 screening within a year. Currently, there are no
13 NQF-endorsed quality measures for children with
14 sickle cell disease, and development of quality
15 measures for sickle cell was determined by CMS,
16 through a public process, to be a priority for
17 the nation.

18 This measure specifically is supported
19 by strong evidence because without intervention,
20 11 percent of children with sickle cell anemia
21 will have a stroke by the age of 18.
22 Importantly, these strokes can largely be

1 prevented. Transcranial Doppler or TCD screening
2 is a non-invasive ultrasound method to identify
3 children that are at high risk of stroke.

4 TCD measures the blood velocities in
5 the brain and among those with highest risk,
6 receipt of chronic blood transfusion can
7 dramatically reduce the risk of stroke. In a
8 randomized control trial, a 92 percent reduction
9 of risk was observed. Given the fact that TCD is
10 the only method in which to identify which
11 children with sickle cell anemia are at the
12 highest risk of stroke, an expert panel at the
13 National Heart, Lung and Blood Institute, or
14 NHLBI, strongly recommends that all children with
15 sickle cell anemia should receive one TCD
16 screening per year from ages 2 up until 16.
17 Therefore, in concordance with these NHLBI
18 guidelines, our measure uses administrative
19 claims to assess the proportion of children ages
20 2 through 15 with sickle cell anemia that receive
21 a TCD screen within a year.

22 As you know, there are many hemoglobin

1 variations, and our measure focuses specifically
2 on HBFS or sickle cell anemia cases, and this is
3 consistent with the NHLBI recommendations. Our
4 denominator is the number of children with sickle
5 cell anemia identified through the presence of at
6 least three sickle cell anemia claims within a
7 year.

8 Our denominator definition has both
9 high sensitivity and specificity to identify
10 these children, as compared to the gold standard
11 of newborn screening records. Our numerator is
12 the number of children with sickle cell anemia
13 that receive a TCD screen, and this is identified
14 using administrative claims. Again, we found
15 that this method was valid as it was highly
16 correlated with the TCD screens found within the
17 medical record. In addition to the evidence that
18 our definitions of numerators and denominators
19 were valid, we performed a signal-to-noise
20 analysis using Medicaid data across six different
21 states. We found that the reliability of this
22 measure was extremely high using this method, as

1 all reliability coefficients were over .96 on a
2 scale of 0 to 1.

3 We then used the same Medicaid data
4 from the six states to assess the TCD screening
5 rates from 2005 to 2010. Across the period, TCD
6 screening rates ranged from 7 percent to 51
7 percent, depending on the state, and they did
8 increase over time. However, the average
9 screening rate in 2010 was still only around 38
10 percent, indicating that there is substantial
11 opportunities for improvement.

12 In closing, we do feel that this
13 measure is highly important, and it has the
14 potential to make a positive impact on the
15 quality of children's lives. Our measure focuses
16 on TCD screening, which is currently the only
17 method in which to identify children with sickle
18 cell anemia that need to initiate stroke
19 prevention efforts. We found that this measure
20 is highly reliable and valid, and that the data
21 elements to calculate this measure are readily
22 available and administratively straightforward.

1 Finally, we found that there is an
2 important performance gap, and we strongly
3 believe that endorsement of this measure can have
4 a positive impact on the health of these
5 high-risk children. We very much look forward to
6 addressing any questions or concerns that you may
7 have. Thank you for your time.

8 CO-CHAIR SUSMAN: Thank you so much.
9 We should record that as an example of a great
10 succinct and complete presentation. With that,
11 let me turn it over to Jim, first, to see if he
12 has some comments or questions, and then maybe
13 some discussion around evidence.

14 MEMBER DUNCAN: I think there's a very
15 strong level of evidence, given the NHLBI's
16 recommendation and systematic review. There's
17 also, I think, quite feasible, as their data
18 extraction showed the only concern, and they
19 really did the testing to assess the difficulty
20 of identifying children with sickle cell anemia
21 and requiring three separate iterations of the
22 appropriate code in the medical record. I think

1 the subgroup, as we talked about it, said just
2 like their summary was so succinct and straight
3 on that the measure seems that way.

4 CO-CHAIR SUSMAN: Very good. Keith,
5 any further comments? Hearing none from Keith,
6 John, do you want to add anything?

7 CO-CHAIR BROOKEY: No, I think this is
8 one of the measures that seemed to have the
9 strongest evidence and reliability and validity.
10 The only thing that we did talk about -- it's not
11 going to be addressed in this measure -- is that
12 there may be variation from center to center, in
13 terms of the quality of the studies, but that
14 doesn't preclude having this measure go forward
15 because of the importance of the measure and,
16 really, the ease of measuring it and the
17 importance of identifying these children early.

18 CO-CHAIR SUSMAN: I invite questions
19 from the group. I see Ricardo.

20 MEMBER WHITE: I'm sorry to interrupt.
21 This is Keith. I was talking before on mute. I
22 apologize.

1 (Simultaneous speaking.)

2 CO-CHAIR SUSMAN: It was fabulous
3 comments. We loved your insights.

4 MEMBER WHITE: They were brief,
5 weren't they? I just was interested again in the
6 methodology used for the transcranial Doppler and
7 the availability of that across the country. Are
8 there any issues or questions with access of
9 skillset and expertise in performing this exam
10 geographically?

11 CO-CHAIR SUSMAN: Any comments from
12 the panel? John, you were mentioning --

13 CO-CHAIR BROOKEY: -- whispering over
14 here. Our sickle cell experts, even within Los
15 Angeles, feel there are definitely some centers
16 that they rely on more than others, so I think
17 there is intercenter issues, in terms of -- I
18 think there's some variability that, again, this
19 measure is probably not going to address. But
20 again, as I mentioned before, I don't think it
21 precludes moving forward.

22 It's just I think that is an issue

1 that will have to be addressed separately. I was
2 thinking that it's probably going to hopefully
3 coordinate the care of children with the severe
4 sickle cell because the imaging is only part of a
5 therapy. Trying to monitor and treat these
6 children on an island would be extraordinarily
7 difficult.

8 CO-CHAIR SUSMAN: Okay, Ricardo.

9 MEMBER QUINONEZ: Just a quick
10 clarification of whether we can vote all four,
11 since I didn't see any mention of grading of the
12 evidence or performance of a comprehensive
13 review, other than the NHLBI guideline.

14 CO-CHAIR SUSMAN: I think, actually,
15 there was based on a systematic review of the
16 evidence, and then was ranked a strong
17 recommendation with moderate quality evidence.
18 When looked at the guts of that previously, I
19 think it's actually there pretty explicitly. I
20 don't know if our developer wants to comment on
21 that.

22 DR. REEVES: Absolutely. The NHLBI

1 guidelines do exist, but also, there was a
2 systematic review of about at least 50
3 observational studies in two randomized control
4 trials, and the evidence from all of that
5 collectively was rated as moderate quality
6 evidence with a strong recommendation.

7 CO-CHAIR SUSMAN: Thank you. Is that
8 okay, Ricardo? Okay, Kerri.

9 MEMBER FEI: I have no doubt that this
10 measure is very appropriate for the Medicaid
11 population. I'd like to see testing in the
12 commercial, to make sure that it would function
13 the same in the commercial health plan
14 population.

15 CO-CHAIR SUSMAN: Okay, any other
16 questions about evidence? Debbie.

17 MEMBER FATTORI: Just to add to
18 Kerri's comment, I believe after a relatively
19 short period of time, most patients with sickle
20 cell disease do qualify for Medicaid, so I think
21 the vast majority of those patients do get
22 shifted to that insurance carrier pretty quickly.

1 DR. REEVES: That's actually true. We
2 found at least 70 percent of children with sickle
3 cell anemia are enrolled in Medicaid.

4 MEMBER FATTORI: Right, and that's --
5 if it's going to be listed in the NQF site as a
6 health plan measure if it does get endorsed, it
7 might not be all health plans that are able to
8 implement, use, and get reliable results.

9 DR. BURSTIN: It's a really
10 interesting point, Kerri. We don't typically
11 make that distinction. I think the key thing
12 would be people would need to consider sample
13 size and appropriateness. Not every measure
14 should be used for everything, but we would say
15 it's appropriate for the health plan, and
16 obviously you'd need to consider whether it's
17 logical. As those measures get selected for use,
18 there'd be a lot of discussion of exactly the
19 point you raised, but not so much on the
20 endorsement side.

21 CO-CHAIR SUSMAN: Other questions,
22 particularly now, about the evidence? Kevin?

1 MEMBER SLAVIN: Just in terms of the
2 evidence and the timing of the transcranial
3 Doppler studies and the recommendation, is it
4 once per calendar year, once per year depending
5 on when the last study was done, just some stuff
6 about that, in terms of what the recommendations
7 actually specify?

8 CO-CHAIR SUSMAN: I'll let the
9 developer respond.

10 DR. REEVES: The recommendations are
11 specifically for one TCD annually, from ages 2 to
12 16 years old.

13 CO-CHAIR BROOKEY: Meaning a rolling
14 12 months, right?

15 DR. REEVES: Correct.

16 CO-CHAIR SUSMAN: Any other
17 clarifications, questions, comments? Okay, let's
18 go on then to vote on evidence. We have 1 for
19 high, 2 for moderate -- oh, I'm taking your job.

20 MS. CHAVEZ: Thank you. Now voting on
21 Measure 2797 on evidence, 1 high, 2 moderate, 3
22 low, 4 insufficient, and we are expecting 27

1 votes. Voting's open, 23, 27.

2 CO-CHAIR SUSMAN: I'm happy to trade
3 jobs with you for a while.

4 MS. CHAVEZ: Okay, 18 voted high, 8
5 voted moderate, 1 voted low, 0 voted
6 insufficient. This measure passes evidence.

7 CO-CHAIR SUSMAN: As John was saying,
8 it's probably the strongest one we've had thus
9 far. Okay, so let's move on to the gap,
10 opportunity for improvement. I think there's
11 fairly clear documentation. Jim.

12 MEMBER DUNCAN: Right. I thought the
13 Medicaid data that they submitted, while it isn't
14 current, was showing that there were gaps from
15 state to state, and also a pattern towards
16 improvement.

17 CO-CHAIR SUSMAN: Okay. Amy, did you
18 --

19 MEMBER HOUTROW: I just wanted to say
20 it was pretty obvious, given the range of
21 reported percentage of children that received
22 them, that there's a large practice area of

1 variation that is evidence of the gap. We're not
2 going to find ethnic disparities, and we're not
3 going to find likely socioeconomic disparities,
4 given that a vast majority of these children will
5 be in a Medicaid population.

6 CO-CHAIR SUSMAN: Okay. Other
7 questions about gap? If not, let's go ahead, 1
8 high, 2 moderate, 3 low, 4 insufficient.

9 MS. CHAVEZ: Now voting on gap.
10 Voting is open, 22, 25, 26.

11 CO-CHAIR SUSMAN: Lauren, we're
12 waiting on your vote, please, if you're there.

13 MEMBER AGORATUS: Sorry, I did it, but
14 I'll put it through again.

15 DR. NISHIMI: Okay, we got it.

16 CO-CHAIR SUSMAN: Okay, so maybe just
17 add the one vote to the total count.

18 MS. CHAVEZ: So it would be 23 high,
19 4 moderate, 0 low, 0 insufficient.

20 CO-CHAIR SUSMAN: Okay, thank you, so
21 passes on gap. Let's move forward to
22 reliability. Any comments on the reliability? I

1 think there was signal-to-noise testing. There
2 was actual testing at the performance level.

3 MEMBER DUNCAN: What I saw was that
4 the exam is coded, very reliable. The only
5 concern was identifying the children with sickle
6 cell, and again, they worked through a process to
7 show their reliability.

8 CO-CHAIR SUSMAN: Any questions?
9 Ricardo, do you have a question, or are you just
10 -- yes, okay, no problem. Then let's go ahead
11 and vote on -- oh, excuse me. I'm sorry.

12 MEMBER MORROW-GORTON: I just have a
13 procedural question.

14 CO-CHAIR SUSMAN: Please.

15 MEMBER MORROW-GORTON: The notes say
16 that the rating may be high or moderate, and
17 those are the only choices, correct?

18 DR. NISHIMI: I'm sorry. It should be
19 all four. It's eligible for the highest, though,
20 because it's at the performance core.

21 CO-CHAIR SUSMAN: Vote your conscience
22 here on reliability, and it can be any of the

1 four ratings.

2 MS. CHAVEZ: 1 high, 2 moderate, 3
3 low, 4 insufficient. Voting's open.

4 CO-CHAIR SUSMAN: Thank you, Vanna.

5 MS. CHAVEZ: Twenty-four.

6 CO-CHAIR SUSMAN: We're having the
7 sidebar. Is Vanna still out there? Does anybody
8 know?

9 MS. CHAVEZ: Twenty-six, 26. Okay, so
10 we are expecting 26 votes. Seventeen voted high,
11 nine voted moderate, zero for low, zero
12 insufficient. This measure passes reliability.

13 CO-CHAIR SUSMAN: Let's move on to
14 validity. Comments, Keith, Jim, others who took
15 a look at this?

16 MEMBER WHITE: From the articles cited
17 and the research that's done, it's clearly
18 indicative that there's a valid, indisputable
19 link between the abnormal ultrasound findings and
20 the incidence of stroke, so I'd say it's a very
21 valid measure.

22 CO-CHAIR SUSMAN: And the validity

1 testing about case definitions seem to be done,
2 so -- any questions? Okay, if not, let's vote on
3 validity, 1 high, 2 moderate, 3 low, 4
4 insufficient.

5 MS. CHAVEZ: Voting is open, again
6 expecting 26 votes, 24, 26. Twenty voted high,
7 six voted moderate, zero low, zero insufficient.
8 This measure passes validity.

9 CO-CHAIR SUSMAN: Feasibility.
10 Comments on feasibility? This seems like --

11 MEMBER WHITE: I think with the
12 administrative claims data, it's going to be
13 almost plug and play. It would be very easy to
14 collect the data.

15 MEMBER DUNCAN: I think their Medicaid
16 data that they collected clearly shows that.

17 CO-CHAIR SUSMAN: This is a health plan
18 measure, administrative data, documented. Let's
19 go ahead and vote on feasibility, 1 high, 2
20 moderate, 3 low, 4 insufficient. You almost beat
21 me to it.

22 MS. CHAVEZ: Voting's open.

1 CO-CHAIR SUSMAN: This is going to be
2 like -- who's Vanna's partner on the show, since
3 I don't -- it'd be like Pat Sajak spinning the
4 wheel or -- gosh. Yeah, turning the letters over.

5 MS. CHAVEZ: Okay, we did get our 26
6 votes. Twenty-four voted high, two voted
7 moderate, zero for low, zero insufficient. This
8 measure passes feasibility.

9 CO-CHAIR SUSMAN: Usability now.
10 Usability.

11 MEMBER DUNCAN: The only comment I saw
12 was that it would be -- if the New York State
13 data is available, and also sort of seeing it go
14 forward. I think that's a minor -- it doesn't
15 impact usability.

16 CO-CHAIR SUSMAN: Any questions on the
17 usability of this measure? Your turn.

18 MS. CHAVEZ: Okay, voting on
19 usability, 1 high, 2 moderate, 3 low, 4
20 insufficient. Voting's open, we're looking for
21 26 votes, 22, 26. Twenty-two voted high, four
22 voted moderate, zero for low, zero insufficient.

1 This measure passes usability and use.

2 CO-CHAIR SUSMAN: So we can vote on
3 the overall measure. I think there's been pretty
4 consistent feeling about this one. Is there any
5 final comment? If not --

6 MS. CHAVEZ: Now voting on Measure
7 2797 for its overall suitability for endorsement,
8 1 yes, 2 no. Voting's open.

9 CO-CHAIR SUSMAN: Can I buy a vowel?

10 MS. CHAVEZ: Twenty-three, 26. Twenty-
11 six voted yes, 0 no. This measure, 2797 --

12 CO-CHAIR SUSMAN: Congratulations.

13 MS. CHAVEZ: -- has been recommended
14 for endorsement.

15 CO-CHAIR SUSMAN: Thank you to our
16 measure developer.

17 DR. REEVES: Thank you guys very much.

18 CO-CHAIR SUSMAN: That's probably the
19 first person who leaves real happy.

20 (Laughter.)

21 CO-CHAIR SUSMAN: Including -- yes,
22 John and I are ecstatic over here. Am I doing

1 this one, or are you doing this one?

2 (Pause.)

3 CO-CHAIR SUSMAN: So we're going to
4 move on and do the mental health follow-up
5 measure, Timeliness 1, delayed coordination of
6 care following mental health discharge. This is
7 2815. It's collaboration for pediatric quality
8 measures, CAPQuaM.

9 MEMBER WHITE: This is Keith. I'm
10 going to sign off the meeting now. I don't think
11 I'm going to be contributing much to the
12 remainder.

13 CO-CHAIR SUSMAN: Thank you very much,
14 Keith. We really appreciate your help and
15 expertise.

16 MEMBER WHITE: Thank you.

17 CO-CHAIR SUSMAN: Do we have the
18 developers either here in person -- yes, here
19 they are, materializing from the ether.

20 So, introduce yourselves, and then
21 provide us a brief overview. I like that
22 contraption you have for your glasses. That's

1 interesting. Good design.

2 DR. KLEINMAN: It's a wonderful
3 adjunct to aging.

4 CO-CHAIR SUSMAN: There you go.

5 (Laughter.)

6 DR. KLEINMAN: I'm Larry Kleinman.
7 I'm the PI of the Collaboration for Advancing
8 Pediatric Quality Measures, one of the seven
9 CHIPRA centers. I'm joined by Dr. Eyal Shemesh,
10 who was the co-lead with me in developing this
11 measure.

12 Dr. Shemesh is a pediatrician, a
13 psychiatrist, and a child psychiatrist, so
14 clearly overqualified for most tasks, but ideally
15 qualified for this one. I'm very pleased to be
16 here. First, I actually, having been here for
17 much of yesterday and some of this morning, I
18 want to express my appreciation for the work all
19 of you are doing and acknowledge the challenge
20 that you're facing.

21 There are seven centers of excellence
22 that emerged from a peer review competition among

1 many worthy applicants. Some of you may have
2 been among them. We're all presenting, really,
3 new science that is trying to move the field
4 forward, and you're being asked to do an
5 assessment of the standards of that, which I
6 think is an incredibly hard task. I want to
7 share with you the pediatric quality measures
8 program, some of the tasks that we were asked to
9 do, because I think this context will be helpful
10 in understanding some of how we went about our
11 measure development -- was to improve and
12 strengthen children's healthcare quality
13 measures, including expanding on existing
14 pediatric quality measures and advancing their
15 development, with the goal of increasing the
16 portfolio of quality measures available to public
17 and private purchasers of children's healthcare
18 services, providers and consumers.

19 That's all language from the act that
20 funded us. I want to start with -- our approach
21 began with the IOM definition of quality, which
22 is the degree to which health services for

1 individuals and populations increase the
2 likelihood of desired health outcomes and are
3 consistent with current professional knowledge.

4 In this view, quality is a continuum,
5 and not a dichotomy of good and bad, which is one
6 of the things that also makes it more challenging
7 in this endorsement context. It also
8 acknowledges that uncertainty exists and we're
9 making decisions in measures that reflect the
10 best of what we know. I'll also note that the
11 IOM created -- or, identified six key attributes
12 or domains of quality, and timeliness is one of
13 them.

14 The peer review process that we used
15 -- and I want to spend a little time on this; I
16 know we don't have very much time -- because on
17 the call, it was clear that some of you didn't
18 know why this didn't come out of thin air. Our
19 process began with the principle that it's
20 possible to develop excellent quality measures
21 even when there's meaningful uncertainty, and
22 that medicine is a clinical practice for which

1 the evidence is rarely dispositive for any
2 specific patient.

3 One corollary to that is there may be
4 more than one good measure. The challenge for
5 you is to identify whether this is one of them.
6 Our 360-degree process starts with an assignment
7 from AHRQ and CMS, so these were topics that the
8 feds thought were important. We did a scoping
9 literature review, started with several thousand
10 articles, leading to 653 articles being
11 abstracted and reviewed and incorporated into our
12 expert process. We had a parent focus group. We
13 had discussions with clinical practitioners, and
14 then we had a RAND-style expert panel that had
15 pediatricians, a family doc, a discharge planner,
16 hospitalist, psychiatrist, child psychiatrist,
17 psychologist, and a patient navigator all on the
18 committee.

19 We asked the committee to develop
20 explicit criteria to guide the measure
21 development, and from that, we developed
22 something we called a boundary guideline. I'm

1 not going to go into it, but we had a formal and
2 pre-specified process for doing this. Then our
3 staff worked with our stakeholders and our
4 steering committee to develop and refine the
5 measures.

6 We had a broad array of stakeholders,
7 and then we would consult the expert panel as
8 necessary and appropriate along the lines of that
9 path. Outside the process -- and this is not in
10 anything you have, but in response to the
11 committee and to NQF's feedback, we sent the
12 measure to the expert panel, as it's specified,
13 and a strong majority of them have said yes, that
14 it is a good measure and that they support its
15 use. We build off the NQF-endorsed HEDIS measure
16 as good stewards of our federal funding. We did
17 not reassess data at the element level, rather
18 used administrative data as the established
19 standard that had been demonstrated in the NCQA
20 submission previously.

21 The construct validity, as provided by
22 the expert panel process, who assessed the

1 capacity -- I'm sorry, and then we assessed the
2 capacity of the measure to distinguish between
3 different levels of care, which we established in
4 an iterative set of testing with our partners in
5 New York State Medicaid using a year of New York
6 State Medicaid data. We did this in consultation
7 with our steering committee.

8 We went through nine rounds, that I
9 could identify, of assessment using a full year
10 of New York State Medicaid data to end up where
11 we are today. There was a question from the
12 committee about why primary care physicians. We
13 found in the New York State data that the absence
14 of primary care physician visits and,
15 independently, the absence of mental health
16 visits, and jointly even more so, was associated
17 with a higher re-admission rate. The smallest of
18 the signal-to-noise ratios measured as a
19 difference over co-efficient of -- I'm sorry,
20 over standard error was four, of those three
21 categories. We also analyzed national data and
22 have shown high levels of comorbidity in

1 concomitant use of mental health and physical
2 health drugs, also providing a clinical
3 justification and rationale for why both are
4 important.

5 This is a novel contribution to the
6 measure, one of the specific enhancements, in
7 addition to simply optimizing for a child age
8 range. We sent to the committee, in our written
9 response, the expert panel results regarding
10 timing, use of ICD-9 and other things. I'm happy
11 to get specific if you have questions and go over
12 any of that.

13 But I want to acknowledge that it's
14 not the only meaningful timing. We were given
15 the opportunity to submit one measure, so we
16 submitted this one. But there was a timeliness
17 measure, there was an absence measure, and there
18 was a delay measure. This is the delay measure,
19 which we chose to submit after consulting with
20 some clinical experts. There was a question
21 specifically regarding follow up the same day.
22 We addressed it in the response. But some of the

1 reasons that's problematic is it provides no
2 insight as to the status of the patient as an
3 outpatient, so it reflects the inpatient care.

4 It's a measure that can be easily
5 gained, and in our data, we found that people who
6 had visits on the day of discharge were very
7 unlikely to be followed up with a second visit,
8 even within another 30 days, so it doesn't seem
9 to be establishing, actually, follow-up care.
10 It's just a visit.

11 That wasn't the construct we were
12 going for, and our panel has endorsed this. In
13 conclusion, we set out to optimize the HEDIS
14 measure for children. We're convinced we've done
15 so in a rigorous, clinically meaningful and
16 evidence-grounded fashion, and I look forward to
17 being a resource to help you answer whatever
18 questions you have. Thank you.

19 CO-CHAIR SUSMAN: Thank you very much
20 in your responsiveness to our subcommittee's
21 request for information. Let's go ahead, then,
22 and ask our chief discussants here, Jim maybe

1 first, and then we'll go down the line here.

2 MEMBER DUNCAN: Going through the
3 algorithm, I think one -- and on the workgroup
4 call, one of the primary concerns is that is
5 there strong evidence showing that this measure
6 is related to an outcome, and a lot of concerns
7 that 30 days -- clearly an arbitrary number. I
8 know it's a little bit different, also, from your
9 expert panel. Really, it's driven by largely the
10 opinion of an expert panel, rather than testing
11 data from the literature.

12 DR. KLEINMAN: The re-admissions data
13 was actually using the 30-day measure, so that
14 actually -- that's with a full, large state of
15 Medicaid data, which is one of the obvious
16 important consumers of this. There's good
17 evidence that delayed follow up is associated
18 with re-admissions.

19 We sent you one of the articles in the
20 summary from their abstract about that, that
21 absence of visits hasn't -- might be in there,
22 plus the expert panel did endorse it. I want to

1 say that they actually did -- the expert panel
2 said 30 days was okay, both a priority and in our
3 assessment of the overall measure. They also
4 would've been fine with 28 days, but in an effort
5 to harmonize with existing data, we were not
6 looking to gild the lily. We were looking to
7 make a practical, useful, helpful measure.

8 CO-CHAIR SUSMAN: Deb.

9 MEMBER FATTORI: Just to speak first
10 to the evidence, in the summary that we have that
11 NQF put together for us and part of the
12 discussion that we had in our subgroup meeting,
13 there wasn't a systematic review done for
14 evidence. Is that -- could you describe that a
15 little bit?

