

NATIONAL QUALITY FORUM

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RENAL STANDING COMMITTEE

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THURSDAY
MAY 7, 2015

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The Committee met at the National Quality Forum,
9th Floor Conference Room, 1030 15th Street,
N.W., Washington, D.C., at 8:00 a.m., Constance
Anderson and Peter Crooks, Co-Chairs, presiding.

PRESENT:

CONSTANCE ANDERSON, BSN, MBA, Northwest Kidney
Centers (Co-Chair)

PETER CROOKS, MD, Kaiser Permanente (Co-Chair)

ISHIR BHAN, MD, MPH, Partners Healthcare,
Massachusetts General Hospital

LORIEN DALRYMPLE, MD, MPH, University of
California Davis

ELIZABETH EVANS, DNP, American Nurses
Association

MICHAEL FISCHER, MD, MSPH, Department of
Veterans Affairs

STUART GREENSTEIN, MD, Montefiore Medical
Center

DEBRA HAIN, PhD, APRN, ANP-BC, GNP-BC, FAANP,
American Nephrology Nurses' Association

LORI HARTWELL, Renal Support Network

FREDERICK KASKEL, MD, PhD, Children's Hospital
at Montefiore

MYRA KLEINPETER, MD, MPH, Tulane University
School of Medicine

ALAN KLIGER, MD, Yale University School of
Medicine

MAHESH KRISHNAN, MD, MPH, MBA, FASN, DaVita
Healthcare Partners, Inc.

LISA LATTS, MD, MSPH, MBA, FACP, LML Health
Solutions and CMO, University of California
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KARILYNNE LENNING, MHA, LBSW, Telligen

FRANKLIN MADDUX, MD, FACP, Fresenius Medical
Care North America

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JESSIE PAVLINAC, MS, RD, CSR, LD, Oregon Health
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DODIE STEIN, PhD, MSW, LCSW, Indiana University
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JOHN WAGNER, MD, MBA, Kings County Hospital
Center

JOSHUA ZARITSKY, MD, Nemours/Alfred I. duPont
Hospital for Children

NQF STAFF:

POONAM BAL, Project Manager

ALEXANDRA OGUNGBEMI, Project Analyst

KATHRYN STREETER, Senior Project Manager

ALSO PRESENT:

JOEL ANDRESS, PhD, Centers for Medicare and
Medicaid Services

AMY BECKRICH, Renal Physician=s Association

CLAUDIA DAHLERUS, PhD, MA, University of
Michigan

BARBARA FIVUSH, MD, Johns Hopkins University*

EDWARD JONES, MD, Delaware Valley Nephrology
and Hypertension

JOE MESSANA, MD, University of Michigan

LISA MCGONIGAL, MD, MPH, QMRI

PAUL PALEVSKY, MD, University of Pittsburgh*

SARAH SAMPEL, NQF Consultant

DOUG SCHAUBEL, MD, University of Michigan

DALE SINGER, MHA, Renal Physicians Association

* present by teleconference

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

2 (8:02 a.m.)

3 CO-CHAIR ANDERSON: All right. Well,
4 thanks, everyone, for coming a half hour early,
5 so we can get started. We have a large agenda to
6 get through today. Yesterday -- thank you,
7 everyone -- we did make a lot of progress, but
8 we've got a lot more to do.

9 Just a reminder that we are going to
10 try and get through all of the measures. So if
11 we could keep our comments and not repeat the
12 same comments, that would be very helpful to move
13 through the agenda.

14 At the end we will have a wrap-up, and
15 we would really like to hear your comments about
16 the process and how things went.

17 Peter, do you have anything else to
18 say?

19 CO-CHAIR CROOKS: I'm still -- I'm up
20 first, so I have to get ready.

21 CO-CHAIR ANDERSON: Oh, you're up
22 first. Okay.

1 CO-CHAIR CROOKS: I'd just like to
2 add, again, thank you for coming in early. For
3 those of you who enjoyed the swank Helix Hotel,
4 and happened to get charged for the full price,
5 the staff is looking into it, and we'll let you
6 know later if they were able to reverse charges
7 or you'll be billing it back to NQF.

8 CO-CHAIR ANDERSON: Okay.

9 CO-CHAIR CROOKS: So we will have more
10 on that later.

11 CO-CHAIR ANDERSON: All right. Our
12 first measure is 0249, and the developers,
13 Claudia and Joel? You guys are already here.
14 You're right on top of things.

15 DR. DAHLERUS: Okay. Good morning.
16 So I will keep the opening statement very, very
17 brief, just because some of the things that we
18 discussed with the peritoneal dialysis adequacy
19 measures apply to the HD measure.

20 So the first one and the prior one
21 being that, as you are aware, this also included
22 the upper threshold of 5.0 for the individual

1 measure. And as we discussed yesterday, that
2 will be removed. We will redo the reliability
3 and validity testing for this measure and then
4 resubmit updated documentation. And, again, that
5 is something that is very manageable.

6 The only other thing that I wanted to
7 note, because I think this may have come up in
8 some of the remarks about the measure, is the
9 2006 guidelines that were cited in our evidence
10 summary, and recognizing that, you know, those
11 are obviously quite a few years old.

12 However, the HD adequacy workgroup for
13 KDOQI did meet last year, and there were draft
14 guideline updates that were released, and the
15 important point being really no new updates in
16 terms of a revision to the minimum Kt/V for
17 dialysis adequacy.

18 So I will just I think end my comments
19 there in the interest of time, because we also
20 have similar adequacy measures to move through,
21 and I think a lot of the same issues apply.

22 Thank you.

1 CO-CHAIR ANDERSON: All right. And,
2 Peter and Ishir, for discussion of the measure?

3 CO-CHAIR CROOKS: Yes. Would you like
4 to take the lead?

5 DR. BHAN: Sure.

6 CO-CHAIR CROOKS: Yes, please do.

7 DR. BHAN: I can kick it off? So this
8 is somewhat similar to the last measure that we
9 looked at, in that it is looking at hemodialysis
10 adequacy. It is an outcome measure using claims
11 and electronic data. But this one is at the
12 facility level as opposed to the individual
13 clinician level.

14 So just going to the evidence, there
15 is -- I think we went through this with the last
16 measure as well. There is the -- as was just
17 mentioned, there is the KDOQI guidelines from
18 2006, which had a grade A but are somewhat old.
19 There are a number of studies showing clearance
20 correlations with outcomes, and there is the hemo
21 study showing that higher clearances aren't
22 necessarily helpful, at least overall.

1 So I think overall the feeling was
2 that, you know, 1.2 is a reasonable threshold.
3 That is sort of where things have settled out,
4 and we thought the evidence was, you know, as
5 good as it is for this kind of thing. There is,
6 you know, obviously ongoing debates about optimal
7 clearances, but it's as reasonable as it was for
8 the previous measure we discussed. And we talked
9 about the birth threshold, but I think that has
10 been addressed.

11 CO-CHAIR CROOKS: Yes. I felt the
12 evidence review was based on KDOQI. Well, to be
13 a little picky, I noticed little things -- and
14 this gets to the issue of filling in the forms
15 and answering the questions, that the answers to
16 1A 7.7 and 1A 7.8 were identical. They were just
17 cut and pasted in.

18 And the second one was about harms,
19 and it really didn't address the question.
20 Again, I'm being picky, but I'd like to see the
21 developers, you know, help us out so we don't
22 have -- you know, to take us down the path to see

1 what it is they are trying to show us.

2 But the evidence is grade A. There
3 was no new evidence presented since 2006.

4 So the floor is open for other
5 comments on the evidence.

6 MS. BAL: So just a reminder, please
7 speak into the mic and speak loudly. This is the
8 loudest the system can go, so please remember to
9 focus on that so the whole committee can hear
10 you.

11 CO-CHAIR ANDERSON: Mahesh?

12 DR. KRISHNAN: Just a clarifying
13 question. I know we said this yesterday. I just
14 -- I'm trying to reconcile this in my mind. We
15 are thinking about the evidence of the two pieces
16 as opposed to the evidence of the totality of the
17 measure, right? Because it's a combination as
18 opposed to one measure.

19 We are looking at the evidence grading
20 for adult Kt/V, pediatric Kt/V, separately, as
21 opposed to the evidence that supports the use --
22 the combined measure.

1 CO-CHAIR CROOKS: This is adults only,
2 but it's the same --

3 DR. KRISHNAN: Concept.

4 CO-CHAIR CROOKS: Same thing.

5 CO-CHAIR ANDERSON: Any other
6 comments? Discussion? Are we ready for voting?

7 MS. BAL: Turn your mics off. Thank
8 you.

9 So we are voting for evidence for
10 0249. The options are one, high; two, moderate;
11 three, low; four, insufficient. And voting is
12 open. We do need a couple more. We're at 19,
13 and the full committee is here, so we should have
14 23.

15 Please remember to point at me. With
16 your clicker.

17 Well, 20 is quorum. And if everyone
18 has put their vote in, I don't -- okay. So the
19 results are six high, 15 moderate, zero low, zero
20 insufficient, and we can move forward to gap.

21 CO-CHAIR ANDERSON: All right.

22 DR. BHAN: Okay. So for the

1 performance gap, and I think this is where there
2 is going to be the most attention, and we
3 addressed this a little bit in our last
4 discussion with the last item, so the performance
5 data is based on 2013 CROWNWeb and Medicare
6 claims data.

7 And out of -- with about 5,500
8 facilities, the mean performance score was 93.5
9 percent, with a standard deviation of seven, so
10 crossing 100 percent actually. There were
11 disparities data presented, which had some
12 significance based on the large numbers, but at
13 least I didn't feel were that dramatically
14 impressive.

15 But our key comments here were -- in
16 our call were regarding how much room for
17 improvement there really is with a mean of
18 93.5 percent. I think this came up with the last
19 HD clearance discussion as well.

20 CO-CHAIR CROOKS: Yes. I agree. I
21 have concerns about the gap in the standard
22 deviation going over 100 percent, very narrow.

1 Other thoughts?

2 DR. FISCHER: Just briefly to remind
3 everybody the similar measure that we discussed
4 at the end of the day drew data from USRDS. I
5 think there was 97 percent. It was a very
6 similar measure, just kind of furthering that up.
7 These are slightly different data sources,
8 probably different time periods. I don't
9 remember which time period that was from that
10 Paul mentioned off my head. But just going back
11 to the point about topped out.

12 CO-CHAIR ANDERSON: And the QIP data
13 shows it at 98 percent, and so it really is a
14 measure that I think we might want to put into
15 reserve as being a topped out measure. And, you
16 know, there is really very little room for
17 performance improvement.

18 Any further discussion? Call for the
19 vote.

20 MS. BAL: Okay. So we are voting on
21 gap for 0249. The options are one, high; two,
22 moderate; three, low; four, insufficient. And

1 voting is open.

2 Please look at your clicker. If
3 you're getting any sort of error, let us know.

4 Okay. The results are zero high, six
5 moderate, 16 low, one insufficient. So this
6 measure does go down on gap. We can ask the
7 committee if they would like to consider reserve
8 status.

9 Okay. I'm seeing shakes of the head
10 as yes. So let's go ahead and do a hand vote.
11 So if you would like to do reserve, put your hand
12 up, please. Okay. That's a majority. So we can
13 move forward with reliability.

14 DR. BHAN: Okay. So for reliability,
15 for the specifications, the data elements were
16 defined based on a treatment file for the
17 patients who are on dialysis, and for testing it
18 was performed using the data from 2013, CROWNweb
19 and Medicare claims with, as I mentioned, over
20 5,500 facilities.

21 The IUR was 0.942, so pretty high.
22 Let me just see our comments. Basically, people

1 felt the specifications for reliability seemed
2 pretty solid.

3 CO-CHAIR CROOKS: Nothing to add.

4 CO-CHAIR ANDERSON: Lorien?

5 DR. DALRYMPLE: So it was unclear to
6 me, are four times per week hemodialysis
7 treatments excluded? At the top it does not
8 appear they are, but then there is denominator
9 logic that says patient is not on frequent
10 dialysis? So I think I would argue if you're on
11 dialysis four times per week you shouldn't be
12 required to need a single pool of 1.2.

13 DR. DAHLERUS: So that's correct.
14 Patients on -- adult patients on four times or
15 greater are not included. It is just thrice
16 weekly dialysis, and we can clarify that in the
17 specifications.

18 DR. DALRYMPLE: Okay.

19 DR. DAHLERUS: Thank you.

20 DR. DALRYMPLE: Thanks.

21 CO-CHAIR ANDERSON: Alan?

22 DR. KLIGER: I just want to piggyback

1 on that for a moment, because the specifications
2 I think here are clear that it's three times a
3 week. Period. Right? It is neither more nor
4 less than three times a week, and single pool
5 Kt/V can only be used if there is a single
6 frequency.

7 We'll get to talking about that with
8 the next measure, but for this measure my
9 understanding is that it's a single frequency,
10 three times a week. It could be if it's three
11 times a week. It's frequency -- it's a frequency
12 measure.

13 CO-CHAIR ANDERSON: Any further
14 discussions or comments? Are we ready to vote on
15 reliability?

16 MS. BAL: Okay. We are voting on
17 reliability for 0249. The options are one, high;
18 two, moderate; three, low; four, insufficient.
19 And voting is open.

20 Still waiting for a couple, if
21 everybody could try to vote again. Yes. Please
22 vote again, just so we can get everyone.

1 Okay. We have four high, 18 moderate,
2 three low -- I'm sorry, four high, 18 moderate,
3 zero low, zero insufficient, for 0249
4 reliability.

5 We can move forward to validity.

6 DR. BHAN: Okay. So for validity, you
7 know, this is based on the association of
8 clearance with mortality. They did do some
9 testing here looking, again, at the Spearman
10 correlations between achieving the target and the
11 SMR and SHR. And the coefficients we have seen
12 before are -- they are statistically significant,
13 although the magnitude is relatively small. So
14 with SMR it was negative 0.085, and the SHR was
15 negative 0.159.

16 And I think that's all the comments we
17 had. There weren't any significant exclusions.

18 CO-CHAIR ANDERSON: Any discussion?
19 All right. We'll call for the vote.

20 MS. BAL: Okay. Voting for validity
21 for 0249, the options are one, high; two,
22 moderate; three, low; four, insufficient. Voting

1 is open.

2 The results of the vote for validity
3 for 0249 is three high, 19 moderate, one low,
4 zero insufficient, and we'll move forward.

5 CO-CHAIR ANDERSON: All right. On to
6 feasibility, Ishir?

7 DR. BHAN: Okay. So for feasibility,
8 this data is in CROWNWeb, and certainly there is
9 lots of claims data. It has been done. It seems
10 feasible.

11 CO-CHAIR CROOKS: I agree.

12 CO-CHAIR ANDERSON: All right. Any
13 discussion? Call for the vote.

14 MS. BAL: Okay. Voting for
15 feasibility for 0249, one, high; two, moderate;
16 three, low; four, insufficient. Voting is now
17 open.

18 Okay. The results for feasibility for
19 0249 is 18 high, five moderate, zero low, zero
20 insufficient, and we'll move on to usability and
21 use.

22 DR. BHAN: Okay. So for usability, it

1 is being used. It is publicly reported. Not
2 much more to say. I think there is not too much
3 question here.

4 CO-CHAIR CROOKS: And to the gap
5 issue, they were unable to show improvement in
6 the last -- I think this is the last four
7 quarters of -- I'm not sure what year, 2013,
8 suggesting that, you know, it is consistent with
9 the notion that it's topped out.

10 CO-CHAIR ANDERSON: Any further
11 discussion on usability? All right. We'll call
12 for the vote.

13 MS. BAL: Okay. The vote for
14 usability and use of 0249 is open. The options
15 are one, high; two, moderate; three, low; four,
16 insufficient.

17 Okay. The results for usability and
18 use for 0249 is 17 high, six moderate, zero low,
19 zero insufficient, and we can move on to the
20 overall vote.

21 DR. KRISHNAN: Can I ask a clarifying
22 question just about the term "usability" for the

1 NQF staff? When we say "usability," we have
2 often in this setting been using it as it can be
3 used for public reporting.

4 Is a component of use that the
5 dialysis unit or whoever is being evaluated can
6 receive that data back and actually do something
7 with it in a timely fashion? Or is it only about
8 it can be used for a public metric? How do you
9 balance out the operational?

10 So, for example, if a metric is there
11 but the facility can't calculate it itself --
12 clearly not this one, but just as an example --
13 they can't improve because they don't know where
14 they are. Is that part of usability? Or is that
15 part of implementation? Or could you help me
16 with that?

17 MS. BAL: I mean, I'll refer it to
18 Sarah, but I'll let her --

19 MS. SAMSPEL: Yes. I mean, you know,
20 so one of the first requirements is the fact that
21 it is publicly reported, and that we are moving -
22 - you know, we want the entire industry, renal,

1 everybody else, to be moving towards public
2 reporting, at the same time that usability is an
3 overall criteria even on the development phase of
4 something that whoever is reporting on the
5 measure can then take that measure back and use
6 it to improve performance or improve quality in
7 some way.

8 So, yes, that is one of the things
9 that you should be considering under use and
10 usability.

11 Did you have anything you wanted to
12 add, Marcia?

13 DR. KRISHNAN: So just so I can
14 clarify, it's the ability to get real-time access
15 to the data, so whoever you're evaluating can
16 say, "Oh, my gosh, I'm not performing well. I've
17 got to improve."

18 MS. SAMSPEL: Well, it's not
19 necessarily real time.

20 DR. KRISHNAN: Not real time. I keep
21 using the wrong word, and we keep clarifying.

22 MS. SAMSPEL: The ideal situation is

1 you would have real time, but, you know --

2 DR. KRISHNAN: The facts on the data.

3 MS. SAMSPEL: -- even if you're
4 talking about HEDIS, you know, it is something
5 that should be coming back that has an
6 opportunity for the organization to use to
7 improve quality.

8 DR. KRISHNAN: Okay. Yes. I
9 apologize. I keep using the wrong words, but we
10 have different terminologies.

11 CO-CHAIR ANDERSON: Any further
12 discussion before we call for the vote for
13 recommendation for endorsement for reserve
14 status? All right.

15 MS. BAL: Okay. And as a reminder,
16 the specifications for reserve status is that it
17 is topped out, but it would be harmful to lose
18 the measure, and that it is very strong in
19 reliability and validity.

20 So the vote for reserve -- for
21 endorsement meets potential for reserve status
22 for 0249. The options are one, yes; two, no.

1 Okay. The results are 22 yes, zero
2 no, so this has a potential for reserve status,
3 and we can move on to the next measure.

4 CO-CHAIR ANDERSON: Okay. All right.
5 Measure 1423, and, well, you guys are ensconced
6 there, Claudia and Joel?

7 DR. DAHLERUS: So this is a measure of
8 pediatric hemodialysis adequacy based on Kt/V.
9 It's a percentage of patient-months that achieve
10 Kt/V 1.2 or more. And this was developed in 2010
11 by the pediatric hemodialysis adequacy TEP, and
12 it was originally endorsed in 2011.

13 The underlying context of the TEP's
14 recommendation recognizing that there was not a
15 lot of -- a large body of evidence defining a
16 specific threshold for the pediatric population,
17 but they did cite the KDOQI, the 2006 KDOQI
18 guidelines, which recommended -- and these were
19 opinion-based, expert opinion, but the guidelines
20 recommended that for pediatric patients Kt/V
21 should align with the minimum dialysis adequacy
22 for adults of 1.2. And so that was the rationale

1 for the TEP defining this threshold.

2 Thank you.

3 CO-CHAIR ANDERSON: All right. And
4 it's Alan and Frank?

5 DR. KLIGER: So as we just heard, it
6 is a measure for pediatric hemodialysis, and the
7 specifications are for patients dialyzing three
8 or four times a week whose average delivered dose
9 of hemodialysis using UKM or Daugirdas II are a
10 single pool Kt/V of 1.2.

11 So I want to ask first a clarifying
12 question of the developers. The three or four
13 times a week, is that what was in the original
14 2011 version that was approved?

15 DR. DAHLERUS: Yes, it was. And that
16 was also stated in the TEP's formal
17 recommendations. The rationale, as I understand
18 them, is they wanted to ensure that children that
19 are dialyzing four times a week would still be
20 evaluated for adequate dialysis.

21 DR. KLIGER: Yes. So we will go
22 through the evidence in each of the categories,

1 but I want to lay out from the outset what I
2 think is a fundamental flaw and problem in this
3 measure. And it is -- it will apply for this
4 measure and others as well.

5 The first, which we will deal with
6 quickly, is that as in many pediatric measures,
7 we don't have very much direct evidence for kids.
8 And so this is really based on adult data with
9 the assumption that children should be doing at
10 least as well as adults do, and that's, I
11 believe, a very reasonable position to take.

12 The problem is a kinetic measurement
13 problem, the way that the measure is currently
14 constructed. And just because I wanted to make
15 sure that I had this right, I spoke to John
16 Daugirdas, the kineticist who constructed the
17 Daugirdas II formula to make sure that what I was
18 saying and what I am going to be sharing today is
19 accurate.

20 When either the urea kinetic
21 measurements overall or specifically Daugirdas
22 worked with his group in 2003, and then

1 eventually made the recommendations to KDOQI in
2 2006, the challenge was to come up with a measure
3 that somehow approximated what the kidney really
4 does. Kidney works 24 hours a day, seven days a
5 week, obviously.

6 But in hemodialysis that is
7 intermittent treatment. The dynamics are very
8 different, because you have a burst of clearance
9 and then a long period between them of no
10 clearance at all.

11 And so a formula that measures what
12 happens in one specific treatment will be very
13 dependent on what happens around it, how frequent
14 the treatments were. So, for example, in the
15 measure as it is currently constructed, if a
16 child is dialyzed three times a week, and the
17 single pool Kt/V is measured -- and, of course,
18 the way it's done is a single treatment is
19 assessed with pre- and post-dialysis urea, and
20 you calculate the Kt/V . You'll have a number,
21 whatever it is. If that same child is increased
22 to four times a week, or five times a week, using

1 the methodology that is here, the Kt/V will not
2 change. It will be exactly the same because of
3 the way it is calculated.

4 And the kineticists have been clear,
5 and they were back in 2006, that if we are
6 looking at varying frequencies of dialysis that
7 rather than using a single pool Kt/V , the tool
8 that we should be using is a continuous tool, one
9 like what they have called the standard Kt/V .

10 And, in fact, in the KDOQI document
11 back in 2006, they have a table, Table 18, in the
12 Appendix that Dr. Daugirdas referred me to that
13 shows what the relative clearance would be
14 required depending on frequency.

15 So, for example, the minimum Kt/V of
16 1.2, giving patients who are dialyzed an average
17 of 3.5 hours a week, is where we currently sit
18 for three times a week dialysis. If you look at
19 patients who are dialyzed four times a week, that
20 same point would not be 1.2. It would be 0.77.

21 So if we were looking at adults or
22 kids, all dialyzed four times a week, the minimum

1 dose that we would be asking for is not 1.2. It
2 would be .77, but that's only if all the patients
3 were dialyzed four times a week.

4 So my point is that using single pool
5 Kt/V in patients dialyzed at different
6 frequencies is like using a tape measure to
7 measure somebody's weight. It is the wrong tool,
8 and it really cannot consistently be used. And
9 Dr. Daugirdas was clear with me that he felt
10 passionately about that as well.

11 The rejoinder could be that, well,
12 that is okay, as long as they're achieving that
13 minimum of 1.2, if they're dialyzed four or five
14 times a week, then they're way over the threshold
15 anyway. The problem with that, I believe, is
16 that by setting up a minimum of 1.2 with whatever
17 frequency it would be a disincentive to put
18 patients on increasing frequency of dialysis,
19 because that wouldn't change their Kt/V.

20 So a large child with a Kt/V of 1.0,
21 done three times a week, with this measure, if
22 you went to four times a week it wouldn't change,

1 or five times a week it wouldn't change. So the
2 incentive would be instead of going to more
3 frequent dialysis to extend the time, which --
4 during single sessions, which if you do the
5 calculation is not nearly as efficient a
6 treatment as increasing the frequency would be.

7 So my point I guess is that there is,
8 I believe, a fundamental flaw when we use this
9 tool, if we are looking at varying frequencies of
10 dialysis. And in the real world we now know that
11 varying frequencies are becoming more and more
12 common, not only for kids but for adults as well.
13 So I believe that that is really a fundamental
14 flaw in this particular measure.

15 The second thing that I will mention,
16 but we have -- I mentioned yesterday as well is
17 that for hemodialysis we are not including
18 endogenous kidney function. And it is reasonable
19 to do that, I believe, since most patients in any
20 case lose virtually all of their endogenous
21 kidney function within the first year.

22 But I would love to see these measures

1 allow for -- not require, but allow for including
2 endogenous function in this measurement. So that
3 incident patients with substantial kidney
4 function still available could have crafted
5 therapy to give them less dialysis time initially
6 until their endogenous kidney function was
7 reduced to the point that they required more
8 treatment. So that is just my general comment.

9 When we go now specifically to the
10 evidence, the evidence here is based on the adult
11 experience. We have heard already the evidence
12 for the adult experience, which is strong for
13 three times a week, Kt/V of 1.2. And the
14 statement in KDOQI, as we have heard, is that
15 kids should have at least as good treatment as
16 adults. So that is where the evidence is.

17 Now, I don't know, Connie, whether you
18 think we should vote on sort of the flaw in the
19 design, at least my perception of the flaw of the
20 design, in the evidence phase or in the
21 specifications phase.

22 CO-CHAIR ANDERSON: Well, I think we

1 would be talking about it in the specification
2 phase.

3 DR. KLIGER: Okay.

4 CO-CHAIR ANDERSON: I would like to
5 hear from our pediatric experts over here.

6 MS. BAL: If you wouldn't mind, could
7 we also discuss it during the specification?
8 Just so we can make sure that, you know, what
9 people are hearing is focused on evidence, and
10 people vote on that, and then we'll move to the
11 specifications.

12 CO-CHAIR CROOKS: And it's a tough
13 overlap between where it should be I guess. I
14 have trouble voting on the evidence if this is an
15 issue. So I'd prefer to get it talked about now.

16 DR. SOMERS: In terms of evidence,
17 although most of the evidence was within the
18 KDOQI, there was some CPM data that pertained to
19 adolescents particularly that showed that Kt/V
20 less than 1.2 is associated with a greater risk
21 of hospitalization. There is some other
22 literature from Europe that supports that as

1 well.

2 CO-CHAIR ANDERSON: Lorien?

3 DR. DALRYMPLE: But with respect to
4 our evidence voting, to my knowledge most of the
5 evidence -- but this is where the pediatric
6 nephrologist would be very helpful -- relates to
7 three times a week assumptions. So if it is
8 specified on three or four times a week, doesn't
9 it fail on evidence on the four times a week
10 frequency? Because the evidence doesn't support
11 that frequency unless our pediatric nephrologist
12 can inform us.

13 CO-CHAIR ANDERSON: Josh?

14 DR. ZARITSKY: I mean, you would have
15 a hard time, even if you just substitute
16 "pediatric" for "adult," and you said, well,
17 you're going to have four times a week or daily
18 dialysis, and use a cutoff, a standard single
19 pool Kt/V of 1.2.

20 So I don't -- I have a problem with
21 using it for four times a week. If they are
22 going to use a standardized Kt/V or other than

1 single pool, I think that would be different, and
2 we get into the evidence of a standardized Kt/V,
3 but -- and there are quite a few children that
4 are dialyzed more than three times a week for
5 fluid issues as well.

6 I will tell you, practicality, it is
7 usually fairly easy to achieve a Kt/V above the
8 standard in pediatrics, but the four times --
9 just on a technical basis, I have the same type
10 of feeling about the inclusion of the four times
11 a week.

12 CO-CHAIR ANDERSON: Lori?

13 DR. SOMERS: But what Alan said would
14 still pertain. If you are meeting a Kt/V of 1.2
15 four times a week, then you obviously would be
16 avoiding all the bad sequelae of having poor
17 adequacy with your dialysis. And my
18 understanding of kind of the proportion of
19 children who are dialyzed four times a week is
20 somewhere between five and six percent, so it is,
21 you know, a relatively small number of kids at
22 this point in time.

1 MS. HARTWELL: I just wanted to
2 piggyback on Alan's comment. It kind of
3 frustrates me to hear that, you know, the
4 residual kidney function is a secondary issue,
5 and to the patient that is the primary goal, I
6 mean, of any patient on dialysis is to keep their
7 residual kidney function. It makes such a
8 difference in their quality of life, their diet,
9 and to think that a measure doesn't help that or
10 maintain that is extremely frustrating to hear.

11 And I think that that should be in
12 consideration when a developer creates a measure,
13 because we don't -- first, we don't want to do
14 any harm. And if a physician can help keep the
15 kidney function, and, for example, when I was on
16 Next Stage, I had quite a bit of kidney function,
17 and so I only needed it three times a week. And
18 that went on for about six to eight months
19 because I was able to maintain my own kidney
20 function.

21 But what I'm hearing is is that may
22 not always be the case, if a doctor is

1 prescribing -- you know, so that's just my
2 comments. So I'm a little concerned about
3 hearing that.

4 DR. KASKEL: So in the small infant
5 and small child, it is very common to be doing
6 dialysis at least four times a week. And even if
7 you achieve the goal and they are not growing,
8 yet your nutritional assessment is adequate, and
9 most of these infants are on G tubes, so they are
10 getting the nutrition at night, we increase the
11 dialysis time. We'll go to five days a week. We
12 have infants on dialysis sometimes five days a
13 week, most of them four, and we measure growth.
14 If they don't grow, they may need more, despite
15 the calculations.

16 So it's a very soft sign, and it takes
17 a long time to determine growth. It's not just a
18 week; you're looking at months.

19 CO-CHAIR ANDERSON: Frank?

20 DR. MADDUX: So as we talked about
21 this in the workgroup, and we brought up
22 yesterday, one of the issues with a number of

1 these, and certainly with this one, with the
2 small body mass that patients have, and the
3 others, is whether the urea kinetic model, or
4 simply the Daugirdas formula, really equate to
5 the same thing.

6 I would ask my pediatric colleagues
7 whether the urea kinetic model that was
8 predominantly built in adults is 100 percent
9 applicable, especially when you get down to the
10 very smaller sized children, especially looking
11 at the urea generation rates and the nutritional
12 issues that I think were just brought up.

13 And these are just issues where we are
14 applying something to a population that really
15 was developed for a different population. I
16 think we need to make sure we are aware of that
17 as we look at this one.

18 DR. KASKEL: I wouldn't go too far
19 into the urea modeling or kinetics for us in the
20 growing -- you know, maybe a stable adolescent
21 who is not sick and losing weight. That's one
22 thing. But not in the growing child or the not

1 growing child or adequately growing child, no, I
2 wouldn't.

3 DR. MADDUX: One other corollary
4 question on that for you all is, do you even do
5 formal urea kinetic modeling often in children?

6 DR. KASKEL: I think that we are --
7 you know, we are stuck, once again, with the
8 tools that -- there is a limited set of tools,
9 and so we do use this as a tool. So I do think
10 it's still an important measure for us to be
11 calculating it and to -- especially as, you know,
12 our children grow.

13 But, obviously, we take a lot of other
14 things into consideration, but we just don't --
15 you know, we don't have the body of evidence.
16 And, you know, you could make the argument it's
17 small solute -- you know, is there just
18 overemphasis on small solute calculations because
19 they're easy to do? We know the modeling, but
20 they're still a tool that you have to use, and
21 maybe that's the best tool we have now. So it's
22 still a very valuable tool for us.

1 CO-CHAIR ANDERSON: Alan?

2 DR. KLIGER: So let me ask you what
3 tool you are using. Are you using the standard
4 Kt/V or the single pool Kt/V when you have
5 patients that have varying frequencies of
6 dialysis?

7 DR. SOMERS: Standard for varying.

8 DR. KLIGER: You're using the standard
9 Kt/V, not the single pool.

10 DR. SOMERS: At least that's what I'm
11 using.

12 CO-CHAIR ANDERSON: Any further
13 discussions or comments? All right. We are
14 ready for the vote on evidence.

15 MS. OGUNGBEMI: The committee is now
16 voting on evidence for Measure 1423. The options
17 are one, high; two, moderate; three, low; and,
18 four, insufficient. Voting is open.

19 The results are zero votes high, nine
20 votes moderate, 11 votes low, and three votes
21 insufficient. The measure does not fail on
22 evidence. This is Measure 1423. It does fail,

1 I'm sorry, does not pass on evidence.

2 MS. SAMPEL: Actually, and so what we
3 want to do here, and something that we have
4 afforded to other developers, is -- and what a
5 fail means at this point is that we do not move
6 forward with the vote.

7 However, what we would ask, and I
8 think Alan has already expressed, you know, some
9 of his concerns, but also any additional advice
10 that you can provide to the developers as they
11 consider this measure, if they do take it back to
12 a TEP, et cetera, what are those types of things
13 that would change the game on this measure and
14 how you would vote in the future.

15 DR. ZARITSKY: Just a procedural --
16 are we allowed to move forward with the other
17 consideration, that there is not enough evidence
18 but we are still -- what is that fourth -- the
19 exception? Or that has to be -- then they have
20 to have a majority of insufficient evidence vote.
21 Can you remind me of the procedure there?

22 MS. BAL: Yes. We can still move

1 forward and vote on insufficient with exception,
2 if that's what the committee would like to do.

3 DR. KLIGER: Can I just raise an
4 understanding of that? Because if it's approved
5 with exception, doesn't that say that we think
6 that it's a valid measure, it's just that it
7 doesn't -- it either has topped out or there is
8 some other reason not to be using it, but that
9 has strong evidence for it? That's the way you
10 have instructed us, that there is strong evidence
11 for it.

12 MS. BAL: No. For the exception with
13 -- the evidence with exception -- I'm sorry,
14 insufficient evidence with exception, it is that
15 there is low or insufficient evidence to support
16 the measure; however, you feel that other factors
17 are strong enough to move this measure forward,
18 such as you think that this is an important
19 enough measure, or that the other factors, such
20 as reliability, or the fact that it is in use and
21 it is being used well, that kind of thing.

22 So if you think that other factors

1 will be higher, and this is a measure that should
2 be kept, then yes. The exception is on the
3 evidence, so if evidence would be low, everything
4 else you should consider would be higher.

5 DR. KLIGER: I would just argue I
6 guess that it means that that would be an in-
7 practice measure. And I think this is really a
8 fatally flawed measure as currently constructed.
9 I think if the team goes back and substitutes
10 standard Kt/V, and does the work to do the
11 measure -- you know, the background work to do
12 the gap analysis, et cetera, using standard, then
13 we might feel differently. But I would -- I just
14 have trouble approving this with exception in its
15 current form.

16 DR. SOMERS: I mean, or we could just
17 restrict it to children being dialyzed three
18 times a week because it's such a small proportion
19 of kids who have more than three times a week.

20 CO-CHAIR CROOKS: Well, we can't do
21 that. The developers could take that --

22 DR. SOMERS: Right. No, but that's

1 our suggestion.

2 CO-CHAIR CROOKS: Yes. I'm thinking
3 of the exception as, for instance, you know, we
4 know it's important; the evidence just isn't
5 there, like jumping out of a plane without a
6 parachute is a bad thing, but no one has ever
7 done the trial. I think we would give that an
8 exception. That's the sort of -- but here we are
9 saying that the -- we are not sure it's that
10 important, and as it's constructed it has flaws.

11 But I think -- anybody else who would
12 like to speak to considering this as an
13 exception?

14 DR. ZARITSKY: So with just that in
15 mind, I mean, you know, I think that this is, you
16 know, an important measure, and I would like to
17 see the four times a week -- I would rather not
18 see a standardized Kt/V. I would rather see the
19 three times a week, you know, single pool
20 implemented.

21 And I brought up the exception issue
22 because I do think it's an important -- it's an

1 important measure that we have and that we don't
2 just totally, you know, get rid of it. It's --

3 CO-CHAIR ANDERSON: We can call for
4 the vote for exception.

5 DR. ZARITSKY: So just in the future,
6 if you're going to -- if you have an idea that
7 you want to do an exception, then the category
8 you should be voting for is, then, number four,
9 right? Yes?

