

NATIONAL QUALITY FORUM

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RENAL STANDING COMMITTEE

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WEDNESDAY
MAY 6, 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 8:30 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, University of Illinois and 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 LATTI, MD, MSPH, MBA, FACP, LML Health
Solutions and University of California
Health Plan

KARILYNNE LENNING, MHA, LBSW, Telligen

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

ANDREW NARVA, MD, FACP, FASN, National Institute
of Diabetes and Digestive Kidney Diseases
- National Institutes of Health

JESSIE PAVLINAC, MS, RD, CSR, LD, Oregon Health
& Science University

MICHAEL SOMERS, MD, American Society of
Pediatric Nephrology, Harvard Medical
School, Boston Children's Hospital

DODIE STEIN, PhD, MSW, LCSW, Indiana University
Health Home Dialysis

BOBBI WAGER, MSN, RN, American Association of
Kidney Patients

JOHN WAGNER, MD, MBA, Kings County Hospital
Center

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

NQF STAFF:

POONAM BAL, Project Manager

HELEN BURSTIN, MD, MPH, Chief Scientific Officer

ANN HAMMERSMITH, JD, General Counsel

ALEXANDRA OGUNGBEMI, Project Analyst

KATHRYN STREETER, Senior Project Manager

MARCIA WILSON, Senior Vice President for Quality
Management

ALSO PRESENT:

JOEL ANDRESS, PhD, Centers for Medicare and
Medicaid Services

AMY BECKRICH, Renal Physician's Association

CLAUDIA DAHLERUS, PhD, MA, University of
Michigan

LOUIS DIAMOND

JOE MESSANA, MD, University of Michigan

LISA MCGONIGAL, MD, MPH, QMRI

PAUL PALEVSKY, MD, University of Pittsburgh*

SARAH SAMPSEL, NQF Consultant

DALE SINGER, MHA, Renal Physicians Association

* present by teleconference

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

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

2 (8:38 a.m.)

3 CO-CHAIR CROOKS: Good morning
4 everyone, your co-chair for the Renal Standing
5 Committee for the NQF, measures to consider renal
6 measures.

7 Welcome everyone. Thank you for
8 making the journey. Thank you for the, all the
9 work, preliminary work that you put into place.
10 And we have quite a challenge today.

11 And so I thank you for preparing.
12 First rule is jackets can go off if you like it
13 that way. I see most of you do. Ties can be
14 loosened.

15 It's not going to be overly formal in
16 that sense. Is it a practice to use, Sarah, to
17 use first names, or do we go Doctor, Doctor,
18 Doctor, Nurse?

19 MS. BAL: It can off of preference,
20 but first names is usually how we do it at NQF.

21 CO-CHAIR CROOKS: Okay. Very good.
22 My co-chair is Constance from Northwest Kidney

1 Center.

2 CO-CHAIR ANDERSON: Welcome everybody,
3 and thank you for coming again. Formal name is
4 Constance, but I go by Connie. So you can use my
5 not so formal name.

6 I also want to say thank you for
7 coming, for all the hard work that's gone into
8 the four calls that we've had reviewing all the
9 measures.

10 And I really forward to the work we
11 have to do over the next couple of days. We have
12 a great group, and I think it's going to be a lot
13 of work and a very interesting time as we get
14 through the measures.

15 And I'd like to thank Peter as my co-
16 chair. This is my first time co-chairing, and so
17 I'm going to learn from the master over here.

18 And I told him if you see him kicking
19 me under the table, it's okay. He said that he
20 would do that to keep me in line.

21 CO-CHAIR CROOKS: I won't need to do
22 that.

1 Okay. Sarah, did you have any
2 introductory comments?

3 MS. SAMPSEL: I don't other than, I'm
4 sorry. The one thing I'll have to remind
5 everybody. When you're done talking, you always
6 need to turn off your mics because if we have
7 more than two mics on at one time, then the mics
8 don't work.

9 So that will just be one reminder
10 you'll hear more than once. But good morning,
11 I'm Sarah Sampsel.

12 I'm a consultant to NQF and have met
13 many of you on other work I've done with renal
14 measurement for other programs and again, look
15 forward to today and tomorrow to, I think, very
16 active discussions and making sure that we go
17 through the process deliberately and
18 purposefully.

19 And we'll just ask that we turn it
20 over to the staff for introductions.

21 CO-CHAIR CROOKS: And is this the time
22 to mention that if somebody would like to talk,

1 is this our custom to put your name tag up this
2 way so we can recognize you?

3 That will help, so you won't have to
4 get tired of holding your hand up in the air for
5 an hour at a time. Okay. So for introductions -
6 -

7 MS. BAL: Thank you for that reminder.
8 I'm Poonam Bal. I'm the Project Manager on the
9 Renal Committee. And I believe I've spoken to
10 most of you at this point.

11 CO-CHAIR CROOKS: Your voice is very
12 familiar.

13 MS. STREETER: Hi. Good morning. I'm
14 Katie Streeter, and I'm the Senior Project
15 Manager here at NQF. It's nice to meet everyone
16 in person.

17 MS. OGUNGBEMI: Good morning. I'm
18 Alexandra Ogungbemi, and I am the Project Analyst
19 on the renal project. It's good to see everyone.
20 Good morning.

21 MS. HARTWELL: Hi. My name's Lori
22 Hartwell. I'm the President and Founder --

1 CO-CHAIR CROOKS: Yes, I didn't --

2 MS. HARTWELL: Did I go wrong already?

3 CO-CHAIR CROOKS: I was to let you
4 know the staff will go first, and I forgot to do
5 that.

6 MS. HARTWELL: Oh.

7 CO-CHAIR CROOKS: We'll finish the
8 staff introductions --

9 MS. HARTWELL: We're not going
10 clockwise?

11 CO-CHAIR CROOKS: -- and then we'll go
12 clockwise or counterclockwise. I appreciate your
13 enthusiasm though, Lori.

14 MS. HAMMERSMITH: Good morning
15 everyone. I'm Ann Hammersmith. I'm NQF's
16 General Counsel. To those of you who have been
17 on our committees before, you're familiar with
18 this section of the proceedings.

19 What we do is we go around. We ask
20 you to tell us who you are, who you are with and
21 then if you have anything you want to disclose.
22 I'll review the disclosures briefly just as a

1 reminder.

2 The process is you got a rather long
3 form from us -- sorry about that, but we try to
4 be thorough -- where we ask you about your
5 professional activities.

6 You also received a form later where
7 we asked you about specific measures that will be
8 considered by this committee.

9 So for the purposes of this
10 disclosure, we're asking you to tell us if you
11 have something you want to disclose. If you do
12 disclose, it is not necessarily a conflict of
13 interest. Part of the reason we do this is to be
14 open and transparent so that everyone knows where
15 everyone else is coming from.

16 We are particularly interested in
17 grants, research money, speaking engagements that
18 you have or have had in the last five years but
19 only if it's relevant to the topics before the
20 committee today.

21 Please don't summarize your resume.
22 Just disclose things that are relevant to the

1 topics that will be discussed today.

2 A reminder, you sit as an individual.
3 You don't represent your employer. You don't
4 represent anyone who may have nominated you for
5 service on the committee.

6 You're here because you're an expert,
7 and you're not representing any particular
8 interest. So with that, I always start with the
9 chairs. So we'll start with Connie.

10 CO-CHAIR ANDERSON: I'm Connie
11 Anderson. I'm the Vice President of Clinical
12 Operations at the Northwest Kidney Centers in
13 Seattle.

14 And I have been a member of the Kidney
15 Care Quality Alliance and sat on the steering
16 committee as the lead. So I have a conflict of
17 interest in the two measures that were submitted
18 KCQA.

19 CO-CHAIR CROOKS: Good morning again.
20 I'm Peter Crooks. I'm a nephrologist with Kaiser
21 Permanente in Southern California.

22 I have, my career has pretty much been

1 within Kaiser Permanente although I have been
2 involved with National Quality Forum, the KDOQI
3 Advisory Board in the past.

4 The only conflict besides measures is
5 I did recently work on an NIH grant on racial
6 disparities, which sort of bumps up against some
7 of the stuff we do in ESRD care.

8 I have a conflict as a developer on
9 measure 2594: Optimal ESRD Starts and two related
10 measures. Thank you.

11 And I would like people to maybe
12 mention have you served before. This is my
13 fourth go round just a way to remind us that you
14 participated and who the go-to guys are. Thank
15 you.

16 MS. HARTWELL: Hi, my name's Lori
17 Hartwell. I'm the President and Founder of Renal
18 Support Network. I'm very happy to be here
19 today. And my only conflicts are with the Kidney
20 Care Quality Alliance fluid management. I was on
21 that workgroup through KCP.

22 DR. MADDUX: My name's Frank Maddux.

1 I'm a nephrologist. I'm Executive Vice President
2 for Clinical and Scientific Affairs and Chief
3 Medical Officer for Fresenius Medical Care.

4 I have no conflicts with regard to
5 grants or speaking. I have affiliations with
6 many of the organizations around, in the renal
7 community including Kidney Care Partners and
8 Renal Physicians Association.

9 I have not participated actively in
10 any of the measure development for either of
11 those groups as part of that.

12 I have research relationships that are
13 relatively broad in the industry, including some
14 NIH and PCORI grant affiliations as well as other
15 both privately sponsored and publically sponsored
16 research as well as internally sponsored
17 research. That's my disclosures.

18 DR. GREENSTEIN: Hi, I'm Stu
19 Greenstein. I'm a transplant surgeon, vascular
20 access surgeon from Montefiore Medical Center in
21 the Bronx.

22 This is my first time on this

1 committee, and although it said I had a lot of
2 conflicts, the only conflict I sometimes have is
3 with my wife. So I don't think I have any
4 conflicts. I'm not sure how they got all those
5 conflicts.

6 And it's a pleasure to be here to see
7 how this place works. Thank you.

8 DR. KASKEL: Hi. I'm Rick Kaskel,
9 Head of Pediatric Nephrology and Montefiore in
10 the Bronx. This is my second tour on the
11 committee.

12 I have relationships with a lot of the
13 professional groups here, having been Past
14 President of the American Society of Pediatric
15 Nephrology. Thank you. I have some NIH funding.
16 I'm sorry. Thank you, but no conflicts.

17 DR. ZARITSKY: Good morning. I'm Josh
18 Zaritsky. I'm a pediatric nephrologist, Head of
19 Pediatric Nephrology at Nemours/A.I. duPont
20 Hospital in Wilmington, Delaware.

21 No real disclosures or conflicts, and
22 I'd like to thank the group for having the

1 pediatric representation that's here.

2 DR. SOMERS: I'm Michael Somers. I'm
3 also a pediatric nephrologist. We think there's
4 safety in numbers. So that's why we're together.
5 I'm from Boston Children's Hospital. I have no
6 conflicts to disclose, and this is my second time
7 being part of this process.

8 DR. BHAN: I'm Ishir Bhan. I'm a
9 nephrologist and medical informatician at Mass
10 General Hospital. I do adult nephrology. I have
11 no conflicts, and this is my first time. Thank
12 you.

13 DR. DALRYMPLE: My name is Lorien
14 Dalrymple. I'm a nephrologist and epidemiologist
15 at UC Davis. I receive research funding, pardon
16 me, from the NIH and Dialysis Clinic,
17 Incorporated.

18 Because there is a measure from Kaiser
19 submitted, I was a pool physician there almost
20 eight years ago.

21 And my husband is a senior physician
22 and shareholder in the Permanente Medical Group.

1 I don't have conflicts that directly apply to the
2 measures before us.

3 MS. PAVLINAC: Good morning, Jesse
4 Pavlinac. I'm a renal dietician and Director of
5 Clinical Nutrition at Oregon Health and Science
6 University in Portland, Oregon.

7 I was here as steering committee three
8 or four years ago, so my second tour, I guess. I
9 have no conflicts with any of the measures.

10 I do write for the renal specialty
11 exam for our board certification for renal
12 dieticians, so obviously we talk about PCR and
13 phosphorus and all that stuff.

14 MS. LENNING: Good morning. I'm
15 Karilynne Lenning, and my background is in social
16 work. I have no conflicts, and this is my first
17 tour.

18 DR. WAGNER: Good morning. I'm John
19 Wagner. I'm an adult nephrologist based in
20 Brooklyn, New York. I'm Associate Medical
21 Director at King's County Hospital Center there
22 and President-Elect of the Forum of ESRD

1 Networks.

2 I've been involved in a variety of
3 organizations that are focused on quality in ESRD
4 care. The Forum of ESRD Networks is a member of
5 KCQA, although I did not participate in the
6 measure development of the activities of the
7 KCQA.

8 And this is my first tour of duty here
9 at the NQF, and it's my pleasure to be here.

10 DR. STEIN: I'm Dodie Stein. I work
11 for the Indiana University Health Home Dialysis
12 Program in Indianapolis. I have no conflicts of
13 interest, and this is my first time here and
14 delighted to be here.

15 MS. WAGER: Hi. My name is Bobbi
16 Wager. I'm a nephrology nurse. I'm on the Board
17 of Directors for the American Association of
18 Kidney Patients, and I'm conflict free. But I
19 haven't talked to my husband this morning, so
20 thank you. My second time around.

21 DR. HAIN: Hi. I'm Debbie Hain. I'm
22 an Associate Professor at Christine E. Lynn

1 College of Nursing at Florida Atlantic University
2 in Boca Raton.

3 And I am also a nurse practitioner at
4 Cleveland Clinic Florida in the Department of
5 Nephrology. I do not have any disclosures, and I
6 had conflicts listed, but I really didn't have
7 any conflicts, so they have been removed by the
8 staff. And this is my first time.

9 MS. EVANS: Good morning. My name is
10 Beth Evans. I'm a nephrology nurse practitioner
11 out of Albuquerque, New Mexico with a private
12 practice. I have no conflicts to disclose.

13 DR. FISCHER: My name's Michael
14 Fischer. I'm a nephrologist and health services
15 researcher. I'm currently employed by the
16 University of Illinois and the Department of
17 Veterans Affairs.

18 I have no conflicts. Disclosures, I
19 have NIH and VA funding in chronic and end stage
20 kidney disease. And more recently, I've been
21 involved in the VA and the reporting of currently
22 NQF-endorsed measures in dialysis patients in VA.

1 DR. KLIGER: Good morning. I'm Alan
2 Kliger. I'm a nephrologist in New Haven,
3 Connecticut. I'm the Senior Vice President for
4 Medical Affairs and Chief Quality Officer for the
5 Yale/New Haven health system.

6 This is my second tour of duty, thank
7 you. I was past president of the ESRD Forum of
8 Networks. I was also a past president of the
9 Renal Physicians Association.

10 And while I was listed as having
11 conflicts here, indeed I do not. And they have
12 been removed and cleared by the staff.

13 DR. KRISHNAN: My name is Mahesh
14 Krishnan. I am the International Chief Medical
15 Officer for DaVita Healthcare Partners, the Chief
16 Data Officer and the Group Vice President for
17 Research and Development.

18 My conflicts are that I participated
19 on the, this is my first time here. And my
20 conflicts are that I participated on the
21 workgroup for the ultrafiltration measures, the
22 fluid measures for KCQA.

1 Just a question I'm still not clear on
2 is I didn't participate on the vascular access
3 measures as a measure development. It seems it's
4 more, it's organizational than individual. So I
5 don't know how you want to deal with that.

6 MS. HAMMERSMITH: If you personally
7 didn't participate in the development of the
8 measure --

9 DR. KRISHNAN: Yes.

10 MS. HAMMERSMITH: -- it's not a
11 conflict.

12 DR. KRISHNAN: It's the same with
13 others. I just did the fluid --

14 MS. HAMMERSMITH: Okay.

15 DR. KRISHNAN: Great. Thank you.

16 DR. LATTS: Hi. Good morning. I'm
17 Lisa Latts. I'm an internist with a sub-
18 specialty in high risk pregnancy. I am currently
19 working as the Chief Medical Officer for the
20 University of California Health Plans.

21 And I am also, I work as a consultant
22 based in Colorado. This is my second time

1 around. I have no conflicts and no disclosures.

2 DR. KLEINPETER: Hi, I'm Myra
3 Kleinpeter, a nephrologist from Tulane University
4 in New Orleans. I think this is my third time
5 around and have nothing to disclosure, membership
6 in the nephrology societies like many of you.
7 Thank you.

8 MS. HAMMERSMITH: Okay. Thank you for
9 those disclosures. Do any of you have any
10 questions of each other, comments, questions of
11 me?

12 Okay. Just one last reminder, and
13 then I'll go away. Part of our conflict of
14 interest process is that we rely on all of you.

15 We can't know everything, so we really
16 rely on committee members to let us know if
17 during the course of the meeting they think they
18 have a conflict that you didn't disclose or you
19 overlooked, or if you think one of your fellow
20 committee members has a conflict or is acting in
21 a biased manner, we want you to speak up in real
22 time.

1 We don't want you sitting here
2 thinking, "Hmm, maybe I have a conflict. I'm
3 pretty sure Joe has a conflict." Let us know so
4 that we can do something about it.

5 If you'd like to bring it up in the
6 meeting itself, you're welcome to do that. If
7 you prefer not to do that, you can go to your co-
8 chairs who will talk to NQF staff. Or you can go
9 directly to any NQF staff member.

10 Any questions about that? Okay.

11 Thank you.

12 CO-CHAIR CROOKS: We've been joined by
13 two other, we have two other staff. Helen?

14 MS. BURSTIN: Good morning everybody,
15 Helen Burstin. I'm the Chief Scientific Officer
16 here at NQF. I guess I've been around for the
17 three tours of duty, as they say.

18 In my eighth year here at NQF on the,
19 on our renal work, so thanks for so many of you
20 for returning, and thanks for so many of you
21 coming to join us.

22 The tour of duty makes me worried,

1 that you're worried this is going to be a really
2 tough, kind of slogging through battle. It won't
3 be.

4 The beauty of having a standing
5 committee is in fact, the nice thing about having
6 so many of you who've been together before, is
7 that we really have seen that by having a
8 standing committee, a group that stays together,
9 you feel much more comfortable with the process.

10 You feel more comfortable with the
11 criteria and can actually bring measures back and
12 have a good discussion. So we're really glad to
13 have you back again.

14 And I'll be popping in and out. But
15 you're in great hands with Sarah and amazing co-
16 chairs. Thanks.

17 CO-CHAIR CROOKS: And in the back?

18 MS. WILSON: My name is Marcia Wilson,
19 and I'm the Senior Vice President for Quality
20 Measurement. Thank you.

21 CO-CHAIR CROOKS: Thank you, Marcia.
22 Okay. Then I think at this time, Sarah's going

1 to take us through a little more introduction and
2 overview of the evaluation process before we jump
3 in.

4 MS. SAMPSEL: Sure. Thank you, and
5 are you, actually Poonam's going to make a couple
6 of introductory statements about logistics and
7 the committee overall. And then I'll go.

8 MS. BAL: Thanks, Sarah. So just a
9 reminder, we did go through this during the
10 orientation call, but we just want to remind
11 everyone that the role of a standing committee is
12 really to act as a proxy for the NQF multi-
13 stakeholder membership.

14 As you heard Ann say, you're
15 representing yourselves as experts, not your
16 organization. You will be serving two year or
17 three year terms.

18 And we'll do a random selection after,
19 actually on Day 2, we'll do random selection.
20 You're literally pulling out of a hat or a jar
21 really.

22 Well, also we want you to work with

1 NQF staff to achieve the goals of the project,
2 which is to review the measures and provide
3 recommendations for them.

4 Evaluate the candidate measures
5 against measure evaluation criteria, and Sarah
6 will go into a little more detail about that.

7 And respond to comments submitted
8 during the review period. So you were informed
9 about pre-meeting comments that you received and
10 will receive even more comments after this
11 meeting on your recommendations.

12 And we'll have a post-meeting call for
13 you to discuss those. And then respond to any
14 directions from CSAC. This is later down the
15 road.

16 Once your recommendations are given to
17 the next body, the CSAC, they'll review them.
18 And if they would like you re-review anything or
19 reconsider anything, that would be, we would
20 bring the committee back together for that as
21 well.

22 So for the measure evaluation duties,

1 all members review all measures unless you have a
2 conflict. Discussants are assigned each measure.
3 You became familiar with this process during the
4 workgroup calls. We have provided a script for
5 you, in this big pile of papers you've been
6 given, to guide you in your evaluation.

7 We want to evaluate measures against
8 each criterion. We really try, as you saw in the
9 workgroup, to stay on the criteria that we're on.
10 You discuss evidence at evidence, usability at
11 usability, and so on.

12 Make recommendations to NQF membership
13 for endorsement. So after commenting, after the
14 post-comment call, we do go to a membership vote.
15 So they need your feedback for that as well.

16 And then overall see the renal
17 portfolio of measures. We went over this during
18 the orientation call, but we'll let Sarah now
19 start a quick review of the portfolio again for
20 you.

21 MS. SAMPSEL: Great. Thanks, Poonam.
22 I think one of the first things to remind you all

1 of, especially those of you who have served
2 before, is the prior iterations of this group had
3 been steering committees.

4 And one of the differences here is you
5 are now a standing committee, meaning that you
6 really have, I think ownership might be too
7 strong of a word, but management of an entire
8 portfolio of measures.

9 And so I think we talked about this on
10 your orientation call and the Q&A call, but we
11 want you to all be aware of all of the renal
12 measures that are out there.

13 Not all of them will be before you
14 today and tomorrow; some of them are delayed.
15 But we'd also like you keep in mind things that
16 go under the Measures Application Partnership and
17 other measures that are out there that might be
18 coming in the future.

19 And this is basically so you have a
20 more holistic view of the measures but also a
21 longer term view of the measures so that you're
22 not just seated once, get together for two days

1 and kind of a three month period and we reconvene
2 you in three years.

3 We really want you to have a more
4 active role on an ongoing basis with this
5 portfolio of measures.

6 So with that, we're going to walk
7 really quickly through the current renal
8 portfolio. The vast majority of those we'll talk
9 about together over the next couple of days.

10 I think, as mentioned before, we have
11 a number of maintenance measures, but to the same
12 degree, we have a number of new measures, meaning
13 that they have not been endorsed in the past,
14 even though I do understand some of the measures
15 have been discussed in the past.

16 But you do need to consider them on
17 the merits that they are being brought to you
18 today and tomorrow and the discussions that have
19 happened so far.

20 So starting, there's a suite of
21 hemodialysis, pediatric hemodialysis and then
22 some vascular access measures that are before

1 you.

2 Then there's some sets of dialysis
3 monitoring, both pediatric and then adult as well
4 as I know there's at least one that covers both
5 peds and adults.

6 There's the patient safety measure,
7 which is 1460, the blood stream infection
8 hemodialysis patients, and then -- that should
9 say CDC as the measure developer on the measure.

10 And then peritoneal dialysis, there
11 are a few measures that have been brought forward
12 for peritoneal as well.

13 And then we have all of the new
14 measures, which are all listed here. And I think
15 for the vast majority of these measures, they
16 fall into some of the groups that I just
17 discussed.

18 And we will acknowledge, this is a lot
19 of new measures and almost half of the suite that
20 you will be looking at or half the portfolio that
21 you'll be looking at.

22 And what you really do, and staff will

1 help you, is to really consider these measures
2 based on the merit of the rationale, the evidence
3 provided on them but also the testing and where
4 there looks to be opportunity for improvement.

5 And that's why we have such a
6 deliberate structure. Then we have a number of
7 measures that right now, as we did the call for
8 measures, had received indication that the
9 measures need to be retired.

10 And so there are a couple AMA-PCPI
11 measures, and the rest are CMS measures, and just
12 wanted you all to be aware and have those in
13 front of you, that there are some measures that
14 the developers and the stewards have decided that
15 they no longer want to retain endorsement on
16 those.

17 We also have two measures where
18 evaluation has been delayed, and we've worked
19 with CMS to understand the reason for delaying
20 those evaluation.

21 And that did go through a formal,
22 internal process of understanding the reason for

1 delay and also the work that CMS intends to do
2 over the next year.

3 And as a standing committee, those
4 measures will eventually come back to you, we
5 think, either later this year or early next year
6 but have to do with some significant revisions to
7 the measures that just don't make, it doesn't
8 make sense to review them now, have revisions to
9 the measures and then bring back to you.

10 So those are pending maintenance
11 review, and staff will keep an eye on those to
12 make sure that we work with CMS to get those back
13 in within the next year.

14 And then, finally, there are some
15 measures that cross into other projects, meaning
16 that they've been assigned to other standing
17 committees based on really kind of how the
18 measure is structured or some of the other work
19 that they're doing that you still, we'd still
20 like you to be aware of, specifically looking at
21 things like care coordination and person and
22 family centered care, where we're looking at some

1 of those cross-cutting issues that may not just
2 be specific to the renal population.

3 And then, of course, it happens a lot
4 that we have endocrine measures that sometimes
5 cross into this area as well, but we're finishing
6 up an endocrine project. So the measure had
7 actually gone under the endocrine project versus
8 this one.

9 And then some, again, cross-cutting is
10 all-cause admissions and readmissions. And so
11 what we look for there, and this is one of the
12 staff obligations, is to make sure that if any
13 measures come before this group that have related
14 or competing issues that we would bring those
15 measures to you as well, with overviews of the
16 measures so you can consider that.

17 And then there's still more with
18 health and well-being, surgery, and
19 cardiovascular. All of these measures are
20 available to you in these slides as well as in
21 previous slides that we've talked on at least the
22 first conference call that we all had.

1 The other thing we wanted to bring to
2 your attention is the MAP measures, so the
3 Measures Application Partnership. This is also a
4 process between CMS and NQF and specifically the
5 Measurement Application Partnership where works
6 with CMS to assess and determine measures
7 applicable or up and coming for use in CMS
8 programs.

9 The measures are not evaluated the
10 same way that they are for endorsement projects,
11 but we do -- we did want to bring these to your
12 attention because they, these measures seem to
13 cross into the renal space, some of them very
14 clearly into the renal space.

15 Many of them are up and coming
16 measures, so they're still being tested. They're
17 still being evaluated. They're not ready for
18 endorsement but thought it would be important for
19 you to also realize there are some measures that
20 are being considered under the Measures
21 Application Partnership that will most likely
22 eventually come to you.

1 DR. KRISHNAN: Could you speak to that
2 a little more? You said they're evaluated
3 differently because of process?

4 MS. SAMPSEL: Right. So the Measures
5 Application Partnership is not going through the
6 same NQF consensus development criteria. Do you
7 want more information specifically on their
8 criteria?

9 DR. KRISHNAN: No.

10 MS. SAMPSEL: Okay.

11 DR. KRISHNAN: Just so eventually it
12 will come to us --

13 MS. SAMPSEL: Correct.

14 DR. KRISHNAN: --- or what do you
15 think?

16 MS. SAMPSEL: Yes. That's -- or they
17 could, it could be determined they're not ready
18 for endorsement and stay in testing or wherever
19 they are. Yes.

20 MS. BAL: So I will go over the time
21 line. So as I mentioned earlier, we have our in-
22 person right now going on right now. And we will

1 be having, we have a post-meeting webinar
2 scheduled for next week.

3 However, if we are fortunate enough to
4 finish all the things that we need to do in this
5 meeting, we don't need to have that meeting, and
6 it will be cancelled.

7 However, if we're not able to get
8 through all the measures or get through all the
9 topics that we need to discuss, that meeting is
10 there as a buffer for us to get through
11 everything we need to get to.

12 After that point, staff will draft a,
13 will draft the draft report. And we'll post it
14 for NQF member and public comment. The public
15 comment will last until July 13th. After that
16 point, staff will take the comments and kind of
17 consolidate them for you and make a memo from
18 that.

19 And we'll provide that you in advance
20 of the post-comment call. You will discuss those
21 comments and provide responses as necessary.

22 And then we'll take that and create

1 the voting report. The voting report will go out
2 to NQF members. They'll vote on the measures if
3 they would like, if they agree with your
4 recommendation or not.

5 That will be all taken to the CSAC.
6 Again, they'll review the recommendations, see if
7 they agree or if there's anything else that they
8 feel needs to be discussed.

9 That will, if all goes well, that'll
10 go to our board who will ratify the measures.
11 And one more step before they're completely
12 endorsed is the appeals process.

13 For any recommended measures if
14 someone feels that they would be harmful, or if
15 they found a good reason for why they should not
16 be endorsed, there is the appeals process. And
17 there is criteria for that but I won't go into
18 detail.

19 But that appeals process will happen.
20 After the appeals process, if there are no
21 appeals, measures are considered endorsed. And
22 that will done in about December.

1 So I did want to just go over ground
2 rules for the meeting today. So NQF continuously
3 strives to improve our committee meetings based
4 on input from a variety of stakeholders.

5 And we always appreciate getting
6 feedback from our committees and developers and
7 any members of the community. We are constantly
8 trying to improve.

9 We are fortunate to have the measure
10 developers present at our meeting, and we'll be
11 asking them to briefly introduce their measures
12 as they come up for discussion.

13 There are two seats over there
14 reserved for developers. Selected committee
15 members will begin the discussion of the measures
16 in relation to the measure evaluation criteria.
17 Again, we did start that in the workgroups, and
18 we'll continue that in the meeting today.

19 We will provide a designated place for
20 developers, as I mentioned earlier, to do their
21 introduction and also to answer any of the
22 questions that you may have.

1 They are a resource for you. As I
2 mentioned in the workgroups, we really want the
3 discussion to be among the committee members, but
4 if there's a question that needs to be clarified,
5 or at any point they feel that the, I guess, the
6 path that the committee is going on doesn't
7 really correlate with what they meant for the
8 measure, they can provide clarification.

9 The developers will put up their card
10 just like committees would, committee members
11 would, to indicate that they would like to make a
12 comment. And then the co-chair would select them
13 to respond.

14 During the measure evaluation,
15 committee members often offer suggestions for
16 improvement to the measures. These suggestions
17 can be considered by the developer for future
18 improvements.

19 However, the committee is expected to
20 evaluate and make recommendations on the measure
21 per the submitted sophistications and testing.

22 Committee members act as a proxy for

1 NQF membership, as I mentioned earlier. There is
2 a need for respect for differences of opinion and
3 cordial interactions among committee members and
4 measure developers are expected.

5 Our meeting agendas are typically
6 quite full. We have 25 measures, which is a lot
7 of measures to get through.

8 All committee members, co-chairs,
9 developers and staff are responsible for ensuring
10 that the work of the meeting is completed during
11 the time allocated.

12 So during the discussion, committee
13 members should be prepared to, be prepared,
14 having reviewed the measures beforehand and you
15 all have been doing a great job. The workgroup
16 calls have been wonderful. Everyone's been very
17 prepared, and we really appreciate that.

18 To base their evaluation and
19 recommendations on the measure evaluation
20 criteria and guidance, you'll see that we
21 provided algorithms for you.

22 It's one of the pile of documents in

1 that big pile we provided to you. Please remain
2 engaged in the discussion without distractions.
3 We really need everyone to be involved in every
4 measure.

5 Attend the meeting at all times except
6 for our breaks. We really, obviously, everyone
7 has to go to the bathroom. That's
8 understandable. But I mean if you can avoid not
9 leaving the room discussion, it would be
10 appreciated.

11 Keep the comments concise and focused.
12 Don't repeat comments that others have made.
13 Again, just trying to keep time in mind and
14 trying to keep the meeting going.

15 Foster a meaningful participation.
16 Again, avoid downgrading or encouraging, I'm
17 sorry. Prevent dominating the conversation, and
18 always encourage contribution.

19 And then, again, indicate agreement
20 without repeating what has already been said. So
21 that's generally the ground rules. And with that
22 said, so we've kind of already repeated this, but

1 I'll say it one more time. For the process for
2 measures discussion, the measure developer will
3 introduce their measure. They'll have about two
4 to three minutes to introduce the measure.

5 Lead discussants will be the
6 committee discussion by providing a summary of
7 the pre-meeting evaluation comments, so basically
8 what was discussed in the workgroup. And then
9 starting their discussion with evidence and
10 saying their point of view on that and then going
11 to gap and so on.

12 And again, the script is there for
13 you. It'll provide you guidance on how we'll be
14 discussing the measures and when we'll be voting.

15 And then, developers will be available
16 to respond to questions at the direction of the
17 committee. And the committee will vote on
18 criteria and sub-criteria when it's that point.

19 So that is the basic structure. I do
20 want to pause to see if there's any questions
21 before we start our first measure.

22 Okay. So I'll actually give it to

1 Alexandra to discuss voting, and the method.

2 Does everyone have a clicker?

3 Oh, Andy's here. Also, Andy Narva has
4 joined us. And once he gets his clicker I'll ask
5 him to do a quick introduction and also
6 disclosures as everyone else did.

7 DR. NARVA: I'm Andy Narva. I direct
8 the National Kidney Disease Education Program at
9 the NIH. I don't think I have any conflicts. I
10 am on the ABIM sub-specialty board in nephrology.

11 But I have a Kevlar vest on for you
12 nephrologists in here, so don't throw anything.

13 MS. BAL: Okay, perfect. Thank you so
14 much. And so now I'll give it to Alexandra to go
15 over voting.

16 MS. OGUNGBEMI: Good morning again.
17 All committee members have a small blue remote
18 with you at your seat.

19 Fortunately, all committee members are
20 slated to attend today's meeting and are actually
21 here in person, so there will be no proxy voting
22 necessary.

1 It is important to note that once
2 ready, I will instruct you that voting has
3 opened. I will read the criteria that we are
4 voting on, and then I will let you know that
5 voting has opened.

6 Once you make your selection, you may
7 point the remote towards me and press the number
8 of your choosing. After pressing your choice,
9 the display window of the remote will flash the
10 number briefly.

11 If you would like to change your
12 selection, please do so immediately. You will
13 not duplicate a response by pressing more than
14 one button. The system will only collect the
15 last response received from your remote.

16 Does anyone have any questions? All
17 right, thank you.

18 MS. BAL: Okay. And so we'll go ahead
19 and start the first measure. I do want to call
20 the developer up. So if anyone -- let's see
21 here.

22 We'll be starting with 1454, so I just

1 wanted to see if the University of Michigan and
2 CMS were ready to present.

3 MALE PARTICIPANT: Claudia and Joe.

4 MS. BAL: Yes.

5 DR. DAHLERUS: Okay. Good morning,
6 and thank you for the opportunity to speak to our
7 measures. So we're going to, first off, I'm
8 Claudia Dahlerus from the University of Michigan
9 Kidney Epidemiology and Cost Center.

10 So we're going to begin with
11 hypercalcemia, so Measure 1454 is the percentage
12 of patient runs for adult dialysis patients, and
13 this includes hemodialysis, home hemodialysis and
14 peritoneal dialysis patients with a three month
15 rolling average of total, uncorrected serum or
16 plasma calcium greater than 10.2.

17 The measure was originally developed
18 in 2010 by a mineral and bone disorder TEP and
19 endorsed by NQF in 2011. In 2013, an additional
20 mineral and bone disorder TEP was convened.

21 They reviewed the measure, and they
22 affirmed the measure, describing it as an

1 important safety measure as opposed to just a
2 target threshold base measure.

3 The TEP, in its deliberations,
4 recognized the current body of evidence that
5 warranted monitoring of calcium levels in order
6 to manage elevated calcium and the increased
7 associated potential of adverse events, notably
8 all-cause mortality and cardiovascular events.

9 In its deliberations, both TEPs also
10 cited the 2003 and 2009 KDIGO guidelines and the
11 2009 KDOQI guidelines.

12 We did want to note that in our review
13 of the measure as part of the comprehensive
14 reevaluation, we made a slight revision to the
15 denominator to include patients that had missing
16 calcium values within the three months, in order
17 to discourage gaming of the measure.

18 So, in other words, a facility could
19 not be included in the measure if they didn't
20 have calcium values, and therefore, they would
21 not be evaluated for hypercalcemia.

22 Finally, we want to note that in

1 response to community comments, the measure was
2 expanded to include serum or plasma calcium based
3 on evidence provided to the University of
4 Michigan and CMS, suggesting sufficient
5 equivalence between the two laboratory based
6 values. And I'll stop there.

7 DR. MESSANA: Well, the only
8 additional comment about the missing is the, I
9 think the TEP in 2013 were considered a
10 hypercalcemia reporting measure for maintenance
11 at that point.

12 And they felt that if we included
13 missing in the denominator here that would cover,
14 that would be the most parsimonious approach.
15 And so they did not recommend moving forward with
16 the hypercalcemia reporting measure, but one
17 measure that included a reporting component,
18 essentially, in it.

19 CO-CHAIR CROOKS: Okay. Thank you
20 very much. Our primary reviewers were Joshua and
21 Lisa. Would one of you like to kick off with
22 discussing the evidence?

1 DR. ZARITSKY: Yes. As a newbie, I'll
2 start off and Lisa's promised to keep me in, step
3 in when I get too far astream.

4 Basically, this is a rather
5 straightforward intermediate outcome measure.
6 The evidence is largely associative, but it's
7 been reviewed by both the KDIGO, which gave it a
8 2D recommendation and KDOQI, which again, it was
9 basically expert opinion.

10 They recommend toward the lower end of
11 the normal, which would get up to 9.5 while the
12 measure does do 10.2.

13 And I think the measure overall is
14 more of a safety kind of net measure where we're
15 trying to catch patients who are over 10.2 rather
16 than trying to keep people unnecessarily in a
17 specified range.

18 I don't know if they want more details
19 about the evidence or, it's fairly
20 straightforward.

21 CO-CHAIR CROOKS: Let's restrict the
22 discussion to the evidence at this point. Lisa,

1 did you have any other comments about that?

2 DR. LATTIS: No.

3 CO-CHAIR CROOKS: Okay. Other
4 committee members?

5 Okay. So I think if there's no other
6 discussions of the evidence, then we're ready to
7 vote on the evidence. Do we need to use that
8 chart to determine --

9 MS. BAL: So Peter's just asking if we
10 would need to use the algorithm that is a
11 resource for the committee. And we can go over
12 the algorithm for you, if you like.

13 However, if you feel comfortable with
14 the evidence you reviewed, and you feel that you
15 are prepared to vote on that, we can go to the
16 vote as well. So I guess as a committee --

17 DR. ZARITSKY: I forgot to comment.
18 I would place this in the moderate degree of
19 evidence.

20 MS. BAL: Okay. Were there any other
21 comments?

22 DR. KRISHNAN: When KDIGO or the other

1 set a specific threshold for greater than or less
2 than, some specific number, how do we account for
3 lab to lab variances?

4 So, I'm told that if you split a lab
5 sample and you send it to three different labs,
6 you may get slightly different values for that
7 exact same patient.

8 How do we think about the crispness of
9 that number versus the vagueness of the
10 laboratory science?

11 DR. ZARITSKY: I think the one thing
12 that kind of helps us out in that aspect is that
13 we're looking at the upper range of normal, and
14 then I think that looking at the actual when we
15 get to the gap, you'll see that the actual rate
16 of average is like 2.1 percent.

17 DR. KRISHNAN: Small.

18 DR. ZARITSKY: It's a very small gap,
19 so I'm not too concerned that we're missing. And
20 I think if we're going to go on expert opinion,
21 there's very limited evidence.

22 Most of the evidence is associative as

1 well, is that most of us would feel that we want
2 to be on the lower end of normal. So 10.2 as
3 being the upper cut off of the norm, I think,
4 provides enough of a, kind of a wiggle room.

5 DR. KRISHNAN: I don't know enough
6 about laboratory science or how big the standard
7 deviation is between labs, but I just wonder. I
8 don't know enough to know enough.

9 I don't know if the developer knows,
10 but I just don't know how big of a spread that is
11 and whether or not if you get sent to one lab
12 versus another lab that helps you with the
13 metric, hurts you with the metric. I --

14 DR. ZARITSKY: You also have to
15 recognize that the 10.2 is considered the,
16 different labs have different standards of what
17 the upper limit of a normal is. 10.2 is kind of
18 agreed upon.

19 So even if we looked at the inter-lab
20 variation or intra-lab variation, you also have
21 to recognize that there's probably some labs out
22 there that might consider something over 10.2 --

1 DR. KRISHNAN: Normal.

2 DR. ZARITSKY: -- normal.

3 DR. KRISHNAN: Yes.

4 DR. ZARITSKY: But I think that
5 because it's expert opinion, and there isn't,
6 we're never going to find a number as a cut off,
7 I think, with that gap that's in place of only
8 2.1 percent.

9 It's a fairly safe, and I mention the
10 measure, at least in my opinion, is more of a
11 safety net than anything else rather than
12 necessarily a quality improvement.

13 DR. SOMERS: Since it's a three month
14 rolling rate, I think that would smooth out the
15 concerns about single laboratory variations as
16 well.

17 DR. KRISHNAN: I don't follow that
18 because the lab is the question, right. So if
19 the lab, to Josh's point, if the lab was
20 consistently higher or lower, the three month
21 average would still be consistently higher or
22 lower.

1 DR. SOMERS: But your individual test
2 result will vary from month to month.

3 DR. KRISHNAN: No, true. That's true.

4 DR. SOMERS: So it's going to be less
5 common that you'll be right at the edge.

6 DR. KRISHNAN: Sure.

7 FEMALE PARTICIPANT: Lorien?

8 DR. DALRYMPLE: I was hoping to
9 discuss the evidence a little bit more with the
10 primary workgroup. Since this was a KDIGO 2D and
11 a KDOQI opinion and then a TEP, how did the
12 evidence support a moderate rating as compared
13 with perhaps a low rating?

14 DR. ZARITSKY: I would --

15 DR. DALRYMPLE: Just so I get your
16 insight from that algorithm.

17 DR. ZARITSKY: Yes, I was just using
18 the grading. They give us a grading scale of
19 what's moderate and so --

20 DR. DALRYMPLE: Okay.

21 DR. ZARITSKY: -- I can find that
22 study. So on Table 2 here from --

1 CO-CHAIR CROOKS: So I think this is
2 a good opportunity, as long as we have a little
3 more time in this metric, to use this algorithm.
4 And taking it from the top, it's not an outcome
5 measure, although they initially said so. But I
6 think it's really an intermediate outcome.

7 So to Question Number 1, is it an
8 outcome or a process measure? It goes down to a
9 no. So that brings us to Number 3.

10 And the question at Number 3 is for
11 measures that assess performance on an
12 intermediate clinical outcome process or
13 structure, is it based on a systematic review and
14 grading of the body of empirical evidence where
15 the specific focus of the evidence matches what
16 is being measured.

17 And so in this case, their evidence is
18 based on KDOQI, four KDOQIs. And usually the
19 KDOQI process includes a systematic review of the
20 body of evidence.

21 So in my view I think that would be a
22 yes, but I'm just open to other interpretations.

1 Do others feel differently? I think everybody
2 has this on their, so please pull it out. Follow
3 along with me.

4 So if the answer's yes, then we go to
5 Number 4. Is the summary of the quality,
6 quantity and consistency of the body of evidence
7 from the systematic review provided in the
8 submission form?