16 DR. KLEINMAN: There was a systematic
17 review. We didn't grade evidence. We felt, as
18 do many, that the grading of evidence into levels
19 of A, B, C, D or otherwise creates false
20 distinctions. The question is what is the power
21 of the information that's there? We let our
22 expert panel -- because we gave them a 40-page

1 literature review.

2 It was systematically done, and we
3 outlined some of that in the response. We
4 actually read 653 articles in the literature, so
5 we looked at things like does follow up make a
6 difference, can interventions change follow up?
7 Specifically, we asked is IT a requisite part of
8 that, as part of our review. It was done very
9 systematically, planned, with a research
10 librarian from Columbia University guiding us,
11 and ultimately doing the literature searches. It
12 just -- the question is did we do a systematic
13 review and grade the literature? The answer is
14 we did a systematic review. It was a scoping
15 review.

16 Unlike other, more typical development
17 processes, we didn't start with a measure and set
18 out to demonstrate that that measure was valid.
19 We set out with a topic and looked to the panel
20 to tell us what the measure ought to be. The
21 literature review actually preceded the
22 development of the measure, and the measure was

1 based and extracted from the expert
2 interpretation of the literature review. That's
3 why I said we don't quite fit within the lines.
4 We colored outside the lines a little bit.

5 CO-CHAIR SUSMAN: I think that's a
6 good description of maybe the challenge all of us
7 will face in evaluating this particular measure.
8 Ricardo, and then David.

9 MEMBER QUINONEZ: Since the 30-day
10 follow up was not really informed by evidence,
11 but mostly decided by an expert panel, what would
12 you say to a mental health clinician who
13 evaluates a patient in the inpatient setting and
14 after their evaluation and treatment, decides
15 that the correct follow up for this patient is
16 six weeks, based on what they see with the
17 patient? They would be penalized for this, and
18 the evidence for the 30 day is not very strong,
19 so do you --

20 DR. KLEINMAN: I'm going to let Eyal
21 answer the clinical, and then I'll answer from a
22 measurement perspective.

1 DR. SHEMESH: I think it's just a
2 very, very unlikely scenario. From the clinical
3 perspective, do we really want to capture all the
4 very, very unlikely scenarios in a measure is a
5 question that you should consider. But there is
6 an answer in the data that I think that Larry
7 will describe.

8 DR. KLEINMAN: I'm not sure I know
9 which one that's going to be.

10 DR. SHEMESH: I will help you if you
11 need.

12 DR. KLEINMAN: My answer is to my eye,
13 there are no -- I shouldn't probably say no, but
14 nearly no measures with clinical nuance -- with
15 any level of clinical nuance or substantial
16 levels of clinical nuance -- that are going to be
17 right for every patient. We did not suggest that
18 this measure ought to be used at the level of the
19 individual practitioner, rather at hospital level
20 or system levels because those are the ones who
21 really control both the path and the
22 availability, potentially, of physicians.

1 I would say it may be the case. In
2 that case, this measure will get it wrong. Every
3 measure gets some of them wrong. But at the
4 population level, the levels of aggregation that
5 we are suggesting this be used at, it's a very
6 powerful measure with a clinically reasonable --
7 and with content validity established by a panel
8 in a rigorous process. Every dichotomization is,
9 at some level, arbitrary. It could have been 28
10 days. It could have been 31 days.

11 DR. SHEMESH: If I may?

12 DR. KLEINMAN: Please.

13 DR. SHEMESH: When I speak of data,
14 there is two things that were in -- one of them
15 is we look at the expert panel as data. We
16 actually scored them and so on. In that sense,
17 the expert panel did not at all think that
18 there's anything that's more than a month, than
19 30 days, that's reasonable. It was to the
20 contrary. From the perspective of where they put
21 the range there, 30 was pretty up high there.
22 Again, as a clinician, as somebody who's a

1 division chief, I think that the likelihood that
2 30 days is too little, that you need more than 30
3 days, is about the same as the likelihood that
4 you don't need to sterilize a surgical
5 instrument.

6 You may not need to, and you may not
7 develop an infection. That's what our expert
8 panel told us. But the other thing in the data
9 was that this amount of time was correlated with
10 less re-admissions, which you didn't mention. So
11 there was some evidence that it makes sense to
12 put it there, but I agree that you could have put
13 it somewhere else, also.

14 CO-CHAIR SUSMAN: To be clear on the
15 measure, it's primary care and psychiatric follow
16 up?

17 DR. KLEINMAN: Yes, it's primary care
18 and mental health, not necessarily psychiatric,
19 with a list of clinicians. Those list of
20 clinicians also came directly from the panel,
21 both the primary care list and the other. I'll
22 note that a behavioral and developmental

1 pediatrician actually satisfies both criteria,
2 which is not something, personally, I would have
3 chosen, but it's what the panel said, and we
4 listened to the data.

5 CO-CHAIR SUSMAN: Okay. I'm going to
6 down and around here, so starting with David.

7 MEMBER EINZIG: I hate to bring this
8 up, but the vertical path or the horizontal path?
9 This is listed as a process measure, but maybe we
10 should be looking at it as an outcome measure
11 that routine follow up does improve global
12 outcome. Out of conscience, I just -- it's the
13 right thing to do.

14 DR. KLEINMAN: Yeah, and I think that's
15 a reasonable approach. I actually -- again, I'm
16 uncomfortable with some of the categorizations
17 we're asked to make because I think the world is
18 different shades of gray. I think on the
19 horizontal path, on the validity, I can see a
20 very clear path going across, at least to
21 moderate. I could understand the argument for
22 not making it high, although I think it's

1 actually high. But I think if you think it's an
2 outcome measure, then I'm happy to discuss it in
3 those terms, if that would be better for the
4 panel.

5 CO-CHAIR SUSMAN: I think it would be
6 probably best if we consider this as a process
7 measure. While, again, there can be some nuance
8 here, for sake of expeditious review, unless
9 people feel strongly otherwise. David two.

10 MEMBER KELLER: I'm David two, really?

11 (Laughter.)

12 CO-CHAIR SUSMAN: T-O-O.

13 (Laughter.)

14 MEMBER KELLER: I think not.

15 CO-CHAIR SUSMAN: Now I'm in trouble.

16 MEMBER KELLER: First off, I just
17 wanted to echo and support the measure developers
18 in setting the 30 day. It's hard for me to
19 imagine a child who has been hospitalized for
20 mental health reasons who does not require a
21 follow up at least within 30 days.

22 My question was more about the follow

1 up with both mental health and primary care for a
2 couple of reasons, one being that there's an
3 increasing -- and also to challenge the comment
4 that the hospitals control the access to the
5 providers. Because that may be true in New York
6 State, but in many places, the hospitals have
7 absolutely no control over access to mental
8 health providers and very little control over
9 access -- a little more, but less control over to
10 primary care providers than you might have
11 thought. The two challenges I'd have to that, is
12 one is that there's a number of systems now that
13 are beginning to integrate behavioral health and
14 primary care in different ways.

15 I'm referring specifically to the
16 MCPAP program in Massachusetts, where a lot of
17 follow up is being done by -- that's a program
18 where child psychiatrists are available to
19 consult by telephone with primary care providers.
20 For many, given the shortage of mental health
21 services, that's become a safety valve for a lot
22 of those folks, where they can be seen by the

1 primary care provider, who will then talk to a
2 child psychiatrist or to a mental health
3 counselor while they're working on getting in.

4 I'm not sure that that is the -- I'm
5 not sure that this measure would be able to
6 capture some of the more innovative systems that
7 are being developed to handle the mental health
8 follow-up problem. I guess I'm wondering why it
9 was an and, and not an or?

10 DR. KLEINMAN: Happy to share --

11 MEMBER KELLER: Maybe I misunderstood.
12 I thought it was an and. Is it an or?

13 DR. KLEINMAN: No, it is an and,
14 although we stratify, so that you can actually --
15 for purposes of improvement or understanding.
16 Let me start --

17 CO-CHAIR SUSMAN: It's and that we're
18 considering.

19 DR. KLEINMAN: It is and.
20 Unequivocally it's and. So let me answer this. I
21 think there are three questions, really. The
22 first question is I said two things quickly that

1 clearly were able to be heard conflated as one.

2 Hospitals don't control the
3 accessibility of the physicians, but they do
4 control processes that have been found -- such as
5 follow-up reminders, scheduling before discharge,
6 things like that, which have been found in the
7 literature clearly to be associated with
8 follow-up rates. I'm sorry for not speaking more
9 clearly. The systems obviously handle
10 accessibility, staffing, etc. That's one thing.
11 The second question related to why both? The
12 simple and reductionistic answer is that our
13 panel said it should be both, and our panel said
14 that both should be in person. Telephone wasn't
15 adequate. Now, I would argue that there are
16 probably exceptions and innovations that would be
17 quite good care.

18 I will also say that our other work,
19 as we were doing this, was on medication
20 reconciliation. Some of the evidence that drove
21 our thinking about this is work I did in New York
22 State -- I'm sorry, in Massachusetts Medicaid a

1 decade ago that related to failures of
2 coordination and awareness between clinicians and
3 psychiatrists.

4 I think it takes full attention to do
5 the med rec piece, and that's likely to have some
6 -- and that it's a part of what goes on at follow
7 up, and a critical part of what goes on at follow
8 up, since it's associated with ER visits and
9 hospitalizations, the unsafe medication
10 practices, which we also found are common and, in
11 fact, have a new AHRQ grant to look at that. I
12 think the feeling was face to face, in the
13 current environment is the right way. Remember
14 the IOM definition of based on current
15 professional knowledge. The bleeding edge may
16 have a better way, but it is really the way the
17 world is today. This is important.

18 CO-CHAIR SUSMAN: Okay, thanks. There
19 seems to be a discrepancy in the documentation in
20 reviewing. One part it says and, one part it
21 seems to say or, but just to be clear, your
22 intent is and, both primary care and mental

1 health?

2 DR. KLEINMAN: Yes, I apologize. I
3 will say we originally had it as distinct and
4 combined measures, but in the need to put it as
5 one submission, and in consultation with NQF
6 staff and our clinical experts, this is how we
7 did it. It's supposed to be and, and then broken
8 down so that for purposes of improvement, or if
9 some organizations only cared about one or the
10 other, they could choose to focus where they
11 wanted to.

12 CO-CHAIR SUSMAN: But the reported
13 measure would be on the and?

14 DR. KLEINMAN: The top line measure is
15 and. We hope that actually everything gets
16 reported.

17 CO-CHAIR SUSMAN: Okay, thanks. I'm
18 going down to Kerri, and we'll continue.

19 MEMBER FEI: Sure. Hopefully this is
20 a quick question. In the denominator, the
21 inclusion of the birth to five-year range, are
22 there lots of newborns that get discharged from

1 the hospital for mental health issues?

2 DR. KLEINMAN: Yes.

3 MEMBER FEI: Okay.

4 DR. SHEMESH: We had that struggle,
5 too.

6 MEMBER FEI: I'm asking from a place
7 of probably ignorance, but --

8 DR. KLEINMAN: No, here's the issue.
9 There were at least two issues. One is neonatal
10 abstinence and the resulting problems actually
11 trail through. They're relatively common in the
12 epidemiological data. They were among the most
13 common single reasons that children of zero to 21
14 are admitted with a mental health diagnosis, so
15 that's there.

16 We also felt -- and we pushed our
17 panel on this because we actually initially
18 thought it would be two or six. But what our
19 panel said to us was if a kid is given a mental
20 health diagnosis as an inpatient, a clinician may
21 view that as a license to use a potentially very
22 dangerous and/or inappropriate mental health

1 drug. So if they carry the diagnosis, we expect
2 the number to be low, but there it transcends
3 from a quality to a safety issue, so that's why
4 we've done it. But it's a great question, and we
5 were skeptical, as we were going through the
6 process ourselves, until we handed it on. Thank
7 you.

8 CO-CHAIR SUSMAN: Let's move this
9 along. Kevin.

10 MEMBER SLAVIN: Can you explain the
11 logic or the reasoning behind a patient with
12 multiple discharges, each discharge counting as a
13 next 30 days, rather than there being a rolling
14 30 day from a subsequent discharge within that 30
15 days?

16 DR. KLEINMAN: Yes, practicality. The
17 issue comes in are we going to -- what's the unit
18 of analysis, is it the patient or the discharge?
19 What we did is consistent with the unit of
20 analysis being the discharge. It gets
21 problematic when you're trying to figure out what
22 counts, what doesn't. After talking with our

1 partners at New York State Medicaid, other
2 places, in terms of the steering committee, this
3 was the ultimate decision that we made. We
4 looked at it a number of different ways. This
5 was part of -- when I said we did those eight
6 iterative or nine iterative rounds of testing --
7 it was nine ultimately -- this is part of what
8 came out of that.

9 CO-CHAIR SUSMAN: Okay, thanks. I'm
10 just going to try to move us along, so we can
11 keep -- Carol?

12 MEMBER STANLEY: I have some questions
13 about denominator statement, one being the 180
14 days following date of discharge. Because if
15 this is going to be used at a health plan level,
16 why wouldn't you be looking at continuous
17 enrollment before the date of discharge?

18 Because if we're going to hold health
19 plans accountable for this, we need to look at if
20 they had any continuous enrollment before the
21 admission and discharge. I'm not really
22 understanding why it's truly 180 days following

1 date of discharge. Then another thing is you
2 have an exclusion for children who are readmitted
3 to any hospital just on the day of discharge, but
4 what if they're -- why wouldn't that be within 30
5 days if you're looking at the 30 days? Why is it
6 just they have discharged, they would be excluded
7 from this? I have a couple of questions about
8 your denominator and the exclusions and why the
9 180 days of continuous enrollment after discharge
10 versus a shorter time period?

11 CO-CHAIR SUSMAN: Okay, good.

12 DR. KLEINMAN: Okay. The continuous
13 enrollment, the typical justification for
14 continuous enrollment relates to ability to
15 control the outcome if something happens, so
16 emergency department visits or other things. But
17 if they're in the plan at the time of discharge,
18 that discharge should be known by the plan, and
19 the management of post-discharge things should be
20 able to happen. So that's why.

21 We developed the measure set -- and
22 there's a whole number -- there's a number of

1 measures that go up to 180 days. Otherwise, it
2 really would have been reasonable to say for 30
3 days post discharge for this particular measure,
4 but we didn't want -- again, we're trying to be
5 harmonized for when we submit the others, so we
6 said 180 days. The reason you exclude something
7 on the day of discharge is -- because if
8 someone's being transferred to another facility
9 and it's done as not a direct transfer, but a
10 discharge and a re-admission, we're not looking
11 to -- we're looking to exclude those. Now the
12 issue of excluding re-admissions came up a number
13 of times. Actually, I was comfortable with
14 either way.

15 I think our team was comfortable with
16 either way. What we heard from the purchaser
17 perspective -- and we had the Northeast Business
18 Group on Health and Medicaid, from the purchaser
19 perspective, on our team -- is that they were
20 concerned that this would allow gaming for
21 re-admission. They didn't want something that
22 promoted re-admissions. In reality, when we

1 looked at the data, we found it made virtually no
2 difference, in terms of the rates.

3 So it was inconsequential in the data.
4 This was -- we are a collaboration, and this was
5 what our collaborators urged us to do. I
6 actually would have preferred to have done it the
7 exclusions, personally.

8 CO-CHAIR SUSMAN: Okay, Jon.

9 MEMBER FINKELSTEIN: I think the and,
10 requiring a follow up with both primary care and
11 mental health professional puts us in a difficult
12 box with respect to evidence, specifically.
13 Because I'm willing to accept, both because of
14 the process and the studies that are presented,
15 that some follow up is related to outcome.

16 I think when I ask myself the question
17 do I know that follow up with both is different
18 than follow up with one, I understand the expert
19 panel said so, but that, to me, puts me in the
20 insufficient evidence, where we could make an
21 exception. It puts me in that bottom pathway.
22 We could make an exception if we believe the

1 process and the opinion is the opinion of the
2 field. But they're very different. So on
3 evidence, I just think we've done something very
4 difficult by combining those.

5 Every time, if a patient is
6 discharged, patients with psychiatric illness,
7 sees their psychiatrist two weeks later and
8 doesn't come to me -- every visit to any medical
9 professional is half a day off of work for the
10 family. It's a big deal. It's not a little
11 deal. It may be very good care for me, as the
12 primary care doc, not to see them.

13 CO-CHAIR SUSMAN: I just reflect on my
14 own experience in a location where mental health
15 and primary care are closely linked that I don't
16 think that's the bleeding edge anymore. I think
17 that's an increasingly prominent way to deliver
18 high-quality care. The and, for me, is very
19 problematic. Marlene.

20 MEMBER MILLER: I'm hoping this
21 question is quick, Larry. You can help me. I
22 see an increasing number of children that go from

1 an inpatient setting to a day hospital program,
2 and that can be a month or two. How does that --
3 does that count as a provider? Does that count
4 as an inpatient? They're not eligible? When
5 does that clock start running when a day hospital
6 program is the step down from an inpatient?

7 DR. KLEINMAN: A couple of things.
8 One is it does count as an exception, and I
9 honestly don't remember -- I'd have to look to
10 see if it was in the codes for counting as a
11 re-admission, which is, I believe, what it is, or
12 if it counts as a visit. What's that?

13 (Off microphone comment.)

14 DR. KLEINMAN: I think -- okay, let me
15 not say re-admission, under the re-admission
16 exclusion. It's not that it counts as a
17 re-admission, you're right. It is clearly very
18 different. It's a lower level of care. But yes,
19 we don't want those children who go into day
20 hospitals to show up on the negative end of this.
21 It is written to do that. I just would have to
22 look at the specific codes to do that.

1 I also wanted to say, in response to
2 what Jon said, that we did a focus group. We
3 heard from parents that they felt the primary
4 care visits were often much more helpful than the
5 mental health visits, because the mental health
6 clinicians did not have time, and they wanted
7 primary care visits as a part of it in the focus
8 group.

9 Also, our evidence showed, in New York
10 State data, distinct and additive improvement of
11 one versus the other. So mental health made a
12 difference on its own, primary care made a
13 difference on its own, and adding the other on
14 made a difference, so both was better than
15 either.

16 CO-CHAIR SUSMAN: Okay, thank you.
17 I'm going to try to -- let's see, do we have
18 another question down here? Okay, Amy.

19 MEMBER HOUTROW: To your point, I
20 think day hospitalization is an outpatient -- the
21 way that it's hospital administered is
22 outpatient, so I think that is a question. I

1 have a concern about whether or not telehealth
2 would count or not count for the mental health
3 providers.

4 I also have a question related to
5 Jon's point about or versus and. To be a little
6 bit more specific, is there data, beyond what the
7 expert panel says, that follow up at any time
8 frame is beneficial from the primary care
9 perspective, or from the mental health
10 perspective? What is the data besides what the
11 expert panel said for each of those, and how do
12 those differ?

13 CO-CHAIR SUSMAN: If I gather
14 correctly, there's re-admission data?

15 DR. KLEINMAN: Re-admission data in
16 New York State Medicaid over the course of a
17 year, population level data.

18 MEMBER HOUTROW: For primary care
19 doctors or --

20 DR. KLEINMAN: Yes, for primary care
21 only, mental health only, both is better than
22 either, all three of those.

1 CO-CHAIR SUSMAN: With regard to that
2 one outcome?

3 DR. KLEINMAN: Yes, with regard to the
4 outcome of re-admissions, but that's -- yes.
5 Telemedicine was specifically considered by the
6 panel. Again, our process required us to follow
7 the panel's recommendation, and they specifically
8 did. And then, again, they have subsequently
9 re-affirmed that in their endorsement of the
10 measure as specified.

11 CO-CHAIR SUSMAN: I'm going to cut you
12 off just because we do have some time limits.
13 Jim.

14 MEMBER DUNCAN: I'm looking at Page 18
15 of the supplemental materials. It sounds like
16 the expert panel said a telephone call would be
17 appropriate, but the problem is, again, how would
18 that be captured in this, especially if it's an
19 and? Because I would imagine that might be a
20 very common process that one sees, and they have
21 a phone call, and it won't get scored as an and.

22 DR. KLEINMAN: Which -- I don't have

1 this numbered, so I'm -- I apologize --

2 (Simultaneous speaking.)

3 MEMBER DUNCAN: It's Page 18. It's
4 when you're going through your Delphi panel.

5 DR. KLEINMAN: What's the top
6 sentence? And I'll find it.

7 MEMBER DUNCAN: Continuity of care
8 requires an actual timely visit to an appropriate
9 mental health provider. That's scored an 8.89.

10 DR. KLEINMAN: It says, the timely
11 visit may be on the telephone for a Tier 1
12 patient. Our entry criteria follow Tier 1
13 exactly. So that's -- tier 1 was a conversation
14 that wasn't rated, but where there was unanimity
15 where we defined it. It's 2.3, which is very
16 low.

17 MEMBER DUNCAN: But it's nearly the
18 same as follow up within 30 days will be
19 considered be timely.

20 DR. KLEINMAN: That's right, 30 days
21 is not considered timely.

22 MEMBER DUNCAN: But it's not that

1 different than 21 days.

2 DR. KLEINMAN: Seven days for a mental
3 health professional, 21 days for a primary care
4 professional is what they consider timely.
5 Remember, we're measuring delay. So anything
6 that's not timely is delayed, so that's how --
7 the telephone visit was 2.3, which puts it in the
8 lowest tertile, 1 to 3, 4 to 6, 7 to 9 is how we
9 think of these typically. I'm sorry that wasn't
10 clear.

11 CO-CHAIR SUSMAN: All right. Ricardo,
12 do you have a final comment here?

13 MEMBER QUINONEZ: Just let me point
14 out another problem with the and that probably
15 hasn't been discussed. Your inclusion in the
16 denominator of 0 to 21 days, and your
17 justification for that, which was some of these
18 were kids with --

19 DR. KLEINMAN: That's one of the
20 justifications.

21 MEMBER QUINONEZ: Units, right --

22 DR. KLEINMAN: Right, one of two --

1 (Simultaneous speaking.)

2 MEMBER QUINONEZ: -- the units with --
3 yes. A lot of pediatricians would challenge that
4 those babies, which there a lot of nowadays, a
5 growing number nowadays -- a lot of pediatricians
6 would challenge that those babies need to be
7 followed up by a mental health professional.
8 Pediatric primary care follow up is more than
9 sufficient for kids with that problem.

10 DR. SHEMESH: I will answer this
11 because my group does this. We do allow a
12 developmental pediatrician, so I guess that's the
13 answer to your question. The --

14 (Off microphone comment.)

15 DR. SHEMESH: Right, but the question
16 now is do we want to have a measure that is about
17 good care, or do we have a measure about what's
18 around? And that Larry can speak to.

19 CO-CHAIR SUSMAN: I think --
20 appreciate your response. I'll ask for any final
21 questions before we start to the evidence.
22 Marlene.

1 MEMBER MILLER: I'm still confused if
2 the day hospital issue is solved or not? We
3 don't want to ding people for doing a day
4 hospital as the right kind of step down. It's
5 very important.

6 DR. KLEINMAN: Could I stipulate that
7 we can have a conversation afterwards and
8 resolve, if there's a problem we'll clean that
9 up?

10 (Simultaneous speaking.)

11 CO-CHAIR SUSMAN: I don't think that's
12 going to fly. I'll look to our --

13 DR. KLEINMAN: Then I need a moment to
14 look it up. I would need a moment to review it
15 because I just don't remember how we handled it,
16 but I remember we addressed it specifically. I
17 just don't remember how.

18 DR. NISHIMI: You have seconds to look
19 it up.

20 DR. KLEINMAN: What's that?

21 DR. NISHIMI: You have seconds to look
22 it up.

1 CO-CHAIR SUSMAN: We're about to vote
2 on evidence. Frankly, I don't know that the day
3 hospital might be an important issue for a few of
4 us, but there's probably --

5 DR. KLEINMAN: As I said, I can assure
6 you they're not dinged for a day hospital. I
7 just don't remember exactly how --

8 (Simultaneous speaking.)

9 CO-CHAIR SUSMAN: Okay.

10 DR. NISHIMI: Let's consider that
11 under the specifications discussion for
12 reliability and validity and vote on evidence
13 now.

14 CO-CHAIR SUSMAN: I know it seems like
15 we're pushing you. You're correct, we are
16 because we want to go home at 3:00. We're going
17 to vote on evidence. I'll turn it over.

18 MS. CHAVEZ: Now voting on evidence
19 for Measure 2815, 1 high, 2 moderate, 3 low, 4
20 insufficient. Voting's open, and we are
21 expecting 26 votes, 0 voted high, 8 voted
22 moderate, 10 voted low, 8 voted insufficient, and

1 this measure does not pass evidence.

2 CO-CHAIR SUSMAN: Okay, feedback to
3 the developer. I know that you've worked very
4 hard and put a lot of effort into this. I think
5 it's useful to sort of have a debrief. Jon?

6 MEMBER FINKELSTEIN: I wonder, because
7 our process that I learned about yesterday was
8 that changes can be made and these can be brought
9 back quickly, even to our post-meeting call. I
10 don't know if the chairs -- I wonder how much
11 this is hinging on this and problem and if you
12 want to take one of our straw votes or get the
13 sense of the group if this wasn't the and, would
14 this have been the result?

15 CO-CHAIR SUSMAN: No, I think that's
16 a perfect --

17 DR. KLEINMAN: We wouldn't submit it
18 that way, just to -- part of the real importance
19 of this measure is that it addresses the issues
20 both of continuity and of coordination of care.