10 CO-CHAIR ANDERSON: Any more
11 discussion in terms of calling for the vote for
12 exception?

13 DR. FISCHER: Can you just clarify
14 what we are going to vote on? The exception of -
15 - maybe I'm just a little bit confused. The
16 exception of what? What exactly are we voting
17 on, please?

18 MS. SAMSPEL: So basically, you know,
19 when the votes fall down into this three or four
20 category, so low or insufficient evidence,
21 typically a high number of votes in insufficient
22 would mean that you think that while the evidence

1 provided did not support the measure that it is
2 still an important enough measure that you would
3 like to see it continue through the voting and
4 recommend endorsement with exception to the
5 evidence.

6 You know, I think in this case, you
7 know, it also sounds like there was some
8 confusion, how do you get to that vote of
9 exception for evidence, is it low or is it
10 insufficient, and so, you know, I think what I
11 have heard is that there may be a consideration,
12 and we might just want to get out on the table,
13 do the vote of how many people want to say, you
14 know, we think this is an important enough
15 measure to continue to move it forward through
16 the voting process.

17 I think the other things that I keep
18 in mind here are the fact that this is all going
19 to be documented in the report, that there is
20 also this opportunity during public comment to
21 get more information out of the public on how
22 they feel about the measure that will come back

1 for your consideration as well.

2 So the measure doesn't technically die
3 here in this room today if it does not go all the
4 way through.

5 DR. KRISHNAN: But just to what Josh
6 said, Sarah, if he wants to have the exception --
7 or if he wants to have the measure only apply for
8 three times a week, am I voting on what is
9 written, or do we have to go back and --

10 MS. SAMSPEL: In this case, we are
11 voting on what is written based on --

12 DR. KRISHNAN: Okay. So without the
13 three times a week.

14 MS. SAMSPEL: Correct.

15 DR. KRISHNAN: Okay.

16 DR. FISCHER: So if we vote yes, then
17 regardless of concerns about evidence we are
18 going to move forward and discuss the measure and
19 potentially move to endorse it. If you vote no,
20 then you feel that it's not -- regardless of the
21 evidence, you don't feel it's worth further
22 discussion. Is that correct?

1 MS. SAMSPEL: So I -- I mean, if you
2 vote yes with exception, we will continue with
3 both the discussion and the vote, you know, as
4 long as it then passes reliability and validity.
5 In the event that you vote no, that you don't
6 feel that it needs exception, then, you know,
7 technically the votes stop, you could still
8 discuss and give some recommendation, so that we
9 have it in the report, and that goes out to
10 public comment.

11 We work with the developers in the
12 meantime to see if they can make revisions prior
13 to the post-comment call.

14 DR. KASKEL: I think it's important
15 enough with all of the flaws that Alan so
16 beautifully brought up, is that this should be an
17 exception, and we don't -- we used this, and we
18 need this. It's a guideline. I don't want it to
19 sound like we don't use it. We do.

20 Small percentage of patients may need
21 dialysis more than three times a week because of
22 growth issues and, et cetera, but I still think

1 it's all we've got. And, yes, there needs to be
2 some development, some TEP, and input, to make it
3 better.

4 CO-CHAIR ANDERSON: Andy?

5 DR. NARVA: No. That was exactly my
6 question. I -- because if we -- this goes away,
7 we have no pediatric adequacy measure. And I
8 realize we are only supposed to talk about
9 evidence, but my sense is that pediatric
10 nephrologists want this as a tool to improve
11 care, despite its flaws, and that would be
12 correct.

13 CO-CHAIR CROOKS: There is a later
14 measure coming up that does include this as kind
15 of a compilation of the four. And does that have
16 the same specification? It does.

17 DR. ANDRESS: There are two more
18 measures. One is a combined pediatric and adult
19 human dialysis measure, and it is a combination
20 of the adult and human dialysis measure that was
21 just discussed and this measure.

22 And then there is the composite

1 measure, which -- well, the overall measure that
2 includes the human dialysis and the peritoneal
3 dialysis measure that we discussed yesterday.

4 And that would include the same specifications
5 for pediatric patients on human dialysis.

6 CO-CHAIR CROOKS: So I think we need
7 to discuss and vote on whether we want to
8 consider this an exception, this other --

9 DR. SOMERS: The other measures, the
10 frequency for children can still be four times a
11 week. Is that correct? I thought that was the
12 case.

13 DR. ANDRESS: As currently specified,
14 that is correct.

15 DR. SOMERS: But the same issue.

16 DR. KLIGER: That would be the same
17 issue for children and adults.

18 DR. DAHLERUS: So the three or four
19 times was only specified for the pediatric
20 measure. It is not -- has not been specified for
21 the adult, and, again, that change would be
22 reflected in the other measures.

1 DR. KRISHNAN: Can we do what we did
2 yesterday for the upper bound gate thing? Can we
3 do -- it's the exception but with the stipulation
4 of this exclusion?

5 CO-CHAIR CROOKS: I don't view it
6 parallel because it -- in that case, it just --
7 it didn't change a thing except to remove it.
8 But here the evidence base is changed. We don't
9 know should they be going to standard or to
10 single pool only three times a week, and there's
11 other things that the developer would need to
12 consider, I believe.

13 CO-CHAIR ANDERSON: Frank?

14 DR. MADDUX: So I just want to be
15 clear, again, to Michael's point, what we're
16 going to be voting on here. It strikes me that -
17 - I'm a little concerned about the degree of the
18 way we view stipulations. I certainly understand
19 it, and think for the typos and the
20 administrative sort of logistics item that is
21 fine. But to me this is much more fundamental.

22 And my assumption is, recognizing that

1 this is an existing measure that is in use, yet a
2 measure that has some distinct flaws because of
3 the three or four times, is the exception for us
4 to say that this measure, as designed, would
5 still be okay, versus this measure needs
6 reconfiguring to be designed properly in either a
7 future iteration or an adjustment?

8 CO-CHAIR CROOKS: I would take it to
9 mean that voting for an exception means that we
10 think the measure is okay as it is, and not
11 necessarily recommending a reconfiguration,
12 whereas if we don't give an exception, they do
13 have the opportunity to -- that almost pushes
14 them to make it better somehow.

15 CO-CHAIR ANDERSON: Josh?

16 DR. ZARITSKY: Just for the sake of
17 the exception, which I would recommend that we at
18 least put it up to a little vote, is that I could
19 make the argument that the evidence, as it
20 stands, even for a 1.2 Kt/V, there is very
21 limited evidence, where, again, borrowing from
22 the adults, and so I think that's another avenue.

1 So to get hung up on the -- you know,
2 the four times a week when it's five percent, and
3 we really don't know, is that really 1.2, maybe
4 if we do 1.2 for four times a week there is
5 additional benefit.

6 You know, technically I have a problem
7 with it, but philosophically I would like to see
8 it put up for the exception.

9 CO-CHAIR ANDERSON: Alexandra?

10 CO-CHAIR CROOKS: Lisa is first.

11 DR. LATTIS: So I am struggling with
12 hearing the evidence here versus hearing our
13 pediatric colleagues who know more -- way more
14 about this than I will ever ever know, telling me
15 they need this measure.

16 And then I am also struggling with
17 there are other measures that we will need to
18 reconcile at some point. So I guess I'd like to
19 see this one go through the process, then
20 reconcile and we sort it out.

21 DR. DALRYMPLE: Can I just ask a
22 procedural question? Because I think it's clear

1 we all want a pediatric measure, but we want it
2 to be valid with kid specifications.

3 (Laughter.)

4 So just for our own understanding,
5 Sarah, suppose we decide not to pass making
6 exception for insufficient evidence. So we
7 decide today that the majority does not go that
8 way, in theory, now that we are a standing
9 committee, how quickly could CMS bring a new
10 measure back to us, us reconvene via telephone
11 workgroups, if they followed, for example, the
12 pediatric recommendations saying just -- just
13 make it three times a week for it to have
14 evidence that supports -- I mean, how quickly
15 could it come back to us for review and make it
16 to public comment, et cetera?

17 MS. SAMSPEL: So, I mean, procedurally
18 what would happen in this case for this measure
19 is that if you fail it here, you know, again,
20 technically the votes stop, you could still
21 continue your discussion for sake of the future
22 measures as well, and that we have it in line and

1 also have direct feedback to the developers on
2 what would need to be done in the future for you
3 all to want to reconsider it.

4 However, if it -- basically, a failed
5 vote here means you do not recommend it for
6 endorsement. It still goes out for public
7 comment, so -- and then -- so that, you know, it
8 takes us a month to get the report together,
9 another month for public comment, we get you all
10 back together. During that time, if CMS can make
11 those adjustments, you know, and provide the
12 data, et cetera, that you would need to put it
13 through, you could revote on it technically in a
14 couple months.

15 However, you know, that is kind of an
16 ideal situation. If that doesn't happen, then,
17 you know, I think it's up to CMS to say these are
18 significant -- you know, these are significant
19 changes to the measure, and, you know, it is
20 between CMS and NQF to determine, is it a lost
21 endorsement or is it something that holds for a
22 while while they have a plan in place to resubmit

1 the measure with significant changes.

2 CO-CHAIR ANDERSON: Yes?

3 DR. ANDRESS: So in terms of timeline
4 and responding, I agree, I think this is a
5 somewhat different circumstance than the measures
6 discussed yesterday, in part because I think the
7 stipulation there was a fairly straightforward
8 case of not changing the measures, and we knew
9 what the answer was at the time, without changing
10 the measure.

11 In this case, of course, there is the
12 potential that the measure itself is changing.
13 You know, is the answer -- you know, just a
14 question I would have for -- to look at it, is
15 the answer to retain patients who are treated
16 four times weekly with a different target, or is
17 it a different way of -- should there be a
18 different way of calculating target, or just
19 simply to remove the four times weekly patients
20 entirely? I mean, I think that's a question to
21 be investigated and not something to be
22 stipulated to in this meeting.

1 In terms of the timeline, I think we
2 are pretty confident that we can investigate that
3 and get back to the committee following the
4 public comment period, you know, and that can be
5 considered.

6 I think the other issue to consider is
7 that there is -- we are planning on a renal
8 project next year as well, where we are already
9 going to be submitting some other measures, and
10 keeping in mind of course that this -- this
11 probably rebounds to the two following measures
12 as well. That might also be -- if we can't
13 resolve it in the two months until the public
14 comment period is over, that might be another
15 opportunity to address the concerns.

16 I think from our perspective of course
17 we want to retain pediatric patients in the
18 assessment of adequacy for a number of reasons
19 that are not entirely related to evidence. I
20 think from a policy perspective it is important
21 to keep a focus on the treatment of pediatric
22 patients, and they are already systematically

1 excluded from a number of other quality measures
2 in our various programs.

3 And I think that is certainly
4 something that is worth pursuing as this
5 committee sees fit, and we are certainly willing
6 to put the effort into ensuring that the measure
7 both comports with the quality standards but also
8 addresses what I think is a continuing need for
9 quality in the dialysis community.

10 MS. SAMSPEL: Did that answer your
11 question? I mean, do you -- does everybody feel
12 clear on what the timelines could be based on the
13 vote? Yes. Okay.

14 CO-CHAIR ANDERSON: Are we ready to
15 make a vote on insufficient evidence with
16 exception or no exception?

17 MS. OGUNGBEMI: The committee is now
18 voting on Measure 1423, evidence, potential
19 exception to empirical evidence. The options are
20 one, insufficient evidence with exception; and,
21 two, no exception. The vote is now open, and I
22 will be voting for Ms. Hartwell, since she

1 stepped out of the room.

2
3 The results are 14 votes insufficient
4 evidence with exception, and nine votes no
5 exception. The measure passes with insufficient
6 evidence with exception.

7 CO-CHAIR ANDERSON: All right. So
8 let's move on to performance gap. Alan and
9 Frank.

10 DR. KLIGER: Okay. Performance gap,
11 the developers did look at a relatively small
12 group of patients. Congratulations, you found
13 the pediatric patients to examine for this in the
14 CROWNWeb 2013 data set showing 85 percent
15 adherence with a range between 56 and 100
16 percent. There were no -- not enough evidence to
17 look at skewedness or subgroup analysis.

18 DR. MADDUX: The only thing I would
19 add is that there was a mild gap recognized in
20 the small population that was studied.

21 CO-CHAIR ANDERSON: Any further
22 discussion? Are we ready to vote on performance

1 gap?

2 MS. OGUNGBEMI: The committee is now
3 voting on performance gap for Measure 1423. The
4 options are one, high; two, moderate; three, low;
5 and, four, insufficient. Voting is open.

6 The results are one vote high, 17
7 votes moderate, two votes low, and two votes
8 insufficient. Measure 1423 passes on performance
9 gap.

10 CO-CHAIR ANDERSON: Moving on to
11 reliability.

12 DR. KLIGER: Reliability of the
13 specifications, I guess we've already beat that
14 dead horse. So I think that there is a real
15 problem with the specifications and personally
16 would find trouble passing this on the
17 specifications.

18 In terms of the reliability testing,
19 there was, again, testing on this small group of
20 patients showing an IUR of 0.81, saying that
21 about 81 percent of the variation of the measure
22 is attributed to between facility variation. The

1 pre-reviewers, who incidentally did a fabulous
2 job -- thank you very much -- found that this
3 translated to moderate reliability, and I agree
4 with that.

5 CO-CHAIR ANDERSON: Any further
6 discussion on reliability? All right. Ready to
7 call for the vote?

8 MS. OGUNGBEMI: The committee is now
9 voting for Measure 1423, reliability. The
10 options are one, high; two, moderate; three, low;
11 and, four, insufficient. Voting is open.

12 The results are one vote high, 11
13 votes moderate, seven votes low, and two votes
14 insufficient. Measure 1423 fails on reliability.
15 Possibly not. One moment. Yes, it -- is it --

16 MS. BAL: So we would need a high
17 moderate to be at least 60, so it's actually gray
18 zone. Sorry, I shouldn't have said failed. It
19 is a gray zone measure. So for -- I think we
20 briefly went over it through one of the workgroup
21 calls, but for anyone who was not on the call,
22 the gray zone is a place between 40 and 60

1 percent. So that's the point we're at. We're at
2 57 percent of agreement.

3 So basically what that means is that
4 we were not able to come to consensus on
5 reliability, and we would open that up -- when we
6 do our draft report, we will write that in the
7 draft report and say, "Ask for comments from the
8 public," but we do move forward with the measure.
9 But we basically said the committee didn't come
10 to consensus.

11 DR. FISCHER: People didn't vote. Two
12 people --

13 MS. BAL: Lori is not in the room.
14 So, and we can't vote for her. Well, she wasn't
15 at her -- we can do a revote and --

16 DR. FISCHER: Yes. I'm just pointing
17 it out because we didn't have --

18 (Simultaneous speaking.)

19 MS. BAL: And please check your
20 batteries, if we're not getting your vote.

21 DR. FISCHER: So we're voting on --
22 just so I'm clear, we're voting on both the

1 specifications and the reliability. So it's not
2 just about the reliability of testing. It's also
3 about the specification, which have been -- I'm
4 just confirming, just so I understand what we're
5 voting on again.

6 CO-CHAIR CROOKS: Yes, you're correct.
7 We're voting on both, which may or may not have -
8 - be the right way to do it, but --

9 MS. BAL: So we will go ahead and
10 revote, and just, again, to clarify, to answer
11 Michael's questions, when you're voting on
12 reliability, you are voting on both 2(a)(1),
13 which is the precise specifications, and the
14 testing, so the appropriate method and scope with
15 adequate results of the testing.

16 The other thing I am just going to ask
17 is that when you vote, and you point at
18 Alexandra, that you make sure your number is
19 showing up in your little screen. And I know
20 people are, but this is really kind of a really
21 important place where we need all the votes.

22 MS. OGUNGBEMI: The committee is now

1 voting for Measure 1423 on reliability. Options
2 are one, high; two, moderate; three, low; four,
3 insufficient. Voting is open.

4 MS. BAL: As you've seen, we do need
5 those two other votes.

6 MS. OGUNGBEMI: The results are zero
7 high, 11 votes moderate, 11 votes low, and one
8 vote insufficient. The measure is still in the
9 gray zone. So we will continue with the next
10 criteria.

11 CO-CHAIR ANDERSON: All right. Moving
12 on to validity.

13 DR. KLIGER: This one is easy. It's
14 on face validity, so that is the criteria.

15 CO-CHAIR ANDERSON: Frank, any other
16 comments?

17 DR. MADDUX: No other comments.

18 CO-CHAIR ANDERSON: Any further
19 discussion? Are we ready to vote for validity?

20 MS. OGUNGBEMI: The committee is now
21 voting on validity for Measure 1423. The options
22 are one, high; two, moderate; three, low; and,

1 four, insufficient. Voting is open.

2 Results are zero votes high, 18 votes
3 moderate, four votes low, and one vote
4 insufficient. Measure 1423 passes on validity.

5 CO-CHAIR ANDERSON: Moving on to
6 feasibility?

7 DR. KLIGER: It's used in CROWNWeb.
8 It has been used. I don't whether we can do both
9 of them together, but it has been used and it
10 appears to be feasible.

11 CO-CHAIR ANDERSON: Any further
12 comments or discussion? Call for the vote.

13 MS. OGUNGBEMI: The committee is now
14 voting on feasibility for Measure 1423. Options
15 are one, high; two, moderate; three, low; and,
16 four, insufficient. Voting is open.

17 Results are 14 votes high, eight votes
18 moderate, one vote low, and zero votes
19 insufficient. Measure 1423 passes on
20 feasibility.

21 CO-CHAIR ANDERSON: Usability and --
22 use and usability?

1 DR. KLIGER: So it's currently
2 reported in Dialysis Facility Compare, and the
3 QIP, so it appears to be usable.

4 CO-CHAIR ANDERSON: Any other further
5 comments or discussion? Call for the vote?

6 MS. OGUNGBEMI: The committee is now
7 voting for Measure 1423 on usability and use.
8 Options are one, high; two, moderate; three, low;
9 and, four, insufficient. Voting is open.

10 Results are 17 votes high, six votes
11 moderate, zero votes low, and zero votes
12 insufficient. Measure 1423 passes on usability
13 and use.

14 CO-CHAIR ANDERSON: Before we move on
15 to endorsement, is there any further discussion
16 regarding this measure, or comments or questions
17 for the developers?

18 All right. We are ready to move on to
19 vote for endorsement, and it is with exception.
20 Is that how we state it?

21 MS. BAL: The exception is only for
22 evidence.

1 CO-CHAIR ANDERSON: Oh, just for
2 evidence. Okay. To move on recommendation for
3 endorsement.

4 MS. SAMSPEL: Actually, overall
5 suitability for endorsement. Sorry. And I'm
6 just making a point about this. So you are
7 recommending endorsement. Technically, the
8 endorsement body is the board of NQF. So yours
9 is a recommendation for suitability for
10 endorsement.

11 DR. LATTS: Okay. So, wait, so with
12 all of the previous discussion and the
13 exception/approval of the evidence, when we are
14 doing the endorsement, is it forgetting all of
15 that and just taking it as it is written? Or is
16 it understanding that there is this exception and
17 we have asked the developers to go back and
18 rewrite it?

19 MS. SAMSPEL: So, in this case, there
20 is the exception, and then there is also the gray
21 zone. So this measure has work to do, and you
22 will have an option of revoting.

1 MS. BAL: Just a clarification. The
2 exception is not that you are telling the
3 developer to do so. The exception is just
4 stating that you take -- you have seen the
5 evidence, you don't feel that it's strong enough
6 to support it, but you feel the measure is
7 important enough, and you are going to -- where
8 normally you would have to stop at evidence, you
9 are saying that you fully can bypass that.

10 So your -- the exception was not that
11 the developer has to make this change. However,
12 you have given that recommendation to the
13 developer, and they can take that and provide
14 changes for you. I just want to make that clear,
15 that there was an exception.

16 CO-CHAIR CROOKS: And what is the
17 ultimate impact of the gray zone vote?

18 MS. BAL: So the gray zone, since it
19 was only on reliability at this point, we would
20 send it -- you know, put it in the draft report,
21 ask for public comment. You can choose to
22 revote, if you want. If you feel that whatever

1 you receive is not enough for you to revote, we
2 would leave it as is. The only vote you would
3 need to reconsider is if on this vote, overall
4 suitability for endorsement, you were in the gray
5 zone.

6 So same thing, we would, you know, put
7 in the draft report, ask for comments, and then
8 we would ask you to revote at that point to get -
9 - see if we can get you to come to consensus,
10 only if this vote goes that way.

11 DR. ZARITSKY: So it seems that it is
12 a safe -- I mean, it would be sort of a
13 compromise, then, if we had the option of saying
14 we want to revote on that gray zone depending on
15 they had -- they had made a change, right? That
16 would give us -- that would say we have to revote
17 on that to then pass it on the measures. Is that
18 my understanding?

19 MS. BAL: Well, you can revote either
20 way. So you can have the gray zone and revote,
21 or you can just say, "Listen, based on what we
22 have received from the developer, and what we

1 have received from public comment, we feel that
2 we need to revote." And then you can make that
3 decision as well. So does it -- you have that
4 opportunity no matter what.

5 DR. ZARITSKY: Are we voting a
6 revote -- I mean, I guess what I'm getting at is,
7 how do we know that we are going to -- I think
8 people in the room would feel a lot more
9 comfortable if there was a revote on that gray
10 zone as a safety measure to say, "Hey, you know,
11 I'm not comfortable with the way that it's
12 written now." I guess that's the question I'm
13 getting at.

14 MS. BAL: We generally just do a
15 verbal disclosure, and then we'll vote on that.
16 And, unfortunately, there is no way for us to
17 trigger a gray zone, but we can definitely make
18 this a guaranteed item on our agenda for the
19 post-meeting call. So we would discuss this and
20 you would get to decide if you want to revote on
21 this measure or not.

22 CO-CHAIR CROOKS: I still am not

1 exactly clear on process. In order for us to
2 recommend for endorsement, we have to have
3 60 percent or greater, especially on the top two,
4 importance and scientific acceptability of the
5 measure. And if we haven't achieved that, then
6 we haven't reached consensus, and how can we be
7 voting to endorse it? Does that make -- so I'm
8 asking if the process is that we must reach
9 consensus on each category in order to be voting
10 for endorsement. And we haven't reached
11 consensus on reliability, so how can we be voting
12 for it? So the vote is we're going to endorse it
13 if the gray zone can be cleared, or how can we
14 even --

15 MS. SAMSPEL: So this is in one way
16 why I was trying to make that distinguishment.
17 So in this case, basically what you're saying is
18 overall for Measure 1423 -- that's where we are,
19 correct? So for Measure 1423, you have actually
20 passed it through on importance because -- with
21 an exception to the evidence. You're in the gray
22 zone, so you did not reach consensus on

1 reliability.

2 However, it did meet -- and you did
3 pass it through on validity, feasibility,
4 usability and use. This overall suitability for
5 endorsement is then looking at a whole in all of
6 the criteria. Would you currently have your
7 recommendation be this measure is suitable for
8 endorsement as it is currently specified in front
9 of you?

10 Either way, what will happen with the
11 gray zone is during -- you know, we will be
12 seeking public comment. The developers have also
13 a period of time to make changes to the measures.
14 That all comes back to you during the public
15 comment call, you know.

16 Kind of to address your question,
17 Josh, it is actually up to the committee. If we
18 got no comments, if the developer said, "Forget
19 it. I'm not going to do anything. We're not
20 going to put investment into this." You could
21 say, "No, we're not going to revote. We want to
22 leave our vote as stands." Or you could say,

1 "No. You know, we want to revote," and then you
2 turn it down.

3 So technically this is an initial
4 indication that right now you think this measure
5 is recommendable to continue its endorsement
6 process.

7 DR. LATTS: And that is if we vote
8 yes. If we vote yes, you're saying --

9 MS. SAMSPEL: If you vote yes. Or you
10 could vote no, and still -- there is still that
11 almost a cure period of the public comment where
12 you get more -- a broader range of information
13 from NQF members and the public as well as what
14 the developer may or may not plan to do, and you
15 would take that into consideration. And on the
16 call, we would say, "Okay. With all this new
17 information, do you want to vote or revote?" You
18 know, I'm guessing you guys would say yes, and
19 then we would do a revote and it would be an
20 online revote --

21 DR. LATTS: So it's almost --

22 MS. SAMSPEL: -- of all criteria.

1 DR. LATTS: So this vote is
2 essentially not binding right now, one way or the
3 other.

4 MS. SAMSPEL: Well, it's -- well, yes,
5 I mean, I think it's binding in the fact that it
6 puts it through the NQF process. It helps us
7 understand where it is slated, what additional
8 information we need to gather, how we put it into
9 the report, what your issues were, bringing to
10 the attention some of the important concepts that
11 you brought up.

12 You know, the reality is is even after
13 that final public comment vote, you know, the
14 measures go through the CSAC, and the CSAC is an
15 additional layer before it goes to the board.

16 DR. ANDRESS: I'm sorry. One
17 clarification I would ask for. My prior
18 understanding had been that if we -- if the 40
19 percent threshold is not met for the gray zone,
20 then the measure does not continue through public
21 comments. Is that correct? Or will it go
22 through public comments regardless?

1 MS. SAMSPEL: Everything goes through
2 public comment.

3 DR. ANDRESS: Okay. All right.

4 MS. SAMSPEL: It's just the
5 nomenclature on the measure.

6 DR. ANDRESS: Okay.

7 MS. BAL: You may be confusing that
8 with voting. We don't vote on measures that
9 don't go through, but we would still do public
10 comment. I'm sorry, not -- the committee would
11 vote. The membership does not vote on those
12 measures. I think that's new here.

13 CO-CHAIR ANDERSON: All right. Are we
14 ready to vote for suitability for endorsement?

15 MS. OGUNGBEMI: The committee is now
16 voting for overall suitability for endorsement on
17 Measure 1423. The options are one, yes; two, no.
18 Please vote.

19 MS. BAL: So the measure is in gray
20 zone, so you will get to vote on it at the post-
21 meeting comment -- I mean, the post-comment
22 meeting.

1 CO-CHAIR CROOKS: How are you enjoying
2 the land of Kt/V today? It just never ends.

3 Okay. So we are moving on to
4 Measure 2703. I'm going to take the helm as
5 Connie is recused on this particular --

6 CO-CHAIR ANDERSON: No. I'm not
7 recused. I'm evaluating.

8 CO-CHAIR CROOKS: There's a conflict?
9 Oh, it's not this one.

10 CO-CHAIR ANDERSON: No.

11 CO-CHAIR CROOKS: Oh. Okay. Well,
12 then, you may continue. You're doing a great
13 job. I guess I'll -- okay. This is Measure --
14 CMS measure minimum delivered dose, hemodialysis
15 dose. Our developers are at the table, and take
16 it away.

17 DR. DAHLERUS: And, again, I will keep
18 our remarks very brief. So this is the combined
19 hemodialysis adequacy measure. So it includes
20 both the adult and pediatric populations, and the
21 assessment is whether the respective adult and
22 pediatric populations achieved minimum Kt/V, and

1 that in this case is 1.2.

2 As we stated earlier, and in
3 yesterday's discussion, we will be removing the
4 upper threshold of 5.0.

5 DR. MADDUX: So we won't go through
6 the entire discussion we just went through, but
7 basically this is the combined measure. For the
8 evidence, the KDOQI guidelines were used from
9 2006. The guidelines related to pediatrics, and
10 adults were similar to what has been previously
11 presented.

12 And there was evidence presented from
13 the hemo trial as well, comments from the
14 workgroups recognized some of the same issues
15 surrounding the criteria for three times per week
16 versus other, you know, pediatric, as well as the
17 distinction between the various mechanisms of
18 calculating this.

19 CO-CHAIR CROOKS: Okay. The evidence
20 is open for discussion. I'd just like to mention
21 there was a long list of references of additional
22 evidence, and which in the instructions requests

1 a summary for each article, and that wasn't done,
2 this long list of references. And interested as
3 I am, I'm not going to go look up the articles to
4 see what they say. So, again, I'd encourage the
5 developers to follow the directions on the form.
6 I don't know about the quality of the evidence
7 beyond KDOQI.

8 DR. MADDUX: And I would just ask the
9 developers to confirm that for the pediatric
10 component of this there was the three or four
11 again.

12 DR. DAHLERUS: Correct. So the
13 discussion that we had for the last measure
14 applies here as well.

15 CO-CHAIR CROOKS: Other discussion
16 about the evidence? I'm sorry. Mahesh.

17 DR. KRISHNAN: Is there any direct
18 evidence that a combined measure has utility? Or
19 we're saying the fact that the two components
20 each independently have utility means that we
21 should confer the associative property to the
22 combined metric, is that correct?

1 CO-CHAIR CROOKS: Well, I am going to
2 presume that the reason is similar to what we
3 heard yesterday, that for small units or units
4 that have a small number of peds, we want to make
5 sure the peds patients get included. But you're
6 asking, is there evidence that this is a good
7 measure.

8 DR. KRISHNAN: Yes. It wasn't just in
9 the policy, get the policy component, the minimal
10 cell size, the intent. Just ask about the
11 evidence itself.

12 CO-CHAIR CROOKS: Right. Do the
13 developers have any comment?

14 DR. DAHLERUS: So, again, we --
15 because the thresholds of 1.2 are based on the
16 evidence cited in the individual measure, we
17 would argue that this also applies to the
18 combined measure. I think the discussion
19 yesterday about the combined PD measure also
20 applies here, whether there are any concerns
21 about the values for adult somehow masking the
22 result for the pediatric population. But, again,

1 that would probably be less the case given the
2 slightly larger HD population.

3 DR. KRISHNAN: And I have scrolled
4 down to validity, but was this discussed at the
5 TEP, this combined measure?

6 DR. DAHLERUS: Not the combined
7 measure. The individual measures were, though.

8 CO-CHAIR CROOKS: Alan?

9 DR. KLIGER: And just to clarify, the
10 three or four treatments a week is true for both
11 adults and children?

12 DR. DAHLERUS: No. Just children.

13 CO-CHAIR CROOKS: Okay. Any other
14 comments?

15 DR. KRISHNAN: So, Frank and others,
16 how did you guys rate the evidence for this?

17 DR. MADDUX: So having been on both
18 1423 and 2703, the same issues apply
19 predominantly to the pediatric application. So
20 for the adult portion, I think the evidence is
21 pretty good, and that would be either high or
22 moderate. For the pediatrics, my thought is that

1 this is suspect because of the same discussion we
2 just had.

3 DR. KRISHNAN: How do you synthesize
4 the two of those in one measure? Is that --

5 DR. MADDUX: I think the flaw in the
6 measure, as a combined measure, has to be the
7 same flaw as the least common denominator of the
8 two -- of both measures.

9 DR. KRISHNAN: Agreed.

10 CO-CHAIR ANDERSON: And I guess from
11 my perspective, if you have a separate measure
12 for pediatrics and a separate measure for adults
13 -- and, again, I'm not really sure what you
14 gained by combining the measures into another
15 measure unless you are able to harmonize the
16 measures at the very end.

17 So I was struggling with all of the
18 different measures. And then combining them into
19 one where the evidence for the pediatrics is what
20 we want there, certainly very strong evidence for
21 the adults, but the pediatric evidence, even in
22 the guidelines, was a grade C.

1 CO-CHAIR CROOKS: Okay. Other
2 discussion? Measure developers.

3 CO-CHAIR ANDERSON: Let's get the
4 committee --

5 CO-CHAIR CROOKS: Yes. I'm sorry.
6 Lori?

7 MS. HARTWELL: To my understanding,
8 combining the measures was to pick up the extra
9 11 kids that would not be normally measured. Is
10 that correct? The reason for this?

11 DR. DAHLERUS: Correct. Yes. So more
12 facilities and more children will be evaluated in
13 the combined measure.

14 CO-CHAIR CROOKS: Mahesh?

15 DR. KRISHNAN: And this is just why I
16 struggle, right? I mean, the difference between
17 -- I get the policy objective. It makes complete
18 sense to me. I just don't get the evidentiary
19 basis for the construction of that. If there was
20 an attachment, there wasn't -- there isn't strong
21 enough evidence, if we're just evaluating -- I'm
22 assuming we're just evaluating it based on the

1 evidence and not on the policy implications.

2 CO-CHAIR CROOKS: You dropped your
3 card.

4 DR. KRISHNAN: Yes.

5 (Laughter.)

6 CO-CHAIR CROOKS: Don't say I'm not
7 observing things up here. Okay?

8 Any other discussion about the
9 evidence before we vote? Yes, Michael.

10 DR. SOMERS: You know, just all the
11 discussion about the evidence and as it pertains
12 to kids. I mean, some of it is focused on the
13 four time a week, but, again, as I said before, I
14 mean, where actually, if you are meeting this
15 criteria with four time a week dialysis, you are
16 exceeding adequacy standards.

17 So, you know, as a quality measure,
18 this is ensuring that you are giving good care to
19 those children. So, you know, I wouldn't use
20 that necessarily to speak against this measure
21 from an evidence standpoint.

22 DR. KLIGER: And while I understand

1 and respect what you say, Michael, I also want to
2 point out that as written it would be a
3 disincentive to increase the frequency of
4 dialysis. If you have a borderline child who is
5 not meeting the 1.2 standard single pool on three
6 times a week, if you wanted to meet the standard
7 you would not be able to increase the frequency.

8 DR. SOMERS: I think if you were to
9 look at that five or six percent of children who
10 are dialyzed four times a week, they are being
11 dialyzed four times a week for volume issues.
12 And so, you know, in terms of the amount of
13 clearance you're getting, you're far exceeding
14 what you ever need.

15 DR. MADDUX: If I could comment, too,
16 Michael, the way I look at this is we have a
17 particular set of measures here, and we have
18 opportunities through the process to get it
19 right. Rather, in my opinion, get it right or as
20 right as we can understand it, than to try to say
21 it's right enough, because I do think as we went
22 through previously there are multiple ways in

1 which to not diminish the opportunity to look at
2 the pediatric population and those on dialysis,
3 and yet also not have some of the issues with the
4 particular measures.

5 CO-CHAIR CROOKS: Okay. It looks like
6 we're ready to vote on the evidence.

7 MS. OGUNGBEMI: The committee is now
8 voting on evidence for Measure 2703. The options
9 are one, high; two, moderate; three, low; and,
10 four, insufficient. Voting is open.

11 MS. BAL: We're contacting IT about
12 that, but that screen is available.

13 CO-CHAIR CROOKS: So unlike the last
14 one where we voted no, this is a gray zone. It's
15 above 40 percent, with a one or a two.

16 MS. OGUNGBEMI: The results are zero
17 votes high, 10 votes moderate, nine votes low,
18 and four votes insufficient. So the measure is
19 gray zone, Measure 1423.

20 CO-CHAIR CROOKS: Thank you. Sorry I
21 got ahead of you. Just doing numbers today.

22 Okay. So I think we don't need to

1 vote for exception in this case, or maybe we do
2 just for insurance. I don't know.

3 MS. BAL: No.

4 CO-CHAIR CROOKS: No.

5 MS. BAL: We would move forward as if
6 this measure had been accepted.

7 CO-CHAIR CROOKS: Okay. So we'll
8 continue this gray zone measure and go on to the
9 performance gap.

10 DR. MADDUX: So the gap -- the
11 discussion of the gap recognized the data for
12 both the CROWNweb and the Medicare claims data,
13 and the performance of the elements, the
14 pediatric element and the adult element. I don't
15 think there was substantial disparity recognition
16 there.

17 And the comments of this measure
18 surrounded the similar comments that we have had
19 related to the predominant driver of this
20 aggregate measure being adults, because of the
21 number of patients, questioning whether it has
22 topped out, knowing that independently the adult

1 looked like there was not much of a performance
2 gap, and there was a mild to moderate performance
3 gap in the limited number of patients tested in
4 the pediatric population.

5 CO-CHAIR ANDERSON: No further
6 comments, other than the risk adjustment. There
7 was not significant -- and it does, in the 2015
8 QIP, it is at -- Kt/V is at 98 percent.

9 So, again, there is little room for
10 performance improvement in the adult population.
11 And I think that's one of the difficulties in
12 combining the measure is that you have -- the
13 adult population really is pretty well topped out
14 and has shown increased improvement.