9 And without opening it up right now,
10 I don't know that they actually provided a, I can
11 open it up and see or maybe somebody else knows.
12 Do you feel that, and these are questions that
13 are asked within the form.

14 What's the consistency, the quantity,
15 the quality and consistency of the evidence? And
16 so what's the committee's input on that or
17 feedback on that?

18 DR. DALRYMPLE: Am I correct that
19 KDIGO's recommendation was a 2D, and KDOQI was
20 opinion only?

21 DR. ZARITSKY: Expert opinion, yes.

22 DR. DALRYMPLE: Is that correct?

1 DR. ZARITSKY: Yes.

2 DR. DALRYMPLE: Okay.

3 DR. KLIGER: Lorien, it would be
4 helpful for us if you give us the inference of
5 that, why you're pointing that out to us.

6 DR. DALRYMPLE: My apologies. I was
7 trying to pull up what KDIGO D is. Are others on
8 the committee able to say it off of the top of
9 their head?

10 I do have it somewhere in my
11 worksheet, or maybe the committee, can you read
12 to us what the D stands for. It's very low or
13 lacking evidence is my -- right?

14 But if anyone has the exact wording,
15 that would be helpful.

16 DR. ZARITSKY: I have very low
17 evidence.

18 DR. DALRYMPLE: And two is also the
19 weaker of the two choices. There's one or
20 there's two.

21 CO-CHAIR CROOKS: Looking at the
22 application, the section where they are to

1 discuss the systematic review is 1.7.7, 1A7. And
2 within that are subcategories about the quantity,
3 consistency and quality of the evidence. And
4 those areas are blank.

5 So I would have to say that they did
6 not address the first question in Number 4. They
7 didn't address and summarize for us the quantity,
8 consistency and quality of the evidence.

9 So if the answer is no, then it goes
10 down to Box 6. Does the grade for the evidence
11 of recommendation indicate high quality, high
12 certainty or strong recommendations. So I think
13 that's where the conversation you're having about
14 what grades were used from the committee.

15 DR. ZARITSKY: But then we move to
16 this Table 2 here.

17 CO-CHAIR CROOKS: Pardon me?

18 MS. BAL: So there is a secondary
19 table that provides information for you. But the
20 arrows kind of point to you where, what you would
21 rate as what, maybe. I think Connie has
22 additional comments.

1 CO-CHAIR ANDERSON: Right. So on the
2 table on the algorithm, if the grade does find
3 evidence or recommended high quality evidence,
4 then you can rate it as moderate. But if the
5 answer is no to that, then you rate it as low.

6 CO-CHAIR CROOKS: My problem with this
7 is that KDOQI does a systematic review, but the
8 developers didn't lay it out for us and really
9 show us how that is done and how it relates to
10 this measure.

11 So we're kind of left trying to guess.
12 Maybe it did. Maybe it didn't. If you say they
13 didn't, then you go down to Box 6, as you just
14 did. And then we have the option of saying,
15 well, with what we do have, is this high quality
16 evidence, high certainty, strong recommendation
17 by the grading.

18 And so I guess it's a judgment call.
19 If it is, then we can call it moderate. If it
20 isn't, then it's low. Am I, sorry, Alan?

21 DR. KLIGER: Peter, I think that KDOQI
22 made clear because it gave a rating and the

1 rating is low evidence.

2 CO-CHAIR CROOKS: Okay.

3 DR. FISCHER: Regardless of whether
4 you go horizontally from Box 4 or down to Box 6,
5 I don't see a scenario where it's not low, either
6 through Box 5c or through Box 6. Seems like it
7 winds up as low.

8 CO-CHAIR CROOKS: Okay. Is everybody
9 happy with the conclusion on the evidence review?
10 Now does evidence low translate into a no vote on
11 the evidence, or does that mean we can still vote
12 for it?

13 MS. BAL: So we would still vote.
14 That's just what the verbal discussion would be.
15 That's what you concluded, but everyone does have
16 the right to vote otherwise if they would like.

17 So due to that, we, since it's an
18 intermediate outcome, we would vote on high,
19 moderate low, insufficient. If it was an
20 outcome, we would just vote yes or no.

21 So since it's an intermediate outcome,
22 we'll be voting on all three options. And then

1 there is one additional option that I want to
2 inform everyone. If you so feel, there is
3 additional option with evidence was insufficient
4 evidence but with exception. So you feel that
5 while the evidence may be weak, overall the
6 measure is strong.

7 And you would like to continue to
8 review and discuss it. That is just an option I
9 wanted to make everyone aware. We would vote on
10 that only if, we voted on these four options
11 first so high, moderate, low, insufficient.

12 And then if it was low or
13 insufficient, we would then give you the option
14 of voting on exception if you so choose. So
15 we'll go ahead and start this vote, and then
16 based on the result, we can see what option you
17 would like to go with.

18 CO-CHAIR CROOKS: So we're going to
19 vote.

20 MS. BAL: Yes, that's correct.

21 CO-CHAIR CROOKS: Okay. High, medium,
22 low or insufficient. Alexandra?

1 MS. OGUNGBEMI: Yes, thank you. The
2 committee is now voting on evidence. You may
3 vote high, moderate, low or insufficient
4 evidence. High is one, moderate is two, low is
5 three, and insufficient evidence is four.

6 CO-CHAIR CROOKS: We need to point to
7 you?

8 MS. OGUNGBEMI: Yes.

9 MS. BAL: And I want to just point
10 out, there is no conflicts on this measure, so
11 all 23 committee members should be voting. And
12 so that's the number we're looking for, just so
13 everyone knows.

14 MS. OGUNGBEMI: Since we have 23
15 votes, the voting is closed. And we have 4
16 percent for moderate, 96 percent for low, 0
17 percent for insufficient and high.

18 MS. BAL: Okay. So it seems like we
19 don't want to do an exception, but I do want to
20 offer that as an option to the committee. Does
21 anyone feel that we should give the exception, or
22 should we end this measure right now?

1 DR. KLIGER: I just want to
2 historically remind some of us that the last time
3 we went through this measure, which was several
4 years ago, we found that the evidence was low.

5 But because it was not a performance
6 measure but considered a safety measure, we
7 continued on with our discussion, even in the
8 face of relatively low evidence.

9 CO-CHAIR CROOKS: So are you proposing
10 that again?

11 DR. KLIGER: I'm just pointing out
12 that's what we did the last time.

13 CO-CHAIR ANDERSON: But I think since
14 then it's become a performance measure, and it's
15 measured through the QIP. And at the 98th
16 percentile, zero percent is the topped out
17 measure.

18 And so facilities are measuring this,
19 and 98 percent of the nation is at 0 percent with
20 calcium is greater than 10.2. So it leaves
21 little opportunity for improvement.

22 CO-CHAIR CROOKS: So if we did make an

1 exception and decided to continue, then we get to
2 gap, which is where it may not pass there.

3 MS. SAMPSEL: And then you would also,
4 when you get to gap, also have the opportunity to
5 talk about reserve status. And that is when the
6 measure meets the criteria, in this case with
7 exception on the evidence, but has to meet the
8 rest of the criteria but may be topped out but
9 it's still important to monitor, and you want to
10 signal that it's important to monitor.

11 CO-CHAIR CROOKS: Lisa?

12 DR. LATTIS: I guess I would like to
13 see us get to that gap discussion and discuss the
14 implications of not moving farther with this
15 measure from the safety perspective rather than
16 just stopping right here with no discussion
17 moving faster.

18 CO-CHAIR CROOKS: Other thoughts?

19 Andrew, if you want to speak, turn your card
20 upward so I can see your name. There you go.
21 Andrew?

22 DR. NARVA: Thank you. The other

1 historical fact was this was the only bone and
2 mineral measure that we passed. And there were
3 many others at that time. And it's still the
4 only bone and mineral measure, isn't it?

5 (Off microphone comments)

6 CO-CHAIR CROOKS: There is a measure
7 related to phosphorus, but if it's measured it's
8 not --

9 FEMALE PARTICIPANT: It's a process
10 measure.

11 CO-CHAIR CROOKS: It's a process
12 measure. I personally am okay with considering
13 an exception for safety.

14 DR. MESSANA: So I just wanted to
15 raise one question before this gets too far
16 along. Under Section 1.8, we did, under other
17 evidence, we did provide a discussion of more
18 recent literature. And I just wanted to make
19 sure that the committee was aware of that. 1.7
20 was answered negatively because we didn't do a
21 formal grading of that, of those additional, more
22 recent articles. If, in fact, you all are aware

1 of that, then that's fine. I just wanted to make
2 sure that that was the case.

3 MS. BAL: So did we want to go ahead
4 and vote to see if there, the committee would
5 like to give exception to this measure? Okay.
6 So --

7 MS. OGUNGBEMI: The committee is now
8 voting on evidence, a potential exception to
9 empirical evidence. The choices are one for
10 insufficient evidence with exception, and two is
11 no exception. Voting is now open. We have 83
12 percent insufficient evidence, and 17 percent no
13 exception.

14 CO-CHAIR CROOKS: Okay. So we can
15 move on to considering the gap then. Lisa?

16 DR. LATTS: I think Josh is going to
17 --

18 CO-CHAIR CROOKS: Okay, Josh.

19 DR. LATTS: Josh is going to continue,
20 and I'll continue to --

21 (Simultaneous speaking)

22 DR. ZARITSKY: -- forge on ahead. As

1 we've already alluded to that the gap is very low
2 at 2 percent and that this is really more of a
3 sort of a safety gap measure, rather than an
4 improvement, an area for improvement.

5 As far as the other gap, any data
6 disparities, I mean there's some, with the large
7 numbers that are presented, there are some very,
8 there are some statistically significant
9 differences between some groups, but I think
10 they're largely clinically insignificant.

11 CO-CHAIR CROOKS: Other comments on
12 opportunity for improvement? Lisa?

13 DR. LATTS: Yes, I mean as we've sort
14 of discussed, as Alan brought up, with this
15 performance there's very little opportunity for
16 improvement, so this is not an improvement
17 measure. It's more of a safety and a monitoring
18 measure. And so the question that it brings to
19 my mind is what happens if this measure goes
20 away.

21 Does it mean that facilities will not
22 monitor this anymore? Those of you who are in

1 the business can speak to it. I think that's
2 probably unlikely because it is a safety measure.
3 On the other hand, if they're going to continue
4 to monitor it because it's a safety measure, why
5 do we think it's not important enough and the
6 evidence is now there?

7 So it's a little bit of a paradox in
8 that sense. So I'm a little torn on the sense
9 that the performance is high. Do we really need
10 the measure? On the other hand, you know, it's a
11 safety measure.

12 DR. ZARITSKY: You really want to make
13 it a performance, I mean you'd have to lower that
14 threshold. Then we'd get into, then the evidence
15 isn't there basically. So you're stuck.

16 CO-CHAIR CROOKS: In terms of process,
17 if we vote the gap is insufficient, we still have
18 to go through the rest of the evaluation, if
19 we're going to consider it for reserve status.

20 MS. BAL: Yes, so what I would do, I
21 do want to direct everyone to this document,
22 which is inactive endorsement reserve status.

1 This is an option we have. There are
2 stipulations obviously to reserve status. It
3 needs to be very strong on scientific
4 acceptability, reliability and validity, needs to
5 be very strong.

6 You do need to see this measure. If
7 you think the gap is low, you need to do, you do
8 need to feel that if we remove this measure, then
9 this will be, it will hurt performance, and
10 performance will go down. So those are some of
11 the things to think about, and we would vote on
12 gap as regular. If it was low or insufficient,
13 we would just do a verbal discussion, if we would
14 like to consider this measure for reserve.

15 If that was the case, we would go
16 through all the other criteria and vote on them
17 as if this measure was going through, and then
18 vote at the end for reserve status. So that is
19 the process. But we do want this measure to be
20 strong in almost every other aspect to go on
21 reserve status. Were there any questions at this
22 time? Okay.

1 DR. LATTS: Can I just ask, is it
2 possible to turn up the mics a little bit? I'm
3 finding everybody just a little bit hard to hear.

4 CO-CHAIR ANDERSON: Yes.

5 MS. BAL: I can check with IT group
6 but, unfortunately, it is pretty hard to hear
7 people. So we always recommend, as you see, I'm
8 very close to the mic. Please speak close to the
9 mic. Please try to really speak loudly. We have
10 this problem, often, unfortunately. We'll try to
11 get the mics up higher, but I can't guarantee
12 anything. But, please, actually, it's a good
13 reminder. A good reminder, please speak directly
14 at the mic.

15 CO-CHAIR ANDERSON: So, Mahesh, do you
16 have comments?

17 DR. KRISHNAN: Yes, just to ask the
18 question, I think, Lisa, you posed, what would
19 happen if this measure goes away. At least,
20 looking at our own data, over the time period
21 pre- and post- when this was actually a measure
22 in the QIP. We didn't see any substantial

1 differences. So I don't think we would see that.

2 And then, two, we'll get into this
3 later on, because now of the inclusion of the
4 missing values of the denominator, we will have
5 to talk about the CROWNWeb data issue where we're
6 having data integrity issues in terms of data
7 transmission. Which I just fear, you know, in a
8 measure that only has a 2 percent gap, I suspect
9 that significant amounts of data transmission
10 issues.

11 The fact that values aren't making it
12 from the clinic into the system may also
13 contribute to that false positive. And I ask
14 myself, well, what is the clinic going to do?
15 They are managing in real time with their data.
16 We don't see any issues. Now, they're being
17 told, potentially a year later, that there was a
18 problem. I don't see that changing too much to
19 answer your question.

20 CO-CHAIR ANDERSON: Frank?

21 DR. MADDUX: Yes, I just want to make
22 the point because it came up, I think, in Andy's

1 comment. I think simply because, with the
2 performance gap being extraordinarily narrow, the
3 evidence being low, the fact that we don't have
4 another bone and marrow measure shouldn't play a
5 role in our assessment of this measure and its
6 value, either as a performance measure or a
7 safety measure for threshold or a reserve
8 measure. We should, in my mind, look at it
9 independently.

10 CO-CHAIR CROOKS: So I think I'm
11 hearing sentiment that the case, it's a hard case
12 to make that this should even be a reserve
13 measure because of its lack of real importance.
14 And it doesn't seem likely that it's going to
15 deteriorate if it's not an NQF measure. Am I
16 gauging the sentiment correctly? Okay, so I
17 think --

18 MS. BAL: Before we move forward, I
19 just want to confirm that if there is, this
20 agreement means that if measure goes down in gap,
21 then we're done. We wouldn't continue to discuss
22 it. That's all I wanted to clarify. We can do a

1 hand vote if everyone --

2 DR. ZARITSKY: If it comes back as
3 insufficient here, that's it anyway, right?

4 FEMALE PARTICIPANT: Let's do the vote
5 and then we'll deal with what happens next.

6 CO-CHAIR CROOKS: We're voting on
7 whether to consider it, oh, we're going to vote
8 the gap first. I'm sorry. Okay.

9 DR. KRISHNAN: Is this the operating
10 definition between low and insufficient? Can you
11 just review that? Is low, there's too small of a
12 gap, as Connie said. Or is insufficient, there's
13 not a gap, or how does that work?

14 MS. SAMPSEL: So that would be low.
15 Insufficient is when there wasn't enough
16 information or you don't have enough information,
17 correct?

18 MS. OGUNGBEMI: The committee is now
19 voting on performance gap for measure 1454. The
20 performance gap is, they have demonstrated
21 considerable variation or overall less than
22 optimal performance across providers and/or

1 population groups. The options are 1-high, 2-
2 moderate, 3-low, 4-insufficient, and voting has
3 opened. For performance gap on Measure 1454, we
4 have zero for high, zero for moderate, 91 percent
5 for low and 9 percent for insufficient. The
6 measure fails on performance gap.

7 MS. SAMPSEL: And so the
8 interpretation of this is that the measure failed
9 one of the must-pass criteria, which is
10 performance gap under importance, which means we
11 would not move forward with additional
12 discussions on scientific acceptability, what
13 would go into the report is that you do not
14 recommend this measure for endorsement. Just
15 want to make sure everybody understands that.
16 And to summarize one more time --

17 CO-CHAIR BROOKS: And there would be
18 an opportunity for an exception but the committee
19 has vocally, sort of vocal consensus, that they
20 don't think that an exception is appropriate. Am
21 I summarizing it correctly?

22 DR. ZARITSKY: As a newbie, I'm

1 getting to recognize here that this is -- we're
2 not necessarily considering safety issues here,
3 we're considering a performance measure that we
4 can look in between units, and that there's no
5 difference between, you know, we're all
6 performing at this level. It's like if this
7 measure was a calcium of 15.5, what's the point.
8 If we were going to push the data down and say,
9 hey, I want a lower end of normal calcium to 9.5,
10 obviously, there would be a performance measure
11 there.

12 But we just don't have the data to
13 back that up. We do have expert opinion to back
14 up, you know, 10.2 as being a higher level of
15 normal what we would think. But that's my
16 feeling, now, of me being the first, a new person
17 at this first. And for this first measure that
18 we're looking for performance measures,
19 obviously, not necessarily something that's going
20 to provide a safety net.

21 CO-CHAIRMAN BROOKS: Yes, we have some
22 discretion, or have in the past, but in this

1 particular case, I think we're ready to let this
2 go, unless I'm missing any other procedural
3 points.

4 MS. SAMPSEL: I just want to make sure
5 that the endorsement isn't for a measure as a
6 performance measure, an accountability measure, a
7 safety measure, et cetera. It's the overall
8 merits of the measure, no matter what its use
9 would be.

10 So I don't want you to think that you
11 should only be evaluating measures because it has
12 an opportunity to be in a performance measure. I
13 mean, this is an instance where the measure, in a
14 semantics thing, of there's very little
15 opportunity for improvement. Have we already
16 reached that threshold? So that should be the
17 vein that you're looking at.

18 DR. MADDUX: So, Sarah, can I ask you
19 a question about that, because if a measure is
20 endorsed but would only be appropriate for
21 certain categories where it shouldn't really be a
22 performance measure, but might qualify for safety

1 uses, how do we address that with regard to our
2 role?

3 MS. BURSTIN: Yes, this has been a big
4 issue, Frank, you have had for a while. So we
5 actually now have an expert panel convened that's
6 meeting in the next couple of months to
7 potentially move us away from a binary, yes/no
8 endorsement decision, but instead to move towards
9 endorsement for the intended use of the measure,
10 and potentially flexing the criteria to make that
11 more logical to see if that works.

12 But, at this point in time, it is fair
13 to assume you're using the criteria regardless of
14 the intended use of the measure. I would argue
15 the safety issue is not really an intended use
16 issue. It's really looking at the measure
17 through a different lens.

18 So we routinely put forward some of
19 the safety indicators that have rates very low,
20 in some instances, as low as this one as almost
21 being sentinel events. So that is appropriate if
22 that is something you think is an important thing

1 to keep an eye on. But, you know, the question
2 is the measure was framed more so is there a
3 basic rate kind of base measure you would look at
4 in terms of performance.

5 It's still important to consider the
6 safety measure. It's something you could
7 potentially consider for reserve status just to
8 kind of keep an eye, you know, indicated should
9 at least have somebody keeping an eye on those
10 rates and ensuring that they don't start creeping
11 up, if it's not something that's part of an
12 ongoing monitoring approach.

13 DR. KASKEL: Did we review, is there
14 any evidence that there's disparities in the data
15 set with this value at all?

16 CO-CHAIR CROOKS: As part of the gap
17 discussion, yes, that would be appropriate, I
18 think, although we voted already. Did you want
19 to make a point about that?

20 DR. KASKEL: There is some evidence in
21 the literature that there are some disparities in
22 vitamin D, we know that, and potentially, calcium

1 and metabolism. Just thought I'd mention that.

2 DR. ZARITSKY: Yes, when you look at
3 the actual data there, the disparities are, I
4 mean, there are some statistically significant
5 disparities.

6 But the clinical, you know, you're
7 going from 2.1 to 1.9 percent. So I think what
8 we're facing here is that that cutoff of 10.2,
9 you know, it's at the higher, you know, it's the
10 higher end of normal, like I said, if we wanted
11 to, you know, bring it down without evidence,
12 then there would obviously be a gap. And then
13 some of those disparities might become larger and
14 more clinically significant. But at that upper
15 rate of 10.2, it's very hard to find something
16 clinically significant.

17 CO-CHAIR BOOKS: Where are we at?
18 So, oh, Lori. Lori has her card up.

19 MS. HARTWELL: I just want to make a
20 comment, that this is the only measure for bone
21 and mineral metabolism. So I would like it to
22 consider it for reserve or something. I just get

1 worried, as a patient, that we aren't measuring
2 anything for patients in this area.

3 CO-CHAIR BROOKS: Alan.

4 DR. KLIGER: You've got a sense of the
5 group, but there have been about six people
6 who've been vocal and 15 who've not, so the
7 question about reserve status, I suggest you put
8 to a vote. I want to add two things quickly,
9 though. I agree with Frank that the absence of a
10 measure in any particular area shouldn't be our
11 criterion. Our criterion is strictly whether
12 measures measure up to the standards that NQF has
13 established.

14 And that, in this particular measure,
15 with the evidence being low and the performance
16 gap being very low, I personally don't see the
17 wisdom of putting it into a reserve status. I
18 think that we need to await better evidence
19 before we vote affirmatively for a measure like
20 this.

21 DR. DALRYMPLE: And I know we voted on
22 performance gap, but since we have the developers

1 here, one part I'm trying to reconcile is, I
2 think, the 75th percentile was about 3 percent.
3 Yet, in meaningful difference, 15 percent of
4 facilities performed lower than expected. Is
5 that correct?

6 So as we move forward on some of these
7 measures, in trying to understand gap, I just
8 want to try and reconcile that difference. And I
9 wonder if you can give us insight. I'm not sure
10 if this is a good time to do it. But I think
11 there's a number of measures that appear topped
12 out, you know, a large percentage of facilities
13 are performing worse than expected. So, as we're
14 trying to figure out, moving forward, gaps and
15 performance.

16 DR. MESSANA: So my interpretation as
17 a clinician, non-epidemiologist, but in talking
18 to our analytic team, is that the measure has
19 topped out for the majority of facilities but
20 there's a skewed distribution. And I think that
21 the meaningful differences come from the tail,
22 right. So there are a relatively small number of

1 facilities that are relatively far from the high-
2 performing group.

3 DR. DALRYMPLE: But it's 15 percent
4 that are worse than expected, is that correct?
5 Am I interpreting that correctly?

6 DR. MESSANA: According, to the
7 analyses that were done, yes.

8 DR. KRISHNAN: And part of that may be
9 the data issue, right. So CROWNWeb data
10 performance varies by facility, even by chain.
11 So we have a variable data loss of anywhere from
12 5 to 15 percent of data transmission on a monthly
13 basis. And that also has asymmetrical
14 distribution. So that's why I don't know how to
15 reconcile the data integrity issues, the data
16 quality issues with the gap, because they're both
17 confounded.

18 CO-CHAIR BROOKS: Dr. Wagner.

19 DR. WAGNER: Yes. I had a question
20 about the forthcoming NQF focus on safety. If
21 the committee that is looking at safety as a goal
22 of a metric decides to incorporate such a goal,

1 then would that change the status of this
2 particular metric?

3 MS. SAMPSEL: No, this is under this
4 committee's purview at this time.

5 MS. BURSTIN: And this committee is
6 perfectly able to look at safety measures in the
7 KD arena, as well, obviously.

8 DR. WAGNER: I was just curious,
9 though. If we put it in reserve status, would it
10 then enable us to revisit this at a time when the
11 safety committee has spoken?

12 MS. BURSTIN: I'm not sure they would
13 add much to the discussion beyond what you've
14 already had. I think the real question for those
15 of you at the table is, is a 2 percent number
16 sufficient such that, particularly if there's a
17 tail, you know, regardless of what it might be,
18 that there should be some ongoing assessment to
19 make sure it's not particularly skewed for some
20 facility rather than others, where they might, in
21 fact, have safety issues.

22 CO-CHAIR CROOKS: Jessie.

1 MS. PAVLINAC: I just have a process
2 question. So if the measure is retired, it goes
3 into the big black hole and never is seen again
4 versus, if it's a reserve, then periodically, we
5 might look at it to see if that tail has become a
6 significant -- if there's been some change. Is
7 that exactly correct?

8 MS. BURSTIN: Yes.

9 MS. PAVLINAC: Thank you.

10 MS. BURSTIN: So, apparently, there is
11 an expectation that reserve measures come back up
12 for a maintenance review, at least in terms of
13 the gap.

14 CO-CHAIR CROOKS: If it's not in
15 reserve, it could always be brought again as a
16 new measure with fresh, better data and so on.
17 Lisa.

18 DR. LATTS: I guess my question is for
19 the developers and for CMS. If this measure goes
20 away or if it is put in reserve status, either
21 way, might there be an appetite to drop the level
22 so that there would be more of a gap. Look at it

1 as, I mean, it just, you know, what would sort of
2 be your perspective, the CMS perspective, if this
3 actually does go away? I don't know if you guys
4 can speak for CMS.

5 DR. MESSANA: I generally attempt not
6 to do that. But, you know, this measure was
7 developed, as you all have talked about, with the
8 TEP process. So this was not CMS setting a
9 threshold. This were two subsequent, two TEPs, a
10 couple of years, two, three years apart, setting
11 the measure threshold. When an expert panel
12 suggests, in the future, you know, depending upon
13 what happens here and what happens in the
14 dialysis community down the road is just
15 impossible to answer.

16 CO-CHAIR ANDERSON: And, again, once
17 again, the QIP measure isn't going away. So it's
18 still a part QIP in pay for performance. So
19 facilities have to meet that 98 percent threshold
20 of zero percent. Calcium's greater than 10.2, so
21 it still has to be monitored by the facilities to
22 meet those target goals as a QIP measure.

1 DR. LATTS: Although if it goes away,
2 as an NQF endorsed measure, does that affect then
3 the QIP measure down the road?

4 CO-CHAIR ANDERSON: Yes, I was going
5 to say, go ahead Joel.

6 DR. ANDRESS: Thank you. My name is
7 Joel Andress. I'm the measure development lead
8 for CMS for dialysis facilities. So to your
9 earlier question, I think Joe's absolutely right.
10 I suppose CMS could arbitrarily reduce the target
11 level. I think we'd have a difficult time
12 justifying that in any venue.

13 So, you know, if additional evidence
14 comes along which indicated that a lower target
15 was appropriate, say 9.5, as was mentioned
16 earlier, then that's certainly something that we
17 could look into. Until then, I think, 10.2 is
18 the threshold we have available for
19 consideration.

20 In terms of the question of the
21 measure's implementation, so implementation or
22 retirement of the measure, the QIP is held under

1 purview of the rule making process. So the
2 decision here has no necessary consequence for
3 that, I think. There are statutory requirements
4 in the QIP for measures of mineral bone disease
5 that we certainly have to consider as we are
6 thinking about the measures that are implemented.

7 So that would probably factor, that as
8 well as, any decision here at NQF, would factor
9 into our thinking for the measure in the future.
10 But it would be, well, first of all, it would be
11 inappropriate for me to say that we would have a
12 particular response with regard to the QIP, and I
13 would note that any response would be noted in a
14 proposed rule in the future. Does that answer
15 the question?

16 CO-CHAIR CROOKS: I think the point
17 is, though, that I would emphasize is even if it
18 is continued in the QIP, that has no bearing on
19 our considerations here, it should not. Mehesh.

20 DR. KRISHNAN: I'm just struck by the
21 history that Andy and Alan provided where we've
22 kicked the can down the road two or three times.

1 It sounds to me like the answer in this
2 discussion is, we think it's important to have a
3 bone and mineral measure, there are requirements
4 to have a bone and mineral measure, but that this
5 particular measure has had the same discussion
6 twice in the same forum.

7 And so it may be worthwhile thinking
8 about an alternative measure. I know there's one
9 coming up on phosphorus. But if we desire a
10 safety measure, maybe we need another TEP to talk
11 about that. But it just seems like, it seems to
12 me, and I wasn't -- I'm a newbie here as well.
13 It seems to me like this parallels a discussion
14 that y'all had, you all had, sorry. I'm from
15 West Virginia originally, you had in the past and
16 so it just seems like we're repeating history and
17 it may be time to change that.

18 CO-CHAIR CROOKS: I'd like to limit
19 the comments. I mean, I want you all to say what
20 you need to say, but please make sure it's
21 something important. Andrew. If you catch my
22 drift.

1 DR. NARVA: Joel, do you remember when
2 this was developed and considered in 2010, what
3 the gap was at that time? Because this may just
4 be a very successful measure and since there's no
5 additional burden on anybody, everyone's dialysis
6 unit's going to continue to collect calciums, no
7 matter what. I'm just curious.

8 DR. ANDRESS: Sorry, I do not
9 personally remember. I was not part of the
10 project at the time. I think, so when the
11 measure was originally developed, the denominator
12 was defined slightly differently from what we're
13 talking about now. It was, essentially, a
14 proportion of the data that we received for
15 calcium.

16 And it was using test data, yes, I
17 know. It was using test data from CROWNWeb as
18 the basis for testing and developing the measure.
19 So I think the data we have now are certainly
20 more complete. Speaking to the issue of the
21 completeness of data and CROWNWeb, certainly, it
22 is true that there are issues that the CROWNWeb

1 team are working through. I think there're also
2 gaps in the submission of calcium data that also
3 need to be addressed on the provider's side.

4 And that was one of the reasons that
5 we modified this measure to require more fulsome
6 reporting of the data through CROWNWeb from the
7 facilities. I think that's, you know, part of
8 the rationale for the measure. That there needs
9 to be a, not only a performance assessment, but
10 also a requirement for reporting and so that was
11 part of the rationale in moving forward.

12 I also want to speak to the issue of
13 holding another TEP to review a potential
14 alternate measure. So, we've done that, and
15 we've held three TEPs on this topic. I think
16 that's the most TEPs we've had on any topic and
17 this is the most soundly supported measure that
18 has come out of those deliberations.

19 So I just want to make it clear
20 there's not a measure we're hiding in our back
21 pocket with evidence demonstrating, you know,
22 that it is the performance measure and that's

1 what we should be using. We have, in fact, been
2 pushed to develop additional measures in mineral
3 bone disease and we have attempted to do so.

4 Speaking to the issue of reviewing the
5 issue on its own merits, I think that's
6 absolutely correct. I just want to be clear.
7 We're not going to be able to pop out a new
8 measure of mineral bone disease next year as a
9 consequence of this measure not being endorsed.
10 And I want that to be clear when you're
11 considering your vote.

12 CO-CHAIR CROOKS: Okay. We'll soon be
13 voting on whether to consider this for reserve
14 status. Frank.

15 DR. MADDUX: Sure. So I appreciate
16 the comments that John, Claudia and Joel have
17 made. But it strikes me that we do, although, we
18 need to truly vote on each individual measure, we
19 need to also think of what I would call, the
20 unintended consequences, of something like
21 reserve status.

22 And, the unintended consequences that,

1 despite there being three prior TEPs, I think the
2 three prior TEPs having difficulty coming up with
3 a measure is indicative of the complexity of this
4 part of the associated condition for end stage
5 renal disease patients.

6 And my concern would be is that
7 reserve status might actually limit the ability
8 of developers, whether it's CMS or other
9 developers at really working hard at trying to
10 figure out what an appropriate measure for bone
11 marrow metabolism should be.

12 CO-CHAIR CROOKS: Thank you. Dr.
13 Zaritsky.

14 DR. ZARITSKY: Just one last comment.
15 Because, you know, with this measure. I mean,
16 obviously, we're talking about things that we're
17 going apply to subsequent measures. And I just
18 wanted to just touch upon the patient's safety
19 aspect.

20 To look, let's say the measure before,
21 even if only 50 percent of the facilities were
22 making this measure ten years ago, you know,

1 because the gap has narrowed or come down, that
2 doesn't necessarily reflect the ruling here, but
3 rather also the general consensus in what the
4 expert opinion is.

5 So we've gone, you know, I'm rather
6 junior, but we've gone from, you know, this idea
7 of, okay, high calciums are okay, et cetera, to
8 this recognition now that, you know, there's too
9 much calcium out there in a general thing. So
10 I'm not worried that by, at least in a pediatric
11 setting, the units that I know and the people
12 that I talk to that if this measure is, you know,
13 dropped from that perspective that we're going to
14 adversely affect patient outcomes.

15 And then the final thing is lowering,
16 I think part of the, and I'll use the word
17 weakness, that the 10.2 is, is that you recognize
18 if we tried to move that measure down, you know,
19 which I think we would have -- you know, some of
20 us might have an argument, I could make an
21 argument to bring it down to 9.5. The evidence
22 that I would use it is largely associative and

1 it's very weak from that, you know, from a very,
2 very high standard that you'd want to go to.

3 So I think that, there's that idea
4 that 10.2 well, because it's upper level of
5 normal and we all kind of agree with that. But,
6 you know, if I thought about bringing it down,
7 we'd have even more problems.

8 CO-CHAIR CROOKS: Right, and just as a
9 passing note. We generally aren't going to be
10 rewriting or changing metrics here. We take the
11 metric and the information as it's presented.
12 Okay. I see no other, I see one other card up,
13 that's Josh. Put your card down, Josh. All
14 right, anybody else?

15 I think we can now vote on whether to
16 -- this isn't whether, if it's going to be a
17 reserve, it's just whether to even consider this
18 because of there would be a whole process after
19 that. Am I right? A hand vote, this will be a
20 hand vote. So those in favor of continuing of
21 exploring making this a reserve measure, raise
22 your hands. And keep them up, raise them high.

1 One, two, three, four, five, six. I'm counting
2 six.

3 CO-CHAIR ANDERSON: One, two, three,
4 four, five, six. I have six.

5 CO-CHAIR CROOKS: Sort of up and down,
6 there's three there and three here. Okay. And
7 those not in favor of exploring it as a reserve,
8 raise your hands. So I would say this vote has
9 it. So we're going to not consider it further as
10 a reserve measure. Okay. That concludes our
11 business on this particular metric. I think we
12 get to the bio break, or our break a little
13 early. The 4 percent --

14 (Laughter.)

15 MS. BAL: So before everyone leaves
16 though, we will be taking our break early. About
17 ten minutes. So we'll ask everyone to come back
18 ten minutes early. So, please, by 10:20 be ready
19 to review our next measure. Thank you.

20 (Whereupon, the above-entitled matter
21 went off the record at 10:05 a.m. and resumed at
22 10:20 a.m.)

1 CO-CHAIR ANDERSON: All right. We're
2 going to move to measure 2594, and -- which is
3 the Optimal End-Stage Renal Disease Starts, and
4 Peter is here as the developer.

5 MS. BAL: Actually, sorry, Peter --

6 CO-CHAIR ANDERSON: Oh, I am sorry.

7 MS. BAL: It's okay. Before you
8 start, I forgot to mention related and competing
9 before, and this is the first one we'll be having
10 those kinds of measures, so I did want to bring
11 that to everyone's attention.

12 So before -- prior to the in-person
13 meeting, we did notify developers if there was a
14 related or competing measure identified there for
15 their measure. They were asked to respond, and
16 they have provided responses to all the measures
17 listed on the annotated agenda.

18 You can find that on the link I sent
19 to you on, I believe it was, Monday. There was a
20 link filled -- it was a folder filled with all
21 the different documents. If you want to open
22 that up, you can. We'll have it open -- we'll

1 open it up for you as well when we talk about it.

2 Again, the procedure is that we talk
3 about each measure individually as they are, and
4 then if they are chosen to be recommended for
5 endorsement, we would consider if they were
6 related or competing to other endorsed --
7 recommended for endorsement measures.

8 So that's not a factor we take into
9 consideration until the end, because we do want
10 to make sure that these measures pass endorsement
11 on their own, and then at that point. And so,
12 again, it's the same procedure. You'll be asked
13 to consider if these are related and competing
14 measures, do you think there is a best in class?
15 You can ask the measure developer clarification.

16 Were there any questions about that?
17 And that -- we'll do our first round of related
18 and competing after the -- these next four
19 measures. Any question before we start?

20 (No audible response.)

21 MS. BAL: Okay. So now I'll give it
22 to Peter.

1 CO-CHAIR CROOKS: Okay, and before you
2 start my two to three minutes, I am -- just to
3 let the Committee know, I am now a developer. I
4 won't be able to vote. I won't be able to say
5 anything unless asked, so please feel free to ask
6 if you have any questions. Okay. So this is --
7 okay.

8 Measures that matter: I have been told
9 that this is the new NQF motto, measures that
10 matter. Well, I believe Optimal ESRD Starts is a
11 measure that matters, and it's a measure that
12 works.

13 By now, I hope you have had time to
14 become familiar with this measure. Optimal ESRD
15 Starts is a process metric. The focus is on pre-
16 emptive kidney transplant, starting ESRD on a
17 home dialysis modality, or starting in-center
18 hemodialysis with a fistula or graft.

19 The process measured is the success at
20 identifying high-risk CKD patients, educating
21 them about modality choices, and helping them
22 make those choices, and then once they have

1 selected that, see that they have prepared before
2 they reach ESRD. The better those processes
3 perform, the higher the optimal ESRD starts.

4 Now, this measure is not intended for
5 dialysis facilities. This measure is intended
6 for the broader U.S. healthcare system, CMS and
7 health insurance companies, ACOs and other
8 integrated care delivery systems, and nephrology
9 groups and organizations. But while not intended
10 for the dialysis facility use, it will deliver
11 better patients: prepared, educated, with a
12 fistula and a graft, so the dialysis industry
13 will benefit.

14 The data elements are very simple, and
15 the calculation is back-of-the-envelope easy.
16 Date of ESRD, the modality, be it transplant,
17 home dialysis, in-center hemodialysis, and if in
18 center, what is the vascular access used at the
19 very first treatment? If a patient recovers GFR,
20 they did not have ESRD, and they are not
21 included.

22 Now, to clarify the ten percent limit

1 on grafts, let's think about what that means.

2 Let's say a large nephrology group or insurance
3 company has 100 patients that start hemodialysis
4 in a year. 10 percent of those patients, or 10
5 of them, may have grafts and meet the definition.

6 So, typically, 70 percent start
7 hemodialysis with a catheter in their neck,
8 unfortunately, and 30 have prepared --
9 surgically-prepared accesses. That means 1 in 3,
10 10 of the 30, could be grafts, and it would be
11 acceptable.

12 So 1 in 3 is not really that
13 encumbersome, and we've found in practice that it
14 does allow for choice in individual patient
15 decisions, yet it is consistent with the Fistula
16 First Initiative, which we I think all have to
17 recognize has done a lot to improve dialysis care
18 in this country. So does this measure pass the
19 NQF criteria? Let's run it down.

20 Evidence: multiple guidelines, and
21 more importantly, systematic evidence reviews
22 support the following conclusions: one, a pre-

1 emptive kidney transplant has better health
2 outcomes than starting hemodialysis with a
3 catheter; two, starting from home dialysis
4 modality has better outcomes than starting in-
5 center hemo with a catheter; three, starting
6 hemodialysis in center with a surgically-prepared
7 fistula or graft is better than starting with a
8 hemodialysis catheter.

9 The evidence is strong: Optimal ESRD
10 Starts reduces mortality, reduces bloodstream
11 infections, reduces hospital days, while
12 improving quality of life. I hope you agree that
13 the evidence is strong.

14 Gap: extracted data from USRDS and
15 Fistula First shows that optimal ESRD starts in
16 the U.S. in 2012 was 35.5 percent. For KP
17 nationally in 2012, it was 51 percent, and since
18 then, it was increased to 58 percent in mid-year
19 2014.

20 What is the upper limit? I suspect
21 that using urgent-start PD and the new immediate-
22 use grafts, the level may be able to reach as

1 high as 80 percent or even higher. So there is a
2 gap, and that gap can be closed.

3 Reliability and validity: the testing
4 of critical data element accuracy showed the
5 measure to be both reliable and valid to a high
6 degree of certainty, and while we did not
7 specifically utilize phase validity argument, I
8 think the medical evidence provides that. It
9 does link optimal ESRD starts to improved health
10 outcomes.

11 Now feasibility and usability and use:
12 well, it is feasible, as KP has been doing it
13 across the U.S. It is usable, and it is
14 improving outcomes. Now, I have heard concern
15 that this may only be usable within Kaiser, and
16 that the data elements are not easily
17 electronically accessible. Well, I hold in my
18 hand CMS Form 2728, and as you all know, this
19 form is filled out for every patient who starts
20 dialysis in the United States, whether they have
21 Medicare insurance or not.

22 Let's see if it contains the data

1 elements necessary for calculating optimal ESRD
2 starts: date of ESRD, check; ESRD modality,
3 check; and if they start in-center hemo, item
4 18(d), what access was used on first outpatient
5 dialysis, AVF, graft, catheter? It's all there.
6 CMS has the data, and they can start calculating
7 optimal ESRD starts today.

8 The Permanente Federation, the measure
9 steward, looks forward to working with CMS to put
10 this measure on the PQRS Reporting System, to
11 work with RPA to put it on their registry, and to
12 work with any other groups that would like to
13 implement this measure.

14 So there it is. All the criteria seem
15 to be fulfilled. And to repeat, this measure is
16 not intended for the dialysis facility, but is
17 aimed at the broader U.S. healthcare delivery
18 system, but it will deliver better, healthier,
19 educated patients into the dialysis facility with
20 a usable AVF or AVG. Optimal ESRD Starts: it's a
21 measure that matters, and it's a measure that
22 works. Thank you.

1 CO-CHAIR ANDERSON: Thank you, Peter.

2 All right. And so we have our -- our two
3 reviewers, who are Beth Evans and Lori Hartwell.
4 Beth, are you going to start, or Lori?

5 MS. EVANS: Yes, I am. All right.

6 CO-CHAIR ANDERSON: So we'll start
7 with the --

8 MS. EVANS: Right. So the evidence is
9 based on four clinical practice guidelines, KDOQI
10 2006 grade a and b; U.K. Renal Association 2008,
11 2011, grade 1b, which was strong opinion and
12 moderate evidence; and Vascular Access Society,
13 unknown date, and it's not defined what their
14 level III evidence is; and the Canadian Society
15 of Nephrology, 2006, grades C and D, which C is
16 not defined and D is opinion.

17 It was also based on a systematic
18 review of 62 studies of over 500,000 patients.
19 It was not graded, but a retrospective study.
20 Moderate evidence per the NQF algorithm based on
21 retrospective patients.

22 Pre-emptive kidney transplant was one

1 clinical practice guideline of the U.K. Renal
2 Association rated 1a, which was strong opinion
3 and high evidence. Systemic review and a meta-
4 analysis was also retrospective study with low to
5 moderate quality, moderate evidence per NQF
6 algorithm.