21 CO-CHAIR BROOKEY: I think the
22 committee members were giving input.

1 DR. KLEINMAN: Okay, I appreciate
2 that, but --

3 CO-CHAIR BROOKEY: I think --

4 DR. KLEINMAN: Thank you.

5 CO-CHAIR BROOKEY: I think we can just
6 say that would be some of the input of the
7 committee. I think Jon's request was how many
8 people feel like that is the sticking point with
9 this particular measure? Is that what your
10 question is, Jon?

11 MEMBER FINKELSTEIN: Yes.

12 CO-CHAIR SUSMAN: But if it isn't
13 going to sway you one way or the other, then
14 there's really no point.

15 (Simultaneous speaking.)

16 DR. KLEINMAN: -- information, but
17 this is what we were told to do, and to follow
18 the process requires that at this point.

19 CO-CHAIR SUSMAN: Okay. Any other
20 feedback to the measure developer? Clearly just
21 making sure about things like the specification,
22 day hospital, other follow up? Jim.

1 MEMBER DUNCAN: I think this is a
2 classic chicken and the egg that it's very
3 difficult for you to develop a measure without
4 data, and you don't get their data without having
5 a measure. I think lots of folks fall into the
6 same boat.

7 DR. KLEINMAN: This is what we were
8 asked to do by AHRQ and CMS, so this is where I
9 think the challenge is to the field, to figure
10 out how to recognize and move measures forward
11 with that.

12 CO-CHAIR SUSMAN: As you were here
13 earlier today, you recognize that sometimes
14 you're in a box by CMS or AHRQ or whoever is the
15 person paying the bills, and we may or may not
16 agree with how that is framed. It is what it is.
17 David, final comment?

18 MEMBER KELLER: Sure. The thing I was
19 wondering about -- because I was a little
20 surprised how this played out. I thought we were
21 going to go with insufficient and exception
22 which, again, would have been a way for us to

1 move forward. I guess I'm wondering what
2 criteria would have -- or whether there were any
3 criteria that would have swayed committee
4 members? One of the problems with our algorithm
5 is that if you go with low -- I'm so sorry.

6 CO-CHAIR SUSMAN: We were having a
7 sidebar. We can do that. If you believe, as a
8 committee, that we want to vote insufficient, or
9 an exception with insufficient evidence, we can
10 do that, and we can have that vote now and see
11 where it falls.

12 MEMBER KELLER: Oh, so --

13 (Simultaneous speaking.)

14 CO-CHAIR SUSMAN: I'm sorry?

15 MEMBER KELLER: That's what I was
16 wondering. The criteria -- again, this is a
17 procedural question for NQF is the criteria to be
18 able to do the exception are what? What do we
19 need to have up there on the board to be thinking
20 about that path forward?

21 DR. BURSTIN: Somebody like you
22 requests it, and your group agrees to consider

1 it.

2 MEMBER KELLER: Oh, okay, so it's not
3 about having a majority of people say
4 insufficient?

5 DR. BURSTIN: No, it's not. It's your
6 choice --

7 (Simultaneous speaking.)

8 MEMBER KELLER: Okay, that's where --

9 DR. BURSTIN: It just has to fail.

10 MEMBER KELLER: I'm sorry?

11 DR. BURSTIN: It has to fail.

12 MEMBER KELLER: It has to fail --

13 (Simultaneous speaking.)

14 CO-CHAIR SUSMAN: So it's failed. Now
15 I hear you asking the question of the committee.

16 MEMBER KELLER: My question would be
17 whether the committee -- I do think -- I'll just
18 put out there I do think that this is an
19 important issue.

20 I think that we have some -- I think
21 there are -- I think we, as a committee, have
22 some issues with the methodologies chosen and

1 with the specifics -- with the details of the
2 measure, but that conceptually, the notion that
3 these children require follow up and that's a
4 reasonable measure for this small, but really
5 significant group of children is important to
6 consider. I'm asking my fellow committee members
7 whether we should consider the exception in this
8 case? I'm open to -- I'm interested in doing
9 that, but I'm open to discussion.

10 CO-CHAIR SUSMAN: Virginia.

11 MEMBER MOYER: I agree that this is a
12 really important topic and a way needs to be
13 found to do this. I don't think we will get to a
14 pass on this. I certainly, having reviewed the
15 measure, I think there are so many other issues
16 with it that we would spend a lot of time getting
17 to nowhere. I think that we'd be better off,
18 having given feedback to the developers, to allow
19 this to come back another time.

20 CO-CHAIR SUSMAN: I'm seeing a lot of
21 heads nodding yes at the table. Let's just take
22 a straw vote. How many want to reconsider this

1 for an exception, just raise your hands? We have
2 two or three. It does not look like there's
3 great appetite for that. I appreciate, though,
4 your bringing it up, and remember that as an
5 option for this group. Thank you very much, and
6 we look forward to new measures. I think we're
7 at the point where we can take our break. We
8 need public comments and NQF member comments, and
9 whoever has the keys to the operator, I'll turn
10 it over to you.

11 DR. NISHIMI: Operator, can you see if
12 there's any public comment?

13 OPERATOR: At this time, if you would
14 like to make a public comment, please press Star
15 1.

16 DR. NISHIMI: Is there anyone --

17 OPERATOR: There are no public
18 comments.

19 DR. NISHIMI: Anyone in the audience
20 wish to make a public comment? Okay.

21 CO-CHAIR SUSMAN: We're about a half
22 hour ahead, which is a good thing. There's no

1 clue about how long future measures will take, so
2 we have 11:30 to noon for lunch. If you have any
3 questions in the meantime, please come up. I
4 think John's going to take over after lunch.
5 Thank you all.

6 (Whereupon, the above-entitled meeting
7 went off the record at 11:31 a.m. and resumed at
8 11:32 a.m.)

9 CO-CHAIR BROOKEY: We're going to make
10 a transition to --

11 CO-CHAIR SUSMAN: Bring us home, John.

12 DR. BURSTIN: The developer has
13 requested, John, that we do the tobacco measure
14 first, and then the two antipsychotics together
15 -- three antipsychotics together.

16 CO-CHAIR BROOKEY: So we're going to
17 start from the end and work backwards. We're
18 going to do 2803. We have one recusal. Any
19 other recusals? Okay. Do we have the developer
20 here or on the line? Oh, okay, step forward.

21 CO-CHAIR SUSMAN: Come on up,
22 developers.

1 CO-CHAIR BROOKEY: Good morning. Can
2 you introduce yourselves, and then give us a
3 brief overview of your measure, please?

4 MS. BYRON: Yes. Hi, I'm Sepheen
5 Byron. I'm an assistant vice president at the
6 National Committee for Quality Assurance. NCQA
7 is part of the National Collaborative for
8 Innovation in Quality Measurement, or NCINQ
9 Center of Excellence. I have with me here Mary
10 Barton, and on the line, I think we should have
11 Sarah Hudson Scholle, who is the PI of this
12 center, but is actually at the CMS
13 Medicaid/Medicare quality meeting right now.
14 Sara, are you on the line?

15 DR. SCHOLLE: I am. Good morning,
16 everyone.

17 MS. BYRON: Great, thanks. We're
18 going to talk about this tobacco measure first.
19 We have three antipsychotic measures coming up,
20 but it felt it made sense to batch them together.
21 This is the tobacco use and help with quitting
22 among adolescents measure.

1 It is a clinician level measure, and
2 it was tested at the clinician level in
3 electronic healthcare records. With this
4 measure, we are hoping to standardize the way
5 tobacco use is documented. It looks to see if
6 adolescents were screened for tobacco use and, if
7 they are users, whether they received help with
8 quitting.

9 We think tobacco is a very important
10 topic. It's really something that I think many
11 consider almost like a vital sign. Tobacco use
12 is -- it's slightly decreasing among adolescents,
13 which is good news, but it's still being used.
14 The evidence has shown that a physician's advice
15 to quit can be very effective. It's based on a
16 guideline from the U.S. Public Health Service, as
17 well as a more recent review by the U.S.
18 Preventive Services Task Force.

19 CO-CHAIR BROOKEY: Before we ask for
20 member comments or questions, can you just
21 clarify, this is two measures, or is it sort of a
22 composite measure? Describe just a little bit,

1 in more detail, the specs.

2 MS. BYRON: It is one measure. I know
3 there was some discussion about the way it was
4 structured in the workgroup, but the denominator
5 is all adolescents with a visit, and then the
6 numerator is those who were screened for tobacco
7 use and if they're found a user, did they receive
8 help with quitting, so it's all one numerator, so
9 you get one rate.

10 Basically you're getting credit for
11 having non-smokers, or treating your smokers.
12 The structure of it really, I think, aligns with
13 the way we have seen other measures done, such as
14 depression screening and follow up. So screen
15 for depression, if you find a problem, is a
16 follow-up plan in place? That's an NQF measure.
17 We were encouraged to align with that sort of
18 structure, so that you have this population-based
19 measure.

20 CO-CHAIR SUSMAN: I should know this,
21 but are you counting counseling, V codes for
22 counseling? Are you counting medication?

1 MS. BYRON: Yes.

2 CO-CHAIR BROOKEY: Tell me what counts
3 for these.

4 MS. BYRON: Yes, it's actually pretty
5 broad. You can look in the medical record, as
6 well. We include counseling. We include
7 referral to services, treatment services,
8 medication. We've aligned it to the way we
9 specify these sorts of counseling measures in
10 other measures in HEDIS.

11 CO-CHAIR BROOKEY: Just one more
12 question because I know health plans can game
13 this. After visit summaries can include this for
14 everybody. Is that going to count?

15 MS. BYRON: After visit summaries?

16 CO-CHAIR BROOKEY: Yes.

17 MS. BYRON: It should count.

18 CO-CHAIR BROOKEY: Okay. Because you
19 can put that instruction, sort of 800 numbers, in
20 everybody's after-visit summary, so I just want
21 to make sure that you've considered that for the
22 measure.

1 MS. BYRON: We did. It's at the
2 clinician level. We wanted to be broad, in terms
3 of what counted as treatment. Our expert panel
4 felt that --

5 CO-CHAIR BROOKEY: That's been the
6 issue with the Joint Commission measure because
7 you can put the instructions in 100 percent of
8 discharges and get credit for it, so I just want
9 to make sure that you considered that for this
10 measure, because that's how some people will
11 manage it. I just want to call that out. With
12 my biased comments -- yes, go ahead, Kevin.

13 MEMBER SLAVIN: Just for
14 clarification, the discussion has been about
15 tobacco use, but a lot of this says smokers, so
16 are we talking about all tobacco use, or
17 specifically just smoking?

18 MS. BYRON: All tobacco use. We
19 specifically used the word tobacco use versus
20 smoking in most of the specification, I believe.

21 CO-CHAIR BROOKEY: Good question.

22 MEMBER SLAVIN: Actually, no. The

1 specifications say specifically adolescents who
2 are not smokers, or adolescents who are smokers
3 but are receiving cessation counseling. That's
4 why I wanted the clarification. So we are
5 talking about all tobacco use, not just smokers?

6 MS. BYRON: Deeper in the
7 specifications we do say tobacco use, but thank
8 you for pointing that out.

9 MEMBER AGORATUS: This is Lauren. Are
10 we also including the e-cigs?

11 MS. BYRON: So that's as good
12 question. We developed this measure several
13 years ago, when it was not as big of an issue.
14 It doesn't specifically say e-cigarettes anywhere
15 in here.

16 CO-CHAIR BROOKEY: That would be a no
17 then. We have our experts here from the
18 committee would be Maureen, Carol and Sue. Which
19 of you want to kick off and give some comments?
20 Can we first go to our members, and then we'll
21 ask further questions? I want them to give a
22 summary, if they could -- our members who were on

1 the subcommittee, that is. Don't all volunteer
2 at once.

3 CO-CHAIR SUSMAN: You go. You go.

4 MEMBER STANLEY: Our discussion with
5 our group brought up some of the issues you
6 talked about, specifically the numerator
7 statement including both non-smokers -- or
8 non-tobacco users and tobacco users. The
9 evidence was strong from the standpoint of
10 obviously tobacco use is very harmful, and
11 adolescents should quit.

12 The evidence of physician
13 recommendation or intervention seems to focus on
14 adults, so we wanted to hear a little bit more
15 about the evidence for physician recommendation
16 or intervention specifically with adolescents.
17 We were also interested in hearing how things
18 went with your HEDIS 2015 results in using this
19 specific measure. Then there were some questions
20 about the disparity between your results using
21 the electronic record versus medical record
22 abstraction.

1 CO-CHAIR SUSMAN: Would you like to
2 respond?

3 MS. BYRON: First easy one. This
4 measure's not actually a HEDIS health plan
5 measure. It's specified at the clinician level,
6 so it's not in HEDIS. In terms of the evidence,
7 it is based on a U.S. Public Health Service
8 recommendation that says clinicians should screen
9 and if they find tobacco use, they should be
10 treating it. Then there are also numerous
11 studies out there that have found that a
12 physician's advice to quit, even brief, has been
13 effective.

14 Then also, the U.S. Preventive
15 Services Task Force guideline, which is a little
16 more recent, that actually came out, was in
17 process as we were developing the measure,
18 focused in more on the physician providing
19 interventions to prevent tobacco use, which is
20 another component. Taken together, we felt the
21 evidence really supported this, and our expert
22 panels and public comment results also felt that

1 the evidence was strong.

2 CO-CHAIR BROOKEY: For the age group,
3 correct?

4 MS. BYRON: Yes, for adolescents.

5 CO-CHAIR SUSMAN: Because that was
6 your question, right, Carol?

7 MS. BYRON: Yes, and those guidelines
8 are specific to adolescents, as well. Was there
9 one -- I think there may have been one more
10 question.

11 CO-CHAIR SUSMAN: Just to clarify, I'm
12 looking at the U.S. Preventive Services Task
13 Force website. It's a B recommendation.

14 CO-CHAIR BROOKEY: I think David had
15 his hand up.

16 MEMBER EINZIG: Is counseling defined?
17 In other words, just saying smoking is bad for
18 you, it causes cancer, does that count as -- as
19 opposed to more gold standard motivational
20 interviewing strategies, digging deeper, what do
21 you like about smoking? I wonder if there's a
22 definition of what is counseling?

1 MS. BYRON: Right. The specification
2 actually lists advice given to quit smoking or
3 tobacco use counts, counseling on the benefits of
4 quitting smoking or tobacco use, we give some
5 examples, assistance with or referral to an
6 external program, or current enrollment in a
7 tobacco treatment program.

8 I do recognize that it may be
9 difficult to define counseling, but because the
10 studies have shown that even brief interventions
11 by doctors giving advice to quit, we did allow
12 that to count. What we want to see is that if
13 you find a smoker, you're at least doing
14 something to try to get them to stop.

15 CO-CHAIR BROOKEY: Just to my earlier
16 point, you can easily create your smart sets to
17 have a counseling code for 100 percent of your
18 patients, whether it be screen time, exercise,
19 nutrition and smoking. I just want to call that
20 out. This is very important.

21 I just want to call out the issue with
22 V codes and how they may not really relate to

1 what actually happened in the office. I think
2 it's getting to your point a little bit that it's
3 a pretty broad definition of what counseling is.
4 If you code it, you've done it, and it gets
5 counted. Marlene.

6 MEMBER MILLER: I was just going to
7 echo that same thing. There's so many measures
8 like adult care and they're gamed with a
9 pre-templated sentence in the discharge summary,
10 and everyone's at 100 percent, not to mention the
11 fact that tobacco screening is a meaningful use
12 measure, so everyone's already building their EHR
13 systems to automatically do this. I just really
14 worry it doesn't get at what we want, and that it
15 essentially will be, very soon, a measure at 100
16 percent. That may not be what we have achieved,
17 but it's going to be a documentation, make your
18 smart set do it type of thing.

19 CO-CHAIR BROOKEY: Jim.

20 MEMBER BOST: Does the denominator
21 come from the claims data, but the numerator
22 requires chart review? If there are multiple

1 visits in a given year, does the cessation need
2 to be indicated in every visit?

3 MS. BYRON: This is a medical record
4 measure. It was tested in electronic health
5 records, but I wouldn't call it an e-measure with
6 a capital E. It's probably like an e-measure
7 with a lower case E, which is why we categorized
8 it medical record.

9 You would look to see adolescents at
10 the physician level, all of your adolescents who
11 had a visit, and they would be included in your
12 denominator at that point in time, in the
13 measurement year. Then you would look back to
14 see if there was documentation of screening and
15 all the other numerator components. Once you do
16 that measure in that measurement year, you're
17 counting them once.

18 Adolescents with a visit, children.
19 Think of it as children, right, but at the
20 clinician level, in order to assign
21 accountability, we also look for a visit.

22 CO-CHAIR BROOKEY: To clarify, is it

1 a hybrid measure, or is it a chart review
2 measure?

3 MS. BYRON: It's really a chart review
4 measure.

5 CO-CHAIR BROOKEY: So you're not
6 basing it on codes at all?

7 MS. BYRON: You can look at codes in
8 charts, but it's not a claims-based measure.

9 CO-CHAIR BROOKEY: Just to clarify
10 Marlene and my concern about using V codes, is
11 that going to count for the numerator? That's
12 the reason we're bringing it up. Because what
13 Tim is asking, are we opening up charts and
14 looking for actual documentation, or if it's in
15 the diagnosis code on an electronic chart, will
16 that count?

17 MS. BYRON: Sara, do you know the
18 answer to that question? I believe we are
19 looking.

20 DR. SCHOLLE: I think the answer is
21 yes. I think I understand the concern that what
22 we want is an activity to document tobacco use

1 and if there is tobacco use, to provide some help
2 or some response. This is aligned with an
3 existing measure for adults that basically has
4 the same construction.

5 The main difference is that this does
6 not include prescribing of the patch, I think,
7 because that's not recommended for adolescents.
8 It's looking for some activity to happen at the
9 visit where the tobacco use was identified. In
10 an electronic record, that could be documented in
11 the notes -- I mean in a medical record, whether
12 it's electronic or paper, that could be
13 documented in the notes.

14 It could be documented in the
15 diagnosis code or procedure code if they're
16 relevant, or it could be documented -- what's in
17 the visit summary, as you say, that is part of
18 the notes. We are trusting that clinicians who
19 include something on their smart set are actually
20 reviewing that information with the families and
21 adolescents as they're handing out that visit
22 summary.

1 CO-CHAIR BROOKEY: Yes.

2 DR. SCHOLLE: I understand there's a
3 concern that it's just going to be automatically
4 implemented.

5 CO-CHAIR BROOKEY: Right, you answered
6 the question. We want to know whether or not
7 it's filled out in a questionnaire -- the nurse
8 fills out the questionnaire -- whether it's
9 documented in a diagnosis code, whether
10 counseling is a diagnosis code, and whether, in
11 the after-visit summary instructions are
12 included, whether it would count. From what you
13 just said, the answer is yes. I just want to be
14 clear about that.

15 DR. SCHOLLE: Yes, right.

16 CO-CHAIR BROOKEY: Okay, Jon?

17 MEMBER FINKELSTEIN: I was on the
18 subgroup, too. I think the issue we're grappling
19 with is the big one, but it's the big one with
20 any counseling measure. We only have the chart.
21 I can just lie in the chart. I can say I talked
22 to you about X, Y, and Z, and if I didn't, I

1 didn't. We can do that with coding, as well. I
2 would hate for us to not put forward quality
3 measures because we don't have dash cams on the
4 clinician's forehead yet to prove what was
5 actually said or how good the counseling was. I
6 think this is -- we're talking about evidence
7 right now. The evidence, I think, for this is
8 incredibly strong, especially in the domain of
9 counseling interventions. Of all the counseling
10 we do, there's a lot of evidence around this in
11 an area where there often isn't.

12 I think what we're talking about that
13 everybody could game it and get to 100 percent,
14 that gets to whether there's currently a gap. I
15 think if this was put out as a quality measure
16 and five years from now, everybody had engineered
17 things to be at 100 percent, it's no longer a
18 useful measure, but I don't think we're there
19 yet. I think we'll hear about that in gap.

20 CO-CHAIR BROOKEY: David, go ahead.

21 MEMBER KELLER: Echoing that just a
22 little bit, but also pointing out that the fact

1 that the measure developers have mirrored this on
2 an adult measure makes this an incredibly
3 practical measure because large organizations
4 that do both adults and children have experienced
5 pulling this measure in their adult population,
6 and it's relatively -- from a feasibility
7 standpoint and a usability standpoint, it's
8 wizard to be able to take what you're already
9 doing and match it.

10 The other thing is that for -- in our
11 state innovation model plan, the fact that this
12 would become a measure would allow us to extend
13 the measure that we put in for adults down into
14 the adolescent population, which we currently
15 can't do because we decided to use only
16 NQF-approved measures for that.

17 Again, I think it takes work that's
18 going on and is very well documented in the adult
19 world and allows us to move that into the
20 adolescent world in a really good way. I had
21 exactly the same concern in the adult measure
22 that there's no assessment of the quality of the

1 counseling that's given or the type of counseling
2 or exactly what that is.

3 But again, we're taking the
4 temperature. We're not doing an X-ray. We're
5 just trying to see if it happens, and that's
6 often useful for moving the mark. I'd just put
7 out there that I'm very, very excited about this.

8 CO-CHAIR BROOKEY: Sounds like we're
9 converging on our opinions. Kevin.

10 MEMBER SLAVIN: Just in terms of the
11 practicalities of putting a blanket statement
12 about tobacco use in an after-visit summary for
13 an adolescent, is that something that you want in
14 an after-visit summary for an adolescent? Isn't
15 that something that we're supposed to sort of be
16 doing in private, without the parents present?
17 If that's the case, that kind of thing can't be
18 the blanket way that an institution or a practice
19 decides to solve this.

20 CO-CHAIR BROOKEY: I think we're
21 getting close to agreeing that this is probably
22 strong evidence for this. I just want to call

1 the issue that screening, in and of itself, is
2 important, but you can do two at the same time
3 with templated documentation.

4 If you screen and don't do the follow
5 up, which may be very inadequate, you may still
6 get credit for it if you automatically import it
7 into your note. After-visit summaries, to your
8 point, I think it depends on the specificity of
9 it. If you put your child smokes on the
10 after-visit summary, that's an issue. If you
11 have a general statement about smoking, then I
12 think it's not an issue. Same thing with STDs
13 and pregnancy and everything else. There are
14 certain things we would agree not to put in an
15 after-visit summary. I think everybody around
16 the room nodding their heads probably feels this
17 is an important measure. Am I getting a sense?
18 Are we getting close to voting on the evidence
19 part of this measure?

20 MEMBER AGORATUS: This is Lauren. I
21 have a question.

22 CO-CHAIR BROOKEY: Go ahead, Lauren.

1 MEMBER AGORATUS: Just looking at the
2 evidence also, just doing a quick survey, CDC,
3 HHS websites and so forth. The prevalence of
4 e-cigarettes are actually surpassing smoking. I
5 don't know if there's a way to capture that, in
6 terms of adding e-cigs, because of the nicotine
7 piece, to this. The percentage is much higher
8 now, with the new generation not actually
9 smoking.

10 CO-CHAIR BROOKEY: Your point is very
11 well taken. We're going to vote on this measure
12 the way it's specified, but we can provide that
13 as input to the developer for future. Is that
14 all right?

15 MEMBER AGORATUS: Sure.

16 CO-CHAIR BROOKEY: We don't want to
17 lose your comment, for sure.

18 CO-CHAIR SUSMAN: I think that's
19 important. I don't see the strength of evidence
20 behind that that we have for actual tobacco use,
21 as formally defined.

22 CO-CHAIR BROOKEY: Okay, are we ready

1 to vote?

2 MS. CHAVEZ: Okay, now voting on
3 evidence for Measure 2803, 1 for high, 2
4 moderate, 3 low, 4 insufficient. Voting is open,
5 we are expecting 24 votes, 23, 24, 11 voted high,
6 12 voted moderate, 0 voted low, 1 voted
7 insufficient. This measure passes evidence.

8 CO-CHAIR BROOKEY: Okay, we have
9 another decision now. I think we might be able
10 to get through the rest of these fairly quickly,
11 but I also have no problem breaking now and
12 coming back to finish up. How many would like to
13 try to finish before lunch?

14 PARTICIPANT: Just tobacco.

15 CO-CHAIR BROOKEY: Just tobacco. How
16 many want to break, and then come back?

17 CO-CHAIR SUSMAN: Break and come back?

18 CO-CHAIR BROOKEY: So can we keep
19 rolling then? Okay, so reliability.

20 PARTICIPANT: No, gap.

21 CO-CHAIR BROOKEY: I'm sorry, gap.

22 MEMBER KONEK: There was pretty good

1 evidence that there was a gap. It was looked at
2 in a variety of ways. It was looked at the
3 National Youth Tobacco Survey, which was in 2011,
4 with only 32 percent of the adolescents reported
5 being asked about tobacco use. Several other
6 things were related to that. Looking at
7 respondents with commercial insurance who
8 received help was at 82 percent, while Medicaid
9 was 60, and other insurances were 39, so it did
10 seem to be a gap in a variety of ways.

11 CO-CHAIR BROOKEY: Is there any
12 disagreement with that? Any other comments about
13 gap? Could we vote for gap? Okay.

14 MS. CHAVEZ: Okay, now voting on gap,
15 1 high, 2 moderate, 3 low, 4 insufficient.
16 Polling is open, 15, 23, we're looking for 24
17 votes, thank you, 12 voted high, 11 voted
18 moderate, 0 for low, 1 insufficient. This
19 measure passes gap.