15 CO-CHAIR CROOKS: All right. Other
16 comments about the performance gap?

17 DR. KRISHNAN: Frank, is this the
18 exact -- Connie, is this the exact same number
19 for the performance gap from the adult measure?
20 It seems like it, right? The 93.5 percent?

21 CO-CHAIR ANDERSON: In the 2015 QIP,
22 it is 98 percent.

1 DR. KRISHNAN: No, I understand. But
2 in the performance gap for this measure, the
3 combined measure compared to just the adult
4 measure --

5 CO-CHAIR ANDERSON: Oh, yes.

6 DR. KRISHNAN: -- it is the exact same
7 number?

8 DR. MADDUX: So, Mahesh, I did not
9 interpret this as being the aggregate, at 93-1/2,
10 that as being the pediatric. I may be wrong, but
11 --

12 DR. KRISHNAN: It is just the adult,
13 again, so that is the exact same number. So you
14 don't have a gap for the combined?

15 CO-CHAIR ANDERSON: I think the 93-
16 point is the 2013 percentages and is the gap
17 analysis combined.

18 CO-CHAIR CROOKS: Yes. Can you
19 clarify what the gap for this measure was when it
20 was determined?

21 DR. DAHLERUS: So in the section on
22 meaningful differences, we do show that about 15

1 percent of facilities are performing worse than
2 expected, and that would -- and so we provide
3 that in the meaningful difference analysis.

4 CO-CHAIR CROOKS: Right.

5 DR. DAHLERUS: And just to clarify,
6 this combined measure is not implemented in the
7 QIP.

8 CO-CHAIR CROOKS: Do you have a mean
9 performance and a percentage?

10 DR. DAHLERUS: Ninety-three percent.

11 CO-CHAIR CROOKS: Yes. That's what I
12 -- okay. This measure is at 93 percent. They
13 can calculate outliers, you know, statistically,
14 but the mean is 93.5 percent.

15 Okay. Other discussion on the gap?
16 Okay. Let's vote.

17 MS. OGUNGBEMI: The committee is now
18 voting on performance gap for Measure 14 -- or
19 2703, pardon me. The options are one, high; two,
20 moderate; three, low; and, four, insufficient.
21 The voting is open.

22 Results are one vote high, eight vote

1 moderate, 11 votes low, and three votes
2 insufficient. And the measure does not pass on
3 performance gap. It's Measure 2703.

4 CO-CHAIR CROOKS: Okay. So that puts
5 it in the category of possibly being eligible for
6 reserve status. So we will continue.

7 MS. BAL: If the committee would like
8 to consider it for reserve, we can do a hand
9 vote. But it does not have to be considered in
10 that manner. So it would be more, do you feel
11 that this should be a candidate? If not, this
12 measure will fall here, and we will move on to
13 the next one.

14 DR. MADDUX: So I have one question.
15 A measure that has never actually been used can
16 be put in reserve? It's like being the
17 designated hitter forever.

18 (Laughter.)

19 CO-CHAIR CROOKS: Sarah? Can you help
20 us with this question? We have even managed to
21 baffle Sarah. All right. Very good.

22 DR. ANDRESS: Okay. Sure. So I think

1 from a certain standpoint it makes some sense.

2 And we talked about the adult measure going -- as
3 possibly going into reserve status as a candidate
4 for that. You know, and the reasons, of course,
5 for that measure also apply here because the vast
6 majority of the denominator in the combined
7 measure is driven by that measure. So it makes a
8 certain degree of sense.

9 And I think the classification for why
10 it would -- if you think of it as an ultimate
11 potential replacement measure, then certainly
12 that makes sense, because the same reason for
13 having the measure in place still stands.

14 You know, there is the additional
15 concern of course of the specifications for the
16 pediatric population that are combined within the
17 measure, but I think that is a separate issue
18 from whether or not it should be considered for
19 reserve status, you know, of course pending the -
20 - pending our efforts to kind of resolve and get
21 back to you the specification issues.

22 I mean, I think, you know, the purpose

1 ultimately of this measure is to take on the --
2 you know, to generally take on the same role as
3 the measure that is going into reserve status,
4 and so I think it makes sense to consider it for
5 reserve status on that basis.

6 I don't know procedurally if NQF would
7 allow for that, but I think it's -- you know, I
8 mean, in some ways, you know, we propose it here
9 as a distinct measure, or we present it here as a
10 distinct measure because, you know, there are the
11 measures implemented, and we wanted to ensure
12 that we retained a continuity of endorsement
13 status if the combined measure was not something
14 that the panel was willing to consider.

15 But it can also be considered a
16 modification of the existing measure to try to
17 address at a particular policy need. At the end
18 of the day, it is addressing -- it is assessing
19 the adequacy of dialysis received by these
20 populations.

21 You know, if that is something that we
22 consider to be an important measure of quality

1 that goes forward, even given the high level of
2 performance in the overall population, then I
3 think the reserve status -- I think it makes
4 sense. And, again, you know, it's -- whether or
5 not NQF can support that, I -- you know, I leave
6 that to Sarah to respond.

7 MS. SAMSPEL: So I'll ask Michael to
8 make his comment, and we are still gathering our
9 responses.

10 DR. FISCHER: If I could just a quick
11 -- I mean, I looked at the -- because we looked
12 at this yesterday, the NQF documents, and going
13 to Franklin's point it says this is for --
14 talking about retaining endorsement.

15 And, specifically, there is a line in
16 here that says, "Would not grant an active
17 endorsement status for a measure that has not
18 been used." This measure has not been used
19 before. So I guess, if I understand your own
20 documentation correctly, kind of -- this isn't
21 possible in this situation with a composite
22 measure that has not been promulgated and used

1 previously.

2 MS. SAMSPEL: So I think technically
3 we could argue both ways. This is precedent-
4 setting. You know, I really -- we don't have a
5 precedent to go back to on this one. But we have
6 the issue of a component of this measure is an
7 endorsed NQF measure that you earlier voted
8 reserve status.

9 The other portion of this measure,
10 another component of this measure, you know, is
11 in gray zone because that was the one that -- you
12 know, and thus has not -- is not implemented or
13 not endorsed.

14 And so -- and really going back to
15 what, you know, you just pulled out as well,
16 Michael, is, you know, I -- in light of the fact
17 that the second component of the measure actually
18 has to come back to revote as well, I mean, what
19 I really would do is not deal with reserve status
20 right now at this meeting until we can deal with
21 the rest of the measure issues through the public
22 comment period and through post-public comment

1 voting on the second half of the measure.

2 CO-CHAIR CROOKS: Well, I don't know
3 about you guys, but I'm getting dizzy. So then
4 at this point, then, we'll stop considering this
5 measure, as I understand it, and move to the
6 next.

7 Okay. That cleared my head.

8 2705 is the next measure. This is, as
9 we know, a CMS measure combining other measures.
10 So if you are ready to -- are you ready to go
11 ahead?

12 DR. DAHLERUS: Yes.

13 CO-CHAIR CROOKS: Okay.

14 DR. DAHLERUS: Yes, we're ready. Are
15 we ready? Okay. So, again, in the interest of
16 time, just to clarify. So this is the overall
17 combined dialysis adequacy measure. So it's a
18 combination of each of the individual measures
19 that we have discussed in the past two days.

20 And so this is -- and, again, the
21 intent here was to include as many patients and
22 facilities and the assessment of adequate

1 dialysis. So it's a combination of the
2 respective pediatric hemodialysis and peritoneal
3 dialysis adequacy measures, and then the
4 respective adult HD and PD measures as well.

5 This is -- the combined measure is a
6 new measure, and it has not been implemented in
7 Dialysis Facility Compare or QIP. And, again,
8 the stipulation about the upper threshold is
9 something that will also be revised for this
10 overall combined measure.

11 And in terms of the evidence that we
12 summarize in the evidence form, the evidence
13 draws on specific minimum thresholds for each of
14 the distinct populations.

15 CO-CHAIR CROOKS: All right. Our
16 primary reviews are Alan and Elizabeth. Who
17 would like to kick it off?

18 DR. KLIGER: Yes. So there are two
19 facts about this measure that are I think
20 different than the others. It obviously has the
21 same issue that we have just spent the last
22 torturous two hours talking about. But, in

1 addition, if you look carefully at what they have
2 said, the denominator statement says for adult
3 hemodialysis patients receiving dialysis,
4 excluding those who receive dialysis less than
5 three or greater than four times a week. So this
6 does include indeed adults getting four times a
7 week dialysis.

8 The other thing to note that is
9 somewhat different is unless I misread this, it
10 does not exclude home dialysis patients. And if
11 it does not, then there have been, as we all
12 know, an increasing number of adults and kids,
13 but mostly adults, who are dialyzing at home with
14 much higher frequencies, five, six times a week
15 treatments using equipment that facilities that.

16 So the evidence issues are the same
17 here, except that it does include adults on
18 variable frequency of dialysis, and includes a
19 larger -- you know, larger than a minimal number
20 of adults for whom that really is an issue.

21 The evidence is the same evidence, and
22 I hate to go through it again. It really is the

1 same, and I think the fatal flaw is the same one.

2 MS. EVANS: I have nothing else to
3 add, but I would like to ask, could we not, to
4 save time, put this on hold right now? I mean,
5 it's the same issue that we had before, rather
6 than going through all of this again?

7 DR. DAHLERUS: So the denominator
8 exclusions state that adult HD patients receiving
9 less than three or greater than four -- four or
10 greater times weekly dialysis are excluded. So
11 they are not included in the denominator.

12 DR. KLIGER: Correct. That's what I
13 said. Greater than four is excluded; four is
14 included, not excluded. It's not greater than or
15 equal to four. The specification says greater
16 than four.

17 DR. DAHLERUS: So we apologize. That
18 is something that was not clearly stated in the
19 denominator. The statement for the denominator
20 does limit it to thrice weekly.

21 CO-CHAIR CROOKS: Yes. I agree with
22 Alan's reading. It doesn't say excluding four or

1 greater; it says excluding greater than four.

2 DR. KLIGER: Correct.

3 CO-CHAIR ANDERSON: Okay. I think
4 what has happened is there is a discrepancy in
5 what they wrote, because in the denominator
6 statement they do say thrice weekly for the
7 adults. But in the denominator exclusion, which
8 is where the discrepancy is, it says greater than
9 four times a week. So you can't -- they're
10 inconsistent.

11 CO-CHAIR CROOKS: So we've had a
12 request to shorten the process, if possible. I'm
13 not sure how we can -- does the staff have
14 suggestions on how we --

15 MS. BAL: I mean, we can just advise
16 the committee not to rehash issues that have
17 already been rehashed and just speed to the vote.
18 But we do need to vote on this measure.

19 CO-CHAIR CROOKS: Okay. Thank you.

20 So is there further discussion on the
21 evidence before we vote? Okay. Let's vote.

22 MS. OGUNGBEMI: The committee is now

1 voting on Measure 2705, evidence. The options
2 are one, high; two, moderate; three, low; and,
3 four, insufficient. Voting is open.

4 Results are zero votes high, four
5 votes moderate, 12 votes low, and six votes
6 insufficient. Measure 2705 does not pass on
7 evidence.

8 CO-CHAIR CROOKS: So that brings us
9 back to the possibility of an exception. Does
10 anyone want to propose that and make the case for
11 that? Okay.

12 So that being the case, I think we can
13 end discussion of this measure at this point.
14 Okay, Elizabeth?

15 All right. So I have good news for
16 you. It's break time. We are going to come
17 back, and then we are going to jump into the
18 related competing measures for all of the Kt/V
19 measures. And we'll be moving on to --

20 CO-CHAIR ANDERSON: We are not going
21 to be doing the related and competing --

22 CO-CHAIR CROOKS: Oh, we're not. Oh.

1 Because?

2 MS. SAMSPEL: So the issue, if you'll
3 -- the issue with related and competing measures
4 is that they are only discussed for the measures
5 that have been recommended for endorsement. So
6 we have measures that both failed and went into
7 gray zone or consensus has not been reached.

8 So we will be taking that offline, and
9 the related and competing discussion will happen
10 post comment, post public comment, and those
11 calls. So when we come back, we will be jumping
12 into the next set of measures.

13 CO-CHAIR CROOKS: Thank you for
14 clarifying.

15 Okay. So our break is scheduled for
16 15 minutes, which would get us back at 10:05.

17 Thank you.

18 (Whereupon, the above-entitled matter
19 went off the record at 9:50 a.m. and
20 resumed at 10:04 a.m.)

21 CO-CHAIR ANDERSON: We're going to
22 change the order of the agenda a little bit

1 because of the developers that are available to
2 us. So, instead of starting with 1424, we're
3 going to start with 1667, then do 1660, and then
4 go back to 1424 and start there. So, Dale and
5 Amy. 1667.

6 MS. BECKRICH: So, we should have
7 Barbara Fivush on the line, and she's going to
8 introduce 1667.

9 DR. FIVUSH: Thank you. This is Barbara
10 Fivush. Can everybody hear me?

11 CO-CHAIR CROOKS: Yes, Barbara.

12 DR. FIVUSH: All right, thank you. So,
13 1667 is a Pediatric ESRD Patients Receiving
14 Dialysis Hemoglobin less than 10 measure. It's
15 the percentage of calendar months within a 12-
16 month period during which patients aged 17 years
17 and younger with a diagnosis of ESRD receiving
18 hemodialysis or peritoneal dialysis have a
19 hemoglobin level less than 10.

20 The rationale for this measure is that
21 in pediatrics, as you all know, anemia is a major
22 complication of ESRD in children. And the anemia

1 is associated with cardiovascular dysfunction,
2 cardiomyopathy, and death. Correction of anemia
3 in children has been shown to improve cardiac
4 dysfunction, exercise tolerance, and reduce left
5 ventricular hypertrophy.

6 We also strongly weigh the potential
7 quality of life benefits that correction of
8 anemia will bring, and the available literature
9 in adults should be enriched by consideration of
10 quality of life measures that are critical to
11 children, including neurocognitive development,
12 school attendance, exercise capacity, and family
13 support.

14 The measure has recently been
15 reclassified as an intermediate outcomes measure,
16 and it is a physician-level measure. Currently,
17 it is being measured in PQRS, and included in the
18 RPA Kidney Quality Improvement Registry for 2015.

19 There is some strong evidence for this
20 measure. Their KDOQI Clinical Practice
21 Guidelines, 21.1 in particular, which say the
22 lower limit of hemoglobin which is fully

1 applicable to children in patients with CKD, the
2 hemoglobin level should be 11 or greater, and
3 that's a very strong recommendation.

4 So, Pediatrics feels strongly. This
5 has been approved in the past but this measure
6 should be reapproved, and agree with the
7 reclassification, as you believe that measurement
8 of hemoglobin is critical to insure the best care
9 for children with ESRD on peritoneal and
10 hemodialysis.

11 CO-CHAIR CROOKS: Okay, thank you. The
12 discussants are Bobbi Wager and Frederick Kaskel.
13 Have you decided who's going to be on first?

14 MS. WAGER: Yes, this is Bobbi. I will
15 go ahead and start. Thank you, Barbara. She did
16 an excellent job. The evidence, as she pointed
17 out, the KDOQI Guidelines, and the data also
18 comes from different patient registries and
19 cohort studies demonstrating the adverse effects
20 of anemia. We all know, as she stated,
21 cardiovascular disease, et cetera.

22 Myra, do you have anything else that

1 --- oh, I'm sorry, it's Dr. Kaskel.

2 DR. KASKEL: It's a very important
3 measure, obviously, as Barbara has summarized
4 very nicely.

5 CO-CHAIR CROOKS: I have a comment,
6 that the measure calls for hemoglobin less than
7 10. The guidelines state the target should be
8 between 11 and 12. And is there justification in
9 the evidence why that particular number is
10 targeted? Michael.

11 DR. SOMERS: So, there is evidence in
12 children with CKD and ESRD that hemoglobin values
13 less than 10 are associated with higher rates of
14 hospitalization, higher rates of mortality, as
15 well as the quality of life standards, and the
16 cardiac effects that have been discussed
17 previously.

18 CO-CHAIR CROOKS: Okay, that's --- that
19 evidence wasn't, I don't think, in the
20 submission, but duly noted. So, that as a
21 pediatric nephrologist you think the number 10 is
22 valid, or is a good choice?

1 DR. KASKEL: I believe it's a good
2 choice and, if anything, we tend to even think
3 about higher levels depending on the age and
4 conditions. Neurocognition are very difficult
5 area to measure and quantify, needs to come into
6 this picture, as well, at certain periods of
7 development. And there may be racial disparity
8 issues.

9 DR. SOMERS: And even though that's ---
10 the evidence supporting less than 10 isn't
11 provided specifically with this measure, but it's
12 going to come up in 1424 when that evidence was
13 actually given.

14 CO-CHAIR CROOKS: Very good.

15 MS. WAGER: Peter, can I make a
16 comment? On our conference call, I believe the
17 developer was asked why below 10, and I believe
18 they said something about they wanted a floor
19 level, or the bottom level. That's why it was
20 below 10.

21 CO-CHAIR CROOKS: Right. I was just
22 wondering if there's also data or medical

1 evidence that, you know, makes that appear to be
2 the right target. Lorien, you have your card up.

3 DR. DALRYMPLE: Can I just clarify from
4 the work group how they graded the evidence using
5 the NQF Criteria? Was this a clinical practice
6 recommendation from KDOQI? That's just what I
7 wrote in my notes, but I'd like to clarify how
8 the evidence rated by NQF criterion?

9 CO-CHAIR CROOKS: Do you remember what
10 grade level it was assigned? I can ---

11 MS. SAMPSEL: I don't necessarily that
12 in each of the work groups that the Committee on
13 the work group call that they went through the
14 official process. I mean, what I would ask though
15 is that, you know ---

16 DR. DALRYMPLE: What are their thoughts
17 after discussion ---

18 MS. SAMPSEL: The Committee members who
19 looked closely at this, did you have any thoughts
20 on that?

21 DR. DALRYMPLE: Yes, did you think this
22 was perhaps insufficient because of pediatrics

1 and the challenges around it, or was there a
2 higher grade? And we've talked about insufficient
3 with exception because we think it's important,
4 but I just was hoping to get those who looked at
5 in depth for their sense of where this fell on
6 evidence.

7 DR. SOMERS: In terms of the level
8 being less than 10, I do think there is specific
9 pediatric evidence that supports the adverse
10 effects of your hemoglobin being less than 10,
11 and that mark is supported by pediatric evidence.

12 CO-CHAIR CROOKS: According to the
13 submission, the grade from the KDOQI process was
14 moderately strong, which is their second-level
15 grade.

16 Let's see. I think Michael Fischer was
17 next. That was accidental card turning. Dr.
18 Wagner.

19 DR. WAGNER: Thank you. Just so I
20 understand the process; if the evidence is not in
21 this particular submission, even though it is in
22 another submission, does --- are we allowed to

1 then consider that, or are we obliged to follow
2 what has been in this submission?

3 CO-CHAIR CROOKS: I would say that when
4 it comes to evidence, in our past discussions,
5 Sarah, we heard that if the Committee is aware of
6 other evidence that bears on the measure, that
7 it's okay to consider it at this level. That may
8 not be true when it comes to other parts of the
9 submission, but I think if you're aware of
10 evidence that supports it, you can use that in
11 making your reasoned judgment. Okay? Mahesh.

12 MS. HARTWELL: I had my ---

13 CO-CHAIR CROOKS: Oh. Well, I'll call
14 on Mahesh first, because I'm the Chair. I can do
15 that. No, I'm sorry. I didn't see Lori.

16 MS. HARTWELL: I think you're ignoring
17 me.

18 CO-CHAIR CROOKS: You're just --- when
19 I have my glasses --- okay, Lori.

20 MS. HARTWELL: I just had a quick
21 question because it talks about transfusion
22 avoidance, but also it doesn't make mention of,

1 you know, when children get blood transfusions,
2 it's more difficult to transplant. And I just
3 wanted to have any comments from the Committee
4 about that, because it's a very serious issue for
5 children if they get transfused.

6 CO-CHAIR CROOKS: What about the impact
7 on blood transfusion, pro or con, does it work
8 against that?

9 DR. KASKEL: We would really worry
10 about having to transfuse with the attendant
11 risks of infection, but also the need to keep
12 them less sensitized for transplant for sure. We
13 would want to avoid that at all costs.

14 CO-CHAIR CROOKS: Does the measure push
15 from --- end up causing more transfusions because
16 of that floor, than maybe you would do otherwise?

17 DR. KASKEL: Well, this is a big issue
18 to consider down the line. If the Pediatric
19 Centers caring for the children would want to
20 keep the level, if anything that would be the
21 minimum level here at this floor, but be higher
22 to avoid the need for transfusion.

1 CO-CHAIR CROOKS: So, if you have a
2 ESA-resistant child and the hemoglobin is 9,
3 you're going to have to transfuse him, probably.

4 DR. KASKEL: In rare instances, if you
5 can't correct the resistance and they're
6 symptomatic, you would.

7 CO-CHAIR CROOKS: So you try everything
8 you can to avoid it, obviously.

9 DR. KASKEL: Right.

10 CO-CHAIR CROOKS: Yes, Josh?

11 DR. ZARITSKY: And, ironically, it's
12 usually an upper limit that leads to this type of
13 thing because no one is going to transfuse a
14 patient to make a recommendation. Do you know
15 what I mean to say? Oh, my God, you know, I'm not
16 going to make my, you know --- whatever you want
17 to say, and then transfuse the patient. Whereas,
18 if you look at probably the effects of the upper
19 limit, that might actually have a little bit more
20 of a significance, or the range that you're
21 trying to keep the patient in rather than the
22 lower limit. I hope that helps.

1 CO-CHAIR CROOKS: Rick.

2 DR. KASKEL: I just want to mention
3 that this area of anemia in CKD in children is
4 being actively studied through some cohort
5 studies. And the CKiD Study, Chronic Kidney
6 Disease in Children, is one of the main ones.
7 This is for children with CKD Stage 2 and 3, and
8 anemia is one of the major comorbidities that's
9 being evaluated in terms of progression of kidney
10 failure, neurocognition, growth, and
11 cardiovascular risks, so it's an active, ongoing
12 collaboration of most of the large pediatric
13 centers across the country, something like 600.
14 So, it's ---

15 CO-CHAIR CROOKS: Okay, good to know.

16 DR. KASKEL: --- a work in progress
17 that you need to know that from our standpoint,
18 the information that we're getting about
19 appropriate targets at least in CKD is accurate.

20 CO-CHAIR CROOKS: Okay. Mahesh.

21 DR. KRISHNAN: I just had a question
22 for the pediatricians. Anemia management in

1 adults has clearly got a seismic shift in the
2 last four or five years. The guidelines that are
3 referred predate that. I don't know enough to
4 know enough about how much that's impacted the
5 pediatric guidance. Could you guys help us with
6 that?

7 DR. KASKEL: This is a concern because
8 when the black box warning came out, you know,
9 from the two studies; obviously, not including
10 children, it --- we were concerned that it would
11 set a level lower for our field. And there are no
12 randomized controlled trials of target ---

13 adequate target levels in pediatric nephrology
14 for the hemoglobin for ESA, that's one. And the
15 rate of rise of hemoglobin is another
16 consideration which in the adult studies was one
17 of the major factors for the cardiovascular
18 morbidity. We have no idea in children whether
19 the rate of rise of hemoglobin is a risk factor,
20 so there's a lot of unanswered questions about
21 this. And the black box warning did siphon down
22 to us, and knowing that we may need a higher

1 hemoglobin in some children for growth. Okay, so
2 it's a concern.

3 DR. KRISHNAN: Is it accurate to say
4 that there wasn't really much of a --- you guys
5 didn't extrapolate anything from the adult
6 studies to kids with all the shifting?

7 DR. SOMERS: In terms of the higher
8 limit, I mean, there's absolutely no data
9 whatsoever in children that having a hemoglobin
10 above 12 results in any sort of adverse outcome.
11 And unlike the adult data, there is specific data
12 showing that hemoglobin less than 10 results in
13 adverse outcomes in children.

14 CO-CHAIR CROOKS: Okay.

15 DR. SOMERS: Specifically, that level
16 of 10.

17 CO-CHAIR ANDERSON: I'm trying to keep
18 the discussion to what we need in order to vote.
19 Dr. Wagner.

20 DR. WAGNER: Quick question. So, are
21 the data specific to ESA treated patients or all
22 comers?

1 DR. SOMERS: The data that --- less
2 than 10 dealt with kids with CKD. I'm not sure
3 what proportion of them were receiving ESAs, but
4 as common practice, since in general pediatrics
5 there's evidence that any normally healthy child
6 having anemia results in all kinds of adverse
7 outcomes that pediatric nephrologists tend to
8 start treating when we start to see anemia.

9 CO-CHAIR CROOKS: Okay. I don't see any
10 other cards up, so let's vote on the evidence.

11 MS. OGUNGBEMI: The Committee is now
12 voting on Measure 1667's evidence. Options are 1
13 high, 2 moderate, 3 low, and 4 insufficient.
14 Voting is open. The results are five votes high,
15 13 votes moderate, three votes low, and one vote
16 insufficient. Measure 1667 passes on evidence.

17 CO-CHAIR ANDERSON: Okay. Bobbi, on the
18 gap.

19 MS. WAGER: The performance gap
20 included, for instance, racial disparity because
21 it's such a small scale, a small size sample of
22 patients that it was difficult to differ

1 treatments with the gender, the patient's gender,
2 age, and race. 2008 CMS PQRI data is showing
3 about a third of the patients not meeting the
4 goal, and 2010 Elab data provided showing that 20
5 percent of pediatric patients have hemoglobin
6 values less than 10. And that proportion
7 increased a bit over 2009. But, again, the
8 performance does not include really a thorough
9 investigation due to the small sample size.

10 CO-CHAIR CROOKS: Rick, any other
11 comments on the gap?

12 DR. KASKEL: No, there is clearly a
13 percentage of patients not meeting what we think
14 is a target. That is somewhat of a concern to our
15 community, and even in the CKiD data set we found
16 a surprising number of patients in Stage 2 or 3
17 who were anemic and were not getting effective
18 treatment, so it's a concern.

19 CO-CHAIR ANDERSON: Okay, other
20 considerations on the performance gap? Lori.

21 MS. HARTWELL: The data says 2008. What
22 year was the black box warning; so this data is

1 prior to the black box warning, so it might be
2 different. Is that correct? I was just saying the
3 gap might be higher.

4 CO-CHAIR ANDERSON: If I'm reading this
5 right it says --- and, Bobbi, I'm probably ---
6 this may be repetition, but the 50th percentile,
7 66.23, does that mean that's two-thirds of kids
8 are below 10, or is that for the 10 to 20 ---
9 maybe that's for the 10 to 20 range. Yes,
10 please.

11 MS. SINGER: There was data from the
12 International Pediatric Peritoneal Dialysis
13 Network Registry of 1,394 pediatric patients
14 showing that 25 percent of patients had
15 hemoglobin levels below the target. That's in the
16 evidence.

17 DR. ZARITSKY: You have to --- I don't
18 want to argue against this, but the IPPM, you
19 know, International ---

20 MS. SINGER: Right. It is
21 international.

22 DR. ZARITSKY: They don't get --- they

1 don't have Epogen available, and there's a cost.

2 CO-CHAIR CROOKS: So, whether it's 15
3 percent or 16 percent, I guess there's a large
4 performance gap. Okay. Any other discussion on
5 the performance gap? I see voting machines in the
6 air. Let's do it.

7 MS. OGUNGBEMI: The Committee is now
8 voting on the performance gap for Measure 1667.
9 Options are 1 high, 2 moderate, 3 low, and 4
10 insufficient. Voting is open. The results are for
11 performance gap, 10 votes high, 13 votes
12 moderate, zero votes low, and zero votes
13 insufficient. Measure 1667 passes on performance
14 gap.

15 CO-CHAIR CROOKS: Okay. Next up,
16 specifications and reliability.

17 MS. WAGER: Okay. Reliability, measure
18 was tested at the critical data element level
19 using inter-rater reliability for medical culture
20 rater for the measure, where the patients were
21 randomly selected from visits. For ESRD, they
22 used four nephrology practices in the Midwest,

1 the West, the East, and Southern. The number of
2 patients seen per month was averaged at 240 to
3 2,800. Sample size per physician organization
4 ranged from 24 to 30 for a total of 169 patients
5 on PD or hemo.

6 The data was collected from medical
7 records, data abstraction completed for multiple
8 patient visits per patient for a total of 2,012
9 patient visits. Data abstraction was done in
10 2008, and testing results indicate from that
11 there's a high reliability.

12 CO-CHAIR CROOKS: Okay. Rick, any other
13 comments on ---

14 DR. KASKEL: No, that covers it.

15 CO-CHAIR CROOKS: The source of the
16 data is from CROWNWeb, or it's from some other --
17 -

18 MS. SINGER: Chart extractions.

19 CO-CHAIR CROOKS: For the testing.

20 MS. SINGER: Yes.

21 CO-CHAIR CROOKS: But, in general?

22 MS. SINGER: PQRS.

1 CO-CHAIR CROOKS: PQRS. Thank you.

2 Okay. Any other comments on specs reliability?

3 DR. DALRYMPLE: Can I ask a question of
4 either the ---

5 CO-CHAIR CROOKS: Oh, Lorien, sorry.

6 DR. DALRYMPLE: --- developers? Oh,
7 sorry, I thought you were ---

8 It was --- I think when I looked at
9 this, the reliability testing seemed to be the
10 same as the adult measure. So, can we get clarity
11 as whether the reliability testing occurred in a
12 pediatric population? And then I think the kappa
13 I saw was for a plan of care for anemia measure,
14 and is that the same as a hemoglobin less than
15 10? And maybe I'm missing the hemoglobin less
16 than 10 kappa, but I was just hoping for clarity
17 on the reliability testing.

18 MS. SINGER: Yes, we did not test this
19 in pediatric practices, so it's the same testing
20 that was done for the other measures.

21 CO-CHAIR CROOKS: Is there any reason
22 to think the reliability testing would be

1 different if you'd done it on pediatric patients?

2 Why is the sky blue? Oh, we know that

3 ---

4 DR. DALRYMPLE: Can we discuss it as a
5 Committee whether that changes things for anyone,
6 the lack of pediatric sampling, or the kappa is
7 on a plan of care for anemia, as opposed to
8 hemoglobin cutoffs, which is what I think the
9 focus is in this one?

10 CO-CHAIR CROOKS: I agree, it does
11 raise some questions. Michael.

12 DR. FISCHER: Quite simply, the
13 reliability testing is supposed to be on the
14 measure proposed. If it's not, I'm not sure how
15 it's germane to the application.

16 CO-CHAIR CROOKS: Other comments?

17 DR. KASKEL: One of the deficiencies
18 already mentioned was the fewer numbers of
19 patients and inability to get any real signals
20 regarding gender and race, and certain periods of
21 development like pre-pubertal/post-pubertal.
22 These are all lacking in the analyses. We don't

1 have enough patients entered.

2 CO-CHAIR CROOKS: Okay. Are we ready to
3 vote? Reliability.

4 MS. OGUNGBEMI: The Committee is now
5 voting on reliability for Measure 1667. The
6 options are 1 high, 2 moderate, 3 low, and 4
7 insufficient. Voting is open. The results for
8 reliability on Measure 1667 are one vote high,
9 eight vote moderate, four votes low, and 10 votes
10 insufficient. The measure fails on reliability.
11 It's Measure 1667.

12 CO-CHAIR CROOKS: That's a critical
13 element, so do we stop at this point, or do we --
14 --

15 So, we would like to offer the
16 Committee the opportunity to provide additional
17 comments to the developer.

18 DR. KASKEL: I'm concerned about this
19 now, so I'd like to have a further discussion
20 about the reliability in detail.

21 CO-CHAIR CROOKS: So, are you arguing
22 that the reliability was --- testing was

1 suitable?

2 DR. KASKEL: My comments about gaps
3 related to need for further studies, just like
4 target hemoglobin and all the factors that go
5 into the distribution, racial, gender. But the
6 reliability of this assessment, I don't believe
7 was insufficient from the data source. That's a
8 concern.

9 CO-CHAIR CROOKS: I need to make sure
10 I'm understanding you; that you think the
11 reliability testing is sufficient, or it is not
12 sufficient?

13 DR. KASKEL: For this measure, it's
14 sufficient.

15 CO-CHAIR CROOKS: You think it is
16 sufficient. I think to summarize the opinion I'm
17 sensing from the Committee, that when you don't
18 test it on the target audience and show that your
19 bullet is hitting in the same place every time
20 because you're not even looking at that
21 population, it's not being judged reliable.
22 That's my sense of it. Let's start with --- who's

1 up first? Michael.

2 DR. SOMERS: It may not have been
3 tested on a target population, but I think it
4 would --- I'm not sure why doing record
5 abstraction looking at the same data element in
6 adults would be different in a pediatric
7 population at these facilities, as well. So, I'm
8 not sure the outcome of reliability testing, if
9 there were a pediatric cohort that could have
10 been tested, would have been any different than,
11 you know, this measure being tested in adults,
12 because the process is the same of looking at
13 something ---

14 CO-CHAIR CROOKS: Right, we hear you.
15 Yes.

16 DR. SOMERS: Yes.

17 CO-CHAIR CROOKS: Okay. Lori.

18 MS. HARTWELL: I just want to clarify,
19 we're just talking about testing hemoglobin.
20 Correct? That's the test. I mean, hemoglobin --

21 CO-CHAIR CROOKS: No, the reliability
22 test is that the data elements, whoever finds

1 them, or whatever method they're found, they're
2 going to come out the same.

3 MS. HARTWELL: So, can you explain that
4 to me just a little bit relating to hemoglobin? I
5 mean, is it the method --- I'm trying to
6 understand this one, because I'm like I don't ---

7
8 CO-CHAIR CROOKS: Yes, it's beyond the
9 scope of my duties as Chair to explain
10 reliability beyond what I can, but the notion is
11 that the data elements are --- however they're
12 brought in, that they are accurate, that the
13 number --- it doesn't matter how high or how low
14 the number is, it's that it's accurate time after
15 time it's being compared.

16 MS. HARTWELL: Just so I can understand
17 the process, so the data elements, if it's
18 brought in an adult, they measure the hemoglobin,
19 it comes in and it's the fact that it wasn't
20 measured on the pediatric patient the same number
21 is making it not reliable? I'm just trying to
22 understand this. Is that ---

1 CO-CHAIR CROOKS: Well, we don't know
2 if it's reliable in the pediatric patients. We
3 don't know if they're missing values. We don't
4 know that inter-rater reliability would have been
5 good. We don't know, because they didn't do it.
6 And that's causing us some --- giving us pause.
7 It's very important that if we endorse a measure,
8 that it's reliable and valid.

9 MS. HARTWELL: Okay.

10 CO-CHAIR CROOKS: And that's part of
11 the NQF mission. Measures that matter, if they're
12 not reliable and valid, why should we be putting
13 a lot of health care resources into making them
14 better when we don't know that they work?

15 DR. FIVUSH: Can I speak as the measure
16 developer?

17 CO-CHAIR CROOKS: You may have a brief
18 comment.

19 DR. FIVUSH: I would strongly support
20 Michael's comments on this. There would not be a
21 reason to believe that this would be different in
22 a pediatric or adult population, not the level of

1 hemoglobin, but the reliability of being able to
2 obtain the hemoglobin value that is accurate from
3 chart abstraction. I can't --- I think that his
4 points are very valid, and there would not be a
5 particular reason, or any reason to assume that
6 this would be different if it was tested in the
7 pediatric population by chart abstraction.

8 CO-CHAIR CROOKS: Okay, thank you. We
9 have other people who would like to speak.
10 Michael.

11 DR. FISCHER: I don't want to be too
12 rigid. I guess, my vote was informed by following
13 this algorithm, but perhaps I went to the boxes
14 improperly. But given there's some concern about
15 reliability, as Lori mentioned, perhaps it would
16 be useful ---

17 CO-CHAIR CROOKS: Yes.

18 DR. FISCHER: --- for us to --- which
19 I think is what you were going to do, anyway.

20 CO-CHAIR CROOKS: Can you step us
21 through it really quickly, the recommended way to
22 consider it?

1 DR. FISCHER: Yes, so --- and I'll be
2 candid. I wasn't part of the working group for
3 this measure, so I'm basing how I went through on
4 the preceding comments, but it's Algorithm 2, I
5 think that's page 12.