7 New recent studies, all with positive
8 outcomes, with transplant, which was a cohort
9 retrospective study, and a 2007 article
10 evaluating lifelong cost for transplant. So the
11 process of care is directly related to improved
12 health outcomes with improved cost effectiveness.
13 So it's a process measure. Okay.

14 CO-CHAIR ANDERSON: Lori? Do you have
15 anything to add, Lori?

16 MS. HARTWELL: To what -- could you
17 briefly -- I couldn't hear you.

18 CO-CHAIR ANDERSON: The evidence, do
19 you have anything to add to --

20 MS. HARTWELL: You know, the only
21 thing I would add is that, you know, in reading
22 this, and I'm reading this from the patient's

1 perspective, this seems like a very meaningful
2 measure, and the evidence is there of pre-emptive
3 transplant, of starting home dialysis, I mean,
4 just in the community.

5 And so I think this is a -- an
6 excellent measure that would help patients, and
7 especially push the grid in pre-emptive
8 transplant, so it was a very easy measure to
9 understand. I just had one question for you,
10 though. When it said -- is it okay to ask a
11 question -- home dialysis starts, was it PD and
12 home hemo? Was there -- what were the
13 percentages in starts?

14 CO-CHAIR CROOKS: Yes, any home --
15 either home modality is an optimal start, and,
16 you know, in terms of percentages, within Kaiser,
17 actually, since we started this initiative, we're
18 up to 30 percent incidence rates in Northern
19 California, one of our larger regions, and home
20 -- home hemo is, as many know, there are -- we
21 have maybe 1 percent of our patients on home
22 hemodialysis.

1 MS. HARTWELL: 1 percent?

2 CO-CHAIR CROOKS: About 1, yeah,
3 roughly.

4 CO-CHAIR ANDERSON: Andy?

5 DR. NARVA: Sure. I like this
6 measure a lot, and I think one of the reasons is
7 that it's a way of driving improvements in care
8 prior to initiation of dialysis, which -- which I
9 think is really important.

10 I was just wondering, since I think
11 you started -- this started -- this measure was
12 first implemented in Kaiser Permanente Southern
13 California, it's been implemented across the
14 country, do you have data to show how formal
15 adaptation of this as a measure changed care in
16 other facilities as well?

17 CO-CHAIR CROOKS: Is that a question?
18 Do I --

19 DR. NARVA: Yes.

20 CO-CHAIR CROOKS: Yes, in the appendix
21 is all the results for the last -- since we
22 started measuring it nationally, and there's been

1 improvement in all of our regions. Some go up --
2 some of the small regions may go up and down a
3 little bit because they have smaller numbers of
4 patients, but overall, the trend has been
5 upwards, and there has been a great growth in
6 home peritoneal dialysis during that time as
7 well. Does that answer your question?

8 DR. NARVA: Yeah, it confirms my bias,
9 I like it.

10 CO-CHAIR ANDERSON: And we would like
11 the committees to discuss the measure within the
12 Committee and ask Peter the questions after there
13 has been discussion. Okay. Stuart?

14 DR. GREENSTEIN: I am just curious
15 about Kaiser Permanente, what is your pre-emptive
16 rate, what is your rate of fistulas at beginning,
17 and also grafts, graft rate? Do you know -- do
18 you know what the numbers are?

19 CO-CHAIR CROOKS: If I -- I guess I am
20 the one that has the answer. We average 2.5 to 3
21 percent pre-emptive transplants, which is what
22 you see, I think, in most any health care system,

1 showing that pre-emptive transplant is largely a
2 family endeavor, and -- and we should be able to
3 do better, and we're thinking hard about how can
4 we improve pre-emptive transplants, but we're
5 stuck below 5 percent. You know, sometimes we've
6 seen 5 percent in a region temporarily.

7 For our -- our fistula and grafts, I
8 can tell you that the graft -- the fistula
9 prevalence is over 80 percent, and incidence
10 rates I can't quote you right off the top of my
11 head.

12 DR. GREENSTEIN: Another question, how
13 soon from the time of initiation of dialysis to
14 referral for transplant? I ask that because now
15 they've changed it in terms of waiting times,
16 that you get your waiting time starts from start
17 of dialysis.

18 Which, you know, is a way of
19 preventing patients from being penalized from not
20 being referred, but at the same time, what
21 happens is patients then say oh, I'll wait five
22 years before I go for transplant. I'm wondering

1 if you have any numbers along that line of where
2 -- how long after they start dialysis do they get
3 referred?

4 CO-CHAIR CROOKS: Well, one -- while
5 not relevant to the measure per se, we do -- I
6 believe we do a very good job screening patients,
7 getting them in early, and whatever the sorting
8 system is, that they should be out early, and a
9 hard search for living donors.

10 CO-CHAIR ANDERSON: All right. Just
11 a reminder to the Committee that we really do
12 need to look and keep our comments related to the
13 evidence based on this measure. So Frank?

14 DR. MADDUX: Sure. So a couple of
15 comments and one question for Beth and Lori.
16 First of all, I think this is an unbelievably
17 important area of measurement that we need to
18 develop, and -- and I am pleased this was brought
19 forward, and I think measures go through a
20 maturity cycle, and even if this one has some
21 immature elements, I think, nationally, we need
22 to consider it very strongly.

1 I have a couple of questions about the
2 fact that if we extrapolate the Kaiser
3 experience, we all believe Fistula First has been
4 a success in most ways, but I am concerned about
5 the elderly patient that is getting fistula after
6 fistula after fistula that will never mature.

7 And I am a little bit concerned about
8 the 10 percent graft, sort of, hurdle here, and I
9 can see how it kind of fits into the existing
10 numbers, but I don't want to create targets by
11 saying well 10 percent should be your overall
12 global target for a graft. I think that this is
13 permanent access or non-permanent access, and I
14 see this as a catheter avoidance strategy
15 measure.

16 But one question that I have, which I
17 don't -- either didn't read it well enough, or I
18 don't understand the measure quite well enough is
19 does home hemodialysis trump the vascular access
20 type for that population of patients, or is it
21 home hemodialysis and catheter avoidance, or home
22 hemodialysis in spite of catheters?

1 MS. EVANS: I'll answer that because
2 actually Peter answered that for us at the -- in
3 the conference call. And it has to be home hemo
4 with fistula or graft. Catheters are not
5 acceptable at any times in that as an optimal
6 start.

7 Okay. I do want to add one thing. I
8 think he clarified nicely that 10 percent of
9 grafts is really based on their entire new
10 starting dialysis population or transplants, so
11 of 100 patients, 10. So that does give a bit
12 more of a liberal amount. I didn't understand
13 that initially, so that makes it a little more
14 achievable, based on this measure.

15 CO-CHAIR ANDERSON: Alan?

16 DR. KLIGER: I wonder then based on
17 the discussion we just had what your assessment
18 of the strength of the evidence is?

19 MS. EVANS: The only, to me, weakness
20 is that it was retrospective studies for the
21 systematic review. I don't think it's possible
22 at this level right now to do a prospective

1 study, so using what we have for the NQF, I had
2 to rate it moderate, but I still feel if we could
3 maybe even put it tiered in there between
4 moderate and high, it would be a moderately high
5 evidence, as kind of a modifier with that.

6 CO-CHAIR ANDERSON: Bobbi?

7 MS. WAGER: I have to agree with Dr.
8 Greenstein. I think this -- and Lori, this
9 measure is very important because of the new
10 kidney allocation policy that I feel does not
11 promote pre-emptive transplants, which I think
12 pre-emptive is -- as we all know, it's a gold
13 standard of care for ESRD, but this -- this
14 measure will help keep the pre-emptive
15 transplants out there for the patients.

16 CO-CHAIR ANDERSON: All right. Are we
17 ready to vote on the evidence?

18 MS. OGUNGBEMI: The Committee is now
19 voting on evidence for measure 2594. The options
20 are 1 for high, 2 for moderate, 3 for low, and 4
21 for insufficient. Voting is now open.

22 (Pause.)

1 We have 6 votes for high, 2 votes for
2 moderate, 0 for low, and 0 for insufficient for
3 evidence for measure 2594. The measure passes on
4 evidence.

5 CO-CHAIR ANDERSON: All right. Let's
6 move on to performance gap. Okay. Kaiser data
7 suggests a performance gap and supports the need
8 for a national performance measure. The gap is
9 apparent in evaluating new starts to a therapy to
10 replace the usual function.

11 This optimal start process has been in
12 place for ten years with KP in California and
13 five years nationally, and using abstracted data,
14 has calculated the U.S. national 2012 AVF rate as
15 35.5 percent. The KP data for June 2014 is
16 approximately 58 percent for AVF and optimal
17 starts total. So it's a significant performance
18 gap between the U.S. and the Kaiser Permanente
19 performance.

20 Disparities, do I cover that also at
21 this time? Disparities in care has very little
22 evidence regarding fistula, with just one article

1 suggesting arm vein differences resulting in
2 lower fistula creation in Caucasian versus
3 African Americans with private insurance. No
4 recent articles found comparing PD to
5 hemodialysis disparities except higher
6 utilization of PD in other countries. I think we
7 all know that.

8 One article that suggested zip codes
9 with higher African American population are
10 associated with lower nephrology care, and
11 unclear evidence of disparities with this process
12 in the literature. So the -- and the USRDS
13 Fistula First data shows a significant gap in
14 performance of pre-dialysis education, and
15 certainly an opportunity for improvement. And
16 this is also considered a high priority -- I am
17 sorry, next one, left, so. Lori, any comments?

18 MS. HARTWELL: I think you summed that
19 up really well.

20 CO-CHAIR ANDERSON: Any other comments
21 from the Committee, or discussion?

22 (No audible response.)

1 CO-CHAIR ANDERSON: Are we ready to
2 vote? All right.

3 MS. OGUNGBEMI: The Committee is now
4 voting on performance gap for measure 2594. The
5 options are 1 for high, 2 moderate, 3 low, and 4
6 for insufficient. Voting is now open.

7 MS. BAL: As a reminder, since Peter
8 is the only one with a conflict, we are looking
9 for 22 votes.

10 MS. OGUNGBEMI: We have 18 votes for
11 high, 4 votes for moderate, 0 for low, and 0 for
12 insufficient. The measure passes on performance
13 gap, for measure 2594.

14 CO-CHAIR ANDERSON: All right, Beth,
15 high priority?

16 MS. EVANS: That --

17 CO-CHAIR ANDERSON: Okay, that -- now
18 that was brought up as a question. We do or do
19 not discuss priority?

20 MS. EVANS: We do not, we do not.

21 CO-CHAIR ANDERSON: We do not. Okay.

22 MS. SAMPSEL: So just -- and let me

1 just clarify, technically, with high priority,
2 while it's not -- no longer a voting criteria,
3 that would be something that you would want to
4 discuss as part of evidence and part of gap, and
5 certainly if folks -- and I think it did come out
6 quite a bit with some of the comments, so just,
7 it's not a clear not discuss, but more of a let's
8 encompass it in the other important criteria.

9 CO-CHAIR ANDERSON: Thanks, Sarah.
10 Okay, moving on to validity. Okay.

11 MS. SAMPSEL: Actually, generally, on
12 scientific acceptability and any -- this is the
13 first part of reliability would be a discussion
14 of the measure specifications.

15 CO-CHAIR ANDERSON: Okay.

16 MS. SAMPSEL: And any questions
17 anybody might have on the specifications or
18 comments on the specifications, to make it clear.

19 CO-CHAIR ANDERSON: Okay, Beth?

20 MS. EVANS: The numerator is the
21 number of new ESRD patients who initiate renal
22 replacement therapy in the 12 month measurement

1 period with an optimal ESRD start, which is
2 defined as fistula, graft, pre-emptive
3 transplant, or home dialysis without a catheter,
4 home hemo.

5 Denominator is the number of patients
6 who receive a pre-emptive kidney transplant or
7 initiate long-term dialysis therapy and do not
8 recover kidney function by 90 days for the first
9 time in the 12-month measurement period, and
10 there are no exclusions to the denominator.

11 CO-CHAIR ANDERSON: Lori? Okay.

12 MS. HARTWELL: I don't have anything
13 to add.

14 CO-CHAIR ANDERSON: Any further
15 discussion on the part of the Committee?
16 Questions? Alan?

17 DR. KLIGER: Yeah, I want to raise the
18 question about the specification that Frank
19 mentioned, that is, home hemo patients and their
20 vascular access.

21 I am unaware of any studies showing
22 for home hemodialysis patients that catheters

1 afforded a higher risk to them than do fistulas
2 or grafts, and I say that in the setting of
3 speaking to some of the zealots for home
4 hemodialysis who have at least anecdotally, but
5 also reported in the literature their experience
6 that catheters, when handled by patients rather
7 than by staff, have a far better outcome than in
8 the hands of our staff in dialysis units.

9 Only to say I don't know of any
10 evidence that would say for the home hemo patient
11 that an optimal start is necessarily with a graft
12 or a fistula, and so I have just some concern, in
13 the absence of that evidence, for that part of
14 this measure, that we really don't know that.

15 CO-CHAIR ANDERSON: Mahesh?

16 DR. KRISHNAN: Question for Peter, do
17 we -- have you considered as an exclusion some
18 patients who may have a limited life expectancy,
19 or are coming on to dialysis for a transient
20 period of time where converting from a temporary
21 access to a permanent access may not be
22 consistent with the general plan? How would you

1 handle that, or should that be an exclusion? I
2 don't know how you would quantify that, but just
3 a question.

4 CO-CHAIR CROOKS: Okay, two questions.
5 Taking the last first, the -- if a patient
6 chooses not to start dialysis, then they are not
7 ever in the denominator, and in fact, if you
8 think about it, having a good, active palliative
9 care -- you know, palliative care program
10 improves your optimal starts, because you don't
11 get elderly patients who shouldn't be starting
12 dialysis in the unit with a catheter, so that
13 actually helps optimal starts improve.

14 I do believe that we need a new
15 paradigm for looking at elderly, fragile
16 patients. The concept of a trial of
17 hemodialysis, which I have always kind of shied
18 away from, but I think is a viable consideration
19 in some cases with a catheter. And there's some
20 data that elderly patients with catheters may not
21 have as many bloodstream infections. Right now,
22 though, they would be treated as a non-optimal

1 start.

2 DR. KRISHNAN: Right.

3 CO-CHAIR CROOKS: You know, measures
4 can change as time goes along, and we will be re-
5 endorsing. Maybe there will be new paradigms and
6 better strategies for handling elderly, frail
7 patients.

8 As to Alan's remark about the home
9 hemodialysis with a catheter, this was a debate
10 that went on back and forth among the measure
11 developers. For years, we've been talking about
12 that. And I favored Bob Lockridge's strategy,
13 and I was outvoted. But I think this is
14 something that we could, you know, if this was a
15 measure-buster, that we could really take back
16 and re-discuss.

17 My sympathies are with Alan's
18 position. The data that we do have shows that
19 catheters are worse than fistulas and grafts, you
20 know, and that's sort of where they went back to.
21 But I think that that's worthy of consideration
22 for tweaking in the future.

1 CO-CHAIR ANDERSON: Ishir?

2 DR. BHAN: Yes, so this is probably an
3 issue that would come up on many measures, but
4 one question relates to how we deal with the
5 implications for patient selection.

6 So, for example, I think these are
7 certainly worthwhile goals for patients who are
8 being followed pre-dialysis to try to achieve,
9 you know, better access before initiation. But
10 there are also patients, particularly at sort of
11 tertiary care institutions, who show up, often
12 from other countries, with no pre-dialysis care
13 and therefore would end up with a catheter.

14 And so my question is regarding how
15 that might influence, you know, selecting certain
16 patient populations to focus on, sort of
17 unintended consequences of this type of measure.
18 I'd love to hear from people who have been around
19 for a couple cycles to hear how that would affect
20 things, or how those factors are considered.

21 CO-CHAIR ANDERSON: Well, I think also
22 with the new starts, new to dialysis, and the

1 evidence of 2728, they do ask how long patients
2 have been under the care of a nephrologist prior
3 to the start. And if you look at that data,
4 about I think it's 62 percent -- is that right --
5 I think it's 62 percent are under the care of a
6 nephrologist for at least a period of six months.
7 But there is some where they're going to be
8 urgent starts that come in --

9 DR. BHAN: And that would probably
10 vary by institution or region.

11 CO-CHAIR ANDERSON: Right.

12 DR. BHAN: And my concern is the
13 exclusion criteria don't have any of that baked
14 into it. It's just anyone starting dialysis, not
15 anyone starting dialysis who has had pre-dialysis
16 care.

17 CO-CHAIR ANDERSON: Under a
18 nephrologist, yeah. Lorien?

19 DR. DALRYMPLE: And I actually have a
20 similar concern and was hoping as a Committee we
21 could discuss it and then ask Peter questions.
22 But there are institutions where 50 percent of

1 your incident patients present to the ED. So in
2 this specification of the measure, if it's at a
3 physician level, and your quality is reflected, I
4 think the question is, should the specifications
5 take into account that a lot of this depends on
6 access to care? And depending on where you
7 practice, access to care will be very different.
8 So I share that concern in terms of
9 specification.

10 I also had a question for the
11 pediatric nephrologists in our group. My
12 understanding is because children are often going
13 to transplant or hoping to get transplanted, we
14 don't often put fistulas or grafts in them. I
15 hope you guys can weigh in on that a little bit
16 more, but it seems, at our institution at least,
17 they often start with catheters, and mom is going
18 to be their donor in two months, and no one
19 attempts to put access in.

20 And do you feel this measure, as I
21 understand it, and Peter will clarify for us if
22 I'm wrong, pediatric patients are included in

1 this measure?

2 DR. SOMERS: Well, you know, happily,
3 a good proportion of pediatric patients are going
4 to be covered by PD, so that takes them off the
5 table, and there's a growing number having pre-
6 emptive transplants.

7 I think it is true that, especially in
8 the U.S., a large number of kids who we think who
9 are going to go to transplant quickly will be
10 dialyzed by catheters, but I am not sure that
11 there's actually evidence to -- when you look at
12 practices in other parts of the world, there is
13 actually more of a push to put in fistulae, for
14 all the reasons that have been shown that
15 fistulae are better.

16 But I do think that, you know, as a
17 practice, that it would be difficult for
18 pediatric nephrologists to have a high degree of
19 performance on this because of current practice.

20 CO-CHAIR ANDERSON: Josh, go ahead.

21 DR. ZARITSKY: Just also answering to
22 the pediatric is, if you looked at any individual

1 unit, the numbers are so small that, you know, if
2 you had two or three children who are, you know,
3 under age five or something, it's just not
4 practical to put a fistula or a graft in, that
5 we'd have to deal with it.

6 But I think it's still, you know, from
7 a pediatric standpoint, it's still an interesting
8 thing for us to have on the table.

9 CO-CHAIR ANDERSON: Frank?

10 DR. MADDUX: So, two thoughts. When
11 I think about what the potential intended or
12 unintended consequences might be, is this would
13 drive programs with a lot of urgent starts to
14 doing urgent start PD, which may or may not be
15 clinically appropriate, and the measure could
16 drive certain clinical behaviors that we don't
17 really know what the result would be of that. We
18 need to be aware of that.

19 The other which concerns me about this
20 is the rapidity with which our delivery systems
21 are moving towards risk-based models for end
22 stage renal disease care. And it strikes me that

1 the re-evaluation of this measure in the context
2 of palliative care, and potentially palliative
3 dialysis for somebody that really just wants to
4 get to the wedding in three months or the
5 graduation in six months or something as a
6 primary goal for therapy could also create some
7 fairly unintended behavior that it would be nice
8 to see that considered within the measure on the
9 front end. Because three years from now, if
10 we're reassessing a measure that's beginning to
11 get into the system, our delivery system could be
12 fundamentally different.

13 CO-CHAIR ANDERSON: And I think going
14 back to the whole Fistula First Initiative, it
15 was all surrounding vein mapping for AVFs and
16 AVGs, and we still had the unintended
17 consequences of these little old ladies getting
18 multiple, multiple, multiple attempts at fistulas
19 because AVGs weren't included in the Fistula
20 First Initiative.

21 And so I am really pleased that, at
22 least with this, there is AVGs considered. And I

1 am concerned about the elderly, and also our
2 cancer patients that, you know, catheters may be
3 the best alternative for them, and those that are
4 at end of life. John?

5 DR. WAGNER: Thank you. I guess in
6 talking about measure specifications, it really
7 raises in my mind the question as to, to what
8 audience is this measure targeted? Is this a
9 measure to assess the quality of integrated care
10 delivery systems? Is this a measure that targets
11 hospitals? Is this a measure that targets
12 physicians?

13 And it's important to understand who
14 the audience is because then we can tailor the
15 specifications, perhaps, in a more measured
16 manner.

17 CO-CHAIR ANDERSON: John, can we hold
18 that to the feasibility/usability, because that's
19 exactly where that discussion would go?

20 DR. WAGNER: I mean, I think it drives
21 the specifications discussion as well.

22 CO-CHAIR ANDERSON: Yeah.

1 Sorry, Lorien?

2 DR. DALRYMPLE: And is this a time
3 where we can ask Peter questions about some of
4 the things the Committee has brought up, or would
5 you --

6 CO-CHAIR ANDERSON: Yes.

7 DR. DALRYMPLE: So I was wondering,
8 Peter, do you have any data, at least within
9 Kaiser, about how this measure performs when
10 patients have only been under a Kaiser
11 nephrologist's care for, let's say, two months
12 versus a year?

13 And I am sorry if I missed that in the
14 submission. Or if you're knowledgeable of does
15 this have vastly different performance? I would
16 assume so, but you may have actual numbers on
17 that.

18 CO-CHAIR CROOKS: Okay, well, I've got
19 a couple remarks related to specifications. And
20 to start with that one, when we initially
21 developed the measure, we limited the denominator
22 to patients who had been under a nephrologist's

1 care, or who had at least been identified in our
2 data system as having CKD Stage 4 for three
3 months or longer. So, we felt that was a group
4 the nephrologists felt comfortable, they had
5 control.

6 As we expanded the measure, we made
7 the decision to go with all ESRD patients, in
8 part because of the data systems problems. It's
9 easy to say, "this patient started dialysis,
10 they're in," as opposed to, you know, putting
11 some qualifications on them.

12 I will say that if you're limited to
13 patients who have been under the care of
14 nephrologists, the numbers bump up about 10
15 percent. And the discussion about what about
16 these patients who just walk in the door, you
17 know, well, first of all, this will never be 100
18 percent because there will be those patients that
19 walk in the door and they end up in a
20 hemodialysis center with a catheter in their
21 neck.

22 But this is a healthcare system

1 measure, so it's not only up to the nephrologist
2 to find these patients. If there's patients
3 walking around with a high risk for ESRD, we
4 should be finding them. And this measure
5 encourages early identification, and then
6 referral, appropriate referral and education of
7 patients.

8 So it's broader than just the
9 nephrologist's practice, and it's broader than a
10 hospital. It's the healthcare system's
11 responsibility to find these patients and then
12 have a process. It's measuring their process.
13 Did you find the patients? Did you educate the
14 patients? Did you take them step-by-step until
15 they're ready for ESRD?

16 Peds. I don't have the measure in
17 front of me. I don't think the pediatric
18 population was included in the specs. I could
19 find out in just a minute, but I think it says
20 adults. But it doesn't --

21 CO-CHAIR ANDERSON: It says "all new,"
22 yeah.

1 CO-CHAIR CROOKS: It's been a few
2 months since I looked at that particular --
3 you're right. It doesn't eliminate -- what do
4 you think? It's the standard for pediatrics,
5 too. Not being a pediatric nephrologist, should
6 they be excluded?

7 DR. KASKEL: I would think they should
8 be excluded, I would think so. We don't have
9 enough information. There's lots of variation
10 here, and geographic distribution too. PD is the
11 recommended treatment, not only because of age,
12 but because they're far from any center and they
13 do better on PD, so there's lots of factors that
14 need to be addressed.

15 CO-CHAIR ANDERSON: And the population
16 numbers are so small, especially as you get into
17 the littler kids and pre-emptive transplants.

18 DR. KASKEL: And as Michael said, our
19 goal is to transplant, not to dialyze.

20 CO-CHAIR ANDERSON: Right.

21 DR. KASKEL: The time on dialysis is
22 minimal, and that sets us apart.

1 DR. GREENSTEIN: Maybe that's what it
2 should be, pre-emptive transplant. You should be
3 looking at it for the pediatric patients rather
4 than the fistula rates or graft rates.

5 First of all, doing the surgery, I can
6 tell you right now, I have never put a graft into
7 a little kid. It's just technically impossible.
8 The vessels are just too small, and it never
9 would work. Fistulas are even difficult to do on
10 the kids sometimes.

11 CO-CHAIR CROOKS: I presume that we
12 can modify it, if the Committee suggests, and the
13 developer -- no?

14 MS. SAMPSEL: No, what we would have
15 to do is vote on it as it has been presented.
16 And so if the peds population and their inclusion
17 presents a significant concern, you would
18 actually vote the measure down. You could make
19 the changes during the comment period, and the
20 Committee would then make a decision if they want
21 to re-vote with the changes to the measure.

22 CO-CHAIR ANDERSON: At the return

1 conference call next week, or later?

2 MS. SAMPSEL: No, thank God, it
3 wouldn't be next week.

4 (Laughter.)

5 MS. SAMPSEL: Basically, it would go
6 through the -- and it could go either -- you
7 know, if your vote is gray zone, meaning you
8 don't have 60 percent criteria to pass, or if it
9 is voted down as low because of that ped
10 population, you would then make that
11 recommendation to say, you know, if the measure
12 did not include peds, you know, we might be more
13 favorable towards the measure.

14 Then we, as staff, have about a month
15 to prepare a report. That goes out for public
16 comment for another month, and during that public
17 comment period is when Kaiser or any developer
18 could come back and say we would make these
19 following adjustments. And with those
20 adjustments and public comment, you would have
21 the opportunity to re-vote. But it's a couple
22 months away.

1 CO-CHAIR ANDERSON: Mahesh?

2 DR. KRISHNAN: I mean, I think on this
3 issue, the number of pediatric patients at any
4 given facility is so small that, on aggregate --
5 I know we're talking about it because we're
6 thinking of it specifically in our context -- but
7 realistically, for the vast majority of the 6,000
8 dialysis units with the limited number of health
9 systems, it seems like that is less of an issue.

10 CO-CHAIR ANDERSON: Lorien?

11 DR. DALRYMPLE: And I was just hoping
12 for a clarification to follow up Mahesh's
13 question. So, perhaps we want to discuss
14 pediatrics, but we don't think it's significant
15 enough to say it's not going to pass on this
16 criterion. Do the developers, though, then have
17 the opportunity to revise a measure that has
18 passed if they think, after further comment --
19 this might save the developers -- if comments
20 come up today that afterwards the measure would
21 be stronger with that modification, but the
22 measure passed today, could it be modified in one

1 to two months and then brought back to the
2 Committee?

3 MS. SAMPSEL: That would be through
4 the annual review -- you can do it? Okay.

5 DR. DALRYMPLE: Because these issues
6 come up that perhaps aren't significant enough
7 for us to say, "this measure doesn't warrant it,
8 but it could be optimized."

9 MS. BAL: So, it would be the same
10 procedure. So, if you endorse it or if you do
11 not endorse it, they have the opportunity to make
12 changes based on what you stated.

13 So, if you want to move forward with
14 this measure but you have provided this
15 recommendation, the developer can choose if they
16 would like to do that and then present that
17 information to you at the post-comment call.

18 What Sarah was also referring to was
19 that if they weren't able to make the changes by
20 the post-comment call, and the measure is
21 endorsed, there's an annual review process. So
22 in a year from now, the measure developer would

1 basically say there's minor changes, or there's
2 this major change that's been added, and then at
3 that point, staff would decide if it needs to be
4 reviewed again.

5 So, with something small like this, we
6 would probably just, you know, say, include it in
7 the description of the measure. So during the
8 annual review, they could provide new
9 information, say this is a minor change, but this
10 is something the Committee asked for, and then we
11 would just basically add a little asterisk, I
12 guess, to the measure.

13 Does that answer your question?

14 CO-CHAIR ANDERSON: Ishir?

15 DR. BHAN: So, just with regards to
16 the sentiment that, as a healthcare system, we
17 should be trying to capture patients who are sort
18 of underserved pre-dialysis, I wholeheartedly
19 agree with that.

20 My question is regarding the level of
21 analysis that is specified here. It says the
22 first item is clinician, which would effectively

1 -- I don't know, penalize isn't the right word --
2 but disproportionately affect clinicians who take
3 care of an underserved population that may not
4 have access to care pre-dialysis. And I wonder
5 how much are we taking into account this level of
6 analysis specification here?

7 CO-CHAIR ANDERSON: Any comments from
8 the Committee? I mean, there are certainly --
9 yes, Frank?

10 DR. MADDUX: I would just say I think,
11 for all of these new measures, there's a period
12 of needed benchmarking across a broader audience
13 than maybe just one integrated system like
14 Kaiser. And it strikes me that a lot of these
15 questions are really valid, I think, that you
16 brought up.

17 And the measure is attractive. There
18 are these features that need a better sense of
19 how they'll play and what influences they'll have
20 on the delivery of care and the outcomes for
21 patients. And it strikes me that that can't --
22 it's a little bit of a chicken-and-an-egg. We

1 advance the measure and the measure moves into a
2 realm that it might get used in a way that isn't
3 what we intended, or isn't what the measure
4 intended. Or we don't endorse the measure, and
5 there is not really the capacity to go out and do
6 national benchmarking, for example, from a single
7 organization that has proposed the measure.

8 So I struggle with the choice that's
9 sort of black or white with regard to this
10 particular measure.

11 DR. ZARITSKY: I think probably the
12 inclusion of pediatrics might have just been an
13 oversight, that all patients here, but I think
14 when you look at the denominator, that, yes,
15 there's large units out there that have one or
16 two pediatric patients, but there's also units
17 out there that are exclusively pediatric.

18 In fact, we would argue that's
19 probably the best model of care. And in some
20 senses, that would hurt those specific units.

21 DR. NARVA: It's kind of hard to
22 imagine any quality measure which isn't going to,

1 you know, penalize providers who are taking care
2 of people who have decreased access to care and
3 have poor socioeconomic status. And is that
4 normally something that's taken into account when
5 we consider measures?

6 MS. SAMPSEL: I'm going to ask you to
7 repeat it and rephrase it because I'm not sure I
8 understand the question.

9 DR. NARVA: Sure. I guess it's hard
10 to imagine any quality measure that wouldn't
11 penalize providers who take care of disadvantaged
12 populations with decreased access to care. And I
13 think there are other reasons to implement
14 quality measures, in part to lift all boats.

15 And I am wondering, is that generally
16 a factor in assessing quality measures through
17 NQF?

18 MS. SAMPSEL: So, this is another
19 example of, if Helen were here, she'd say it's
20 one of those areas that NQF is constantly dealing
21 with, is how to deal with some of those issues
22 with the measures, and especially, you know,

1 socioeconomic status, access to care, et cetera,
2 and putting those criteria and those components
3 in to have clearer guidance for the committees.

4 So, you know, I think, in this case,
5 it's something you have to consider, you know,
6 based on your knowledge and expertise as a
7 committee for this specific measure. But more
8 globally, it is something that NQF is dealing
9 with, and I don't know if you guys have more
10 information on that.

11 MS. BAL: There is going to be a trial
12 for SDS that will focus on that topic and how to
13 incorporate that into measures. It's currently
14 underway. And so we'll have more information for
15 that.

16 But as Sarah said, it is something to
17 consider, but the guidelines are being worked on,
18 and we're really testing how, at NQF, best to use
19 that.

20 DR. DALRYMPLE: So, I think, at least
21 my take on that question, is a number of the
22 measures we're reviewing, for example the

1 dialysis facility-level, require that patients
2 are on dialysis more than 90 days. And I
3 interpret that as a build-in to allow facilities
4 to assume responsibility of care for the patient.

5 And so that's my only caveat about
6 this measure, which is heavily linked to access
7 to care. And if it was only at the integrated
8 health system level, I think that would be one
9 issue, because you could identify patients who
10 belong to a health system and make them
11 accountable. But as clinicians who never had an
12 opportunity to provide an optimal start, how do
13 you make them accountable?

14 If you're at a hospital where 50
15 percent of your patients present at the ED, how
16 do I as an individual clinician become
17 accountable that they did not start optimally
18 when there was no opportunity?

19 So, that's what I find challenging,
20 because I think all of us believe optimal starts
21 are needed, necessary, and we don't do a good
22 job. At least that's my bias. We underperform

1 in this. So I think we need a metric. The
2 question is how do you make it that the people
3 who are accountable were given the opportunity to
4 be accountable?

5 So, that's my only comment. The
6 dialysis facilities often get these 90-day
7 periods. Now, they might tell us that's actually
8 not enough time, but it is something. It's three
9 months.

10 CO-CHAIR ANDERSON: We are really
11 going to have to wrap up the reliability section.
12 And so if there are some new comments or
13 additional comments -- Mahesh?

14 DR. KRISHNAN: Yeah, I think we've got
15 to keep in mind what Peter said, right? This is
16 an integrated health system view of the world,
17 right?

18 And so I think, Lorien, to your point,
19 if we think about that, in this context, there's
20 a lot an integrated health system could do. You
21 know, there's great integrated health systems
22 across the country that do community outreach to

1 try to get pre-dialysis.

2 I just think it aligns people's
3 incentives, where we think about it from our own
4 perspectives, whether it's the dialysis facility
5 or the physician. But in reality, we're
6 incentivizing the Geisingers and the Kaisers of
7 the world to do the right thing.

8 So, for me, it's an aligned incentive.
9 I just think we have to be careful about how we
10 vote. We need to vote for the right perspective
11 for which the measure is being construed, rather
12 than applying our own -- because what you're
13 describing is, if your sphere of influence is far
14 smaller than your sphere of responsibility, how
15 the heck do you fix that? But if you're an
16 integrated health system, which is the nature of
17 the measure, your sphere of influence and your
18 sphere of responsibility are much more aligned.

19 CO-CHAIR ANDERSON: Okay. Lori?

20 MS. HARTWELL: Just to clarify, this
21 is a process measure. So, one of the things that
22 I believe is good about a process measure is it

1 helps people see who is doing well and then helps
2 people understand that and perform.

3 Does a process measure always become
4 a performance measure? Because I see right now
5 this is just a process measure, and I think this
6 may give the community or the healthcare systems
7 ability to look at the leaders and say, oh wow,
8 this is what they're doing. And I think that was
9 the purpose, if I am not mistaken. Is that
10 right, Dr. Crooks?

11 CO-CHAIR ANDERSON: Peter, I think
12 what she was getting at is, this is a process
13 measure, this isn't a performance outcome
14 measure, and so --

15 CO-CHAIR CROOKS: Right, it measures
16 the outcome of the process --

17 CO-CHAIR ANDERSON: Right, of the
18 process, so you're right, Lori, that is what it
19 is.

20 CO-CHAIR CROOKS: May I just make one
21 other comment on specs, that it is suggested that
22 there should be at least 50 patients within a

1 year's period in order to do the metric.

2 So, for small pediatric units and for
3 an individual practitioner, it's not appropriate
4 to say, you know, this year, you had 80 percent
5 and last year you had 20 percent. There is going
6 to be a lot of variability. So you needed a
7 large enough denominator, and that is in the
8 specifications.

9 CO-CHAIR ANDERSON: All right. I
10 think we're going to need to look at voting on
11 the reliability.

12 MS. BAL: Sorry, actually, before we
13 start, let's discuss reliability testing, that
14 was specifications, and then we'll vote on
15 reliability as a whole.

16 CO-CHAIR ANDERSON: Okay.

17 MS. EVANS: So, at the performance
18 metric level, accuracy is very good. The
19 positive predictive value is excellent, at 0.94,
20 and the negative predictive value is good at
21 0.79. So that region correctly identified true
22 optimal ESRD starts at 11.6 times more often than

1 it incorrectly identified a non-optimal ESRD
2 start as optimal, which is a very good ratio.

3 2,681 patients were scored for this
4 measure from July to June of 2014, which is an
5 adequate sample size to generate the results for
6 widespread implementation. So it's demonstrated
7 sufficient validity as an indicator of quality.
8 I think that was kind of short, to the point.

9 CO-CHAIR ANDERSON: Any other comments
10 on reliability testing?

11 (No response.)

12 CO-CHAIR ANDERSON: All right. Are we
13 ready to vote?

14 MS. OGUNGBEMI: The Committee is now
15 voting on reliability for Measure 2594.

16 Reliability includes precise specifications and
17 testing. The options are 1 for high, 2 for
18 moderate, 3 for low, and 4 for insufficient.
19 Voting is now open.

20 (Pause.)

21 MS. OGUNGBEMI: The results are 10
22 high, 10 for moderate, 1 for low, and zero for

1 insufficient. The measure passes on reliability.

2 Thank you. For Measure 2594.

3 CO-CHAIR ANDERSON: All right. Moving
4 on to validity. Beth?

5 MS. EVANS: Okay. So, there was no
6 risk adjustment. Meaningful differences:
7 regional rates compared to national rates show
8 meaningful differences. Missing data rate is
9 low.

10 Statistically, the calculated
11 statistic is 29.73 with 5 degrees of freedom.
12 This is statistically significant.

13 Region differences demonstrated that
14 performance differences can be identified within
15 the optimal ESRD start metric, and the region's
16 results were also statistically significant from
17 the national rate of optimal ESRD starts.

18 So missing data was very low. It was
19 less than 3 percent, posed no statistically
20 significant effect on the results. So, one
21 interesting thing on the missing data was non-KP
22 clinics. They did not obtain the data from them,

1 so that was the difference with that.

2 CO-CHAIR ANDERSON: Lori? Oh, sorry.

3 MS. EVANS: My assessment of validity
4 was it was very good.

5 CO-CHAIR ANDERSON: Lori, any
6 additional comments?

7 (No response.)

8 CO-CHAIR ANDERSON: Discussion by the
9 Committee on the validity? Any comments,
10 questions? Frank?

11 DR. MADDUX: Peter, I have a question.
12 You, in your preface, held up the 2728 Form. At
13 Kaiser, did you use the 2728 Form for your data,
14 or did you use internal sources?

15 CO-CHAIR CROOKS: We did not use the
16 2728. And that has not been validated per se,
17 but the validity check and data element check was
18 to take what was submitted by case managers
19 through our electronic system. And then we faxed
20 dialysis units and said, what was the access
21 used? And then we matched that.

22 So it was a more authoritative source

1 going right to the dialysis unit. But we didn't
2 use 2728, and that would need to be validated,
3 you know, going forward, if that source is going
4 to be used.

5 CO-CHAIR ANDERSON: Any other
6 comments? Questions by the Committee?

7 (No response.)

8 CO-CHAIR ANDERSON: Are we ready to
9 vote?

10 MS. OGUNGBEMI: The Committee is now
11 voting on validity for Measure 2594. Validity
12 includes specifications consistent with evidence,
13 testing, and threats addressed, exclusions, risk
14 adjustment/stratification, meaningful
15 differences, comparability, multiple
16 specifications, and missing data. The options
17 are 1 for high, 2 for moderate, 3 for low, and 4
18 for insufficient. Voting is now open.

19 (Pause.)

20 MS. OGUNGBEMI: The results are 6 for
21 high, 13 for moderate, 2 for low, and zero for
22 insufficient. The measure passes on validity for

1 Measure 2594.

2 CO-CHAIR ANDERSON: All right. Moving
3 on to feasibility.

4 MS. EVANS: Recent data has described,
5 regarding AV graft versus fistula placement in
6 the elderly, might recognize that the presence of
7 a permanent vascular access versus an ideal
8 vascular access is preferred. A catheter is
9 preferred in certain sub-populations of all
10 patients. This may invalidate some of the
11 detailed criteria in this measure, with the 10
12 percent AV graft placement based on a single
13 organization's results.

14 Also, this measure has been tracked
15 with the regional coordinator within the Kaiser
16 Permanente system that uses part of their
17 connected system. With a national measure, there
18 are hundreds of different electronic sources, and
19 of course there is the 2728 for tracking access
20 start, date of start, type of modality, but does
21 not track transplant, pre-emptive transplant, and
22 would require a definite coding system to be

1 identified across many dialysis centers,
2 transplant centers, and offices.

3 This measure is important and could
4 promote better health outcomes, so it's really
5 the tracking consistency and compiling that data
6 into that requiring more burden on the staff to
7 collect that, and of course, not counting the
8 2728 Form.

9 CO-CHAIR ANDERSON: Lori, any
10 comments?

11 (No response.)

12 CO-CHAIR ANDERSON: Peter, can I ask
13 you a question? Why are you not using the
14 CROWNWeb data? Because the 2728s are a part of
15 the CROWNWeb, and it has all of that information.
16 It would be very easy to extract the data from
17 CROWNWeb, except for pre-emptive transplant, that
18 would be the only one that wouldn't be there.

19 CO-CHAIR CROOKS: Right. We just
20 haven't tried it yet. We have been put off -- I
21 don't know if you've ever opened up the CROWNWeb
22 site and tried to get data out of it. I don't

1 know that -- you know, you'd have to do a special
2 project with Medicare, I guess, to do that.

3 But that's what we look forward to
4 doing. We really do. I think once Medicare
5 adopts this, they will be able to slice and dice
6 it and look at it from all sorts of perspectives,
7 including racial disparities, income groups,
8 health plans, and so on.

9 CO-CHAIR ANDERSON: Because otherwise,
10 the burden of getting the data is going to be
11 pretty significant.

12 CO-CHAIR CROOKS: Right. I think
13 that's the ultimate way to go.

14 CO-CHAIR ANDERSON: Okay. Other
15 comments? Mahesh?

16 DR. KRISHNAN: An alternative, I don't
17 know if you considered this, Peter, would be to
18 use a combination of 2728 and the SRTR, the
19 transplant registry.

20 I mean, as long as you can do the
21 attribution for a population of patients, you
22 should be able to pull that data on the back-end

1 from pre-existing submission systems so that the
2 data collection burden would be almost zero.

3 CO-CHAIR ANDERSON: Yes?

4 DR. FISCHER: Just about feasibility,
5 I mean, I guess what I am struggling with, and I
6 think this will come up with other measures, is
7 this appears to be feasible in Kaiser, but
8 already, you know, we have no idea about how it
9 will be for places outside of a vertically
10 integrated system like that. So, while the
11 feasibility at face value in Kaiser seems fine,
12 to me, it's difficult to evaluate that in terms
13 of endorsing a measure, considering that that
14 will be something that will be used elsewhere.

15 And I am not saying that that's
16 negative, it's just I think this comes up with
17 other measures, and I don't know if others have a
18 way of perhaps framing that in a way that we can
19 make an informed evaluation of the feasibility.