20 CO-CHAIR BROOKEY: Okay, reliability,
21 comments from our subcommittee? Jon, you have a
22 comment?

1 MEMBER FINKELSTEIN: Just that the
2 reliability -- the developers told us that the
3 variability they found was based largely on the
4 availability of data elements in different
5 systems. I don't know if they want to comment on
6 that. The issue was already raised, and the
7 developers raised it, that it's not ready as an
8 EHR automated data. This has to be digging
9 through the chart because when you just look in
10 an automated way, you don't find stuff. That
11 impacts the reliability a little bit.

12 CO-CHAIR BROOKEY: Do you want to
13 comment?

14 MS. BYRON: Yes, you're correct. It's
15 not an e-measure. We still see that these things
16 are not available in standardized fields that you
17 can automatically extract from. You do need to
18 go into notes and that sort of thing. We're
19 hoping that EHRs will catch up with meaningful
20 use, specifying how tobacco use should be
21 defined, and we've aligned to that. We're hoping
22 that eventually, we'll get there.

1 DR. SCHOLLE: Just to clarify, our
2 testing was done several years ago, so that's
3 before -- so first of all, meaningful use has
4 progressed somewhat. As others on the panel
5 noted, the adult version of this measure has been
6 in reporting, so we really expect that if we did
7 this today, we might be better uptake in the
8 electronic health record setting. There can be
9 measures -- our testing found issues also where
10 the fields existed, but they weren't being used.
11 Until the measure's really deployed, there's not
12 really an incentive to use those structured
13 fields.

14 CO-CHAIR BROOKEY: It might be a
15 little bit more about feasibility than
16 reliability. You're opening the record. There's
17 a fair amount of reliability, but it's not that
18 feasible, would you agree? So any other comments
19 about reliability? There was testing done,
20 right? Yes.

21 DR. SCHOLLE: Right, our inter-rater
22 reliability and our ability to pull the data out

1 of the record was good between different raters.

2 CO-CHAIR BROOKEY: It's just high
3 effort to get the data that's the issue.
4 Reliability, are we ready to vote on reliability?

5 DR. NISHIMI: Just a reminder this is
6 at the data element level, so not the performance
7 scores. The eligible ratings are moderate, low,
8 insufficient.

9 CO-CHAIR BROOKEY: Okay, ready to
10 vote?

11 MS. CHAVEZ: Now voting on
12 reliability, 1 high, 2 moderate, 3 low, 4
13 insufficient. Polling is open, 20, 23, 24, 0
14 voted high, 20 voted moderate, 4 voted low, 0
15 insufficient. This measure passes reliability.

16 CO-CHAIR BROOKEY: Very good. Let's
17 go to validity. Any comments about validity from
18 our subcommittee?

19 MEMBER KONEK: There was face validity
20 discussed, assessed by the developers by
21 convening a number of stakeholders, lots of
22 people that you would expect on that group. They

1 supported this.

2 CO-CHAIR BROOKEY: So there was this
3 just face validity, so that would be --

4 MEMBER KONEK: There was face
5 validity. Validity testing involved the study of
6 400 patients, as well, who had well-care visits,
7 who were at 58 percent documented tobacco use and
8 received help to stop smoking. That was also
9 reported. It looked like, by the algorithm, it
10 would be moderate.

11 (Simultaneous speaking.)

12 CO-CHAIR BROOKEY: Moderate or below.

13 DR. NISHIMI: They did do empirical
14 testing at the performance score level, however,
15 so it is eligible for high.

16 CO-CHAIR BROOKEY: Eligible for high.
17 Other comments about validity? Ready to vote for
18 validity? Okay.

19 MS. CHAVEZ: Now voting on validity
20 for Measure 2803, 1 high, 2 moderate, 3 low, 4
21 insufficient. Polling is open, 10, 21, 23.

22 MS. ALLEN: Lauren, I'm waiting on

1 your vote.

2 MEMBER AGORATUS: Yes, my computer
3 just crashed. I'm waiting for the screen to come
4 back up. Sorry.

5 CO-CHAIR SUSMAN: You could just tell
6 us.

7 PARTICIPANT: You don't have to.

8 MS. ALLEN: You can email us. No, I'm
9 sorry, you can't.

10 PARTICIPANT: Her computer crashed.

11 MS. ALLEN: Sorry.

12 MEMBER AGORATUS: I can't believe this
13 just went -- the whole thing just went down, and
14 I can't get it back. Here we go. This is the
15 second time, too. I don't know why it's doing
16 this.

17 CO-CHAIR SUSMAN: You could text.

18 PARTICIPANT: We can give you a phone
19 number to text.

20 MS. ALLEN: I can give you my phone
21 number to text your response. It's 240-320-4744.

22 PARTICIPANT: Expect a lot of phone

1 calls tonight.

2 MEMBER AGORATUS: Okay, I'll see if I
3 can do this. I've got to get on the other phone
4 now.

5 PARTICIPANT: Do we need to wait for
6 her to vote?

7 MEMBER AGORATUS: I'm sorry, got to
8 love technology.

9 CO-CHAIR BROOKEY: We're going to go
10 ahead and move forward --

11 PARTICIPANT: And we'll add your vote
12 in.

13 CO-CHAIR BROOKEY: -- and we'll add
14 the vote in later.

15 MEMBER AGORATUS: Thank you.

16 CO-CHAIR BROOKEY: We won't tell you
17 how it all --

18 MS. CHAVEZ: Okay, for the 23 votes we
19 received, 2 voted high, 19 voted moderate, 2
20 voted low, 0 insufficient, and this passes
21 validity.

22 CO-CHAIR BROOKEY: I wasn't going to

1 tell Lauren that because we just influenced her
2 vote. I'm sorry. Let's just move forward to
3 feasibility. I think we just stated the issues
4 with feasibility, in terms of it not being an
5 e-measures, other issues with the use of smart
6 text, smart sets, and the issue with being a
7 chart review measure. Are there any other
8 comments about feasibility?

9 Okay, Sue, go ahead.

10 MEMBER KONEK: It is noted that it is
11 -- of course, the CMS meaningful use is now in
12 place. That's been already discussed. But it's
13 --

14 CO-CHAIR BROOKEY: I'm sorry, can you
15 use your -- is your mic on?

16 MEMBER KONEK: Oh, yes.

17 CO-CHAIR BROOKEY: I just can't hear
18 you.

19 MEMBER KONEK: Physician quality
20 reporting system, as of 2/2015, the data elements
21 can be generated through that.

22 CO-CHAIR BROOKEY: Any other comments

1 about feasibility? Can we vote on feasibility?

2 MS. CHAVEZ: Okay, Lauren will we be
3 able to get your vote now?

4 MEMBER AGORATUS: No, I'm going to
5 send comments, and I'll put what it's for, okay?
6 I'm going to try a different browser.

7 MS. CHAVEZ: Okay, now voting on
8 feasibility, 1 high, 2 moderate, 3 low, 4
9 insufficient. Polling is open, 23, okay, 1 voted
10 high, 18 voted moderate, 4 voted low, 0
11 insufficient. This measure passes feasibility.

12 CO-CHAIR BROOKEY: Okay, the next is
13 usability and use. Any comments about that?
14 Subcommittee?

15 MEMBER KONEK: It's in the EHR
16 incentive program, meaningful use, and also the
17 PQRS, now it's already in use. There were no
18 real comments about use from the group otherwise.

19 CO-CHAIR BROOKEY: Okay. Any other
20 comments about usability? Can we vote?

21 MS. CHAVEZ: Okay, now voting on
22 usability, 1 high, 2 moderate, 3 low, 4

1 insufficient. Polling is open, 18, 23.

2 MEMBER AGORATUS: I'm still trying to
3 get on, so just add mine again later.

4 MS. CHAVEZ: Okay, thank you, Lauren.

5 PARTICIPANT: It could be the deciding
6 vote.

7 MS. CHAVEZ: 5 voted high, 15 voted
8 moderate, 3 voted low, 0 insufficient. This
9 measure passes usability and use.

10 CO-CHAIR BROOKEY: Okay, so the last
11 is overall. Any comments before we vote on
12 overall suitability for endorsement? Can we
13 vote?

14 MS. CHAVEZ: Okay, now voting on
15 Measure 2803, overall suitability for
16 endorsement, 1 yes, 2 no. Open, 23.

17 MEMBER AGORATUS: Again --

18 (Simultaneous speaking.)

19 MS. CHAVEZ: Lauren, you'll send us
20 your vote later?

21 MEMBER AGORATUS: I'm writing them all
22 down, and I'll send it all in the comments. I'm

1 still trying -- Mozilla's not working. I'm
2 trying Internet Explorer now.

3 MS. CHAVEZ: Okay, so if we had 24
4 votes, we needed 15 votes for this to pass. We
5 have 20 yeses, 3 nos. This Measure, 2803, is
6 recommended for endorsement.

7 CO-CHAIR BROOKEY: Thank you
8 developers. You've heard the input. There was
9 input about e-smoke, which you can follow up on,
10 may or may not belong here, but at least you can
11 follow up on it, questions just about the sources
12 of information. I think the after-visit summary
13 was one of the concerns. Were there any other
14 concerns people wanted to make sure the
15 developers took back with them? Go ahead, Carol.

16 MEMBER STANLEY: I think this is a
17 really important measure. We have a lot of spit
18 tobacco users in Virginia, so please be sure --
19 and across the country, I'm sure -- to be sure
20 it's tobacco use and not just smoking.

21 CO-CHAIR BROOKEY: Sue? And David?

22 (Simultaneous speaking.)

1 CO-CHAIR SUSMAN: I'm not sure that
2 you had it, but it would be really interesting to
3 look at disparities as you accrue more data. My
4 understanding is you didn't quite have enough
5 sample to really look at some of those issues,
6 but I think it's going to be real important.

7 CO-CHAIR BROOKEY: Including what
8 payer type, yes. We want to be mindful of
9 people's time, so I would recommend that people
10 grab your lunch, and when I see that everybody's
11 sort of back at their seats, in maybe 15 minutes,
12 we can resume. Would that work for people?

13 Okay.

14 (Whereupon, the above-entitled meeting
15 went off the record at 12:08 p.m. and resumed at
16 12:23 p.m.)

17 CO-CHAIR BROOKEY: Looks like the
18 majority of people are back at their seats, so
19 we're going to start going. We were just talking
20 about these psychiatry measures. We're going to
21 go on to -- I believe the first one is the -- I
22 believe it's the multiple concurrent

1 antipsychotics, is that correct? I'm sorry; I'm
2 mixing up my notes here. Who is the subcommittee
3 for this particular measure? Okay.

4 MS. BYRON: Hello, everyone, it's me
5 again. The next three measures, actually, are
6 part of a set, so I'm going to tell you about all
7 of them. These are a set of measures that we
8 developed to assess the safe and judicious use of
9 antipsychotic medications in children and
10 adolescents. They're based on the problem that
11 we're seeing that antipsychotic medications are
12 being used increasingly more frequently,
13 particularly among children in Medicaid, children
14 in foster care. While they have been approved
15 for a limited, narrow amount of conditions, such
16 as bipolar disorder, we do see a lot of
17 prescribing patterns that are problematic, such
18 as too many medications, too long of duration,
19 poor management, off-label use. There was
20 actually a very high state need for these
21 measures.

22 There has even been a recent Office of

1 the Inspector General report from Health and
2 Human Services that highlighted problematic
3 prescribing for Medicaid kids. Given the
4 medications' effect on long-term health, it leads
5 to hyperlipidemia, diabetes, weight gain,
6 metabolic disturbances. These are all long-term
7 health consequences.

8 We developed these measures to really
9 encourage a think before you prescribe, and if
10 you are using these, proper management of these
11 kids who are on these powerful medications.
12 They're developed and tested at both the state
13 and the health plan level. We actually started
14 with seven measure concepts and put them through
15 the whole process. Three rose to the top as
16 being prioritized for the HEDIS health plan set,
17 and so those are part of the HEDIS health plan
18 set. Consequently, they've gone through multiple
19 multi-stakeholder advisory committees, two public
20 comment periods, and I think that the common
21 theme here is that many people prioritize these
22 as really high-need measures. They tested well,

1 were found to be reliable and valid.

2 In addition to what we submitted in
3 our form, we had some late-breaking data from the
4 first year of HEDIS reporting that we sent in
5 after submission because those were not available
6 during the time of submission, but those results
7 also confirmed that the measures are valid and
8 reliable.

9 CO-CHAIR BROOKEY: If we could have
10 our subcommittee members speak about the
11 measures. We're going to do one at a time. The
12 first one will be the multiple antipsychotics,
13 right?

14 MEMBER THACKERAY: Similar to some of
15 the discussions we've had already, I think where
16 the workgroup had some concern in discussing the
17 evidence was the fact that the use of multiple
18 antipsychotics really hasn't been studied
19 rigorously. It makes sense to all of us that if
20 the side effects of one are bad that multiple use
21 is potentially worse. But obviously, those
22 studies aren't out there. A good point was

1 raised about the lack of clarity with the risks
2 of different combinations. If you have a
3 combination of two or more, is the risk of that
4 combination less or the same or the greater than
5 another combination of different medications?

6 The point was raised that in certain
7 individual cases, it may be reasonable to have
8 two antipsychotics on board. The measure's,
9 instead, really based on clinical practice
10 guidelines. There's four guidelines from three
11 different organizations referenced, probably the
12 most prominent and largest area of focus being
13 the American Academy of Child and Adolescent
14 Psychiatry, the AACAP. That'll be referenced
15 throughout these three measures.

16 They're very clear in saying the
17 simultaneous use of multiple concurrent meds has
18 not been studied rigorously and generally should
19 be avoided. Their guidelines, their opinions are
20 based on a lit review of about 150 publications.
21 By their acknowledgment, and to our knowledge, I
22 think there's a couple case reports, but none of

1 those publications are rigorous studies that
2 directly address concomitant use of
3 antipsychotics. The developers had initially
4 indicated the evidence would be graded as high.

5 I think our workgroup decided that in
6 the absence of a systematic review and empirical
7 evidence, I think we felt like this might lead us
8 down the pathway to a decision that the evidence
9 is insufficient, but certainly such an important
10 topic that we would consider an exception to
11 that, but I'll open it up to the rest of the
12 subcommittee and the larger group.

13 CO-CHAIR BROOKEY: Did your group talk
14 about the -- in my experience, it's not just two
15 medications. It's more than two. Did the group
16 or did the developers talk about the cutoff of
17 two versus more than two? I just wonder if the
18 evidence shows that there is a difference between
19 -- I think in your remarks, you have low doses of
20 Risperdal or something else versus higher doses
21 of two or more medications. Was that addressed
22 during the development or the testing?

1 MS. BYRON: We focused mostly on two
2 or more. We didn't necessarily distinguish
3 between whether you were only on two, and whether
4 you were on five.

5 CO-CHAIR BROOKEY: I guess the
6 question is why two and not three, I guess, is
7 really what I'm asking.

8 MS. BYRON: Why two and not three?

9 CO-CHAIR BROOKEY: Or four, yes.

10 MS. BYRON: There is evidence -- the
11 evidence is what it is. Really, there's a lack
12 of evidence about long-term safety of
13 antipsychotic use in general. When you add in,
14 too, you have the risk of drug-drug interactions,
15 really felt that the safety evidence was lacking.

16 In light of that, given those case
17 studies on polypharmacy, two or more, we felt
18 that two -- and it's not actually just being on
19 two. It's being on at least two at the same time
20 for a sustained period of time. That's another
21 component of the measure. The expert panels, and
22 based on our review of the evidence, we felt that

1 two was the right threshold.

2 CO-CHAIR BROOKEY: Right, but is that
3 based on consensus, really, the cutoff between
4 two and three, or is it based on clear evidence
5 is my question?

6 MS. BYRON: Yes, it is in the clinical
7 practice guideline. I'm going to see if,
8 actually, Molly Finnerty has joined us yet.
9 Molly, are on the line?

10 DR. FINNERTY: Yes, hi.

11 MS. BYRON: Do you want to introduce
12 yourself and maybe address some of the issues
13 around events with polypharmacy?

14 DR. FINNERTY: Yes, hi. I'm Dr. Molly
15 Finnerty. I'm a psychiatrist as a research
16 associate professor at NYU, in their department
17 of child and adolescent psychiatry, and director
18 for the New York State Office of Mental Health,
19 Bureau for Evidence-Based Services and
20 Implementation Science.

21 CO-CHAIR BROOKEY: Molly, I don't mean
22 to interrupt you, but the question we'd like you

1 to address is the cutoff between two and anything
2 above two. Where do you draw -- is the evidence
3 supportive of two versus three versus four? I'm
4 talking about the threshold for the measure.
5 That's really what we're looking for, in terms of
6 evidence.

7 DR. FINNERTY: Right. The types of
8 evidence that we considered were one, the reviews
9 and clinical consensus that has come out of
10 clinical practice guidelines from experts in the
11 field. There, they focus on two or more as being
12 a practice to be avoided in children, with a
13 strong recommendation across all of the
14 guidelines available. The other type of evidence
15 is through studies. There has been a review
16 published that found a couple of studies.

17 There was an analysis of some
18 retrospective and prospective clinical reports
19 that suggest that a patient's risk of weight gain
20 can be influenced by the synergistic interaction
21 between age and polypharmacy, but there was other
22 studies that looked at the relationship between

1 age and polypharmacy that demonstrated strong
2 positive associations with increased risk of
3 obesity with odds ratios of, say, 2.28 in one
4 study, and cardiovascular and cerebrovascular
5 hypertensive adverse events in children of odds
6 ratio of 1.72. We don't have a wealth of
7 studies, but to the extent that the issue has
8 been examined, it does suggest that there is an
9 increased risk here.

10 CO-CHAIR BROOKEY: Right. So there's
11 nothing wrong with it being consensus based, but
12 the decision for two is really based on
13 consensus, is that correct, primarily?

14 MS. BYRON: I'd say it's
15 evidence-informed consensus.

16 CO-CHAIR BROOKEY: Okay. Jon?

17 MEMBER FINKELSTEIN: I was part of the
18 small group, as well. I really do see this as
19 resting on the consensus guidelines. To their
20 credit, that's all it can rest on. It's not like
21 there's a randomized trial of two versus a high
22 dose of one. I think we can't have an

1 unreasonable threshold. That said, the guideline
2 statements, which the developers included, aren't
3 quite black and white. They say these haven't
4 been studied and generally should be avoided.
5 Another one says the prescriber needs a clear
6 rationale for using medication combinations.

7 It doesn't say never, ever. It says
8 you better be thoughtful about it and not jump to
9 polypharmacy right off the bat. I think that's
10 where we're going to have to really do some
11 thinking. I have some more comments about the
12 reliability/validity stuff that I'll make later,
13 but that's a challenge.

14 CO-CHAIR BROOKEY: Again, there's
15 nothing wrong with it being consensus based. We
16 do have to think about the unintended
17 consequences to an individual prescriber who may
18 be doing the right thing, and for the kids who
19 are being treated. Amy.

20 MEMBER HOUTROW: My question is
21 exactly based on that. The way I understood
22 previous measures, such as the tobacco one, is

1 that we knew that using counseling is effective
2 in reducing smoking. More counseling, therefore,
3 on every patient who is a smoker, then, is
4 beneficial. The goal would be 100 percent. But
5 there is no goal here that I can see from the
6 literature.

7 There's no epidemiologic data that
8 says how many kids are on polypharmacy, and
9 there's no epidemiological data on which kids
10 have the most severe conditions for which
11 polypharmacy may be appropriate, so there's no
12 possible way that this represents to me a quality
13 measure. It represents a practice measure of
14 what people are actually doing. But because
15 there's no data to say what percentage of kids
16 would be appropriately treated with more than one
17 medication because there's not the evidence for
18 that, I can't see this -- or maybe I'm just
19 missing something. I don't see this as a quality
20 measure because there's no appropriate threshold
21 or goal set. There's just we're going to measure
22 it, and we want it to be low. We aren't going to

1 know whether or not that was appropriate or not.

2 CO-CHAIR BROOKEY: I think that, as
3 Jon mentioned, it's not very tight, in terms of
4 where a threshold should be drawn, but I think
5 generally, people are in agreement that it's a
6 red flag if anybody's on multiple psych meds, and
7 we know that psych meds do have problems,
8 especially with drug-drug interactions and weight
9 gain and everything else. I think the issue that
10 you're describing is a threshold issue, is what
11 I'm hearing. Let's go around the room. Go
12 ahead. Who's got their -- is that David? They
13 both have blue shirts on.

14 MEMBER EINZIG: Just to take a step
15 back, and I apologize if I rehash some of the
16 comments that were already made, but talking
17 about semantics because semantics are important
18 to me, we're calling these medications
19 antipsychotics, even though majority of the time,
20 they aren't used for psychosis, per se. What
21 these medications are, by definition, are they're
22 dopamine modulators. Majority of them are

1 dopamine blockers. Some of them are dopamine
2 modulators, like Abilify. What we're doing is
3 we're targeting specific brain chemistry to help
4 improve quality of life or quality of
5 functioning.

6 The concerns about weight gain and
7 maybe two might be more risky than one, I don't
8 know if that really floats with me. I think 15
9 milligrams of Zyprexa, compared to low doses of
10 two other medications in the same class that are
11 less likely to cause weight gain, I don't think
12 there's strong evidence to back that up. I'll
13 stop.

14 CO-CHAIR BROOKEY: Okay. David,
15 Number Two? Oh, I'm sorry, Jill?

16 MEMBER MORROW-GORTON: So, I just
17 wanted to kind of get back to the question, I
18 think again, it may be just semantics. We're
19 talking about polypharmacy, polypsych-pharmacy.

20 Are we talking about antipsychotics?

21 CO-CHAIR BROOKEY: Antipsychotics.

22 MEMBER MORROW-GORTON: Are we talking

1 about other -- well, just because when people
2 talk about polypharmacy, sometimes, you know,
3 these kids are probably on six or seven drugs.
4 But, they may not all be antipsychotics.

5 CO-CHAIR BROOKEY: Yes. I just gave
6 an example to Dave in Number One there that I
7 recently had a kid that was on Risperdal,
8 Adderall, Valium, Methadone, and some sort of an
9 opiate.

10 I'm not kidding, a six year old
11 autistic kid. So, it may have been one
12 antipsychotic, but so it wouldn't fall into this
13 measure.

14 But your question I think is really
15 about the class of drugs. And I'm interpreting
16 it to be an antipsychotic class. Is that
17 correct? Okay.

18 So, David?

19 MEMBER KELLER: And I topped him with
20 the kid who was on seven different meds and was
21 coming to us for Viagra because he was impotent
22 because of all the medications he was on.

1 CO-CHAIR BROOKEY: Yes, that did top
2 my story.

3 MEMBER KELLER: So, we all have a
4 story. And by the way, you all can refer to me
5 as The Doctor.

6 (Laughter.)

7 MEMBER KELLER: So, -- no, the point
8 I was going to make though was I agree that this
9 is not a measure where the goal is to get the
10 number down to zero.

11 I think this is a -- though I think it
12 is a useful measure to get -- start getting a
13 handle on what is I believe a problem.

14 Which is that very often these
15 psychiatric medications are being prescribed in
16 multiple ways. Some of which may be appropriate.

17 But I think that at a population
18 level, particularly as this measure is being
19 proposed, it gives us a way of looking at the
20 population and trying to recognize outliers in
21 treatment.

22 And the most important thing that

1 we're going to be able to do with this is to, I
2 think, is to be able to recognize when we have
3 places where more kids than usual are getting
4 treated with multiple medications. Which should
5 prompt investigation, what's going on here.

6 Very often, now I would hope we would
7 discover that these are people who are taking
8 care of folks with serious emotional disturbance
9 and require that.

10 But, it's a -- again, it's a measure
11 that prompts us to look at things. It's not
12 necessarily a judgement that the thing we're
13 looking at is bad.

14 And I think with that in mind, I
15 actually like this measure. Picking two or
16 three, I see the rationale for picking two.

17 And so I don't have a problem with it.
18 But again, I think we have to keep in mind that
19 it's not a measure that's to be run into zero.

20 CO-CHAIR BROOKEY: We may be headed
21 towards a situation with insufficient evidence
22 with exception. I just want to call that out

1 when people are thinking of formulating their
2 ideas here.

3 Because I think that we all agree this
4 is an important problem. Ricardo, you're next.

5 MEMBER QUINONEZ: Yes, I just want a
6 clarification maybe from the developers. Where
7 in -- is there a specific population of kids
8 where this is more of a problem?

9 So, for example, ADHD, where I could
10 get my head around? That's probably if you're on
11 two or more medications, it shouldn't be a high
12 percent.

13 Versus kids who actually have
14 psychosis. What was this -- was there a thought
15 of narrowing the population of kids?

16 DR. FINNERTY: We wouldn't recommend
17 that approach. In children, most of the children
18 receiving antipsychotics do not have a psychotic
19 disorder or any primary indication for the
20 medication.

21 It's often used for sedation. To try
22 to manage maladaptive behaviors. And

1 particularly when clinicians are struggling, as
2 they can, that sometimes medications just get
3 added.

4 It may be of interest to the Committee
5 to note that at the outset, an overall
6 psychotropic polypharmacy measure was there. But
7 that doesn't have the same level of either
8 clinical consensus nationally or evidence.

9 And even though the evidence is
10 limited here for antipsychotics, it's fairly
11 clear about risks and new onset of diabetes and
12 hyperlipidemias and things like that in children.
13 It's also fairly clear that children are at an
14 increased risk.

15 And there's just a bit of evidence
16 suggesting that polypharmacy further exacerbates
17 that risk. So, I guess the restriction of
18 diagnosis would maybe not sort of be pointing the
19 flashlight.