6 So, are submitted specifications
7 precise, unambiguous, and complete, they can be
8 consistently implemented? Yes. So, I went to
9 number 2. Was empirical reliability testing
10 conducted using statistical tests that the
11 measure specified? No, because once again, that's
12 where I thought about the population thing, but I
13 don't --- once again, just trying not to make
14 assumptions. Was empirical validity testing of
15 patient level data conducted? When I looked
16 quickly it was no, but I know we haven't talked
17 about validity yet, and that's how I wound up
18 with my vote. But, once again, I'm happy as
19 others look at this, I can be corrected, but I
20 was just going through this as to the NQF
21 process.

22 CO-CHAIR CROOKS: Okay, thank you.

1 Lorient.

2 DR. DALRYMPLE: Can I ask the
3 developers a point for clarity? So, even if we
4 accept that perhaps there are no differences in
5 the adult --- in the pediatric population, the
6 one thing I want to make sure I understand is the
7 kappa that's provided for plan of care of anemia
8 the same as this measure as specified percentage
9 with a hemoglobin less than 10, or is that
10 actually a different measure?

11 MS. SINGER: The plan of care was part
12 of the original measure. It's not part of this
13 current measure. And the current endorsed measure
14 does not have a plan of care component, either.
15 So, I guess to clarify the reliability testing
16 issue, though, the process for testing the
17 measure would be the same in the pediatric
18 population, and I just want to emphasize that
19 point. And the numbers of patients are so small
20 that the cost involved in the testing was placed
21 in the larger population of patients so that we
22 could get larger numbers. But the process is the

1 same for testing.

2 DR. DALRYMPLE: But this kappa does not
3 apply to the measure as specified, even if we
4 negate the pediatric issue. Is that the correct
5 understanding?

6 MS. BECKRICH: So, the measure, I mean,
7 as it was tested would include the hemoglobin
8 element as specified in the measure. And, in
9 addition, it included a plan of care element
10 which was in the original, I think, 2007 version
11 of this measure, but that measure --- that
12 element of the measure was dropped when it was
13 brought before the NQF Committee last time, I
14 believe 2012. So, the current endorsed measure
15 does not include the plan of care.

16 CO-CHAIR CROOKS: Frank.

17 DR. MADDUX: So, just to --- you had
18 asked, Peter, if we'd make comments to the
19 developers given the result of the vote, and it
20 strikes me that what we're really talking about
21 here is for reliability testing using a proxy.
22 And you're using a proxy to --- so, part of the

1 defense I think might be more than just
2 elucidating the data of the proxy, but why the
3 proxy can be used in a valid way for reliability
4 testing on this particular measure, because a lot
5 of the kinds of things you're been talking. I
6 think if that path was laid out, there probably
7 would have been a different result.

8 CO-CHAIR CROOKS: I think I'm sensing,
9 though, a request to re-vote on the specs and
10 reliability. Are there any objections to the
11 Committee --- from the Committee to re-vote?
12 Okay, let's re-vote.

13 MS. OGUNGBEMI: The Committee is now
14 voting on reliability for Measure 1667. Options
15 are 1 high, 2 moderate, 3 low, and 4
16 insufficient. Voting is open. The results are one
17 vote high, 15 votes moderate, one vote low, and
18 six votes insufficient. The measure passes on
19 reliability. That's Measure 1667.

20 CO-CHAIR CROOKS: Should we make it two
21 out of three? No? Okay, we'll go on. Validity.

22 DR. KASKEL: So, for the validity the

1 comments from the group were that incorrect entry
2 of data and codes, not following harmonized
3 reporting at specific time points may have
4 affected some results. There's missing data. The
5 test sample is adequate, however, for widespread
6 implementation; however, normative adult data
7 should not be used for comparison to pediatric
8 age, gender, and race specifications.

9 Medical record abstraction data from
10 over 2,000 patient visits showed appropriate
11 reliability for medical record abstraction. So,
12 moving forward with EHR, this can only improve,
13 especially with CROWNWeb. The panel thought this
14 was high validity from the TEP.

15 CO-CHAIR CROOKS: Elizabeth, any other

16 ---

17 Bobbi, sorry, Bobbi.

18 MS. WAGER: No, no more comments.

19 CO-CHAIR CROOKS: You're so far away.

20 Okay, other --- so, it was a TEP --- basically,
21 it was based on TEP recommendation, the validity
22 argument. Any other discussion on validity? Okay,

1 let's vote.

2 MS. OGUNGBEMI: The Committee is now
3 voting on validity for Measure 1667. The options
4 are 1 high, 2 moderate, 3 low, and 4
5 insufficient. Voting is open. The results are
6 three votes high, 18 votes moderate, zero low,
7 and one vote insufficient. Measure 1667 passes on
8 validity.

9 CO-CHAIR CROOKS: Very good. So, we're
10 up to feasibility. Bobbi or Rick?

11 DR. KASKEL: So, for the feasibility,
12 again this was electronic sources, data
13 collection, and care processing, so the
14 electronic reporting needs to be --- it was felt
15 needs to be more complete and uniform across
16 sites. Analyses of data needs to target specific
17 factors, such as, again, age, gender, and race,
18 and the normative --- same comments about
19 normative adult population data should not be
20 used to assess performance in the pediatric
21 population. And, again, this will improve with
22 electronic medical record, or electronic health

1 records.

2 CO-CHAIR CROOKS: Bobbi, any other
3 thoughts; feasibility?

4 MS. WAGER: No comment. He said it.

5 CO-CHAIR CROOKS: And, again, this is
6 PQRS data, so it's submitted by physician
7 practices?

8 MS. SINGER: Individual physician
9 providers.

10 CO-CHAIR CROOKS: Okay. Are we ready to
11 vote on feasibility?

12 MS. OGUNGBEMI: The Committee is now
13 voting on feasibility for Measure 1667. The
14 options are 1 high, 2 moderate, 3 low, and 4
15 insufficient. Voting is open. The results are for
16 feasibility 10 votes high, 13 votes moderate,
17 zero votes low, and zero insufficient. Measure
18 1667 passes on feasibility.

19 CO-CHAIR CROOKS: Okay. Bobbi and Rick,
20 is it in use, and is it usable?

21 DR. KASKEL: Sorry. This is a public
22 database and accessible because of that. And it's

1 --- the data can be used to determine anemia
2 management and records of deviation from expected
3 norms can be used to investigate specific
4 etiologies of inadequate response to anemia
5 treatment, which is a good thing to have. And the
6 benefits, however, at present outweigh any
7 unintended consequences. We did also recommend
8 that data provided more recent than 2010 would be
9 useful as we move forward; that it was
10 transparent, as well.

11 CO-CHAIR CROOKS: Bobbi, anything else?

12 I think they stated in the submission that there
13 is evidence for improvement that the curve is
14 shifting to the right. Is that a result of their
15 measure? Maybe. Okay. Other discussion on
16 usability and use? Okay, I think we're ready to
17 vote.

18 MS. OGUNGBEMI: The Committee is now
19 voting on usability and use for Measure 1667.
20 Options are 1 high, 2 moderate, 3 low, and 4
21 insufficient. Voting is open. The results are 14
22 votes high, nine votes moderate, zero votes low,

1 and zero votes insufficient. Measure 1667 passes
2 on usability and use.

3 CO-CHAIR CROOKS: Okay. Before the
4 final vote to submit it for endorsement, open it
5 up for general comments. Just to summarize from
6 the pediatric nephrologist's point of view, maybe
7 if I can --- you can tell me if I'm right. You
8 feel this is an important measure. It's the only
9 measure --- NQF measure relating to anemia
10 management in children, and you think it's a good
11 measure.

12 DR. KASKEL: I think it's very
13 important as we move forward. And I think we're
14 on the verge of having more information regarding
15 the etiology of the anemia in certain groups,
16 such as with disparities. We have some
17 information on hepcidin and racial disparities in
18 hepcidin and how that may affect anemia, and
19 cardiovascular and neurocognitive outcomes, and
20 growth.

21 DR. SOMERS: And I think the fact that
22 it's very much data based with the target level

1 of 10, is very important to the pediatric
2 community.

3 CO-CHAIR CROOKS: Okay. Any other
4 comments before vote? Okay, let's do it.

5 MS. OGUNGBEMI: The Committee is now
6 voting for Measure 1667's overall suitability for
7 endorsement. The options are 1 yes, 2 no, and
8 voting is open. The results are 20 votes yes, and
9 three votes no. The measure passes for meeting
10 NQF criteria for endorsement.

11 CO-CHAIR CROOKS: Well, that was a
12 squeaker, but the process worked. Thank you.

13 Okay. We're going to move to Measure
14 1660, same developers, ESRD patients receiving
15 dialysis, hemoglobin level less than 9.

16 MS. SINGER: Okay, thank you. We have
17 Paul Palevsky on the line, I believe, who's going
18 to introduce this measure.

19 CO-CHAIR CROOKS: Paul, are you there?

20 DR. PALEVSKY: I was trying to get an
21 open line, sorry.

22 CO-CHAIR CROOKS: Okay. We hear you. Go

1 ahead.

2 DR. PALEVSKY: Okay. I guess I now have
3 the open line, so thank you.

4 This is Measure 1660, ESRD patients
5 receiving dialysis, hemoglobin level less than 9
6 grams per deciliter. The description of this
7 measure is percentage of calendar months within a
8 12-month period during which patients aged 18
9 years and older with a diagnosis of end stage
10 renal disease who are receiving hemodialysis or
11 peritoneal dialysis have a hemoglobin level less
12 than 9 grams per deciliter.

13 Our rationale for this measure is that
14 it is intended to look at the outliers at the low
15 end of the hemoglobin distribution curve to
16 identify patients --- to identify quality of care
17 of patients for treatment of anemia.

18 This --- establishing a threshold for
19 a measure such as this has been somewhat
20 problematic. I appreciate that you just accepted
21 the pediatric measure with the hemoglobin level
22 at 10. This measure in a prior iteration had not

1 been endorsed by NQF using a hemoglobin level of
2 10, and we have revised this with a threshold at
3 9.

4 We are not contending that 9 is some
5 absolute level at which a hemoglobin less than 9
6 is really bad, and above 9 is really good. That's
7 not what we're trying to establish here. We're
8 trying to have a way of looking at the less ---
9 if you're looking at a distribution curve, at
10 the left side tail with the contention that the
11 larger the percentage of patients with a
12 hemoglobin in that left-sided tail would
13 represent lower quality of care.

14 What we have noted is that over the
15 past several years there actually has been an
16 increase in the number of patients with
17 hemoglobins less than 9, and there are also data
18 suggesting that there's an increase in
19 transfusion rate associated with the changes in
20 ESA therapy.

21 This, obviously, is an intermediate
22 outcome measure. It is included in the RPA Kidney

1 Quality Improvement Registry for 2015.

2 The evidence supporting any specific
3 threshold for --- at the lower end for
4 hemoglobin, we recognize is problematic, but the
5 KDIGO 2012 guidelines do suggest that for adult
6 CKD 5D patients, ESA therapy be used to avoid
7 having a hemoglobin concentration below 9 grams
8 per deciliter by starting ESA therapy when the
9 hemoglobin is between 9 and 10.

10 We know that from the Treat trial
11 which was designed to give rescue therapy when
12 the hemoglobin was less than 9, that that
13 strategy of therapy of waiting until the
14 hemoglobin of less than 9 was associated with an
15 increase in transfusion rates. So, we think that
16 this is an important safety measure for looking
17 at the inadequate treatment of anemia. And,
18 hopefully, you will find that this is a worthy
19 measure where you did not find it so with a
20 threshold of 10 when this was considered several
21 years ago.

22 CO-CHAIR CROOKS: Okay. Thank you very

1 much. Our discussants are Michael Somers and Myra
2 Kleinpeter. Who's going to go first?

3 DR. KLEINPETER: So, I'll start first.
4 The summary provided gives a good idea of the
5 rationale for the measure at this time. There's
6 significant evidence coming forward that levels -
7 - hemoglobin levels less than 9 can lead to worse
8 outcomes, increased risk of transfusions, and the
9 anemia guidelines from 2007 updates have a target
10 range between 11 and 12, and then concurrently
11 with the implementation from some of the data we
12 have with the bundle payments there's been a
13 trend downward of the overall average hemoglobin
14 such that they're having higher proportions of
15 patients with lower hemoglobins.

16 The first set of the information, also
17 from other member comments, specifies the
18 consequences of the lower hemoglobin may be
19 indirect, and also increase in risk of
20 transfusions which will impact candidacy for
21 kidney transplantation.

22 Other information in terms of

1 performance gap, 38 percent of the patients do
2 not receive the target hemoglobin supported by
3 national performance, disparities exist in
4 various populations, but there was insufficient
5 data available for suitable comparisons. And at
6 this time, some of the health disparities
7 primarily exist among African American patients,
8 and Hispanic patients. This may be
9 multifactorial, but there are some disparities
10 with care.

11 CO-CHAIR CROOKS: Okay. So, we're on
12 the evidence discussion. Michael, did you want to
13 add anything right now?

14 DR. SOMERS: No.

15 CO-CHAIR CROOKS: Okay. So, we open it
16 to the Committee, discussing the evidence for
17 Measure 1660.

18 MS. WAGER: I have a comment. When we
19 talk about this less than 9, you mention adverse,
20 you know, effects, events, or whatever. I don't
21 hear one word about quality of life for the
22 patient.

1 CO-CHAIR CROOKS: What would you like
2 us to know?

3 MS. WAGER: Well, you don't have one,
4 you know. Us professionals want the patient to
5 continue working while on dialysis with a
6 hemoglobin --- I remember dialyzing an 82 and my
7 hemoglobin was around then. I couldn't work. I
8 could just make a bed. So, I think that quality
9 of life has to be an important component.

10 CO-CHAIR CROOKS: Lori.

11 MS. HARTWELL: I would just state, I
12 would just double back. I remember I got two
13 units of blood every six weeks for pretty much my
14 whole entire age 12 to almost 23, and I would get
15 a blood transfusion at a 26 hematocrit, and one
16 time --- and I was telling --- I felt so bad at
17 that time, I would drink Big Gulps before they
18 drew my blood. And just to emphasize how awful
19 you feel, and that's about an 8, 8.5 hematocrit,
20 hemoglobin, excuse me. So, when you're at a 9, I
21 mean, this is such a safety issue for patients,
22 and I don't know if a lot of physicians today

1 understand the true effects of how bad you feel
2 with anemia. And I think, you know, we get emails
3 at our organization, patients tell us they don't
4 feel good. They're not even aware their
5 hemoglobin is making them feel bad, so there
6 needs to be more awareness to this. And it is ---

7 I mean, we're doing all this so patients can
8 live the life they were meant to live, and
9 hemoglobin and feeling good is such a big part of
10 that.

11 CO-CHAIR CROOKS: Thank you. And I
12 believe that --- well, that may be addressed in
13 the body of evidence, is related to quality of
14 life improvement. It should be. If it isn't ---

15 DR. KLEINPETER: Some quality of life
16 information in terms in the references presented.

17 CO-CHAIR CROOKS: Okay. So, that is
18 part of the evidence base, too, that we know that
19 keeping it above a threshold, and this is a low
20 threshold. Okay, Frank.

21 DR. MADDUX: So, I'd only make one
22 comment. I mean, to me, this is a measure that's

1 a proxy for transfusion need. And the fact that
2 there are no uniform transfusion policies in end
3 stage renal disease patients makes it a little
4 bit difficult to interpret how this might have
5 unintended consequences.

6 My biggest concern about the less than
7 9 is the if used widely in the field, then
8 suddenly it becomes a new target range. And that
9 instead of saying that 9 to whatever, or 10 to
10 whatever, it's pretty clear that the FDA guidance
11 has been without a range. And in some way we
12 might de facto create a range because of measures
13 specifically being used, and that might be an
14 unintended result of what is a reasonable concern
15 here; and that is, that we begin to measure what
16 happens for people that have very low
17 hemoglobins. So, it's --- I'm quite conflicted on
18 this particular area.

19 CO-CHAIR CROOKS: Thanks. Alan.

20 DR. KLIGER: Paul pointed out that
21 there really is no consistent evidence for having
22 a cutoff period --- a cutoff for hemoglobin for

1 adults. You guys did present some evidence for
2 children. Having had the opportunity to review
3 all of this for a publication last year, I can
4 tell you that when you look objectively at it,
5 looking at a whole population, that there really
6 has been no compelling evidence that any specific
7 cutoff, that any specific level, risk is
8 increased below a particular level. Rather, it
9 looks more likely that we need to be paying
10 attention to individual patients.

11 You know, what we've heard from our
12 patients here is absolutely right, that there are
13 some individuals for whom a hemoglobin below 10
14 is impossible, and others who go and live really
15 very comfortably with hemoglobins of 8 or 8.5. I
16 have a real problem. And that's what the data
17 show, so I have a real problem with a measure
18 that goes across the board giving an arbitrary
19 cutoff without any data suggesting that there are
20 adverse consequences of the hemoglobin below that
21 level.

22 CO-CHAIR CROOKS: Ishir.

1 DR. BHAN: Yes, I would agree with
2 that. And, also, one of the comments earlier was
3 that the goal was to --- well, one of the
4 potential adverse effects of being below 9 in,
5 for instance, Treat, was that there were more
6 transfusions. I think if anything, an unintended
7 consequence of this might be to increase
8 transfusions, or maybe an intended consequence
9 depending on how you look at it. But, regardless,
10 an increase in transfusions as opposed to
11 emphasizing EPO, there's no particular reason
12 this would shift people more towards EPO or to an
13 ESA than to transfusions. I think that's exactly
14 that point.

15 CO-CHAIR CROOKS: Bobbi.

16 MS. WAGER: Dr. Maddux, thank you very
17 much, because you spoke just how I was feeling
18 when I read this measure. It scared me because
19 I'm thinking oh, my God, now it's being lowered.
20 There's going to be another target level. Thank
21 you.

22 CO-CHAIR CROOKS: Lisa.

1 DR. LATTS: The other folks were first.
2 Do you want --- are you going to --- okay. Well,
3 I just have a question for the developer. If
4 there's so much --- because this is not an area
5 that I'm familiar with the science of. So, if
6 there's so much science that shows there isn't a
7 range, what's the developer's interest in
8 creating a below number?

9 DR. PALEVSKY: So, while there is not
10 --- we agree that ESA therapy should be
11 individualized to the patient to maintain the
12 hemoglobin in a range where the patients feel
13 best. For the majority of patients, that's going
14 to be a hemoglobin greater than 9. And I agree
15 with --- I remember the patient in the pre-ESA
16 era who were chronically transfused, iron
17 overloaded, developed heart failure from their
18 iron overload from the transfusions they received
19 to maintain hemoglobins of greater than 8.

20 We are not --- and I tried making it
21 clear, we are not implying that this number sets
22 a range for treatment. This is set below the

1 level that most individuals would consider where
2 you would treat patients with an ESA to maintain
3 the hemoglobin level. I will say that since there
4 has been removal of a target range, we have seen
5 not only a downward trend in hemoglobin levels,
6 but an increase in transfusion rate, which is the
7 unintended consequence, I believe, of having
8 eliminated a bottom level for hemoglobins.

9 CO-CHAIR CROOKS: Paul, I'm going to
10 need to cut you off pretty soon.

11 DR. PALEVSKY: I understand the concern
12 over this possibly being a stimulus to
13 transfusion, but I suspect that it would not
14 actually increase transfusion rates. Right now
15 we're seeing the absence of a measure resulting
16 in an increase in transfusion rates.

17 CO-CHAIR CROOKS: Okay, thank you.
18 Stuart.

19 DR. GREENSTEIN: As a transplant
20 surgeon, I would have to just chime in that my
21 biggest concern when you put a number is that you
22 will increase the transfusion rate, and it'll

1 make it much more difficult for me to ever
2 transplant people. Especially, when I look at a
3 patient, I will individualize what kind of
4 hemoglobin they have in terms of when I can go a
5 transplant on them. So, if I have a patient who's
6 in his 30s and his hemoglobin is 8, you know,
7 8.5, I don't have a problem doing it, but if he's
8 55-60 years old, cardiac disease, I would have a
9 big problem doing it. I mean, so I don't think
10 you can give an absolute number. You have to
11 individualize, otherwise you're going to
12 sensitize everybody, and we're going to have a
13 lot more people waiting, and waiting, and waiting
14 for transplant.

15 CO-CHAIR CROOKS: Okay, thanks. Lori.

16 MS. HARTWELL: I just have a quick
17 question, because I know in the previous years
18 that I wasn't, there was a hemoglobin of 10 or
19 below that was rejected. And I'm just having a
20 little bit of difficulty understanding, because
21 hemoglobins aren't being individualized to
22 patients. Patients are way too low. I hear it

1 every day, and it --- you know, I mean, it's kind
2 of unconflicted because I understand like you
3 don't want to put a number on it. But then how do
4 you make a safety issue so patients don't get too
5 low? And they are too low in the community. So, I
6 mean, I'm not an expert on it, but it would be
7 nice if there was some kind of direction, maybe
8 not from this body, the community that --- to not
9 let people drop so low.

10 And just a comment to Alan, when I
11 hear somebody being at an 8 or 8.5, I can only
12 imagine that this patient is elderly and not
13 moving around that much, because anybody who's
14 younger can't really --- I can't --- I know many
15 of my friends cannot move with a --- are just not
16 very active at that low of hemoglobin. That's
17 just my only comment.

18 CO-CHAIR CROOKS: Just to back up Alan,
19 there is a lot of variability. There are patients
20 who are quite comfortable, but many who are not.
21 Lorien, I think you're next.

22 DR. DALRYMPLE: So, I was trying to

1 recall our discussion from a years ago, and I
2 think the way at least I perceive this measure is
3 it's a safety measure. There have been a lot of
4 incentives put in place to insure hemoglobins
5 don't go high, but we have not --- we no longer
6 have lower boundaries for hemoglobin. And I think
7 less than 10 is challenging in adult population
8 because there's black box warnings, FDA, all of
9 us who care for advanced CKD patients often have
10 patients with hemoglobins of 9.2.

11 And if you believe the trials, that's
12 probably acceptable, so I think, in part, my
13 interpretation is the RPA responded to our last
14 discussion of this measure saying okay, you're
15 not comfortable with less than 10. Let's go to
16 the guidelines and still try and develop a safety
17 measure, which is really how I perceive this.

18 I don't know if it could incentivize
19 transfusion. That's not how I perceive it. I
20 perceive as perhaps adjusting EPO protocols and
21 other things to insure we don't have a lot of
22 these aids, and, hopefully, we individualize

1 therapy, and if people feel comfortable at a
2 hemoglobin of 8, we leave them alone and don't
3 give them excessive ESA.

4 But the RPA did submit supplemental
5 material with the KDIGO guideline from 2012 that
6 Paul mentioned with a grade of 2B. And I
7 understand that's not a wonderful grade, but at
8 least we do have a guideline grade now, which I
9 think is more than we had a few years ago. So,
10 from my perspective this is a safety measure to
11 try and put a floor in, again. And it's not a
12 target. I think it's like KT over Vs of 1.7. It's
13 a floor, not a goal.

14 CO-CHAIR CROOKS: Okay. Back to Alan.

15 DR. KLIGER: Okay. Maybe the developers
16 can help me with this. I see no evidence that as
17 the hemoglobins have, indeed, come down as they
18 have recently, I've seen no evidence of the
19 community negative effects that you've described.
20 Surely, there are individuals who are under
21 treated, but in the absence of evidence of an ill
22 effect by creating a single floor, rather than by

1 a showing that we're attending to each
2 individual's needs, I see the risk as being
3 greater than the potential benefit of setting up
4 an arbitrary floor.

5 CO-CHAIR CROOKS: Okay. Any other ---

6 DR. PALEVSKY: Do you want me to
7 respond to Alan's ---

8 CO-CHAIR CROOKS: If you can do it in
9 30 seconds or less.

10 DR. PALEVSKY: Alan, the only evidence
11 that I can point to is the increasing rate of
12 transfusion that has been reported since we have
13 removed a floor.

14 CO-CHAIR CROOKS: Okay, thanks. So, I
15 think the ---

16 DR. PALEVSKY: There's been almost a 50
17 percent increase in transfusion rate.

18 CO-CHAIR CROOKS: Correct. Okay. So,
19 are we ready to vote on the evidence supporting
20 this measure? Okay.

21 MS. OGUNGBEMI: The Committee is now
22 voting for Measure 1660 evidence. Options are 1

1 high, 2 moderate, 3 low, and 4 insufficient.

2 Voting is open. The results are one vote high,
3 nine votes moderate, six votes low, seven votes
4 insufficient. Measure 1660 is in the gray zone
5 for evidence.

6 CO-CHAIR CROOKS: Moving forward then,
7 the gap.

8 DR. KLEINPETER: All right. So, for the
9 performance gap, they have 38 percent of patients
10 did not receive the target hemoglobin supported
11 measure for a national performance goal. I
12 already mentioned that there are some disparities
13 regarding age and race, as well as gender, but
14 there was insufficient data available for
15 comparisons.

16 And in terms of disparities, some of
17 those are that there are higher rates of anemia
18 in African Americans. Why this exists may be
19 multifactorial, but there still is a disparity in
20 that number.

21 CO-CHAIR CROOKS: Okay. So, the gap is
22 low, 5.4 percent, but we're considering this as a

1 safety issue. Who else would like to speak about
2 the performance gap? Mahesh.

3 DR. KRISHNAN: Maybe just to give you
4 some more contemporary data, I'm just looking at
5 our data from March, and it's similar. It hasn't
6 changed a lot since 2012 to now, so it's still
7 about 5 percent, 6 percent. I mean, that's just
8 the variance that there is.

9 CO-CHAIR CROOKS: Lisa.

10 DR. LATTIS: And we do we know that 5 or
11 6 percent, based on the expert opinion of the
12 people here, I mean, are those probably people
13 that shouldn't be above 9, or are those people
14 that probably should be there?

15 DR. KLEINPETER: So, at least in
16 looking at our cohort and our population from
17 both LSU and Tulane, a lot of those are the new
18 patients that are presenting de novo to the ED
19 who have had been in no care, and some of our
20 sickle patients have sickle cell disease where
21 our target overall is lower, so that we are
22 keeping them a lower hemoglobin.

1 CO-CHAIR CROOKS: I believe the
2 denominator exclusion includes --- I've looked at
3 so many measures, but I think it excludes sickle
4 cell anemia and other chronic anemia.

5 DR. PALEVSKY: It does.

6 DR. FISCHER: Just so I know what I'm
7 voting on, so the performance gap that was
8 characterized, does that exclude all the
9 exceptions they have, sickle cell, cancer? What
10 we just quoted, the 5 percent is not including
11 any of those individuals?

12 CO-CHAIR CROOKS: I expect that's the
13 case. Would you like to ask the developer? The
14 quote, that's the measure. Alan. Put your card
15 down, Alan. Okay. Josh first.

16 DR. ZARITSKY: So, when I read what
17 they've provided in 1b.2, right, they say, you
18 know, the gap here is 5.4 percent who had less
19 than, you know, hemoglobin less than 9. I'm just
20 --- you know, then they go on to say 36.5 percent
21 of patients reported did not receive the optimal
22 care. I guess that's referring to those not

1 within 11 to 12. Right? So, that's not --- I
2 don't know why that's included in the gap.

3 CO-CHAIR CROOKS: Ishir.

4 DR. BHAN: So, just a question for
5 Mahesh. You said you got a similar number, but
6 you were not excluding people with chronic
7 anemias and such, so that's all comers. So,
8 presumably some of those people do have some
9 other cause of anemia, and it's not really clear
10 to me that this states that those are being
11 excluded here, as well. So, I mean, ideally they
12 should be, if that's what it's --- you know, if
13 it's part of this document, but it's not clear to
14 me that ---

15 DR. KRISHNAN: I can get into the
16 specifications but I don't know how --- we can't
17 exclude those patients either in our own data,
18 because we don't have enough granular data to
19 exclude them off those things, so I don't know
20 you would do that, in practicality, for the other
21 measure.

22 DR. BHAN: So, it may be as great as

1 5.4 or whatever the number is percent, but it may
2 be lower than that, as well.

3 CO-CHAIR CROOKS: I think even
4 including the exclusions, 5.4 percent is the
5 noise of new patients coming in and patients, you
6 know --- I conclude the gap is essentially zero,
7 and it's kind of a quandary because you may
8 believe it's a safety net, and it's an important
9 safety net, but yet you have to vote on the gap.
10 And the gap is not there, so it's a little bit of
11 a conflict for me. So, with that in --- okay,
12 Lisa, would you like to shed light on our
13 dilemma?

14 DR. LATTS: No, no, not at all. It's
15 just --- and Poonam and Sarah are gone, but it
16 does almost beg the issue of some feedback to
17 NQF, that for those measures that are safety
18 measures it suggests a different criteria would
19 be most appropriate than a gap for a performance
20 measure.

21 CO-CHAIR CROOKS: So, let's vote on it,
22 and then we can let them, you know, inform us if

1 we need to do something different. Mahesh.

2 DR. KRISHNAN: Just, you know, I'm
3 looking now at the DOPPS National Sample Data,
4 right, so the gap was as high as, in August of
5 2010, of 9 percent of 9s. Now it's about, sorry,
6 3 percent. Now it's as high as 5 or 6 percent,
7 the gap has widened. Yes, widened over the
8 implementation of the black box, which I think
9 drove of this not bundled, but we won't go into
10 that. But I think that that gap has widened,
11 clearly, from 3 to 6 percent of the country.

12 CO-CHAIR CROOKS: You think the gap is
13 increasing?

14 DR. KRISHNAN: Correct. In August of
15 2010, the sub-9 was 3 percent, and now it's 5
16 percent.

17 CO-CHAIR CROOKS: Okay. Are we ready to
18 vote?

19 MS. OGUNGBEMI: The Committee is now
20 voting on performance gap for Measure 1660.
21 Options are 1 high, 2 moderate, 3 low, and 4
22 insufficient. Voting is open. The results are

1 zero votes high, five votes moderate, 16 votes
2 low, and two votes insufficient. Measure 1660
3 fails on performance gap.

4 CO-CHAIR CROOKS: The pause that
5 refreshes. So, we have voted that the performance
6 gap is too low, even though this is really being
7 considered as a safety measure. We're concerned
8 that NQF maybe should have different criteria for
9 evaluating a safety net measure, versus another
10 kind of measure, or maybe not. Sarah or Poonam,
11 can you ---

12 MS. BAL: In response to that, we do
13 have a panel selected that will be meeting in
14 the next couple of months. Helen mentioned it
15 earlier, that will be working on if we need to
16 change our criteria based on the type of measure,
17 and possibly what the future use of it would be.
18 But at the current time, the criteria stands, and
19 it should be treated as if it was any other
20 measure.

21 CO-CHAIR CROOKS: So, we can go on with
22 our considerations. Although it's new, you know,

1 we --- it's in that borderline, maybe it's a
2 reserve measure, maybe not.

3 MS. BAL: They would need --- have you
4 guys discussed if you want to make it a reserve
5 measure?

6 CO-CHAIR CROOKS: We haven't yet.

7 (Simultaneous speaking)

8 CO-CHAIR CROOKS: Yes, so we're in the
9 gray zone, again, the double gray zone I'd call
10 this.

11 MS. BAL: And before we move forward,
12 Sarah and I disappeared for a little bit, mainly
13 because we need to come up with a plan to get
14 through all the measures. We are very far behind
15 where we need to be. We really encourage you not
16 to repeat anything what's already been said.
17 Please just make any notes, you know, quickly.
18 And, also, going through the measures, if you
19 feel that reliability is good, no need to explain
20 why.

21 Just say that you think the
22 reliability is good, and we'll move forward. If

1 you ---obviously, if there are concerns, you
2 should bring those up, but if the --- if you feel
3 that the criteria is met and there's no further
4 discussion needed, just state that and we'll move
5 forward. You know, try to go as quickly as
6 possible. We want to give the measures the due
7 review, but we are very far behind at this point.

8 CO-CHAIR CROOKS: Yes, I'd point out
9 that's not the Committee's fault that we're
10 behind. I think we're doing a --- you know, I
11 think --- I congratulate the Committee for doing
12 its best job to fairly consider these measures.
13 But with all that in mind, let's move on. So,
14 we're now going to get --- so, do we move to the
15 new measure then, or do we ---

16 MS. BAL: We go back to ---

17 CO-CHAIR CROOKS: Are we going to ask
18 for --- we can't get reserve status if it's not -
19 --

20 (Off microphone comment)

21 CO-CHAIR CROOKS: Okay. So, while
22 that's all being considered, we're going to move

1 on to the next measure then. Why don't you take a
2 measure, which one ---

3 CO-CHAIR ANDERSON: All right. The next
4 measure is 1424, and the developers are Joe and
5 Joe.

6 DR. MESSANA: My status has declined so
7 much no one will sit with me any longer.

8 (Laughter.)

9 DR. MESSANA: So, in the spirit of
10 brevity, I'm not going to make any specific
11 opening comment except for to try to address a
12 question that was raised in the work group. When
13 I was reviewing the comments in preparation for
14 this, someone asked -- one of the work group
15 participants asked if the --- related to patients
16 missing hemoglobin, this is pediatric patients,
17 and whether these patients --- there was a
18 correlation with other missing values from
19 CROWNWeb, so we did a small additional analysis
20 in CROWNWeb data.

21 Looking at the concordance between
22 missing for calcium, phosphorous, and hemoglobin

1 from the CROWNWeb data, through each of the
2 months of 2013, and there's a little bit of
3 variation month to month, but generally there was
4 concordance in that all three of those values,
5 two bone and mineral intermediate outcomes,
6 calcium and phosphorous, and hemoglobin were
7 missing from somewhere between 35, and say 45
8 percent of patients in any given month from
9 CROWNWeb in 2013.

10 There was concordance in that all
11 three were present in similarly about 40 percent
12 give or take from month to month. And then the
13 remainder, which was somewhere between 10 and 20
14 percent in any month, there was a mixed pattern,
15 a hemoglobin was there, calcium was not,
16 hemoglobin was there, phosphorous was not,
17 calcium and phosphorous were there, but
18 hemoglobin was not. So, hopefully, that answers
19 the work group question, and I'll stop there.

20 CO-CHAIR ANDERSON: All right. Bobbi
21 and Myra, who's going first?

22 MS. WAGER: I am. Evidence shows that

1 it's a process measure and it's supported by
2 KDOQI, how do you say it, I'm sorry, guidelines
3 of 2006. There was a systematic review, and they
4 rated it 2b.

5 CO-CHAIR ANDERSON: Myra, do you have
6 anything else?

7 DR. KLEINPETER: Nothing else to add.

8 CO-CHAIR ANDERSON: Committee
9 discussion? Josh.

10 DR. ZARITSKY: I'm going to include
11 some other --- you know, in 1a.8(2), there's some
12 additional evidence presented also. There's some
13 additional evidence presented also in 1.8(2) that
14 I think we've brought up before in a previous
15 measure.

16 CO-CHAIR ANDERSON: Any further
17 discussion? Let's call for the vote on evidence.

18 MS. OGUNGBEMI: The Committee is now
19 voting on evidence for Measure 1424. The options
20 are 1 high, 2 moderate, 3 low, and 4
21 insufficient. The voting is open. The results are
22 three votes high, 19 votes moderate, one vote

1 low, and zero votes insufficient. Measure 1224
2 passes on evidence.

3 CO-CHAIR ANDERSON: All right. Moving
4 on to the performance gap.

5 MS. WAGER: On performance gap, based
6 on 2013 CROWNWeb clinical data from January 2013
7 to December 2013, there's a quartile range of 22
8 percent, the mean and medium performance scores
9 were 75 and 85 percent, with an inter-quartile
10 range of 22 percent. Again, there's a gap due to
11 the sample size used for the performance scores
12 were considered too small to display useful
13 disparities.