20 CO-CHAIR ANDERSON: Mahesh?

21 DR. KRISHNAN: I think it's a good
22 question. I mean, if I look at some of these

1 similar measures in our Medicare Advantage data,
2 for example, where it is an integrated system and
3 all the claims are going to one place, it's
4 definitely doable, right? I mean, anyone that
5 takes risk should have all the claims data to
6 substantiate this, and then you'd have to get
7 some of the dialysis data.

8 But in my opinion, while it was tested
9 in Kaiser Permanente, it would be feasible
10 because there's other, similar measures that are
11 used in Medicare Advantage for star ratings, et
12 cetera.

13 CO-CHAIR ANDERSON: Any other
14 comments, questions for Peter?

15 (No response.)

16 CO-CHAIR ANDERSON: Are we ready to
17 vote for feasibility?

18 MS. OGUNGBEMI: The Committee is now
19 voting on feasibility. This includes data
20 generated during care, electronic sources, and
21 data collection which can be implemented. This
22 is for Measure 2594, and the options are high 1,

1 moderate 2, low 3, and insufficient 4. Voting is
2 now open.

3 (Pause.)

4 MS. OGUNGBEMI: Results for
5 feasibility are 4 for high, 15 votes for
6 moderate, 3 votes for low, and 0 for
7 insufficient. The measure passes for feasibility
8 for Measure 2594.

9 CO-CHAIR ANDERSON: All right, moving
10 on to usability and use.

11 MS. EVANS: So, the usability is
12 reported for Kaiser in six regions. No data for
13 wider usability. So, this rating is uncertain,
14 unknown.

15 The denominator must be careful to
16 include only new starts and not modality shifts,
17 as that could obviously impact the results.

18 Potential for this to be submitted to
19 CMS as a potential PQRS measure. Within Kaiser,
20 it has not yet been tied to a payment program,
21 and it's not being used by any entity for
22 licensing or certification. Obviously, it could

1 be as a public reporting measure.

2 In Kaiser, they actually evaluate
3 every six months, and there has been a steady
4 trend of improvement. 47 percent increased to
5 57.7 percent, compared to the U.S. estimate of
6 35.5.

7 Unintended consequences is unsure, not
8 tested, but there potentially could be surgical
9 complications from AV fistula or AV graft
10 surgeries, or creating an AV fistula or graft and
11 it never being used.

12 And the benefits of the measure
13 outweigh the potential negative consequences are
14 yes. So it's not currently publicly reported,
15 and we do know that patient education leads to
16 informed decision-making and patient empowerment.

17 CO-CHAIR ANDERSON: So Peter, can I
18 ask you a question? In terms of the patient
19 education, how are you going to capture the data
20 that patients are being educated as part of the
21 optimal starts? Is there a mechanism that will
22 be in place for capturing that data, and is that

1 part of the measure?

2 CO-CHAIR CROOKS: No, it isn't per se,
3 but it's the result of that process.

4 So we set the bar and say this is what
5 your goal is, and every other health care system
6 is not Kaiser, and every other health system that
7 adopts the metric will then have to figure out
8 how do we do these processes? How do we find the
9 patients, how do we educate the patients, how do
10 we then taken them from making a choice to being
11 ready? Three, I think, distinct steps.

12 And it's not a patient satisfaction
13 measure, it's not a tracking their education,
14 it's really the end stage of all of that, but
15 then it expects -- the implication is that
16 systems that adopt this measure will then go back
17 and work on those processes that will improve the
18 metric.

19 CO-CHAIR ANDERSON: Oh, sorry, Frank?

20 DR. MADDUX: I had a question, Peter,
21 about is your intention that the measure would in
22 a person's lifetime only be -- have one instance

1 of that measure? So returning from transplant
2 back to renal replacement therapy via dialysis
3 would be excluded?

4 CO-CHAIR CROOKS: Yes, at this time,
5 it's a once-in-a-lifetime, you're only -- you
6 only reach ESRD one time.

7 CO-CHAIR ANDERSON: Lorien?

8 CO-CHAIR CROOKS: Unless you're Lori,
9 whose hit five times now, I think.

10 MS. HARTWELL: I'm an overachiever.

11 CO-CHAIR ANDERSON: Lorien?

12 DR. DALRYMPLE: And this is a question
13 for Peter. So currently within Kaiser, is this
14 reported more at the regional level or at the
15 center level?

16 Because I know earlier you mentioned
17 there were going to be recommendations for
18 usability, how this gets implemented into other
19 systems. So at Kaiser, is it currently reported
20 regionally? Is that the level?

21 PARTICIPANT: Could you make your mic
22 a little louder?

1 DR. DALRYMPLE: Oh, sorry.

2 Currently within Kaiser, is this
3 metric reported at a regional or network level?
4 How do you use it currently for internal QI?

5 CO-CHAIR CROOKS: We're using it in
6 six different regions across the country, and the
7 data is submitted to our Federation office, and
8 -- and we've -- and they do the calculation and
9 disseminate the reports.

10 DR. DALRYMPLE: Because I was thinking
11 of something earlier, you said -- and I just
12 wanted to clarify before we discuss usability, is
13 the recommendation that this is more at -- used
14 at a regional level or a center level or a larger
15 health center?

16 Because I think some of the issues
17 that were coming up earlier is at the very top of
18 the measure, where it says level, it includes
19 clinician and a number of other things. So I'm
20 trying to reconcile that very first page with
21 what you envision --

22 CO-CHAIR CROOKS: The --

1 DR. DALRYMPLE: -- as the best
2 usability of this measure.

3 CO-CHAIR CROOKS: So you're -- you're
4 addressing the level that this measure intended
5 to be used at?

6 DR. DALRYMPLE: Yes.

7 CO-CHAIR CROOKS: And, you know, when
8 you're clicking -- when you're doing these forms,
9 there's check boxes for some of these, and so
10 they come out in the order they come out in.

11 You know, my preference would have
12 been that the top level, this is oriented towards
13 the large payers: CMS, large insurance companies,
14 integrated health care systems.

15 Now large nephrology groups will want
16 to look at their optimal starts. FMC has a very
17 creative program where they put a case manager in
18 with a large nephrology practice, and in fact,
19 they're measuring a metric that is almost
20 identical to this optimal starts. I am just glad
21 I got it here before you guys did because -- you
22 know.

1 So nephrologists will want to know how
2 they're doing and how they're participating in
3 the system. So I think it is a clinician level,
4 but not the single clinician, not -- if you only
5 start 30 patients on dialysis in a year, it
6 doesn't mean -- but it's within the larger health
7 care system that it matters the most.

8 CO-CHAIR ANDERSON: Dodie?

9 DR. STEIN: Thank you. I am going to
10 bring up this education issue again because it
11 bothers me.

12 It seems to me that this is the
13 assumption underlying whether this measure is
14 going to be effective or not, and I understand
15 that Kaiser is its own system and can build that
16 in and build it in effectively, but I am
17 concerned about the rest of us and the rest of
18 the world.

19 And especially because you can deal
20 with education, and then there's effective
21 education, and the kinds of emotionality that we
22 see with patients during education, and that's

1 going to affect when they get to dialysis and how
2 they get to dialysis.

3 I am -- I am just concerned that there
4 is not that component that's specified and
5 clarified on this.

6 CO-CHAIR ANDERSON: Yes, it -- this is
7 more for Committee discussion, so Michael?

8 DR. FISCHER: I just wanted to go back
9 to the level of analysis because philosophically
10 -- and perhaps I'm incorrect, that you choose the
11 analysis about how you want to incentivize
12 quality.

13 Meaning some things probably require
14 a facility-level policies to improve performance
15 in an area, others perhaps it's individual
16 provider/physician performance.

17 So going back to this measure, that's
18 why ---- maybe I just wanted to ask Peter, I
19 guess, in terms of envisioning it, I thought when
20 I read this that this was a provider physician-
21 level measure. It seems like in the preceding
22 discussions, that's not as clear, but I wanted to

1 ask him, you know, in terms of using this measure
2 to promote quality, is it really targeting
3 physician-level practice, facility-level
4 practice, and if so, what -- what really is the
5 -- the level of analysis that it's targeting?

6 CO-CHAIR CROOKS: Yes, as I mentioned
7 twice in my presentation, this is not intended
8 for dialysis facility use, and it's aimed at the
9 broader health care system, and you know, it
10 takes a village sort of thing, you know.

11 This -- we, in our practices, think so
12 much on the ground and what we're doing today,
13 but there is a whole health care system around us
14 that we are part of -- we respond to, and the
15 responsibility for this is shared between all the
16 -- all the entities: the payer, the providers, et
17 cetera. Keeping my answer brief. Thank you.

18 CO-CHAIR ANDERSON: All right. Ishir?

19 DR. BHAN: So I very much agree with
20 that sentiment.

21 I guess the question is when we're
22 voting on this, are we voting taking in -- that

1 into account, or are we voting based on what's
2 listed in the documents here? That's what's
3 unclear to me.

4 CO-CHAIR ANDERSON: You should be
5 voting what's on -- what's listed in the
6 documents. This is -- and actually we have too
7 many mics on -- but we, I mean, the measure --
8 your vote is on, you know, the current usability
9 and use, how it has been presented in the
10 documents versus how it might be used in the
11 future.

12 DR. BHAN: Okay. And the sponsor has
13 the opportunity to revise the -- this.

14 So I guess my -- my comment would be
15 that if we feel that the individual clinician
16 level feels out of place to us, then my
17 suggestion would be to give that feedback and
18 allow the revision of the document.

19 CO-CHAIR ANDERSON: Yes, in that case,
20 what we would do as staff is we'd make sure that
21 that's one of the notes in the overall report.

22 Not necessarily that the measure would

1 need to be revised, because again, the other
2 thing that the developers have to do is bring in
3 front of you, through these forms and their
4 presentations and responses to questions, the
5 actual level of analysis that they used in the
6 testing and the development of the measure.

7 So you know, even though, you know,
8 there's a form or we know that the data is in
9 CROWNweb, et cetera, that's not -- we're not --
10 you're not endorsing it for use in a specific
11 area.

12 DR. GREENSTEIN: I'm just curious, how
13 do you handle those patients who are in your data
14 analysis who are -- you know, when you capture
15 the data, there are patients who adamantly refuse
16 fistulas and grafts and only want a hemo
17 catheter.

18 CO-CHAIR CROOKS: They're non-optimal
19 starts, and, you know, we refuse to believe that
20 no is really no.

21 You have to kind of -- if you're
22 having a high rate of denial, then, you know, you

1 need to think about, you know, is there other
2 ways to get at that? Patient advocates and so
3 on.

4 CO-CHAIR ANDERSON: Frank?

5 DR. MADDUX: I'd like to just make a
6 comment to Dodie's question and comment.

7 And I think ---- the way I look at it,
8 my perspective is that the education aspect is --
9 is one subsystem process that this particular
10 measure, in my mind, is above that level, because
11 not only do you have to educate people, but you
12 then have to have action after that that leads
13 towards some decision or some surgery or some
14 other preparation.

15 And so it's, you know, as a -- as a
16 process measure, it's really a system process
17 assessment and outcome. And education is
18 certainly a part of that, but I don't think
19 inside the measure you need to get the sub-
20 components sub-measured. If we need a separate
21 measure for education itself, I would say we --
22 that's a different question.

1 CO-CHAIR ANDERSON: All right. I
2 think we're running out of time, and so if --
3 sure, John?

4 DR. WAGNER: Sorry, I just -- I want
5 to clarify something.

6 So is it not our concern that this
7 measure could be applied to other-than-integrated
8 health care delivery systems because the data are
9 presented in terms of usability with respect to
10 an integrated health care delivery system, so we
11 don't need to get involved in those kinds of
12 details?

13 MS. SAMPSEL: Correct. I mean,
14 really, this measure is coming before you as
15 endorsed as the way that it was presented, and
16 should somebody else want to use it in another
17 way, we don't control that. NQF doesn't control
18 the use of the measure.

19 CO-CHAIR ANDERSON: Okay. We will be
20 voting on usability and use.

21 MS. OGUNGBEMI: The Committee is now
22 voting on usability and use for measure 2594.

1 That includes accountability, transparency,
2 reporting within six years or, if new, a credible
3 plan, and improvement, as well as benefits
4 outweigh evidence of unintended negative
5 consequences.

6 The options are 1 for high, 2 for
7 moderate, 3 for low, and 4 for insufficient
8 information, and voting has now opened.

9 (Pause.)

10 The results are: four votes for high,
11 11 votes for moderate, three votes for -- six
12 votes for low, and zero for insufficient. The
13 measure passes on usability and use for 2594.

14 CO-CHAIR ANDERSON: We do have some
15 related and competing measures which will follow
16 later, after we do the final vote on this
17 measure.

18 Any other general comments, discussion
19 by the Committee?

20 Yes, Alan.

21 DR. KLIGER: I just want to remind all
22 of us that we're voting on all of the

1 specifications the way they're written on the
2 sheet.

3 CO-CHAIR ANDERSON: That is correct.

4 All right. I think we are ready to
5 vote on whether to recommend the measure as
6 suitable for endorsement.

7 MS. OGUNGBEMI: The Committee is now
8 voting on overall suitability for endorsement:
9 does the measure meet NQF criteria for
10 endorsement?

11 Voting is now opened. The options are
12 1 yes, 2 no.

13 (Pause.)

14 The results are 17 votes for yes,
15 three votes for no. The measure passes for
16 endorsement, that's measure 2594.

17 MS. BAL: Okay, so we'll move on to
18 the next measure, but I just wanted to call the
19 developer, they'll be on the phone.

20 See if the developer could -- not the
21 developer, Cathy, could you make sure that Robyn
22 Nishimi is on the phone?

1 THE OPERATOR: She has disconnected.

2 MS. BAL: Oh okay, never mind,
3 actually, she is not going to be on the line.

4 CO-CHAIR ANDERSON: Oh, okay. So the
5 next -- next measure is 0251, the vascular access
6 measure, and it's Lisa, and Robyn dropped off.

7 DR. MCGONIGALIGAL: Okay, I am Lisa
8 McGonigal with the Kidney Care Quality Alliance,
9 which is a coalition of patient groups,
10 providers, health care professionals, and
11 suppliers working together in kidney care, trying
12 to improve quality.

13 We are very pleased to be here to
14 discuss our vascular access measure with the
15 Standing Committee. Thanks for having us.

16 The measure is NQF 0251. This is a
17 clinician-level measure. It was first endorsed
18 in 2007, re-endorsed in 2011, and now it's --
19 it's up for consideration again.

20 The measure assess the percentage of
21 adult ESRD patients on chronic hemodialysis who
22 have either a functional AVF or an AV graft, or

1 they have a catheter but were evaluated for a
2 permanent access at least once during the 12-
3 month reporting period of the measure.

4 So the intent of the measure is to
5 reduce the frequency of vascular access-related
6 complications and to improve patient survival by
7 promoting AVF and/or AV graft placement.

8 Supporting evidence for the measure.
9 As we noted in the documents, the measure stems
10 from KDOQI's 2006 guideline update for vascular
11 access. We note that in addition to recommending
12 fistulas as the preferred access, the guideline
13 also specifically notes that the Fistula First's
14 at-all-costs approach may not be the most cost
15 effective or optimal for each individual patient
16 and that an AV graft is an acceptable alternative
17 to fistulas in some patients.

18 So the KCQA vascular access measure is
19 unique and advantageous in two regards. First of
20 all, as I just mentioned, the measure recognizes
21 the fact elucidated in the KDOQI guideline that
22 AV grafts are the more appropriate permanent

1 access in certain patients, and so the measure
2 gives credit for both AVFs and AV grafts.

3 Second, the measure recognizes that
4 clinical circumstances can and sometimes do
5 change over time, and that some patients who were
6 previously not candidates for permanent access
7 may be able to support a fistula or a graft at a
8 later date.

9 The measure thus encourages an annual
10 evaluation by a vascular access specialist as
11 defined in the measure specifications, and the
12 specialist is to reassess patient status so as to
13 further maximize permanent access placement and
14 to minimize catheter use.

15 So we do acknowledge, as pointed out
16 in a pre-meeting comment that we received, that
17 the evidence supporting the measure doesn't
18 specifically address the inclusion of this
19 evaluation component of the measure. There is no
20 published literature addressing this issue that
21 we can turn to in this instance.

22 However, the process does have face

1 validity. It was the consensus that both our
2 clinical experts and patient representatives
3 within KCQA that this aspect of the measure is of
4 vital importance for the reason that I just
5 stated, to assess and reassess the patient
6 appropriateness and readiness for permanent
7 access so as to minimize catheter use, and to use
8 AVFs and AVGs to the greatest degree possible.

9 As noted in the documents that were
10 submitted to NQF, the measure has been tested in
11 both dialysis facilities and nephrology offices,
12 and it was found to be both highly reliable and
13 valid in both settings.

14 And finally, I would like to address
15 one additional issue that was brought up in pre-
16 meeting comments that we received that the
17 measure has not yet been in use since it was
18 first endorsed. We do acknowledge that this is a
19 weakness, and we note that at the time the
20 measure was tested, it did rely on CPT codes to
21 capture the surgical evaluation component.

22 However, there has been subsequent

1 release of vascular access G-codes that are now
2 included in the measure's microspecifications,
3 and this data element can be more easily
4 captured, and it significantly increases measure
5 feasibility.

6 Secondly, CVS -- or CMS, I am sorry,
7 convened an ESRD Vascular Access Technical Expert
8 Panel just late last month to evaluate the
9 existing NQF-endorsed vascular access measures
10 that CMS uses in its programs, the QIP and the
11 DFC 5-Star Program.

12 The KCQA vascular access measure was
13 included in the TEP's deliberations, and the
14 output of these deliberations are anticipated in
15 the fall of this year, so we should have
16 information on that before too long.

17 And I'll stop there to try to keep it
18 close to the three minutes.

19 CO-CHAIR ANDERSON: Thanks, Lisa.

20 All right. Our two discussants are
21 Karilynnne and Jessie, and we'll start with
22 evidence, and --

1 MS. LENNING: Okay, we're going to
2 tag-team this here, the dietitian and the social
3 worker doing vascular access.

4 So we are thrilled to be part of the
5 Committee, and thank you very much to the
6 developer for doing a nice, thorough introduction
7 of your measure as well.

8 The evidence you speak to -- KDOQI
9 being the basis of your evidence, is there -- I
10 don't have anything in addition. Jessie, do you,
11 regarding the evidence?

12 MS. PAVLINAC: Only that they did
13 describe, unlike some other ones, that the KDOQI
14 grade was grade B, and went through that process
15 pretty thoroughly.

16 CO-CHAIR ANDERSON: Can you turn your
17 mic on?

18 MS. PAVLINAC: Sorry. Okay. Don't
19 mind us.

20 Because it is KDOQI, it is -- their
21 process does lead down the path to moderate based
22 on the algorithm.

1 And we're trying to keep it quick. If
2 you want us to be more specific, we can, but
3 given the hour, we thought we'd do this quickly.

4 CO-CHAIR ANDERSON: Well, I think the
5 KDOQI has been the evidence, and also all of the
6 Fistula First initiatives, and they are at a
7 grade B, right? Any discussion, comments?

8 Stuart?

9 DR. GREENSTEIN: I just have a
10 question: how do you define vascular access
11 complication? Are you just referring to hemo
12 catheters and infections, or complications
13 relating to fistulas and grafts, which can be
14 also present, and how do you follow them/track
15 them?

16 DR. MCGONIGAL: Well, the measure
17 actually doesn't follow complications. We are
18 just looking at the degree of placement, so we
19 don't specifically define that.

20 DR. GREENSTEIN: But the rationale is
21 because you want to decrease the complications,
22 so --

1 DR. MCGONIGAL: Yes, yes, absolutely,
2 so infections --

3 DR. GREENSTEIN: -- if you can't track
4 them, how do you know if you were truly doing
5 that?

6 DR. MCGONIGAL: Based on the evidence
7 that currently exists that catheter placement is
8 associated with a high degree of complications,
9 infections --

10 DR. GREENSTEIN: Right, so --

11 DR. MCGONIGAL: -- is the one that
12 comes to mind.

13 DR. GREENSTEIN: -- you're looking
14 only at the complications related to catheters,
15 not related to fistulas and grafts, which can
16 also be --

17 DR. MCGONIGAL: Absolutely.

18 DR. GREENSTEIN: -- fairly common,
19 given that, you know, you can put a fistula in
20 somebody and it will take them nine months before
21 it can be used and they're getting ballooned
22 constantly or thrombosed and things like that,

1 and the same thing for grafts.

2 DR. MCGONIGAL: Right, right, right --

3 DR. GREENSTEIN: I just bring that up
4 because I think one of the problems that we have
5 in a lot of the things that are being developed
6 is that we don't -- we don't look at the other
7 side of the coin, and that is that there are
8 complications in fistulas and grafts, and we
9 don't track them well at all.

10 DR. MCGONIGAL: Absolutely, and so the
11 issue is the -- the evidence that exists right
12 now ---- basically there is the tiered
13 preference: the fistulas are the primary choice,
14 followed by grafts, then catheters. Catheters
15 are still known to have the highest complication
16 rate.

17 The beauty of the measure is that it
18 does allow grafts as well. So if someone is
19 unable to support a fistula, there is that. You
20 could have a graft as you're maturing your
21 fistula, and we do have the re-evaluation
22 component.

1 So there is there the rare patient
2 that was mentioned in the last discussion who
3 maybe can't support either, or your patients who
4 are in hospice, or your patients who have cancer,
5 elderly patients who really can't support them.
6 So in those instances, they may actually need a
7 catheter, but as long as they're reassessed and
8 that is determined to be the case, you get credit
9 for the measure.

10 CO-CHAIR ANDERSON: And also from a
11 provider's standpoint, you are looking at
12 thrombotic episodes for AVF/AVG, you're looking
13 at infection rates for AVF/AVG, and you do also
14 report that through the NHSN Safety Network. So
15 those are part of the MAT that are required to be
16 reviewed through QAPI, at least at the provider
17 level, so the data is there.

18 DR. GREENSTEIN: Do you know if they
19 tracked at all the stenting? Many times,
20 fistulas or grafts will get stented higher up.

21 And actually, having been doing this
22 for 25 plus years already, from the transplant

1 side, I am seeing more and more patients who have
2 central vein occlusions, and that's because they
3 are getting constantly manipulated up there and
4 stented, and I think that kind of complication is
5 worse than some of these other complications we
6 tracked.

7 CO-CHAIR ANDERSON: Right, yeah, I
8 don't think -- I don't think they are. I am sure
9 they're not.

10 MS. LENNING: I have a comment from a
11 social work perspective.

12 The one piece that I really picked up
13 on in this measure is that it did allow the
14 flexibility, it seemed to meet the numerator
15 based on what was best for the patient.

16 DR. DALRYMPLE: So I was hoping just
17 for broader Committee discussion on the issue of
18 the numerator as it relates to the evidence and
19 this issue of does evaluation by a vascular
20 surgeon or other qualified surgeon in the last 12
21 months deserve equal weighting to having a
22 fistula or a graft, and does the Committee think

1 evidence supports the numerator as specified that
2 way?

3 I think the intent is clear, I am just
4 curious about the Committee's view on the
5 evidence before we vote.

6 CO-CHAIR ANDERSON: Alan?

7 DR. KLIGER: Before going to my
8 question, I thought it might be more appropriate
9 to seek responses to Lorien's question.

10 DR. DALRYMPLE: So I'm just curious,
11 the Committee at large, how people perceive that
12 with respect to evidence in its current state.

13 I think the intent is understandable.
14 My question is more the evidence --

15 CO-CHAIR ANDERSON: Michael, do you
16 have -- ?

17 DR. SOMERS: I agree with what you
18 just said.

19 I think, you know, the evidence that
20 is presented for -- for this measure supports
21 AVF, but really, it doesn't address all the
22 complex factors that may go into the impact why

1 you may end up with an AVF or not with an AVF, so
2 I don't think the evidence necessarily supports,
3 you know, what they're trying to get at here.

4 DR. LATTS: So I'm -- I don't know the
5 clinical evidence beyond what's presented here,
6 but I guess my take on it is that in an era where
7 we're trying to get to more shared decision-
8 making and more weight on patient choice, the
9 ability to have met with a vascular surgeon,
10 discussed the pros and cons of a particular
11 approach, and then taking the patient preference
12 into account, because I think that's what this
13 represents, is incredibly important.

14 DR. DALRYMPLE: Do you think it's
15 potentially an easy out?

16 DR. LATTS: I think it's appropriate,
17 and I think to take it out would be to disregard
18 patient preference to some degree.

19 CO-CHAIR ANDERSON: Alan?

20 DR. KLIGER: So I want to respond but
21 also ask my question.

22 Just a point of clarification: is this

1 measure identical to the last, or were there any
2 adjustments or changes made from the last version
3 that was passed three -- or whatever, four years
4 ago?

5 DR. MCGONIGAL: The change -- from
6 when it was initially endorsed in 2007, there
7 were actually two separate measures. There was
8 an AV fistula and an AV graft measure.

9 The NQF Standing Committee at that
10 time actually advised that we put them together
11 and make it into a compound measure. They also
12 advised that we change the -- it was initially a
13 referral measure, and they recommended that it be
14 a seen evaluation measure as well.

15 And since the last re-endorsement, we
16 have included in the G-codes because they do sort
17 of help capture that evaluation component a
18 little more clearly.

19 DR. KLIGER: So -- so that's helpful.

20 Last time around, again, we were
21 really concerned, as I remember, with making sure
22 that patient choice and patient-informed choice

1 was part of the measure, and having clear
2 evidence, not only of a referral to a vascular
3 surgeon, but an assessment and discussion with
4 the patient by a vascular surgeon was the
5 component that we felt helped in -- in the
6 pursuit of endorsing patient choice.

7 So my own opinion is that yes, in one
8 sense, it's an easy out if you look at it from
9 the standpoint of ways of accommodating that
10 need, but from the standpoint of the patient, I
11 think that this is an appropriate measure.

12 CO-CHAIR ANDERSON: John?

13 DR. WAGNER: So I'm just curious, if
14 one sees an interventional nephrologist to have
15 one's catheter replaced in the prior year, does
16 that count as within the measure specification as
17 being someone who has now seen an interventional
18 nephrologist?

19 DR. MCGONIGAL: Yes, it counts. There
20 should be an accompanying reason why they cannot
21 support it, the patient needs to be documented as
22 not being able to support a permanent access.

1 I'd also like to also note that the
2 easy out part of the discussion, we -- we like to
3 think that the measures that are being used right
4 now sort of do complement each other, and so some
5 of the outcome measures out there will -- if
6 someone is taking a constant easy out to just
7 keep catheters in, their mortality and their
8 hospitalization rates are going to be higher, so
9 we like to think of the measures as complementing
10 each other as well. So I just wanted to bring
11 that up.

12 CO-CHAIR ANDERSON: Frank?

13 DR. MADDUX: To Lorien's comment and
14 question about evidence, I think when you have
15 these composite measures that have really been
16 combinations of narrow things you could do, it's
17 going to be very hard to have a uniform body of
18 evidence across that, and I certainly think the
19 evidence on the -- on the vascular side for AV
20 fistulas and grafts is stronger than the evidence
21 on the impact on quality from a referred and
22 assumed visit with the -- with the vascular

1 surgeon for reassessment.

2 But I think if we don't allow there to
3 be some variability of evidence in these
4 composite measures, we'll never get composite
5 measures, and so that is one of the challenges we
6 have to just make individual decisions on.

7 CO-CHAIR ANDERSON: Lorien?

8 DR. DALRYMPLE: Quick clarification
9 though, we are allowed to vote insufficient
10 evidence with exception, correct? So it doesn't
11 stop a measure if there is insufficient evidence,
12 it's just a way of appraising it, is that
13 correct?

14 MS. SAMPSEL: Correct.

15 DR. DALRYMPLE: Okay.

16 CO-CHAIR ANDERSON: Okay. I think we
17 are ready to vote on evidence.

18 MS. OGUNGBEMI: The Committee is now
19 voting on evidence: structure, process, and
20 intermediate outcome measures.

21 The options are 1 for high, 2 for
22 moderate, 3 for low, and 4 for insufficient, and

1 this is for measure 0251. Voting is now open.

2 Results for evidence are 2 votes for
3 high, 14 votes for moderate, 1 vote for low, and
4 5 votes for insufficient evidence. The measure
5 passes, measure 0251 passes for evidence.

6 CO-CHAIR ANDERSON: All right, moving
7 on to performance gap.

8 In relation to performance gap, on our
9 evaluation forms, there were numerous notations
10 regarding gap in performance with fistulas,
11 grafts, and catheters. In part of our discussion
12 this morning, we have already brought that up as
13 well.

14 MS. PAVLINAC: So this was interesting
15 that it was -- in 53 dialysis units, they did
16 for-profit and not-for-profit, they had 1057
17 dialysis patients in their sample size and showed
18 a significant performance gap.

19 I rated it moderate.

20 CO-CHAIR ANDERSON: Any further
21 discussion, comments?

22 All right. We're ready to vote on

1 performance gap.

2 MS. OGUNGBEMI: The Committee is now
3 voting on performance gap for measure 0251. The
4 options are 1 high, 2 moderate, 3 low, and 4
5 insufficient. Voting is now open.

6 The results are 3 votes for high, 18
7 votes for moderate, 1 vote for low, and 0 votes
8 for insufficient. Measure 0251 passes on
9 performance gap.

10 CO-CHAIR ANDERSON: All right, moving
11 on to reliability.

12 MS. PAVLINAC: So under -- excuse me
13 -- specifications, it is a process measure, and
14 it is not risk-adjusted or -stratified.

15 The difference between the two
16 previous times this measure, in various forms,
17 was presented is the availability of the G-codes.

18 MS. LENNING: I don't have anything to
19 add to that.

20 CO-CHAIR ANDERSON: Any comments by
21 the Committee, any further discussion or
22 questions?

1 All right --

2 DR. DALRYMPLE: Can --

3 CO-CHAIR ANDERSON: -- we are ready to
4 vote.

5 DR. DALRYMPLE: -- I have a quick
6 clarification?

7 CO-CHAIR ANDERSON: Oh, sorry.

8 DR. DALRYMPLE: Is there any intent to
9 use CROWNWeb for this? Can you remind us on that
10 issue please?

11 DR. MCGONIGAL: Yes, the -- the
12 measure is actually a clinician-level measure,
13 but it was specified and it was tested such that
14 it could be used within CROWNWeb or either data
15 collected administratively or --

16 DR. DALRYMPLE: But does CROWNWeb have
17 a field that captures the vascular surgeon
18 evaluation within the last 12 months?

19 DR. MCGONIGAL: I am not entirely
20 clear on that. I understand that they can
21 capture the G-codes, but I am not sure right now
22 if they have that incorporated in or not.

1 CO-CHAIR ANDERSON: They don't. To my
2 knowledge, CROWNWeb does not have that field in
3 there.

4 DR. KRISHNAN: With that being said,
5 in the CROWNWeb users group, we are always -- CMS
6 and us are always thinking about what measures
7 need to be put in, so for example, we're now
8 doing the microspecifications for the depression
9 and pain screening which were not there in the
10 past, but the data collection system could
11 support that as long as it was collected in the
12 dialysis unit.

13 MS. LENNING: All right. Are we
14 ready -- do we also need to discuss reliability
15 testing, do we talk about that now too or not?

16 This measure also did have reliability
17 testing within the physician office groups,
18 inter-rater reliability as well.

19 CO-CHAIR ANDERSON: Josh?

20 DR. ZARITSKY: So I am sorry if I
21 missed this, but just remind me, for that
22 numerator, for the patients that go to the

1 referral, what is your proposed mechanism of
2 tracking that?

3 DR. MCGONIGAL: When we tested it, we
4 used CPT codes. Now, there are G-codes available
5 that capture whether the fistula was placed, an
6 alternative access was placed, and a rationale
7 for why a fistula was not placed.

8 DR. DALRYMPLE: So there is a G-code,
9 sorry, that captures that an evaluation occurred
10 even in the absence of access being placed, is
11 that correct, that --

12 DR. MCGONIGAL: That is my
13 understanding, yes.

14 DR. ZARITSKY: So how frequently --
15 how -- I just have no, you know, I have never
16 filled out the G-code there because I am not a
17 vascular surgeon, how frequently are these
18 utilized, these G-codes, what is the evidence for
19 them being used? I am just addressing this
20 numerator, because this is an important part of
21 your proposal is including this group of
22 patients, and I just want to make sure that they

1 are somehow captured in a meaningful way.

2 DR. MCGONIGAL: Yeah, my understanding
3 is within -- particularly within PQRS, they are
4 now turning almost exclusively to G-codes to
5 capture their numerators. I am not sure exactly
6 -- they're working this in right now, so I am not
7 sure how far along they are.

8 And again, as Mahesh pointed out, if
9 it's determined to be appropriate, it is
10 something that could be worked into CROWNWeb as
11 well.

12 DR. GREENSTEIN: Doing this procedure
13 for the last 27 years, I don't even know what the
14 G-code is. I don't think they track it in my
15 place, so I wonder if -- and I'm at an academic
16 institution, I wonder how many other places have
17 the same problem, that they don't track that,
18 because I don't know what it is even.

19 DR. MCGONIGAL: And I'm assuming you
20 do use the CPT codes to capture the -- ?

21 DR. GREENSTEIN: The biller does,
22 yeah. I mean, I just mark down office visit and

1 x, y, z, and that's it, you know.

2 DR. MCGONIGAL: Yeah, that's with the
3 administrative data, the CPT codes are included
4 in there as well. So any way that we can capture
5 it, it's been included into the specifications
6 so there are multiple roots that get at the
7 information.

8 CO-CHAIR ANDERSON: All right, I think
9 we're ready to vote on reliability.

10 MS. OGUNGBEMI: The Committee is now
11 voting on reliability.

12 The options are 1 high, 2 moderate, 3
13 low, 4 insufficient. This is for measure 0251.
14 Voting is now open.

15 The results are as follows: 2 votes
16 for high, 14 votes for moderate, 5 votes for low,
17 and 1 vote insufficient. This is for measure
18 0251. The measure passes for reliability.

19 CO-CHAIR ANDERSON: All right. Moving
20 on to validity and validity testing.

21 MS. PAVLINAC: Yes, validity. Chart
22 validation results showed high validity for

1 sensitivity, specificity, positive predictive
2 value, and negative predictive value. There were
3 no exclusions to this measure, and there is no
4 risk adjustment.

5 There was a meaningful difference that
6 was defined as a significant spread of greater
7 than 20 percent between minimum and maximum
8 scores. The performance for each individual
9 facility in the pilot ranged from 41 to 100
10 percent, with a mean of 93.8 percent in those 53
11 facilities.

12 CO-CHAIR ANDERSON: Karilynne, any
13 other comments?

14 MS. LENNING: It just seemed like on
15 our work group call, this was also where the G-
16 code discussion came up again, where we had a
17 lack of any evidence or data, you know, because
18 they are so new, I just remember that discussion
19 as well.

20 MS. SAMPSEL: So let me just comment
21 on that because staff was doing some research on
22 this as well, and so basically, the way that

1 these measures can currently be reported are
2 through PQRS, and so PQRS is well-established,
3 and physicians are able to report CPT and G-codes
4 based on once they're in the system.

5 As already mentioned, those measures
6 -- you know, the G-codes are -- they morph as the
7 PQRS measures get developed, get added into PQRS,
8 but they have been tested and are well-utilized.

9 When we looked at the last year of
10 kind of summary reports for PQRS and ability of
11 nephrologists to report on the measures, only
12 about 20 percent of qualified nephrologists are
13 reporting on PQRS.

14 You know, that's not necessarily an
15 indication of able-to-report or not, that's more
16 of an indication are they reporting or not, but
17 you see that number coming up. They're just not
18 really in the -- nephrologists really just aren't
19 in the top 10 of those participating in PQRS
20 right now.

21 So, you know, I guess just really kind
22 of talking about capturing of the data and able

1 to capture the data, it's institutionalized now
2 across PQRS measures.

3 CO-CHAIR ANDERSON: John?

4 DR. WAGNER: It's talking about
5 nephrologists or vascular surgeons with respect
6 to that?

7 MS. SAMPSEL: I mean, so vascular
8 surgeons didn't show up anywhere in PQRS in the
9 top 20, so all I can tell you is when talking
10 about renal specifically and looking for these
11 measures, you know, there are a number of renal
12 measures in PQRS. Only 20 percent of
13 nephrologists are, so you have to make some
14 conclusions.

15 CO-CHAIR ANDERSON: Lorien?

16 DR. DALRYMPLE: So with respect to the
17 PQRS issue, those that are reporting, do we know
18 the accuracy of that reporting around these new
19 G-codes, I guess is my question? Just because
20 they exist doesn't mean they are being used
21 correctly.

22 MS. SAMPSEL: I don't think that we

1 know about specifically these codes other than
2 the fact that, you know, it's the same process
3 used to develop any G-code and test it for any G-
4 code when it goes through those AMA committees in
5 establishing the coding structure.

6 DR. DALRYMPLE: So just so that we
7 have a good understanding, at least that process
8 ensures some testing to make --

9 MS. SAMPSEL: There is some very
10 rigorous standards codes have to go through to be
11 approved by something called -- I think it's
12 called the PUG, and don't ask me what the PUG
13 stands for, but, you know, it's another acronym
14 that goes through an entire clinical review as
15 well as coding review.

16 CO-CHAIR ANDERSON: We would like to
17 try and get through this measure before the
18 public comment period, which is in a couple of
19 minutes, so I would like to call for the vote on
20 the validity testing.

21 MS. OGUNGBEMI: The Committee is now
22 voting on validity. This is for measure 0251.

1 The options are 1 high, 2 moderate, 3
2 low, and 4 insufficient. Voting is now open.

3 The results are 1 vote for high, 15
4 votes moderate, 3 votes low, and 3 votes for
5 insufficient. Measure 0251 passes on validity.

6 CO-CHAIR ANDERSON: All right, moving
7 on to feasibility. Jessie or Karilynne?

8 MS. LENNING: Feasibility we've talked
9 a lot about already and being able to capture
10 those data elements through CROWNWeb or using the
11 G-codes --- excuse me --- or the CPT codes. So
12 it appears feasibility would be high.

13 CO-CHAIR ANDERSON: Jessie, any
14 comments?

15 Any questions or comments on the part
16 of the committee? Can we vote on feasibility?

17 MS. OGUNGBEMI: The committee is now
18 voting on feasibility for measure 0251. The
19 options are 1 high, 2 moderate, 3 low, and 4
20 insufficient. The voting is now open.

21 The results are 6 votes for high, 15
22 votes for moderate, 1 vote low, and zero votes

1 insufficient. Measure 0251 passes on feasibility.

2 CO-CHAIR ANDERSON: All right, moving
3 on to usability and use.

4 MS. LENNING: This particular measure
5 currently is not being used, but there are plans
6 for it to be used in public reporting and payment
7 program, and also planned for use in quality
8 improvement with benchmarking -- with external
9 benchmarking to multiple organizations and
10 planned for use in quality improvement as well.

11 CO-CHAIR ANDERSON: Andy?

12 DR. NARVA: Yes, I just wanted to ask
13 Lisa a question.

14 You envisioned this being most useful
15 in combination with other outcome measures, so if
16 we have those outcome measures, what do you see
17 this adds to them?

18 So, I mean, it sounds like an outcome
19 measure is --

20 DR. MCGONIGAL: Yes, that -- oh, I am
21 sorry -- that is not exactly what I -- I meant or
22 said --

1 DR. NARVA: Okay.

2 DR. MCGONIGAL: -- basically, I am
3 saying that when the measures are used in tandem,
4 as they are a lot in the QIP, that they do
5 provide a nice balance for each other, so it
6 helps prevent that gaming the system, which is a
7 word I hate to use, but it does help prevent
8 that, as someone suggested that perhaps someone
9 could just always check the box and say that
10 catheters were done.

11 So I am not saying to envision it in
12 tandem with any particular outcome measure, I am
13 just saying that that's sort of a way of
14 preventing the gaming.

15 CO-CHAIR ANDERSON: All right, are we
16 ready for the vote for usability and use?

17 MS. OGUNGBEMI: The Committee is now
18 voting on usability and use for measure 0251.

19 The options are 1 high, 2 moderate, 3
20 low, 4 insufficient. Voting is now open.

21 The results are 4 votes for high, 16
22 votes for moderate, 0 votes low, and 2 votes

1 insufficient. The measure 0251 passes on
2 usability and use.

3 CO-CHAIR ANDERSON: All right. So
4 now, we will be voting on whether to recommend
5 the measure as suitable for endorsement.

6 MS. OGUNGBEMI: The Committee is now
7 voting on measure 0251, overall suitability for
8 endorsement.

9 The options are 1 yes, 2 no. Voting
10 is open.

11 The results are 19 votes yes, 2 votes
12 no. The measure passes suitability for
13 endorsement.

14 DR. MCGONIGAL: Thank you.

15 CO-CHAIR ANDERSON: All right. We
16 will now open up for public comment.

17 THE OPERATOR: At this time, if you
18 would like to make a comment, please press star,
19 then the number 1.

20 At this time, there are no public
21 comments.

22 CO-CHAIR ANDERSON: Is there anyone --

1 anyone in the room that has comments?

2 MR. DIAMOND: So I am Lou Diamond,
3 speaking for myself.

4 Just a couple of comments. I
5 obviously stand between you and lunch, which is
6 probably better than standing between you and a -
7 - laid off and a gin and tonic, so I am in good
8 shape.

9 So first, just three quick comments,
10 if I could. One is, as an outside observer
11 sitting at the back here, the structured process
12 that you used for voting was in fact very
13 helpful. I am not sure whether this has been
14 used before, but it was very helpful.

15 I do observe that it appeared to me at
16 least that you -- you should have been voting, or
17 you are voting, on the measures as submitted and
18 specified in the documents before you, and I
19 think Alan made that comment, and I observe
20 anecdotally that the -- in my own opinion that
21 some of the voting was not congruent with some of
22 the discussion you had about some of the concerns

1 with the measures, so it might be kind of helpful
2 to look at that because the distinction between
3 voting on what you think the measure should look
4 like based on your discussion is different from
5 voting on the actual measure as specified.

6 I am aware that we are at the
7 beginning of a process, so the measure can be
8 modified by the developer going forward, which
9 obviously will occur based on the discussion and
10 the personal comments.

11 The second comment I wanted to make is
12 I thought that, Sarah, the -- the summary you
13 provided at the beginning of the meeting, and I
14 am not -- it was very helpful.

15 I am not sure what the full scope of
16 the Committee is in terms of what you can or
17 cannot do, but you spoke there about urging the
18 Committee to take a "holistic" approach to the
19 overarching issue that is on the table, which is
20 measures for the end stage renal disease patient
21 population and -- and the providers.