20 That these measures are a powerful
21 tool for doing that. And might not point it in
22 the right direction.

1 There are some populations that not
2 diagnostically, but really for psychosocial
3 reasons, like children in foster care, are very
4 much at increased risk for receiving
5 polypharmacy.

6 And also geographic regions. You
7 know, things that don't always make clinical
8 sense. Sort of regional variation. You know
9 poverty, foster care, things like that put you at
10 increased risk.

11 Children in Medicaid increased risk.
12 So, I think restricting to diagnosis might -- we
13 might miss an opportunity to help increase
14 awareness that this is a concern.

15 CO-CHAIR BROOKEY: Yes, thank you.

16 MEMBER AGORATUS: This is Lauren. I
17 have a clarification question.

18 I actually was just going to ask about
19 the foster care and Medicaid subgroups. And
20 also, a third subgroup, children of color who are
21 more likely to be prescribed psychotropic
22 medications.

1 Are they also at increased risk for
2 polypharmacy?

3 CO-CHAIR BROOKEY: Are you looking at
4 disparities I guess is the question.

5 MEMBER AGORATUS: Yes.

6 DR. FINNERTY: We have looked at
7 disparities. I think that once you control for
8 these other statuses, we did not see that. So,
9 the regional variation is stronger.

10 And foster care status is stronger.
11 So, once you're controlling for things like that,
12 you wouldn't observe. And you know, this isn't
13 something that, you know, I could just say in the
14 study that I have fresh in my mind because we did
15 them for example in New York State.

16 But, I think it's more Medicaid versus
17 not. And foster care versus general population,
18 where you really see it.

19 So, to the extent that children of
20 color are more represented in those populations,
21 yes. They would be more impacted.

22 But it may not be due to race or

1 ethnicity alone.

2 CO-CHAIR BROOKEY: Okay. Thank you.

3 DR. FINNERTY: It's more their status.

4 CO-CHAIR BROOKEY: Kerri, you have a
5 comment?

6 MEMBER FEI: Sure. I know we've
7 talked a little bit about population level. But
8 at a health plan level, talking with some of our
9 member plans, they see this as an important
10 safety measure.

11 As a red flag for them. Not that they
12 would necessarily score or consent or reimburse.
13 But, if there is something awry, it would be
14 something for them to trigger them to look into
15 it.

16 CO-CHAIR BROOKEY: Yes. And just
17 remember, the health plan measure can also drill
18 down to an individual prescriber. So it doesn't
19 mean that it's at a higher level.

20 It just depends on the health plan,
21 right. Okay. Let's see, go ahead, Kevin.

22 MEMBER SLAVIN: So, and I was -- I've

1 been looking at the recommendations. And
2 certainly recommendation eight, which is probably
3 more strongly worded than principle 12.

4 But it specifically talks about
5 atypical antipsychotic agents. And not using
6 multiple atypical antipsychotic agents as opposed
7 to, you know, multiple antipsychotic agents in
8 general.

9 So I'm wondering if there's some
10 comment on that? And mixing classes or mixing
11 atypicals with more traditional?

12 And the second thought is, you know,
13 a lot of what we do in medicine is balancing the
14 -- sometimes very substantial risks of treatment
15 versus the potential benefits. And I see this as
16 one of those situations where there is an unknown
17 at the moment about which patient might benefit
18 from polypharmacy.

19 And that at the time that the
20 prescribing is done, hopefully there is a
21 discussion with the parents. And if the child is
22 old enough to assent to this, an understanding of

1 what the risks might be.

2 And I think if that discussion
3 happens, I don't necessarily know that I see this
4 -- that there's evidence that that -- that this
5 is a problem as long as that discussion of risk
6 benefits has occurred.

7 And as long as there's a plan if the
8 success is not being seen that we remove part of
9 that risk.

10 MS. BYRON: So, I agree. The recent
11 Office of Inspector General Report that I just
12 referenced actually came out in March 2015 did a
13 study across on -- across six states that account
14 for about 40 percent of the antipsychotic
15 prescribing.

16 And they found that at least I think
17 40 percent of them, of the claims that they
18 looked at, it was the same with both claims, had
19 at least two quality concerns. And of the
20 highest ones, it was poor management.

21 And it was, you know, too long
22 duration. And too many measure -- I mean, too

1 many medications.

2 Recognizing that clinicians need to
3 weigh whether or not the benefits of the
4 medication would outweigh the risk, they also
5 looked to see how many claims were associated
6 with conditions that are included in the FDA
7 boxed warning.

8 The boxed warning states that if you
9 have a certain condition such as depression, you
10 would have an increase in suicidal ideation and
11 suicidal behavior. And found that a third of the
12 claims were associated -- were prescribed in
13 light of those conditions.

14 And so, I think that what you're
15 describing is the ideal. And unfortunately, it
16 particularly in Medicaid, I think it's not
17 necessarily the norm.

18 CO-CHAIR BROOKEY: Let's see, Jeff?

19 CO-CHAIR SUSMAN: So, again, in an
20 integrated primary care psychiatric setting that
21 was one of the only places where children with
22 serious chronic mental illness could get service.

1 And having some I think very topnotch folks
2 working.

3 There were times when multiple
4 antipsychotics seemed at least the appropriate
5 thing to try. If not continue.

6 So, I agree with the conversation
7 around, this probably shouldn't be a zero
8 percent. But, in looking at the data of people
9 both referred in and then across our community
10 when I was down in Cincinnati, it's pretty clear
11 that there is overuse and not regular
12 reassessment that would justify the ongoing use.

13 Versus what I think are some tangible
14 harms of ongoing therapy. Therefore, this is one
15 of those measures that I see as, you know,
16 there's not that much evidence.

17 It's mostly expert opinion. Consensus
18 based. But it's probably the right thing to do.

19 CO-CHAIR BROOKEY: So, I'm going to
20 ask the final commenters to reflect on the
21 evidence so that we can move forward to a vote
22 for evidence. Because I think we've heard a lot

1 about how much there is or isn't about evidence
2 irrespective of the importance of the measure.
3 Which is a different question.

4 So, I'll ask those comments to go
5 quickly. We'll go with Jeff I believe has a
6 comment.

7 MEMBER SCHIFF: So, just to -- and
8 I'll just say evidence that we have in our
9 Medicaid program is that this is a particular
10 issue just for -- especially for foster care
11 kids.

12 And I think that I'm in support of
13 this measure. But part of it is because when
14 people look at polypharmacy, they often look at
15 ADHD drugs and SSRIs. And we're really just
16 looking here at the antipsychotics and the issues
17 around those.

18 I have other comments, but I think
19 I'll wait until further down the discussion.

20 CO-CHAIR BROOKEY: Okay. Amy?

21 MEMBER HOUTROW: I appreciate that the
22 number shouldn't be zero. Right, there are kids

1 that it is appropriate for them to be on more
2 than one medicine.

3 But what I'm missing here is the
4 evidence to support this. This isn't an overuse
5 measure. This isn't just a measure of the
6 clinical behavior.

7 And while I think that the issue is
8 important, overuse. This isn't -- there's no
9 evidence that we know of where the appropriate
10 number should be to look at overuse.

11 And we don't have any ability using
12 this measure to do anything other than red flag
13 potential overuse. And so, I've heard that red
14 flag statement a couple of times. It's totally
15 an important point.

16 But, the measure is a quality measure,
17 not a red flag measure. And I just don't think
18 that there's evidence that this is giving us
19 enough to use it as a quality measure as it
20 stands.

21 CO-CHAIR BROOKEY: Okay. Dave?

22 CO-CHAIR SUSMAN: Would you find it

1 important if one plan had 20 percent of
2 individuals who had more than two? Or two or
3 more? And then three percent in another plan?

4 Would that be something worth looking
5 into?

6 MEMBER HOUTROW: Right. Variations in
7 care are important to evaluate. But we just
8 don't have whether the 3 percent number is right
9 or the 7 percent number is right. Or the 2.1
10 percent number is right.

11 We just don't have that information.

12 CO-CHAIR SUSMAN: Yes. I think all
13 you can say about it is that this calls for
14 further review. If you have an outlier, it calls
15 for further review.

16 It doesn't necessarily mean that
17 they're a bad outlier, right? These kids could
18 be totally, appropriately treated.

19 I think we would agree with that Amy.
20 David?

21 CO-CHAIR BROOKEY: I think Marlene was
22 next. I can't see very far down there.

1 MEMBER MILLER: I wasn't next. But I
2 just have a quick comment I wanted -- because it
3 builds off of there.

4 I think the problem we all have, or at
5 least what I feel, is that I know we sometimes
6 think this is a measure just for internal quality
7 review. But then it gets put out for
8 accountability.

9 And some arbitrary measure of this
10 should be zero gets out there. And it's the
11 wrong way.

12 And we -- every measure group I've
13 ever been on, we've always had this discussion is
14 this for QI or accountability? And every time
15 the usual answer is, it's going to be -- end up
16 used for any of those.

17 And so we don't control whether this
18 will be put out there for accountability and then
19 some arbitrary number gets put on the right
20 level.

21 CO-CHAIR BROOKEY: Okay. I think we
22 may be back down to the last comment by David.

1 MEMBER EINZIG: As usual.

2 CO-CHAIR BROOKEY: David One.

3 MEMBER KELLER: No, I'm The Doctor.

4 You're David. My Tardis is outside.

5 MEMBER EINZIG: I appreciate the

6 differences. And it's a legitimate issue.

7 But my concern is, so I wouldn't rate
8 the evidence as insufficient. I would rate the
9 evidence as low.

10 Because there is -- there just is no
11 evidence. It's not studied. There's no studies
12 of looking at this long term.

13 People on one medication versus on two
14 medications. And so I don't see a way around
15 that.

16 And then with the expert consensus,
17 you know, stated as polypharmacy should be
18 avoided. It's not saying it shouldn't be done.

19 Granted, there are doctors out there
20 that do wacky things with medications. But, I
21 just don't think this measure really flies with
22 me.

1 CO-CHAIR BROOKEY: So, I'm going to
2 see if maybe we can get close to a vote. I think
3 that most of us are thinking this is probably not
4 going to be a high or a moderate in terms of
5 evidence.

6 But I think if people want to move it
7 forward, then they -- and if they don't think
8 it's high or moderate, they're going to have to
9 vote it insufficient.

10 And then we can go for exception. So,
11 to David's point, if you think it's low and you
12 vote low, that means you're not really wanting it
13 to move forward.

14 So, I just want to be clear about how
15 we're voting. And you know, it's a really good
16 discussion. I guess the question is about the
17 unintended consequences of a measure like this.
18 How it's going to be used? You know, what does
19 it mean? And so forth.

20 Go ahead Helen.

21 DR. BURSTIN: I just want to respond
22 to your comment and Marlene's as well. It's

1 really important to remember, this is a health
2 plan level of analysis measure.

3 NQF measures are only intended at the
4 level of which they're tested, submitted, and
5 endorsed. So, that is what it is.

6 So, to invoke how it might be used at
7 the clinician level, if that measure is intended
8 ultimately at the clinician level, it has to
9 return and demonstrate testing. And look at all
10 those other issues you're raising at the
11 clinician level.

12 It's truly, only at the health plan
13 level.

14 CO-CHAIR BROOKEY: Health plans use
15 data though to get down to individual practice.
16 And so I think we have to be clear about how
17 health plans may use data.

18 It's not necessarily just going to be
19 aggregated data. It can go down the practice.
20 It can go down --

21 MEMBER MILLER: Accountability of the
22 health plan level, right?

1 CO-CHAIR BROOKEY: Yes.

2 MEMBER MILLER: Of someone judging a
3 health plan does or doesn't provide good care
4 based on some arbitrary -- or lack of evidence as
5 we were saying of what is the right number? Or
6 right level or acceptable performance on this
7 measure?

8 So it would be at the clinician.

9 CO-CHAIR BROOKEY: If the health plan
10 isn't doing well on a measure that pressure can
11 trickle right down to the individual practice of
12 a doctor. There's no question about that.

13 Right Kerri?

14 MEMBER FEI: Absolutely.

15 CO-CHAIR BROOKEY: So, I just want to
16 be clear, this is maybe a health plan level. But
17 that doesn't mean that it's not going to have
18 implications for individual practitioners.

19 MEMBER FEI: The other thing is that
20 it really as far as holding health plans
21 accountable, it would be up to their accrediting
22 body to do that.

1 To my knowledge, it is not included in
2 the health plan accreditation standards as a
3 HEDIS measure to which plans are evaluated at
4 this present time.

5 And I don't see where this would --
6 this one specifically, I don't see where they
7 would consider adding that at any time. Maybe
8 some of the others.

9 But, I don't think this would be one
10 that would rise to the top for that purpose.

11 MS. BYRON: I just wanted to say, it's
12 health plan and State level. So, it's both.

13 And to Kerri's point, you're right.
14 Not all HEDIS measures are used in accreditation.

15 We have another process where an
16 external multi-stakeholder body would look to say
17 does this measure make sense in an accreditation
18 context? And they would consider all of the
19 things that have been actually very, you know,
20 well thought out and raised in this Committee.

21 And you know, some of the issues I
22 will just say, these are issues that do apply to

1 all over use appropriateness measures, whatever
2 you may call them. Where lower is better. We
3 don't know that we necessarily want to get to
4 zero.

5 I would submit that there are other
6 measures where higher is better. And we don't
7 necessarily think we can get to 100. And it may
8 not make sense there either.

9 And so, you know, in the context of
10 thinking about appropriateness and overuse, which
11 is where I think we do want measurement to be
12 headed towards, where you can be looking at the
13 appropriateness of clinical care. And not
14 advocating for more, is better.

15 We do have the challenge of where do
16 you set a threshold? But, we do hope that the
17 measure can shine a light on issues and flag
18 problems. And allow for comparison.

19 CO-CHAIR BROOKEY: So, I don't --
20 unless we have anything new to say about
21 evidence, I mean, I think we all have heard.

22 I think we all understand the

1 implications that having a measure that's based
2 on consensus and not evidence. And how that our
3 first charge is to really evaluate the evidence
4 of a measure before it goes to the second
5 question.

6 So again, I'm going to repeat that
7 what you decide on will determine whether or not
8 this could move forward either as a medium or
9 insufficient evidence with exception.

10 If you vote low, that means you're not
11 wanting it to move forward at this time as
12 specified. It doesn't mean that it's forever
13 dead.

14 It just means that as specified,
15 you're voting it low. And will not move forward.

16 Are we ready to vote on the evidence
17 aspect of this? Okay. So, let's vote.

18 MS. CHAVEZ: Okay. We're getting
19 ready to vote for Measure 2799. One for high,
20 two moderate, three low, four insufficient.
21 Polling is open.

22 (Pause.)

1 MS. CHAVEZ: Ten. Twenty-one.
2 Twenty-three. We are expecting 23 votes. Okay.
3 Zero voted high. Zero voted moderate. Six voted
4 low. Seventeen voted insufficient.

5 CO-CHAIR SUSMAN: I think it would be
6 worth asking if we want to have an exception on
7 the evidence for this one.

8 CO-CHAIR BROOKEY: Can we just get a
9 straw vote of how many would like to open this up
10 for discussion and vote for exception?

11 CO-CHAIR SUSMAN: A vote, no
12 discussion.

13 CO-CHAIR BROOKEY: Why don't we just
14 vote then. We will put this up for a vote for
15 insufficient evidence with exception.

16 Which means it can move forward to the
17 full review. Okay?

18 MS. CHAVEZ: Okay. One for
19 insufficient evidence with exception. Two, no
20 exception.

21 (Pause.)

22 MS. CHAVEZ: Sixteen. Twenty-two.

1 We're expecting 24 votes. Twenty-three. Twenty-
2 four.

3 Okay. Seventeen voted insufficient
4 evidence with exception. Seven for no exception.

5 CO-CHAIR BROOKEY: So I think that
6 means that we think it's an important issue.
7 Whether or not we agree with the specification.
8 So that's -- well, that's the way it will be
9 presented.

10 The next question has to do with
11 performance gap. And do our Subcommittee Members
12 have some comments about performance gap?

13 MEMBER THACKERAY: Yes, sorry. My
14 computer is now updating Windows and restarting.
15 But, I think --

16 (Laughter.)

17 MEMBER THACKERAY: It couldn't be
18 worse timing. But I think we touched on it in
19 the previous conversation.

20 The developers cite several -- thank
21 you -- systematic review that found one in ten
22 youth being prescribed any antipsychotic were on

1 multiple, concurrent antipsychotics.

2 They also cite data from their own
3 analysis of Medicaid data showing that there were
4 average rates of 6 percent in the general
5 Medicaid population. A slightly higher average
6 rate for children in foster care.

7 And then the disparities we already
8 touched on in previous discussions. So, I think
9 it's pretty clear about that.

10 CO-CHAIR BROOKEY: I think we talked
11 about this quite a bit earlier. Is there any
12 other discussions about performance gap? If not,
13 could we -- go ahead Jeff.

14 MEMBER SCHIFF: I have a question
15 probably for NQF Staff. You know the -- my
16 understanding is our measure goal here is around
17 accountability.

18 And so this seems like a quality
19 improvement measure that we're applying at a
20 health plan level. And I just -- I guess I just
21 want to -- it seems like we're a little off.

22 And I mean, I think -- I don't think

1 this is an unimportant issue. I could talk for a
2 long time about why it's important.

3 I just -- I'm just trying to figure
4 out, you know, it seems to me like this is a
5 quality improvement topic that we're applying to
6 an accountability standard where we don't have a
7 threshold.

8 And I just -- I don't know if any --
9 I think along the same lines that Amy maybe had
10 said. So, I think we have to -- you know, I
11 think it's -- I would love for this to be
12 measured in a lot of places to look at the
13 quality of it.

14 But, I'm not sure that at the
15 measurement level it's the right thing.

16 MS. BURSTIN: Again, I think it's a
17 judgement call. I mean, it is certainly -- we
18 say measures can be used for accountability and
19 quality improvement.

20 So, I don't think we're making a
21 distinction saying it's one or the other.
22 Ideally it would be intended for accountability.

1 And certainly I think the way NCQA
2 would use it would have some element of bench
3 marking, et cetera. Which would fit under
4 accountability as well.

5 CO-CHAIR SUSMAN: And if I'm correct,
6 NQF has developed a process to consider this
7 particular issue. Is that?

8 MS. BURSTIN: Yes.

9 CO-CHAIR BROOKEY: Any other comments
10 about performance gap? Otherwise can we go to a
11 vote?

12 (No audible response.)

13 CO-CHAIR BROOKEY: Okay.

14 MS. CHAVEZ: Okay. We're now voting
15 on gap. One high, two moderate, three low, four
16 insufficient. Polling is open.

17 (Pause.)

18 MS. CHAVEZ: Thirteen. Twenty-two.
19 Twenty-three. Twenty-four. Five voted high.
20 Seventeen voted moderate. Two voted low. Zero
21 for insufficient.

22 This measure passes performance gap.

1 CO-CHAIR BROOKEY: Thank you. Let's
2 move onto reliability. Does our Subcommittee
3 have any comments about reliability?

4 MEMBER EINZIG: So, reliability
5 testing at the State level was deemed as good.
6 But at the Medicaid level, I'm not a
7 statistician, so I can't really speak strongly
8 about that.

9 But, it was not seen as reliable at
10 the Medicaid level.

11 CO-CHAIR BROOKEY: Okay. Jon, did you
12 have a comment?

13 MEMBER FINKELSTEIN: Yes. So, I'm
14 part of the Subgroup as well.

15 CO-CHAIR BROOKEY: Um-hum.

16 MEMBER FINKELSTEIN: So, the
17 reliability issue is that these are relatively
18 rare events. So that you need very large
19 populations to meet any reliability standards.

20 So, it came out okay at the State
21 level. At the Medicaid health plan level, if
22 they're big enough and have enough of these kids

1 in the denominator, it was eh, okay.

2 And that at the commercial plan level,
3 they had to eliminate 24 of 72 commercial plans
4 because they had less than 30 patients in the
5 denominator. So, it's all about only in big
6 populations.

7 I understand NCQA's approach to say
8 this is only reasonable at the State level or
9 very large Medicaid health plan levels. How it
10 will be used in practice we can't control.

11 I just -- I'll do validity here as
12 well. Which is that they used psychometric
13 validity methods which are good.

14 And they came out again with
15 coefficients and rankings that are okay. But,
16 what we don't have, and I think this measure is
17 supremely important.

18 What we don't have is taking people
19 that would fail the measure based on claims. And
20 looking in the chart for some sample and saying
21 would three other psychiatrists agree that this
22 was terrible care? Or 90 percent of the time,

1 would they be acceptable?

2 So, we don't have any of that
3 validity. We do have face validity because of
4 the process they used, the stakeholders they got,
5 and the guidelines that it rests on.

6 So that's -- it's a very -- for me
7 it's a very complicated reliability and validity
8 picture.

9 CO-CHAIR BROOKEY: So, this is a plan
10 level measure. But it could become a Medicaid
11 plan measure, right?

12 So I mean, theoretically, this could
13 just be -- it doesn't have to become a commercial
14 measure. It could be --

15 MS. BYRON: Right. So -- and actually
16 so, -- so, you're right. I mean, those points
17 are well taken.

18 In the more recent HEDIS data that we
19 used to assess, you know, based on first year
20 results from HEDIS, the Medicaid results were
21 actually reliable at .95.

22 So, you know, in our field tests, they

1 were moderate. But then when we went to the
2 larger HEDIS reporting, it was high.

3 So, it was lower for commercial
4 though. And it is for the reasons that you
5 stated about the denominator.

6 And right now it's in HEDIS. It
7 applies to Medicaid and commercial plans.

8 CO-CHAIR BROOKEY: Um-hum.

9 MS. BYRON: But, we will be publically
10 reporting for Medicaid plans only because of the
11 issue with the commercial plans and the
12 denominators.

13 CO-CHAIR BROOKEY: So that gets to
14 John's point. So, we're not voting right now as
15 to whether or not it's going to be a Medicaid
16 plan or -- a measure, or a commercial measure.

17 It sounds like the reliability is high
18 in the appropriate population. So, keep that in
19 mind when you're voting for reliability.

20 That it's going to be more reliable in
21 a higher risk group that is more -- that has more
22 exposure. I think that's all intuitive, right?

1 So, do we have enough information to
2 vote on reliability? Go ahead Jill.

3 MEMBER MORROW-GORTON: So, if we -- if
4 this is reliable at only a big plan, so you know,
5 if you have a State that has five Medicaid plans
6 and they're all really small, then you can only
7 use this at the State level, right?

8 CO-CHAIR BROOKEY: Possibly.

9 MEMBER MORROW-GORTON: But, States
10 aren't going to know that. I mean, States aren't
11 going to know that.

12 And they're going to try to use it at
13 a plan level that's not going to be reliable.

14 CO-CHAIR BROOKEY: So that's a
15 limitation of the measure because of the small
16 volume. So, that's what John just stated.

17 Anything else new about this
18 particular issue? Karen?

19 MEMBER DORSEY: Yes, I mean, I'll just
20 that that can be pretty readily dealt with.
21 Because if the cases are too small to report a
22 reliable number, you can report that the cases

1 are too small to report a reliable number.

2 And that in and of itself in this
3 context is useful information. Because it shows
4 comparatively the population of kids who were
5 even considered for mono-therapy in private plans
6 versus Medicaid plans. Right?

7 So, in the context that we're talking
8 about this, it's still useful information to be
9 reporting.

10 CO-CHAIR BROOKEY: Okay. Just go up
11 the line. John?

12 MEMBER THACKERAY: So I think in our
13 small group discussion, we had one or two
14 questions regarding specifics of the numerator
15 for the developers. One was, if you have a child
16 who's on a scheduled medication and one that's
17 prescribed on a PRN basis, would that count
18 towards the numerator?

19 And the other question was, if you
20 have a child who's on one medication throughout
21 the period of measurement, is on a second
22 measurement for 45 days, gets switched from that

1 to a different second medication for 45 days,
2 would those kids be included in the numerator as
3 well?

4 MS. BYRON: Okay. You're having me do
5 math in my head.

6 (Laughter.)

7 MS. BYRON: Let me see if I can
8 explain and answer the question. And Molly, feel
9 free to jump in as well.

10 So, if you are on one -- it's any two.
11 So, if you're on one for 40 -- I think we
12 specified 90 days actually. So, it's 90 days of
13 sustained use.

14 We do allow for a gap in case of
15 titration. So, we do want to account for that.
16 And that's where the -- we place that.

17 And I -- Molly, do you want to respond
18 to the questions about --

19 DR. FINNERTY: Yes, sure. You know,
20 we look at a day's supply. So, if you say that
21 you have a second antipsychotic on as a PRN, you
22 know, one of -- the challenges with PRNs is we

1 don't, you know, when folks go home, we don't
2 know exactly how they're using them.

3 This would say that if they're using
4 it enough that they have a day's supply that
5 covers the majority of the 90-day period, then it
6 really is a concomitant use.

7 If on the other hand they're using it
8 so rarely that they don't need to fill that
9 second PRN, you know that they had very few days'
10 supply, then they won't meet criteria for
11 polypharmacy.

12 MEMBER THACKERAY: Okay. Thanks.

13 CO-CHAIR BROOKEY: Okay. David?

14 MEMBER EINZIG: So, from a clinical
15 perspective, you know, are we hitting the right
16 target on this in terms of equating single
17 medication as better quality than polypharmacy?