14 CO-CHAIR ANDERSON: Myra.

15 DR. KLEINPETER: Nothing else to add.

16 CO-CHAIR ANDERSON: Discussion on the
17 part of the Committee? Call for a vote on
18 performance gap.

19 MS. OGUNGBEMI: The Committee is now
20 voting on performance gap, Measure 1424. Options
21 are 1 high, 2 moderate, 3 low, and 4
22 insufficient. Voting is open. The results are two

1 votes high, 18 votes moderate, one vote low, and
2 zero votes insufficient. Measure 1424 passes on
3 performance gap.

4 CO-CHAIR ANDERSON: All right.
5 Reliability testing.

6 MS. WAGER: Reliability testing
7 demonstrates that the measured data elements are
8 repeatable, on the measures collectively of
9 CROWNWeb and the specifications described data
10 element identification criteria, clearly. The
11 measure is not risk-adjusted.

12 CO-CHAIR ANDERSON: Myra.

13 DR. KLEINPETER: Nothing else to add.

14 CO-CHAIR ANDERSON: Further discussion
15 on the part of the Committee? Lorien.

16 DR. DALRYMPLE: Can I just ask one
17 quick question. So, if children are hospitalized
18 they're not excluded. Is that correct? And the
19 only reason I bring that up is the N is so small
20 in the pediatric practices, so the unit would be
21 perceived not to have measured a hemoglobin if,
22 in fact, it was because the child was

1 hospitalized. And maybe those hemoglobins get put
2 in and counted.

3 DR. KLEINPETER: So, it all depends on
4 when the unit measured the lab value. If they
5 were hospitalized and did not receive the minimum
6 number of treatments for that month, it would not
7 be included, otherwise, it is included.

8 DR. KRISHNAN: It's not put in, though.
9 So, there was a point in time over 2013 where
10 patients were --- we were instructed to auto
11 discharge patients, so if patients were in the
12 hospital for a prolonged period of time in
13 CROWNWeb, we were instructed to auto discharge
14 them so that they didn't come up with errors.

15 So, the probability that that happened
16 is there, and then on top of that --- I won't
17 tell you specifically that labs are consistently
18 reentered, right, because there's now a monthly
19 close for CROWNWeb, so we have to get the data
20 back in a certain period of time, then put it in
21 before it's closed. So, there's a lot of
22 ambiguity there.

1 And this is just --- my concern is
2 this metric --- I know we've talked about
3 CROWNWeb data transmission issues. This metric
4 will emphasize those data transmission issues.
5 Maybe that's what it is, it's measuring --- it's
6 assuming that the data reflects reality and that
7 the lab wasn't drawn, not that the lab was drawn
8 and not transmitted, if that makes sense.

9 CO-CHAIR ANDERSON: Michael.

10 DR. SOMERS: I think at least for the
11 children who are dialyzed in pediatric dialysis
12 facilities, since the vast majority of them are
13 associated with the center or actually physically
14 in the center where they'd be hospitalized, I
15 think you wouldn't lose those hemoglobin values.
16 I can't comment on facilities outside of that.

17 DR. MESSANA: So, this CROWNWeb-based
18 data, it's based on patient being admitted to the
19 facility for a month, and Mahesh's statement
20 regarding discharge for prolonged
21 hospitalizations, if a patient was hospitalized,
22 I think, for over a month, or some value like

1 that, they were discharged from the facility.
2 Right? But short of that, they would be
3 considered in the facility if they were
4 hospitalized for 25 days. There might be a
5 missing related to prolonged hospitalization and
6 missed monthly blood draws.

7 Regarding the data transmission issue
8 that Dr. Krishnan brings up, so whatever effect
9 that has, dependent upon --- differing from
10 organization to organization, when you compare
11 adult CROWNweb months with a hemoglobin value to
12 the pediatric, there is a significant difference.
13 The adults are much higher, so there's something
14 well beyond this data transmission issue that
15 Mahesh brings up. The gap is larger for the
16 pediatric patients than it is for the adult
17 patients.

18 DR. DALRYMPLE: But couldn't that be
19 because in pediatrics just one patient will make
20 your number look quite different. If you have an
21 N of 12 in your unit, one or two children can
22 drastically change your statistics. And adults,

1 you know, we have 100 patients, so ---

2 DR. MESSANA: I'm talking patient-level
3 analysis, the total ---

4 DR. DALRYMPLE: The number of
5 hemoglobins available, though. Is that correct?

6 DR. MESSANA: Yes.

7 DR. DALRYMPLE: So, a facility's
8 percentage could quickly drop with just one child
9 missing.

10 DR. MESSANA: It could --

11 DR. DALRYMPLE: Is that correct?

12 DR. MESSANA: -- but the statement
13 that I'm making about a gap is a patient level
14 analysis, national patient level analysis. There
15 is something greater --- there's a greater
16 shortfall of patient months with a hemoglobin in
17 the pediatric population, not in the population
18 of pediatric facilities.

19 CO-CHAIR CROOKS: Just one comment.
20 This, unlike other pediatric measures, this does
21 not exclude facilities with less than 11
22 patients. Right? This is all pediatric patients

1 which is, I guess, in its favor compared to some
2 of the other ones.

3 DR. KLEINPETER: It still states that
4 includes those that had 11 ---

5 CO-CHAIR CROOKS: 11 or more?

6 DR. KLEINPETER: 11 or more.

7 CO-CHAIR CROOKS: Oh.

8 DR. KLEINPETER: It's only 59 of the
9 facilities had 11 people to report.

10 CO-CHAIR CROOKS: So, why would you
11 need that, for just knowing that it was measured?

12 DR. MESSANA: Consistency sake in terms
13 of small cells. We performed the analyses that
14 way to be --- so that the information was
15 consistent for you to consider.

16 CO-CHAIR ANDERSON: All right. Are we
17 ready to vote for specifications and reliability?

18 MS. OGUNGBEMI: The Committee is now
19 voting on reliability for Measure 1424. The
20 options are 1 high, 2 moderate, 3 low, and 4
21 insufficient. Voting is open. The results are
22 zero votes high, 22 votes moderate, one vote low,

1 and zero votes insufficient. Measure 1424 passes
2 on reliability.

3 MS. WAGER: On feasibility, our data
4 source for measure is CROWNWeb and ---

5 MS. BAL: Hold on.

6 MS. WAGER: I'm sorry.

7 MS. BAL: We're on validity.

8 MS. WAGER: I apologize. Again, data
9 from CROWNWeb from January 2013 to December 2013,
10 calculate facility level monthly and annual
11 performance scores. Again, as Myra stated, it was
12 59 facilities and at least 11 eligible patients.
13 And that included 1,280 patients in total during
14 the testing.

15 Spearman correlation to assess the
16 association between the annual performance scores
17 and the NQF endorses standard mortality ratio
18 using the 2013 SMR. Measure is maintained on the
19 basis of face validity, the measure of hemoglobin
20 as a dialysis quality measure was initially
21 developed and approved by clinical TEP, which
22 agreed that this is a quality measure.

1 CO-CHAIR ANDERSON: Myra.

2 DR. KLEINPETER: They also reported
3 that the Spearman correlation coefficient was -
4 .20 to P value .13, so those patients that had a
5 higher percent of pediatric patients, the
6 measures associated with a lower risk of
7 mortality relative to those facilities with a
8 lower percentage of pediatric patients where
9 there's hemoglobin values measured. But it was
10 not statistically significant.

11 CO-CHAIR ANDERSON: Any further
12 discussion? All right. We're ready to vote on
13 validity.

14 MS. OGUNGBEMI: The Committee is now
15 voting on validity for Measure 1424. The options
16 are 1 high, 2 moderate, 3 low, and 4
17 insufficient. Voting is open. The results are
18 zero votes high, 22 votes moderate, one vote low,
19 and zero votes insufficient. Measure 1424 passes
20 on validity.

21 CO-CHAIR ANDERSON: All right, Bobbi,
22 now you get feasibility.

1 MS. WAGER: Again, our data source for
2 measure is CROWNWeb, the data is collected and
3 generated and use by health care professional
4 during the provision of care.

5 DR. KLEINPETER: Nothing else to add.

6 CO-CHAIR ANDERSON: Any further
7 discussion by the Committee? All right, ready to
8 vote on feasibility.

9 MS. OGUNGBEMI: The Committee is now
10 voting on feasibility for Measure 1424. The
11 options are 1 high, 2 moderate, 3 low, and 4
12 insufficient. Voting is open. The results are 14
13 votes high, seven votes moderate, one vote low,
14 and zero votes insufficient. Measure 1424 passes
15 on feasibility.

16 CO-CHAIR ANDERSON: Moving on, use and
17 usability.

18 MS. WAGER: On usability, the
19 information we got, it stated the measure is not
20 currently in use, but is available for public
21 use. On our conference call, I believe that
22 someone had stated that Network 13 is collecting

1 data.

2 DR. KLEINPETER: So, nothing else other
3 than we look at it among our pediatric population
4 because it was a special project in our network.

5 CO-CHAIR ANDERSON: Any further
6 discussion?

7 CO-CHAIR CROOKS: Are there --- I'd
8 like to ask the developers, are there plans for
9 using this in the future?

10 DR. MESSANA: I'm not aware of plans,
11 but I'm also not aware of a lot of things that go
12 on 7500 Security Boulevard, so ---

13 (Laughter.)

14 CO-CHAIR CROOKS: Well, let me ask the
15 Committee Members, in the submission did they
16 make a case for future use, public reporting or
17 accountability? I don't think that they did. I
18 have it here.

19 CO-CHAIR ANDERSON: John.

20 DR. WAGNER: I was just curious, since
21 we have this high percentage of patients who are
22 not entering --- who are not being tested for

1 either calcium, phosphorous, and hemoglobin, are
2 there -- will there be unintended consequences?
3 Is the reason that those tests are not being done
4 that it is difficult for the patients to present
5 for blood draws and-or difficulty in
6 venipuncture? Do we understand anything about
7 that?

8 CO-CHAIR ANDERSON: Any comments?

9 DR. KLEINPETER: So, just the only
10 comment, that they're on hemodialysis, we get it
11 as part of their regular monthly blood draw. The
12 issue is that they're in the hospital, or if
13 they're on home hemo and the parent or care giver
14 forgets to collect it. Those are our missing
15 values for our --- among our pediatric patients.

16 CO-CHAIR CROOKS: I just have to say
17 that I'm puzzled by why you would want to go
18 through the trouble of having a measure endorsed,
19 and then there's no planned use for the measure.
20 I'm a little puzzled what the reason for that is.

21 DR. MESSANA: So, I think the question
22 is well taken. There have been a couple of things

1 that we've been assessing at CMS. The first is,
2 you know, I think you've seen some of the
3 consequences of just how to address assessing the
4 pediatric population with measures, the minimum
5 case size presents some issues any time you have
6 a measure that is specific to the pediatric
7 population, so there's that, and considering how
8 best to use the measure.

9 I think the other concern is --- or
10 not concern but issue is that there's an
11 increasing focus on measures that assess
12 performance of care as opposed to reporting of
13 data. I think the distinction here, which causes
14 some conversations internally to CMS, that are
15 still kind of being hashed out.

16 In terms of the measure itself, my
17 position on that would be that, you know, where
18 there is a --- no clear gap --- where there is a
19 gap in terms of data being available for a
20 process measure like this, or for data being
21 collected, I think it makes sense to have the
22 measure available. It has been used for --- by

1 different --- by the networks and is available
2 for use by other bodies, as well, regardless of
3 its implementation by CMS. And I think that its
4 availability for that use certainly continues to
5 make sense.

6 CO-CHAIR ANDERSON: Mahesh.

7 CO-CHAIR CROOKS: You've got carditis,
8 too.

9 CO-CHAIR ANDERSON: All right. I think
10 we're ready to call for the vote on usability and
11 use.

12 MS. OGUNGBEMI: The Committee is now
13 voting on usability and use for Measure 1424. The
14 options are 1 high, 2 moderate, 3 low, and 4
15 insufficient. Voting is open. The results are two
16 votes high, 17 votes moderate, one vote low, and
17 three votes insufficient. Measure 1424 passes on
18 usability and use.

19 CO-CHAIR ANDERSON: All right. Is there
20 any further discussion before we vote on
21 recommendations for endorsement and the overall
22 suitability for recommendations for endorsement?

1 All right, let's call for the vote.

2 MS. OGUNGBEMI: The Committee is now
3 voting on overall suitability for endorsement for
4 Measure 1424. Options are 1 yes/2 no. Voting is
5 open. The results are 22 votes yes, one vote no.
6 the measure passes meeting NQF criterias for
7 endorsement.

8 CO-CHAIR ANDERSON: Moving on ---

9 CO-CHAIR CROOKS: Keep going.

10 Obviously, you're better than I am. You're moving
11 things --- obviously, you're the better
12 facilitator for this, so please go ahead with 16
13 ---

14 CO-CHAIR ANDERSON: No, 2699, and it's
15 Joe. Are you by yourself again?

16 DR. MESSANA: No. Dr. Doug Schaubel
17 flew in today. He's the biostatistician who is
18 the lead statistician on the transfusion metric,
19 so he joined me in case there are any technical
20 questions. I would like to take the two to three
21 minutes allotted to developers for this measure,
22 because I think I have a bit of perspective and

1 history that may help answer some of the
2 questions that were raised during the work group.
3 And I prepared a written statement.

4 The transfusion ratio measure is a
5 direct product of the 2012 anemia TEP that I
6 facilitated. TEP members included Jeff Berns, who
7 is the Chair, Klemen Meyers, John Stivelman, the
8 late Kathe LeBeau, Diana Hlebovy, I always
9 mispronounce her name, I apologize again to her.
10 Sheila Doss-McQuitty, Dr. Robert Kane, and Dr.
11 Harvey Luxemburg both from the Food and Drug
12 Administration. They were non-voting participants
13 of the TEP. There was a pediatrician who was
14 supposed to participate but couldn't because of a
15 family emergency.

16 So, the context for the 2012 TEP, as
17 most of you know, included emerging safety
18 concerns about the use of aggressive hemoglobin
19 targets and high doses of ESA at approximately
20 the same time that a fundamental revision to the
21 Medicare ESRD PPS bundle was made that shifted
22 financial incentives and clinical incentives from

1 more use of ESA to less use of ESA. The TEP's
2 concern was largely in protecting patients from
3 both overuse and under-use of ESAs, and I think
4 some of that discussion from the RPA measure
5 discussed a few minutes ago kind of reflects some
6 of those concerns.

7 Also, the 2011 revised FDA package
8 insert for EPO, which included a statement about
9 transfusion avoidance being one of the major
10 goals of EPO therapy in this population was
11 reviewed by the TEP. The deliberations. First,
12 the TEP reaffirmed the dialysis facility central
13 role in anemia management. They recommended three
14 measures, hemoglobin less than 10, hemoglobin
15 greater than 12, and a risk-adjusted transfusion
16 measure.

17 Regarding the relationship between
18 anemia management and transfusion, the TEP was
19 impressed by the impact the introduction of ESAs
20 and the evolution of anemia management practices
21 have had on transfusion rates in dialysis
22 patients from the initial reports of Eschbach and

1 Neil Powe over two decades ago, the secondary
2 outcome from some of the larger clinical trials,
3 the Canadian and European trial, in particular.

4 They used the paradigm that the
5 decision to transfuse a patient is based on
6 clinical judgment, but that that clinical
7 judgment depended on both the patient's achieved
8 hemoglobin and the clinical context, be it
9 planned surgery, unplanned surgery, GI bleeding,
10 et cetera. They felt that the clinical context
11 was often not under the dialysis facility's
12 control, but the hemoglobin concentration often
13 was.

14 A major area of discussion related to
15 which comorbidities and events should comprise
16 the exclusion list. The TEP recommendations for
17 exclusions were followed in development of this
18 measure. They settled on an exclusion list that
19 reflected conditions that were very likely to
20 result in decreased ESA responsiveness, and were
21 also conditions that may well reflect either
22 strong relative or absolute contraindications to

1 ESA use in many cases.

2 They explicitly chose not to recommend
3 inclusion of other diagnoses, such as GI
4 bleeding, and other conditions to the list.
5 Regarding the identification of transfusion
6 events in Medicare claims which has come up in a
7 work group discussion and public comments, the
8 TEP should not be held responsible.

9 That was an implementation issue, and
10 we developed the methodology, based on American
11 Red Cross transfusion billing guidelines
12 published within the last several years. This
13 technique has been used extensively by Dr.
14 Collins and colleagues to publish several
15 research papers in peer reviewed clinical
16 journals over the last five years, and to support
17 Dr. Collins' presentations at national meetings
18 on the topic of increasing transfusion rates
19 subsequent to 2011.

20 The methodology's validation has been
21 limited to one article that I could find from
22 2000 or 2001 from Dr. Powe's group describing the

1 high specificity and moderate sensitivity of
2 identifying transfusions through these claims
3 when compared to electronic medical record system
4 review in a single large referral medical center.
5 I'll stop there.

6 CO-CHAIR ANDERSON: Thanks. And the
7 discussants are Dodie and John. John.

8 DR. WAGNER: Thank you. I will lead
9 off. So, we have the standardized transfusion
10 ratio, and the numerator statement is the number
11 of eligible observed red blood cell transfusion
12 events, and they are defined, as we've just heard
13 from revenue codes, procedures codes. And the
14 denominator is the number of eligible red blood
15 cell transfusion events as defined in the
16 numerator statement that would be expected, so
17 there is a statistical modeling of the expected
18 events, and a ratio is created around those.

19 The evidence to support this is based
20 on KDIGO in 2012. There are three guidelines
21 cited, two of them have to do with reducing blood
22 transfusions as a goal with 1b evidence, and one

1 of them has to do with managing chronic anemia
2 without excessive risk of ESAs, and, therefore,
3 in such instances where there's a concern, red
4 cell transfusions may be preferred. And that
5 evidence is rated 2c.

6 There were also 17 articles reviewed
7 by the TEP, and many of those have to do with
8 issues related to the reduction in transplant
9 suitability resulting from aloe sensitization,
10 and hemoglobin target analyses. So, there really
11 is not the risk tradeoff as to what would be the
12 ideal use of ESA versus the risk-benefit ratio of
13 transfusing is not cited in any of the
14 literature. So, that is the evidence. As far as
15 the performance gap goes, there is a listing ---

16 CO-CHAIR ANDERSON: John, I think we'll
17 just ---

18 CO-CHAIR CROOKS: Yes, hold on a
19 minute.

20 CO-CHAIR ANDERSON: Yes, we'll just do
21 the evidence for right now.

22 DR. WAGNER: Okay.

1 CO-CHAIR ANDERSON: Dodie.

2 DR. STEIN: There was one statement
3 about there are no empiric data per se, but
4 transfusions are considered suboptimal care,
5 therefore, the adverse outcomes and things.

6 CO-CHAIR CROOKS: Okay. So, this
7 measure is claimed to be an outcome measure and,
8 in fact, this is an outcome measure. I think it's
9 the only one that's been presented to us that
10 really is an outcome measure in the sense that
11 it's --- they didn't claim it to be an
12 intermediate outcome.

13 So, the burden of evidence is
14 different in an outcome measure, and it's not to
15 show --- link it to mortality or other outcomes,
16 but it's to show that it can be changed by
17 something up stream, a process, an intervention.
18 And I don't think they approached it that way, so
19 it left me a little confused. So, I'd like to ask
20 developers what you were thinking about, or am I
21 misreading your application?

22 DR. MESSANA: Well, maybe we weren't as

1 explicit as we should have been. There were ---
2 the TEP was presented with information about
3 achieved hemoglobin and subsequent transfusion
4 risk in the subsequent quarter after an average
5 hemoglobin in the preceding quarter, which showed
6 an inverse relationship between transfusion
7 events and that prior achieved hemoglobin.

8 In addition, since the TEP, and as
9 part of the submission, Dr. Collins presented a
10 facility-level publication in 2014 in American
11 Journal of Kidney Disease dividing achieved
12 facility-level hemoglobin by quintiles and
13 looking at transfusion risk, showing that that
14 achieved hemoglobin was predictive of subsequent
15 transfusion rates at the facility. That's the
16 only additional evidence that I would offer to
17 suggest that there is an intermediate outcome
18 that is fairly significantly associated with
19 transfusion events.

20 CO-CHAIR CROOKS: So, maybe making the
21 case that how you manage anemia will impact this
22 outcome?

1 DR. MESSANA: That was the belief and
2 the intent of the TEP when they recommended this
3 measure.

4 CO-CHAIR CROOKS: Just like mortality
5 as an outcome, we know zero mortality isn't
6 achievable. Is there a target transfusion ratio
7 that we --- the units should be striving for? Is
8 one the right ratio?

9 DR. MESSANA: Well, one is ---
10 describes the average, if you will, use of
11 transfusions by peer facilities in a risk-
12 adjusted rate within that particular year, so
13 it's like the standardized mortality ratio,
14 standardized hospitalization ratio, it is a
15 relative ranking of transfusion use in that year,
16 adjusted for patient and facility characteristic.

17 CO-CHAIR CROOKS: Right. So, you know,
18 I'm --- I know that mortality, it's better to
19 have less, you know. And is there a --- is it
20 best to have no transfusions, or have a zero? I
21 mean, what is the target, if this is an outcome?
22 Which way are we trying to move this outcome?

1 DR. MESSANA: I think that that's a
2 question that's more appropriate for the group,
3 but since you directed it at me, I would suggest
4 that lower rates would, generally, be better.
5 There may be some exceptions, particularly in
6 patients that are not good candidates for ESA
7 use, and I think for the most part those are
8 addressed by the exclusions. About 20 percent of
9 patients are covered by exclusions in any given
10 year, 19-20 percent, something like that.

11 CO-CHAIR CROOKS: To help you do your
12 work, I do think this is an important outcome.
13 It's an important measure, and I think the case
14 that you should have probably made to us is this
15 outcome, standardized transfusion ratio is
16 related to how you manage anemia, processes up
17 stream do affect it, and to make that link for us
18 in a very clear way. Then I think the discussion
19 on evidence is over. It's not --- it doesn't have
20 to link to other outcomes. So, I'll stop beating
21 that horse, and open it up to the floor for
22 discussion of the evidence.

1 CO-CHAIR ANDERSON: Alan.

2 DR. KLIGER: Just very quickly, it's
3 hard for me to imagine this as an outcome
4 measure. It's either an intermediate outcome, or
5 a process measure. We're not seeking to have a
6 ratio. I mean, that's not an outcome.

7 Furthermore, the standardized
8 measures, Peter, as you pointed out, we have to
9 be very careful about understanding what those
10 mean. A standardized hospitalization or mortality
11 ratio, the direction of that, and the goal of
12 that looks fairly clear. But if you talk about
13 things like a standardized infection ratio, for
14 example, we'll be talking about that later,
15 achieving the same level that everybody else in
16 the country achieves, gosh, I don't want to be
17 judged if my medical center, that we're so good
18 with infections that we're just as bad as
19 everybody else.

20 The standardized infection ratio
21 doesn't make a whole lot of sense to me. A
22 standardized transfusion ratio is only useful, as

1 you point out, to understand what direction
2 you're going in, and why. I'm not certain that
3 zero transfusions are right. I'm also not certain
4 that high transfusions are wrong. I don't know.
5 So, I think this is sort of a process measure,
6 and I think we should judge it according to the
7 standard route for a process measure.

8 CO-CHAIR ANDERSON: Josh.

9 CO-CHAIR CROOKS: Well, they did claim

10 ---

11 CO-CHAIR ANDERSON: Oh.

12 CO-CHAIR CROOKS: I'm sorry, just to
13 finish the conversation.

14 CO-CHAIR ANDERSON: Sorry.

15 CO-CHAIR CROOKS: They do claim it's an
16 outcome measure, and even in the evidence section
17 they checked the box outcome measure. And I can
18 see it that way, I can see it as parallel to
19 standard hospitalization ratio, mortality ratios,
20 and so on, but that's the case they're trying to
21 make, I think.

22 DR. KRISHNAN: I have a question on

1 that very specific aspect. When we started this
2 conversation, we said that two of the measures,
3 SHR and SMR were moved into the future because
4 they're looking at the --- sorry, because they
5 were moving the SMR and SHR further up, because
6 we're looking at the risk adjustment methodology.
7 Is this the same risk adjustment methodology, or
8 different?

9 DR. MESSANA: No. There --- so, the
10 risk adjustment strategy for this metric, in
11 addition to incident comorbidity is 27-28
12 comorbidities which are included in the first
13 level, the patient-level metric. The risk
14 adjustment strategy is the exclusion of
15 approximately 20 percent of patients with
16 comorbidities from prevalent comorbidity claims
17 that are associated with malignancies, sickle
18 cell anemia, other acquired --- excuse me, other
19 hereditary hemoglobinopathies, so in addition to
20 the incident comorbidity adjustments, there are
21 prevalent comorbidity adjustments from Medicare
22 claims.

1 DR. KRISHNAN: So, this is sort of a
2 hybrid between the two?

3 DR. MESSANA: Well, it has additional
4 ---

5 DR. KRISHNAN: So, will the
6 deliberations that you have for the SMR and SHR
7 affect this risk adjustment methodology, as well,
8 or should we not think that way?

9 DR. MESSANA: Don't know. The SHR and
10 SMR TEP is charged with addressing those. I
11 suppose that depending upon where that discussion
12 goes, who knows. I can't predict the future, and
13 I don't think you should make any decisions based
14 on that statement.

15 CO-CHAIR ANDERSON: Okay. Josh.

16 DR. ZARITSKY: I have a real problem
17 with this as an outcome measure, and that really
18 affects how you're going to judge the evidence.
19 And going toward the evidence, you know, for the
20 denominator, you know, what's the evidence that
21 that denominator is valid in this --- I mean,
22 there should be some evidence presented that

1 there's --- that that denominator has some
2 validity.

3 I guess I'm asking for evidence that
4 there is --- you know, what is the evidence that
5 this is a valid measure, that there is a
6 standardized expected transfusion ratio in this
7 population? I mean, I could stop with number one,
8 the outcome. You know, I want to know is it an
9 outcome versus intermediate, and then I'm just
10 having a hard time --- I'd like to see some
11 evidence here using this standardized --- maybe I
12 just don't know it because I'm not an adult
13 nephrologist, that this standardized transfusion
14 --- expected transfusion has validity --- you
15 know, there's evidence for its use in this
16 population.

17 DR. MESSANA: So, Doug, do you want to
18 try to comment? I'm not sure I understand the
19 question, but Doug apparently does.

20 DR. SCHAUBEL: I'm not totally sure I
21 understand either, but just a comment pertaining
22 to your question, is that the --- so, every

1 center is observed, transfusions are compared to
2 the expected, and that's the same general
3 procedure as what's used in mortality and
4 hospitalization. And, ideally, perhaps you'd like
5 to be much lower than expected, and perhaps what
6 happens at the national level is not really the
7 target because it should be lower in the nation
8 as a whole. But at the end of the day, I'd say as
9 a target, it's a way to compare each center in a
10 uniform way.

11 DR. ZARITSKY: How do you --- just tell
12 me since I don't know, how do you calculate the
13 expected, then?

14 DR. SCHAUBEL: Yes. So, it's
15 considering the patient characteristics and the
16 national --- there's a baseline rate which is
17 independent of patient characteristics which
18 applies to everybody, which applies to every
19 patient across the country. And then that
20 patient's characteristics scale up what the
21 expected is for that patient, either scales it up
22 or scales it down, depending on what those

1 characteristics are. And then the sum is taken
2 for every patient within that center to come up
3 with that expected count, which is then compared
4 to the observed. That's the same --- in a general
5 sense, that's the same as the SMR and the SHR.

6 CO-CHAIR ANDERSON: Frank.

7 DR. MADDUX: So, I'll ask Joshua's
8 question a little bit differently, but similarly
9 to colleagues on the Committee and others. I
10 don't understand why a standardized ratio is
11 appropriate for this particular measure, because
12 I believe that if we're looking at trying to
13 understand both the distribution of transfusions
14 and the rationale for transfusions, I don't
15 understand how this particular measure actually
16 gives us complete clarity, other than we know
17 that you can rank them across a distribution
18 against an expected range.

19 And I can tell you without any
20 transfusion guidelines, unlike there may be in
21 hospitals for cardiac surgery, I know of no
22 transfusion guidelines for end stage renal

1 disease patients. It's very much a one by one
2 decision, so I'm just struggling with the
3 rationale of creating the standardized ratio and
4 the evidence that supports in another way what an
5 expectation should be.

6 CO-CHAIR ANDERSON: Andy.

7 DR. NARVA: Yes. I think, you know,
8 what this reflects is an assessment of management
9 of anemia, and we're often looking for ways of
10 improving quality of care while at the same time
11 promoting individualized decisions. And I think
12 that this sort of measure, which really gets at
13 avoidance of anemia, avoidance of transfusion
14 really has that built in. And I think the lack of
15 a guideline on transfusion isn't necessarily a
16 negative thing. Here I think that this allows ---
17 some patients clearly are candidates for
18 transfusion, some patients aren't.

19 In general, we try to avoid
20 transfusion and that's --- even the FDA agrees
21 with that, so I think this sort of is ---
22 embodies the opportunity to improve care while

1 at the same time promoting sort of individualized
2 patient decisions. And I don't know how that fits
3 into the outcome versus process measure, but I
4 think it allows us --- in some ways it may be the
5 best reflection of quality management of anemia.

6 And I also think --- you know, I'm
7 sure many people here have been on medical review
8 boards and networks, but these ratios are
9 extremely good at identifying outliers, at least
10 for the examination of quality issues. And I
11 think that's an important purpose, presumably, of
12 this measure.

13 CO-CHAIR ANDERSON: Lorien.

14 DR. DALRYMPLE: And I think I have more
15 of a procedural clarification question, for
16 perhaps Sarah or the Chairs. So, have we come to
17 agreement on what type of measure this is, as to
18 whether it's an outcome or an intermediate
19 clinical outcome? Because I think that would
20 then help the Committee have an active discussion
21 about whether we're grading, or voting yes/no.

22 And then when there are these

1 methodologic issues, especially with standardized
2 ratios which are inherently complicated and risk-
3 adjusted, should we be conferring some of that
4 discussion to the reliability and specifications
5 where we all argue about the merits of
6 biostatistical techniques to report meaningful
7 data, of which there are many choices, or do we
8 need to be discussing that in the evidence?

9 MS. SAMPSEL: Okay, so that's two
10 questions. First question, process or outcome?
11 The developers have submitted this as an outcome
12 measure. They did attempt to provide a link,
13 which is the NQF requirement between a process of
14 care and an outcome. They are indicating the
15 outcome that they are, you know, assessing
16 measurement of as transfusion, so, you know, I
17 think that Dr. Narva said it correctly, that this
18 is kind of management of anemia to prevent
19 transfusion as the outcome. Correct me if I'm
20 interpreting that incorrectly.

21 DR. MESSANA: I think that reflects our
22 opening statement, and the introductory statement

1 in the application.

2 MS. SAMPSEL: So, you are --- you will
3 when you vote on this, you'll evaluate this based
4 on the question, does the rationale that was
5 provided support the relationship of the health
6 outcome of a transfusion to at least one health
7 care structure, process, intervention, or service
8 as provided in the evidence?

9 Your second question regarding two
10 discussions on the methodology, the statistics,
11 that fun conversation I'm sure is going to happen
12 under reliability and validity.

13 CO-CHAIR ANDERSON: Michael.

14 DR. FISCHER: Just going back to what
15 Frank said, and if you look at, again, the
16 algorithm we used, you know, if it is an outcome
17 measure, then really it's pass or no pass. And I
18 think there's no ambiguity when you think of SHR
19 and SMR, in terms of the opinion that higher is
20 worse.

21 But this is a case where I think that
22 there's a lot more ambiguity about higher --- if

1 you're higher, if your standardized transfusion
2 ratio happens to be higher, is that unambiguous
3 that that reflects a problem with quality of
4 car,, and that there's a process or a structure
5 that needs to be changed to improve quality? And
6 I guess that's why I have --- I distinguish this
7 from the aforementioned two ones that I mentioned
8 because, to me, I think there's a lot more
9 ambiguity and uncertainty about how it's
10 interpreted, and, hence, what a facility is
11 supposed to do in terms of quality of care.

12 CO-CHAIR ANDERSON: Lisa.

13 DR. LATTIS: Well, and it's sort of ---
14 Michael, in response to that, I think that it is
15 one of those measures that you have to get away -
16 - you can't think of it as higher or lower, as
17 better or worse. It's only an observed versus
18 expected, and it's very --- that's why it's
19 critical that whoever is doing the measuring then
20 does the expected accurately, and you as a
21 facility, or whoever is submitting it, won't know
22 until you get the data crunched whether --- how

1 you performed.

2 Because you won't know until you know
3 how your relationship is from observed to
4 expected, because it's not supposed to be low,
5 it's not supposed to be high. It's your
6 relationship of that observed to expected that is
7 the key outcome. And it's a very uncomfortable
8 place to be, because you don't know if you're
9 supposed to be high or low.

10 CO-CHAIR CROOKS: I'd like to suggest
11 a way forward, and that is let's accept the
12 application that this is an outcome measure, and
13 let's vote based on the evidence, based on that
14 they have or you believe there's a linkage to a
15 service, an intervention, health care structure,
16 or process. And let's just vote on it that way,
17 because that's what they're asking us to do. It's
18 not necessary for them to link it to other
19 outcomes. And in my opinion, the case is made, or
20 I'm going to give them that in my own personal
21 opinion. But I think we should just vote on it
22 that way, and then we can move on from there.

1 Does that make sense?

2 CO-CHAIR ANDERSON: I'd just like to
3 make one other comment, and that's where it's at
4 a facility level, this measure is at a facility
5 level. And dovetailing on what you said, Michael,
6 I'm not sure that's where the right place is. If
7 this shouldn't be at a clinician level versus the
8 dialysis facilities, because many of the
9 facilities aren't doing standardized, or blood
10 transfusions, within their facility. They're
11 sending their patients to the blood bank, or
12 wherever, so I have concerns about it being a
13 facility-level measure.

14 DR. MESSANA: The reason that this is
15 a facility-level measure, and the TEP felt very
16 strongly about this, dialysis facilities are held
17 responsible under the CFC 494 regulations for
18 anemia management. Dialysis facilities are paid
19 for anemia management, and are the sole source
20 for administration of ESAs in chronic dialysis
21 patients on Medicare. And the TEP felt very
22 strongly that anemia management contributed to

1 the decision to transfuse because achieved
2 hemoglobin in, you know, different clinical
3 context was a main contributor to a decision to
4 transfuse given the situation, or given the
5 clinical context. That's why they supported this
6 or they recommended this as a dialysis facility
7 level metric.

8 CO-CHAIR ANDERSON: But I guess I would
9 also argue that it's the clinician's decision to
10 transfuse. It's not the facility's level to make
11 that decision whether or not to transfuse the
12 patients.

13 DR. MESSANA: I accept that, but the
14 clinician uses --- it's the accepted standard of
15 practice for me to transfuse a patient who has
16 some absolute achieved hemoglobin threshold, and
17 the achieved hemoglobin threshold is at least
18 partially in most situations under the facility's
19 control and responsibility.

20 There are situations where the
21 achieved hemoglobin that you would choose to ---
22 that I, as a clinician, would choose to

1 transfuse is going to be different than an
2 absolute that Red Cross would set based on active
3 GI bleeding or other conditions. But still the
4 achieved hemoglobin in almost every decision I've
5 ever made to transfuse is a major contributor, a
6 major clinical input, to that decision.

7 CO-CHAIR CROOKS: Lisa.

8 DR. LATTIS: Just one quick sort of
9 comment and, again, from sort of an outsider
10 perspective as I'm looking at this, is that this
11 might be a nice compromise if you can
12 operationalize it, which maybe you can't. If you
13 don't know what the hemoglobin targets are, if
14 they should be 8, 9, 10, or something, or none if
15 we can't come up with a target, maybe an observed
16 to expected is a better way to measure it.

17 CO-CHAIR ANDERSON: All right. Are we
18 ready to call for the vote based on evidence?

19 CO-CHAIR CROOKS: We're linking the
20 outcome to process, structure, intervention.

21 MS. OGUNGBEMI: The Committee is now
22 voting on evidence as an outcome measure. The

1 options are 1 yes, 2 no. This is for Measure
2 2699. Voting is open. The results are one or 12
3 votes yes, 10 votes no. The Measure 2699 is a
4 gray zone measure for evidence.