22 I do think it would be helpful in the

1 future, and you may have already done this, and
2 maybe in your briefing books, to display --
3 display the measures against the -- the national
4 priority strategy domains so you can get a sense
5 of which measures are in fact mapped to those
6 domains.

7 It would also be helpful to be able to
8 map the measures that you're looking at against
9 the measures that are currently in use in various
10 programs.

11 And thirdly, and I think very
12 importantly, and this Committee could play a role
13 in that, map the measures in terms of facility-
14 level versus physician measures in terms of the
15 domains that they are actually tackling, because
16 the ESRD program is in very -- in some respects
17 very unique in terms of physicians and facilities
18 working so closely together, and yet having
19 distinctly different -- well, not distinctly
20 different measures, but they have different
21 measures, certainly differently specified and
22 sometimes in different domains. And some kind of

1 alignment and harmonization of that would be
2 helpful if the Committee could actually tackle,
3 that to kind of figure out how you would do that.

4 My last comment, and I did speak
5 offline to Peter on that, I thought the
6 discussion on the -- what is it, the Optimal End
7 Stage Renal Disease Starts was a fascinating
8 discussion.

9 Let me say up front, this is an
10 incredibly important measure. There is no debate
11 about that.

12 I came away, as an outsider, totally
13 unclear about what the level of analysis was for
14 this measure. There was a lot of discussion
15 about this being a PQRS measure, which is a
16 physician-level measure, and then there was a
17 discussion -- and in fact some discussion that it
18 was going to be loaded into perhaps in the future
19 in the RPA Registry, which is in fact a
20 physician-level registry at the moment.
21 Hopefully it will be changing in the future.

22 And then there was discussion that

1 this was at the -- at the organizational level,
2 and those are two distinctly different kind of
3 levels of analysis.

4 And then there was a lot of discussion
5 about feasibility, and yet you guys -- and some
6 concerns about the feasibility, and yet you guys
7 voted in favor of -- of feasibility.

8 And finally, relating to that, it does
9 seem to me that the question of optimal starts,
10 end stage renal disease starts, really has to
11 deal fundamentally with looking at some measures
12 of shared decision-making in addition to the
13 outcome because that's going to be kind of
14 important going forward.

15 So thank you for allowing me to
16 comment.

17 CO-CHAIR ANDERSON: Any other
18 comments?

19 Well, do you want the good news or the
20 bad news?

21 The bad news is our lunches are stuck
22 downstairs because the elevators are out, so what

1 we'd like to do -- which Poonam just informed us
2 -- so what we'd like to do is keep going on the
3 measures until the elevators work and we can get
4 our lunch up here.

5 So if you don't mind, we'll just move
6 on to the next measure, which is 0256, and it's
7 Claudia and Joel for the developers.

8 DR. DAHLERUS: All right. Okay. So
9 we're going to start.

10 We have two paired vascular access
11 measures for CMS.

12 So the first one is measure 0256. It
13 is a facility-level intermediate outcome measure
14 which reports the percentage of adult patient
15 months on maintenance hemodialysis for patients
16 on maintenance hemodialysis during the last
17 treatment of the month, and that have a chronic
18 catheter continuously for 90 days or longer prior
19 to the last hemodialysis session.

20 Catheter rates have been decreasing
21 since the Fistula First Initiative launched in
22 2003. Based upon data from the CMS Fistula First

1 breakthrough initiative, a gradual trend has been
2 observed towards lower catheter use among
3 prevalent maintenance hemodialysis patients in
4 the United States, declining from approximately
5 28 percent in 2006 to 24 percent by May of 2007.

6 Furthermore, the percentage of
7 maintenance hemodialysis patients using a
8 catheter for greater than 90 days has declined
9 over this time from 12 percent to approximately
10 9.5 to 10 percent, which is something that we
11 reported in our testing in our submission.

12 Lower mortality has been observed in
13 many studies, with reduction in catheter use and
14 an increase in fistula use in facility- and
15 patient-level studies.

16 The goal of the catheter measure as
17 paired with the fistula measure is to continue
18 encouraging further reduction in chronic catheter
19 use.

20 The measure was originally developed
21 in 2006 by a clinical TEP, citing among the
22 evidence and guidelines the 2006 update of the

1 KDOQI Vascular Access Clinical Practice
2 Guidelines. It was originally endorsed in 2007
3 and retained endorsement in 2011.

4 In response to community concerns
5 about unintended consequences of promoting
6 fistula use over catheter use and relative to
7 graft use, and that there may be circumstances
8 when facilities should not be penalized for
9 prolonged catheter use, we on behalf of CMS
10 convened a Vascular Access Technical Expert Panel
11 that just met late last month to consider these
12 two paired measures in order to recommend
13 potential revisions to the measures that would
14 address these concerns.

15 As was noted earlier, the TEP recently
16 met, and we are currently working on the report
17 of the TEP deliberations, which will be released
18 later this summer, so we really cannot go into
19 specific recommendations.

20 However, the general consensus among
21 the TEP members was that chronic catheter use
22 should continue to be discouraged.

1 We tested the catheter measure using
2 calendar year 2013 CROWNWeb data. We are also
3 able to calculate the measure using Medicare
4 claims. And the testing involved approximately
5 between 5600 and 5900 facilities.

6 And so I think we'll just end our
7 opening statement there.

8 CO-CHAIR ANDERSON: All right. We
9 have Stuart and Jessie as reviewers of the
10 measure. I don't know of Jessie or Stuart, who
11 would like to go first?

12 DR. GREENSTEIN: Sure, I'll take it.
13 So in terms of the evidence, there were numerous
14 articles that -- since the last few, that support
15 the concept that decreasing use of catheters
16 leads to improved survival rates for hemodialysis
17 patients, and it's a direct measure. It's an
18 outcome measure that shows that you have improved
19 survival rates, and there's evidence to that.
20 It's important.

21 CO-CHAIR ANDERSON: Jessie? No
22 comments?

1 All right. Any further discussion on
2 the part of the Committee? Alan?

3 DR. KLIGER: I guess I am just a
4 little confused in that the measure is being
5 asked to be re-upped again, but we have no data
6 since 2007. Is that correct?

7 DR. DAHLERUS: No, that's not correct.
8 We were just citing the trend, the decreasing
9 trend which had included data up to 2007. When
10 we did our testing, we used calendar year 2013
11 CROWNWeb data.

12 DR. KLIGER: What's been the trend
13 since the last eight years?

14 DR. DAHLERUS: So the current national
15 performance rate is at approximately 10 percent.

16 DR. KRISHNAN: Ten percent catheters?

17 DR. DAHLERUS: Yes, 10 percent
18 catheter rate.

19 DR. KRISHNAN: I'm looking at Frank,
20 Frank is looking at me --

21 DR. DAHLERUS: Greater than 90 days.

22 DR. KRISHNAN: It's a little low. I

1 mean, between Frank and I, that's two-thirds of
2 the country. We're not at 10 percent. We're at
3 13 percent.

4 DR. DAHLERUS: Well, that's -- again,
5 that's what we're reporting with the CROWNWeb
6 data. We can -- we can look it up again.

7 DR. MADDUX: Either way, though, I
8 think it's representative that there has been a
9 vast improvement, as is described, and there is
10 still room for improvement.

11 But there's probably a limit to the
12 level --

13 CO-CHAIR ANDERSON: It could be a
14 problem with CROWNWeb data too, in terms of
15 especially with access, and so it could be with
16 the extraction of the data, that's why there is a
17 discrepancy. I mean, I agree with you. Our data
18 doesn't show that either, so --

19 DR. MADDUX: So it strikes me there
20 are a couple of things here that I think are
21 really important as this remarkable reduction
22 that has occurred since the mid-2000 period, the

1 rate of that reduction is clearly going to hit
2 some asymptotic level, and nobody knows exactly
3 where the delimiter is on that, so -- .

4 DR. GREENSTEIN: Well, I think that
5 what is going to happen is that as these patients
6 get dialyzed, go for transplant, come back on
7 dialysis, you are going to see that they will end
8 up with more and more catheters and that we will
9 reach a bottom where we won't be able to go below
10 that number. I would think 10 percent is not
11 bad, actually.

12 CO-CHAIR ANDERSON: Any other
13 discussion or comments or questions?

14 Yes, Claudia?

15 DR. DAHLERUS: So I just wanted to
16 sort of clarify a response to you, Dr. Krishnan.

17 So the calculation of the national
18 rate is defined, and it's reported in the DFR,
19 and it's using the definition based on -- it
20 matches Fistula First, so the percent of catheter
21 that we report in the DFRs as well as what we
22 report for the DFC, using Medicare claims, is

1 just about between 10 and 11 percent, and
2 similarly in CROWNWeb.

3 When we remove -- so for the -- when
4 we calculate the fistula measure, we also include
5 cases where the patient has a catheter present.
6 If we revise that definition and only report --
7 and report the percentage of catheter which also
8 could include the presence of a fistula, then the
9 rate goes up to 14 percent.

10 And so some of this is a function of
11 how the data definitions are in both sources.

12 DR. KRISHNAN: And Claudia, what --
13 just so I understand that, I mean, we consider a
14 catheter as a risk as long as it's there, right,
15 because they're a wick for infection --

16 DR. DAHLERUS: Correct.

17 DR. KRISHNAN: -- and that definition
18 of catheter with fistula still has a risk for
19 catheter? Is that --

20 DR. DAHLERUS: So, and that is an
21 artifact of the data elements as defined in
22 CROWNWeb, and this is actually something that was

1 discussed at length by the recent vascular access
2 TEP who were equally uncomfortable with the fact
3 that you get credit for a fistula if a catheter
4 is present.

5 DR. KRISHNAN: Yes, that makes sense.
6 So just so I am clear, we talked about the data
7 issues with CROWNWeb perform, specifically around
8 vascular access, and I know the ESRD networks
9 have been very vocal around this issue because of
10 how they're incentivized. How do you think that
11 the data errors are affecting the gap analysis
12 and the other analyses? Do you have a sense of
13 what that would be?

14 DR. DAHLERUS: So I am not sure we
15 would characterize it as data errors. Are you
16 referring to missing data?

17 DR. KRISHNAN: Sure.

18 DR. DAHLERUS: Well, I guess we don't
19 feel entirely comfortable saying that there are
20 data errors in the CROWNWeb because when we
21 calculate the measure in claims, the percentages
22 are pretty comparable.

1 DR. KRISHNAN: Yes, the -- we can talk
2 about this later on. The trick there is not to
3 say what's the correlation between data that
4 makes it into CROWNWeb to claims, the data there
5 is to say what's the percentage of patients who
6 don't have data in CROWNWeb who have claims data
7 for a dialysis session? It's a slightly
8 different nuance.

9 DR. ANDRESS: I think it's also a
10 question of what you're defining as a data error.

11 I mean, I think -- I think, you know,
12 data error, I think, implies that there is an
13 issue with the system that's collecting the data.
14 I think there are cases where we have incomplete
15 data for patients through the CROWNWeb system. I
16 think it would be inappropriate to attribute all
17 -- all of that to issues within the system, and
18 it's something that can be addressed at the
19 submitter level, and in fact, a number of those
20 issues are -- you know, vary by the submitter,
21 and we've seen evidence that they can in fact
22 reduce the rates of errors with some investment

1 of their own time.

2 So I think, you know, pushing for
3 better submission of data is certainly within the
4 purview of a quality measure and a quality
5 program.

6 I think the point to be made is that,
7 one, performance using common definitions for the
8 measures yields similar results; two, direct
9 comparisons are not feasible in the entire
10 population because of course the claims data
11 yield only data for Medicare patients, and so
12 there's going to be some degree to which we don't
13 know the entire picture, comparing the two data
14 sources.

15 But based on the best data that we
16 have available, we seem to get comparable results
17 using two different data sources, and that seems
18 to us to be a good indication that we're getting
19 close to the correct story for the catheter
20 measure.

21 DR. KRISHNAN: Sure.

22 CO-CHAIR ANDERSON: Any other comments

1 or questions for the developer on evidence?

2 If not, again, this is an outcome
3 measure, and so we will be voting.

4 MS. OGUNGBEMI: The Committee is now
5 voting on evidence for an outcome measure, 0256.

6 The options are yes, 1, 2, no. Voting
7 is up.

8 For health outcome measures, the
9 rationale supports the relationship of the health
10 outcome to at least one health care structure,
11 process, intervention, or service. Voting is now
12 open.

13 The results for evidence for measure
14 0256 are 21 votes yes, 0 votes no. The measure
15 passes on evidence, measure 0256 passes on
16 evidence.

17 CO-CHAIR ANDERSON: All right, moving
18 on to performance gap.

19 DR. GREENSTEIN: So in terms of the
20 data that was presented, there clearly was
21 disparities in care being measured based upon an
22 analysis both for between sex or age,

1 ethnicity/age, and diabetes, and the same was
2 true for gap performance, that there was clear
3 cut disparities.

4 CO-CHAIR ANDERSON: Lorian?

5 DR. DALRYMPLE: Just one comment on
6 disparities that came up on our work call.

7 This was one of the measures where
8 there were statistically significant differences
9 but the Committee may want to discuss whether
10 they were clinically meaningful differences.

11 There are very large sample sizes, so
12 the power to detect very small differences was
13 present, so there was some discussion on our call
14 as to whether people felt this was clinically
15 meaningful, differences by disparities, so if
16 other Committee members have thoughts on that?

17 CO-CHAIR ANDERSON: Alan?

18 DR. KLIGER: Just a question: what
19 was the year that these were carried out? Was
20 this in the '07 period or something more
21 contemporary?

22 DR. DALRYMPLE: Can we actually pull

1 up the page so we can all look at it together
2 with the disparities testing? Is that possible?

3 CO-CHAIR ANDERSON: And it says that
4 the data was January 13th through December 13th.

5 DR. DALRYMPLE: I think this is all
6 CROWNWeb 2013.

7 So yeah, it's just -- just -- we'll
8 have to capture the two there.

9 So I think on the work group call,
10 maybe you're all driving this for yourselves, is
11 for example if you look at quintiles for females,
12 between quintile one and quintile five, it's 9.5
13 percent versus 9.2 percent, so yes, the P value
14 is statistically significant, but most of us
15 would not necessarily consider a 0.3 percent
16 absolute difference to be clinically meaningful.

17 I think on age greater than or equal
18 to 75, perhaps there's a little bit more spread,
19 9.1 percent versus 10.7, but I think this issue
20 is going to come up again and again when we're
21 reviewing disparities for any measures with such
22 large sample sizes, so it might be worthwhile as

1 a group to discuss it now if we are being asked
2 to decide whether these are disparity-sensitive
3 conditions by NQF, the statistical significance
4 versus clinically meaningful.

5 CO-CHAIR ANDERSON: Jessie?

6 MS. PAVLINAC: I may be wrong, but
7 four years ago, didn't we have the whole big
8 discussion about we don't talk about clinical
9 relevance with this, that it's all -- I am
10 looking at Alan because I thought you were the
11 impassioned one about we're talking about quality
12 and not clinical, or maybe it was NQF staff,
13 because -- like I said, I may be totally wrong.

14 CO-CHAIR ANDERSON: Go ahead, Alan.

15 DR. KLIGER: No, I mean, I -- again,
16 Lorien's question I think is exactly the right
17 question.

18 When we look at this, we have to talk
19 about what's clinically important, and the data
20 we look at here shows a very small difference.

21 CO-CHAIR ANDERSON: Frank?

22 DR. MADDUX: So I -- I have a question

1 for the developers and the group that analyzed
2 this in detail, is other data has shown
3 substantial socioeconomic and geographic
4 disparity, and yet it's never included in this
5 data, and it just strikes me that we know that it
6 exists to some degree, and yet we don't speak to
7 it when we're looking at these measures, and I
8 just would like some conversation about that.

9 DR. ANDRESS: Fantastic. So I think
10 there are -- as has been mentioned, this is a
11 fairly dynamic circumstance anytime we're talking
12 about SES.

13 The measures were developed of course
14 at a time when NQF guidance was pretty clear that
15 we should not be risk adjusting for socioeconomic
16 status, and I think while the question has
17 certainly become more prominent in recent years,
18 the matter itself is not entirely settled, hence
19 the purpose of the trial.

20 This was an issue that I believe came
21 up during the TEP's discussions as well, although
22 I think it was more driven in the fistula measure

1 discussion than the catheter measure discussion.

2 I think, you know, there's relatively
3 little to be gained by arguing the point for or
4 against risk adjustment for SES here. I think
5 the ground is well-trod. The measure as it is
6 currently specified does not adjust for SES.

7 We are certainly capable of providing
8 supplementary analyses to allow this Committee to
9 look at variation by SES within the constraints
10 of indicators that are currently available to us.
11 And I suspect that this is something that when we
12 have final recommendations out of the Technical
13 Expert Panel that met last month, this will be
14 something that we will again be addressing, at
15 least in part, because we will have passed the
16 NQF's own timeline for -- submission timeline for
17 when the trial becomes active.

18 I think when we submitted these
19 measures, it was prior to their deadline for
20 including that kind of information.

21 So we can certainly provide
22 supplementary information on an ad hoc basis if

1 that would be of interest to the Committee to
2 look at, but that was not a focus of our analyses
3 in preparation for the submission here.

4 DR. KRISHNAN: Do you think, though,
5 Joel and Claudia, that that would play a role
6 here? Do you think that there is variance where
7 facilities could be inadvertently penalized
8 because of the patients they serve?

9 DR. ANDRESS: I think that we probably
10 don't have time to discuss my opinion on SES risk
11 adjustments in general.

12 It's a fairly complex issue. I think
13 that it is possible that facilities are assessed
14 on measures that may vary by SES. I think it's
15 an open question as to whether or not we can
16 truly disentangle what is actually the
17 responsibility of the facility and what is
18 outside of the facility's control.

19 Most indicators of SES that I have
20 seen proposed include a little bit of both, and
21 at that point, I think it becomes a value
22 judgment. Do you value more holding a facility

1 harmless for matters that are outside of its
2 control, or do you value more holding facilities
3 responsible for variations in care that may be
4 due in part to factors that are inside of its
5 control, including how its treatment varies for
6 patients of different categories, resources, you
7 know, language proficiency and so on?

8 That is an open question. I think
9 it's a difficult one to answer, and again, I
10 suspect that the answer is -- the answer
11 ultimately is going to be a little bit of both,
12 and then what do we do about it from there? And
13 I think that's what the trial is actually
14 intended to help us disentangle.

15 CO-CHAIR ANDERSON: Alan?

16 DR. MADDUX: I was just going to say,
17 we've talked a -- the responses and conversation
18 was a lot about SES. What about geography?

19 DR. ANDRESS: So the -- I mean, you
20 know, we've talked about geography.

21 I think the focus in talking about
22 geographic differences in care has been,

1 historically, it was in my experience about
2 differences in standards of practice, patterns of
3 practice in the United States and for the -- for
4 CMS, for its quality program purposes, we have a
5 standing policy to not risk adjust for that, and
6 that's been true of quality measures that have
7 been implemented well beyond the dialysis
8 facility programs.

9 And I think that that is, you know,
10 not something that I would be able to address on
11 my own. It's a much larger policy issue at CMS.
12 So no, we have not accounted for geographical
13 variation. We do typically have the capacity to
14 look at it, but it was not, again, a focus of the
15 analyses that we have provided here.

16 And I think the other point to make is
17 that catheters are bad, and it doesn't much
18 matter where you are, catheters are still going
19 to be bad for you. So I think the question then
20 becomes, you know, a little bit of, you know, is
21 it okay if catheters are more prevalent in one
22 area or another, and again, I am not sure that's

1 a question we have the data to answer
2 definitively.

3 DR. KLIGER: So I want to just go back
4 to is there a performance gap or not?

5 We talked about the limitations of the
6 data, and particularly large data sets, so among
7 ourselves, can I ask those of us that are exposed
8 to large groups of patients on dialysis, and I am
9 looking at Frank and Mahesh I guess, what's your
10 opinion about is there a performance gap?

11 DR. MADDUX: I'll answer first.

12 I think there is a performance gap
13 still. I don't think we've hit that sort of
14 delimiting area where you've got all the
15 patients. I think there are some moving parts.

16 I do have a sense that Fistula First,
17 despite all of its good results, which I don't
18 want to minimize, has had some unintended results
19 in some people with perpetual inability to get
20 fistula placed by the lack of recognition, so I,
21 in my own mind, divide the world up into
22 permanent access/non-permanent access

1 predominantly and recognize that fistulas are
2 better than grafts, but grafts are a whole lot
3 better than catheters.

4 I also think that in this measure, and
5 certainly for others, the gap should be looked at
6 based on a number of factors like vintage, which
7 this one does to some degree. The vintage of the
8 patient is really fundamentally different, and I
9 think the outcomes are fundamentally different in
10 the long-term survivor and the brand new patient
11 to dialysis.

12 So from my perspective, I still see
13 performance gaps, but I do see differential
14 performance gaps not just based on practice
15 patterns, but actually populations of people for
16 all of those reasons that exist in different
17 areas when I see more gaps in some places than
18 others, let's put it that way, and some of that
19 is process and culture, and some of that could be
20 demographics and background. It's not clear to
21 me what those are.

22 DR. KRISHNAN: Yes, I think there is

1 still a gap.

2 We think about an intractable catheter
3 rate. There's always going to be a floor where
4 you're going to have patients, either because
5 they're new to dialysis or between accessessors or
6 whatever, are going to have that number, and we
7 look at within our integrated care setting where
8 we have a ton of resources to pour into this what
9 the lowest number should be. It's about 8
10 percent.

11 So there are some clinics that hit
12 that. No matter what you try to do, they're not
13 going to get any better. There are other
14 clinics, as Frank said, that have a high
15 proportion of incident patients just from where
16 they are, but no matter what you try to do, no
17 matter how many resources you pour in, it doesn't
18 change, so there is still a gap, and we could
19 debate how reasonable it is to try to modify some
20 of those things or not, but there is still a gap,
21 I think.

22 CO-CHAIR ANDERSON: Our lunches are

1 here, but what we'd like to try and do is finish
2 this measure and then take lunch, so we'd like to
3 try and wrap this up by one o'clock so that
4 people can get some lunch.

5 So are we ready to vote on -- oh,
6 sorry.

7 MS. HARTWELL: Just for information
8 purposes, I had a question.

9 Do you see a performance gap in areas
10 where the clinics do not have access to good
11 vascular surgeons? And I was just curious for
12 that. I mean, is that the reason? Because --

13 DR. KRISHNAN: Yes, I mean definitely,
14 right?

15 MS. HARTWELL: -- it's just not more
16 patient-driven, it's more vascular-access-
17 surgeon-driven --

18 DR. KRISHNAN: I mean, any outcome in
19 medicine is due to one of three factors: the
20 patient, the provider, and the disease, right?
21 So as it relates to the surgeon and the
22 availability and, sorry Stuart, the quality of

1 the surgeon, we see that, right? We see certain
2 markets where even though the patients can't get
3 access to surgery, so it takes a while, we see
4 other markets where the patients get access to
5 the surgeons and they never mature, and so it
6 doesn't really help you because you still have
7 those catheter days coming on, so yes,
8 definitely.

9 DR. MADDUX: Lori, I see the root
10 causes as being really multi-factorial, and
11 surgeons may be one of those root causes, but
12 coordinating the entire process and creating
13 actionable elements that decrease the time to a
14 surgical visit, the time to an assessment, the
15 time to surgery, the time to maturation, the time
16 to cannulation. If we begin looking at how you
17 look at those durations and say what could you do
18 from a root cause standpoint to squeeze those
19 down, that's the kind of granularity we have to
20 get to.

21 So I don't think we can lay it just in
22 the hands of the surgeons. It's the whole

1 system.

2 CO-CHAIR ANDERSON: All right. Are we
3 ready to vote on performance gap?

4 MS. OGUNGBEMI: Measure 0256 is open
5 for performance gap. The options are 1 high, 2
6 moderate, 3 low, 4 insufficient.

7 This is data demonstrative of
8 considerable variation or overall less than
9 optimal performance across providers and/or
10 populations groups.

11 The results are 5 for high, 17 votes
12 for moderate, 0 votes low, and 0 insufficient.
13 Measure 0256 passes on performance gap.

14 CO-CHAIR ANDERSON: All right.

15 We'd like to do both the reliability
16 specifications and the reliability testing
17 together.

18 DR. GREENSTEIN: So the measure is
19 well-defined, numerator and denominator clearly
20 defined, and the data form is from claims and
21 also CROWNWeb data, so from a specification point
22 of view, there was no concerns.

1 In terms of reliability, again, it
2 appeared to be very reliable in terms of data,
3 and there were no exclusions, so the patient
4 population does not include pediatrics, and this
5 was appropriate also.

6 CO-CHAIR ANDERSON: Jessie, anything
7 further? Nothing? Mahesh?

8 DR. KRISHNAN: I guess I'd just be
9 interested, on the data, Joel, you mentioned that
10 there were some correlations done. I haven't
11 seen those, so it would be helpful just to
12 understand that because clearly we have a
13 disconnect between what we perceive as data --
14 how much data is there and how much you perceive
15 the data is there, so it would be helpful to see
16 that validation of the CROWNWeb data.

17 DR. DALRYMPLE: So on our work call,
18 a similar question came up. So would it be
19 possible to show the table to the Committee to
20 discuss comparing claims to CROWNWeb? Because
21 there actually is an absolute difference of 3
22 percent, which on a performance measure where

1 it's 8 versus 11 percent seems relevant, and the
2 developers, you know, we could get a response,
3 but I think it's worth the Committee being able
4 to see, that's the table 2 facility-level measure
5 mean percent, page 30 on my version, but these
6 versions have changed.

7 And the correlation data is presented,
8 and the correlations were strong, but on the work
9 group call, one of our concerns was the absolute
10 difference was large, and is this because it's
11 medical claims versus CROWNWeb all payers, or is
12 there some other explanation? And given the
13 transition to CROWNWeb, we thought it was
14 valuable to understand why those differences were
15 observed.

16 So keep -- it will be a table. Are
17 you guys to your page 30? Keep going. If
18 there's other members from the work group, you
19 guys can help us find this table. Okay, just a
20 little bit lower. This one.

21 It's a facility-level measure, so you
22 can see catheter greater than or equal to 90 days

1 in CROWNWeb, 8.5, this is from 2012-2013, versus
2 claims, 11.4 percent overall, so the correlation
3 is high, but the absolute difference seems very
4 real to me on a measure with 11.5 percent
5 performance to have a 3 percent difference.

6 So I don't know if other Committee
7 members had thoughts, or if we should go ahead
8 and then, because of time, go to developers, but
9 I think this is one of the questions Mahesh and
10 also the work group had concerns about.

11 DR. DAHLERUS: Yeah, so this did come
12 up as an issue during the work group call, and as
13 a result of that, we actually reran the analysis
14 using much more current data, so we used calendar
15 year 2013 data, and we did the analysis to
16 compare agreement using Medicare claims and
17 CROWNWeb.

18 And the difference, the absolute
19 difference, goes away. So again, both sources
20 report very similar mean -- facility-level means,
21 10.8 percent, in claims, 10.3 percent, and the
22 correlation was 0.8, so moderate to strong, and

1 it was statistically significant, and then the
2 kappa was 0.81, and again, statistically
3 significant.

4 DR. KRISHNAN: So this was -- just for
5 clarity, this was a number of patients who had
6 data from claims compared to the number of
7 patients who had data from CROWNWeb for the same
8 facilities, or across the entire population.

9 DR. DAHLERUS: No, they were matched,
10 patients were matched in both sources.

11 DR. KRISHNAN: And the percentages you
12 gave are for the entire aggregate population, or
13 is there a variance by facility at -- if you did
14 it by facility, or did you do it by facility, or
15 did you do it at the universal level?

16 DR. DAHLERUS: This is facility-level.

17 DR. KRISHNAN: So the -- but if you
18 did the measure by claims, and if you did the
19 measure by CROWNWeb, the kappa at the -- you're
20 looking at the kappa per facility across all the
21 different facilities, right? Great, yes, I'd
22 love to see that.

1 CO-CHAIR ANDERSON: Any other comments
2 or questions? Yes, Frank.

3 DR. MADDUX: Just a clarification,
4 Claudia. How do you handle missing data on this
5 measure, or unknown?

6 DR. DAHLERUS: So for the catheter
7 measure, if there is missing data, I believe
8 those patients are still included in the
9 numerator, and so that would count against the
10 facility, and if they are missing -- so this is
11 for catheter, and then if they're missing for
12 fistula, they are not given credit.

13 DR. KRISHNAN: Well you may know this,
14 but I wasn't at the CROWNWeb users' group,
15 because I know the networks track this, do you
16 know what the percentage of -- I think the
17 networks are incentivized to have a zero percent,
18 or some really low, vascular access failure rate.
19 Do you know what the current rate is? Did they
20 say in the meeting?

21 DR. ANDRESS: I'm sorry, the current
22 vascular access failure rate?

1 DR. KRISHNAN: The missing data,
2 right? So the networks, that is the metric they
3 track. Did they say -- I wasn't in the meeting
4 last week -- did they say what their current,
5 most recent percentages of --

6 DR. ANDRESS: I am not sure -- I am
7 not sure what it is specific to the fistula data,
8 no.

9 DR. KRISHNAN: Or the vascular access
10 in general, they didn't say?

11 DR. ANDRESS: I -- I don't recall from
12 the meeting. I am sure we can probably ask them
13 and follow up, but I don't have that information
14 right now.

15 CO-CHAIR ANDERSON: All right. Let's
16 go ahead and vote on reliability, both the
17 specifications and the testing.

18 MS. OGUNGBEMI: For measure 0256, the
19 Committee is now voting on reliability. This
20 includes precise specifications and testing.

21 The options are 1 high, 2 moderate, 3
22 low, 4 insufficient, and voting is open.

1 The results are 4 votes high, 16 votes
2 moderate, 2 votes low, and 0 votes for
3 insufficient. Measure 0256 passes on
4 reliability.

5 CO-CHAIR ANDERSON: All right. Let's
6 go ahead and move on to validity and validity
7 testing, or validity.

8 DR. GREENSTEIN: So there were no
9 exclusions, and the patient population does not
10 include pediatrics, and it was felt to be
11 appropriate, and there was no risk adjustment
12 either, so we all thought there was -- the
13 consensus was that it was fine from a validity
14 testing point of view.

15 CO-CHAIR ANDERSON: Jessie, any
16 additional comments?

17 MS. PAVLINAC: Just that they looked
18 at both SMR and SHR measures there to get the
19 data, to do the --

20 CO-CHAIR ANDERSON: Any comments or
21 discussion or questions on the part of the
22 Committee?

1 DR. KLIGER: Just quickly. So Stuart
2 and Jess, what was your opinion of the validity?

3 DR. GREENSTEIN: I thought it
4 demonstrated good validity. We didn't have a
5 problem with it, actually.

6 DR. KLIGER: You would say high?

7 DR. GREENSTEIN: Yes.

8 MS. PAVLINAC: I'd say moderate.

9 CO-CHAIR ANDERSON: We're ready for
10 the vote for validity.

11 DR. KRISHNAN: Just curious, why is
12 there such a difference between you two, Jessie
13 and Stuart?

14 MS. PAVLINAC: Yeah, I would say
15 personality. On a Likert scale, I am never a one
16 or a five, so it's really hard for me to get to
17 it being perfect. Sorry.

18 MS. OGUNGBEMI: The Committee is now
19 voting on validity for measure 0256. This
20 includes specifications consistent with the
21 evidence, testing and threats addressed,
22 exclusions, risk adjustments and stratifications,

1 meaningful differences, comparability, multiple
2 specifications, and missing data.

3 The options are 1 high, 2 moderate, 3
4 low, 4 insufficient, and the voting has opened.

5 The results are 8 votes high, 14 votes
6 moderate, 0 votes low, 0 votes insufficient.

7 Measure 0256 passes on validity.

8 CO-CHAIR ANDERSON: All right, moving
9 on to feasibility.

10 DR. GREENSTEIN: So the data is
11 actually collected already via CROWNWeb and
12 Medicare claim forms, so it was felt to be quite
13 feasible in terms of data collection.

14 CO-CHAIR ANDERSON: Jessie?

15 MS. PAVLINAC: I agree, and I even
16 think it's high. I'm sorry.

17 (Laughter.)

18 MS. PAVLINAC: You've got those two,
19 those two -- the only things we've got, right
20 guys?

21 CO-CHAIR ANDERSON: Any further
22 discussion or comments? Yes, Mahesh.

1 DR. KRISHNAN: Is -- so is the intent,
2 maybe for the developer, is the intent to migrate
3 from claims to CROWNWeb for these and the other
4 measures? Is that true?

5 DR. ANDRESS: Are you referring
6 specifically to the QIP, or --

7 DR. KRISHNAN: Yes.

8 DR. ANDRESS: So, you know, again,
9 with the proviso that we can never truly say what
10 we are going to do in the future with regard to
11 the QIP, I think our -- you know, we implemented
12 the collection through claims data because the
13 CROWNWeb system was delayed several years ago.
14 We now have the CROWNWeb system live. We are, as
15 you are well aware, you know, working through the
16 -- working through the, sort of the startup bugs.

17 I think we have not yet decided upon
18 a process for making the decision for a
19 transition. I think we find CROWNWeb to be
20 ultimately a preferable data source because it is
21 not limited only to Medicare patients.

22 What that portends for the, you know,

1 for the QIP, one can only imagine.

2 CO-CHAIR ANDERSON: Okay. Ready to
3 vote for feasibility.

4 MS. OGUNGBEMI: The Committee is now
5 voting on feasibility for measure 0256. This
6 includes data generated during care, electronic
7 sources, data collection that can be implemented.

8 The options are 1 high, 2 moderate, 3
9 low, and 4 insufficient. Voting has opened.

10 The results are 21 votes high, 1 vote
11 moderate, 0 votes low, and 0 votes insufficient.
12 Measure 0256 passes on feasibility.

13 CO-CHAIR ANDERSON: All right, moving
14 on to usability and use.

15 DR. GREENSTEIN: So the measure is
16 publicly reported, and there is an accountable
17 application, both via the Dialysis Facility
18 Compare and also ESRD QIP so that clearly, there
19 is a usability element to this, and I thought it
20 was fine. I don't know what Jessie thought.

21 MS. PAVLINAC: Yes.

22 CO-CHAIR ANDERSON: Any comments or

1 questions, further discussion?

2 All right, we are ready to vote on
3 usability and use.

4 MS. OGUNGBEMI: The Committee is now
5 voting on usability and use for measure 0256.
6 This includes accountability and transparency,
7 improvement, and if benefits outweigh evidence of
8 unintended negative consequences.

9 The options are 1 high, 2 moderate, 3
10 low, 4 insufficient. Voting is now open.

11 The results are unanimous: 22 votes
12 high, 0 votes moderate, 0 low, and 0
13 insufficient. The measure 0256 passes on
14 usability and use.

15 CO-CHAIR ANDERSON: All right. We
16 will now be voting on whether or not to recommend
17 the measure as a suitable measure for
18 endorsement.

19 MS. OGUNGBEMI: The Committee is now
20 voting on overall suitability for endorsement for
21 measure 0256, answering the question does the
22 measure meet NQF criteria for endorsement?

1 The options are 1 yes, 2 no. Voting
2 is open.

3 Again, unanimous decision. For
4 overall suitability for endorsement, the measure
5 passes. There are 22 votes and 0 votes no, for
6 measure 0256.

7 MS. BAL: All right. So that does
8 conclude this measure, and lunch is here now. We
9 will grab food and come back at the scheduled
10 time, which is 1:15. We were going to do a
11 working lunch anyway, we just did it backwards.

12 We did have to get through one more
13 measure in this selection and do related and
14 competing for that, and then continue on our
15 schedule, so please go ahead and grab food and
16 whatever else you need and be back by 1:15.

17 (Whereupon, the above-entitled matter
18 went off the record at 1:03 p.m. and resumed at
19 1:16 p.m.)

20 CO-CHAIR ANDERSON: Okay, so the next
21 measure is 0257 hemodialysis vascular access.
22 The developers are Claudia and Joel and the

1 discussants are Stuart and Lorien. Are Claudia
2 and Joel here?

3 DR. DAHLERUS: I'm sorry. So this is
4 the paired measure to the catheter measure that
5 was just reviewed. This is measure 0257. It's a
6 facility level intermediate outcome measure that
7 reports the percentage of adult patient month for
8 patients on maintenance hemodialysis during the
9 last treatment of the month using an endogenous
10 AV fistula with two needles.

11 The intent of the measure, as paired
12 with the catheter measure, was to recognize
13 facility efforts to increase fistula use as the
14 primary vascular access. This measure treats
15 fistula as a positive outcome in prolonged use of
16 channel catheter as a negative outcome and treats
17 AV graft use as neutral. AV fistula has a longer
18 median survival time, required less costly and
19 invasive intervention to maintain patency and are
20 less likely to become infected.

21 As we mentioned in our response on the
22 April 23rd work group call of us and just

1 recently in the last session, a TEP was recently
2 convened to review both measures. And there was
3 a lot of discussion at the TEP about the current
4 specifications to the fistula measure that, as
5 currently defined, allows a facility to get
6 credit for fistula even in the presence of a
7 catheter. And this again has to do with the
8 function of the data elements as defined in
9 CROWNweb which is used to calculate the measure
10 for the testing.

11 The measure is going to be undergoing
12 further revision as a result of the TEP
13 deliberations, so obviously no revisions were
14 made to the measure that was submitted at this
15 time. And the TEP is currently, we're currently
16 summarizing the recommendations that were made by
17 the vascular access TEP. One of the concerns
18 that was discussed by the TEP during the
19 deliberations was cases where a fistula may not
20 be appropriate for a patient due to multiple
21 failed attempts at having fistula mature and this
22 could be the case, for example, in older, infirm

1 patients and therefore a graft may be more
2 appropriate and currently there is no way that
3 the fistula measure would account for that and
4 give credit to that for facilities. I think I
5 will just end there.

6 CO-CHAIR ANDERSON: All right, Stuart,
7 Lorien.

8 DR. GREENSTEIN: So, this is really
9 part two of the previous one, my online. It's an
10 intermediate outcome which correlates AV fistula
11 impact on mortality. The evidence does support
12 that AV fistula is the primary choice. But again
13 as was mentioned, it doesn't really address the
14 complexity of the issue of decisionmaking of
15 whether or not you should go for fistula versus
16 whether or not you should have a graft put in and
17 minimize the torture to the patient over time.
18 But overall, it was felt to be a good measure.

19 DR. DALRYMPLE: So as part of the
20 evidence KDOQI guidelines were submitted that
21 fistula preferred access type with a grade B.
22 The quantity quality consistency were not

1 directly presented in the measure. However,
2 there was a summary of a literature review.
3 There was not a systematic review of the body of
4 evidence presented within the measure. However,
5 there was a literature review since the last
6 maintenance cycle. And there were 52 articles
7 listed. However, there were not summaries for
8 each of the cited articles, so we could not
9 access the findings from that. So based on the
10 algorithm and the materials as submitted in the
11 measure, I gave the evidence rating as moderate.

12 CO-CHAIR ANDERSON: Discussions or
13 comments?

14 Mahesh.

15 DR. KRISHNAN: We've mentioned the
16 unintended consequences of fistula first multiple
17 times, how do we think about this measure based
18 on the discussion we had. I know we've talked a
19 few times about little old ladies getting
20 multiple fistulas placed, never maturing, how do
21 we balance this out in terms of the evidence?

22 DR. GREENSTEIN: I agree with you.

1 There's definitely an outcome that can be very
2 negative to the patient and that is they keep
3 trying to do a fistula and you keep doing
4 balloonings, angioplasties, whatever. The
5 problem is you don't collect that data and I
6 would maintain that that's something that's just
7 as critically important because without that data
8 we have no way of really knowing whether or not
9 we should go the fistula route versus the graft.
10 I have my own preferences when I evaluate a
11 patient and that's in clinical practice. I know
12 because I have somebody who's, let's say, 75 or
13 80 years of age, there's no point for me to
14 torture them to try to do a fistula if their
15 veins really are plus minus. But not everybody
16 goes that route. There's no doubt about it.

17 DR. DALRYMPLE: So, I think in terms
18 of unintended consequences, that will also come
19 up in usability and there was some discussion of
20 that. In terms of the evidence helping us
21 understand the complexity of vascular access
22 decision making, I don't think it's there. We

1 have guidelines and again, it comes out as what
2 was this KDOQI these are your preferred sites and
3 order, but that really doesn't get at those of us
4 who have patients we know are not fistula
5 candidates who go straight to graft because it's
6 medically appropriate.

7 I guess the counter balance would be
8 this ends up being combined with catheter plus
9 fistula, but I think this issue, I don't know if
10 the committee wants to discuss an evidence or
11 usability, but there was concern about unintended
12 consequences. I think as many of us have come to
13 realize with fistula first that perhaps catheter
14 last is the better emphasis.

15 CO-CHAIR ANDERSON: Alan?

16 DR. KLIGER: Can I ask the developer,
17 please? You said that you have a committee that
18 has looked at this and has some suggestions or
19 changes they intend to make, but are not ready to
20 make yet. Were any of them driven by the
21 evidence? Can you help us with the evidence and
22 what your committee thought about the evidence?

1 DR. ANDRESS: So any summary I provide
2 you is going to be my impressions during the
3 discussion. I think we're working on getting the
4 formal report together and that will be available
5 publicly at a later date.

6 The kinds of things that we were
7 looking at, as I recall, tended to focus on
8 circumstance, tended to focus on looking at
9 strategies for risk adjustment or exclusion in
10 circumstances where a patient is potentially a
11 poor candidate for fistula use where, for
12 instance, where conditions are in place or
13 conditions are present where fistula failure is
14 deemed to be a substantial risk. These were the
15 kinds of things that were considered by the TEP
16 in modifying the measure. I think that's about
17 as much detail as we can get into that.

18 DR. DAHLERUS: And I just wanted to
19 provide a little bit of clarification in terms of
20 the sequence of events. So we did our initial
21 reliability and validity testing and assessment
22 of both the measures late last fall in order to

1 have the forms ready to submit to NQF in
2 February.

3 The TEP only convened at the very end
4 of April and considered the evidence, as well as
5 later preliminary analyses, that we conducted in
6 preparation for the TEP. So what you have
7 reviewed on the form is not as current as some of
8 the later analyses and summary of the literature
9 that was discussed with the TEP.

10 DR. KLIGER: Right, just quickly in
11 follow up. So I get that, but did the TEP
12 identify new or additional evidence that would be
13 helpful for this committee to hear?

14 DR. DAHLERUS: So at this time I think
15 it's a little premature to discuss TEP
16 recommendations as we are still preparing the
17 final report which needs to be reviewed by the
18 TEP. They did recommend additional analyses, but
19 I don't think we would feel comfortable
20 presenting anything as final recommendations
21 since they just met two weeks ago and haven't had
22 an opportunity to review our draft summary

1 report.