18 And I still don't think that I'm there
19 in terms -- if that's accurate to say if that's a
20 validity question.

21 If, you know, when the examples that
22 we used in our telephone discussion was, so

1 Risperdal is six milligrams, is that safer than
2 one milligram of Risperdal with 25 milligrams of
3 Seroquel at night? Not that you would do that at
4 first.

5 But if ultimately you try different
6 things and they get elevated prolactin or
7 elevated dystonias. Other problems with
8 Risperdal, but it works great. Every other
9 medicine fails.

10 You know, so there's going to be
11 scenarios where it does make more sense and is
12 clinically indicated to go with the polypharmacy.
13 And it's maybe safer.

14 CO-CHAIR BROOKEY: Yes. So that's a
15 validity question I think. So, we want to talk
16 about reliability.

17 And I think the major issues that I'm
18 hearing about reliability have to do with the
19 size of the plan. And the mix of the plan in
20 terms of payer source.

21 Because Medicaid will probably yield
22 more. But irrespective of that, a small plan

1 will be challenged to produce a report that's
2 statistically significant and comparable.

3 So, having -- understanding all those
4 limitations of the measure, can we vote on
5 reliability?

6 MS. CHAVEZ: Okay. Now voting on
7 reliability. One for high, two moderate, three
8 low, four insufficient. Polling is open.

9 (Pause.)

10 MS. CHAVEZ: Twelve. Twenty. Twenty-
11 three. Twenty-four. Zero voted high. Ten voted
12 moderate. Twelve voted low. Two voted
13 insufficient.

14 This measure does not pass. It's in
15 the gray zone. This brings us in the gray zone.

16 CO-CHAIR BROOKEY: What's the
17 percentage? You had three and four, right?

18 MS. CHAVEZ: For 24 votes, between 14
19 and 10, it takes us to the gray zone.

20 CO-CHAIR BROOKEY: Okay. So validity,
21 we heard there is some face -- I'm sorry, can we
22 move on? Yes.

1 So, validity we had a little bit of
2 conversation about face validity. Any other
3 comments about validity from the Subcommittee?

4 MEMBER HOUTROW: I'm reading under
5 specifications, the section to determine if a
6 measure of specifications are consistent with the
7 evidence. The statement is that the
8 specifications are consistent with the evidence.

9 The goal of the measure is to assess
10 inappropriate prescribing of antipsychotic
11 medication to children and adolescents. And what
12 I would say is this does not measure the
13 inappropriate prescribing.

14 It only measures the prescribing of
15 antipsychotic medications. So, therefore it
16 doesn't meet validity specifications.

17 Because it doesn't do what they
18 intended. Which is to assess the inappropriate
19 prescribing. The numerator is two or more. The
20 denominator is any.

21 So therefore they're only measuring
22 the percentage of prescribing with no

1 relationship to whether or not that's appropriate
2 or not.

3 CO-CHAIR BROOKEY: Other comments?

4 (No audible response.)

5 CO-CHAIR BROOKEY: So, I think we're
6 challenged with the evidence. Amy's point is
7 that just because somebody is prescribing more
8 doesn't necessarily comment on the inappropriate
9 prescribing.

10 David's made his comments about his
11 concerns. Any other concerns about validity or
12 comments before we vote on validity?

13 (No audible response.)

14 CO-CHAIR BROOKEY: No? Okay.

15 MS. CHAVEZ: Okay. Now voting on
16 validity. One high, two moderate, three low,
17 four insufficient. Polling is open.

18 (Pause.)

19 MS. CHAVEZ: Sixteen. Twenty-one.
20 Twenty-two. Twenty-four. Zero voted high. Six
21 voted moderate. Fifteen voted low. Three voted
22 insufficient.

1 This measure does not pass validity.

2 CO-CHAIR BROOKEY: So we stop here.

3 And we'll pause to make any comments that we have
4 not already made.

5 I don't want to repeat comments that
6 we've already made. I think the developers have
7 taken notes.

8 I think we all think it's a very
9 important issue. We're just not thinking that
10 the measure is getting to the specificity of the
11 individual practitioner's problem with
12 prescribing.

13 It's just a question of how much is
14 prescribed and not whether it's appropriate or
15 not. And really, the evidence does not support a
16 specific threshold.

17 And I think those are the reasons why
18 we have concerns about this. Jeff?

19 CO-CHAIR SUSMAN: So, I personally
20 think this was a good enough measure. It wasn't
21 a perfect measure.

22 But if we're going to get to the

1 issues of appropriateness more granularly, then
2 one approach could be to define those exceptions
3 where using more than one antipsychotic would be
4 appropriate. Or excluded.

5 That would be challenging given the
6 multiplicity of reasons why that might be, you
7 know, needed.

8 But it also if you had two or three
9 exceptions documenting trials with other
10 medications, what have you, documenting
11 improvement over a sustained period of time, one
12 could at least imagine a new measure that is more
13 granularly looking in appropriateness.

14 CO-CHAIR BROOKEY: Really good
15 discussion. And I feel bad that we can't move
16 this measure forward. A better measure forward I
17 guess is my point.

18 Let's go to the next discussion unless
19 there's any other --

20 CO-CHAIR SUSMAN: You do have cards.
21 I don't know if --

22 CO-CHAIR BROOKEY: Oh, I'm sorry. I

1 just kind of went blind with the cards that are -
2 - if you have new comments that have not already
3 been said, let's go ahead and make those.

4 So, Ricardo?

5 MEMBER QUINONEZ: So, just a point of
6 -- a challenge to the developers. I think this
7 one suffered a little bit, not as badly.

8 But suffered a little bit from the
9 same problem as the overuse of imaging. Where it
10 is definitely a problem.

11 But the bigger problem is kids who are
12 on antipsychotics inappropriately versus this
13 probably smaller population of kids who are on
14 multi -- multiple antipsychotics.

15 So, a great numerator would be kids
16 who have been diagnosed appropriately with the
17 right DSM-5 criteria, with psychosis. And then
18 the number of children on antipsychotics or
19 whoever.

20 But just getting at the bigger problem
21 rather than a little bit more -- such a specific
22 one.

1 CO-CHAIR BROOKEY: David?

2 MEMBER KELLER: So, I'll respectfully
3 disagree with my colleague. And in that I think
4 the other approach you might think about and it
5 might be worth thinking about on our phone call
6 coming up, is to accept that we are not measuring
7 inappropriate use.

8 That we are measuring use. And that
9 there is value in measuring and tracking use.
10 And in that you can look for variation.

11 Please keep in mind that I said both,
12 crossing thresholds and finding practice
13 variation. And I think that is something that's
14 worth doing.

15 So, I'd think about that.

16 CO-CHAIR SUSMAN: You weren't
17 disagreeing at all. I think --

18 MEMBER KELLER: Yes. No, I was
19 disagreeing with the last. I don't -- I was
20 disagreeing with him.

21 (Laughter.)

22 CO-CHAIR SUSMAN: Well, then disagree

1 with Ricardo.

2 MEMBER KELLER: I'm disagreeing with
3 Ricardo. And it's just another approach.

4 But, I do think, and again, I fully
5 believe that if we don't measure it, we don't fix
6 it.

7 And by having no measures, even of the
8 -- of use of antipsychotic medications right now,
9 it gets swept under the rug except when the GAO
10 does a big expose about it.

11 And it has been identified by our --
12 by the GAO and by HHS as a problem that we need
13 to deal with.

14 So, while we're building that better
15 measure, which I think will take time and is
16 worth doing, I think we need to have something to
17 be able to track this.

18 CO-CHAIR BROOKEY: I agree. Jeff?

19 MEMBER SCHIFF: So, I think part of
20 the Agency for Families and Children, which does
21 overseas foster care in the country is one of the
22 groups that has really flagged this.

1 I just want to say really quickly,
2 9,000 kids in foster care in Minnesota for 30
3 days or more. A little over a third of them on
4 psychotropic meds.

5 Only about 350 to 400 on four or more
6 meds. And we sort of had a freebie on -- we
7 figured that a lot of them were on ADHD drugs or
8 SSRIs first.

9 So, that's the case. And then we
10 looked at that 350 and saw whether or not they
11 had adequate mental health interventions in terms
12 of therapy.

13 Because I think the goal of a measure
14 like this is to make sure these kids are treated
15 appropriately for their mental health disorders.
16 And 80 percent of those in our population had 10
17 or more mental health visits during that year.

18 So, I guess what I'm really saying to
19 the developers is that I don't think a measure --
20 we're never going to get to a measure that is
21 going to perfectly look at the correlation of
22 diagnosis with the number of psychotropic meds.

1 And I would rather put our chips on
2 looking at whether these kids in health plans or
3 not in health plans are actually getting some
4 sort of trauma informed therapy as part of their
5 care.

6 CO-CHAIR BROOKEY: Okay. Carol, last
7 comment?

8 MEMBER STANLEY: Yes. Actually we're
9 using this measure currently with our foster care
10 population in a special study. And we're
11 approaching it as being able to gain a snapshot
12 and a potential baseline.

13 So, we're going to see what we end up
14 with. We're going to look at regional variations
15 within our State. Racial disparities and that
16 type of thing.

17 So, we're approaching it as being able
18 to have a snapshot.

19 CO-CHAIR BROOKEY: That's great. So,
20 we're going to move on. I'll use the Chair's
21 prerogative to make the final final comment.

22 Which is, we can't figure out who our

1 foster care children are. And I wish the plans
2 could. Because I think that would be a whole
3 other level of reporting.

4 So I'm glad that you can do it. So,
5 thank you very much. You have the comments.

6 And we're going to move onto the
7 metabolic monitoring. For which a lot of the
8 earlier discussion reflects on this measure as
9 well.

10 So, anything new that you want to
11 present -- than what you presented earlier about
12 this particular measure.

13 MS. BYRON: Well, actually I think
14 that, you know, I'm glad that you -- the
15 Committee has identified those concerns. Because
16 I think both this measure and the one on
17 psychosocial care that's coming up, does get at
18 some of the things that you've highlighted here.

19 So, nice segue.

20 CO-CHAIR BROOKEY: Thank you. To
21 those in the Subcommittee, and I don't have the
22 list in front of me, so who are you?

1 (Laughter.)

2 CO-CHAIR BROOKEY: So, who wants to
3 start out on making some comments about this
4 particular measure? Jon, do you want to start?
5 Or Maureen?

6 MEMBER FINKELSTEIN: So, this measure
7 addresses -- it's -- I think we have to decide
8 whether it's a processor or an intermediate
9 outcome. It could be either.

10 But, metabolic monitoring,
11 specifically glucose monitoring and lipid
12 monitoring for kids on antipsychotics. I think
13 it rests on a fair amount of evidence.

14 And in this case, real clear
15 recommendations by the professional societies.
16 That even though safety of these drugs hasn't
17 been fully evaluated in kids, there's concern for
18 these metabolic derangements. And that there
19 should be blood testing for metabolic monitoring.

20 If you ask whether we have evidence
21 for the long term outcomes, we don't. But that
22 doesn't bother me in this particular case.

1 I think -- I'll stop there. Because
2 that's the evidence piece.

3 CO-CHAIR BROOKEY: Maureen? Anything
4 to add? David? So, you're saying the evidence
5 for this one is much stronger.

6 And there was a question about age
7 group, but irrespective of age, we all agree that
8 kids should have metabolic screening? Okay.

9 So, any other question about evidence?
10 Carol, you have your flag up? Marlene?

11 MEMBER MILLER: Well, I guess I -- oh,
12 I would just like a little information about the
13 two or more. Does it really have to be two or
14 more?

15 CO-CHAIR BROOKEY: Well, where are --

16 MEMBER MILLER: In the measure. It
17 doesn't say if you have two or more -- two more
18 prescriptions had metabolic testings. Is that
19 two more drugs?

20 MEMBER FINKELSTEIN: No, no, no.
21 That's two or more dispensings. I read that as
22 having two or more dispensings.

1 CO-CHAIR BROOKEY: Right. It could be
2 one medication.

3 MEMBER MILLER: Oh, I read that as two
4 or more medications.

5 CO-CHAIR BROOKEY: Yes. So just one
6 medication would put you in. Yes, yes.

7 MEMBER MILLER: So, two prescriptions
8 ever? Or --

9 CO-CHAIR BROOKEY: During the
10 measurement year.

11 MEMBER MILLER: You know, serial --

12 MS. BYRON: During the measurement
13 year.

14 CO-CHAIR BROOKEY: During the
15 measurement year.

16 MS. BYRON: It can be the same.

17 CO-CHAIR BROOKEY: Two or more
18 dispensings. And irrespective of the number of
19 days.

20 MS. BYRON: It can be -- we wanted to
21 operationalize some sort of ongoing use. So,
22 more than one.

1 It could be two prescriptions of the
2 same drug. Or it could be two different.

3 CO-CHAIR BROOKEY: Okay. Ricardo?

4 MEMBER QUINONEZ: So, this is not
5 going to be a popular opinion. But, I always
6 have difficulty with screening measures.

7 Because this really is a screening
8 measure. It's screening for complications of a
9 drug.

10 And every time there's a screening
11 measure that has very little outcome data to
12 validate it, many of them are later reversed.
13 Because the screening is not necessarily tied to
14 the outcome.

15 And so it does bother me that there is
16 no outcome. Because of previous experiences with
17 screening measures.

18 CO-CHAIR SUSMAN: I mean, I think
19 there's a pretty clear causal pathway here from
20 metabolic outcomes to patient oriented outcomes
21 that we really would think are important. Pardon
22 me?

1 MEMBER QUINONEZ: To get to from an
2 antipsychotic?

3 CO-CHAIR SUSMAN: No, from the
4 metabolic issues that occur with the use of
5 antipsychotics.

6 So, while I agree, it is not A Level
7 evidence, I think there is a believable sort of
8 nice connection that puts the dots. At least for
9 me.

10 CO-CHAIR BROOKEY: Yes, in my mind, if
11 you call it screening, I'd call it almost like
12 secondary screening.

13 I think the term monitoring is
14 probably more appropriate. Because you're really
15 monitoring for side effects of a drug.

16 So, I don't see this as a screening
17 measure per se. I see it more as -- more like
18 any other medication for which it requires
19 monitoring.

20 So, I think it's different than the
21 screening of a low risk population. You're doing
22 monitoring of this very targeted population of

1 kids on a particular class of medication.

2 So, I'm just seeing it differently.

3 Any other? Okay.

4 MEMBER QUINONEZ: Is there any
5 evidence that any interventions that you would do
6 after this monitoring, actually are beneficial?

7 CO-CHAIR BROOKEY: We have a
8 psychiatrist who can answer that questions.

9 MEMBER EINZIG: Yes. Is a --

10 MEMBER QUINONEZ: Especially on long
11 term outcomes?

12 MEMBER EINZIG: Well, the -- if it's
13 a direct effect of the mediation. You stop the
14 medication. You go with an alternative approach.

15 Or you do dietary or nutritional or
16 omega-3. Lots of things you can do for it.

17 MEMBER HOUTROW: So, I have a question
18 that goes back to the original numerator
19 question. Does that also include children who
20 are on PRN medication that they might have only
21 taken two or three times in a given year?

22 If you have Risperdal, and you got a

1 prescription in January, and then in December.

2 CO-CHAIR BROOKEY: Is there a day
3 supply? Or is it just a dispensing?

4 MS. BYRON: It's just a dispensing.
5 Molly, do you want to elaborate?

6 DR. FINNERTY: Yes. I think the
7 thinking here is that the guidelines recommend
8 that you should test children at baseline. And
9 then on follow up.

10 And this is sort of more -- it allows
11 that you could have done it at baseline, or you
12 might have done it at follow up. But, it's only
13 looking for one lab at any time.

14 So, it's a generous measure in that
15 way.

16 CO-CHAIR BROOKEY: Well, the question
17 though is, if you just got five pills of
18 Risperdal, I'm just making something up. And
19 then you got a second prescription for two pills
20 six months later, you'd still be in the
21 denominator, right?

22 DR. FINNERTY: Yes.

1 CO-CHAIR BROOKEY: But that probably
2 doesn't happen that often. I mean, I'm not a
3 psychiatrist.

4 But, just -- so, I'm thinking people
5 get at least maybe 30 pills or something. Okay.
6 So, I think your question is a good one Amy, but
7 I think it's answered. Right?

8 Okay. And Sue?

9 MEMBER KONEK: The fact that it does
10 have the baseline screening. Which is really
11 critical for this to work.

12 CO-CHAIR BROOKEY: Yes, yes. To know
13 where you started. Are there any other questions
14 or comments about -- what are we on? Evidence.

15 Can we vote on -- oh, I'm sorry, do
16 you have a comment? David? David Two?

17 MEMBER KELLER: Yes. The -- no, the
18 only -- I actually was following up on the
19 question of screening versus -- this to me is
20 actually a patient safety measure.

21 And so I think about it as -- I think
22 about it a bit differently. But I think that

1 makes it equally important.

2 And the interventions are about that
3 we are doing something and we need to be able to
4 monitor that. So, to me the other piece of this
5 measure is that we're monitoring for specific
6 conditions.

7 But we're also tracking to make sure
8 that a patient on a potentially dangerous
9 medication is being monitored by someone.
10 Because someone's ordering tests around it.

11 CO-CHAIR BROOKEY: Right. Any other
12 comments? Otherwise we'll move towards a vote on
13 evidence.

14 (No audible response.)

15 CO-CHAIR BROOKEY: Okay. Good
16 question. Is this -- do we have sufficient
17 evidence for a high?

18 There was a --

19 MEMBER EDIGER: It was graded.

20 CO-CHAIR BROOKEY: It was graded.

21 MEMBER EDIGER: And the consistency,
22 quality, and quantity, yes.

1 CO-CHAIR BROOKEY: Yes, I think there
2 -- you can vote high if you choose so. Okay.
3 Ready?

4 MS. CHAVEZ: Okay. We're now voting
5 on Measure 2800 on evidence. One high, two
6 moderate, three low, four insufficient. Polling
7 is open.

8 (Pause.)

9 MS. CHAVEZ: Sixteen. Twenty-two.
10 Twenty-three. Okay. Four voted high. Eighteen
11 voted moderate. Zero low. One for insufficient.

12 This measure passes evidence.

13 CO-CHAIR BROOKEY: So let's move to
14 performance gap. Subcommittee Members want to
15 comment on performance gap?

16 MEMBER FINKELSTEIN: Well, I'll start.
17 I think there is some, there's studies that they
18 quote that 31 percent had a glucose test. And 14
19 percent had a lipid test in their field tests.

20 The rates were very low. I hope -- I
21 wonder if the developers can comment on their
22 confidence in the capture in claims data that all

1 of these tests end up as a separate claim?

2 I'm particularly thinking about kids
3 who are in inpatient settings where I'm not --
4 they know more than I do. But I'm not sure that
5 every blood test is billed separately to the
6 insurer given how places are now paid.

7 And I wonder if we have information.

8 MS. BYRON: So, this -- the
9 specification for this is actually modeled on the
10 way we look at metabolic testing for a couple
11 other HEDIS measures. We have a HEDIS measure
12 that looks at schizophrenia for adults.

13 And so, we -- so based on, you know,
14 the experience on those measures as well as our
15 field testing, we do feel pretty confident that
16 we captured it.

17 Our field test findings were really
18 low. The first year HEDIS results were a little
19 higher actually. Probably closer to what we saw
20 in the literature.

21 I think it was between 25 and 30
22 percent in terms of our first year means. So, we

1 -- we're pretty confident.

2 I'd have to check the spec to your
3 question about the inpatient. They may be
4 excluded. And I don't know, Molly, if you
5 remember off the top of your head?

6 DR. FINNERTY: Labs usually drawn in
7 an inpatient setting are not included. But,
8 it's, you know, a minority of children who are in
9 an inpatient setting.

10 And you might wonder whether the
11 outpatient psychiatrist who's prescribing the
12 meds, you also don't for example see the
13 medication. So, whoever is prescribing the meds
14 should also be monitoring.

15 So, that, you know, that -- a
16 medication was prescribed. Or that a monitoring
17 was done in the inpatient wouldn't necessarily
18 cover the child for monitoring in the outpatient
19 setting.

20 CO-CHAIR BROOKEY: I think as well,
21 lipids may not often be a priority when they're
22 at the inpatient. So, I think that unless we're

1 measuring the inpatient, we -- you may not be
2 that much -- there may not be that many more hits
3 that we would get from getting the inpatient
4 data.

5 That's my experience. Any other
6 comments about whether there's a gap? It sounds
7 like there's a relatively low rate of
8 performance.

9 So, that would indicate if we believe
10 this is an important measure that there is a gap.
11 Is that right?

12 So, unless there's any other comments,
13 could we vote on gap?

14 MS. CHAVEZ: Now voting on gap for
15 Measure 2800. One high, two moderate, three low,
16 four insufficient. Polling is open.

17 (Pause.)

18 MS. CHAVEZ: We're expecting 23 votes.
19 Twenty-two. Twenty-two.

20 MS. ALLEN: Lauren, please submit your
21 vote.

22 MEMBER AGORATUS: I did. Did it go

1 through?

2 MS. ALLEN: Yes. Thank you.

3 MS. CHAVEZ: Okay. Ten voted high.

4 Thirteen voted moderate. Zero low. Zero
5 insufficient. This measure passes performance
6 gap.

7 CO-CHAIR BROOKEY: Okay. Let's move
8 onto reliability. Do our Subcommittee Members
9 have any comments about reliability?

10 (No audible response.)

11 CO-CHAIR BROOKEY: This is a health
12 plan level -- is this -- remind me, is this
13 administrative? Or is this a hybrid? Or is it a
14 chart review?

15 MS. BYRON: Administrative.

16 CO-CHAIR BROOKEY: It's an
17 administrative measure. So it's based on claims
18 data or coded data.

19 So reliability should be high.
20 Testing was high. Any other comments about
21 reliability of the measure?

22 MEMBER FINKELSTEIN: I'm waiting for

1 my other subgroup. So, they did testing in the
2 max data sets.

3 The States had a meeting about
4 denominators were about 12,000. So, it doesn't -
5 - it's not as small as the previous measure.

6 Still a problem in some commercial
7 plans not having enough to get very high
8 reliability. But, I thought it was pretty well
9 documented.

10 CO-CHAIR BROOKEY: Yes, so the
11 question is, as specified, is it a reliable
12 measure. Are you going to be able to collect
13 what you're trying to collect?

14 Any other comments? Yes, go ahead
15 Kevin.

16 MEMBER SLAVIN: Just a quick question.
17 Glucose testing I know can be done at the point
18 of care. So, a child with an early morning
19 doctor visit might have a fasting glucose done at
20 the office.

21 Would this measure capture that as
22 something that would be billed?

1 MS. BYRON: I believe it would. Yes.

2 CO-CHAIR BROOKEY: We would code it as
3 a POCT. And if you're -- yes, I would think we
4 could.

5 Any other comments about reliability?

6 (No audible response.)

7 CO-CHAIR BROOKEY: Okay.

8 MS. CHAVEZ: Okay. We're ready to
9 vote on reliability. One high, two moderate,
10 three low, four insufficient. Polling is open.

11 (Pause.)

12 MS. CHAVEZ: Again, we're expecting 23
13 votes. Nineteen. Twenty-two. Twenty-two.

14 CO-CHAIR BROOKEY: Vote again.

15 MS. CHAVEZ: Twenty-three, thank you.
16 Five voted high. Eighteen voted moderate. Zero
17 low. Zero insufficient. This measure passes
18 reliability.

19 CO-CHAIR BROOKEY: Okay. I think
20 we've talked a lot about validity. Other
21 comments about validity? Ricardo?

22 MEMBER QUINONEZ: This does not answer

1 my question about what consequences are involved.

2 CO-CHAIR BROOKEY: Is your microphone
3 on?

4 MEMBER QUINONEZ: Oh, I'm sorry. No,
5 it's not.

6 So, one of the questions that was put
7 forward, and it says what evidence is there to
8 demonstrate that a change in antipsychotics,
9 which I assume would be what you would do, as a
10 result of metabolic tests, is less harmful from a
11 behavioral health perspective to the affected
12 patient then remaining on the antipsychotic that
13 is causing these issues.

14 CO-CHAIR BROOKEY: David, do you want
15 to take a stab at that?

16 MEMBER EINZIG: So you could change --
17 if it's a bipolar diagnosis, you could change to
18 a Depakote, Lithium, other meds that aren't going
19 to affect at least metabolic syndrome.

20 In rare cases you might want to go
21 with typical antipsychotics. Which, you know,
22 would be lower risk.

1 But within the atypical class.
2 Certain medications are clearly higher risk than
3 other meds within the class.

4 MEMBER QUINONEZ: Right. But is there
5 any evidence that changing to those offers less
6 harm? Or -- then, you know, then being on the
7 appropriate antipsychotic?

8 CO-CHAIR SUSMAN: Well, there's
9 different risks by medication and by general
10 class. And even within the class.

11 Whether that then is associated with
12 a reduction in ultimate, say cardiac events or
13 issues related to the abnormal metabolic events,
14 I don't know of any data for that. I mean, is
15 that an accurate?

16 MEMBER EINZIG: Yes. I don't know of
17 any specific studies looking specifically at that
18 questions.

19 But, intuitively, if you want to go
20 with face validity, it makes sense.

21 CO-CHAIR BROOKEY: Okay. I think
22 these patients are on medications for a long,

1 long time. And so I think that's the issue is
2 you have to adjust them to where they're
3 potentially going to cause the least harm, right?

4 But oftentimes you're trading off one
5 medication that has risk for another medication
6 that has a different risk. And that's clear.