5 CO-CHAIR ANDERSON: So, performance
6 gap. John.

7 DR. WAGNER: Okay. So, gee, I was
8 hoping --- oh, well. So, there is based on the
9 STRRs reported from 2009 through 2012, a
10 performance gap in comparing, for example, inter-
11 quartile range of about 0.6 to 0.7 each year. And
12 there were also analyses of disparities, there
13 was some statistically significant changes in
14 transfusion ratios obtained when viewing females,
15 Native Americans, Asians, Blacks, other race
16 versus --- and Hispanics, which were not felt to
17 be clinically significant in that when one
18 adjusted for those, the STRR seemed to have the
19 same results.

20 CO-CHAIR ANDERSON: Dodie, anything
21 else? Any other comments for the Committee?

22 CO-CHAIR CROOKS: The only other

1 consideration for performance gap is you sort of
2 need a target to say there's a gap, and there's a
3 dispersion of results. And if the idea is that's
4 a gap because everybody should be coming together
5 close to one, okay, but then that suggests that
6 the target is one. So, gap is a little hard to
7 interpret. I do agree that there is dispersion of
8 results.

9 CO-CHAIR ANDERSON: Okay. Mahesh.

10 DR. KRISHNAN: I just --- one thing I
11 didn't understand, maybe get the Committee's
12 input. If the standardized, mean standardized
13 transfusion rate hasn't really changed, if I read
14 this correctly, all that much from 2009 to 2012,
15 you guys just described the mean hemoglobin has
16 gone down, how do we reconcile those two?

17 (Off microphone comment.)

18 DR. KRISHNAN: But we're saying it's a
19 surrogate for hemoglobin, but we know that the
20 mean hemoglobin has gone down. If the mean
21 hemoglobin has gone down for the country and this
22 measure hasn't changed, how does that --- that

1 doesn't seem to correlate.

2 CO-CHAIR ANDERSON: Alan.

3 DR. KLIGER: A transfusion ratio just
4 describes variation around the mean of the
5 country. And it's hard for me to understand what
6 a performance gap means given that kind of a
7 measure. I don't see how we can interpret it a
8 performance gap.

9 CO-CHAIR ANDERSON: John.

10 DR. WAGNER: Yes. So, I agree that if
11 you don't know what your target is, it's hard to
12 understand how one should view these dispersion
13 of values. And the fact that the issues that were
14 thought to provoke a concern around this, namely,
15 the change in FDA indications in prescribing
16 information and the impact that the billing
17 reimbursement methodology would have on
18 transfusions doesn't seem to be reflected in any
19 real change in the dispersion of these values.
20 But, again, it depends on how one views the value
21 of the STRR as a clinical outcome.

22 CO-CHAIR ANDERSON: Josh.

1 DR. ZARITSKY: If you just use the gap
2 to say hey, well it's just --- there's this
3 variation and stop there, and say well, that's
4 your gap. There's a variation, because we don't
5 know what's better or worse, but there's a
6 variation. It's not like we're all at one, so
7 there's no point in --- so, there's always going
8 to be a gap.

9 (Off microphone comment)

10 CO-CHAIR ANDERSON: Turn your mic on,
11 Alan.

12 DR. KLIGER: But whenever any of these
13 standardized ratios -- by definition, will just
14 describe the variation around the mean, always
15 will be there, and I just don't know how to ---
16 what a gap means in that context.

17 CO-CHAIR CROOKS: I would suggest as
18 sort of a flaw in the way we're supposed to
19 consider these, if it is an outcome measure, then
20 the gap doesn't mean the same thing, and maybe
21 gap shouldn't be part of the consideration for an
22 outcome measure. But there we are, we have it

1 right now. Sarah, would you have anything to ---

2 MS. SAMPSEL: I don't have anything to
3 add.

4 CO-CHAIR CROOKS: Okay.

5 (Off microphone comment)

6 CO-CHAIR ANDERSON: Very brief, because
7 we're going to have to go to public comment.

8 DR. MESSANA: So, the only issue is
9 that absolute transfusion rates increased after
10 2011. You're looking at risk-adjusted rates here,
11 so in terms of justifying the need or the
12 protection for the population, the absolute
13 transfusion rates may be more important to
14 consider.

15 CO-CHAIR ANDERSON: All right. With no
16 further discussion, let's move to vote on
17 performance gap.

18 MS. OGUNGBEMI: The Committee is now
19 voting on performance gap for Measure 2699. The
20 options are 1 high, 2 moderate, 3 low, and 4
21 insufficient. Voting is open. The results are one
22 vote high, 10 votes moderate, three votes low,

1 and nine votes insufficient. Measure 2699 falls
2 in the gray zone for performance gap.

3 CO-CHAIR ANDERSON: We're going to need
4 to pause on this measure for public comment.

5 OPERATOR: If you'd like to make a
6 comment please press *1. There are no comments at
7 this time.

8 MR. DIAMOND: I would just urge the
9 Committee to ask staff to provide the definitions
10 for structural, process, and outcome measures. I
11 was totally confused about the discussion that
12 this last measure is defined as an outcome
13 measure. My understanding, and I may be totally
14 incorrect, of an outcome measure is a description
15 of a patient's status, and the change in the
16 patient's status.

17 Mortality is an outcome measure. This
18 is a process measure. This is something that has
19 been done to a patient. If this becomes an out --
20 - if this is defined as an outcome measure, then
21 anything we do to a patient and any ratio that we
22 attach to doing something to patients becomes an

1 outcome measure. So, I think the way to resolve
2 this would just be go back to --- I'm sure
3 there's some standard definitions within the
4 archives of NQF that define something called a
5 structural, process, and outcome measure.

6 CO-CHAIR ANDERSON: Did you introduce
7 yourself for the record?

8 MR. DIAMOND: Oh, I'm sorry. For the
9 reporter, thanks, Lou Diamond speaking for
10 myself.

11 CO-CHAIR ANDERSON: All right. Let's
12 continue on our measure --- turn your mic on.

13 DR. DALRYMPLE: Would it be possible to
14 maybe take a short break. I think this is
15 actually a fairly complicated reliability section
16 to go through, even if it's just for five minutes
17 for the Committee, or is that not a choice? I
18 don't perceive this to be a straightforward
19 reliability, in large part because of the
20 statistical methodology, and all of the issues
21 that have come up today. And it's ---

22 CO-CHAIR ANDERSON: Actually, what we

1 would like to propose is to go ahead and get up,
2 and get lunch, but actually do a working lunch so
3 we can get through more of the measures. So, if
4 you could be back by 12:30, and then we'll do
5 that. Thanks, Lorien.

6 (Whereupon, the above-entitled matter
7 went off the record at 12:15 p.m. and resumed at
8 12:30 p.m.)

9 CO-CHAIR ANDERSON: All right. We're
10 back
11 on Measure 2699. And we're at specifications and
12 reliability. Dodie or John?

13 DR. WAGNER: Okay, well pardon my
14 chewing.

15 So, specifications, the numerator
16 includes claims data and various procedure and
17 revenue codes. I guess the comment I would make
18 about that is that it seems there are certain
19 procedure codes that will allow one to capture
20 the number of units transfused versus revenue
21 codes which I think only give a thumbs up or
22 thumbs down on a transfusion event.

1 So, I'm not sure if that affects the
2 reliability of the data. There's no information
3 about that. And if I'm confused about that
4 point, if someone can clarify that, I would
5 appreciate it.

6 Okay, as far as the denominator
7 exclusions, there are the exclusions that are
8 thought to influence anemia management in a way
9 that would make it difficult to use ESAs and,
10 therefore, the things that one has seen in other
11 metrics have been put forth as exclusion events.

12 However, I think unlike other anemia
13 metrics, the only hemoglobinopathy that is
14 mentioned is sickle cell and there is no other
15 exclusion for other hemoglobinopathies and,
16 depending on the coding, I'm not sure if that
17 would then result in some confusion, for example,
18 someone had SC disease or something along those
19 lines.

20 In terms of other exclusions that
21 would relate to the KDIGO Guidelines that were
22 cited, ineffective bone marrow could be the

1 result of other issues such as inflammation,
2 surgical trauma and those events are not
3 exclusion events.

4 As far as the statistical modeling
5 which I think will be a large discussion, this is
6 using a statistical model which is risk-adjusted
7 for age and for nursing home status at time of
8 the ESRD onset and years on ESRD, diabetes status
9 and comorbidities as at the time of filling out
10 the 2728.

11 And the risk-adjustment does not get
12 updated as one accumulates time on dialysis. And
13 this risk-adjustment is then put into a Cox model
14 to come into the expected transfusion rate ratio.
15 I'm sorry, the expected transfusion rate and then
16 observed over the expected delivers the ratio.

17 So, I think there is, again, a
18 question as to whether one can view an expected
19 rate as indicative of good quality care or
20 consistent with recognized standards of care and
21 whether there should be other risk-adjustments
22 within the model that speak to issues such as

1 bleeding events, such as surgical events, such as
2 infectious events and those have not been
3 incorporated into the model.

4 And also locus of transfusion since
5 there are some dialysis facilities which have the
6 ability to transfuse and many which do not. It's
7 not clear what the relationship of the locus of
8 transfusion might bear on this model.

9 So, again, another way of looking at
10 the reliability of the data are to discuss the
11 inter-unit reliability and based on their
12 analysis of the inter-unit reliability, the
13 developers indicated they believe there was a
14 moderate degree of reliability.

15 So, that is my comments. I think this
16 is very problematic to claim that this is a
17 reliable indicator of quality.

18 And, with that, I'll open up the
19 floor.

20 CO-CHAIR ANDERSON: Dodie, any
21 additional comments?

22 DR. STEIN: The only other comment is

1 I may mention the larger facilities are going to
2 have a higher IUR.

3 But I just have problems with the
4 whole calculation of all of this and then some
5 feasibility issues for later.

6 CO-CHAIR ANDERSON: Right. Alan?

7 DR. KLIGER: I guess I'm not surprised
8 that there should be a correlation between a
9 standardized transfusion ratio and
10 hospitalization or mortality. Maybe we're just
11 identifying sicker patients. I'm just not sure
12 what that tells us. I don't know that that
13 validates the measure, it just identifies perhaps
14 a group of sicker patients.

15 CO-CHAIR ANDERSON: Lorien?

16 DR. DALRYMPLE: And I think -- I'm not
17 sure if we're going to discuss this as a
18 committee or further pose it to the --

19 I'm not sure if we're going to further
20 discuss this as a committee or move it to the
21 developers in the name of time, but this issue of
22 how transfusions are counted, depending on if

1 you're a revenue center or a procedure code, it
2 sounds like from this submission, and I do
3 greatly appreciate the transparency on the
4 approach to counting, the procedure codes tend to
5 be a smaller percentage but I don't have an
6 understanding of what percentage.

7 And then this question comes to my
8 mind, well, Facility A is associated with
9 Hospital A and Facility B is with Hospital B and
10 Hospital A tends to use revenue centers, so
11 there's going to be less events systematically
12 counted compared to B using procedure codes.

13 Is Facility B really just being
14 penalized because they're associated with
15 hospitals that use different billing practices
16 and does this happen systematically?

17 Because my understanding is all
18 inpatient claims are counted unless you are a
19 transplant hospitalization.

20 So, we're now making the facility
21 accountable, not just for their care of
22 practices, but the care of practices at the local

1 hospital may have very different transfusion
2 standards than we have and may also have
3 systematically different billing practices.

4 So, I don't know if we, as a group,
5 should discuss all these issues or, in the name
6 of time, ask for clarity? Peter? Connie?

7 DR. MESSANA: Well, so, Lorien, I'm not
8 sure I can provide a lot of clarity on the latter
9 question. It is certainly, as I pointed out in
10 my introductory statement, this approach is the
11 best one can do with the claims basis.

12 But there certainly is opportunity for
13 a hospital to hospital variation in how they, you
14 know, how they submit those and whether they
15 submit those because inpatient hospitalizations
16 are DRG related on whether they include a
17 specific line item.

18 When we've looked previously at the
19 association between dialysis facilities and
20 hospitals, the paradigm that you develop, it's
21 much more complicated than that.

22 Most freestanding dialysis facilities

1 have relationships with more than one hospital.
2 There's a subset that there's a geographic
3 singularity, but it's much more complicated than
4 that.

5 And I would say I think the majority
6 of facilities have relationships with more than
7 one hospital, although geographic issues may
8 still come into play.

9 The reason I had the card up is in the
10 reviewers statement, I wanted to correct one,
11 what I think, is factual omission. There are a
12 number of hereditary anemias, hemolytic anemias,
13 that are included in a bunch of sickle cell
14 variants, sickle cell C diseases and others.

15 So, there's a whole family from the
16 categorical -- the hierarchical coding system,
17 CMS coding system of hereditary anemias, not just
18 sickle cell that are part of the exclusion list
19 and the code table that was included with the
20 submission.

21 CO-CHAIR ANDERSON: So, just a quick
22 follow-up. Have you empirically tested if you

1 treat procedure codes the way you treat revenue
2 centers, if any findings for facilities change on
3 their O/E?

4 DR. MESSANA: We have not. We have a
5 breakdown of revenue center codes that are
6 isolated that don't have a procedure code with
7 them and how much overlap there is. And a
8 sizable minority are based on revenue center
9 codes only.

10 So, that's why we were careful to
11 label transfusion events because we probably are
12 systematically undercounting units of blood
13 transfused with this methodology. We can say one
14 or more blood transfusion was administered but on
15 this day and only if we have granularity from
16 procedure codes can we say that for sure that
17 were two or more or two or multiple transfusions
18 provided on a day.

19 CO-CHAIR ANDERSON: But for those
20 patients, you have granularity available. I just
21 want to make sure I understand the numerator.
22 You will use it in those cases.

1 So, there's patients that don't have
2 granularity so we just say, okay, you're one.

3 But this patient where procedures were
4 systematically, you could give them a six, you
5 could give them an eight if they got eight units
6 of blood because you -- although I think you can
7 only do one procedure per day, correct?

8 So, it'd be a max of one unit per day.
9 But if you're in the hospital for three weeks and
10 that hospital uses that schema, you can get up to
11 one a day. And then --

12 DR. MESSANA: Right, it's one event per
13 day maximum.

14 CO-CHAIR ANDERSON: But, in theory, if
15 they got transfusions on eight different days,
16 that patient would get a numerator eight, but at
17 this other hospital where we use revenue center
18 codes, they could get 40 units and it would count
19 as one, is that a correct understanding?

20 CO-CHAIR ANDERSON: Frank?

21 DR. MADDUX: So, I would say to
22 Lorien's question, it brings up again the issue

1 that many, many hospitals are, in fact, do have
2 transfusion policies and protocols that will be
3 followed for the transfusions occurring in those
4 hospitals.

5 So, the ability of the measure to be
6 sensitive to what the expected rates are will be
7 highly influenced by these particular areas that
8 I think, fundamentally, puts into question some
9 of the underlying nature of responsibility for
10 this.

11 CO-CHAIR ANDERSON: All right, let's
12 call for the vote for specifications and
13 reliability.

14 MS. OGUNGBEMI: The committee is now
15 voting on reliability for Measure 2699. The
16 options are one-high, two-moderate, three-low and
17 four-insufficient. Voting is open.

18 The results are zero votes high, seven
19 votes moderate, 13 votes low and three votes for
20 insufficient.

21 The measure does not pass on
22 reliability.

1 CO-CHAIR ANDERSON: Are there any other
2 comments for the developer on the rest of the
3 criteria? Okay.

4 MS. SAMPSEL: Right, so as we have in
5 the past, you know, the developer now has, and
6 this will go through public comment.

7 But the developer could also bring
8 additional information back to you when it comes
9 to providing additional information on this
10 measure for consideration.

11 Are there any additional insights or
12 recommendations you would like to provide to the
13 developers?

14 DR. DALRYMPLE: So, my recommendation
15 would be to consider doing the empirical testing
16 to see if what you observed changes if you treat
17 procedure codes the same as revenue centers since
18 you have the data and could just empirically
19 compare those two.

20 DR. MESSANA: Okay, thank you.

21 DR. KRISHNAN: Maybe to follow-up on
22 that, if there's regional variances like Frank

1 was saying, because regional variances may be due
2 to hospital level or physician level, transfusion
3 practices as well as the flavor that they're
4 using for coding the transfusions.

5 DR. DALRYMPLE: So, is there anything
6 we could recommend as a committee that would help
7 reassure us that this isn't all being drive by
8 hospital practices and facilities warrant
9 accountability because we're not managing anemia
10 correctly?

11 Because I think that's one of the
12 concerns, right? We want to make sure this
13 reflects quality of care to dialysis facility,
14 not transfusion practices and behaviors at a
15 hospital level.

16 So, is there any analysis that would
17 help us understand whether that's what's
18 occurring? I think that's what you're proposing,
19 but is there a way to look at that?

20 CO-CHAIR CROOKS: And my comment is to
21 go back and really examine what kind of measure
22 is this? If it seems that it probably is not an

1 outcome, and I like Louis Diamond's definition
2 that an outcome is something that happens to a
3 patient.

4 I haven't really thought the subject
5 through, but that seems to make sense and I don't
6 know if it's a process metric or an intermediate,
7 but I think that needs to be thought through and
8 clearly presented so that the committee doesn't
9 end up having to try to decide what kind of a
10 measure it is.

11 DR. MESSANA: So, I'll respond to that
12 comment, Peter.

13 We spent months trying to figure out
14 whether this was cubbyholed as an outcome measure
15 or as a process measure. Using Dr. Diamond's
16 suggestion that something that happens to a
17 patient, transfusions happen to patients.

18 So, from one perspective, some of the
19 members of our group felt strongly that it was an
20 outcome measure, while others thought of it as a
21 process measure.

22 There's a great deal of uncertainty on

1 our part about what defines whether this fits a
2 definition of an outcome or a process measure.

3 So, I certainly appreciate and
4 understand the multitude of opinions around the
5 table about that.

6 MS. HARTWELL: I just had a quick
7 comment and just looking at it from the patient's
8 perspective, is there ever a way there could be a
9 change in policy where patients could get a blood
10 transfusion in a clinic?

11 Because it's a very big inconvenience
12 to go to the hospital to get a clinic to get a
13 transfusion and have it be reimbursed outside the
14 bundle. But just a thought.

15 DR. MESSANA: So, Lori, maybe we could
16 -- you could ask me that -- my opinion about that
17 offline but you've got a lot of other things to
18 do. So, I'll defer for a time.

19 CO-CHAIR CROOKS: So, we're going to
20 pause -- another pause that refreshes. You are
21 now going to be randomly selected for a two or
22 three year term with this committee, if you still

1 want to serve. No, that's not an option, sorry.

2 And Poonam is going to do the process.

3 MS. BAL: As the process, whenever you
4 pick out a number, please into the microphone say
5 your name and the number that you received for
6 your term. It's going to be a two or a three.

7 MS. HARTWELL: Number three. Oh, Lori
8 Hartwell, number three. So, what does this mean?
9 Oh, okay, I guess that's -- what numbers are in
10 there?

11 DR. MADDUX: This is Frank Maddux, two
12 years.

13 DR. GREENSTEIN: Stu Greenstein, three
14 years.

15 MS. OGUNGBEMI: I mean I'm writing it
16 down but the transcript's also getting it.

17 DR. KASKEL: Rick Kaskel, three years.
18 Does this count if you're retired?

19 CO-CHAIR CROOKS: As an individual, not
20 just for a --

21 DR. SOMERS: Michael Somers, three.

22 DR. BHAN: Ishir Bhan, three.

1 DR. DALRYMPLE: Lorien Dalrymple, two.
2 MS. PAVLINAC: Jessie Pavlinac, two.
3 MS. LENNING: Karilynn Lenning, three.
4 DR. NARVA: Andy Narva, life without
5 parole. No, three.
6 DR. WAGNER: John Wagner, two.
7 DR. STEIN: Dodie Stein, two.
8 MS. WAGER: Bobbi Wager, two.
9 DR. HAIN: Debbie Hain, two.
10 MS. EVANS: Beth Evans, two.
11 DR. FISCHER: Michael Fischer, two.
12 DR. KLIGER: Alan Kliger, one. No,
13 three.
14 DR. KRISHNAN: Mahesh Krishnan, three.
15 DR. LATTS: Lisa Latts, two.
16 DR. KLEINPETER: Myra Kleinpeter,
17 three.
18 CO-CHAIR CROOKS: Peter Crooks, three.
19 CO-CHAIR ANDERSON: Connie Anderson,
20 three.
21 DR. ZARITSKY: Joshua, two.
22 CO-CHAIR CROOKS: Okay. Next up is

1 2701.

2 DR. JONES: Thank you from KCQA in
3 particular for moving the schedule up. We
4 appreciate that.

5 KCQA is pleased to review our two
6 fluid management measures with the committee.

7 2701 is one of the two fluid
8 management measures developed and tested by KCQA.
9 2701 measures the percentage of adult in-center
10 hemodialysis patients in the facility whose
11 average UFR is greater than or equal to 13 ml/kg
12 per hour. In this case, the lower score is a
13 better performance.

14 Facilities succeed on the measure and
15 are not counted in the numerator if the dialyzed
16 patients at an average of UFR less than 13 and/or
17 dialyzed patients for an average of greater than
18 240 minutes per session.

19 I would like to focus on a couple of
20 the pre-meeting committee comments.

21 One reviewer noted that we did not
22 present any information on the reliability of

1 data source used in the testing. That is, the
2 data warehouses of three large dialysis
3 organizations that participated in the testing.

4 With the exception of patient weights,
5 all necessary data elements for the measures are
6 collected via what NQF refers to as an
7 authoritative source currently with care
8 delivery. Specifically, data are entered
9 electronically and are not abstracted, coded or
10 transcribed by any other person.

11 Because the patient weight data in
12 some instances require transactions from chair
13 side to the electronic system, we conducted and
14 reported reliability testing at the level of the
15 measure sources, which, again, is consistent with
16 NQF.

17 The data are the same as those batched
18 submitted to CMS for CROWNWeb.

19 There were questions about the time
20 component in the numerator which is one of the
21 major differences between KCQA and CMS's measure.

22 KCQA considers the time component a

1 critical element. Rather dictating the UFR
2 remain at or below 13, the length of the session
3 component of the measure allows judicious use of
4 UF rates above 13 as long as the patient is
5 dialyzed for more than 240 minutes.

6 With a measure to focus exclusively on
7 the UFR without taking time into consideration,
8 some patients may require significantly longer
9 dialysis treatments beyond four hours, increasing
10 the chance that they may refuse. The time
11 component is also necessary to avoid potential
12 adverse unintended consequences of implementing
13 the measure on other patients who follow that
14 patient.

15 In other words, if they have to go
16 more than four hours, it might bump into the next
17 patient schedule. Only perspective testing can
18 address the frequency with which this scenario
19 can occur.

20 Lastly, I would like to address the
21 other major difference between KCQA and CMS
22 measure, which is that our measure is specific to

1 the average rate for the session during the week
2 that Kt/V is measured and the CMS measure relies
3 on data for a single session.

4 We believe the average is more
5 accurate and voids potential gaming. We also
6 believe relying on a single data point is a
7 threat to validity.

8 We provided the committee with
9 additional data demonstrating that one of the
10 LDOs analyzed and confirmed that facilities who
11 have a Monday/Tuesday, Kt/V cycle perform more
12 poorly than those who have Wednesday/Thursday
13 Kt/V cycle.

14 Thank you for considering this.

15 CO-CHAIR CROOKS: Thank you.

16 All right, our discussants for this
17 measure are John Wagner and Michael Somers.
18 Who's going to kick it off? Michael?

19 DR. SOMERS: I can, yes.

20 So, in terms of evidence, we are
21 provided with a KDOQI Guideline, which is a
22 workgroup consensus opinion regarding the need

1 for the patient to be euvolemic and it does
2 mention that some patients need to have extended
3 HD times and slower UF. There's no real evidence
4 in this guideline regarding outcomes and why this
5 is ---- as a process or intermediate outcome is
6 worthwhile.

7 There's also literature review
8 provided. Three of the pieces are opinion
9 pieces. One's data from a registry, nine are
10 cohort or analysis of large data samples from
11 cohort studies. That's the evidence.

12 CO-CHAIR CROOKS: I should mention that
13 three committee members are precluded from
14 discussing or voting, Constance Anderson, Lori
15 Hartwell and Mahesh Krishnan.

16 Okay, John?

17 DR. WAGNER: Right. I just would point
18 out that the measure requires either having 240
19 minutes and if one does not have 240 minutes, one
20 needs to have an ultrafiltration rate that is
21 less than the threshold.

22 And none of the articles addressed

1 that kind of a combination, why one 240 minute
2 time threshold would be equivalent to an
3 ultrafiltration rate that is whatever one wishes
4 to define.

5 And although many of -- some of the
6 articles -- at least I guess the modality of the
7 articles mention four hours as a cut point. Some
8 of the articles mention different timeframes as
9 cut points and other articles mention different
10 ultrafiltration rates as cut points for risk.

11 CO-CHAIR CROOKS: Okay. The floor is
12 open for other comments on the evidence. You've
13 got it.

14 MS. EVANS: I just have a question. On
15 the UFR rate, is it greater than 13 ml/kg per
16 hour or is it greater to or equal to -- it's
17 conflicting in that preceding comment, the data
18 on that?

19 And four hours, is it over four hours
20 or is it over and equal to four hour dialysis
21 time?

22 CO-CHAIR CROOKS: Would you like to

1 respond?

2 DR. JONES: Yes, the UFR is greater
3 than and equal to. The time is more than 240
4 minutes or more.

5 CO-CHAIR CROOKS: Okay, Lorien?

6 DR. DALRYMPLE: And I just have a
7 question for the workgroup and reviewers.

8 In the end, what was your overall
9 sense of the evidence as it relates to this
10 measure? What would you have --

11 DR. WAGNER: I think there are evidence
12 that this associates to increased time with
13 better outcomes. Again, whether it's 240 minutes
14 or not is I think a little bit vague in the
15 literature.

16 And as far as what the actual
17 ultrafiltration rate that should be targeted as
18 the best rate above which one does not wish to
19 go, I think it's unclear. So I think the
20 evidence there is a little bit weaker about what
21 the best rate is.

22 CO-CHAIR CROOKS: Yes, my impression

1 was -- I was in a workgroup ---- that there was
2 no systematic review presented or meta-analysis,
3 but there was quite a few articles and 13, I
4 think, and the preponderances and some way or
5 another, you know, high UF bad, short dialysis
6 bad.

7 And the KDOQI committee in 2006 came
8 up with -- considered it Grade A evidence.

9 DR. WAGNER: Yes, I think though --
10 that guideline really speaks to achieving the dry
11 weight ---- the euvolemic weight in avoiding
12 hypertension.

13 So that really -- while it supports an
14 effort to define how you get there, it really
15 doesn't -- that guideline doesn't speak to how
16 you get there. And of course, this guideline --
17 this metric does not attempt to define what the
18 target weight is by any particular standard.

19 CO-CHAIR CROOKS: Yes, so the evidence
20 isn't as strong as we'd like. It's begging out
21 for clinical trials and I don't know if that'll
22 ever be done or not, but evidence being what it

1 is, I think it's reasonably strong.

2 Oh, I'm sorry, Frank?

3 DR. MADDUX: So I'd just say that as
4 we've moved some of the dose of dialysis measures
5 into reserve status, this kind of measure, I
6 think, begins to breakdown in a more granular
7 nature some of the issues that are components of
8 what the original Kt/V was.

9 And whether it's time, ultrafiltration
10 rate or the impact of intradialytic weight gain,
11 I think all of those become a rationale of which
12 there's a pretty large body of literature that
13 you could extend through the transitive property
14 to say is related to this particular topic.

15 And it strikes me that there's not
16 nearly as much known about this because we've
17 been concentrating on the more global measure at
18 this point and I think we have to recognize that
19 it's not going to be quite as mature as some of
20 the other measures.

21 CO-CHAIR CROOKS: Okay. Other
22 considerations about the evidence -- body of

1 evidence?

2 Okay, we're ready to vote then.

3 MS. OGUNGBEMI: The committee's now
4 voting on Measure 2701 and its evidence.

5 The options are 1 high, 2 moderate, 3
6 low and 4 insufficient. Voting is open.

7 CO-CHAIR CROOKS: Mahesh, I see a
8 voting stick in your -- oh, thank you. You're
9 having a conflict of interest.

10 MS. OGUNGBEMI: So, we will only have
11 20 votes since three committee members recused
12 themselves.

13 The results are zero votes high, 17
14 votes moderate, two votes low and one vote
15 insufficient.

16 Measure 2701 passes on evidence.

17 CO-CHAIR CROOKS: Okay, thank you.
18 Gap?

19 DR. SOMERS: So for gap we're given
20 data from 4,252 hemo facilities, over 412,000
21 patients, shows that from this group a median of
22 10.8 percent would not have met this measure with

1 a range from zero to 50 percent.

2 CO-CHAIR CROOKS: John, any other
3 comments?

4 DR. WAGNER: No.

5 CO-CHAIR CROOKS: Okay. All right,
6 well, let's vote on the gap then if nobody wants
7 to say anything further.

8 MS. OGUNGBEMI: The committee is now
9 voting on performance gap for Measure 2701. The
10 options are 1 high, 2 moderate, 3 low and 4
11 insufficient. Voting is open.

12 The results are three votes high, 16
13 votes moderate, one vote low and zero votes
14 insufficient.

15 Measure 2701 passes on performance
16 gap.

17 CO-CHAIR CROOKS: Okay, thank you.
18 Now specifications and reliability.

19 DR. SOMERS: So for specifications,
20 it's specified for CROWNWeb and all the data
21 elements in the directions for data capture was
22 included. It's not risk-adjusted.

1 In terms of reliability testing,
2 there's data, again, given from the 4,252
3 dialysis facilities. They looked at the facility
4 and treatment month as independent variables and
5 they measured the score as variable intraclass
6 correlation coefficient between 0.6 and 0.7 for
7 the three LDOs which fell into a level of -- a
8 good level of reliability.

9 CO-CHAIR CROOKS: John?

10 DR. WAGNER: Nothing to add.

11 CO-CHAIR CROOKS: Okay. Lorien?

12 Thank you.

13 DR. DALRYMPLE: Can I just clarify one
14 point on this? So, was the reliability testing
15 done with the LDOs all sending their data or was
16 it done on CROWNWeb?

17 Because I thought one of the comments
18 I saw was, does CROWNWeb have three measures of
19 weights each month? And I don't know CROWNWeb
20 well enough to know. So I don't know if other
21 committee members have more insight into CROWNWeb
22 and what data's collected monthly and then maybe

1 the primary reviewers just clarify on how the
2 reliability testing was done versus the stats?

3 DR. WAGNER: Yes, so I didn't know if
4 this was under feasibility, but this is obviously
5 a data set that is generated by proprietary
6 databases and it is assumed that CROWNWeb can be
7 configured to provide the same data.

8 So, the data will be from the week
9 that the Kt/V is calculated in that. It could be
10 three or four treatments during that week. And
11 so, I don't think CROWNWeb currently captures
12 that information, so it would have to be put into
13 the system and software developed around it.

14 CO-CHAIR CROOKS: Is that correct?

15 DR. MCGONIGAL: Yes, that is correct.
16 We collected it through the LDOs. It's not
17 proprietary databases, they were data warehouses,
18 same information that's sent to CROWNWeb.

19 At this point, CROWNWeb is collecting
20 one data point and so that would need to be
21 expanded to the three.

22 And I think that's all you asked. Did

1 I miss something? Okay.

2 CO-CHAIR CROOKS: That's it. Okay.

3 DR. MCGONIGAL: Oh, yes, one other
4 thing, we exclude four or greater treatments per
5 month. So it would only be three maximum.

6 DR. DALRYMPLE: I think in the specs
7 it says greater than four are excluded. So if
8 it's four or more we may just need to be -- and
9 some of the exclusions it mostly says greater
10 than four.

11 DR. MCGONIGAL: Four or more is the
12 exclusion.

13 CO-CHAIR CROOKS: Right. So, they're
14 stipulating that they meant --

15 DR. DALRYMPLE: Details, but we're
16 going to limit to thrice weekly? Okay.

17 Does anyone know if this has been
18 proposed to CROWNWeb and would be feasible in the
19 near future to have the three?

20 DR. JONES: Yes, it has been. There's
21 some discussions about, you know, picking up on
22 the three treatments.

1 CO-CHAIR CROOKS: Okay. Other
2 comments? Okay, let's vote on reliability.

3 MS. OGUNGBEMI: The committee is now
4 voting on reliability for Measure 2701. The
5 options are 1 high, 2 moderate, 3 low and 4
6 insufficient. Voting is open.

7 The results are unanimous, zero votes
8 high, 19 votes moderate, zero votes low and zero
9 votes insufficient. Measure 2701 passes on
10 reliability.

11 CO-CHAIR CROOKS: Thank you. On to
12 validity.

13 DR. SOMERS: In terms of validity, the
14 facility-specific scores were compared to SHR and
15 SMR. The correlations were in the preoperative
16 direction and statistically significant.

17 CO-CHAIR CROOKS: John?

18 DR. WAGNER: I guess the only question
19 I would have is if the SHR and SMR are going to
20 be under review and we don't know what the
21 outcome of those reviews are, is it fair to have
22 validity testing then that relies on those

1 measures or is that a moot point?

2 CO-CHAIR CROOKS: Well, they're not
3 under review yet and we still --

4 MS. SAMPSEL: They're technically
5 endorsed measures.

6 CO-CHAIR CROOKS: Yes.

7 MS. SAMPSEL: And in current use.

8 CO-CHAIR CROOKS: So I don't think we
9 need to worry about that. I'd just like to
10 mention they also claim face validity with this
11 KCQA Steering Committee and testing workgroup,
12 for what it's worth.

13 Okay, any other comments on validity?
14 Let's vote.

15 MS. OGUNGBEMI: The committee is now
16 voting on validity for Measure 2701. The options
17 are 1 high, 2 moderate, 3 low and 4 insufficient.
18 Voting is open.

19 The results are two votes high, 16
20 votes moderate, one vote low and zero votes
21 insufficient. Measure 2701 passes on validity.

22 CO-CHAIR CROOKS: Okay. Thank you.

1 Feasibility?

2 DR. SOMERS: Well, in terms of both
3 feasibility and usability, the comments that have
4 been made already about some tweaks in CROWNWeb
5 were pertaining.

6 But otherwise, the workgroup thought
7 that the data would be generated or collected
8 during usual provision of care through EHRs.

9 CO-CHAIR CROOKS: John?

10 DR. WAGNER: So I guess it would be
11 perhaps important to know how difficult it will
12 be to configure CROWNWeb to capture these data
13 and to understand. Given the issues that
14 CROWNWeb has with capturing all of the data,
15 whether this would be a particular problem in
16 this case for this metric.

17 CO-CHAIR CROOKS: Because as it
18 stands, there's any patient dialysis as an
19 independent or small chain unit is not going to
20 be captured. Right?

21 DR. MCGONIGAL: I'm sorry, are you
22 asking --

1 CO-CHAIR CROOKS: I'm asking you that
2 question, yes.

3 DR. MCGONIGAL: Yes, so I missed part
4 of the question but you're talking about the
5 smaller --

6 CO-CHAIR CROOKS: Well, the --

7 DR. MCGONIGAL: -- that non-batch
8 submitters, is that correct?

9 CO-CHAIR CROOKS: Right. But you're
10 not even using CROWNWeb at all. Right?

11 So, at the present time, when you do
12 this measure it excludes independent dialysis
13 units and small chains.

14 MS. NISHIMI: That was for the
15 testing. We've been in conversation with CMS
16 about adding the two extra data points so the
17 batch submitters would batch three and the rest
18 of the facilities would have to manually enter
19 the additional two, as they now manually enter
20 one.

21 CO-CHAIR CROOKS: So the plan is
22 definitely to get all units under the umbrella?

1 MS. NISHIMI: Oh, yes. No, there was
2 never --

3 CO-CHAIR CROOKS: If we can get the --
4 all right, good.

5 Other issues with feasibility?

6 MS. EVANS: Home hemo will be included
7 or not?

8 CO-CHAIR CROOKS: Pardon me?

9 MS. EVANS: Home hemo?

10 CO-CHAIR CROOKS: Home hemo, will they
11 be included?

12 MS. EVANS: Are they included or not?

13 DR. MCGONIGAL: This is in center.

14 MS. EVANS: In center, okay.

15 CO-CHAIR CROOKS: It's not, yes.

16 Okay. Any other issues on
17 feasibility? Let's vote.

18 MS. OGUNGBEMI: The committee is now
19 voting on feasibility for Measure 2701. The
20 options are 1 high, 2 moderate, 3 low and 4
21 insufficient. Voting is open.