2 DR. KLIGER: Yes, I'm just
3 disappointed, I must admit. We rarely -- we
4 consider these measures twice a decade and so
5 it's a shame not to have the most current data
6 available to us for that.

7 MR. MESSANA: Can I just follow up on
8 that comment? Alan, I agree with you as a
9 general statement. The compact that we make with
10 a TEP is that it's our job to try to record their
11 opinions and their statements. Part of that
12 compact, part of making sure we get it right
13 because these are publicly-available opinions is
14 that we write a draft. They review and edit it
15 and then sign off that it fulfills their -- it
16 accurately represents their opinions and their
17 statements and their ideas about this.

18 What I will say, as an observer there,
19 I wasn't a facilitator at that TEP, but what I
20 will say as an observer is that much of the
21 discussion focused around whether the equipoise
22 about fistula and graft and catheter, that is,

1 that we talked about three years ago at this
2 meeting, where you have an implied mid portion,
3 kind of a mathematically equivalent difference
4 between a catheter and a fistula when you have
5 two linked measures that excludes graft, whether
6 that general relationship is correct or whether
7 fistula and graft are closer together as some
8 members of this group have stated and whether
9 that's true for all or whether that's true for
10 some populations. That's the general discussion
11 that went on, but until the TEP has an
12 opportunity to actually review what we think we
13 recorded, it would be unfair for us to
14 characterize it further out of respect to them.

15 MS. BAL: And just a quick question,
16 when would that be available in case we could
17 bring it to the committee for the post-comment
18 call?

19 DR. ANDRESS: I'm sorry, can you
20 repeat the question?

21 MS. BAL: So my question was when that
22 would be available, if it's going to be available

1 as a post-meeting comment call, we could provide
2 it to the committee at that point, but if it's
3 not going to be available --

4 DR. ANDRESS: I want to be clear on
5 something. When we discussed this with NQF in a
6 previous state, I mean there's an understanding I
7 thought that we'd be submitting the measures as
8 they currently exist for the review for this
9 committee.

10 We are certainly considering the
11 changes that can be made to the measure in the
12 future and those changes we anticipate will be
13 submitted to this committee for its discussion at
14 that point. I think we have a time line for when
15 we think the draft will be ready. That is, of
16 course, subject to change depending on the TEP's
17 feedback and it would be irresponsible to try to
18 provide you with a specific date by which we'll
19 have everything hammered out.

20 We expect, we've been talking
21 generally about having a project early next year.
22 We expect this measure will probably be available

1 for submission at that time and I think we'll be
2 in a position to be able to speak more fulsomely
3 about what recommendations came out of the
4 street.

5 I thank you, Joe, for recentering the
6 discussion on this point. It got a little lost
7 in the weeds out of desire to be helpful, but I
8 want to make clear, the measure is submitted as
9 it is. We are asking for continued endorsement
10 of this measure as it is. This measure is
11 implemented in the Quality Incentive Program.
12 Any alterations to that would require rulemaking
13 and would require time, certainly. And as such,
14 the consideration of endorsement of this measure,
15 as it is currently specified remains relevant
16 even in the face of a TEP that's meeting to
17 address some of the concerns that you have raised
18 here and that I suspect will continue to be
19 raised in this discussion.

20 But we don't have any particular
21 intention to modify the measure as we go through
22 the process here. I think that would be one,

1 incredibly difficult to do, and two, I think it
2 would be inappropriate and well outside the scope
3 of this group.

4 That being said, I think you all have
5 ample opportunity to review the measure when we
6 do submit and to make a decision about whether or
7 not we have addressed many of the concerns that
8 you may have for the measure. And we'd certainly
9 welcome the raising of those concerns here or
10 during public comment. I don't mean to shut off
11 discussion, but on the issue, if we try to fix
12 the measure, if it can be termed that, while
13 going through this process and while going
14 through the development process, we are going to
15 have chaos. And I think that's not particularly
16 helpful to anyone's purposes here.

17 CO-CHAIR ANDERSON: All right, Frank.

18 DR. MADDUX: Knowing that there are a
19 number of vascular access related measures and
20 there's new information that we'll have at some
21 point in the not too distant future, it seems to
22 me one of the questions that we have is whether

1 we re-endorse an existing measure for a length of
2 time that's going to cross over that period where
3 we have new information to base it on.

4 I guess I'm asking Poonam and Sarah
5 and others is there any guidance with regard to
6 the fact that we anticipate we're trying to make
7 a decision knowing that there's additional
8 information that should be considered in front of
9 us. So is it strictly a yes or no on what exists
10 today or is there some way to recognize the fact
11 that we anticipate the decision might be
12 substantially different once there's new
13 information?

14 MS. BAL: Right now, your decision
15 will be only based on what you have in front of
16 you. However, as you mentioned earlier, there is
17 the annual review at which point the developers
18 give it an opportunity to supply any new
19 information. As it seems they supply something
20 that requires additional review, we would bring
21 it back to this committee and do a different
22 review.

1 And so it wouldn't be that it would
2 just be waiting or that changes would be made and
3 they wouldn't come to your attention. If a major
4 change is made, it will come back to the
5 committee.

6 MS. SAMPSEL: Let me just add and
7 because this is something that's happened in
8 other -- for other measures, other topic areas as
9 well. That's one of the reasons that this is a
10 standing committee so that as changes to the
11 measures, you will have those come before you.
12 There will be identification is this a
13 substantial change for measure that could warrant
14 a revote or reconsideration of the endorsement or
15 is it just a minor -- they've added a code or
16 something which we would not bring back.

17 But we can also put in the report and
18 also signal to Joel and the developers that this
19 is something that you want to monitor. A similar
20 situation has to do with there are behavioral
21 health measures that kind of reimbursement for
22 certain types of behavioral health services is

1 changing. And so the committee strongly advised
2 the developers for that project that we want to
3 know in a year where you are in changing your
4 codes on getting this measure up to standard and
5 up to evidence. And so absolutely, that can be a
6 clause put in, we approve as it's specified right
7 now or we recommend it or we don't recommend it
8 as is specified right now, but developer, we want
9 to see this back and we do want updates on it.

10 DR. KLIGER: I apologize, but just one
11 last piece which is it surely would use this
12 committee's time much more effectively if we
13 didn't go through this whole process now only to
14 look at it again in the near future because
15 there's a simultaneous look at the measure.
16 Wouldn't it be wiser to wait until that's in
17 before we spend our time doing this?

18 MS. SAMPSEL: I would say the other
19 thing that NQF is in the process of is
20 identifying a more streamlined review process
21 when there are just minor changes to the measure
22 so that in the event that it does come back with

1 minor changes, it may not be all the criteria
2 that you're going through and voting on, but just
3 for whatever specific portion of that measure.
4 And it's hard to say without an assumption of
5 what's being changed in the measure, but that is
6 part of the process that's being looked at. And
7 we do understand, but at the same time the way
8 that this measure is submitted right now and the
9 interest in keeping it endorsed as it's
10 specified, the process sits.

11 CO-CHAIR ANDERSON: Yes, Josh.

12 DR. ZARITSKY: Just a technical note
13 here. This is a clinical outcome we're looking
14 at evidence for, not as the analysis as an
15 intermediate clinical outcome, right, the
16 preliminary analysis?

17 DR. DALRYMPLE: I believe during some
18 of the work group pre-evaluation, it was listed
19 as an intermediate clinical outcome, but I guess
20 we as a group can -- if that's how it was
21 initially specified, but clearly here it's being
22 weighted as an outcome.

1 MS. SAMPSEL: So I'll just have to --
2 I need to comment on that, too. So right now and
3 we just ask that you all not hold the developers
4 accountable for this, but the way that you fill
5 out the forms in the NQF system right now in that
6 very front part of the form that identifies if it
7 is a process and outcome, et cetera, they don't
8 have a choice of intermediate outcome which is
9 why all of them either say process or outcome.
10 We don't have any of the other types of measures.

11 It's when you get into the evidence
12 portion of the measure that you can identify if
13 it's an intermediate outcome or not. And for the
14 most part, staff caught those before they came to
15 you. Sometimes it happened in the work group. I
16 think there was only one or two that we didn't
17 catch it, but then the developer did make those
18 changes subsequent to coming to this meeting
19 today. So that's -- unfortunately, it's the way
20 that the information is collected through the NQF
21 system right now.

22 DR. ZARITSKY: We need to vote on the

1 high, moderate, right?

2 MS. BAL: Ignore the voting slides
3 right now, those aren't actually what's up.
4 Those are just a place holder for now.

5 We'll make sure to keep the correct
6 ones up. Thank you.

7 CO-CHAIR ANDERSON: John.

8 DR. WAGNER: I would just like to
9 clarify. On the annual review, is the measure
10 developer obligated to incorporate the new
11 information that we're discussing here into the
12 view that they then present about the necessity
13 to change the measure?

14 MS. SAMPSEL: Let me make sure I
15 understand. So based on the information that
16 we've provided here during their annual review,
17 are they required to respond to that?

18 DR. WAGNER: We've said that we
19 believe there will be new information forthcoming
20 that may influence -- if that information was
21 present today that might influence our decision
22 making today. But we're not privy to that

1 information or we're to take that information
2 into account because we're supposed to take the
3 information as presented to us today into
4 account.

5 If there is new information, does the
6 measure developer -- must that measure developer
7 take that information into account in their
8 annual review so that we know that that
9 information is incorporated into whatever
10 decision is made with respect to changing the
11 measure?

12 MS. SAMPSEL: So that's part of the
13 documentation and reporting process in that we do
14 -- we will have continual conversations with the
15 developers to make sure that the changes --
16 although we don't know what they are, but one
17 that they're substantial and then two, that they
18 would come back as substantial for consideration.

19 DR. KRISHNAN: Just so I'm clear,
20 we'll vote on this measure now as we did the
21 prior one, the TEP will report out. That may
22 result in additional measures being developed or

1 current measures being tweaked. Then it will
2 come back to this committee at some point in the
3 future to reconcile. Is that the way I should
4 think about it?

5 MS. SAMPSEL: I would say it's not
6 necessarily -- I'm having a little bit of a
7 problem with the reconcile part of it. But yes,
8 I mean so basically --

9 DR. KRISHNAN: Wrong word.

10 MS. SAMPSEL: No, no, no, that's
11 right. What I would see would happen here is
12 that whatever decision comes out of this, but
13 let's say that the measure is recommended as it's
14 currently endorsed. So it stays with this in its
15 current recommendation. And then apart from this
16 NQF process, CMS and University of Michigan are
17 reacting to their TEP maybe making changes to
18 that specification.

19 While it's required during the annual
20 review that they then provide us any changes to
21 the measure, in the meantime we're having ongoing
22 discussions with CMS and University of Michigan

1 to know where they are in their TEP cycle,
2 understanding measures, and this has implications
3 otherwise as well. So yes, it will then come
4 back to you as a standing committee.

5 DR. KRISHNAN: Thank you.

6 CO-CHAIR ANDERSON: Any further
7 comments or discussions on the evidence of the
8 measure? We are ready to vote.

9 MS. OGUNGBEMI: The committee is now
10 voting on evidence for measure 0257. The options
11 are one, high; two, moderate; three, low; and
12 four, insufficient. Voting is now open.

13 MS. BAL: And also just to comment,
14 you can start voting once the slide is up, so you
15 don't have to wait for Alexandra to finish.
16 We're going to try one more time. Give us a
17 second.

18 Go ahead and try one more time for us.
19 Are you still getting error message? Okay. So
20 we're going to have to go old school for a
21 second. And start voting with hands until we can
22 get this technology problem fixed.

1 So I'll go ahead and ask for a hand
2 vote. So if you vote high, please raise your
3 hand. I count two. So moderate. Okay, so low.
4 And insufficient.

5 Okay, so the total is 2, high; 19,
6 moderate; 0, low; 0, insufficient. And we'll
7 move -- for evidence, 0257, and we'll work on
8 technology while you guys discuss gap.

9 CO-CHAIR ANDERSON: All right. We're
10 moving on to performance gap.

11 DR. GREENSTEIN: So similar to the
12 other one, we did recognize that there was a
13 disparity in performance gap although not that
14 large. Again, just like the other one, we felt
15 that it should be listed as a disparity-sensitive
16 gap.

17 DR. DALRYMPLE: So in terms of
18 opportunity for improvement, CROWNWeb data from
19 2013 presented. The mean percentage of patient
20 months with AV fistula was 67 percent. The first
21 quartile was 60 percent and the third quartile
22 was 75 percent. No national goal rate is stated,

1 but I think you could infer from the bottom
2 quartile that there is room for improvement.

3 In terms of disparities, can you pull
4 that up first? I believe it's page 16. So this
5 is one where I think as a work group we were more
6 impressed by the differences, by -- pull it up so
7 everyone can see it.

8 So as you can see here in females, for
9 example, patients who are black, white, Hispanic,
10 in some of these groups, bigger spreads between
11 the first quartile and the fifth quartile such as
12 71 percent versus 60 percent. So I don't know if
13 you all want us to go through each disparity
14 listed as a committee or if you just want us to
15 acknowledge disparities were present and it
16 depends on -- is that what you would like?
17 Disparities were present on our assessment.

18 CO-CHAIR ANDERSON: Any comments or
19 discussions regarding performance gaps and
20 Lorien's comment about the disparity issues?

21 MS. BAL: We're going to try the
22 software again.

1 CO-CHAIR ANDERSON: We are ready to
2 vote on performance gap.

3 MS. OGUNGBEMI: For measure 0257 the
4 committee is now open for voting on performance
5 gap. The options are one, high; two, moderate;
6 three, low; and four, insufficient.

7 MS. BAL: We're still short a couple.
8 If everybody could put their -- we need 22.

9 MS. OGUNGBEMI: The results are 24
10 percent high; 76 percent moderate; 0 low; and 0
11 insufficient. The measure 0257 passes on
12 performance gap.

13 CO-CHAIR ANDERSON: Moving on to
14 reliability and reliability testing. Stuart or
15 Lorien.

16 DR. GREENSTEIN: Let me just get to --
17 so again similar to the other measure, the data
18 elements were clearly defined and we felt that
19 the measure was primarily designed for collection
20 via CROWNWeb and Medicare forms and that there
21 was good specification and reliability. We had
22 no concerns.

1 DR. DALRYMPLE: I think we had one
2 concern, Stuart, if you don't mind me weighing
3 in.

4 DR. GREENSTEIN: Sure.

5 DR. DALRYMPLE: On the specification
6 and I think the developers may want to respond
7 because this came up on the work call and may be
8 relevant to the TEP, although they may be able to
9 give us limited information.

10 So if you look at the specification in
11 CROWNWeb, you're counted as having an AV fistula
12 with two needles if you "have an AVF combined
13 with a catheter." And also from the claims data,
14 if you have vascular cath. which I think is
15 vascular catheter, yes, or a fistula, yes.

16 So one of the issues that came up is
17 that actually appears what's being captured are
18 people who have catheters plus fistulas and do we
19 think this is consistent with the title of the
20 measure that specifies fistula with two needles
21 in place because we took this to mean potentially
22 those patients who have developing fistulas and

1 are either still relying on their catheter or
2 doing one-to-one needles for example. So that
3 came up with a concern about specification being
4 consistent with what the title implies of this
5 measure. So I think the developers were going to
6 give us more feedback here today.

7 DR. DAHLERUS: So again this is
8 something that got a lot of discussion at the
9 vascular access TEP about the fistula measure.
10 And the way the measure is currently scored, yes,
11 facilities will get credit for having a fistula
12 even if a catheter is present. This is going to
13 likely be one of the recommended changes to the
14 fistula measure, but again we haven't revised the
15 measure yet to reflect such a change. And again,
16 this is also attributed to how the different data
17 fields are defined in the respective Medicare as
18 well as CROWNWeb data sources.

19 CO-CHAIR ANDERSON: I think I'm a
20 little confused here because I thought what's in
21 the CROWNWeb data is two needles with a fistula.
22 If you still had a catheter in place, catheter

1 still is what's actually recorded, even though
2 you have a fistula with two needles. As long as
3 the catheter is remaining in place, it still
4 counts as a catheter versus as the fistula.

5 DR. KRISHNAN: So let me try to help.
6 We've gone through this with CMS and CMS actually
7 recognizes this issue starting with what happened
8 with the KQRV on the claims in 2010 or 2011. The
9 microspecifications of exactly what people want
10 as it relates to what we map from our EMR are
11 being defined specifically for the fistula first
12 initiatives and some of these other things.

13 So it will clarify it because right
14 now there is some component of subjective
15 interpretation on the part of the person making
16 the link up between what's in the EMR and what
17 gets submitted. And the goal is to provide
18 sufficiently granular microspecifications to
19 minimize that variability. So even though I harp
20 on this, it is definitely something that we're
21 working with CMS. CMS recognizes that we
22 recognize it because if we're just told

1 "fistula", there's a lot of variance of fistulas,
2 right? So it was very eye opening when we had
3 this discussion amongst four major batch
4 providers that control 90 percent of the
5 submissions for U.S. We all had slightly
6 different definitions and so our mapping was
7 slightly off, but there is a macro initiative for
8 everything data to specify that in a
9 microspecification manual.

10 So I'm confident we'll solve it by the
11 time this gets there, but the operating
12 definitions aren't as smooth because we don't get
13 to that level of detail necessarily when we
14 specify measures, but you need to when you do the
15 implementation.

16 CO-CHAIR ANDERSON: Lorien?

17 DR. DALRYMPLE: And so I think perhaps
18 one of our recommendations would be simply that
19 if we correctly understand the specification that
20 you can have a fistula and a catheter and be
21 counted in the numerator and that the brief
22 description of the measure is perhaps not as

1 accurate as it could be because it states using
2 an AV fistula with two needles which we don't
3 think these specifications are per se consistent
4 with.

5 DR. DAHLERUS: We'd actually like to
6 speak to this issue, but I'm going to defer to
7 Dr. Messina.

8 MR. MESSANA: So in preparation for
9 the vascular access TEP and at the vascular
10 access TEP and this wasn't an opinion from the
11 TEP members, but we did work with someone who was
12 on the TEP who has high level working knowledge
13 from the network perspective. If you look at the
14 CROWNWeb definitions, there is a separate
15 definition in CROWNWeb for one lumen or one
16 needle in the fistula and blood flow through one
17 lumen. So there is that level of granularity in
18 the CROWNWeb data.

19 The problem that the networks
20 identified as being particularly relevant here is
21 that if you have a fistula and a catheter is
22 still in place, but you use the fistula and a

1 catheter is still in place, but you use the
2 fistula with two needles, it still counts -- it
3 counts in CROWNWeb as the numerator is the
4 fistula. So there's the potential to hide a
5 catheter if you use a fistula early.

6 The claims definition is different,
7 but has been developed to be consistent with or
8 attempt to be consistent with the CROWNWeb
9 definition. Under the Medicare claims right now
10 you use V modifiers, right? And you are
11 instructed to if a catheter is present at all,
12 whether it's being used or not, you have to
13 report V5.

14 If a fistula is present, okay, you are
15 instructed to report -- and a catheter, you are
16 instructed to report both. And so a claims-based
17 metric could be defined either way, the complete
18 absence of a catheter or the presence of a
19 catheter and a fistula with the fistula being
20 used.

21 Right now, the claims definition is
22 being -- has been defined to be consistent with

1 the CROWNWeb reporting instructions. So for
2 clarity, it raises all the sediment in the pond
3 for everybody, but the fact of the matter is the
4 specific thing that you raise as an issue
5 shouldn't be happening in CROWNWeb if people are
6 interpreting the instructions correctly.

7 There is a difference between one
8 lumen and one needle versus fistula with two
9 needles, but a catheter is still hiding in the
10 background.

11 DR. DALRYMPLE: So in CROWNWeb, when
12 the numerator is counted then should this field,
13 AV fistula combined with a catheter be included
14 in the numerator for this measure or should it
15 only be those who have AVF with two needles
16 checked? I don't know what CROWNWeb looks -- so
17 I'm just looking at what fields were quoted to us
18 in the specifications.

19 MR. MESSANA: So I guess the numerator
20 right now means from CROWNWeb that fistula was
21 used with two needles, whether or not a catheter
22 was present. And that's because that's the

1 current instructions for reporting in CROWNWeb.

2 DR. DALRYMPLE: So in the
3 specifications for this measure, where it says
4 the numerator counts if the following is checked
5 AVF combined with a catheter in CROWNWeb is what
6 shows up in our measure specifications for review
7 of the numerator. It says if this or this is
8 checked, then they get counted as a yes and one
9 of those is AVF combined with a catheter, the
10 specifications that were submitted to us for
11 review. But if we're misunderstanding, please
12 clarify it because this was one of the struggles
13 on our work call to understand these
14 specifications.

15 MR. MESSANA: Apparently it's a
16 struggle on my work call as well. But the
17 definitions are in CROWNWeb whether they've been
18 applied as you think is appropriate or not is a
19 reasonable question. The definitions in CROWNWeb
20 are clear. You can specify two needles and a
21 fistula, one needle and a fistula with one needle
22 in a lumen or using two lumens from a catheter.

1 So that granularity is available. So I'll stop
2 there.

3 DR. KRISHNAN: The definition in the
4 specification, not the data definition?

5 DR. DAHLERUS: So you're talking about
6 the measure description is misleading, yes, yes.
7 And that is something that we plan to revise when
8 we resubmit a potentially revised measure.

9 DR. GREENSTEIN: So how will you
10 revise it to say that it's fistula hemo catheter
11 equals hemo catheter? Will it be revised that
12 you have a fistula hemo catheter it will be
13 considered a hemo catheter or will it be
14 considered a fistula?

15 DR. DAHLERUS: So I think the more
16 fundamental revision would be a more conservative
17 measure for fistula that only gives credit for
18 fistula if that is the only access present. If
19 there is a catheter still present, they would not
20 be given credit for fistula, but that we would
21 count as part of the more comprehensive revision.

22 I think it is probably possible to

1 revise the title of the current measure because I
2 think that requires a minimal change to the
3 measure title for the measure that's up for
4 endorsement maintenance.

5 CO-CHAIR ANDERSON: Any further
6 comments, discussion on the part of the
7 committee? All right, seeing none, I guess we're
8 ready to vote on reliability and reliability
9 testing.

10 MS. OGUNGBEMI: The committee is now
11 voting on reliability for measure 0257. The
12 options are one, high; two, moderate; three, low;
13 and four, insufficient. Voting is now open.

14 There are still more votes that we are
15 missing. Could we just try and get those two in,
16 please.

17 Pardon me. The results are 0 votes
18 for high; 17 votes moderate; 1 vote low; and 2
19 insufficient. The measure passes on reliability.
20 This is measure 0257.

21 CO-CHAIR ANDERSON: All right, moving
22 on to validity and validity testing.

1 Stuart or Lorien?

2 DR. GREENSTEIN: So there were no
3 exclusions and no risk -- I'm sorry, the
4 exclusions were consistent and there was no risk
5 adjustment supplied and there seemed to be
6 meaningful difference between in terms of quality
7 by looking at fistulas and catheters.

8 Lorien?

9 DR. DALRYMPLE: We got hung up on
10 specifications so just so the whole group is
11 aware as we're about to hit validity, they did do
12 IUR. It was 0.76 CROWNWeb versus claims had a
13 kappa of .91. In terms of validity, it was done
14 at the performance measure level. And divided
15 into quintiles and then AV fistula -- percent of
16 patients stylizing with an AV fistula was
17 associated with both the SMR and SHR. I'm not
18 sure that you all want me to read these to you,
19 but that was the process for validity. If some
20 measurers want to weigh in, there also was data
21 provided on CROWNWeb versus claim. My assessment
22 of validity was that it was moderate.

1 DR. GREENSTEIN: Is there an updated
2 analysis, Claudia, for this as well as there was
3 for the catheters?

4 DR. DAHLERUS: Yes. I can't walk and
5 speak at the same time. Yes, so we recalculated
6 the fistula measure using Medicare claims
7 calendar year 2013 as well as CROWNWeb data
8 calendar year 2013. And the agreement for the
9 fistula measure in both sources, the kappa was
10 .92 and it was statistically significant and the
11 correlation between the measure in both sources
12 was .869.

13 DR. KRISHNAN: Just so I understood
14 this, I wasn't clear on this before, so that
15 means for the same patients if you ran them in
16 claims versus CROWNWeb you got that correlation?

17 DR. DAHLERUS: Yes, for patients that
18 were in both sources.

19 DR. KRISHNAN: In both sources. But
20 you don't necessarily know how many patients, you
21 don't know the delta between the number of
22 patients you had a claim in the dialysis unit for

1 that period of time versus the number of patients
2 whose CROWNWeb data made it for that facility?

3 DR. DAHLERUS: No, we do not. Not
4 today.

5 CO-CHAIR ANDERSON: Any further
6 discussions?

7 DR. DALRYMPLE: I just had one more
8 comment that we didn't get to address --

9 CO-CHAIR ANDERSON: Sorry, Lorien.

10 DR. DALRYMPLE: -- which was
11 exclusions. There were none other than the
12 denominator, but I didn't know if the committee
13 wanted to discuss whether there actually should
14 be exclusions in circumstances where an AV
15 fistula would be deemed to be medically
16 inappropriate. And that's come up with other
17 measures and just in general consensus, but it's
18 one of the things we're asked to assess in terms
19 of threats to validity are exclusions or the lack
20 thereof appropriate.

21 CO-CHAIR ANDERSON: And I think this
22 is part of the difficulty because as the TEP met,

1 there may be additional revisions to the measure
2 based on whatever the discussions for the TEP
3 were, so it makes it kind of difficult to know.
4 We're really voting on the measure as the measure
5 is presented and whether or not we want to move
6 it forward with or without the exclusions that
7 are currently in place.

8 DR. DALRYMPLE: And I think we'll be
9 reconciling competing measures, but it's just
10 that discussion of does the committee think there
11 are threats to validity if, for example, patients
12 with a life expectancy less than six months are
13 not excluded from an AV fistula measure or if you
14 can think of other circumstances. The ones that
15 I can think of are, you know, scheduled living
16 donor plan, but need an approximate mixture of
17 ADPKD so we're not going to use a fistula.

18 So I'm just bringing this up as part
19 of our script that was sent out if committee
20 members think there are threats to validity by
21 the lack of exclusions.

22 CO-CHAIR ANDERSON: So Lisa?

1 DR. LATTS: I guess my only comment on
2 that and a very thorough review, outstanding,
3 would be that I think those are all probably
4 true, but I wouldn't expect any systematic bias
5 by any one facility to have any more than any
6 place else. So it's just one of these many
7 measures where you just wouldn't expect the rate
8 to be 100 percent. You expect it to be something
9 less because of all those exclusionary
10 circumstances.

11 DR. WAGNER: Do we collect data on
12 that though? It seems reasonable to say that,
13 but since this is an important question, if the
14 facility is of small size and there are a
15 significant number of patients who either have a
16 lower than expected life expectancy or are old
17 and have frail veins, isn't that something that
18 would be important to collect information about?

19 DR. DAHLERUS: I'm sorry, could you
20 repeat the question?

21 DR. WAGNER: We are deciding that we
22 don't have data on exclusions, but wouldn't that

1 be important to collect such data to see if
2 there are facilities that would particularly be
3 at risk for being judged to have lesser quality
4 because they have patients with limited life
5 expectancy for whom they're not placing fistulas
6 or facilities that have a particularly older
7 population that might have difficulty in having
8 access placed by fistula.

9 DR. DAHLERUS: So that's a great
10 question and actually these were analyses that
11 were recently recommended by the vascular access
12 TEP to look at those factors, those patient
13 characteristics as potential exclusions or for
14 consideration for risk adjustment, but we did not
15 submit these analyses as part of the current
16 measure under consideration.

17 DR. WAGNER: And similarly would there
18 be a role for querying facilities regarding
19 patient preference since there are patients who
20 prefer not to have anything but a catheter? So
21 again, we're assuming that this gets smoothed out
22 in the aggregate, but an individual facility may

1 be particularly affected by these kinds of
2 patients.

3 DR. ANDRESS: So something that's
4 worth -- what I hear is that patient preference
5 is not something that's currently collected
6 through the existing data sources. So the
7 capacity to capture something like that would be
8 extremely limited. I think certainly it would be
9 something that would be of interest to us, but
10 it's not something that we could capture or
11 provide analysis on at this time.

12 DR. WAGNER: We're in the era of
13 patient centeredness, so I think this is an
14 extremely important area to explore and we need
15 to develop information about this because we're
16 in a vacuum when we're talking about this.

17 CO-CHAIR ANDERSON: Any further
18 discussion before we vote on validity? All
19 right.

20 MS. OGUNGBEMI: The committee is now
21 voting on validity for measure 0257. The options
22 are one, high; two, moderate; three, low; four,

1 insufficient. Voting is open.

2 Results are 2 votes for high; 12 votes
3 for moderate; 4 votes low, and 4 votes
4 insufficient. Measure 0257 passes on validity.

5 CO-CHAIR ANDERSON: Okay, moving on to
6 feasibility.

7 DR. GREENSTEIN: So these measures are
8 routinely generated via CROWNWeb and Medicare
9 forms so the consensus was that there essentially
10 was no concerns in the feasibility of this.

11 CO-CHAIR ANDERSON: Lorien. Any
12 discussion on the feasibility? All right, let's
13 go ahead and vote.

14 MS. OGUNGBEMI: The committee is now
15 voting on feasibility for measure 0257. The
16 options are one, high; two, moderate; three, low;
17 four, insufficient. Voting is open.

18 The results are for feasibility 14
19 votes high, 8 votes moderate, 0 votes low, and 0
20 votes insufficient. Measure 0257 passes on
21 feasibility.

22 CO-CHAIR ANDERSON: All right,

1 usability and use.

2 DR. GREENSTEIN: So the measure is
3 commonly used by the ESRD QIP and also from the
4 dialysis facility compared, so these are used for
5 public reporting and payment programs. So we're
6 using it. Not much we can say.

7 DR. DALRYMPLE: So again, sticking to
8 the script, to the best of my ability I thought
9 it would be valuable as the committee to discuss
10 unintended consequences of just measuring pure
11 fistula rates because I think in the last five
12 years this has rapidly evolved. Obviously, we've
13 changed our language a lot realizing that
14 sometimes intentions can do undue harm.

15 So because usability and use includes
16 unintended consequences, I didn't know if the
17 committee at large wanted to discuss the measure
18 that only includes fistula rates.

19 CO-CHAIR ANDERSON: Frank.

20 DR. MADDUX: I think it's obvious
21 because we brought it up so many times that just
22 the fact that there's another TEP having these

1 discussions sort of begs the question that there
2 are issues beyond simply fistulas alone. Again,
3 I'd reiterate I think my biggest concern here
4 with this measure is the duration by which our
5 endorsement applies before we get to the next
6 iteration and that's really my only concern of
7 this measure from a usability standpoint.

8 CO-CHAIR ANDERSON: Any other comments
9 or questions? Are we ready for voting for
10 usability and use?

11 DR. KRISHNAN: Let me just pick up on
12 Lorien's part. Is there an exclusion criteria
13 that we would consider to avoid the unintended
14 consequence? And I don't know how you track
15 that. Just from speculation, I'm sure you've
16 probably put more of these in than any of us. If
17 you had to come up with trying to avoid the
18 little old lady getting five of these and at the
19 same time accruing many catheter days because
20 we're still using the catheter, right, when we're
21 trying to get a fistula, is there something that
22 you would suggest as the exclusion criteria or

1 how does one do that?

2 DR. GREENSTEIN: I don't think you can
3 because you're going to find that there's
4 judgment and that's so variable, you know. So
5 many access surgeons all around the country --
6 I'm not sure how we can ever do that.

7 DR. KLIGER: Now Mahesh, though I
8 guess from my standpoint that's the reason why
9 you need a mature group discussing a measure from
10 the beginning because the facts around
11 constructing the measure change as our experience
12 and as the evidence changes. So asking that
13 question sort of separately, you know, is hard,
14 but that's the whole reason that we hope that a
15 developer puts that together, puts evidence
16 together, assembles their team in adequate time
17 so that we have that information to use to make a
18 decision about that. So it's a very important
19 question. It's not something we can decide
20 today, but that is something the developer needs
21 to address.

22 CO-CHAIR ANDERSON: Any other

1 questions for the developers, comments? All
2 right, let's vote on usability and use.

3 MS. OGUNGBEMI: The committee is now
4 voting for measure 0257 on usability and use.
5 The options are one, high; two, moderate; three,
6 low; and four, insufficient. Voting is open.

7 The results for usability and use for
8 measure 0257 are 5 votes high, 10 votes moderate,
9 4 votes low, and 4 votes insufficient.

10 CO-CHAIR ANDERSON: Okay. Before we
11 vote on recommendation whether to submit this for
12 endorsement, is there any other issue? I think
13 we want to recognize that we are hearing what the
14 concerns are and what the issues have been raised
15 through the committee and we are -- the time line
16 for when the new measure and the changes to this
17 measure based on the TEP outcomes will just be
18 moving forward and at this point we are voting on
19 the measure as the measure is presented as to
20 whether we want to continue to move it forward
21 for endorsement.

22 DR. KRISHNAN: Just to be provocative

1 because I'm thinking of the question I posed to
2 Stuart. It has been proposed by some that in
3 lieu of a fistula and a catheter metric, one only
4 has a catheter measure, right? So you don't have
5 the unintended consequence. I don't know if
6 that's something to debate or talk about, but I
7 don't know what you guys think or not. Poonam
8 says no, so I'll shut up.

9 MS. BAL: Just for the sake of time if
10 it's not relevant to the vote, we would say to
11 continue that conversation at a different point.

12 DR. KRISHNAN: I think it is relevant
13 because we're going to vote on endorsing it or
14 not. If you endorse it, you'll perpetuate what
15 we've had going on. I don't know if there's a
16 solution for it, but -- or if people have any
17 comments. If not, we'll just vote.

18 DR. DALRYMPLE: Can I just ask a
19 general question?

20 CO-CHAIR ANDERSON: Yes.

21 DR. DALRYMPLE: Because I noticed
22 after this we're going to discuss the relation of

1 competing measures. So then do we have an
2 opportunity to try and reconcile -- can you help
3 us with the process so we know the right time to
4 discuss issues like this such as maybe catheter
5 last is really the only needed metric. I think
6 that will come up during competing or in the face
7 of individual measure review.

8 CO-CHAIR ANDERSON: I think we'll be
9 giving you instructions and it will come up in
10 the review of the competing measures.

11 So are we ready to vote for
12 endorsement or not?

13 MS. OGUNGBEMI: I need to first say
14 that the measure passes on usability and use.
15 That's measure 0257.

16 CO-CHAIR ANDERSON: Sorry. For the
17 record. Thanks, Alexandra.

18 All right, now I guess we're ready to
19 vote on whether or not to endorse this measure.

20 MS. OGUNGBEMI: The committee is
21 voting for overall suitability for endorsement
22 for measure 0257. The options are one, yes; two,

1 no. Voting is open.

2 The results are 17 votes yes, 5 votes
3 no. The measure passes for suitability for
4 endorsement.

5 CO-CHAIR ANDERSON: All right, now
6 we're going to move into the related or competing
7 measures and Poonam is going to explain the
8 process.

9 MS. BAL: So, yes. So this is our
10 first grouping related and competing measures.
11 You were sent a form on Monday, and also it's in
12 your group of papers, which give you the decision
13 logic to identify related and competing. So this
14 was identified by staff as somewhat related. And
15 all the developers have given responses about the
16 measures. And now it's up to you to, one, decide
17 do you agree that these measures are related or
18 competing; and then, two, if so, what result do
19 you want from that? Is there just them
20 harmonizing and changing a couple specs to
21 correlate better, or is it that one measure is
22 better than the other and it should be stated as

1 the best in class? So that's the general
2 process.

3 I will go over quickly what the
4 developers have said about these measures. Okay.
5 So KCQA felt that 0256 and 0257 focus on reducing
6 catheter use exclusively in favor of AVF use.
7 And they're seeing that as the main difference
8 between the two -- or I'm sorry, all these. And
9 then CMS referred that Measure 0257 is a referral
10 process measure and that the most basic
11 requirement to get into a numerator is referral,
12 and that 0256 and 0257 are paired intermediate
13 outcome measures which report to the percentage
14 of patients with current AVA. So basically
15 they're saying the difference is not treating AVA
16 -- sorry, I can't see these words properly, but
17 fistula and AV graft as equivalent outcomes.

18 And then there's other things, but I'm
19 not going to read the whole thing to us in the
20 standard time. And then Kaiser also said that
21 0256 and 0257 are related but not competing and
22 that they have generally a different focus.

1 So I'll start off with the Committee
2 looking at the decision logic. And if you start,
3 the first question is does the measure address
4 the same target population or the same measure
5 focus as another endorsed or new measure? So
6 that would be your first question to answer. And
7 we can move forward with that thought. So I'll
8 open up to the Committee. Do you feel that these
9 measures address the same target population or
10 same measure focus?

11 DR. KLIGER: Yes.

12 MS. BAL: And would you say that for
13 all measures or --

14 CO-CHAIR CROOKS: Target population
15 or --

16 MS. BAL: Yes.

17 CO-CHAIR CROOKS: -- focus?

18 DR. DALRYMPLE: I would argue that
19 Kaiser Measure 2594 is not the same as 251, 256,
20 and 257.

21 MS. BAL: So would the Committee
22 generally agree that we should take that measure

1 out of the equation and just focus on the other
2 three?

3 DR. DALRYMPLE: Yes.

4 MS. BAL: I'm seeing nods all around.
5 Okay. Perfect. So that one's out of the running
6 now.

7 So now, of the three measures you said
8 yes. Did you mean because it was the same target
9 population or the same measure focus?

10 DR. DALRYMPLE: Both.

11 MS. BAL: Both? Okay. So in that
12 case, we will go to step 2. Do the measures
13 address both the same target population and the
14 same measure focus? So is it both, basically the
15 question is.

16 (No response.)

17 MS. BAL: Yes. Okay. So then do the
18 measures address -- I'm sorry. Determine whether
19 or not the measures are specified for at least
20 one of the same care settings. So would you say
21 that these measures have the same care setting?

22 (No response.)

1 MS. BAL: Yes. Okay. So then the
2 last question is, does the measure as specified
3 for at least one of the same levels of analysis?
4 So do you think they have the same level of
5 analysis?

6 (No response.)

7 MS. BAL: So then --

8 DR. DALRYMPLE: What's the level of
9 analysis for the KCQA? Because the other two are
10 dialysis facility level, but is the KCQA
11 physician level reporting?

12 MS. SAMPSEL: It's a clinician level.

13 DR. DALRYMPLE: It's a clinician
14 level.

15 MS. SAMPSEL: Correct.

16 DR. DALRYMPLE: And the other two are
17 dialysis --

18 MS. SAMPSEL: Correct.

19 DR. DALRYMPLE: -- facility level,
20 correct?

21 MS. SAMPSEL: Correct.

22 DR. DALRYMPLE: So this is Number 5,

1 Poonam?

2 MS. BAL: So then, if the answer is
3 no, then you would put it as competing with the
4 rational different levels of analysis, and then
5 it would be up to you to determine if you feel
6 components need to be harmonized or if they're
7 fine as they are for the measure that you said no
8 for. So the KCQA measure. And then for the
9 measures -- the other two measures, as competing,
10 you would determine again the same thing. Do you
11 feel like these measures need to be harmonized or
12 if they can stay together as paired measures as
13 they currently are.

14 So no more algorithm and more just
15 your opinion. I guess I should say the question
16 is, do you feel that any specifications for these
17 measures need to be changed for them to work
18 together, or do you feel that these measures as
19 are already -- are fine the way that they are,
20 basically?

21 DR. KLIGER: Well, maybe I can wade
22 in. The two that are designed to be paired

1 measures are indeed paired measures. The third
2 has a different level of analysis at the
3 physician level rather than at the unit level.
4 And none of them are incompatible with one
5 another. So I guess my own view would be that
6 these are fine to be working together.

7 DR. KRISHNAN: Let me offer a slightly
8 different opinion, because I think we'll get to
9 these when we get to the other adequacy measures
10 as well. Should the math that's used to
11 calculate the facility level outcomes be the same
12 math that's used to calculate the clinician level
13 outcomes? In other words, if you were to add up
14 all the clinicians in the facility, should that
15 equal the facility? But if the math is
16 different, they won't because they're two
17 different comparisons.

18 MS. BAL: I just ask that everyone
19 speak a little bit louder. It's been hard to
20 hear everyone. And I agree, I also need to work
21 on being louder. So, let's all. And then I
22 believe --

1 CO-CHAIR CROOKS: So I'm speaking as
2 a Committee member again. So we have two that by
3 this algorithm are competing, but they're paired.
4 They have the same denominator and they work
5 together. The one that has the clinician level,
6 the question is, can it be harmonized? And it
7 seems to me that I don't see any reason why the
8 one that looks at the clinician level couldn't
9 also look at facilities and vice-versa. So could
10 they be harmonized? Are the data sources
11 different or the same? If the data sources are
12 similar, then it seems to me they could and
13 should be harmonized perhaps. I don't see an
14 advantage to having two different ones.

15 DR. MADDUX: It seems like one of the
16 questions we should try to address is the fact
17 that whether it's the clinician or the facility
18 level measures, we've got one that's measuring a
19 more holistic view and the two paired ones that
20 are measuring the two isolated components: the
21 most optimal, the non-optimal. To me the
22 question is whether we harmonize to try to get

1 measures that are measuring the full set. In my
2 view we should be measuring permanent versus non-
3 permanent access and trying to harmonize towards
4 that, whether it's through the recognition of the
5 KCQA measure of recognizing some proportion of
6 catheters and reassessment or whether it's
7 through saying an AV fistula is not always the
8 most appropriate graft, or the most appropriate
9 permanent vascular access for a patient.

10 CO-CHAIR CROOKS: So, Frank, you're
11 saying that you would hold the KCQA one out as a
12 separate and non-competing, or no need to
13 harmonize, or you lose something of value if you
14 tried to harmonize it?

15 DR. MADDUX: I do think if you look
16 conceptually at where the distinctions are,
17 you've got one that's looking at this essentially
18 catheter avoidance measure in totality. And then
19 the others you've got where you're looking at the
20 two ends of the spectrum, the very best to the
21 very worst, and not sort of this middle ground.
22 And so you could decide that you wanted to make

1 directionally everything consistent or recognize
2 that they're just two separate things. They're
3 really measuring in a different perspective,
4 which I think they are right now.

5 DR. KRISHNAN: Frank, what do you
6 think are the denominators between them? Should
7 the denominators be the same?

8 DR. MADDUX: I think the denominators
9 can clearly be harmonized probably easiest. It's
10 the selection of what you want in the numerator
11 where you got to make a judgment decision. I
12 mean, what do we actually think is driving what
13 would be believed to be better care?