7 Any -- so, any other -- oh, I'm sorry,
8 Kevin, go ahead.

9 MEMBER SLAVIN: I think this is one of
10 those situations where if you were talking about
11 a non-antipsychotic, like if you were talking
12 about Monacolin, which can cause a life
13 threatening lactic acidosis. If the patient
14 started showing signs of that, you would stop and
15 find an alternative therapy.

16 I think having a metabolic derangement
17 on a medication that somebody's going to be on
18 for a long time, I think that the risks of that
19 would certainly outweigh any concerns about
20 trying to find an alternative regimen.

21 CO-CHAIR BROOKEY: Jill?

22 MEMBER MORROW-GORTON: And I think the

1 other thing we have to think about is talking
2 about appropriate medication. I mean, all of the
3 antipsychotics sort of do the same thing in
4 little different ways.

5 And they all have minor differences in
6 terms of their actions and their side effects.

7 So, I'm not sure that you could say that just
8 because drug A gave somebody metabolic syndrome,
9 that drug B would be an inappropriate behavioral
10 health choice to treat their disorder.

11 Does that make sense?

12 CO-CHAIR BROOKEY: Um-hum. Yes.

13 MEMBER SLAVIN: And likewise, someone
14 who's been really difficult to control. You may
15 despite the metabolic effects, just elect to
16 continue to monitor.

17 I mean, you know, there's always a
18 benefit-to-harms.

19 MEMBER FINKELSTEIN: So can I just --
20 that's not what this measure is about though.
21 This measure is only about whether you screened
22 or not.

1 MEMBER SLAVIN: Correct.

2 MEMBER FINKELSTEIN: So, if the
3 patient is obese because of their antipsychotic,
4 but you say look, it's worth it because it's the
5 only way to help them. You may -- you still pass
6 the measure.

7 Unless you say I wouldn't want to know
8 that his glucose --

9 (Laughter.)

10 MEMBER FINKELSTEIN: Was enough,
11 hyperglycemic range. So, I don't think that
12 matters.

13 CO-CHAIR BROOKEY: So, Jon has brought
14 us back to where I think we can vote now on
15 validity. Okay?

16 So, we're talking about validity. Any
17 other comments before we vote?

18 MS. CHAVEZ: Okay. Now voting on
19 validity. One high, two moderate, three low,
20 four insufficient. Polling is open.

21 (Pause.)

22 MS. CHAVEZ: Nineteen. Twenty-four.

1 CO-CHAIR BROOKEY: Twenty-four? Did
2 somebody come back in the room? Oh, Jeff is
3 back.

4 (Laughter.)

5 MS. CHAVEZ: Five voted high.
6 Eighteen voted moderate. One low. Zero
7 insufficient. This measure passes validity.

8 CO-CHAIR BROOKEY: The matters to
9 reflect if you're in the bathroom during the
10 vote. So, I just said.

11 Okay. So, we're up to feasibility.
12 And I believe that this is going to be similar to
13 the previous measure.

14 It's going to be -- is that correct?
15 It's an administrative measure. We are on
16 feasibility, right? I'm getting lost.

17 So, from a health plan perspective, it
18 would be based on coded data. And it should be
19 easy for a health plan.

20 Any other comments about feasibility
21 for a health plan?

22 (No audible response.)

1 CO-CHAIR BROOKEY: Okay. Can we vote?

2 MS. CHAVEZ: Okay. Now voting on
3 feasibility. One high, two moderate, three low,
4 four insufficient. Polling is open.

5 (Pause.)

6 MS. CHAVEZ: Twenty-one. Twenty-
7 three. Twenty-four. Fifteen voted high. Nine
8 voted moderate. Zero low. Zero insufficient.
9 This measure passes feasibility.

10 CO-CHAIR BROOKEY: Thank you. Next is
11 usability and use. Any comments that we haven't
12 already made about usability?

13 (No audible response.)

14 CO-CHAIR BROOKEY: It kind of relates
15 to everything else. Shall we vote? Okay.

16 MS. CHAVEZ: Okay. Now voting on
17 usability and use. One high, two moderate, three
18 low, four insufficient. The voting is open.

19 (Pause.)

20 MS. CHAVEZ: Fifteen. Twenty-one.
21 Twenty-four. Ten voted high. Fourteen voted
22 moderate. Zero low. Zero insufficient. This

1 measure passes usability and use.

2 CO-CHAIR BROOKEY: Okay. So, finally
3 overall suitability for endorsement. Any other
4 comments?

5 (No audible response.)

6 CO-CHAIR BROOKEY: Okay. Can we vote?

7 MS. CHAVEZ: Okay. We are now voting
8 for overall suitability for endorsement for
9 Measure 2800. One for yes, two for no. Polling
10 is open.

11 (Pause.)

12 MS. CHAVEZ: Thank you. Twenty-four
13 voted yes. Zero no. Measure 2800 has been
14 recommended for endorsement.

15 CO-CHAIR BROOKEY: This is your last
16 measure? Great. So, we're up to our last
17 measure. And it's another NCQA measure.

18 And I don't want the clock to prevent
19 us from making good decisions. So, what I'm
20 going to say is, I think it's feasible to get
21 this done in an hour.

22 Would you agree? Because I don't

1 really want to say we're going to finish at 3:00.

2 I think we need to like -- some people need to
3 get to the airport.

4 I'd like to say that we're going to
5 finish by a quarter to. Maybe even earlier. But
6 if we can't, if we're getting crunched on time,
7 then we have the option of finishing this on a
8 phone call later.

9 So, I think we can do it. But I don't
10 want us to feel pressured by the clock. Is that
11 reasonable?

12 So why don't we try to be concise and
13 clear. And we'll move forward. And I'll let you
14 go with a summary if you would.

15 MS. BYRON: All right. So, some folks
16 have actually raised this issue of off-label use.
17 And we explored a measure like that.

18 But for various reasons it was
19 difficult to specify given there aren't many FDA
20 prescribed uses for antipsychotics. So, our
21 attempt to address this issue is with this
22 measure, which is the use of first-line

1 psychosocial care.

2 It looks at kids with a new
3 prescription for antipsychotic who do not have a
4 primary indication as prescribed by the FDA for
5 an antipsychotic. And looks to see that they had
6 psychosocial care either before or immediately
7 after the prescription for an antipsychotic.

8 So, where you see most cases of these
9 drugs being described for ADHD or disruptive
10 behaviors for which they are not indicated. For
11 those conditions, psychosocial therapy is really
12 recommended as first-line care.

13 And so we look to see of that was
14 given.

15 CO-CHAIR BROOKEY: Thank you. Who's
16 our Subcommittee for this particular measure?
17 Okay. Would one of you like to make some
18 comments?

19 MEMBER EINZIG: Yes, so the -- so it's
20 a process measure. It's claims data.

21 Numerator children who have
22 psychosocial care as the first-line treatments

1 prior to or immediately after a new prescription
2 for an antipsychotic. And the denominator is all
3 children who receive antipsychotic for a
4 condition that does not have an FDA indication.

5 Looking at it from an evidence
6 perspective is another one of those measures
7 where it was consensus I believe. That was used
8 for evidence.

9 No other hard core studies that I
10 reviewed in there. The -- most of my other
11 comments will have to do with things other than
12 evidence. So, I'll just hold there.

13 CO-CHAIR BROOKEY: So, let's limit the
14 conversation to evidence right now. And it
15 sounds like that was a very strong consensus and
16 based on a lot of guidelines.

17 So, is that correct? Okay. Other
18 comments about evidence? Go ahead Jon.

19 MEMBER THACKERAY: It was based on a
20 lot of consensus statements. But I think similar
21 to a couple of measures ago, there's a little bit
22 of general wording in them.

1 So, recommendation one, prior to the
2 initiation of and during treatment with an
3 atypical antipsychotic, the general guidelines
4 that pertain to the prescription of psychotropic
5 medications should be followed. Including
6 education and psychotherapeutic interventions for
7 the treatment and monitoring of improvement.

8 And the other one is physicians should
9 consider other medication or psychosocial
10 treatments before initiating antipsychotic
11 treatment.

12 So it's -- I mean, the recommendation
13 is there. But it's not --

14 CO-CHAIR BROOKEY: Specific.

15 MEMBER THACKERAY: It's not black and
16 white.

17 CO-CHAIR BROOKEY: Yes.

18 MEMBER THACKERAY: And I'm a little
19 worried we're going to get into the same
20 conversation we had with the previous measure
21 about what is the threshold for this? Like, how
22 often, you know, in our Subcommittee we talked

1 about there are probably scenarios where it's
2 appropriate to initiate pharmacotherapy without
3 waiting for your psychosocial intervention.

4 And where is that threshold? So --

5 CO-CHAIR BROOKEY: Okay. Amy?

6 MEMBER HOUTROW: My question relates
7 to the evidence in relationship to the numerator
8 and denominator. So, a lot of children who are
9 in health plans are receiving psychosocial care
10 outside of that system.

11 Whether it be in their school or at a
12 community health center. And many plans won't
13 even cover some types of psychosocial.

14 So, I don't know if this belongs in
15 our evidence discussion. But, do we know what
16 percentage of children would receive all of their
17 mental health care within a health plan system?

18 Or how many kids are getting it
19 outside of that? Because that could really
20 change the population since in my own practice, a
21 majority of children are not getting their mental
22 healthcare within their health plan.

1 CO-CHAIR BROOKEY: It's a good point
2 Amy. And of course in California, we have a
3 regional center. I'm sure you all have something
4 comparable in your own States.

5 And we don't necessarily know if
6 children are getting services from the regional
7 center. And with Medicaid, we actually have
8 carve outs.

9 And so we don't actually always know
10 what's happening in the county with the health
11 plan carve out. I don't know if -- I think
12 that's true in more of the States other than
13 California.

14 But, plans do not always know. And so
15 I'm going to ask the developers to comment on
16 that.

17 DR. BARTON: We are aware that there
18 are a lot of State variables such as you
19 mentioned. And NCQA's point of view here is that
20 if you are a State, you're responsible for the
21 children in your State.

22 And carving out is not an excuse. And

1 if you're a health plan, in all honesty, there
2 should be pads in place for bi-directional
3 communication.

4 And we realize that we're not -- we're
5 not God. And so just because we say it, it's not
6 going to be so.

7 But on the other hand, in the absence
8 of a measure that's incentivizing and encouraging
9 plans to start behaving that way, we don't think
10 that it will ever happen. So, it's an
11 interesting situation to be in.

12 And we can appreciate your concern.

13 CO-CHAIR BROOKEY: I hear what you're
14 saying exactly. But, I have to ask you a
15 question.

16 This is an administrative measure.
17 So, it may be true that the psychiatrist knows
18 that the child is getting therapy from here. And
19 they may include that in their --

20 (Simultaneous speaking.)

21 CO-CHAIR BROOKEY: But you wouldn't
22 know --

1 (Simultaneous speaking.)

2 DR. BARTON: With all due respect,
3 that's a validity question I believe, not an
4 evidence question.

5 CO-CHAIR BROOKEY: No, but I'm just
6 trying to get to the issue that's been raised
7 about, can we actually pull the data?

8 So, the question on validity we'll put
9 aside for now. The question on evidence, I'm
10 hearing that it's largely consensus based.

11 And so it's --

12 DR. SCHOLLE: So this is Sarah. I
13 just wanted to weigh in. This does require that
14 the health plans be responsible for the mental
15 health benefit.

16 So the carve out situation you
17 mentioned would not fall in that. The health
18 plans who do not have responsibility for the
19 benefits, mental health benefit, wouldn't be
20 responsible.

21 MEMBER AGORATUS: This is Lauren. I
22 have a clarification question.

1 Children can also get counseling on
2 their individual education plan as a related
3 service under the Individual Disability Education
4 Act. Would that count?

5 CO-CHAIR BROOKEY: If you had a B
6 code, I suppose it might. Right? If we were in
7 the --

8 MEMBER THACKERAY: I just don't
9 believe that's properly been in as administrative
10 claims though.

11 CO-CHAIR BROOKEY: Yes. If the health
12 plan knew about it and somebody has coded it.
13 But, that's a big if, right?

14 So, let's -- I agree. Let's go back
15 to the evidence question. And Jill, you have a
16 comment?

17 MEMBER MORROW-GORTON: I actually had
18 a couple of questions. One was when -- with
19 respect to Jonathan's comment about medication, I
20 think we're only talking about antipsychotics,
21 not other medications.

22 And antipsychotics for kids that don't

1 have one of the diagnosis that there's an
2 indication for it.

3 CO-CHAIR BROOKEY: Right.

4 MEMBER MORROW-GORTON: So, I think
5 that it would be highly unlikely that you would
6 have a kid that you would just start on an
7 antipsychotic de novo.

8 MEMBER THACKERAY: I'll defer to that.

9 MEMBER MORROW-GORTON: Yes. I just
10 think that would be unlikely. My other question
11 was kind of the definition of psychosocial
12 intervention.

13 You know, what -- sort of what does
14 that include? And my third is a comment about
15 kind of as, I mean, there are all these States do
16 things in all different ways.

17 And so does commercial insurance. So,
18 behavioral health is often carved out of the
19 medical benefit. And then you come up with DD
20 services and waiver services and what not.

21 But, I think as you -- as we look at
22 where things are going, things are all moving to

1 having everything, you know, either ACO or
2 behavioral health integration, or that sort of
3 thing.

4 Which may strengthen your ability to
5 get this actual data in a more reliable way.

6 CO-CHAIR BROOKEY: Good comment.
7 Kevin?

8 MEMBER SLAVIN: My question really had
9 to do with the recommendation two. Where there's
10 also the carve out of substantial evidence for
11 effectiveness in addition to FDA indications.

12 Not being familiar with these
13 medications and how they might be used outside of
14 an FDA indication, I don't know how -- how does
15 that get captured?

16 What would be considered substantial
17 evidence that might allow for it to be used in
18 this capacity? And sort of the indications that
19 are specifically listed, are those all FDA
20 approved indications?

21 And if there are others, how would
22 they or would they not be included in this?

1 MS. BYRON: So if the -- so, I'll just
2 say, the FDA conditions -- the conditions listed
3 in the measure are the FDA approved conditions.

4 Molly, did you? Or Sarah, were you
5 trying to go?

6 DR. FINNERTY: For children, for the
7 kids who are receiving antipsychotics who do not
8 have an FDA indication, it's generally for
9 behavioral control. For agitation, for
10 behavioral control, for sedation, for things like
11 that that can be manifest in any diagnostic
12 condition.

13 So, we're saying if there is an
14 indication, those kids are carved out. But for
15 those who don't have an indication where it is
16 being used for behavioral control, you want to
17 see that there's some evidence that first-line
18 psychosocial interventions were tried.

19 And I think it's important to talk
20 about two different kinds of evidence here. And
21 one is the evidence for a treatment sequence.

22 You know, so the first piece of

1 evidence is who has a first-line indication? And
2 that we're relying on the FDA where evidence is
3 substantial.

4 And those who do not have that, the
5 evidence is less. Right, so those are the kids
6 we're talking about.

7 The second is the evidence for a
8 sequence of treatments where you try psychosocial
9 before you try a medication that does not have a
10 primary indication that carries with it some
11 risks for children.

12 And these are the kinds of things that
13 come out of the guidelines and treatment
14 recommendations. And you won't see one stronger
15 than that.

16 Like if you see a treatment algorithm,
17 it's not going to be any stronger then you should
18 try this before you try that. You know, or you
19 should consider all these other alternatives
20 before you go to that.

21 That's kind of as strong as those
22 treatment sequence recommendations will get.

1 But, the other piece of evidence is, what is the
2 evidence for the effectiveness of psychosocial
3 treatments to manage behavioral, maladaptive
4 behaviors?

5 And there, there is good evidence.
6 And those guidelines cite the evidence for
7 psychosocial interventions across an array of
8 diagnosis.

9 And those are recommended treatments.
10 So, the point is, if we have evidence for
11 recommended treatments, why would we jump to a
12 non-recommended treatment?

13 CO-CHAIR BROOKEY: Yes. Thanks for
14 your comments. Although it is about sequencing
15 and whether the evidence is to require it before.

16 And that's what this is measuring. So
17 Jeff, you have a comment?

18 CO-CHAIR SUSMAN: It was just a
19 question. It was on the lines you were
20 following.

21 Is this a blanket exclusion? So, if
22 any of the antipsychotics are approved say for

1 bipolar disorder, then all of them are approved?

2 Or is it a specific drug by drug
3 evaluation of what the FDA approval is? And if
4 it's that, I have a lot of problems with it.

5 If it's the former, then I'm probably
6 not so.

7 MEMBER EINZIG: It's drug by drug.

8 CO-CHAIR SUSMAN: It's drug by drug.
9 Okay. Well, you know, the willy-nilly approach
10 to approving children's medications and
11 children's mental health medications gives me
12 some pause.

13 I mean, I think it challenges the
14 validity at some levels. And while I guess it's
15 a stricter standard just because Zyprexa's been
16 approved for A and another drug has been approved
17 for B, I think is parsing this rather fine, just
18 based on how a pharmaceutical company believes
19 its profits can be maximized.

20 DR. FINNERTY: And I think that's an
21 excellent, excellent point. And that is why this
22 measure actually takes antipsychotics as a class.

1 And it says if even one antipsychotic
2 has an FDA indication, all of them have a pass.
3 So they would not --

4 CO-CHAIR SUSMAN: Okay. So, I'm
5 hearing some discrepancy from -- in the Committee
6 and -- but is it true then, so if one of the
7 antipsychotics has an indication say for a tic
8 disorder, then all -- and David's shaking his
9 head no.

10 DR. FINNERTY: That's, I mean, let's
11 see, I don't have the measure specifications in
12 front of me. But that's my understanding of how
13 it was specified.

14 That for any tic disorder,
15 schizophrenia, bipolar disorder, any psychotic
16 disorder, those children are just taken out of
17 the denominator.

18 CO-CHAIR SUSMAN: Okay.

19 CO-CHAIR BROOKEY: All right. That
20 makes sense. So, let's limit our comments to --
21 right now to the evidence. And we'll get into
22 validity and everything else later.

1 So, David?

2 MEMBER EINZIG: I don't even remember
3 anymore.

4 (Laughter.)

5 CO-CHAIR BROOKEY: Ricardo?

6 MEMBER QUINONEZ: Yes. So I just --
7 I think this is like a really good measure.
8 Because it takes -- it's using a non-
9 pharmacological approach to treat something that
10 has been shown to be -- that you can actually
11 improve with a non-psych -- you know,
12 pharmacological approach.

13 And so I don't think, speaking to the
14 evidence, I don't think we're going to find that
15 this is supported by strong evidence. But I
16 think this is clearly one of those where the
17 evidence might be insufficient.

18 But, it's a very good indicator.

19 CO-CHAIR BROOKEY: So you're saying
20 it's a valid measure.

21 MEMBER QUINONEZ: Very valid.

22 CO-CHAIR BROOKEY: But, we -- you're

1 suggesting that if we don't think the evidence is
2 strong enough, it might be strong enough to vote
3 for insufficient with --

4 MEMBER QUINONEZ: Correct.

5 CO-CHAIR BROOKEY: With exception. Is
6 that what you're suggesting?

7 MEMBER QUINONEZ: Yes.

8 CO-CHAIR BROOKEY: Are there any other
9 comments about evidence before we make our
10 decision? So, the people have their suitcases
11 behind their chairs I see. So, go ahead Dave.

12 MEMBER EINZIG: So, you know, just to
13 throw this out there. So, I would agree that
14 it's insufficient evidence with exception for me.

15 But the, you know, the bigger question
16 is, is there evidence to say that it's
17 inappropriate to move forward with a medication
18 for an unapproved condition? Say we label that
19 mood disorder NOS instead of bipolar, which is
20 probably the majority of the kids out there.

21 Because bipolar is very difficult to
22 diagnose. But the medication still would be

1 appropriate.

2 Is it, you know, is it an unfair
3 measure in that way to imply that it's
4 inappropriate to move forward with medication
5 without the interventions?

6 CO-CHAIR BROOKEY: Okay. So, I'm
7 going to have more questions about validity. But
8 in terms of evidence, do we think we have enough
9 information to vote on evidence? Okay.

10 MS. CHAVEZ: Okay. Voting for
11 evidence for Measure 2801 is now open. One high,
12 two moderate, three low, four insufficient.

13 (Pause.)

14 CO-CHAIR BROOKEY: You cannot vote
15 high I think. Right?

16 MS. CHAVEZ: Fourteen. We're
17 expecting 24 votes. Eighteen. Twenty-three.
18 Twenty-four.

19 Zero voted high. Seven voted
20 moderate. Four voted low. Thirteen voted
21 insufficient. Consensus was not reached.

22 CO-CHAIR BROOKEY: So I would propose

1 that we vote for insufficient with exception.

2 Should we vote for that? Or should we decide to

3 vote on that?

4 We should just vote for it.

5 MS. BURSTIN: You could decide to

6 vote. It will be cleaner in the report.

7 CO-CHAIR BROOKEY: We're going to vote

8 for insufficient with exception or not.

9 MS. CHAVEZ: Okay. All right, now

10 voting on evidence. Yes for insufficient with

11 exception. Two no for no exception. Voting is

12 open.

13 (Pause.)

14 MS. CHAVEZ: Twenty-one. Twenty-four.

15 Twenty-one voted insufficient evidence with

16 exception. Three voted for no exception.

17 CO-CHAIR BROOKEY: Okay. So, we move

18 forward to performance gap. Any of the Committee

19 members want to comment on performance gap?

20 MEMBER THACKERAY: Yes. So the

21 developers cite a study of Medicaid in rural

22 children showing that a third of youth starting

1 an antipsychotic were not receiving concurrent
2 psychosocial therapy.

3 It showed some disparities in
4 adolescents compared to younger children. They
5 also did their own analysis of Medicaid data from
6 11 States and found that a little less than half
7 of children on an antipsychotic were -- had
8 documented psychosocial care.

9 CO-CHAIR BROOKEY: Any other comments
10 on gap?

11 (No audible response.)

12 CO-CHAIR BROOKEY: Should we vote on
13 gap? Okay.

14 MS. CHAVEZ: Okay. Now voting on gap
15 for Measure 2801. One high, two moderate, three
16 low, four insufficient. Polling is open.

17 (Pause.)

18 MS. CHAVEZ: Fourteen. Twenty-one.
19 Twenty-three.

20 CO-CHAIR BROOKEY: We lost another
21 couple of people, didn't we?

22 MS. CHAVEZ: Okay.

1 CO-CHAIR BROOKEY: We lost Jeff and
2 Jim.

3 MS. CHAVEZ: Twenty-three votes.
4 Okay, we received 23 votes. Five voted high.
5 Sixteen voted moderate. Two voted low. Zero for
6 insufficient.

7 This measure passes performance gap.

8 CO-CHAIR BROOKEY: Okay. We started
9 to talk about reliability and validity. I think
10 we made some comments about data collection.
11 It's an administrative measure.

12 And I think Amy raised a concern about
13 where the care might be given. Can you -- can
14 the health plan capture that data?

15 So, to someone else's point, if it's
16 a complete carve out, then the prescriber of the
17 medication may be the same provider as the
18 therapy.

19 If it's a partial carve out/carve in
20 situation, you may still have that issue with
21 therapy being given over here and medication over
22 here.

1 So, other comments about reliability
2 of this particular administrative measure?

3 Carol?

4 MEMBER STANLEY: Yes. In seeing
5 health plans in action and calculating some
6 measures, they want to do well in these measures.

7 And so, they get very diligent and
8 persistent with States and other contractors,
9 other providers to identify supplemental data
10 sets that their HEDIS auditors will approve of
11 them using.

12 So, I really don't have many concerns
13 about the need for supplemental data and
14 identifying those opportunities.

15 CO-CHAIR BROOKEY: Okay. David?

16 MEMBER KELLER: So, I'm just cognizant
17 that when people have looked at who is
18 prescribing the antipsychotic medications in
19 Medicaid, actually it's primary care providers
20 more the psychiatrists who are prescribing them.

21 So, the issue of the separate systems
22 is actually quite -- is more prevalent than I

1 think you implied in your previous statements.

2 It's not the psychiatrists who are part of the
3 behavioral health carve out who are often
4 prescribing these things.

5 So, to your point though, it would
6 require people to be pretty aggressive about
7 being able to cross those data lines. I do think
8 that's an issue.

9 I guess my question for the developer
10 is did you find that to be an issue when you were
11 testing these measures?

12 MS. BYRON: Well, because of some of
13 those concerned, we do require the mental health
14 benefit for the health plans. You know, hoping
15 that that will help.

16 So, -- right.

17 CO-CHAIR BROOKEY: And I will clarify
18 that for California, we cannot get the data from
19 the State or the county or the regional center at
20 a granular enough level for supplemental data.
21 It's just --

22 MEMBER KELLER: Yes. And nor can we

1 in Colorado actually. We can't access behavioral
2 health utilization data easily because it's all
3 carved out at the -- it's actually at the BHO
4 level.

5 It's not even at the county level.

6 CO-CHAIR BROOKEY: Yes.

7 MEMBER KELLER: And then subcontracted
8 to the counties, making it even more complicated.

9 CO-CHAIR BROOKEY: David?

10 MEMBER EINZIG: So, I think this is an
11 appropriate place for me to voice a few concerns.
12 Hopefully it is. Cut me off if it's not.

13 First, -- my first concern is looking
14 at, you know, are we improving quality of care by
15 recommending therapy first before medications?
16 And you know, as far as validity goes, I think we
17 might be missing the mark on that one again.

18 You know, for an example, if a person
19 can't get in to see the psychologist or counselor
20 or tie into those services for several months,
21 and you're not moving forward with medication,
22 into September. You know, that whole school year

1 is gone basically.