22 The results are two votes high, 15

1 votes moderate, one vote low and one vote
2 insufficient. Measure 2701 passes on
3 feasibility.

4 CO-CHAIR CROOKS: Okay. Usability and
5 use?

6 DR. SOMERS: I don't think we have any
7 new comments. We've covered that I think.

8 CO-CHAIR CROOKS: No comments?

9 DR. SOMERS: Well, nothing new than
10 what we didn't discuss with feasibility. I mean
11 I think that with the tweaks that needed to be
12 made, we thought that it could be usable. It's
13 not currently being used.

14 CO-CHAIR CROOKS: Okay, it's not
15 currently in use. Pay -- state plan public
16 reporting, could be used for plan payment, QI
17 use.

18 Okay. Other concerns or comments
19 about usability and use? I see people have --
20 oh, Lorien?

21 DR. DALRYMPLE: I'm not sure, it seems
22 like our developers want to share something with

1 us. Sarah, can we --

2 MS. SAMPSEL: No, I'm --

3 DR. DALRYMPLE: -- inform our
4 conversation about usability because perhaps we
5 don't understand, aside from CROWNWeb, if this is
6 usable.

7 MS. SAMPSEL: So I mean I guess what
8 I'm trying to do is only if there are questions
9 specifically to the developers that would help
10 you in your consideration, that's when we want to
11 direct to the developers. But we're trying to
12 move this along.

13 DR. DALRYMPLE: I will just ask one
14 question with that in mind.

15 Is there usability outside of CROWNWeb
16 implementing these changes?

17 DR. JONES: In at least one large
18 dialysis organization, this is reported out on a
19 monthly basis. And for internal QI purposes,
20 both the length of dialysis and the fluid rate
21 and the time. So at least in that one large one
22 it's used.

1 CO-CHAIR CROOKS: Any other comments?
2 Okay, let's vote, usability and use.

3 MS. OGUNGBEMI: The committee is now
4 voting on usability and use for Measure 2701.
5 The options are 1 high, 2 moderate, 3 low and 4
6 insufficient. Voting is open.

7 The results are two votes high, 15
8 votes moderate, one vote low and one vote
9 insufficient. Measure 2701 passes on usability
10 and use.

11 CO-CHAIR CROOKS: So, so far all the
12 criteria have been met. Now we're going to vote
13 on submitting for recommending endorsement. Any
14 other comments before we vote? Okay, pick up
15 your sticks.

16 MS. OGUNGBEMI: The committee is now
17 voting on Measure 2701's overall suitability for
18 endorsement. Options are 1 yes, 2 no. Voting is
19 open.

20 Results are 19 votes yes, zero votes
21 no. Measure 2701 passes it's meeting NQF
22 criteria for endorsement.

1 CO-CHAIR CROOKS: Okay, thank you.

2 And don't go away because we're going to go next
3 to 2702, Post-Dialysis Weight Above and Below
4 Target submitted by KCQA.

5 You have the floor.

6 DR. JONES: Thank you. Measure 2702
7 is the percentage of patients with the average
8 post-dialysis weight greater than equal to one
9 kilogram above or below their prescribed target
10 weight.

11 First, I want to emphasize that KCQA
12 believes that this measure complements and serves
13 as a check and balance to the measure we just
14 spoke about.

15 Implemented alone, the specifications
16 of 2701 could be met simply by underdialyzing the
17 patient by decreasing UFR.

18 Concurrent implementation of this
19 weight measure will minimize the potential for
20 such an unintended consequences as patients
21 underdialyzed in such manner will unlike meet
22 their target weight.

1 KCQA's testing in over 4,000
2 facilities over 412,000 patients found the
3 measures were both valid and reliable.

4 I understand from the pre-meeting
5 comments and the workgroup call that most of the
6 discussion centered around the identification of
7 the one kilogram weight as the target weight
8 window to be achieved. So, I'd like to talk
9 about that.

10 Evidence suggests that improved volume
11 control can attenuate cardiovascular issues,
12 making a strong case for the diligent avoidance
13 euvoemia overload.

14 KCQA believes that the time for
15 performance measurement in this area is long
16 overdue and that patients will continue to suffer
17 adverse consequences if we wait until an ideal
18 measure is identified.

19 Research also demonstrates that overly
20 aggressive fluid removal can be detrimental.
21 Efforts to achieve euvoemia must, therefore,
22 neither be too aggressive nor too weak with a

1 goal of consistently bringing patients to an end
2 dialysis weight falling within a narrow margin of
3 their defined target weight to achieve optimal
4 state.

5 We know one study found absolute
6 weight is more important than percentage weight.
7 An additional small study of 182 patients
8 suggested adverse consequences when the target
9 weight was missed by more than 0.3 kilograms.

10 Evidence identified during our testing
11 indicated there is significant performance gaps
12 using the one kilogram. This value was the
13 consensus of our steering committee, measure
14 feasibility and testing group for the purpose of
15 this measure.

16 We posit the need for performance
17 improvement and fluid management for dialysis
18 patients and the current absence of measures
19 addressing this important aspect of care are best
20 served by our consensus value of one kilogram.

21 We further acknowledge that the
22 ambiguity is existing in protocols for

1 determining the dry weight. But, again,
2 emphasized the need for performance measures in
3 this area.

4 If the committee does not believe our
5 reliance on our expert opinion and factors, such
6 as lack of standardized protocols are sufficient
7 to specify this target aim, we maintain if you
8 utilize the NQF evidence algorithm you would
9 still end up with insufficient but exception
10 decisions.

11 Thank you.

12 CO-CHAIR CROOKS: And once again, the
13 same three people are excluded from participation
14 and our discussants are Myra and John again.

15 It seems like you guys get called on
16 a lot. Did you get more than two? Who's going
17 to go first? John?

18 DR. WAGNER: Go first? Okay, thank
19 you.

20 So the numerator is the number of
21 patients from the denominator with the average
22 post-dialysis weight gain equal to or greater

1 than one kilogram above or below the prescribed
2 target weight during the calculation period.

3 And the denominator exclusions are the
4 following patients: patients less than 18 years
5 of age, home dialysis patients, patients in
6 facilities less than 30 days, patients with less
7 than seven hemodialysis treatments in a facility
8 during a month, patients without a 2728, kidney
9 transplant patients with a functioning graft.

10 And then there's an unanswered
11 question as to how many in-center hemodialysis
12 patients during the reporting month need to be
13 present in order to have the facility count
14 within this measure.

15 There isn't an exclusion for greater
16 than three treatments as we heard in the other
17 measure. I'm not sure if that was an oversight
18 or not.

19 So the evidence is, again, related to
20 that KDOQI Guideline which argues that patients
21 should be ultrafiltered to a target optimal dry
22 weight. It doesn't -- and the evidence level was

1 A.

2 And in addition, the developers have
3 an expert consensus panel in the KCQA membership
4 and they also reviewed 14 studies that looked at
5 issues related to technology that was used to
6 define target weight, what the intradialytic
7 weight gain were in various populations and what
8 happens when one tries to achieve target weight
9 and various adverse events.

10 The issue here is we're not defining
11 what euvoemia is, we're basically allowing the
12 clinicians to decide whatever target weight they
13 choose based on whatever criteria they use. And
14 then taking the one kilogram plus or minus value
15 as being a surrogate for what presumably is going
16 to be helpful to achieving euvoemia and control
17 of hypertension.

18 So I think in terms of the evidence
19 that is presented and the actual guideline, there
20 is a little bit of a disconnect. This is kind of
21 like the issue with testing for whether
22 parachutes work or not.

1 I mean everyone knows that you want to
2 prescribe a target weight. That's part and
3 parcel of the dialysis prescription. And if one
4 is doing that, one presumably intends that target
5 weight to be achieved. So there should be some
6 metric around that.

7 But in terms of what the evidence that
8 that result will speak to quality, particularly
9 if there are patient-centered factors that also
10 impact on achievement of that target weight and
11 there's no discussion in the evidence about what
12 the patient-centered factors will do to one's
13 ability to change the target weight.

14 And because of patient-centered
15 factors, there might be a decision to move the
16 target weight away from what one conceives to be
17 the euvolemic weight. So there's no evidence
18 presented around that subject either.

19 DR. KLEINPETER: So basically since
20 there's very little evidence that's being
21 presented because it's a new measure, there is,
22 once again, statements regarding the importance

1 of establishing the target weight. But we just
2 had just the testing data provided by the
3 developer thus far.

4 CO-CHAIR CROOKS: Okay. The floor is
5 open for discussing the evidence base linking it
6 to the measure, linking positive health outcomes
7 to the measure.

8 I might comment that I'm having
9 trouble with this issue of knowing what the dry
10 weight is and I know we don't have that worked
11 out yet. But it seems to me that a patient could
12 just be set at some weight and hitting this
13 target all the time and be way off from where
14 they should be.

15 Unfortunately, there's not another
16 measure to link it to which is -- you know, the
17 right target weight is, but I don't know that the
18 evidence can really link this per se to better
19 health outcomes.

20 Michael?

21 DR. SOMERS: I know you have to pick
22 some target, but again, I'm not aware of any

1 evidence saying that one kilo is better than 1.1
2 kilo or 0.8 kilos.

3 CO-CHAIR CROOKS: Who else? Franklin?

4 DR. MADDUX: I just have a question
5 for the developers.

6 Were there any exclusions or how did
7 you expect to deal with patients that sign off
8 early or actually don't have some proportion of
9 their prescribed treatment actually delivered?
10 Were they simply added in as failures or were
11 they treated differently?

12 DR. MCGONIGAL: During our testing,
13 they were not treated differently. If they
14 didn't achieve the target weight, they just
15 weren't counted in the numerator.

16 So it was considered as a fail, part
17 of the rationale being that, you know, increasing
18 patient education on the importance of staying on
19 for their prescribed times and so underlying
20 that.

21 CO-CHAIR CROOKS: I'd like to hear
22 some more thoughts from the committee if you

1 think the evidence really supports that this will
2 improve health outcomes. You do, you don't?

3 Anybody? Frank?

4 DR. MADDUX: I'd just simply say fluid
5 overload hospitalizations are an enormous
6 component of comorbidity in this population and I
7 think trying to shine a light on those particular
8 issues through the achievement -- both the
9 assessment of an appropriate target weight and
10 the achievement of that are, I think, key issues
11 in trying to look at how you prevent that type of
12 morbidity.

13 CHO-CHAIR CROOKS: So it's a window,
14 but not a perfect window to -- other committee
15 members? Lorien?

16 DR. DALRYMPLE: I think sometimes
17 there are practical challenges.

18 For example, we're often -- I think
19 sometimes there are practical challenges that
20 doesn't necessarily negate it but often while
21 we're challenging dry weight, we're not re-
22 prescribing the dry weight on a daily basis, and

1 it's understood that, perhaps, this would make us
2 better and each day prescribe a new dry weight
3 and continue to challenge from there.

4 And then when people return from the
5 hospital, it's not uncommon -- at least in my
6 experience, that they come back eight to ten
7 kilos over their dry weight and it takes us,
8 unfortunately, time to get there. Not that that
9 doesn't mean this isn't important, but it can be
10 very challenging given the frequency of
11 hospitalization in our patients.

12 But I appreciate the balance of these
13 two measures combined. But I could actually see
14 where you would do well on one and poorly on the
15 other. So I'm trying to reconcile then what does
16 your quality look like?

17 And I'd actually be curious what other
18 -- and I know we're short on time -- what other
19 committee members think about if we have two
20 quality measures on volume, one you look
21 wonderful, one you look terrible, what the
22 summary of that meaning is.

1 MS. BAL: I would just say that that's
2 really more related in competing option. And
3 also it wouldn't really fall into evidence. But
4 if you want to bring it up later on, please do.
5 But, just try to focus on evidence right now.

6 Thank you.

7 CO-CHAIR CROOKS: That's what I was
8 going to say.

9 All right, so I see there's not a need
10 to discuss this much more and -- oh, Alan, I was
11 waiting for your card to come up. Thank you.
12 You're on.

13 DR. KLIGER: So just restricting
14 ourselves to the evidence, I think John stated it
15 well that there really is little evidence for a
16 compelling need to have measures for volume.

17 But given the arbitrary way that we
18 clinicians set the dry weight and given lack of
19 data on this plus or minus one kilo, the
20 evidence, unfortunately, is not there yet.

21 CO-CHAIR CROOKS: Michael?

22 DR. FISCHER: I agree. I mean I just

1 was reading -- I didn't review this, I was
2 reading what KDOQI says. I mean their focus is
3 on dry weight, but kind of what Michael said,
4 they don't -- there's no evidence for this
5 parameter around how close you get to it as
6 stipulated.

7 You know, and I haven't reviewed all
8 the other 13 studies, but I don't know if the
9 reviewer or the developer had rationale for
10 choosing ---- putting all the side dishes around
11 determining an optimal dry weight, around kind of
12 this boundary around which is deemed optimal
13 performance.

14 CO-CHAIR CROOKS: Thank you. Other
15 comments? Alan, your card's still up. Okay.

16 All right, I think it's time to vote
17 on the evidence.

18 MS. OGUNGBEMI: The committee is now
19 voting on evidence for Measure 2702. The options
20 are 1 high, 2 moderate, 3 low and 4 insufficient.
21 Voting is open.

22 The results are zero votes high, three

1 votes moderate, seven votes low and nine votes
2 insufficient evidence. Measure 2702 fails on
3 evidence.

4 CO-CHAIR CROOKS: So we can talk about
5 voting on an exception -- is that why you what
6 you were raising your hand for?

7 So the floor is open for proposal to
8 consider an exception at this time.

9 DR. DALRYMPLE: So I propose we vote
10 on insufficient with exception given the evidence
11 discussion.

12 CO-CHAIR CROOKS: Would any others
13 like to provide rationale for, against? Lisa?

14 DR. LATTIS: So I am -- this seems to
15 me to be one where if -- we let the perfect be
16 the enemy of the good. I mean it seems to me
17 like this is a good thing to measure and we might
18 not have the exact right numbers, but it's
19 probably a decent ballpark.

20 And this seems to me one that we
21 should get -- and I realize it's easy for me to
22 say it because I'm not getting reimbursed based

1 on this. It seems to me that this is one as a
2 companion measure to the ultrafiltration measure
3 and it seems to be something that is really
4 important in the scheme of dialysis.

5 And that for that reason, even though
6 we don't have the perfect data to say that these
7 are the exact right numbers, I would be in favor
8 of moving forward with it and tweaking as we go
9 rather than not continuing the discussion.

10 CO-CHAIR CROOKS: Thank you. Would
11 anybody else like to express a viewpoint?

12 Okay, well, then I think we'll just --
13 is this a hand vote that we do?

14 MS. BAL: No, this is a real vote.

15 CO-CHAIR CROOKS: Okay.

16 MS. BAL: I mean machine vote.

17 CO-CHAIR CROOKS: Once again, grab
18 your sticks.

19 MS. OGUNGBEMI: The committee is now
20 voting on importance to measure and report for
21 evidence with the potential exception to
22 empirical evidence.

1 The options are 1 insufficient
2 evidence with exception, and 2 no exception.

3 The results are ten insufficient
4 evidence with exception and nine for no exception
5 and that's actually gray-zoned. So I'm actually
6 not sure -- hold on one second.

7 So we're going to move forward.

8 CO-CHAIR CROOKS: We have a majority
9 who would like to see this continue with an
10 exception to the evidence. So we will go on to
11 gap.

12 DR. WAGNER: Okay. So the measures --
13 there were data from over 400,000 hemodialysis
14 treatments across three organizations.

15 And the interquartile range was 14
16 percent suggesting that there was a potential for
17 some intervention that might -- if one believes
18 this is an outcome, rather something that would
19 improve health, that this lends itself to that.

20 CO-CHAIR CROOKS: Okay. Other
21 comments on the performance gap? Okay, let's
22 vote then.

1 MS. OGUNGBEMI: The committee is now
2 voting on performance gap for Measure 2702. The
3 options are 1 high, 2 moderate, 3 low and 4
4 insufficient. Voting is open.

5 The results are three votes high, 14
6 votes moderate, zero votes low and two votes
7 insufficient. Measure 2702 passes on performance
8 gap.

9 CO-CHAIR CROOKS: Okay, specifications
10 and reliability?

11 DR. WAGNER: So specifications, as I
12 mentioned, we don't have exclusions for more than
13 three treatments during the week.

14 And also, when there's no adjustment
15 or exclusions for patient preference, which I
16 think is one of the major discussions that I
17 think patients will have regarding this.

18 And so -- and as far as the
19 reliability testing goes, the ANOVA analysis
20 indicated a moderately high interclass
21 correlation and a high ratio of between to within
22 facility correlations.

1 CO-CHAIR CROOKS: Okay. Myra?

2 DR. KLEINPETER: Something else, it's
3 available through CROWNWeb so it should be
4 relatively easy to get at this point.

5 CO-CHAIR CROOKS: Okay.

6 DR. DALRYMPLE: Is this three
7 treatments again?

8 DR. KLEINPETER: Yes.

9 DR. DALRYMPLE: So not currently
10 available through CROWNWeb, but we would assume
11 it would eventually be available through
12 CROWNWeb, correct? Okay.

13 CO-CHAIR CROOKS: Okay. Any other
14 comments on reliability specifications? All
15 right, let's vote.

16 MS. OGUNGBEMI: The committee is now
17 voting for Measure 2702 on reliability. The
18 options are 1 high, 2 moderate, 3 low and 4
19 insufficient. Voting is open.

20 Results are one vote high, 13 votes
21 moderate, five votes low and zero votes
22 insufficient. Measure 2702 passes on

1 reliability.

2 CO-CHAIR CROOKS: Okay. Validity
3 testing?

4 DR. WAGNER: So this correlates to the
5 standardized ratios that we've alluded to before
6 and as well as has high face validity by the
7 assessment of the KCQA committee tasked with
8 developing the measure.

9 CO-CHAIR CROOKS: Okay. Myra, any
10 comments?

11 Yes, it looked like they have strong
12 correlation with the measure with SMR and SHR
13 too, from my review.

14 Jessie?

15 MS. PAVLINAC: I should have asked
16 this earlier, we've been having this discussion.
17 Is this a clinician level or a facility level?
18 It's not --

19 CO-CHAIR CROOKS: It wasn't specified.

20 MS. PAVLINAC: -- specified and I --
21 sorry, I didn't --

22 DR. MCGONIGAL: These are all

1 facility.

2 MS. PAVLINAC: Okay, I just wanted to
3 know who's making the hit in the pocketbook.

4 DR. DALRYMPLE: And was the testing
5 done at facility level or organization level, if
6 that makes sense?

7 DR. MCGONIGAL: Facility.

8 DR. DALRYMPLE: Okay, and then
9 presented by organization?

10 DR. MCGONIGAL: Absolutely.

11 DR. DALRYMPLE: Is that correct?

12 CO-CHAIR CROOKS: All right, are we
13 ready to vote on validity?

14 MS. OGUNGBEMI: The committee is now
15 voting on validity for Measure 2702. The options
16 are 1 high, 2 moderate, 3 low and 4 insufficient.
17 Voting is open.

18 Results are one vote high, 16 votes
19 moderate, two votes low and zero votes
20 insufficient. Measure 2702 passes on validity.

21 CO-CHAIR CROOKS: On to feasibility?

22 DR. WAGNER: So feasibility has the

1 same issues that we discussed in the prior
2 metric. CROWNWeb would have to be modified to
3 accept the data.

4 CO-CHAIR CROOKS: Okay. Any
5 additional concerns? Okay, let's vote.

6 MS. OGUNGBEMI: The committee is
7 voting on feasibility for Measure 2702. The
8 options are 1 high, 2 moderate, 3 low and 4
9 insufficient. Voting has opened.

10 Results are one vote high, 14 votes
11 moderate, three votes low and one vote
12 insufficient. Measure 2702 passes on
13 feasibility.

14 CO-CHAIR CROOKS: Next, is it in use
15 and is it usable?

16 DR. WAGNER: So yes, it's not in use.
17 It's a new measure and so -- and presumably, it
18 could be used in public reporting and other ways.

19 And I guess the unintended
20 consequences that I would be concerned about
21 would be impact on patients who are not adhering
22 to their target weight prescribed by their

1 clinicians.

2 CO-CHAIR CROOKS: Developer comment
3 briefly, please?

4 DR. JONES: Again, it is being used in
5 one large dialysis organization for internal
6 quality reporting purposes.

7 CO-CHAIR CROOKS: Lorian?

8 DR. DALRYMPLE: I was just curious if
9 we could discuss as a committee whether others
10 had concerns about unintended consequences, such
11 as misprescribing the dry weight to not appear to
12 be achieving it if this was a measure of quality
13 and if, generally, the committee thinks the
14 benefits outweigh any potential harms or
15 unintended consequences?

16 CO-CHAIR CROOKS: John, you look like
17 you're about to speak.

18 DR. WAGNER: Yes, I mean I think this
19 is a real dilemma for clinicians when one has a
20 patient that is clearly not -- who has defined
21 ideas about what their target weight should be.

22 Whether it's a weight where they're

1 clearly overhydrated, but they tolerate it and
2 they want to be at that weight and one decides
3 that that's not the dry weight, one is left with
4 the dilemma of do you order a dry weight or do
5 you order the weight that the patient is only
6 going to allow you to achieve?

7 And you know, I think in my own
8 practice, after struggling with that with the
9 patient, trying to educate the patient, change
10 the patient's mind, I would choose the weight
11 that the patient will allow us to achieve.

12 And then our facility -- our quality
13 control was that we asked the nurses to document
14 whenever a target weight was not achieved within
15 0.5 kilograms so that there be some record of why
16 that patient did not reach the target weight and
17 which, sometimes, is not easy to discern from the
18 record unless there is a specific note written
19 about that.

20 CO-CHAIR CROOKS: Myra?

21 DR. KLEINPETER: One other thing is
22 those patients who frequently sign off early and

1 are nowhere near their target weight, how do you
2 handle those in terms of will those people be
3 adversely, I guess, dropped from those facilities
4 for noncompliance?

5 Or will you just have people just
6 adjusting things, just to try and meet with what
7 the patient says they're going to get to?

8 CO-CHAIR CROOKS: Well like many
9 measures, you're not going to hit a hundred
10 percent, I don't think. frankly.

11 DR. MADDUX: So I think to John's
12 point, we routinely use nomenclature that's
13 probably imprecise.

14 So we talk about dry weights, we talk
15 about target weights, we probably never really
16 are prescribing a true dry weight. It's very
17 difficult to assess. We're really looking at
18 target weights that we're trying to achieve for
19 an individual treatment. So I think the measure
20 might actually give us an opportunity to really
21 become more specific in how we use that language.

22 The second thing I would want to point

1 out is really a question on use to the group or
2 the developers. We've never actually talked
3 about a patient level measure, and to Myra's
4 point, in otherwise this would be a potential
5 measure that, in fact, a patient level measure
6 might actually apply because so much of the early
7 sign off or the no-show rate or the I'm unwilling
8 to go to that weight you think I should go to
9 discussion really is a patient decision.

10 And I don't think we've ever really
11 had a patient level potential measure quite like
12 this.

13 CO-CHAIR CROOKS: Did you see someone
14 had cards up and I'm not seeing them? Oh, you're
15 saying turn on your mic, dummy. Okay.

16 Okay, so ---- well, Myra, you're --
17 oh, you're putting your card down, okay. I
18 almost got you.

19 Okay, so I think we're ready to vote
20 on use and usability.

21 MS. OGUNGBEMI: The committee is now
22 voting on usability and use for Measure 2702.

1 The options are 1 high, 2 moderate, 3 low and 4
2 insufficient. Voting has opened.

3 The results are one high, 12 moderate,
4 five low and four insufficient. Measure 2702
5 passes on usability and use.

6 CO-CHAIR CROOKS: Okay, so we're going
7 to vote now on suitability for recommendation
8 knowing that the evidence was -- consensus was
9 not reached on making an exception and I think
10 the staff may have some more processing to do on
11 what exactly -- how we proceed, but we can go
12 ahead and vote.

13 Assuming that the exception is upheld,
14 would you recommend this for endorsement to the
15 NQF?

16 MS. OGUNGBEMI: The committee is now
17 voting on overall suitability for endorsement on
18 Measure 2702. The options are 1 yes, 2 no.
19 Voting is open.

20 For Measure 2702, results are 11 votes
21 yes, eight votes no. For Measure 2702, consensus
22 was not reached on meeting NQF criteria for

1 endorsement.

2 CO-CHAIR CROOKS: That's not a gray
3 zone?

4 MS. OGUNGBEMI: So consensus was not
5 reached and this measure would be -- we would
6 have to look at it again at the post-comment
7 call.

8 CO-CHAIR CROOKS: Okay. Thank you
9 very much. Okay, so do we only have two left?

10 You're kidding? I went back to 2700,
11 oh my goodness, all right.

12 Can you go to work again, Connie?

13 CO-CHAIR ANDERSON: No.

14 CO-CHAIR CROOKS: No?

15 CO-CHAIR ANDERSON: None of us can
16 since it's a competing measure with the KCQA
17 measure.

18 CO-CHAIR CROOKS: I'm not even finding
19 it here.

20 CO-CHAIR ANDERSON: On the last page.

21 CO-CHAIR CROOKS: Oh, I went the wrong
22 way. Okay, we'll consider Measure 2700. This is

1 ultrafiltration rate greater than 13 ml/kg per
2 hour from U of Michigan and CMS.

3 Are the developers here? Yes, okay.
4 Take it away.

5 DR. MESSANA: Such as we are.

6 So I would like to say that I love the
7 KCQA measure about ultrafiltration and I know
8 some in my group have commitment disorder kind of
9 issues, and so they just are very fond of it, but
10 I personally love it. Okay?

11 And the reason I love it is that our
12 measure is very similar fundamentally to the KCQA
13 measure that you discussed earlier. And the
14 similarities I'd like to highlight as you debate
15 the two measures -- debate our measure.

16 First, there is an approximately 13
17 ml/kg per hour threshold for the two measures.
18 Second, both measures attempt to exclude
19 transient and new patients. Third, the measures
20 share a common evidence basis. And fourth, the
21 two measures, even though they are somewhat
22 different, as is pointed by KCQA, have almost

1 identical validity and reliability outcome scores
2 when you look at them. So they are fundamentally
3 very similar.

4 There are a couple of differences that
5 are noteworthy. KCQA has pointed out that an
6 additional data requirement will be needed in
7 CROWNWeb before their measure can be
8 operationalized, okay? At least using CROWNWeb
9 data.

10 Ours does not require that. So the
11 potential threat to validity that was raised
12 about our measure when the comments were made
13 needs to be weighed against the feasibility
14 issue. Our measure is calculable right now.
15 Okay?

16 However, it's not to say that we
17 disagree with potentially using thrice weekly
18 ultrafiltration data when it's available, if it's
19 available and if the data collection burden for
20 single user interface facilities is addressed and
21 we'll see what that timeline is.

22 The one difference that I think is

1 important is the 240 minute statement in the
2 numerator that was raised by some. Ours does not
3 include that and we have had some difficulty
4 trying to harmonize over that particular aspect
5 of it.

6 As has been pointed out, the
7 literature doesn't address that particular
8 numerator statement or practical considerations
9 that KCQA used, but we have been working on
10 analyses looking at the 240 minute numerator
11 inclusion or numerator statement, and find that
12 about 20 percent of the patients ---- based on
13 the current CROWNWeb data or recent CROWNWeb
14 data, about 20 percent of the patients who have
15 high UFR rate have high UFR rate with a 240
16 minute or longer treatment time.

17 And if you look at associations with
18 mortality for those patients stratified on
19 treatment time cut at 240 minutes, the increased
20 rate -- the increased mortality associated with
21 high UF rate, the association is at least as
22 strong for patients above 240 minutes as it is

1 for patients below 240 minutes.

2 So if we get around, if we have the
3 opportunity to harmonize measures down the road,
4 that's going to be an important issue to talk
5 about. But other than that, those are relatively
6 small issues. Fundamentally, the two measures
7 are relatively similar.

8 Thank you.

9 CO-CHAIR CROOKS: Okay, thank you.

10 The same three people are, I believe
11 -- yes, excluded from consideration --
12 considering this measure or voting.

13 And our discussants are Rick Kaskel
14 and Dodie Stein. Take it away Dodie.

15 DR. STEIN: According to this, it's an
16 intermediate clinical outcome intended to guard
17 against risk with rapid fluid removal, high UFR,
18 faster UFR.

19 From my own perspective, I think the
20 goal is a good one and it sounds like the
21 evidence is compelling. I have some other
22 concerns about how this thing happens at the

1 clinical level.

2 Rick?

3 DR. KASKEL: Just to add -- and again,
4 basically, we're with this challenge that early
5 data demonstrated that a high ultrafiltration
6 rate was linked to increased mortality, increased
7 intradialytic hypotension as well as myocardial
8 stunting.

9 So it is very important data indeed
10 and there is some data that suggests that this is
11 mechanistic and should be evaluated.

12 CO-CHAIR CROOKS: Okay, Alan?

13 DR. KLIGER: Can I point out that all
14 of those data which are interesting are
15 associative and not causative data.

16 And patients who get those high
17 ultrafiltration rates, particularly those who get
18 long treatments and high ultrafiltration rates
19 may be the very ones at highest risk of death,
20 not because we're dialyzing them or
21 ultrafiltering them but because they're the big
22 weight gainers and have cardiovascular ----

1 underlying substantial cardiovascular disease.

2 So I just think we have to be very
3 careful interpreting those data.

4 CO-CHAIR CROOKS: Other discussion of
5 the evidence? Franklin?

6 DR. MADDUX: I'd just say that as I've
7 looked at the evidence on ultrafiltration rates
8 on a per kilogram per milliliter per hour, it's
9 the -- it seems fairly obvious when you're below
10 ten or you're above 15.

11 Between 13 and 15, there's still some
12 controversy, I think, in some of the articles
13 that I've read as to exactly where that cut point
14 is. So it's a bit of a less clear zone and that
15 was one of the reasons why I thought the
16 additional time-based element to the measure had
17 some value because it mitigated that to some
18 degree for these patients that you mentioned,
19 Alan, that may represent as many as 20 percent of
20 the over 13 people.

21 There is a lot of study still to be
22 done in this area, it seems to me. And so we're

1 not at a high level of maturity, I think, on this
2 particular topic. So it strikes me.

3 And then the other is simply a
4 question that I have probably for the group and
5 then for the developers would be my big concern
6 about the single measurement in this is the long
7 intradialytic interval and the impact that that
8 would have on the results by using that single
9 measure if it happened to be on the Monday or
10 Tuesday -- typical Monday or Tuesday.

11 And I don't know whether that bothers
12 anybody else or not.

13 CO-CHAIR CROOKS: That might be
14 reserved for the specifications section then.

15 So the evidence is not what we'd like,
16 but it's the evidence that we have.

17 Other -- Lorien? I'm sorry, I didn't
18 see your card.

19 DR. DALRYMPLE: So I just have kind of
20 one general question for the group since we did
21 just recently review a measure for KCQA that's
22 very similar except for in the assessment of

1 time.

2 Does anyone have a different
3 assessment of evidence for this measure as
4 compared with that one? Or a different
5 interpretation of the evidence than we did for
6 the prior measure that had a similar target?

7 CO-CHAIR CROOKS: No? Okay.

8 Yes, Michael?

9 DR. SOMERS: Except that some of the
10 evidence in the other measure was the time-based
11 evidence.

12 So I think that would have been
13 considered along with the evidence for the
14 ultrafiltration goal. So I think that's kind of
15 the difference between the two in my mind.

16 DR. DALRYMPLE: Did your impression
17 change between these two measures with that --

18 CO-CHAIR CROOKS: Mic?

19 DR. DALRYMPLE: I'm sorry. And my
20 question just was, you know, to the group.

21 I'm just curious if you would rate the
22 evidence differently based on those differences?

1 And I'm just curious about the group's thoughts
2 on that since we just recently --

3 DR. SOMERS: Well in my mind, I
4 thought the time-based evidence was stronger than
5 the UF rate evidence. And other people on my
6 workgroup said that as well. We didn't ask
7 everyone individually, so I don't know if there
8 was consensus in the workgroup.

9 CO-CHAIR CROOKS: John?

10 DR. WAGNER: I guess I would add that
11 with the double measure, there are two patient-
12 related factors in the metric.

13 In here we have one, namely the
14 patient's intradialytic weight gain can only be
15 handled in a certain way in terms of UFR. And if
16 a patient is willing to extend time to at least
17 the four hour mark in the other metric, then
18 whatever intradialytic weight gain the patient
19 has falls away as an issue.

20 So in this case, we don't have that as
21 a safety valve for the patient in any case.

22 CO-CHAIR CROOKS: Okay. Shall we vote

1 on the evidence?

2 MS. OGUNGBEMI: The committee is now
3 voting on evidence for Measure 2700. The options
4 are 1 high, 2 moderate, 3 low and 4 insufficient.
5 Voting is open.

6 MS. BAL: Could everyone try one more
7 time? We need one more vote. There should be
8 19.

9 Unless someone -- unless you see your
10 friend missing other than -- oh okay, then we're
11 good. Never mind. It's hard to see on this
12 side.

13 MS. OGUNGBEMI: Well, it's a gray zone
14 measure because the results are zero votes high,
15 nine votes moderate, six votes low and three
16 votes insufficient. So Measure 2700 is in the
17 gray zone for evidence.

18 CO-CHAIR CROOKS: Okay. Familiar
19 territory for this group.

20 Okay, so we're going to go on to
21 discuss the performance gap.

22 DR. KASKEL: I'll do it.

1 So this is CROWNWeb analysis of over
2 400,000 hemodialysis entries and it shows a ten
3 percent splay in performance between the 25th
4 percentile and the 75th percentile facilities.

5 Given the number of HG patients
6 nationally, it translates to a large patient
7 population with a potential benefit if the
8 rationale behind the measure holds.

9 There's disparity data presented that
10 looks at key facility demographics separated into
11 quintiles, all of which showed differences in
12 performance across quintiles. However, it's not
13 clear if this is biologically a basis for these
14 differences or changes that might result in care.

15 So the gap information would benefit
16 from the national measure and their suggestion
17 that there is disparity data differences.

18 CO-CHAIR CROOKS: In my interpretation
19 of the disparity data was that there was
20 statistically significant data because they have
21 so many numbers to crunch, but they may not be
22 clinically meaningful, you know, the differences

1 between the quintiles.

2 Okay, let's vote on performance gap
3 then.

4 MS. OGUNGBEMI: The committee is now
5 voting on performance gap for Measure 2700. The
6 options are 1 high, 2 moderate, 3 low and 4
7 insufficient. Voting has opened.

8 Results are zero votes high, 17 votes
9 moderate, one vote low and one zero votes
10 insufficient. Measure 2700 passes on performance
11 gap.

12 CO-CHAIR CROOKS: Okay, so we can
13 continue on our discussion about specifications
14 and reliability.

15 DR. STEIN: Yes, on the reliability,
16 84 percent variation was attributed between
17 facility differences and 16 percent attributed
18 with in-facility variation.

19 Testing was performed on adults
20 hemodialysis patients at dialysis facilities over
21 11 patients. CROWNWeb data overall IUR was 0.84,
22 as I said.

1 CO-CHAIR CROOKS: Okay. So the IUR
2 was good and we were discussing specifications a
3 while back.

4 Franklin, anything else you wanted to
5 underline or make clear?

6 DR. MADDUX: No, I think what I said
7 before is where I am. I'm still concerned about
8 the long intradialytic interval from the one
9 measurement versus several.

10 CO-CHAIR CROOKS: Okay. Other
11 concerns about the specifications or reliability
12 that you'd like to mention?

13 Okay, let's vote.

14 MS. OGUNGBEMI: The committee is now
15 voting on reliability for Measure 2700. Options
16 are 1 high, 2 moderate, 3 low and 4 insufficient.
17 Voting has opened.