14 CO-CHAIR CROOKS: So does that clarify
15 it for the staff? Have we finished this job,
16 this chore?

17 MS. BAL: That sounds good. That's
18 exactly what we need to know to how to -- oh, I
19 believe Andy had a question, though. A
20 statement.

21 DR. NARVA: Well, the two are outcome
22 measures and one is a process measure. So

1 there's a bias in favor of an outcome measure,
2 isn't there, in general, in terms of quality of
3 measures?

4 MS. SAMPSEL: Yes, I mean, I would say
5 if you were choosing best in class, that might be
6 a consideration, but if you're not choosing best
7 in class and have just decided -- from what I've
8 heard from the discussion is these three measures
9 are recognized as competing by going through the
10 NQF algorithm and decision tool for related and
11 competing, however, this Committee has chosen
12 there's no need to further harmonize. But then
13 there are comments heard that perhaps a better
14 measure in the future would be permanent access
15 as well as focusing on outcomes measures.
16 Because I would say, yes, overall everybody would
17 like to see more outcomes measures versus process
18 measures no matter what the content area is.

19 DR. KLIGER: Just one other comment,
20 which is I think that Frank's comment really
21 makes sense to me and I wonder if again we would
22 be better informed by knowing what the TEP is

1 thinking. Because if indeed they're moving in
2 that direction, then we might well have
3 recommended the kind of harmonization that Frank
4 suggested.

5 DR. ANDRESS: So I think there wasn't
6 a great deal of discussion of harmonizing with
7 the KCQA measure. First to clarify a point, and
8 I think this is worth clarifying. It's not just
9 a case of the two ends points being measured. I
10 mean, the way that the measures function together
11 as a pair, the catheter and the fistula measures
12 function as a pair, there is an explicit
13 assessment of the use of grafts within a
14 facility. The consequence of using a graft is
15 that you get a score that is mid-range between
16 using a catheter or a fistula. But the
17 consequence and certainly the way it's used in
18 the QIP but also in pairing the measures together
19 in a measure program is the same. I think the
20 question that's been raised is that tiered
21 process always appropriate, or is that tiered
22 setup always appropriate? But it's wrong I think

1 to say that it ignores the midpoint of the use of
2 a graft.

3 In terms of the recommendations of the
4 TEP, I think there was some interest certainly in
5 keeping the measures capable of functioning
6 together as a paired set. There was some value
7 in that. There was some discussion about having
8 a distinct graft measure that combined with the
9 other two, but if I recall correctly, that was
10 not something that was discussed at terrible
11 length in the TEP. It was raised, but not
12 expounded upon a great deal.

13 In terms of harmonization, I think of
14 course the fact that we're using the measures
15 paired, we want them to be harmonized certainly
16 with each other. It has not been a part of our
17 efforts in the past I think to necessarily
18 harmonize with measures across settings. So I
19 think the extent to which that would be feasible
20 or desirable is something that we would want to
21 look at before we made a final determination of
22 what our position would be.

1 MS. BAL: So that's all we need from
2 staff. And obviously this was the long version
3 of doing related and competing, but we wanted to
4 give you one -- something to do so the work call
5 -- we wanted to go through the algorithm, but it
6 will be a much quicker discussion moving forward
7 because you'll know what you're looking for.

8 And so --

9 DR. KRISHNAN: What was the end
10 conclusion, Poonam, that we decided?

11 MS. BAL: That the measures would
12 remain as they are and they will be classified as
13 competing though but, from what I understood, the
14 Committee did not ask for any changes.

15 CO-CHAIR CROOKS: Right, we're not
16 asking for further harmonization.

17 MS. BAL: Yes, harmonization.

18 CO-CHAIR CROOKS: Recognize them
19 competing, but we don't see value in them
20 necessarily trying to harmonize them at this
21 point.

22 DR. KRISHNAN: Did we say the

1 denominator should be harmonized or not?

2 MS. BAL: Yes, that can be a
3 recommendation that you make to the developer.

4 CO-CHAIR CROOKS: Well, because it's
5 clinician versus facility, you can define the
6 patients the same, but you're not going to get
7 the same patient in the denominators.

8 DR. KRISHNAN: Right, it's just the
9 math. Yes, the math should be the same, I think.
10 The numerator would change and the number of
11 patients in the denominator would change, but the
12 math should be the same, I would think, between
13 measures.

14 CO-CHAIR CROOKS: Well, a clinician
15 measure could cross facilities, right? Is
16 that --

17 DR. ANDRESS: And depending on the
18 physician involved could cross settings --

19 CO-CHAIR CROOKS: Yes, settings and --

20 DR. ANDRESS: -- and, as I think
21 Mahesh would appreciate, potentially areas of
22 responsibility. So I don't know how that would

1 fall out in a vascular access measure, but it
2 would certainly need to be considered for the
3 purposes of harmonization if they were
4 undertaken.

5 DR. KRISHNAN: I guess my question is
6 for the -- even if they across multiple
7 facilities, the business rule is to determine
8 which patients go in --

9 (Simultaneous speaking.)

10 CO-CHAIR CROOKS: Right, so it would
11 be worthwhile to look at the denominator
12 definition.

13 DR. KRISHNAN: Right.

14 CO-CHAIR CROOKS: Adult over age 18,
15 dialyzing for so many months.

16 DR. KRISHNAN: Right. That's what I
17 mean. Yes.

18 CO-CHAIR CROOKS: That type of stuff
19 would be --

20 DR. KRISHNAN: That type of stuff.

21 CO-CHAIR CROOKS: -- approved by the
22 Committee, or encouraged by the Committee. So

1 take a look at how they define their denominator.
2 Then you should take a look at how you define
3 your denominator patients and see if they're the
4 same.

5 DR. KRISHNAN: Right.

6 CO-CHAIR CROOKS: Okay. I think that
7 concludes that.

8 So before our next break, which is
9 scheduled in 45 minutes, we're going to start on
10 the peritoneal dialysis measures. And I'm going
11 to give Connie a break and -- for carrying the
12 load all morning.

13 CO-CHAIR ANDERSON: We're going to do
14 this one first.

15 CO-CHAIR CROOKS: Right, and I've been
16 told that in order to keep the CMS measures
17 together, we're going to move the measure 321
18 first, which is the RPA measure. And so we
19 welcome the developers back and Mahesh and I are
20 the reviewers. And I'm going to take the lead on
21 this one. Is that what we decided?

22 (No response.)

1 CO-CHAIR CROOKS: Okay.

2 MS. BAL: And I'm just going to ask if
3 Paul Palevsky is on the phone from --

4 MR. PALEVSKY: Yes, I am.

5 MS. BAL: Okay.

6 CO-CHAIR CROOKS: Okay. Welcome. You
7 have the floor.

8 MS. SINGER: So, thank you very much.
9 I'm Dale Singer. I'm the Executive Director of
10 the Renal Physicians Association. And I'm going
11 to let Paul Palevsky, who was a member of our
12 Measure Developer Group, take the lead on
13 summarizing this measure.

14 CO-CHAIR CROOKS: Thank you.

15 MR. PALEVSKY: Thank you, Dale.

16 So this is actually a measure that has
17 previously been endorsed by NQF. It's a
18 physician-level measure. Percentage of patients
19 aged 18 years and older with a diagnosis of end-
20 stage renal disease receiving peritoneal dialysis
21 who have a total Kt/V greater than or equal to
22 1.7 per week measured once every four months. So

1 total meaning both residual kidney function and
2 dialysis clearance. The rationale for this is
3 that adequacy of dialysis is strongly associated
4 with better outcomes including decreased
5 mortality, fewer hospitalizations, fewer days in
6 the hospital and decreased hospital costs.

7 This is an intermediate outcome
8 measure. It is currently in PQRS and it is
9 included in the RPA kidney quality improvement
10 registry for 2015.

11 This measure is based on the KDOQI
12 Clinical Practice Guidelines that we acknowledge
13 are a bit dated, but they have not been updated.
14 Guideline 2 from those CPGs state that for a
15 patient with residual kidney function, the
16 minimal delivered dose of total small solute
17 clearance should be the total of peritoneal and
18 kidney clearance of at least 1.7 per week. And
19 for patients without residual kidney function,
20 the minimal delivered dose of total small solute
21 clearance should be a peritoneal Kt/V urea of at
22 least 1.7 per week measured within the first

1 month after starting dialysis therapy and at
2 least once every four months thereafter.

3 There was concern previously regarding
4 performance gap. When we went back -- and
5 whether there was a performance gap -- per the
6 last USRDS annual data report this target is
7 being met by 87 percent of patients. So there's
8 still a gap. We do not have disparities data.

9 So I will leave it at that point
10 unless you have additional questions for me.

11 CO-CHAIR CROOKS: Okay. Please stick
12 around. There will likely --

13 MR. PALEVSKY: I will.

14 CO-CHAIR CROOKS: -- be questions.
15 Okay.

16 Okay. So Measure 321, re-endorsement,
17 adult kidney disease, PD, adequacy, solute.
18 Outcome measure, intermediate. And in the
19 evidence they did use primarily KDOQI. They did
20 provide a systematic review of the evidence and
21 did include the ADEMEX study. And I thought
22 ADEMEX was post-2006. Am I wrong about that? Am

1 I getting -- is it earlier?

2 PARTICIPANT: (Off microphone)

3 CO-CHAIR CROOKS: Yes, okay. So it
4 does include ADEMEX in the analysis.

5 So I felt that given that, nephrology
6 has -- at least has a couple clinical trials in
7 this that the evidence is sufficient and actually
8 strong.

9 Mahesh, did you have any thoughts
10 about the evidence that --

11 DR. KRISHNAN: Yes, I thought there
12 was sufficient evidence. I don't have anything
13 else to add.

14 CO-CHAIR CROOKS: Let's open it up
15 then. Who would like to make comments on the
16 evidence? Alan?

17 DR. KLIGER: Only to add, although
18 it's not analyzed here that the international PD
19 Group reviewed the evidence as well. When they
20 revised this number down to 1.7, they were the
21 first one to do that because KDOQI originally was
22 2.0. And the evidence that they cited was

1 convincing.

2 CO-CHAIR CROOKS: Good. Other
3 comments on the evidence?

4 (No response.)

5 CO-CHAIR CROOKS: Okay. Am I seeing
6 any cards? No. Okay. Then I think we're ready
7 to vote on the evidence.

8 MS. OGUNGBEMI: The Committee is now
9 voting on evidence for Measure 0321. The options
10 are: one, high; two, moderate; three, low; and
11 four, insufficient. Voting is open.

12 (Voting.)

13 MS. OGUNGBEMI: Results are 11 votes
14 high, 11 votes moderate, 0 votes low and 0
15 insufficient. The measure passes on evidence.
16 And that's Measure 0321.

17 CO-CHAIR CROOKS: Okay. Performance
18 gap. I think they make the case. Mahesh?

19 DR. KRISHNAN: Yes, I agree. I just
20 had a question for Paul.

21 When you said 87 percent of patients,
22 since this is a clinician-level measure, we don't

1 have any inter-clinician variation in that,
2 right? It's just the national data?

3 MR. PALEVSKY: No. No, and I'm just
4 -- that's just the most recent data on a patient
5 level. And I don't have clinician-level data.

6 DR. KRISHNAN: Yes. So I know there's
7 a gap because we still see this, but -- that's
8 not supported by the data, but I believe there is
9 a gap.

10 CO-CHAIR CROOKS: Okay. Other
11 comments about the performance gap? Alan?

12 DR. KLIGER: Well, this is a question
13 I'm going to raise related to this and other of
14 our adequacy measures when we talk about
15 performance gap because it really gets to be very
16 subjective, right? If the performance gap were
17 that 98 percent of patients are there and 2
18 percent don't, we might have some agreement that
19 there's not a performance gap. And if it was 50
20 percent of patients that got there and 50 percent
21 who didn't, we might have general agreement that
22 there was a significant performance gap.

1 But when we're talking now about 14
2 percent that don't get there, or 10 percent that
3 don't get there, or later on 6 percent that don't
4 get there, some of the other measures, I think
5 it's worthwhile just discussing for a moment what
6 we as a group think of as a significant
7 performance gap.

8 CO-CHAIR CROOKS: Do you look at the
9 standard deviation? If the standard deviation
10 goes over 100 percent or under 0 percent, that
11 might be another measure of how close they are.
12 When you get to 95 percent in Kt/V, there's
13 always going to be 5 percent who have
14 malfunctioning catheter or a half-obstructed
15 fistula. And I don't think 100 percent is
16 possible. And that might be -- in my mind that's
17 topped out. But at 80 -- what is this, 86
18 percent? Seventy-six percent.

19 MR. PALEVSKY: Eighty-seven percent.

20 DR. KLIGER: And just asking a general
21 -- I'd like to just address our general sense of
22 this.

1 CO-CHAIR ANDERSON: Okay. Josh first.

2 DR. ZARITSKY: As a relative newbie
3 again, when something like this is topped out, I
4 mean, then there's always room for like a
5 backslide or something like that. This still
6 remains a performance measure, so I would be
7 reticent to see -- we're not dealing with one
8 percent or zero -- I mean, that there's -- that
9 it would seem to me that this still needs to be
10 continued.

11 CO-CHAIR CROOKS: There is an option
12 for that. And we're going to be talking about
13 that quite a bit this afternoon, I think, as many
14 of these measures are threatening to be topped
15 out. And that is called reserve status where if
16 all the other criteria are met but the
17 performance gap is low, endorsement can be
18 considered but in reserve, which is saying to the
19 healthcare world that keep an eye on it, but this
20 is not -- don't spend a lot of your resources on
21 it right now. But we're going to continue to
22 keep it on because it is important.

1 DR. KRISHNAN: And there's a
2 mathematical definition. I don't know, Joel, if
3 you have it, but I think in last year's final
4 rule, or it was the year before, CMS actually
5 published a mathematical definition of what they
6 consider topped out. So I think there is -- I
7 think it's interquartile range. I don't
8 remember.

9 I know, Joel or Joe, if you guys
10 remember that. But there is a mathematical
11 definition, at least for public measures that was
12 used which seemed to make a lot of sense. I
13 think we used it for the pediatric measure. I
14 don't remember. Joel, do you remember? You know
15 what I'm talking about?

16 DR. ANDRESS: So there are actually
17 two partner criteria for it being topped out.
18 One is the interquartile range.

19 DR. KRISHNAN: Right.

20 DR. ANDRESS: And I am completely
21 blanking on what the other one is, but we could
22 probably look into it and get that to you in

1 fairly short order.

2 DR. KRISHNAN: Yes, but that's what I
3 use when I think about this. And I think the
4 KECC Group did a really good job when they looked
5 at this for one of the previous measures in terms
6 of the -- is there a clinically meaningful
7 difference amongst the interquartile or
8 interquintile, whatever you want to use, range so
9 you can apply it, to answer your question, Alan,
10 is what that is.

11 DR. ZARITSKY: But philosophically
12 when you mentioned, do organizations spend time
13 and energy -- so but, I know we're not making
14 that assumption, but by taking something and
15 putting in reserve status or taking it off the
16 table, then that energy still needs to be -- we
17 all agree the energy still needs to be made to
18 make sure that people are measuring Kt/Vs and
19 ensuring it's a good level.

20 DR. KRISHNAN: Yes, I mean, I'll tell
21 you what we do. When we hit -- internally when
22 we hit a metric that's topped out, we fix it. We

1 tell the facilities they have to stay there. And
2 then we give them something new to play with,
3 right, whether it's these complicated other
4 measures or something like that. So that's what
5 we do operationally. Because it's sort of like
6 Six Sigma, right? Once you get to a certain
7 level, to get from the fourth to the fifth Sigma
8 takes so much effort you might -- and if it's not
9 clinically meaningful, go play with something
10 else.

11 DR. SOMERS: And just going back to
12 what was asked, I think in my mind very much it
13 depends on the measure itself. And part of it
14 and how I look at it is the evidence that's been
15 given for the importance of that measure itself.
16 So I mean, if there are profound ramifications to
17 the patient for not meeting that measure, then I
18 would want a very, very tiny performance gap,
19 almost what Sarah mentioned earlier today in
20 terms of you know sentinel events, maybe
21 something that you'd still -- if there's a very
22 tiny gap, you'd still want to have that as a

1 measure in place.

2 DR. KLEINPETER: I know that looking
3 at it from some of the networks, the number of
4 units that have 11 patients to report has been a
5 lot of the problem. And so a lot of the units
6 don't feel that they don't have that number of
7 patients. Because it's not going to be a
8 clinically significant number, they aren't
9 significantly looking at it in any systematic
10 process. And so that may be some of the
11 performance gap that exists overall. With two or
12 three nephrologists going to one unit, then each
13 of them having not the number of critical mass at
14 the facility level they need to look at it, not
15 necessarily at the individual level.

16 CO-CHAIR CROOKS: A hidden performance
17 gap perhaps. Franklin?

18 DR. MADDUX: So this may come up in a
19 variety of the adequacy discussions over the
20 afternoon and tomorrow, and I think probably less
21 so with this one than the others, but I think on
22 the specifications, clearly with regard to Kt/V

1 there are a lot of inter-organizational variable
2 ways of doing the actual test. And when that
3 happens, you can get substantial -- not inter-
4 unit variability, but inter-organizational
5 variability. And we've got a -- less so again
6 with PD adequacy, but certainly for some of the
7 others. I think that's one of the things that I
8 would ask measure developers to be very conscious
9 of, is -- the specification is clear enough at
10 the actual level of measurement, because they're
11 not always done the same way and it makes a
12 difference on how the benchmarking goes and what
13 the outcome is.

14 DR. ANDRESS: Excuse me. So I just
15 pulled up the topped-out criteria just real
16 quick. The first is if the -- depending on
17 directionality of the measure, if the 75th
18 percentile and the 90th percentile of the
19 distribution are statistically indistinguishable.
20 Of course in the alternate directionality it's
21 the 10th percentile and the 25th percentile.

22 The second criterion is that the

1 truncated coefficient of variation is less than
2 or equal to 0.1. There's a formula that we
3 provide that we use to calculate that in the
4 rule. And we use that to define whether or not a
5 measure has topped out for the purposes of the
6 QIP.

7 DR. KLIGER: Yes, so my recommendation
8 would be that those measures, that those
9 calculations be part of what we see when we
10 consider these measures.

11 CO-CHAIR CROOKS: Those aren't NQF
12 definitions, I don't -- are they?

13 (No response.)

14 CO-CHAIR CROOKS: No, they're not.
15 But I guess we could ask NQF to look at that.

16 DR. KLIGER: That would be right. I
17 request a recommendation.

18 MS. BAL: We can definitely take that
19 into consideration and moving forward see what we
20 can do to incorporate those, but at this point
21 NQF does not have set boundaries for gap or any
22 of our other criteria.

1 CO-CHAIR CROOKS: Okay. Michael?

2 DR. FISCHER: So, the other issue in
3 performance gap that we had talked in our call
4 was if there was a variation performance across
5 race, sex or disparities. And previously that
6 data was somewhat old and/or it focused on
7 receipt of peritoneal dialysis, not adequacy. It
8 seems like Paul had some more recent data. I
9 know, Peter, you and Mahesh were leading this,
10 but I wanted to just see because I think that was
11 another concern we had raised on our working
12 group call. And before we went to voting I just
13 wanted to circle back to it and also to allow the
14 developer to have a time to respond as well if
15 they had more robust or more recent vintage data.

16 MR. PALEVSKY: As I commented, no, we
17 don't have disparities data.

18 CO-CHAIR CROOKS: Okay. Thank you for
19 bringing up the disparities potential gap.
20 That's important. Even if a measure was topped
21 out, for instance, there could still be
22 significant disparities. And I know of at least

1 one in my research point to some disparities in
2 PD use, at least, by ethnicity. I don't know
3 about hitting the target or not, but it is
4 possible that there is some.

5 DR. KRISHNAN: The data is available.
6 I've just never seen it run.

7 CO-CHAIR CROOKS: Yes.

8 DR. KRISHNAN: And I think to Mike's
9 point, the developer submission had to do with
10 access to PD as opposed to differential
11 achievement of a target Kt/V by race or by any
12 other factor could be done.

13 CO-CHAIR CROOKS: Okay. Other
14 comments before we vote on performance gap?

15 (No response.)

16 CO-CHAIR CROOKS: Then we're ready to
17 vote.

18 MS. SAMPSEL: So I just want to
19 mention real quick this is another area with
20 getting the PQRS data out of PQRS in order to
21 present it to the Committee. And that was
22 something that we were not able to get prior to

1 the meeting, so this is the data that's available
2 for your consideration. There's definitely cases
3 where other developers have provided this age of
4 data, et cetera, based on what was tested. So it
5 is what it is, but we tried to get the data and
6 we tried to get updated data for RPA.

7 DR. KRISHNAN: Are you saying, Sarah,
8 that the RPA didn't have access to the data, or
9 CMS didn't have access to the data?

10 MS. SINGER: Neither. We couldn't get
11 access to the PQRS data from CMS.

12 MS. SAMPSEL: I think there probably
13 is a mechanism to get the PQRS data that requires
14 a level of analysis and obviously that expertise
15 to do so, and that's something that we can
16 continue to explore. But I know other committees
17 have dealt with this as well, that it's just very
18 limited, what is produced in the public reports
19 that you can just pull off the Web, and it's
20 really only for the top reported measures. And
21 that was back to my comment about how many of the
22 nephrology measures are top reported.

1 CO-CHAIR CROOKS: Thank you. Okay.
2 Are we ready to vote?

3 (No response.)

4 CO-CHAIR CROOKS: Let's do it.

5 MS. OGUNGBEMI: The Committee is now
6 voting on Measure 321 for performance gap. The
7 options are: one, high; two, moderate; three,
8 low; and four, insufficient. Voting is now open.

9 (Voting.)

10 MS. OGUNGBEMI: Results are 4 high, 16
11 votes moderate, 1 vote low, 1 vote insufficient.
12 The Measure 0321 passes on performance gap.

13 CO-CHAIR CROOKS: Okay. On to
14 specifications. I had a question about how this
15 is done. From reading through the submission, it
16 seems as if there's a check box the provider
17 checks that says I have measured the residual
18 Kt/V and I've added to the dialysis Kt/V and it's
19 1.7 or greater. And it's a check box. Is that
20 the way the data is collected? Did I get that
21 right? As opposed to looking at lab data and
22 doing some calculation to --

1 MR. PALEVSKY: I believe that as this
2 was originally developed, that is correct, that
3 this was an attestation measure. Amy, you
4 correct me if I'm incorrect on that.

5 MS. BECKRICH: I believe that is
6 correct.

7 CO-CHAIR CROOKS: So then that gets
8 into the reliability and validity parts. How was
9 that checking done? In other words, was there
10 testing that went back -- okay. You checked this
11 box that they have Kt/V over 1.7. Now, I'm going
12 to the records for that period of time where you
13 checked the box yes and I'm going to see if they
14 really did. Is that the type of checking that
15 was done? It mentions use data element and
16 inter-rater reliability. Now, if it was inter-
17 rater reliability about noticing that a check box
18 was checked or was it actually tested against
19 real values in the chart?

20 MS. SAMPSEL: Can you please go to
21 page 24 of the evidence? So it would be the
22 evidence form, or the custom form.

1 Yes. So, I mean I shouldn't be doing
2 this, but I think my interpretation of this was
3 that -- and this measure was tested in
4 conjunction with the AMA-PCPI and RPA as the Lead
5 Clinical Specialty Group when PCPI was developing
6 the PQRI PQRS measures. And so what they did
7 from my recollection was pulled a -- out of a
8 number of practices; and we'd have to go
9 somewhere else to find that, but pulled 30 to 35
10 charts from each practice.

11 And then you can see here on page 23
12 in the testing form what exactly they were
13 looking for documentation of in the medical
14 record. So they were looking for the Kt/V, which
15 I don't know what that is, and I should know from
16 all your work groups so far, but obviously I
17 didn't. So that is what they tested and the
18 information they pulled from each medical record.

19 CO-CHAIR CROOKS: That does seem to be
20 consistent with what they're saying in this
21 section, that they had reviewers on site; this is
22 in the validity section, that looked for the data

1 including -- well, that the clinical records were
2 a valid representation of what had transpired.
3 So the wording is a little loose. I would like
4 to be reassured that this isn't just a check-box
5 metric and that it actually reflects reality.
6 And I'm not totally reassured about that. That's
7 my take.

8 Mahesh?

9 DR. KRISHNAN: Yes, I was just going
10 to add that I think that that data capture
11 mechanism also -- if we look at what Myra was
12 just saying about the minimum cell size. So
13 there has to be at least 11 patients, which we'll
14 see in some of the other measures. I think that
15 having the actual data may help with that. But I
16 think you need to have a minimum number of
17 patients in order to make it reasonable, because
18 I think if it's less than 11, there's just too
19 much variance, right? One patient here or there
20 can completely screw up the values. So I mean,
21 it goes back to data collection, but it's also in
22 the specifications. I'd like to see a minimum

1 number. And we'll get to maybe as we harmonize.
2 But that's something I would comment on.

3 CO-CHAIR CROOKS: Is there a minimum
4 number required for a -- this is a clinician
5 level.

6 MS. SINGER: Yes, and actually moving
7 forward these are in the electronic health
8 record, so they're being reported through PQRS
9 through the electronic health record.

10 CO-CHAIR CROOKS: So the minimum
11 facility size wouldn't apply, I don't think, to
12 this --

13 MS. SINGER: No, they're clinician
14 level.

15 DR. KRISHNAN: It would be the minimum
16 number of patients that a clinician would see.
17 What Myra just said, right? I think that's what
18 you just said, right, Myra?

19 DR. KLEINPETER: Yes.

20 DR. KRISHNAN: You'd want to see 11
21 patients per physician.

22 DR. KLEINPETER: And I think that's

1 what in this -- that's what's required on page --
2 I think it was on page 5 or 6 where they're doing
3 the validity testing. Page 6 of 34, 321. First
4 statement says -- somewhere it mentions were
5 there 11 patients.

6 DR. KRISHNAN: Usually the 11 comes
7 from the facility-level measure. I don't know if
8 it was in -- or is it also in the clinician-level
9 measure?

10 DR. KLEINPETER: I don't think we have
11 it.

12 DR. KRISHNAN: Yes, I don't think it's
13 in the physician-level measure, but the minimum
14 cell size for the facilities is there. I just
15 wonder whether or not there should be a minimum
16 cell size for clinicians for this to be
17 meaningful as well.

18 DR. KLEINPETER: Well, the other thing
19 for clinicians, a lot of times we're seeing
20 people at multiple sites. So you may have your
21 11, but you're going to multiple facilities as
22 opposed to going to one individual provider.

1 CO-CHAIR CROOKS: I'm still left with
2 questions, and I would put the burden on the
3 developer when creating the submissions to make
4 it -- really draw it out for us. Show us the
5 money. Where is the connection, that the Kt/V
6 was actually looked at? And also that validity
7 fits the metric. Because here is this facility
8 testing. I guess you're comparing facility
9 testing to physician office testing. Was that
10 the validity -- in other words, I'm just not
11 seeing a clear line of how this was done and why
12 we should be convinced from this that it's a
13 reliable and valid measure.

14 MS. SINGER: Well, when it was
15 originally tested, it was -- the data was pulled
16 from charts. It was the old days before
17 electronic health records. So now they're all e-
18 specified for electronic health records. And we
19 haven't gone back and tested since the original
20 testing was done on the original measure.

21 Moving forward they're part of our
22 registry, which is a qualified clinical data

1 registry by CMS. So they'll be in our registry,
2 which will allow us easy access to the measures
3 to know what's happening. But in the past it was
4 done by hand by going in and taking charts and
5 checking.

6 CO-CHAIR CROOKS: Okay. Other
7 concerns about specifications or reliability?

8 DR. DALRYMPLE: So, Peter --

9 CO-CHAIR CROOKS: Lorien?

10 DR. DALRYMPLE: Can I just ask a point
11 of clarification? Just when we were looking at
12 the reliability testing, the numerator would only
13 be those who achieve a Kt/V above 1.7, not those
14 with less than 1.7 and a plan of care documented,
15 is that correct? Just since that's included in
16 the reliability testing, I just want to make sure
17 I understand the numerator that's the focus of
18 the measure. You have to achieve the Kt/V, is
19 that correct?

20 CO-CHAIR CROOKS: And I think it would
21 be fair to say it's more a measure that two
22 raters rated it the same.

1 DR. DALRYMPLE: Oh, I just wanted to
2 specify --

3 CO-CHAIR CROOKS: Rater A versus Rater
4 B.

5 DR. DALRYMPLE: -- who gets counted in
6 the numerator, not the inter-rater reliability.
7 In the reliability testing they list people who
8 have a Kt/V less than 1.7 with a plan of care
9 versus without a plan of care. And so, sometimes
10 numerators allow for you not to meet the target
11 as long as you have a plan of care. I just want
12 to make sure I understand this measure. The
13 numerator you have, to achieve the Kt/V, not not
14 achieve it and have a plan of care to get
15 counted.

16 MR. PALEVSKY: That is correct. This
17 is the numerator of the patients who have a total
18 Kt/V greater than or equal to 1.7.

19 DR. DALRYMPLE: Okay. Thank you.

20 MS. SAMPSEL: The other thing I just
21 might want to draw your attention to, one of the
22 documents that the developer did provide that was

1 in your measurement folder are the actual
2 specifications that walk you through very clearly
3 -- I mean, the testing data is one thing, and
4 that was a good question to clarify that, but
5 then how the measure is currently implemented as
6 an e-measure is, in my opinion, extremely clearly
7 specified in a five-page e-specification
8 document.

9 DR. KRISHNAN: So, Dale, the current
10 measure will be done to the e-specification as
11 Sarah said, but the validation data we have is
12 only in the chart review from 2007-2008?

13 MS. SINGER: That is correct.

14 DR. KRISHNAN: Do you have plans to
15 revalidate it with the e-specifications?

16 MS. SINGER: Absolutely. On an
17 ongoing basis that we will have access to the
18 data.

19 DR. KLIGER: I just want to say a word
20 about the cell size that you mentioned before.
21 In peritoneal dialysis, if we are only examining
22 physicians caring for more than 11 patients,

1 we're talking about a handful of physicians in
2 the United States. So my take is that it's less
3 important to show a statistically significant
4 difference for a cell than it is to have in place
5 an appropriate measure of adequacy. So I think
6 it's appropriate in this physician-level measure
7 not to have a minimum cell size.

8 CO-CHAIR CROOKS: Okay. Other
9 comments?

10 DR. DALRYMPLE: Can I just ask one
11 more --

12 CO-CHAIR CROOKS: Yes, Lorien.

13 DR. DALRYMPLE: -- clarification
14 question using the e-specification? So I think
15 the numerator, the last four are all total Kt/V.
16 Are there rules on how long you can carry forward
17 the residual clearance of urea? So for example,
18 we can only see these total Kt/V fields, but I
19 presume residual only is allowed to carry forward
20 for three months or four months and then it drops
21 as being included in the total calculation. Is
22 that correct?

1 MR. PALEVSKY: If a patient has
2 significant urine volume, the residual is
3 supposed to be reassessed when you do the Kt/V
4 calculation.

5 DR. DALRYMPLE: Right, as specified I
6 just can't quite tell from these EHR what the
7 time limiter is on when you allow to use the past
8 measure. Will it cut out in this new data set at
9 four months so that it drops if it hasn't been
10 repeated? And I'm sorry. Does this make sense
11 or should I ask it another way?

12 MR. PALEVSKY: It makes sense. I
13 don't have available to me the full e-
14 specifications.

15 CO-CHAIR CROOKS: I'm a little
16 confused by a comment a while ago about either
17 they have the Kt/V over 1.7 or there's a plan of
18 care. Was that the old measure? Is that still
19 in this measure, too?

20 MR. PALEVSKY: That is not in this
21 measure.

22 CO-CHAIR CROOKS: Okay. That was a

1 prior version, as I recall. Okay. Thank you.

2 DR. DALRYMPLE: Could we just make
3 that recommendation then that perhaps it would be
4 helpful to have clarity on how long your residual
5 kidney function is allowed to carry forward, that
6 perhaps at four months it drops if it hasn't been
7 repeated for your total Kt/V calculation?

8 MR. SAMPSEL: I mean, so what we'll do
9 it is, when we're done with this conversation,
10 everybody has their comments out, we'll go ahead
11 and vote. And depending on the vote, whether
12 it's recommended at this point or not, you still
13 have that opportunity to say this is additional
14 information we'd like to see. And it will be
15 brought back to you before public comment.

16 DR. KRISHNAN: Should we vote?

17 CO-CHAIR CROOKS: I guess so.

18 MS. OGUNGBEMI: The Committee is now
19 voting on reliability for Measure 0321. The
20 options are: one, high; two, moderate; three,
21 low; four, insufficient. Voting is open.

22 (Voting.)

1 MS. OGUNGBEMI: Results are 2 votes
2 for high, 16 votes moderate, 4 votes low and 0
3 votes insufficient. Measure 0321 passes on
4 reliability.

5 MS. SINGER: So, Lorien, can you go
6 ahead and reiterate the comment of additional
7 data that you'd like to see just so we make sure
8 we have it in our notes?

9 DR. DALRYMPLE: Oh, sure. The only
10 recommendation I'd make to the stewards for
11 consideration is creating a drop date for the
12 residual kidney function, that it be measured
13 every four months and that if it's not
14 remeasured, it doesn't get to continue to
15 contribute to your total Kt/V, that that way
16 people are encouraged to measure it as
17 appropriate and not get credit for old measures.

18 CO-CHAIR CROOKS: All right. Moving
19 on to validity. Validity testing was limited to
20 face validity; that is, pulling a TEP panel with
21 some impressive names on it. They voted 4.62 on
22 a scale of 5. Mahesh?

1 DR. KRISHNAN: Yes, I thought that the
2 data was good in terms of that, so I don't have
3 anything else to add.

4 CO-CHAIR CROOKS: Other thoughts on
5 their validity testing?

6 (No response.)

7 CO-CHAIR CROOKS: Okay. Well, let's
8 vote on validity then.

9 MS. OGUNGBEMI: The Committee is now
10 voting for Measure 0321 on validity. The options
11 are: one, high; two, moderate; three, low; and
12 four, insufficient. Voting is open.

13 (Voting.)

14 MS. OGUNGBEMI: The results are 5
15 votes high, 16 votes moderate, 1 vote low, and 0
16 votes insufficient. Measure 0321 passes on
17 validity.

18 CO-CHAIR CROOKS: Okay. Feasibility.
19 They claim it's all electronic, and I guess we
20 just heard that it's moved to electronic database
21 claims. And they state it's feasible and timely.

22 Mahesh, anything else?

1 (No response.)

2 CO-CHAIR CROOKS: Lorien. Sorry.

3 Yes?

4 DR. DALRYMPLE: Sorry. Just one
5 question. So the new database, is this something
6 where individual EHRs transfer to it, or do
7 physicians upload their own data?

8 MS. SINGER: Physicians are
9 responsible for entering their own data, but
10 ideally they integrate with their EHRs. But it's
11 the physician's responsibility.

12 DR. KRISHNAN: And, Dale, is your
13 sense that -- what will that look like between
14 manual data entry and electronic? Do you have a
15 sense?

16 MS. SINGER: It will not be feasible
17 manually.

18 DR. KRISHNAN: It will not be
19 feasible?

20 MS. SINGER: No.

21 CO-CHAIR CROOKS: So just to be sure
22 I understand. You're saying that currently it

1 depends on physicians, but you're trying to get
2 that link out of there?

3 MS. SINGER: I'm sorry. Say that one
4 more time?

5 CO-CHAIR CROOKS: So you're saying
6 currently the data entry depends on nephrologists
7 sitting down and putting numbers into the system,
8 but you're trying to move away from that by
9 getting it directly from electronic health
10 records?

11 MS. SINGER: No, physicians are not
12 entering it manually currently. The registry
13 just launched in March. And so, right now we're
14 uploading data from EHRs.

15 DR. KLIGER: I mean, the challenge it
16 seems to me with this and many of the other
17 measures is that we're doing feasibility
18 measurements retrospectively and talking about
19 the feasibility moving forward, which is in a
20 different system often using electronic records
21 and electronic databases. So I mean, I think all
22 we can do is judge feasibility as it's presented

1 to us and discuss the future, but I think we have
2 to on what the feasibility testing looks like.

3 CO-CHAIR CROOKS: We don't have
4 feasibility testing per se and we only have what
5 they've submitted.

6 Okay. Other discussion on feasibility
7 before we vote?

8 DR. KRISHNAN: Dale, your sense when
9 it was being done prior to the registry, were
10 there any issues? I know we talked about the
11 original feasibility efforts, but then there were
12 eight or nine years, or seven or eight years that
13 elapsed.

14 MS. SINGER: Right. I mean, we do
15 know it was being used in PQRS reporting, so --
16 well, yes, I mean, most of the PQRS reporting was
17 also being done electronically. I mean, yes.

18 DR. KRISHNAN: I think, Peter, we just
19 got to go with that as the feasibility, right?
20 So if it worked originally in the chart review
21 and it worked for the last X number of years, we
22 got to work on that. There will be another data

1 system. It's hard for us to evaluate that. And
2 there's no data.

3 CO-CHAIR CROOKS: We'll go with that.
4 Okay. Are we ready to vote?

5 MS. OGUNGBEMI: The Committee is now
6 voting for feasibility on Measure 0321. The
7 options are: one, high; two, moderate; three,
8 low; and four insufficient. Voting is now open.

9 (Voting.)

10 MS. OGUNGBEMI: The results are 6
11 votes high, 15 votes moderate, 1 vote low, and 0
12 votes insufficient. Measure 0321 passes on
13 feasibility.

14 CO-CHAIR CROOKS: For usability and
15 use. It is currently in the PQRS system. And
16 also payment. So payment is being adjusted by
17 this metric. And on the RPA Kidney Quality
18 Improvement Registry with the possibility of
19 having it used in the future for professional
20 certification and recognition. So it is in use.
21 It's probably usable.

22 (Laughter.)

1 CO-CHAIR CROOKS: Mahesh?

2 DR. KRISHNAN: I concur. I concur.

3 CO-CHAIR CROOKS: Others?

4 (No response.)

5 CO-CHAIR CROOKS: Okay. Let's vote.

6 MS. OGUNGBEMI: The Committee is now
7 voting for Measure 0321 on usability and use.

8 The options are: one, high; two, moderate; three,
9 low; and four insufficient. Voting is now open.

10 (Voting.)

11 MS. OGUNGBEMI: The results are 15
12 votes high, 7 votes moderate, 0 low, and 0
13 insufficient. Measure 0321 passes on usability
14 and use.

15 CO-CHAIR CROOKS: All right.
16 Before we vote on recommending for endorsement,
17 any other general comments? Speak now or --

18 DR. KRISHNAN: I think we'll get to
19 this when we do the competing measures
20 reconciliation, but clearly --

21 CO-CHAIR CROOKS: Yes, we'll talk
22 about competing and related measures in a while.

1 Hopefully not too long a while.

2 (Laughter.)

3 CO-CHAIR CROOKS: Okay. Let's vote
4 then for recommendation for endorsement.

5 MS. OGUNGBEMI: The Committee is now
6 voting for Measure 0321's overall suitability for
7 endorsement. Options are: one, yes; and two, no.
8 Voting is open.

9 (Voting.)

10 MS. OGUNGBEMI: The results are 21
11 votes yes and 1 vote no. Measure 0321 passes for
12 suitability for endorsement.

13 CO-CHAIR CROOKS: Okay. Thank you.
14 And now the coat comes off --

15 (Laughter.)

16 CO-CHAIR CROOKS: -- as we have 15
17 minutes until our break or so. And we're going
18 to jump into the next group of three measures.
19 We're only probably two-and-a-quarter measures
20 behind for the time, so that's not too bad.

21 So I'd like to invite to the stand Joe
22 Messana and, Joel, again, if you'd like to. For

1 Measure 318. Three-one-eight on your programs,
2 folks. Three-one-eight now starting in center
3 field.

4 DR. MESSANA: Okay. So I remember
5 this morning where the Committee and the measure
6 developers were charged with trying to keep this
7 group on time, and I'm going to do my very best.

8 So my opening statement is we're
9 talking about 0318. I think you've all had the
10 opportunity to read it. There were a couple of
11 questions that came up from the work group that I
12 just want to address. I did a little bit of
13 background work with the analysts figuring out --
14 or making sure that I understood the calculation
15 algorithm because people were asking about that
16 based on the measure that was submitted. And I
17 think the other comment that came up for all of
18 our PD adequacy measures was this upper bound
19 issue.

20 So let me start with the upper bound
21 bit first. The upper bound is intended to
22 exclude clinically implausible values from the PD

1 adequacy. A PD Kt/V that's that high is almost
2 impossible -- it is impossible to achieve, in my
3 30 years of clinical experience, unless you have
4 enormous residual kidney function to the point
5 where you wouldn't need to be on dialysis.

6 However, I don't think it's that big a deal if
7 it's not acceptable to the Committee to leave it
8 on. I think we can discuss it further. But it
9 was just intended to weed out clinically
10 implausible values, data submission errors.

11 Okay?

12 The issue about how the calculation
13 actually occurs in CROWNWeb is a bit interesting.
14 So what we do to calculate this measure; and this
15 is consistent with the calculations we did for
16 all the validation and reliability that you see,
17 is at the patient level we obtained PD Kt/V
18 values from CROWNWeb at the patient level. And
19 those have a month associated with them. Okay?
20 And we store those. And those Kt/V values
21 include residual kidney function, because that
22 question came up.

1 But every place we describe the
2 measure, it's dialysis and residual. That's
3 intended to be residual kidney function, but it
4 was shortened or abbreviated just to provide a
5 lack of clarity, because we think that's
6 important. But this is the standard traditional
7 way of calculating PD Kt/V with inclusion of
8 residual kidney function if there's any residual
9 urine. So that patient level value with a month
10 attachment is stored.

11 And so, when we go to calculate the
12 measure, the denominator exclusions apply for any
13 one month. We look at patient months where they
14 meet all the inclusion criteria in the
15 denominator and then we look back and say, is
16 there a PD Kt/V within the four months of that
17 calculation? And we use the most recent one.
18 So that's how it is calculated.

19 So you're not penalized if the data
20 are in CROWNWeb if the patient level data about a
21 Kt/V having been done anywhere are on CROWNWEB.
22 You're not penalized on transfer if you haven't

1 done a Kt/V in the first month or first two
2 months.

3 DR. LATTS: But you're only looking
4 for one value within the four months and then you
5 use the most recent? It's not that you're
6 looking every single month?