2 And so you're altering that
3 developmental trajectory which can worsen quality
4 of care. So, the risk for not treating are
5 there.

6 I think this is a bigger issue then
7 looking at are we over-prescribing. I think the
8 bigger issue is, the reason why we're prescribing
9 these medications in some cases for, you know,
10 foster care, reactive attachment, those type of
11 things, you know, I think the common thread is
12 they aren't getting the early intervention at a
13 younger age.

14 And so we're trying to improve quality
15 of life through the use of medications to target
16 these instant reactions and whatnot. When the
17 bigger picture is, the role for early
18 intervention services, which this measure doesn't
19 really address.

20 CO-CHAIR BROOKEY: Good comment.

21 Kerri?

22 MEMBER FEI: So from the health plan

1 perspective, I think a couples -- others have
2 already said it.

3 The measure does require you to have
4 medical, mental health and pharmacy benefit
5 included within the product. So, if you don't
6 have those, it's kind of a non-starter.

7 Secondly, in my discussion with a lot
8 of plans, they had become way more diligent if
9 they do have a carve out, about being able to get
10 their data. And have that data sharing worked
11 into their contracts.

12 I know it's harder for those that do
13 have Medicaid plans. Because individual by
14 State, like you've highlighted, privacy issues
15 are getting in the way and other things.
16 Obviously they can't get the data.

17 But, for those that do have the
18 control, they become much more proactive in
19 getting their data.

20 CO-CHAIR BROOKEY: Yes. If you have
21 a carve out to another behavioral health plan,
22 that's one thing. If you have a carve out to the

1 county, a.k.a. black hole, that's a difference.

2 (Laughter.)

3 CO-CHAIR BROOKEY: But your point is
4 well taken. There are some plans that do have
5 carve outs to another behavioral health plan.

6 And that's a different situation all
7 together. I agree.

8 MEMBER FEI: It's the complete
9 difference --

10 CO-CHAIR BROOKEY: Yes, exactly.
11 Carol?

12 MEMBER STANLEY: So, along the same
13 lines, this is another measure we're using in a
14 foster care study. And we do carve out
15 behavioral health.

16 So, we have an external organization
17 that's taking our behavioral health data along
18 with the managed care data and doing the study.
19 But, with the way this measure is, our health
20 plans would not be reporting it directly to NCQA.

21 CO-CHAIR BROOKEY: Yes. It's going to
22 vary State by State and so health plan by health

1 plan.

2 Amy? Oh, to Jon. I'm sorry.

3 MEMBER FINKELSTEIN: Yes, so look, I
4 just --

5 MEMBER HOUTROW: I can be quite for
6 once.

7 CO-CHAIR BROOKEY: Amy Finkelstein.

8 MEMBER FINKELSTEIN: It's hard to
9 always just disentangle reliability from
10 validity. But just to focus on reliability for a
11 minute.

12 Someone should say that the
13 reliability testing using statistical approaches
14 was quite reasonable at the State level and for
15 the large health plans. Six of the 19 commercial
16 plans had insufficient denominators.

17 So it's again, this issue of -- at
18 least by the numbers, the reliability was okay.
19 I've comments too on validity. But I'll hold
20 them.

21 CO-CHAIR BROOKEY: Okay. Well hold on
22 validity. Let's limit our comments to

1 reliability. And then we'll go for a vote.

2 So, Jill? Or is that David?

3 CO-CHAIR SUSMAN: That's David. But
4 he's already -- he just has it turned up already.

5 CO-CHAIR BROOKEY: Ricardo?

6 MEMBER QUINONEZ: So, I think this is
7 a case of, you know, the perfect being the enemy
8 of the good. Because you know, I hear what
9 people are saying around the room about this
10 being hard probably to measure from a reliability
11 standpoint.

12 But, the question I think we should
13 ask for, because I feel this is such a beneficial
14 measure for children's health, is it impossible?
15 And I don't think we can answer that question
16 yet.

17 I think this is one of those instances
18 in which a measure may drive improvement.

19 CO-CHAIR BROOKEY: Are we ready to
20 vote for reliability? Oh, --

21 MEMBER HOUTROW: I mean, I --

22 CO-CHAIR BROOKEY: You knew Amy was

1 going to go next.

2 MEMBER HOUTROW: One of the things
3 that I've been feeling, is that we all feel very
4 passionate about the issues. And while we might
5 feel passionate about the issues, what we're
6 supposed to judge is not the importance of the
7 issue.

8 But the how what is presented to us
9 meets specifications that were put forth by NQF.
10 And so, I mean I think that I agree with Ricardo
11 that this is an important issue.

12 And we shouldn't let perfect be the
13 enemy of the good. But we still have an
14 obligation to evaluate based on a certain subset
15 of data.

16 CO-CHAIR BROOKEY: But I kind of want
17 to vote for it just because Ricardo likes it.
18 But I won't do it or base it on that.

19 (Laughter.)

20 CO-CHAIR BROOKEY: But I agree. I
21 think that we have called out the barriers. It
22 doesn't mean that they're insurmountable, right?

1 All that we're doing is calling out
2 the barriers. It doesn't mean that we don't
3 think it's important.

4 It doesn't mean that we don't think
5 that we can overcome the barriers. And there is
6 some testing that would indicate that in some
7 areas it can be reliably obtained.

8 So any other comments before we vote
9 on reliability?

10 (No audible response.)

11 CO-CHAIR BROOKEY: Okay.

12 MS. CHAVEZ: Okay. Now voting on
13 reliability for Measure 2801. One high, two
14 moderate, three low, four insufficient. Polling
15 is open.

16 (Pause.)

17 MS. CHAVEZ: Twenty-four. We're
18 expecting 24 votes. Okay.

19 CO-CHAIR BROOKEY: It's probably
20 moderate. Yes.

21 MS. CHAVEZ: Four voted high.
22 Eighteen voted moderate. Two voted low. Zero

1 insufficient. This measure passes reliability.

2 CO-CHAIR BROOKEY: Okay. So let's go
3 to validity. And Jon, you have some comments?

4 MEMBER FINKELSTEIN: Yes, so I think
5 you can think of validity for this in two ways.
6 And it's where I really get hung up.

7 So, the measure developer did solid
8 validity testing within the body of claims data
9 that they had. And in that they did correlations
10 between measures which weren't that strong.

11 But, I'd love the developers to
12 correct me on that. They were okay. And they
13 did correlations by ranking to see if the plans
14 that ranked high in one ranked high in other
15 things you'd expect them to rank high in.

16 If they were good at one, they should
17 be good at the other. That kind of internal
18 validity testing.

19 I have to say here's my major concern.
20 There are some things I'm willing to take on face
21 value. I love claims-based measures. I really
22 do.

1 That I'm willing to take on face value
2 that claims based do well almost all the time.

3 Right?

4 You have -- you're a woman of a
5 certain age. You either get a mammogram, or you
6 don't. I think -- I wouldn't look for any
7 validation besides that for whether you got a
8 mammogram.

9 These are complex kids with complex
10 stories. They didn't just wake up on Thursday
11 afternoon and need an antipsychotic.

12 They have histories --

13 (Laughter.)

14 MEMBER FINKELSTEIN: They have
15 histories. I'm not making light of this Dave.

16 Histories of difficulties and
17 counseling at school, at home. Different mental
18 health providers. And at some point they get put
19 on a medicine.

20 The kind of validity I would have
21 liked to see, is to see whether the claims, the
22 snapshot, this biopsy of time that we do in

1 claims, actually reflects the story of these
2 children. I would have appreciated it in 20
3 charts.

4 I would have appreciated it in 100
5 charts to see whether the claims-based
6 information got it right. Or when you really
7 read the story, whether it just didn't line up.

8 And I wonder if the developers thought
9 about that? Or did any of that that wasn't
10 included?

11 DR. SCHOLLE: This is Sarah. I do
12 want to say, we did consider that. So, as
13 alluded to those were just huge barriers in
14 getting access to all of the records that we
15 would have needed to really answer your question.

16 Did they get the services at school?
17 That would have required a HIPAA, you know,
18 authorization.

19 So, it's a lot harder to do. And it
20 was something that we considered. Of course,
21 there is various ways to look at validity that
22 we've presented you data on validity that we

1 could present.

2 But, your point is well taken. Molly,
3 in the work that you've done in New York, do you
4 have any insight on this?

5 And actually, a point that I wanted to
6 make, but I'm not sure it's clear, is that this
7 set allowed for sacrificial intervention to occur
8 90 days before and 30 days after. So it does
9 allow for, you know, urgent prescriptions with an
10 expectation of getting kids into care quickly.

11 So, I'll defer to Molly to see if she
12 has any insight on the issue about the claims and
13 validity.

14 DR. FINNERTY: Yes. I think to the
15 heart of this question is, you know, is this
16 really measuring something that there's a problem
17 with?

18 Are we moving to medications before
19 exhausting therapy? Especially when the therapy
20 has evidence to support it and the medication
21 does not.

22 And the answer to that is yes. Things

1 that look at trends in access to services over
2 time have documented increasing use of
3 antipsychotics even in very young children.

4 And simultaneously decreasing trends
5 in therapy. You know, so these are trends over
6 time. They were long tracks of time.

7 Another thing that I can share with
8 you is that at least in our State, there was a
9 study of children in foster care. And you know,
10 we can say well children of foster care by
11 definition have experienced a trauma in their
12 life.

13 It took them away from their parents.
14 And placed them in foster care in the first
15 place. So, I think it was something like a third
16 of those kids had not had any counseling of any
17 kind.

18 And that was really a study done
19 internally trying to improve the quality of care
20 and access to care, appropriate of care given to
21 those most vulnerable of children here in the
22 State.

1 And we have some other studies have
2 suggested children in foster care get more access
3 to psychosocial services then kids not in foster
4 care. So, the question, do we have a problem?

5 I think the, you know, the answer
6 there is yes. We do. And the nice thing about a
7 measure like this is, I think others have said,
8 is we really need to focus on the heart of the
9 problem.

10 The heart of the problem is perhaps
11 overuse of these medications without first
12 exhausting recommended treatments. And that's
13 really what the point of this measure is.

14 CO-CHAIR BROOKEY: So we voted on this
15 to move forward with insufficient evidence. So
16 we have to kind of put that aside a little bit.

17 And then talk about whether or not the
18 clinicians believe this is a -- there is
19 validity. And it relates to reliability.

20 So, let's focus on the question at
21 hand in terms of validity. Other comments about
22 whether we can move this forward on validity.

1 So, David?

2 MEMBER EINZIG: Yes. So, I think it's
3 really complex. Because there's going to be
4 those individuals where you do what to do therapy
5 first.

6 But, there's also going to be those
7 individuals where you send them to a therapist's
8 office without a medication onboard, without
9 their moods being regulated, it would be an
10 absolute joke. That the kids are just going to
11 be too emotionally off to let that therapy to be
12 effective.

13 And if that's the case, unintended
14 consequence of that therapist sucks. And I'm not
15 going back.

16 And then the, you know, the school
17 issue. Of if you hold off on something that can
18 be potentially helpful that you try everything
19 else first, therapy, psychosocial interventions.

20 You move them into a smaller classroom
21 setting that's EBD based with a bunch of
22 oppositional kids, when their issue may not be

1 that they're primarily oppositional. But rather
2 that they just have this difficulty with severe,
3 impulsive, reactive behaviors.

4 But you get that better regulated, all
5 of a sudden they can stay in their mainstream
6 classroom setting. And go along a different
7 trajectory.

8 So I think it's a very complex issue.
9 And it's not straightforward at all.

10 CO-CHAIR BROOKEY: Can I get a
11 clarification? If you do get a kid that comes
12 into the ER. Let's just say full-blown mania.

13 Is that an exclusion if they start
14 somebody on meds in the ER during an acute
15 episode?

16 DR. FINNERTY: They have a month to
17 get the child into services.

18 CO-CHAIR BROOKEY: Okay.

19 DR. FINNERTY: And I think, you know,
20 some of the examples that we're talking about,
21 the need for medications in acute situations or
22 for kids to properly engage in therapy, you know,

1 this says you can start -- you should have the
2 therapy either before or within 30 days of
3 starting.

4 You know, and the idea here is that
5 there is a way that kids, if they need it
6 urgently, can get the medication.

7 But making this a State measure or a
8 plan measure would incentivize States and plans
9 to ensure that there's access. Because we're
10 talking about well, what if there's no access to
11 that therapy?

12 It would ensure that there was access.
13 It would promote access to those services.

14 CO-CHAIR BROOKEY: It actually ties
15 into the earlier measure about 30 day access for
16 services. And so that makes me feel a whole lot
17 better.

18 I missed that in my reading of the
19 measure. I think Jill had a comment.

20 MEMBER MORROW-GORTON: So I'm going to
21 play devil's advocate to David here. I know he's
22 sitting right beside me.

1 But, as I was listening to what you
2 were saying, one, if you get a kid who's manic, I
3 think that's probably possible bipolar disorder,
4 it doesn't count. Two, the kid that you're
5 describing in terms of going into school,
6 behavior being out of control, et cetera, et
7 cetera, as a clinician, I would do both at once.

8 So you would count -- it would count
9 if you did both at once. I wouldn't do
10 medication and then later do the other.

11 I would -- I mean, when kids come to
12 see me I recommend both.

13 CO-CHAIR BROOKEY: Yes. Ricardo?

14 MEMBER QUINONEZ: I think the point
15 that I was making has been made. But just to say
16 it another way, this wouldn't be a zero sum game.
17 Right?

18 You wouldn't expect 100 percent
19 compliance with this I assume? Because there's
20 no benchmarks for -- only for this. So, they
21 would be established as we go on.

22 So, those instances in which

1 medications are used in the acute setting may end
2 up being asked is this operationalized? Being an
3 exclusion, et cetera.

4 I don't think this will be one where
5 we expect 100 percent compliance.

6 CO-CHAIR BROOKEY: Yes. And we know
7 we have a performance gap. And we know as well
8 that reassures me that we have a 30-day window
9 there.

10 It makes it a little bit of a
11 difference. Let see, are we getting close to
12 reaching our conclusion? Jeff?

13 MEMBER SCHIFF: Just a very quick
14 point that I worry. Which I think relates a
15 little bit to the validity.

16 Is I worry about the diagnostic
17 accuracy and the variability. And we're layering
18 a measure on top of a great amount of diagnostic
19 variability.

20 CO-CHAIR BROOKEY: Amy?

21 MEMBER HOUTROW: My question was to I
22 agree clinically you would try to do both. But

1 it's not that at the same time you made a
2 referral.

3 It's that they actually achieved the
4 care within a month? Is that right? Because
5 that is somewhat outside of the practitioner's
6 realm.

7 It's a health care measure. But let's
8 say I work in a health system for which access
9 takes months. And I refer that child to their
10 school counselor.

11 And that won't be -- it's the same
12 issue for me about how you actually capture the
13 data that you need to capture.

14 CO-CHAIR BROOKEY: Yes. Can I respond
15 to that from a health plan -- this is a health
16 plan measure. It is the responsibility of the
17 health plan to provide access.

18 So, it's the accountability is at the
19 health plan level. And I have to say that that
20 is my accountability as a health plan leader.

21 So, is that a correct statement?

22 MEMBER FINKELSTEIN: Yes.

1 CO-CHAIR BROOKEY: Okay. David?

2 MEMBER EINZIG: Real quick. I
3 promise. So, I agree with Gerald that it has to
4 be both at the same time, Medications plus
5 therapy.

6 And yes, that is and should be and is
7 the standard of care to do both. But this
8 measure is saying exhaust therapy before
9 medications.

10 When I think it would be a better
11 measure is if it were medications in conjunction
12 with therapy. Or therapy in conjunct -- the two
13 together. Not necessarily one exhausted before
14 the other.

15 MS. BYRON: I -- okay.

16 CO-CHAIR BROOKEY: Yes, but just to
17 clarify, it sounds to me that the medication can
18 proceed the therapy.

19 MS. BYRON: It -- yes. Yes.

20 CO-CHAIR BROOKEY: There's a 30-day
21 window.

22 MS. BYRON: There is a 30-day window.

1 And I think the -- you know, the concern with
2 some -- with a measure that says use both, you
3 may inadvertently encourage medication use.

4 When we really don't want to see
5 medication use in these kids who do not have an
6 indication. So, ADHD, disruptive behaviors,
7 we're really not looking for medication use.

8 But the measure's bar is well, if
9 you're going to have them on there, I want to see
10 that you've tried psychotherapy first or
11 immediately after.

12 CO-CHAIR BROOKEY: So, any other
13 comments about validity? Jon?

14 MEMBER FINKELSTEIN: So, this will be
15 really quick. Because I feel that it's easy for
16 the conversation to get away from validity.

17 So, just to tick them off, I don't
18 think anyone questions that this is a big
19 problem. That there's evidence that it's a big
20 problem.

21 I don't think anybody questions --
22 well, I don't question that you should try

1 psychotherapeutic approaches before or with
2 medication approaches.

3 So, there's no argument on the thing.
4 The validity question is whether the measure
5 accurately measures the thing.

6 MS. BYRON: Okay.

7 MEMBER FINKELSTEIN: And I just think
8 we have to keep those two things separate. And
9 I'm okay. If we think claims is close enough and
10 feasible and it measures the thing, then fine.

11 But that's the question.

12 CO-CHAIR BROOKEY: Yes. So, I think
13 when we vote, we have to consider all the
14 barriers that we've raised. We know that this is
15 not perfect.

16 This is not a perfect measure. Is
17 that a reason for it not to move forward?

18 So you have to consider all those
19 things when you decide to vote on validity.
20 Because we have -- this is a must pass vote.

21 So, can we vote on validity? Okay.

22 MS. CHAVEZ: Okay. Now voting on

1 validity for Measure 2801. One high, two
2 moderate, three low, four insufficient. Polling
3 is open.

4 (Pause.)

5 MS. CHAVEZ: We're looking for 24
6 votes. I see 23. Twenty-four. Zero voted high.
7 Thirteen voted moderate. Seven voted low. Four
8 voted insufficient.

9 And this measure passes validity.
10 Sorry, it puts us in the gray zone.

11 CO-CHAIR BROOKEY: With 13 out of --

12 MS. CHAVEZ: Thirteen out of 24.

13 CO-CHAIR BROOKEY: Oh, that's below 60
14 percent. Yes, okay. So, it's gray zone. But
15 that's --

16 MS. CHAVEZ: Gray zone.

17 CO-CHAIR BROOKEY: That's still okay.
18 All right. So the next one is feasibility. And
19 I think we've actually already talked about this.

20 Because we've talked about this as a
21 claims-based measure with a caveat that it may be
22 difficult for the plans to collect supplemental

1 data. I don't -- I'm not sure, is there anything
2 else we should say about that?

3 (No audible response.)

4 CO-CHAIR BROOKEY: A recommendation to
5 vote? Okay. We're too quick for you. I know.

6 MS. CHAVEZ: Okay. We're now voting
7 on feasibility. One high, two moderate, three
8 low, four insufficient. Polling is open.

9 (Pause.)

10 MS. CHAVEZ: Twenty-one. Twenty-
11 three. Twenty-four. Okay. Six voted high.
12 Twelve voted moderate. Five voted low. One
13 voted insufficient.

14 This measure passes feasibility.

15 CO-CHAIR BROOKEY: Okay. Usability
16 and use. So we've agreed to pass this with
17 insufficient evidence with exception.

18 We believe there's a care gap. We
19 believe that it's reasonably reliable, reasonably
20 valid. That we believe that we can measure it.

21 So, is there much more discussion
22 about usability is my question?

1 (No audible response.)

2 CO-CHAIR BROOKEY: No? If not, we can
3 vote.

4 MS. CHAVEZ: Okay. We're not voting
5 on usability and use. One high, two moderate,
6 three low, four insufficient. Polling is open.

7 (Pause.)

8 MS. CHAVEZ: Twenty-three. Twenty-
9 four. Four voted high. Thirteen voted moderate.
10 Six voted low. One voted insufficient.

11 This measure passes usability and use.

12 CO-CHAIR BROOKEY: Okay. So we're one
13 vote away from the group hug.

14 (Laughter.)

15 CO-CHAIR BROOKEY: Overall suitability
16 for endorsement. And then we'll do public.
17 Don't leave until we have public comment.

18 So, all right.

19 MS. CHAVEZ: Okay. We're now voting
20 for Measure 2801 and its overall suitability for
21 endorsement. One for yes, two for no. Polling
22 is open.

1 (Pause.)

2 MS. CHAVEZ: Twenty-three. Twenty-
3 four. Seventeen voted yes. Seven voted no. We
4 needed 15 votes to pass.

5 So, this measure has been recommended
6 for endorsement.

7 CO-CHAIR BROOKEY: So I think the
8 developer has heard our comments. Are there any
9 other comments that have not been made for the
10 developer before we wrap up?

11 (No audible response.)

12 CO-CHAIR BROOKEY: Okay. We're going
13 to move to public comment. But I would just like
14 to say that it's been a pleasure working with all
15 of you.

16 I had no training for the job. And
17 it's been on the job training. And --

18 (Applause.)

19 CO-CHAIR BROOKEY: And it's been a
20 pleasure to work with Jeff.

21 CO-CHAIR SUSMAN: Thank you, sir.

22 CO-CHAIR BROOKEY: And I have to say

1 --

2 CO-CHAIR SUSMAN: I'll shake your
3 hand.

4 CO-CHAIR BROOKEY: I'll shake your
5 hand. Really, you know, I think we all recognize
6 that the NQF Staff does do a tremendous job.

7 And they're not through. We're not
8 through yet. We have more to go. More phone
9 calls to go.

10 But, I'm going to turn to the public
11 comment. And then turn it to Robyn to wrap up.

12 DR. NISHIMI: Operator?

13 OPERATOR: Yes, ma'am. At this time
14 if you'd like to make a public comment, please
15 press star one.

16 And there are no public comments at
17 this time.

18 CO-CHAIR BROOKEY: In the room?

19 DR. NISHIMI: In the room? I don't
20 think so. I just wanted to show you one last
21 slide before we go over the -- what the schedule
22 is.

1 This the result of really what has
2 been absolutely stellar work. It's always an
3 interesting prospect when a Committee meets for
4 the first time.

5 And we have some Committees that meet
6 multiple times. And this is really excellent.
7 And I've seen a lot of Committees in my time at
8 NQF. So, thank you very, very much.

9 You approved one, two, three, four,
10 five, six, seven measures. One of which had the
11 multiple components of fact managers.

12 There was one measure for which
13 consensus was not reached. It will go forward in
14 the draft report that goes out for comment with
15 that designation.

16 And you all will revisit it. And then
17 there were eight measures that weren't
18 recommended and the two FECC components that were
19 not recommended.

20 The developer does have the
21 opportunity to bring back information that may
22 sway you for those. And that would be part of

1 the post draft report comment call.

2 So, thank you very much. Nadine, do
3 you want to go through the dates for the next --
4 we won't have to have the post-meeting call
5 because you finished your work.

6 But there are some other key dates
7 coming up.

8 MS. ALLEN: So, we're not having our
9 post-meeting conference call, which was scheduled
10 for December 10. However, we go out for public
11 and Member comment from January 14 to February
12 12.

13 And then we'll have our post draft
14 report comment call where we'll bring back all
15 the comments to you. As well as any additional
16 information we might receive from the developers
17 for you too probably revote on the measures or
18 not.

19 We'll have Member voting starting from
20 March 15 to March 29. CSAC review on April 12.
21 Board review on May 12. And appeals from May 16
22 to June 14.

1 DR. NISHIMI: You will receive a copy
2 through the PEDS mailbox of the draft report.
3 You know, so you have that as a marker of what's
4 happened.

5 Is there anything else the Committee
6 would like to give us feedback on?

7 CO-CHAIR SUSMAN: Yes. The one thing
8 I would note is clarifying the issues in the
9 green boxes and down below.

10 And then secondly, making it explicit
11 when votes should be held for an exception with
12 insufficient evidence. And how you count low and
13 insufficient evidence together.

14 That wasn't entirely clear to us I
15 think as we went through the process.

16 DR. NISHIMI: All right. Thank you.
17 Ricardo?

18 MEMBER QUINONEZ: So, yes. Thank you
19 for this. This was a great process. And it
20 makes me so much more comfortable now accepting
21 quality metrics that are endorsed by NQF.

22 And I would like to challenge NQF

1 though that because, you know, my -- one of my
2 hobbies is to beat a dead horse.

3 (Laughter.)

4 MEMBER QUINONEZ: It would be to --
5 going back to the measure of where we were
6 testing, and adequately so everybody stated this
7 is for monitoring, not for et cetera, et cetera.

8 I would challenge NQF that when
9 somebody presents a test that they require things
10 like number needed to test. Number needed to
11 harm.

12 Because unintended consequences from
13 testing occur. And it's everywhere in the
14 literature.

15 And I think -- I have no problem with
16 getting tests. Because you think you're being
17 safe. Because you think you're monitoring
18 something.

19 But I do have a problem endorsing
20 tests for what is supposed to be a quality
21 measure that is supposed to improve children's
22 health. I think the bar should be higher.

1 DR. NISHIMI: Thank you. Anyone else?
2 Safe travels.

3 CO-CHAIR BROOKEY: Okay. Thank you.

4 (Whereupon, the above-entitled matter
5 went off the record at 2:38 p.m.)
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This is to certify that the foregoing transcript

In the matter of: Pediatric Measures
Steering Committee

Before: NQF

Date: 12-02-15

Place: Washington, DC

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