18 Measure 2700 for reliability has
19 passed. The votes are zero high, 12 moderate,
20 five low and one insufficient.

21 CO-CHAIR CROOKS: Yes, 75 percent.

22 Okay, what's next? I've lost my

1 place. Validity.

2 DR. KASKEL: So validity. The
3 analysis provided showing that there can be a
4 clear separation in measurement performance to
5 group facilities.

6 Given that there was less compelling
7 data to show interquintile validity differences,
8 this would need to be -- one would need to be
9 careful how such a construct was designed to
10 stratify centers to make sure that potentially
11 non-significant differences in quintile
12 distribution were not part of the design.

13 Some units determine kilograms to be
14 removed first then time-allowed resulting in
15 ml/kg per hour measure. What needs to be
16 established and controlled first is the question.
17 What effect would standard would have on
18 patients' comfort -- the standard have on the
19 comfort, adherence to treatment, feasibility of
20 dialyzing patients in a typical four hour window,
21 some units use three to three point five hours,
22 and the impact of staff effort with the patient

1 needing attention for symptoms such as cramping,
2 blood pressure and the costs ---- the unit costs.

3 These are a lot of significant areas
4 here for testing. Should standard specify limits
5 on fluid removal per hour as well? And should it
6 consider mortality rate of the unit relative to
7 ultrafiltration?

8 Some units may have more intradialytic
9 weight issues and treatment non-adherence as a
10 result of the patient mix and during the dialysis
11 treatments would be different with the problems.
12 And what about the socioeconomic or psychosocial
13 issues? All of these things have to be taken
14 into account.

15 You had some other discussion about
16 patient involvement or decision?

17 DR. STEIN: Yes, I'm not sure. This
18 may be feasibility, but just it takes the choice
19 out of the patients. It's not patient-centered
20 and there are a number of other issues that I'll
21 mention under feasibility that go along with
22 this.

1 CO-CHAIR CROOKS: Okay. Let's just
2 stay with the validity question for the moment
3 and then we'll -- can open up these other issues.

4 So any other questions on validity?
5 Lorien?

6 DR. DALRYMPLE: So I just wasn't sure
7 if we wanted to discuss as a committee the
8 findings from the Poisson regression on the SHR
9 and SMR with respect to the highest quintile.

10 There is some explanation by the
11 developer, but the lack of graded association and
12 what other people make of that.

13 CO-CHAIR CROOKS: She's saying the
14 validity testing gave negative results or --

15 DR. DALRYMPLE: So it didn't give
16 graded results and there is some explanation of
17 that.

18 So for example, quintile five, the
19 relative risk for the ---- let me make sure I'm
20 doing the hospitalizations is for quintile five,
21 1.03, but for quintile two, 1.05, for three 1.08,
22 for quintile four 1.06.

1 So in other words, the highest rates
2 of UF have relatively lower hospitalization or
3 mortality. And I think the developer's fairly
4 proposed mechanisms why that may be, you know,
5 are patients that tolerate very high UF rates
6 tend to be younger, perhaps healthier at
7 baseline.

8 But I just didn't know if the
9 committee wanted to discuss, since this was the
10 validity testing put before us, if it influenced
11 out thoughts on UF rate and outcomes.

12 So there's also mortality on my
13 document, this is page 25. I don't know if
14 Poonam or someone could just pull up page 25 and
15 it's a little bit easier if you see it than speak
16 it.

17 CO-CHAIR CROOKS: I'm one measure
18 behind.

19 DR. DALRYMPLE: Page 25 on my
20 worksheet, which I think includes comments.

21 And the developers will correct me if
22 I'm wrong, but they say this is likely a

1 manifestation of selection bias relating to
2 healthier patients being more tolerant of higher
3 UF rates. Facilities in the highest quintile
4 may, therefore, have greater proportions of
5 healthier patients in their panel, blunting the
6 current risk of higher UF rates.

7 Adjustment for this effect would
8 require a complex analyses beyond the scope of
9 what is possible here, which I understand those
10 would be fairly complex. I just didn't know if
11 this affected interpretation of --

12 CO-CHAIR CROOKS: Before we go to the
13 developers, are there other responses?

14 I have to say, it doesn't reassure me
15 that's a valid measure from this analysis.

16 Alan?

17 DR. KLIGER: Yes, great question. So
18 the alternate explanation other than what the
19 developer has is that the underlying hypothesis
20 is incorrect.

21 The other possibility is that these
22 higher ultrafiltration rates don't result in

1 worse outcomes, in fact. Now we don't know
2 because the data all are associative data and not
3 causative data. And so, I think you're
4 observation is a very important one.

5 DR. FISCHER: Did they provide
6 anything else for validity testing other than
7 this?

8 Because if this is it, then if you
9 once again go back to the NQF algorithms, this
10 falls into kind of a low category in terms of
11 validity.

12 But I didn't review this. I don't
13 know if there's anything else in the application
14 beyond this commenting on face validity, et
15 cetera.

16 CO-CHAIR CROOKS: Yes, I was in this
17 workgroup and I share that concern that the
18 validity hasn't been established.

19 DR. DALRYMPLE: Can I ask just a
20 procedural question? Because our committee just,
21 I think two measures ago, voted to pass a very
22 similar measure although the specifications are

1 different.

2 This is one value versus three values,
3 which may be part of why there's a disconnect
4 here. We could argue there's a specification
5 difference.

6 But, Sarah, do you have insight into
7 when committees have this inconsistency between
8 similar measures and how we assess validity?

9 MS. SAMPSEL: Well, I mean in this
10 case, you also -- I mean I assume the testing was
11 different on the other measure. So that's the
12 other difference here.

13 You know, we'll still bring you back
14 to the point, you know, now you need to vote on
15 what was provided here and then during public
16 comment, et cetera, you know, if the developers
17 have additional information for your
18 consideration as well as through public comment
19 have additional information for consideration,
20 that would be brought back to you.

21 But I mean you are correct. That's a
22 really good question because there should be

1 consistency in the voting.

2 I feel that you all did talk about on
3 the evidence side, you know, why that you voted
4 differently on the evidence. And so, this brings
5 out why you may be voting differently on
6 validity.

7 CO-CHAIR CROOKS: Any other comments?
8 Questions? John?

9 DR. WAGNER: So I'm just curious, is
10 this really an insufficient or low validity
11 outcome or is this a no?

12 CO-CHAIR CROOKS: A no validity
13 outcome?

14 DR. WAGNER: Yes.

15 CO-CHAIR CROOKS: I guess that's your
16 choice exactly how to categorize it, but we need
17 to do it now, so let's raise our sticks and do
18 our job.

19 MS. OGUNGBEMI: The committee is now
20 voting on validity for Measure 2700. The options
21 are 1 high, 2 moderate, 3 low, 4 insufficient.
22 Voting is open.

1 The results are zero votes high, four
2 votes moderate, eight votes low and seven votes
3 insufficient. Measure 2700 fails on validity.

4 CO-CHAIR CROOKS: Now that's not the
5 end of consideration for validity -- oh, wait,
6 this is validity, it is, yes.

7 Okay, so we can stop considering this
8 measure. We'd like to offer a chance to give
9 feedback to the developers before we move on.

10 DR. DALRYMPLE: My only question would
11 be, I know in some of the prior measures where
12 there's been inconsistent findings, measure
13 stewards have provided us with face validity
14 which we have credence to.

15 So if there is a TEP or someone else
16 who's weighed in that could grant face validity?

17 DR. FISCHER: My comment would be to
18 look at your own data and maybe rethink
19 alternative hypotheses and explanations.

20 And maybe one of them may be the
21 specification issue that Franklin and other
22 people raised, having a one-time value and maybe

1 that explains why in the validity testing you
2 have an unexpected finding that may not otherwise
3 appear if it's specified differently.

4 CO-CHAIR CROOKS: Okay.

5 MS. WAGER: I'd like to make a
6 comment. I think with this measure, the focus is
7 not, as Dodie mentioned, the patient-centered
8 care.

9 When I worked on the dialysis floor,
10 we always assessed the patient individually.
11 Their goal was individual. I think this --
12 you're taking the patient out of the equation
13 when they are the most, I think, important person
14 of that team at that time when they're dialyzing.

15 If we don't consider them or take what
16 their ideas like Dr. Wagner said, we could have
17 adverse events. I'm sorry, I just think the
18 patient should be involved in it.

19 CO-CHAIR CROOKS: Very good, thank
20 you. Any other comments for the developers?
21 Advice? Dodie?

22 DR. STEIN: I continue to be concerned

1 about the patient and how you juggle all these
2 measures without the patient having any choice in
3 the matter and how one juggles a limited time, a
4 specified time, plus the dry weight or whatever
5 the goal is with that, plus an ultrafiltration
6 rate.

7 And it just seems very complex and
8 burdensome on staff as well.

9 CO-CHAIR CROOKS: Okay. Thank you.
10 Any other comments?

11 Okay, thank you very much.

12 DR. MESSANA: Can I ask for
13 clarification?

14 CO-CHAIR CROOKS: Yes, you may.

15 DR. MESSANA: So regarding the patient
16 participation comments, I'm having a little bit
17 of trouble understanding how this metric is
18 different in that regard and that concern than
19 the metric you passed two measures ago. Thank
20 you, thanks -- that's the M word.

21 So I'm just trying to better
22 understand that because I really -- you know, I

1 value the perspective, but I want to understand
2 it better.

3 MS. WAGER: Again, I'm just one of 23.

4 CO-CHAIR CROOKS: Okay, so moving
5 forward, we are going to -- a couple of points.

6 In 20 minutes, we're going to stop for
7 public comments. The staff has advised me that
8 they want to continue to work as long as we have
9 a quorum, which is 15.

10 So after 3:00 if you need to go, you
11 need to go but we'll try to get a little --
12 squeeze a little more work out of today.

13 We have a two hour call scheduled next
14 week.

15 MS. BAL: Next Tuesday.

16 CO-CHAIR CROOKS: Next Tuesday. Okay.
17 Did I cover it? Okay.

18 I'm turning it over to Connie for the
19 next measure.

20 CO-CHAIR ANDERSON: All right, we're
21 going back to Measure 0225 which is the measure
22 of serum phosphorus concentration. And Claudia

1 and Joel? 0255, what did I say?

2 MS. BAL: 0225.

3 CO-CHAIR ANDERSON: Oh, I'm sorry.

4 It's really hard to sit for an hour and a half
5 and keep your mouth shut. This is really unfair.

6 All right.

7 DR. DAHLERUS: Okay, so yes, this is
8 Measure 0255 and this is a process measure of
9 monthly phosphorus measurement. It was
10 originally developed in 2006 and endorsed by NQF
11 in 2007 and again in 2011.

12 A mineral bone disorder TEP was
13 convened in 2013 and among their activities was
14 reviewing the current process measure to also
15 consider expansion of the measure to include
16 serum or plasma, as well as another review of any
17 additional evidence.

18 The TEP affirmed the measure. They
19 did propose a revision to the denominator to
20 include children in the denominator feeling it
21 was important that children are assessed for a
22 monthly measurement.

1 And then they also wanted to ensure
2 that transplant patients with a delayed graft use
3 ---- a functioning graft, but delayed graft use,
4 would still be included in the monthly assessment
5 of phosphorus feeling that it was important if
6 they were on chronic dialysis they would be
7 included.

8 CO-CHAIR ANDERSON: All right, and the
9 discussants are Ishir and Michael.

10 DR. BHAN: So I'll start this off. So
11 just going quickly.

12 So the evidence here, there is a
13 couple of sources provided, but one is the KDOQI
14 Guidelines -- sorry, these are the KDIGO
15 Guidelines, that suggest for CKD stage 5D or
16 stage 5 including 5D that phosphorus be measured
17 every one to three months.

18 Then there is a whole bunch of other
19 references provided which are not summarized per
20 se, but I know from my own experience, there is a
21 reasonable associative retrospective data on high
22 phosphorus levels and increased mortality, though

1 that's associative data so there is always limits
2 to that.

3 Main comments, this is, of course,
4 focused on the -- it's a process measure, so it's
5 focused on the measurement of phosphate. This
6 data was not directly about the measurement of
7 phosphate, it was largely on the associations of
8 phosphate with outcomes. Of course, if you don't
9 know what the phosphate is, then you wouldn't be
10 able to act on it.

11 That said, there is a little bit of
12 discrepancy here. The KDIGO Guidelines say one
13 to three months and this measure does state a
14 monthly phosphorus, so there is a little
15 discrepancy of note there.

16 Michael, did you have anything to add?

17 DR. FISCHER: I agree with all that.
18 I think we struggled -- and Ishir, please chime
19 in, and our other workgroup members, about
20 evidence. And this was a measure that was
21 endorsed, I think, before and is up for
22 reendorsement.

1 I think at that point, we also
2 struggled a bit ---- I mean I'm almost of two
3 minds about process measures. On one hand,
4 they're tightly linked, obviously, to provider
5 behavior and they're infinitely measurable. On
6 the other hand, there are so many steps between
7 them and what we really care about in outcome.

8 And I think that, to me, always is a
9 struggle in terms of evidence. And I think Ishir
10 nicely pointed out, a lot of the evidence is
11 about actually phosphorus levels, not necessarily
12 the act of measuring phosphorus, and that's what
13 this is about.

14 I think the only thing I would add is,
15 this was reviewed by KDOQI, but my understanding
16 -- and you can correct me, is that it was without
17 grading. And I don't know what without -- and
18 maybe others on the committee know better than
19 me, I don't know what without grading is. Is
20 that D plus?

21 So you know, I'm not really sure how
22 to interpret that, but it certainly is not a high

1 level of evidence. I think otherwise I agree
2 with all the comments and if other people from
3 the workgroup have additional recollections, it'd
4 be good to hear from them.

5 CO-CHAIR ANDERSON: Open for
6 discussion by the committee.

7 No discussion, then let's call for the
8 vote on evidence.

9 MS. OGUNGBEMI: The committee is now
10 voting on evidence for Measure 0255. The options
11 are 1 high, 2 moderate, 3 low and 4 insufficient.
12 Voting is open.

13 Results are one vote for high, 14
14 votes moderate, two votes low and four votes
15 insufficient. Measure 0255 passes on evidence.

16 CO-CHAIR ANDERSON: Moving to
17 performance gap?

18 DR. BHAN: So for performance gap
19 here, the data was generated from the 2013
20 CROWNWeb over 6,000 facilities.

21 And the key numbers here are the
22 quartiles, the 25th percentile was 86 percent,

1 the 50th percentile, 92 percent and 75th, 96
2 percent. So if you look at the median 92
3 percent, that doesn't leave a whole lot of room
4 for improvement.

5 I also wondered out loud without any
6 real answers as to why people aren't having
7 phosphorus measured, but I supposed that's, you
8 know, the same issue came up with the hemoglobins
9 in the pediatric population. But we don't have
10 answers here about that.

11 So I think that was the real concern
12 that came up on our call was how much room for
13 improvement is there? Are there factors that can
14 actually be intervened upon? Is this
15 hospitalization-related issues, et cetera?

16 CO-CHAIR ANDERSON: Alan?

17 DR. KLIGER: Just to point out that a
18 patient would fail this if they missed one month.
19 Right? So if they were in the hospital or
20 somewhere else or -- so, it's not a surprise.

21 DR. BHAN: Although they're an
22 exclusion here. The denominator excludes

1 patients who have not been in the facility the
2 entire reporting month.

3 Although that may be more transfer-
4 related than hospitalization. So you might have
5 a valid point. It also speaks to the discrepancy
6 of the one monthly versus between one to three
7 months.

8 DR. FISCHER: I mean I think over all,
9 is it fair to say I think we felt the performance
10 gap was rather small, is that fair? I think that
11 was kind of the consensus of our working group.
12 Just so everyone has an idea what the -- I think
13 the working group sentiment was at the end of our
14 conversation.

15 CO-CHAIR ANDERSON: Frank?

16 DR. KRISHNAN: I think it's currently
17 measured in the QIP, right? So it's small in the
18 QIP as well, the calcium phosphorus measurement
19 is a QIP measure today is small, the gap.

20 CO-CHAIR ANDERSON: Frank?

21 DR. MADDUX: Could I just -- can I get
22 a clarification?

1 So the denominator exclusion is
2 patients who haven't been in the facility for the
3 entire month, so it would exclude anyone who is
4 hospitalized. Is that correct? Yes, that's the
5 way I interpreted it.

6 DR. BHAN: Can we confirm that with
7 the developer?

8 DR. DAHLERUS: So if the patient was
9 hospitalized for the entire month, they would be
10 excluded. If they were hospitalized for a part
11 of the month, they would not be excluded.

12 DR. MADDUX: So that isn't quite how
13 I read what's on here. It says exclusions are
14 implicit in the denominator definition and
15 include all patients who have not been in the
16 facility the entire reporting month.

17 DR. DAHLERUS: So the entire reporting
18 month is meant to be 30 calendar days. So they
19 have to --

20 DR. MADDUX: So if I was out for five
21 calendar days, I wouldn't have been there the
22 entire reporting month?

1 DR. DAHLERUS: Right, but you have to
2 be out of the facility, discharged from the
3 facility for the entire 30 days. If not, then
4 you would still be included.

5 DR. MADDUX: Okay.

6 DR. DAHLERUS: And we'll confirm with

7 --

8 DR. MADDUX: It's a little -- it's not
9 quite clear --

10 DR. DAHLERUS: Right, we'll confirm.

11 DR. MADDUX: -- the way it's written.

12 DR. DAHLERUS: Agreed.

13 CO-CHAIR ANDERSON: Any further
14 discussion? All right, let's vote on performance
15 gap.

16 MS. OGUNGBEMI: The committee is now
17 voting on performance gap for Measure 0255. The
18 options are 1 high, 2 moderate, 3 low and 4
19 insufficient. Voting is open.

20 Results are zero votes high, six votes
21 moderate, 14 votes low and one vote insufficient.
22 Measure 0255 fails on performance gap.

1 MS. SAMPSEL: So, I muted myself, but
2 this is ---- for consistency sake, this would be
3 very similar to other ones where ---- that you
4 considered for reserve status.

5 CO-CHAIR CROOKS: Right, right, right.
6 Thank you.

7 CO-CHAIR ANDERSON: I guess we're
8 going to do a hand vote. Would the committee
9 like to consider making this measure ----
10 bringing to reserve status?

11 DR. KRISHNAN: Just a question for
12 Sarah, though. This is not currently a fielded
13 metric, right? It's a component of -- calcium
14 phosphorus is a fielded metric, but phosphorus
15 itself is not.

16 DR. DAHLERUS: It is a current
17 measure, yes.

18 DR. KRISHNAN: Calcium and phosphorus
19 is a current measure. Phosphorus itself?

20 DR. DAHLERUS: No. This is the serum
21 phosphorus is a separate current NQF endorsed
22 measure.

1 DR. FISCHER: Right, and again, this
2 was endorsed originally in 2007, re-endorsed in
3 2012.

4 CO-CHAIR ANDERSON: Would the
5 committee like to vote this for reserve status?
6 All right, hands if you would like this to move
7 to reserve status?

8 All right, we'll continue with
9 reliability.

10 DR. BHAN: So for reliability, I'm
11 just going to jump to our comments.

12 The specifications, there was some
13 confusion about inclusion of transplant patients
14 with an active allograft. There was also concern
15 about inclusion of pediatric patients since the
16 evidence cited was from adults. I want to hear
17 from our pediatric colleagues about that, but
18 there was some concern that exclusion criteria
19 would thus need to be modified.

20 And the same discussion we already had
21 about the effects of hospitalization specifically
22 being an issue that people are hospitalized for

1 part of the month would still be included.

2 The reliability testing -- let me just
3 pull that up, looked at IURs that were 0.95 to
4 0.97. Most of the variation was attributed to
5 between facility variation and it looked overall
6 pretty reliable.

7 So to summarize, some concerns about
8 the specifications that we discussed.

9 CO-CHAIR ANDERSON: Michael, any
10 addition?

11 DR. FISCHER: Yes, I agree with Ishir.
12 I think we had questions for the developer about
13 the items he mentioned.

14 I think we already discussed the
15 hospitalization thing, which I found confusing.
16 I interpreted it the way Franklin did when I read
17 this. And then the other two issues were
18 pediatric patients and transplant patients with
19 functioning allografts.

20 CO-CHAIR ANDERSON: I think one of the
21 other questions at least under the reliability in
22 the specifications was about the home dialysis

1 patient population and I'd like to ask the
2 developers if they've come up with what are you
3 going to do -- are you excluding the home
4 patients? Are they included?

5 DR. DAHLERUS: I believe the home
6 patients are included.

7 CO-CHAIR ANDERSON: They are included?

8 DR. DAHLERUS: I believe -- this is
9 something that I'll have to check with our
10 analyst to make sure that they were included in
11 the analysis, in the calculation.

12 CO-CHAIR ANDERSON: Okay. For both
13 hemo and PD?

14 DR. DAHLERUS: Yes.

15 CO-CHAIR ANDERSON: Okay.

16 DR. DAHLERUS: So we do indicate that
17 home dialysis patients are included as I'm
18 looking here at my notes. So I'm not sure why
19 that was a question to begin with.

20 DR. FISCHER: And this is including
21 adult and pediatric patients? Just to confirm.

22 DR. DAHLERUS: Yes, it is. And that's

1 a change from the measure that was originally
2 endorsed in 2007 and again in 2011.

3 The 2013 MBD TEP wanted to add
4 children to the denominator in order -- that they
5 would be assessed on a monthly -- for the monthly
6 measurement as well.

7 DR. FISCHER: Okay, thanks.

8 CO-CHAIR ANDERSON: Any other comments
9 on reliability? All right, let's vote.

10 MS. OGUNGBEMI: The committee is now
11 voting on reliability for Measure 0255. The
12 options are 1 high, 2 moderate, 3 low and 4
13 insufficient. Voting is open.

14 Results are one vote high, 14 votes
15 moderate, three votes low and zero votes
16 insufficient. Measure 0255 passes on
17 reliability.

18 CO-CHAIR ANDERSON: All right, moving
19 on to validity?

20 DR. BHAN: So validity here, we talked
21 about the issue of the where this is coming from,
22 primarily data around phosphorus and outcomes

1 rather than testing per se.

2 The validity testing here looked at
3 Poisson regression models to determine the
4 association with mortality and came up with a ten
5 percent -- a relative risk of mortality of 0.98
6 for a ten percent increase in the performance
7 score.

8 I guess the issue there is how many
9 facilities can have a ten percent increase in the
10 performance score? And even if they achieve
11 that, there's relatively small association with
12 mortality here.

13 And I think there was this -- also a
14 question about the validity given the issue of
15 patient absences.

16 CO-CHAIR ANDERSON: Michael? Any
17 further discussion on the part of the committee?

18 All right, we will be voting on
19 validity.

20 MS. OGUNGBEMI: The committee is now
21 voting on validity for Measure 0255. Options are
22 1 high, 2 moderate, 3 low and 4 insufficient.

1 voting is open.

2 Results are one vote high, 16 votes
3 moderate, two votes low and zero votes
4 insufficient. Measure 0255 passes on validity.

5 CO-CHAIR ANDERSON: We're going to
6 pause here for a minute. It's time for public
7 comment. So we'll take the measure up after the
8 public comment time.

9 OPERATOR: Okay. At this time, if you
10 would like to make a comment, please press star
11 then the number one.

12 There are no public comments at this
13 time.

14 CO-CHAIR ANDERSON: All right, so
15 let's move on. Feasibility?

16 DR. BHAN: So in general, our group
17 felt that this is feasible.

18 It's already part of the QIP and data
19 is routinely generated during the process of
20 care. So it looked pretty feasible.

21 CO-CHAIR ANDERSON: Michael?

22 DR. FISCHER: Let's vote.

1 CO-CHAIR ANDERSON: All right, let's
2 vote.

3 MS. OGUNGBEMI: Committee is now
4 voting on feasibility for Measure 0255. Options
5 are 1 high, 2 moderate, 3 low, 4 insufficient.
6 Voting is open.

7 Results are 12 votes high, seven votes
8 moderate, zero low and zero insufficient.
9 Measure 0255 passes on feasibility.

10 CO-CHAIR ANDERSON: All right, moving
11 on to usability and use?

12 DR. BHAN: It's used in the QIP.
13 There's not any obvious unintended consequences
14 publically reported. It seems useable.

15 CO-CHAIR ANDERSON: Alan?

16 DR. KLIGER: So in terms of usability,
17 I want to ask the pediatricians their opinion.
18 Monthly blood draws from your home dialysis
19 patients?

20 DR. SOMERS: Since almost all of our
21 home dialysis patients are PD patients, they're
22 seen by us on a monthly basis anyway. I don't

1 think that's a big issue in the pediatric world.

2 DR. KASKEL: I concur. They come in
3 and even if they're a small infant, we need to
4 get -- we get the labs.

5 CO-CHAIR ANDERSON: All right, ready
6 to vote on usability and use.

7 MS. OGUNGBEMI: The committee is now
8 voting on usability and use for Measure 0255.
9 Options are 1 high, 2 moderate, 3 low and 4
10 insufficient. Voting is open.

11 Results are 11 votes high, eight votes
12 moderate, zero votes low and zero votes
13 insufficient. Measure 0255 passes on usability
14 and use.

15 CO-CHAIR ANDERSON: All right. We are
16 -- any other comments or issues to discuss before
17 we vote on usability for endorsement and for
18 reserve status? So let's vote.

19 MS. OGUNGBEMI: Committee is now
20 voting on potential for reserve status for
21 Measure 0255. Options are 1 yes, 2 no. Voting
22 is open.

1 Results are unanimous, 19 votes yes,
2 zero no for potential for reserve status for
3 Measure 0255.

4 CO-CHAIR ANDERSON: We still have a
5 quorum and so we would like to continue if the
6 committee is willing to continue on until we lose
7 quorum until at least 3:00.

8 Okay, thanks. Next measure is 1425,
9 Joe and Joel?

10 DR. MESSANA: For the sake of time, I
11 will limit my comments on this measure to
12 clarification of a typographical error that was -
13 --- or a question that was raised about a
14 potential typographical error in 1(b)(2) and
15 1(b)(4).

16 In the workgroup, a question came out
17 was it 30 facilities or 13 facilities. The
18 answer is 30 facilities. I went back and looked
19 at all the analyses supporting the submission and
20 the 13 is a typographical error. It's supposed
21 to be 30 facilities.

22 I will leave it at that since you're

1 pressed for time.

2 CO-CHAIR ANDERSON: All right. Andy
3 and Debra?

4 DR. NARVA: Yes, this is measurement
5 of nPCR for pediatric hemodialysis patients and
6 it's the percentage of patient months of
7 pediatric in-center hemodialysis patients with
8 documented monthly PCR measurements.

9 It's a level analysis is the facility,
10 the evidence is based on KDOQI Guidelines. A
11 general nutrition guideline from 2006 and the
12 2008 KDOQI Guideline on Nutrition in Children
13 with CKD, which recommended nutritional status
14 and growth of all children with CKDs two to five
15 including 5B should be evaluated on a periodic
16 basis. That was given a Grade A strong evidence.

17 They provided data from 2014
18 literature view which was supportive, and in
19 addition to that, there's some evidence that in
20 adolescence, PRC levels were an earlier and more
21 sensitive marker of -- than serum albumin of
22 malnutrition.

1 Despite this, there's not a vast
2 amount of data to support this measure and a lot
3 of this is inferred from benefit in adults.

4 CO-CHAIR ANDERSON: Debra, any
5 additional? Open for discussion to the
6 committee.

7 All right, let's call for the vote on
8 evidence.

9 MS. OGUNGBEMI: The committee is now
10 voting on evidence for Measure 1425. Options are
11 1 high, 2 moderate, 3 low and 4 insufficient.
12 Voting is open.

13 Results are two votes high, 16 votes
14 moderate, zero votes low and one vote
15 insufficient. Measure 1425 passes on evidence.

16 CO-CHAIR ANDERSON: Performance gap?

17 DR. NARVA: Okay. Nutrition is
18 obviously an incredibly important indicator in
19 all dialysis patients, particularly those that
20 are growing or trying to grow.

21 2013 data from CROWNWeb showed a mean
22 score of 80.4 percent and that included 455 in-

1 center hemodialysis pediatric patients from 30
2 dialysis facilities with at least 11 eligible
3 pediatric patients. So there appears to be a
4 gap.

5 CO-CHAIR ANDERSON: Debra? Any
6 further discussion on the part of the committee?

7 All right, we are ready to vote for
8 performance gap.

9 MS. OGUNGBEMI: The committee is now
10 voting on performance gap for Measure 1425. The
11 options are 1 high, 2 moderate, 3 low and 4
12 insufficient. Voting is open.

13 Results are two votes high, 17 votes
14 moderate, zero votes low and zero votes
15 insufficient. Measure 1425 passes on performance
16 gap.

17 CO-CHAIR ANDERSON: Moving on to --

18 DR. NARVA: Reliability?

19 CO-CHAIR ANDERSON: Yes.

20 DR. NARVA: Okay. This measure is
21 meant to be collected and calculated through
22 CROWNWeb. It seems to be fairly clearly

1 delineated.

2 There was a comment that the
3 exceptions to the denominator were confusing, but
4 that wasn't from me and I'm not sure what the
5 commenter meant exactly.

6 It's a process measure and it's not
7 stratified or risk-adjusted.

8 There is in reliability testing, is
9 that a separate -- I can't remember. Did we vote
10 on that separate? Okay. Together, yes.

11 Well, from the 2013 CROWNWeb data, the
12 overall IUR was 0.985, which indicates about 98.5
13 percent of the variation is between facility
14 differences.

15 CO-CHAIR ANDERSON: Debra? Any
16 discussion on the part of the committee?

17 DR. NARVA: Oh, there was one issue
18 with validity, which is that --

19 CO-CHAIR CROOKS: We're not doing
20 validity yet.

21 CO-CHAIR ANDERSON: We're on
22 reliability.

1 DR. NARVA: Oh, sorry. Yes, okay.

2 CO-CHAIR ANDERSON: You're okay, yes.

3 DR. NARVA: I'm rushing it.

4 CO-CHAIR CROOKS: I just wanted to ask
5 the pediatric nephrologists, this calls for the
6 measurement to be done monthly. Is that really
7 what you recommend? Things can change that fast?

8 DR. ZARITSKY: That's what we do, yes.

9 CO-CHAIR CROOKS: Okay, so you agree
10 with that? Okay.

11 DR. ZARITSKY: That's the same data
12 that's a degenerate of Kt/V so it's just added
13 information.

14 CO-CHAIR CROOKS: It doesn't add a
15 further burden to the patient really?

16 DR. ZARITSKY: No, I mean utility is
17 another story, but measuring that once a month's
18 not a problem.

19 CO-CHAIR ANDERSON: All right, ready
20 to vote on reliability.

21 MS. OGUNGBEMI: The committee is
22 voting on reliability for Measure 1425. The

1 options are 1 high, 2 moderate, 3 low and 4
2 insufficient. Voting is open.

3 Results are two votes high, 17 votes
4 moderate, zero low and zero insufficient.
5 Measure 1425 passes on reliability.

6 CO-CHAIR ANDERSON: Moving on to
7 validity?

8 DR. NARVA: The evidence seems to
9 support the measure is consistent except among
10 the facilities with 11 eligible pediatric
11 patients with recorded PCR values.

12 Facilities with a hundred percent
13 reporting had a mean serum albumin of 377 while
14 facilities with less than a hundred percent had
15 higher albumins, which, you know, on the face of
16 it, appears to suggest that the evidence is not
17 consistent with -- the measure's not consistent
18 with the evidence, but it appears likely or leads
19 -- speculation is that the more frequent PCR
20 determinations were done in the patients who had
21 poorer nutritional status, hence the bias.

22 CO-CHAIR ANDERSON: Debra? Any

1 comments, Debra?

2 Michael?

3 DR. SOMERS: You also have the TEP
4 weighing in with the thumbs up?

5 DR. NARVA: Yes.

6 CO-CHAIR ANDERSON: Any further
7 discussion on the part of the committee? All
8 right, ready to vote on validity.

9 MS. OGUNGBEMI: Committee is voting on
10 validity for Measure 1425. Options are 1 high, 2
11 moderate, 3 low and 4 insufficient. Voting is
12 open.

13 Results are zero votes high, 19 votes
14 moderate, zero low and zero insufficient.
15 Measure 1425 passes on validity.

16 CO-CHAIR ANDERSON: Moving on to
17 feasibility?

18 DR. NARVA: The data source is
19 CROWNWeb, it seems to be quite feasible.

20 CO-CHAIR ANDERSON: All right, let's
21 go for the vote.

22 MS. OGUNGBEMI: Committee is voting on

1 feasibility. Options are 1 high, 2 moderate, 3
2 low, 4 insufficient. This is for Measure 1425,
3 voting is open.

4 Results are 15 votes high, four votes
5 moderate, zero votes low and zero votes
6 insufficient. Measure 1425 passes on
7 feasibility.

8 CO-CHAIR ANDERSON: All right, moving
9 on to use -- usability and use.

10 DR. NARVA: So this measure is not
11 currently in use although it's an existing
12 measure.

13 I actually would ask the developers or
14 the potential users why it's not being used?

15 DR. ANDRESS: So this measure faces
16 many of the same issues that we discussed for the
17 pediatric -- the measurement of hemoglobin for
18 pediatric patients.

19 I think it's -- you know, it's
20 available. It's certainly there for use outside
21 of CMS and in the meantime, we're trying to
22 resolve how best to address quality measurement

1 in a critical yet very small patient population
2 in the dialysis community.

3 So this is a measure that I think is
4 still in the running for consideration in public
5 reporting and other uses. We simply haven't
6 managed to conclude the conversation at CMS.

7 DR. NARVA: The pediatric caucus want
8 to weigh in on this?

9 CO-CHAIR CROOKS: So it's usable, but
10 not in use in a sense? You know, it's usable,
11 somebody could take the data from you, the report or
12 the results, but no one's working with you to use
13 it yet, but it's usable?

14 DR. ANDRESS: I think that would
15 summarize it correctly, yes.

16 CO-CHAIR CROOKS: Okay.

17 CO-CHAIR ANDERSON: All right, ready
18 to vote for usability and use.

19 MS. OGUNGBEMI: The committee is now
20 voting on usability and use for Measure 1425.
21 The options are 1 high, 2 moderate, 3 low and 4
22 insufficient. Voting is open.

1 Results are four votes high, 15 votes
2 moderate, zero votes low and zero votes
3 insufficient. Measure 1425 passes on usability
4 and use.

5 CO-CHAIR ANDERSON: All right. Oh,
6 one more time.

7 Any further discussion on the measure
8 before we vote for suitability to recommend
9 endorsement? All right, shall we go ahead and
10 vote?

11 MS. OGUNGBEMI: The committee is now
12 voting on Measure 1425's overall suitability for
13 endorsement. Options are 1 yes, 2 no. Voting is
14 open.

15 I still need two votes.

16 Results are 19 votes yes, zero votes
17 no. Measure 1425 passes on its overall
18 suitability for endorsement.

19 CO-CHAIR ANDERSON: I think we are at
20 the conclusion. The last two measures we're
21 going to have to take up next week as well as the
22 related and competing measures that we didn't get

1 to. I'd like to thank everyone for the past two
2 days, their time, their expertise and their
3 engagement in the process. It's been a great two
4 days. Thank you very much.

5 CO-CHAIR CROOKS: Thank you very much.

6 MS. BAL: Before everybody leaves
7 though, there are some last minute timelines and
8 such. So as a reminder, we're meeting next week
9 on Tuesday 1:00 to 3:00. Please come ready to
10 discuss the last two measures, 1460 and 1662.

11 Also, on behalf of the staff, we do
12 want to thank the committee. It's been a
13 pleasure working with you for the past two days
14 and we really enjoyed how involved all of you
15 are. Thank you.

16 So the meeting's department will be
17 sending an email soon after this meeting to give
18 you reimbursement forms and as Sarah said
19 earlier, the hotel costs have been reimbursed
20 already.

21 (Whereupon, the above-entitled matter
22 went off the record at 2:47 p.m.)

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Before: NQF

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Place: Washington, D.C.

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