7 DR. MESSANA: We have all of those.
8 We use the most recent Kt/V if we have multiples.
9 Okay? So that's a clarification. And we can
10 update the calculation logic and measure
11 specification to represent that, but that is what
12 is happening. I've checked, and I've threatened,
13 and I've plied analysts with candy and all sorts
14 of stuff. But that's what's going on.

15 So I'm going to stop my comments there
16 to save time, and I think that addressed a couple
17 big issues that came out of the work group.
18 Thank you.

19 DR. LATTS: I am going to take this
20 one.

21 CO-CHAIR CROOKS: Lisa?

22 DR. LATTS: We're oh for one so far,

1 so we'll see how we do here.

2 (Laughter.)

3 DR. ZARITSKY: I disagree. Maybe
4 we're one for one.

5 DR. LATTIS: Yes, maybe. Exactly.

6 (Laughter.)

7 DR. LATTIS: So as we've discussed,
8 this is a similar measure to the previous measure
9 in the sense that we're looking at dialysis at PD
10 adequacy. So Kt/V , looking at a lower bounds of
11 1.7. And then this one does have an upper bounds
12 of 8.5. As we discussed on the last measure,
13 there is pretty good evidence now for dropping
14 the bounds from the -- this is a re-approval of
15 this measure. This is a previously existing
16 measure. It was two prior. So we are dropping
17 to 1.7 for this measure. Good evidence from
18 that. From my understanding a lot of questions
19 and perhaps less adequate evidence for the upper
20 bounds.

21 DR. ZARITSKY: (Off microphone)

22 DR. LATTIS: Well, yes, I was being

1 kind. So it is an intermediate clinical outcome
2 measure and there is reasonable evidence that if
3 we achieve this outcome it will lead to lower
4 mortality. At least a small reduction in
5 mortality and hospitalization was shown based on
6 the data. And I will stop there.

7 DR. ZARITSKY: I agree with Lisa. I
8 think that the one thing that we've all --
9 looking at these measures is that the upper
10 bound; and we're going to talk about evidence,
11 we're going to get really stuck. And I
12 understand why it was included, but with that
13 upper bound in place and we have to do an
14 evidence analysis, I don't see how there's any
15 evidence to support an upper bound.

16 CO-CHAIR CROOKS: It seems going to
17 the specifications that any value over 8.5 is
18 thrown out as being a spurious value and it
19 doesn't need to be --

20 DR. KLIGER: Yes, but just to clarify,
21 we often have methods of excluding implausible
22 data that are not part of the specifications of

1 the measure. That's in sort of the Manual of
2 Operations about how we deal with all measures.
3 If you're measuring calcium, if you get a value
4 that's 20.8 rather than 8.8, we don't include
5 that in the specification. We have a way of
6 making sure that we functionally can exclude
7 implausible numbers.

8 But when it's in the specification, it
9 suggests that the outcomes are worse when it's
10 below the lower limit or above the upper limit.
11 That's really what it implies when you have two
12 limits like that. And I would suggest that
13 there's no evidence that the upper limit for any
14 of the measures we're going to look at that are
15 being proposed for adequacy -- no evidence that
16 we have worse outcomes above the upper limit
17 that's been proposed.

18 CO-CHAIR CROOKS: Okay. Other
19 thoughts on the evidence?

20 DR. KRISHNAN: So are we voting on it
21 as is, or are we voting on it with the --

22 CO-CHAIR CROOKS: No, we have to vote

1 on it as it is.

2 MR. SAMPSEL: Yes, you vote as it has
3 been submitted. I mean, so and then just so we
4 can walk through this, in the event that you
5 would vote it down saying there's not enough
6 evidence, we would then -- while it wouldn't go
7 through the full criteria at this in-person
8 meeting, we would then say, okay, help these
9 developers out. What are your recommendations
10 that would make this more plausible for you? And
11 then would have time to revise during the public
12 comment period.

13 DR. LATTS: And then if they revise it
14 during the public comment period, does it come
15 back to Committee for review in totality from
16 soup to nuts?

17 MR. SAMPSEL: Well, basically it would
18 come back to the public. Yes, if you stop it
19 here, it stops. We're not going to have any more
20 votes. But we can have the discussion. And then
21 when it comes back, you would do a total review.
22 At the same time you could say that that's lovely

1 what you did, but to us we don't agree it
2 requires a re-vote. We still don't want to
3 recommend it.

4 DR. LATTS: And could we just for
5 efficiency's sake, since the developers have
6 already told us they'd be okay tossing out the
7 upper bounds, go through the rest of it for --
8 not for actual voting, but to give the developer
9 input now on the rest of it, just again to save
10 us time later since it's so much easier to do
11 this in person than in a phone call?

12 MR. SAMPSEL: Yes, you can do that as
13 well.

14 CO-CHAIR CROOKS: That was my
15 thoughts, too. Right.

16 DR. KLIGER: With the understanding
17 that we're saying for today we'd be saying no.

18 MR. SAMPSEL: Correct.

19 CO-CHAIR CROOKS: Correct, but with
20 the understanding that we're working with the
21 developer to improve their metric. And they
22 might as well hear whatever other feedback we

1 have, but we're not going to vote on the rest of
2 the criteria. So it would be less of a formal
3 structure, but they'll get to hear other thoughts
4 from the Committee.

5 MS. BAL: The only thing additionally
6 I would say is you could also again vote with
7 exception or you can vote it down as well. Or
8 you can continue to vote it as is, and they can
9 still bring that back revised if you recommend or
10 don't recommend it. So either way, if you want
11 them to come back with revisions, they can, and
12 that can be something that we discuss at the
13 post-comment call. So it doesn't necessarily
14 have to be that it's not recommended and then
15 you're given new information. I just wanted to
16 let everyone know that that is -- there's both
17 options. If you recommend it to move forward and
18 then we can discuss it that way. They can bring
19 more information. And if you recommend not to,
20 they can bring more information and then we'd
21 move forward.

22 DR. KLIGER: Yes, but I mean again, I

1 presume you're suggesting that our judgment here
2 about evidence has to be based on what we have
3 currently about the evidence, and the evidence
4 is for the measure as presented to us, right?

5 (No response.)

6 DR. KLIGER: Okay. Thank you.

7 DR. SOMERS: But we can vote
8 insufficient evidence and move forward, is
9 what --

10 (Simultaneous speaking.)

11 MS. BAL: You can vote insufficient
12 with exception --

13 DR. SOMERS: Yes.

14 MS. BAL: -- and move forward, yes.

15 CO-CHAIR CROOKS: With the exception
16 that they need to fix the upper limit?

17 MS. BAL: Well, there would be no
18 exception listed, but all you're saying is that
19 you're moving the evidence forward even though
20 you feel that it's weak or low. And you're
21 saying that despite that you feel that you should
22 move forward with the measure. That's what

1 you're saying. So you can choose that right now
2 what evidence you've been provided you don't feel
3 that it's -- if you vote just insufficient, that
4 means it goes down. If you vote insufficient
5 with exception, you're saying that it's okay to
6 go for now and the developer can bring updated
7 information for you at the post-meeting.

8 CO-CHAIR CROOKS: So if we did vote to
9 accept it with exception and then later they
10 didn't meet our criteria, would we be able to
11 take it down at that point?

12 MS. BAL: Yes. So at the post-meeting
13 call if you -- because it would be with any
14 measure, even if it didn't have to do with this
15 one.

16 MR. SAMPSEL: Can we just go on break
17 for a minute. The steward has some issues. So
18 can we just go ahead and do the break and then
19 come back?

20 CO-CHAIR CROOKS: It's been suggested
21 that we take a break.

22 (Laughter.)

1 CO-CHAIR CROOKS: All in favor?

2 (Chorus of ayes.)

3 CO-CHAIR CROOKS: Okay.

4 (Whereupon, the above-entitled matter
5 went off the record at 3:27 p.m. and resumed at
6 3:45 p.m.)

7 CO-CHAIR CROOKS: We're going to have
8 Sarah I think will give us an update on where
9 we're at with this issue on the upper limit.

10 MS. SAMPSEL: All right. Luckily I've
11 had renal measure training over the past couple
12 of years. So I was ready for you all.

13 But anyways, I think what we're going
14 to do here and have had discussions with our
15 colleagues here at the University of Michigan and
16 CMS. And we're going to do a couple of things.

17 First of all, they're going to make
18 some stipulations to the Measure, which I will
19 let them discuss. And then we want to continue
20 to have the discussion for this Measure.

21 And we'll continue to go through the
22 vote based on the stipulations that they are

1 making. We fully understand then that means what
2 you will be voting on is not exactly what's in
3 the paperwork that you received.

4 But we don't think the changes that
5 they are going to stipulate and the
6 clarifications that they're going to make, are
7 big enough to warrant not considering them now
8 versus the future.

9 So we will go all the way through the
10 discussion. You will vote on the measures. It
11 will be with the stipulations that the Committee
12 is making. Therefore to streamline and have some
13 efficiency in our discussions moving forward.

14 Because the stipulation frankly
15 impacts all of the adequacy measures that CMS and
16 the University of Michigan will be discussing, we
17 will also then try to group discussion of the
18 measures.

19 And although we need to vote on the
20 measures separately, just kind of keep in mind
21 that going forward for the rest of today, we want
22 to make sure that we're drawing out anything else

1 that you think needs to be discussed on these
2 measures. But also recognizing there are a lot
3 of similarities between these measures.

4 And the University of Michigan is
5 going to do that as well. So I'll ask Joel to
6 make the stipulations on how they want to change
7 the Measure.

8 DR. ANDRESS: So I, just -- you know,
9 just to make clear. You know, the upper bounds
10 were put in place more as an administrative means
11 of ensuring that the data integrity were
12 maintained.

13 And they were included in the
14 description of the Measure as a means of being
15 transparent to you and others in the community
16 for understanding how we were calculating the
17 Measure.

18 You know, I -- we are willing to
19 stipulate at this point that we can remove the
20 upper boundaries as a matter of moving forward
21 with the Measure. I think there's no expectation
22 on our part that we're presenting them as a

1 meaningful clinical guideline or boundary of
2 performance of dialysis displays.

3 As I understand it, by doing so, we
4 offer the opportunity to continue discussion on
5 the Measure today. The alternative being that we
6 shut down discussion now and attempt to review
7 all -- I think it's next six or eight, whatever
8 measures in a two-hour time period at some point
9 after public comments.

10 And I would suggest that this is
11 probably not feasible to accomplish. It doesn't
12 make a whole lot of sense since we're all here
13 anyway.

14 So we will stipulate that we will
15 remove that boundary. The expectation will be
16 that as has been stated, that the impact on the
17 measures, the analyses that we have provided,
18 will be negligible to trivial.

19 We will however, provide updated
20 documentation for each of the dialysis adequacy
21 measures. As well as updated analyses prior to
22 the end of the public comment period for you to

1 review.

2 I think the goal in doing this is not
3 to substantively change the measures as we
4 presented them. But to provide us a path forward
5 for discussing the measures. We're often
6 clinical in reporting issues as we would wish to
7 do for all of our measures.

8 And so we lay that before you for your
9 consideration.

10 DR. DALRYMPLE: There's just one other
11 question I wonder if I can bring up as long as
12 there's going to be stipulations made about all
13 the PD measures?

14 I noticed in all of them, weekly Kt/V
15 is interchangeably used with single pool Kt/V,
16 including in this one. And I'm wondering if we
17 could actually specify that's what intended in
18 all the PD measures is not a single pool, but
19 weekly Kt/V?

20 DR. MESSANA: No. Since Microsoft is
21 not represented at the table, we would like to --

22 (Laughter)

1 DR. MESSANA: Glean, replace function
2 and Word for that. Someone went through and was
3 a little over zealous in trying to standardize
4 measures. And got into a couple of the PD ones.

5 Clearly single pool Kt/V is not what
6 we ever intended with this. And part of that
7 stipulation will be to clean that up for all --
8 for the PD measures.

9 It comes up mostly on the pediatric
10 one, 2705 I think.

11 DR. DALRYMPLE: It's in this one for
12 example. And I think it shows up in almost all
13 the PD measures. But I'm just wondering as long
14 as we're stipulating.

15 DR. MESSANA: Yes. That's --

16 DR. DALRYMPLE: Clarifications for
17 purposes of us making progress through today,
18 would that be also acceptable to stipulate that
19 that's not?

20 DR. MESSANA: More than acceptable.
21 It's accurate.

22 CO-CHAIR CROOKS: Thank you for

1 clarifying that. And thank you for reading the
2 measures very carefully Lorien.

3 Okay. Alan?

4 DR. KLIGER: I just have a procedural
5 question for the NQF staff. I don't remember a
6 precedent for this. That is, changing the
7 specifications of a measure based on a discussion
8 and then moving forward with the discussion.

9 So, just help me understand whether
10 this is something that you have entertained and
11 do with stewards other than CMS?

12 MS. SAMPSEL: No. I mean, this is
13 definitely something, it may not have ever
14 happened in renal, but has happened in other
15 measure development activities.

16 And I think folks who have
17 participated on other committees would recognize
18 that. And it's not just for CMS measures.

19 DR. KLIGER: So, I'm sorry, but does
20 that mean that as we continue to hear measures
21 through the rest of today and tomorrow, or in the
22 future, that our policy will be that we will

1 consider revising those measures based on what we
2 say as we move forward?

3 MS. SAMPSEL: Well, I don't think in
4 this case that -- I mean, I think even as Joel
5 said, that there's kind of an interpretation of
6 how the specification is written. That I don't
7 believe that they are substantially revising this
8 Measure based on your input or on the evidence
9 input.

10 And that's still not on the table.
11 You still -- you know, it's still not up to the
12 committees to tell measure developers how to
13 revise the measures.

14 You can make recommendations for their
15 consideration. But, you know, I really think in
16 this case as in the previous cases, that just
17 kind of the -- kind of small magnitude of the
18 change that's being made to this Measure and
19 based on the evidence presented and everything
20 else that's in the submission form it goes in
21 line with that change that they're making.

22 MS. BAL: And just to --

1 DR. KLIGER: I think it's a wise
2 choice. I just want to be clear about the
3 precedent that we're setting here. That's all.

4 MS. SAMPSEL: So, it really is not a
5 precedent. So, go ahead Poonam.

6 MS. BAL: I just wanted to say, the
7 difference is that the change they can make, they
8 are guaranteeing that they're going to implement
9 it before we get to the pre-meeting comment
10 meeting.

11 If the developer said that they would
12 look into it and attempt to make that change,
13 then you should not be taking that into
14 consideration. However, they have said that they
15 can make these changes and will have them made by
16 the next meeting.

17 That's why -- that's the difference of
18 why this is okay and perhaps another one would
19 not be.

20 DR. LATTS: Well, and I would say the
21 other difference to my mind, is that it does not
22 affect any of the downstream reliability,

1 validity or clinical utility.

2 Because it was almost a -- it was a
3 misinterpretation I think of what you were trying
4 to do that this sort of got added into the
5 measure specs. Is my interpretation.

6 CO-CHAIR CROOKS: Okay. Thank you.
7 The Chair is comfortable with this too. And I'm
8 the senior renal steering -- I think I'm the only
9 original one left from all four.

10 So, yes. Okay. So, where were we?

11 (Laughter)

12 CO-CHAIR CROOKS: We're going to vote
13 on evidence that we have to this point. We
14 talked about the bonds and that's gone. Other
15 comments on the evidence before we vote on this?

16 DR. LATTS: And again, just to
17 clarify, we're voting on evidence -- are we
18 voting on evidence based on what's here and then
19 moving on? Or are we voting on evidence based on
20 lopping off the top -- lopping off the top?

21 CO-CHAIR CROOKS: Yes. It's gone.
22 So, we're going to vote on the evidence as it

1 applies to the metric as now stipulated and
2 specified.

3 Okay. Any other comments on the
4 evidence?

5 (No response)

6 CO-CHAIR CROOKS: I think I'm the --
7 Okay, let's vote.

8 MS. BAL: Oh no. You know, evidence
9 is a bad slide. We'll just --

10 (Laughter)

11 MS. BAL: Just for the sake of time,
12 let's just go ahead and do a hand count again.
13 We're having some issues with our evidence slide.

14 So, for -- if you vote high for 0318,
15 evidence, please put your hand up now. Please,
16 very high.

17 Okay. I have three. All right,
18 moderate?

19 All right, that's 20. And then I will
20 just go with zero for the other two because no
21 one else can vote at this point.

22 So then the results for 0318,

1 evidence, is three high, 20 moderate, zero low,
2 zero insufficient. And we can move forward to
3 gap.

4 CO-CHAIR CROOKS: Okay, Lisa?

5 DR. LATTI: Okay. Next up.

6 Opportunity for improvement. So based on 2013
7 Crown Web data, there was -- and again, looking
8 at the four-month spec, which was not something
9 that I understood, so thank you for explaining
10 that.

11 So at least once in four months it was
12 78.6 percent. So just about 79 percent in terms
13 of the PD adequacy across the board. When they
14 looked at subsets of racial and ethnic
15 populations, it was statistic -- again, similar
16 to what we've seen in the previous measures.

17 Statistically significant but not
18 clinically significant with ranges from 76.9
19 percent to 79.3 percent between the old, the
20 young, the black, the white, the Hispanic or not,
21 and male or female.

22 So, I would not take that to be

1 clinically significant. So, my take away is, I
2 think that there is opportunity for improvement.
3 But there are no significant racial/ethnic
4 differences.

5 DR. KRISHNAN: And Developers, when
6 you guys looked at the distribution of PD Kt/V,
7 was it in the bell curve? Or was there -- was it
8 asymmetrical?

9 Because I could just see based on the
10 lack of microspecifications, you know, you're
11 assuming that there's residual renal function in
12 there. I am too.

13 But did you know, did you look at a
14 histogram and see if there was a bimetal
15 distribution suggesting that there are some
16 people that are thinking with or without?

17 DR. MESSANA: I don't think I can
18 answer that question right now and right here
19 without making something up. And I'm not willing
20 to do that.

21 I don't recall exactly. I can find
22 out for you.

1 DR. KRISHNAN: Yes. And it would be
2 worthwhile if you do. I mean, this is something
3 that we've seen before.

4 DR. MESSANA: Yes.

5 DR. KRISHNAN: It's what happened with
6 Kt/V in the claims data before.

7 DR. MESSANA: Yes. Yes.

8 CO-CHAIR CROOKS: Okay. Reliability?
9 That was specs any. I have one question.

10 So the reliability testing in this
11 case -- we're on performance gap. That's well --

12 (Laughter)

13 MS. OGUNGBEMI: The Committee is now
14 voting on performance gap for Measure 0318. The
15 options are one high, two moderate, three low,
16 and four insufficient. And voting is now open.

17 MS. BAL: Or not.

18 MS. OGUNGBEMI: Oh, my gosh.

19 MS. BAL: Okay. Old school it is. So
20 for 0318, gap, please put your hand up for high.

21 Okay. We have one. Okay, so for
22 moderate?

1 Okay, 21. And then low? And
2 insufficient?

3 Someone didn't vote. Or I counted
4 wrong. But, so 0318, gap, one high, 21 moderate,
5 zero low, zero insufficient.

6 And this Measure moves forward to
7 reliability.

8 DR. LATTIS: All right. So
9 reliability, we've talked about the
10 specifications. Basically anybody on PD who --
11 and looking at Kt/V -- weekly Kt/V, but then
12 looking at the most recent measurement within a
13 four-month period.

14 One question I had for the Developer
15 is what if they do not have a Kt/V measured
16 within that four-month period? How does the
17 facility get assessed for that?

18 Because again, we don't want people to
19 be able to get away with not measuring it. So
20 that's one question I had.

21 Otherwise, when they looked at the
22 IUR, it was the inter -- the within clinic

1 variation was very high -- or reliability, sorry,
2 was very high at 91 percent.

3 They did note that it was not a --
4 sorry that it was not a -- what's the word I'm
5 looking for? A standard distribution. So that
6 needs to be viewed with some -- a normal, thank
7 you. A normal distribution.

8 So, and the test was designed to be a
9 normal distribution. So there was some, you
10 know, just something to file away. But that it
11 seems to be a fairly reliable measure.

12 DR. MESSANA: So, the response missing
13 is counted against a facility. I mean, the
14 intent is to -- is to report. And to meet a
15 minimum threshold.

16 DR. FISCHER: I have one minor book
17 editor comment. When you read your denominator
18 statement on the first page as the Developer.
19 You don't specify that it's people on PD.

20 And later down on page 15 or wherever,
21 farther in, it's indicated but on the front it's
22 not. It looks like there was a gap. I'm just --

1 anyway. So that's a minor comment.

2 More major comment is, if the data has
3 a non-normal distribution and you're trying to
4 apply a statistical test that requires that, did
5 you transform the data and then apply the
6 statistical test?

7 Or I just am curious for your
8 rationale, just in terms of the robustness of
9 assessing the statistical significance.

10 DR. MESSANA: So, thank you for the
11 book editor comment. I was going to point out
12 the denominator detail. But for the sake of time
13 we won't -- hopefully won't have to go there.

14 We did check with our biostatistical
15 colleagues. The ANOVA, one of the assumptions
16 for ANOVA is normal distribution. But it's not
17 very sensitive.

18 The IUR analysis is apparently not
19 sensitive to that and still provides a pretty
20 robust comparison between facilities and within
21 facilities. So, they are very comfortable using
22 it even though the data are not strictly

1 speaking, normally distributed or somewhat
2 skewed.

3 DR. KRISHNAN: So I just, back to what
4 I said before. Joe, it may be worthwhile just
5 looking to see if there are some people that are
6 reporting with residual/without residual,
7 depending on how it's mapped.

8 That could be the -- I don't know.
9 I'm just saying that could be the other reason
10 why this normal -- not distributed. You can just
11 file that away.

12 The other question I have is, it may
13 be worthwhile to think about the first value in a
14 month rather than the last value in the month.
15 We've seen facilities that sometimes try to --
16 will keep the lab until they get something they
17 like.

18 So we've gone internally to a system
19 where we just take the first value. Because you
20 can't fix that.

21 DR. MESSANA: So, two comments. The
22 data element and CROWNweb that we use is a

1 complete value. Right? It doesn't separate out
2 the residual renal function from the -- it's the
3 1627.

4 DR. KRISHNAN: I hear you. Just I
5 know how it works in the background, right. It's
6 like a telephone game. Someone has hooked up a
7 data variable to another data variable.

8 I'm not saying it's right or wrong.
9 I'm just saying you may just want to look to see
10 if that's what's happening.

11 I hear you, the specification is like
12 that. I just can't --

13 DR. MESSANA: Okay. Mahesh, thank you
14 for the comment. I can't -- it's not actionable
15 for us based on the CROWNWeb extracts that we
16 have.

17 DR. KRISHNAN: You can't do a
18 histogram to see what --

19 DR. MESSANA: No, no. I can do a
20 histogram. I can't do a residual renal function
21 --

22 DR. KRISHNAN: Yes.

1 DR. MESSANA: Versus without residual
2 renal function.

3 DR. KRISHNAN: Yes.

4 DR. MESSANA: Because the data element
5 is a combined data element --

6 DR. KRISHNAN: Yes.

7 DR. MESSANA: In CROWNWeb. So,
8 thanks.

9 DR. KRISHNAN: Yes. And then the
10 second one was the issue around the first value
11 of the month rather than the last value of the
12 month.

13 DR. MESSANA: Yes, we -- so I'd have
14 to go back and look. I don't think there are
15 multiple values or many cases, if there are any
16 with multiple values in a month.

17 We're talking about multiple values
18 over four months. Remember, the reporting period
19 is four months. So, I can check and see if there
20 are any patients that have more than one PD Kt/V
21 value within a month.

22 As someone who's provided home

1 dialysis and particularly PD for a long period of
2 time, I would think that there would be negative
3 marketing implications of asking people to
4 present multiple 24 hour collections in a month.

5 But, it's possible. We can look at
6 that certainly. So, thanks for the
7 recommendation.

8 DR. KRISHNAN: Yes. It's just we've
9 done that consistently now with all of our
10 internal metrics to preventing gaming of the
11 system.

12 CO-CHAIR CROOKS: I have a comment
13 that is more of a comment than a question. But,
14 it appears to me that this is -- still would fall
15 in the category of a checkbox measurement.

16 You take the -- you have to take them
17 at their word that the criteria was met for and
18 then check that box. Interunit reliability is
19 not going to verify that they checked the box
20 right or not.

21 The fact in the validity testing you
22 did test it against mortality and hospital days,

1 does show that there's some validity to it. But
2 there was really nothing in there to really
3 verify that the patients actually, you know, that
4 when they checked the box the patients actually
5 had that value.

6 And because this is a pay for
7 performance measure, it just worries me that
8 that's not really checked or acted, unless I'm
9 missing something.

10 DR. MESSANA: It's not a checkbox.
11 The value is reported. But it is -- the value is
12 reported combined dialytic and residual renal
13 function Kt/V.

14 So the number that shows up in that
15 data field is a 1.8 or a 1.9 or a 2. And to
16 Mahesh's question about residual renal function,
17 there is no more granular data about what was the
18 contribution of residual renal function.

19 CO-CHAIR CROOKS: Right.

20 DR. MESSANA: So, it's -- we are
21 dependent upon providers reporting accurate data
22 for all measures. And I -- we don't have any

1 evidence that that's not the case here.

2 But it's not a checkbox. It's the
3 actual data volume.

4 CO-CHAIR CROOKS: Yes. I appreciate
5 the difference. They're reporting a value, but
6 you're -- you have to accept it.

7 And there's no place in the
8 reliability/validity testing to actually go in
9 and see that they're, you know, just on a spot,
10 random sample, that they're actually putting in
11 the right values.

12 That would strengthen it, but, okay.
13 Other -- right.

14 DR. MADDUX: Joe and Claudia, I'm
15 wondering if there was any consideration made for
16 patients new to the modality and the timing?

17 You have in the denominator the SRD
18 greater than 90 days in adults. And being in the
19 facility for an entire month.

20 But that period following training
21 with a PD patient is a period that takes some
22 time to modify. And I just was wondering if

1 there had been any analysis done on the
2 reliability results of those new to the modality?

3 DR. MESSANA: I don't believe so.

4 CO-CHAIR CROOKS: Lori?

5 MS. HARTWELL: I just have a quick
6 question following up to Mahesh about the time of
7 the month. As a former PD patient, I'm not
8 always available at the first of the month to do
9 the test.

10 So, it really is based on my
11 availability to accomplish. So it's really not
12 in the control of the person doing the test.
13 It's in control of the patient in this one.

14 DR. KRISHNAN: I was thinking measures
15 in general, right. If you put up a lab measure,
16 people may keep retesting until they get what
17 they want. The way to stop -- the results of the
18 Measure.

19 The way to stop that is you just take
20 the first value and not allow them to do that
21 value in the future.

22 MS. HARTWELL: Yes, what you're

1 saying, I was just -- I didn't want to put it at
2 a time of the month. Maybe they can just do one
3 test. I don't know.

4 DR. KRISHNAN: Right.

5 MS. HARTWELL: As opposed to having
6 the patient have to come in the first of the
7 month. And then the patient is seen as a failure
8 because they're not meeting that goal due to
9 other obligations.

10 DR. KRISHNAN: Yes. It makes sense.

11 CO-CHAIR CROOKS: But this is -- the
12 Measure is that it has been done once in the last
13 four months, right. So, less important than what
14 day I suppose in this metric.

15 Okay. Other thoughts on reliability
16 and specifications before we vote?

17 (No response)

18 CO-CHAIR CROOKS: All right. Let's
19 vote. Maybe?

20 MS. OGUNGBEMI: Well try.

21 CO-CHAIR CROOKS: Okay.

22 MS. OGUNGBEMI: The Committee is now

1 voting for Measure 0318 on reliability. The
2 options are one high, two moderate, three low,
3 four insufficient. Voting is open.

4 The results are three votes for high.
5 17 votes moderate. One vote low and zero
6 insufficient. Measure 0318 passes on
7 reliability.

8 CO-CHAIR CROOKS: Thank you.
9 Validity.

10 DR. LATTS: All right. Validity. So,
11 there was validity testing and I'm a little out
12 of my depth here. Using the Spearman correlation
13 between this Measure and the 2013 SMR and SHR,
14 the numbers were high or low and statistically
15 significant. So it was good.

16 It was also face validity using TEPs
17 and 2006, 2010 and 2013, which were all in
18 agreement that this Measure did have face
19 validity.

20 I'll stop there. It was, you know, it
21 looked pretty solid to me in terms of the
22 validity testing and the face validity.

1 CO-CHAIR CROOKS: Other comments?

2 Lorien?

3 DR. DALRYMPLE: So, my interpretation
4 of the validity is there was no statistical
5 association with the SMR and the SHR association
6 was quite weak at .139. Which I think the
7 Developers acknowledged.

8 So, weak correlation with SHR and SMR.
9 So I think the validity is based on TEP. If we
10 agree there's face validity to it.

11 But I don't think it would meet it on
12 association with outcomes based on these
13 correlations.

14 CO-CHAIR CROOKS: The results were in
15 the right direction though. As opposed to other
16 metrics where we just --

17 (Laughter)

18 CO-CHAIR CROOKS: Okay. Any other
19 comments on the validity testing?

20 (No response)

21 CO-CHAIR CROOKS: Okay. Thrust of
22 validity. Anything else? Okay, let's vote.

1 MS. OGUNGBEMI: The Committee is now
2 voting on validity for Measure 0318. Options are
3 one high, two moderate, three low and four
4 insufficient. Voting is open.

5 Results are one vote high, 17 votes
6 moderate, three votes low and zero votes
7 insufficient. Measure 0318 passes on validity.

8 CO-CHAIR CROOKS: Feasibility?

9 DR. LATTI: From a feasibility
10 perspective, this is being done today, you know,
11 both feasibility and usability, it's feasible.
12 It's done out of CROWNWeb.

13 It's doable. I don't know what else
14 to say.

15 CO-CHAIR CROOKS: You're all over it.
16 Okay. Other comments on feasibility before we
17 vote?

18 (No response)

19 CO-CHAIR CROOKS: Okay. Let's vote.

20 MS. OGUNGBEMI: The Committee is now
21 voting on feasibility for Measure 0318. Options
22 are one high, two moderate, three low and four

1 insufficient. Voting is open.

2 Results are 14 votes for high, eight
3 votes moderate, zero votes low and zero votes
4 insufficient. Measure 0318 passes on
5 feasibility.

6 CO-CHAIR CROOKS: Okay. And usability
7 and use.

8 DR. LATTIS: Nothing else to add.

9 CO-CHAIR CROOKS: No, it's in use.

10 DR. LATTIS: It's being used.

11 CO-CHAIR CROOKS: There has been a
12 slight improvement in 2013 demonstrated. Any
13 other comments in usability and use?

14 (No response)

15 CO-CHAIR CROOKS: Okay. Let's vote.

16 MS. OGUNGBEMI: The Committee is now
17 voting on usability and use for Measure 0318.
18 The options are one high, two moderate, three low
19 and four insufficient. Voting is open.

20 The results are 16 votes high, six
21 votes moderate, zero votes low and zero votes for
22 insufficient information. Measure 0318 passes on

1 usability and use.

2 CO-CHAIR CROOKS: Before we vote on
3 recommendation for endorsement, any other general
4 comments?

5 (No response)

6 CO-CHAIR CROOKS: Is the voting
7 machine working? Okay, let's vote.

8 MS. OGUNGBEMI: The Committee is now
9 voting on overall suitability for endorsement for
10 Measure 0318. Options, one yes, two no. Voting
11 is open.

12 The results are unanimous. 22 votes
13 yes and zero votes no. The Measure passes for
14 meeting NQF criteria for endorsement.

15 CO-CHAIR CROOKS: Okay. We're going
16 to move on -- right onto 2704. Another CMS
17 metric. Same tag team.

18 DR. ZARITSKY: Yes. So for the sake
19 of time, I think I'll defer any comments. What I
20 said about 0318, I think is the same is true for
21 this Measure.

22 This includes children in the Measure

1 along with adults.

2 CO-CHAIR CROOKS: Okay. Who's on
3 first?

4 CO-CHAIR ANDERSON: I think it's going
5 to be me.

6 CO-CHAIR CROOKS: Constance?

7 CO-CHAIR ANDERSON: Yes.

8 CO-CHAIR CROOKS: Okay.

9 CO-CHAIR ANDERSON: Okay. This is an
10 intermediate outcome where the process of care
11 can influence the outcome of patients. This is a
12 combined for adult PD patients and for pediatric
13 PD adequacy targets.

14 The -- it is a -- in terms of the
15 evidence, the measure focus is supported by KDOQI
16 guidelines. There were two randomized control
17 trials.

18 There was a correlation demonstrated
19 between morbidity and mortality. Kt/V less than
20 recommended, of two, has been changed and dropped
21 and lowered to 1.7.

22 And the body of evidence shows a

1 strong correlation between total solute clearance
2 and morbidity and mortality as I said. So, there
3 is a high degree of association with the efforts.

4 CO-CHAIR CROOKS: Okay. Elizabeth?
5 Do you have anything to add?

6 (No response)

7 CO-CHAIR CROOKS: Okay. So this is
8 open for discussion. The one thing that is
9 different is that for the pediatric patient, the
10 minimum is 1.8 instead of 1.7.

11 I believe the submission parallels the
12 last in almost every other aspect. Is that -- am
13 I reading that right? Are there important
14 differences that we should know about?

15 DR. MESSANA: No, just the pediatric
16 criteria are consistent with the clinical
17 performance recommendations and prior TEP
18 recommendations for a 1.8 value. And I think
19 every six months for the interval.

20 So, the numerator includes the number
21 of adults who achieved the 1.7 threshold within
22 four months. And the number of kids who achieved

1 the 1.8 threshold in six months.

2 CO-CHAIR CROOKS: Right.

3 DR. MESSANA: The denominator is the
4 combined set of two.

5 CO-CHAIR CROOKS: Alan?

6 DR. KLIGER: So for the kids, as I
7 understand it, the evidence is basically face,
8 you know, face validity evidence that clearance
9 ought to be at least as good as it is in adults.
10 And maybe a little bit better given, you know,
11 the body surface area relationship.

12 Is that true? Or is there any
13 additional data or evidence to support this?

14 DR. SOMERS: There's a little bit of
15 data from very small numbers of patients about
16 increased solute clearance increase growth. And
17 some data from adolescents.

18 I think they come from the UK, showing
19 kind of better outcomes, fewer hospitalizations.
20 Mortality sort of data.

21 But, very much it's more expert
22 opinion face validity sorts of issues.

1 DR. ZARITSKY: I'll just add that, you
2 know, for pediatrics especially with growth, the
3 importance of a single Kt/V value in the face of
4 other several other parameters, it's sort of
5 weighted.

6 And I think that adding the .1, you
7 know, if there's an extra .1 when you look at
8 surface area, the surface area is tracked pretty
9 well with, you know, peritoneal surface areas.

10 So, there's not necessarily that just
11 a, you got to be better for some reason.

12 DR. KLIGER: So, if I could just
13 follow on. Is there any data to have this
14 particular -- I mean, more sounds like it's
15 better.

16 Is 1.8 -- any evidence for 1.8 versus
17 2 or 1.9, or any of that?

18 DR. KASKEL: We don't have that. We
19 don't have a study to look at that increase.

20 One of the other unknowns is the
21 effect on, besides growth and development, is
22 neurocognition. We have very little information

1 as to how this clearance may affect
2 neurocognition at critical periods of time.

3 So we opt for a higher number without
4 studies.

5 DR. KLIGER: And can I just ask one
6 more question? The Developer, it was confusing
7 to me about why the Developer has submitted
8 several clearly overlapping measures.

9 What do you have in your minds in
10 terms of making so many -- such similar measures?

11 CO-CHAIR CROOKS: Yes, I think it
12 would be a good time to ask kind of why the suite
13 of measures?

14 DR. ANDRESS: Well, I'm a masochist.

15 (Laughter)

16 DR. ANDRESS: So, that was part of it.
17 No, so, this is actually in part a policy issue.

18 We have minimum reporting requirements
19 for most of our programs that includes dialysis
20 facility, compares public reporting. But it also
21 includes the QIP.

22 Wherein, we don't report on facilities

1 that -- or on where -- we don't report measures
2 on facilities with fewer than 11 patients who
3 fill the denominator.

4 The original formulation for these
5 measures essentially created a situation where
6 you had originally three. And you know, with
7 pediatric PD adequacy as a new measure we're
8 presenting here today, potentially four segments
9 that a facility's populations can be broken into.

10 And in order for a facility to have a
11 rating for each individual measure, it must have
12 a total of 44 patients within it. The problem
13 that we were finding is that many facilities
14 would have a handful of PD patients, a handful of
15 pediatric patients.

16 And these patients were systematically
17 excluded from assessment on these measures
18 because of the reporting requirements. The
19 reporting requirements are there for a couple of
20 reasons.

21 The 11 case minimum. One is the
22 reliability of the assessment. The other is the

1 risk of revealing patient identities when you
2 start getting to really small numbers in the
3 facilities.

4 So, there were a couple of reasons why
5 we couldn't do away with that. And but I think
6 we had a very vested interest in ensuring that we
7 were assessing dialysis adequacy for as much of
8 the population as possible.

9 Particularly for peritoneal dialysis
10 patients where, you know, there's a lot of
11 interest in pushing the use of PD as an alternate
12 therapy to -- instead of hemodialysis.

13 But I think, you know, most especially
14 for pediatric patients. Where the conclusion I
15 think we reach is that pediatric only measures
16 have some difficulty getting any traction because
17 you only get an assessment of I think 13
18 facilities, something like that.

19 And the QIP is a good -- 30? Okay,
20 30. So 30 facilities. Very -- it's very low
21 impact.

22 So in terms of how to address this, we

1 hit upon the potential solution of essentially
2 creating combined measures. Where we -- and
3 where we combined the denominator.

4 And the question is less, are you
5 hitting this particular target, and it's more an
6 issue of, are you hitting the -- an adequate
7 level of dialysis dependent upon your modality
8 and your age in the case of peritoneal dialysis.

9 And so we constructed those measures
10 after determining that we felt that they were a
11 reasonable approach. And we presented them here
12 for consideration by the Committee.

13 I think the reason we still have the
14 other four individualized measures is that those
15 measures are, you know, NQF endorsed. They are
16 implemented in the QIP.

17 And it makes sense for us to maintain
18 their endorsement until such time as it's
19 determined whether or not implementation of the
20 other measures is appropriate.

21 Our intention I think is that if that
22 does come to pass, that we would seek to retire

1 the four original measures that divide by -- that
2 divide the population by age and modality.

3 And that we would go forward with the
4 whole peritoneal dialysis measure and the whole
5 hemodialysis measure and the combined measure
6 between the two. And then the purpose of having
7 those three measures together is that you can
8 maximize coverage in a population for assessment
9 with the combined measure.

10 Or you can get some more granularity
11 in terms of how peritoneal dialysis versus
12 hemodialysis are handled within -- or at the
13 facility level as distinct modalities. And that
14 gives us some flexibility in terms of how it can
15 be reported in different programs.

16 So that was the rationale. We didn't
17 want to lose the measures that we had for obvious
18 reasons I think.

19 But we wanted to have the opportunity
20 to present the other measures. And then the
21 anticipation is that we will not maintain all of
22 them forever. But we will eventually start

1 walking back -- or retiring rather, the measures
2 that we deem to be less useful at a later date.

3 CO-CHAIR CROOKS: So, to maybe
4 reinterpret, to make sure I understand. Are you
5 saying that in theory, but not with a guarantee
6 that you might be moving towards Measure 2705 as
7 your Grand Poobah.

8 And that would be the only measure you
9 need in the long run?

10 DR. ANDRESS: I think it would be more
11 accurate to say that we are moving toward getting
12 -- including more patients within our quality
13 assessments. But the degree of granularity
14 that's required for any one program leads us to
15 want to consider both the combined measure, which
16 is itself actually just a -- is a composite of
17 the two -- of the hemodialysis and the peritoneal
18 dialysis measures.

19 Or have the capacity to look at the
20 two modalities separately. And that's really
21 what we're wanting to move toward eventually.

22 CO-CHAIR CROOKS: Right. Yes, with

1 2705 you can always break out your other metrics
2 because they're all within there. And you could
3 break it out and look at it --

4 DR. ANDRESS: Yes.

5 CO-CHAIR CROOKS: As if the other
6 metric still existed. So, okay. Alan, did that
7 answer your question? Okay. Franklin?

8 DR. MADDUX: Just for my pediatric
9 colleagues here, is there any rationale other
10 than logistics why six months instead of four
11 months on the pediatric patient would be chosen
12 as the interval of measurement?

13 DR. SOMERS: No. And I think most of
14 us check it much more frequently than that.

15 DR. MADDUX: Okay. Okay. We're still
16 discussing evidence.

17 DR. KRISHNAN: Is the question, should
18 we formalize those frames? Should they both be
19 in the same time frame?

20 DR. MADDUX: Well, I just think, you
21 know, complexities of measures are one of the
22 issues practically that gets into the usability

1 side of things. And so when you're using 1.7 to
2 1.8 when it's all made up on the 1.8 side as to
3 whether it's really right or not. And then
4 you're using four month interval versus six month
5 interval, it just increases the complexity of
6 interpretation for those you're trying to
7 standardize in the measure.

8 CO-CHAIR CROOKS: Yes, it seems
9 counterintuitive that the growing child should be
10 measured less often than the non-growing adult.

11 Okay, evidence?

12 DR. MESSANA: Well, I just wanted to
13 follow up with a comment. If an organization or
14 facility chose to measure every four months, they
15 would exceed the minimum.

16 And so, there's a work around for the
17 complexity issue. And the only justification for
18 including six months was because the clinical
19 performance recommendation, not guideline, stated
20 it that way.

21 So, it's not evidence based.

22 CO-CHAIR CROOKS: Okay. Any other

1 cards up in the air? Well, Lorien, of course.

2 DR. DALRYMPLE: Can I just ask a point
3 of clarification? Because I'm struggling, before
4 we vote on the evidence.

5 The clarification was very helpful.
6 But it actually brought up several concerns for
7 me when we start adding pediatric to adults.
8 Because I'm actually worried we then lose the
9 children.

10 And now how do you intervene on
11 quality when you don't know who's actually
12 getting the low Kt/Vs? Especially if you have
13 150 adults and ten kids in your program.

14 The program might look good, although
15 eight out of ten of our children may have low
16 Kt/Vs. And so you won't actually know, because
17 my understanding of this measure is we're not age
18 stratifying it by pediatrics or adults.

19 So, as we go to vote on the evidence,
20 yes, evidence for peds stand alone. Evidence for
21 adults stands alone.

22 But for the concept of a quality

1 metric that throws those two groups together, do
2 we consider this during our evidence voting? Or
3 later in our specification voting?

4 In case other Committee members
5 reconcile that.

6 CO-CHAIR CROOKS: I think it's
7 appropriate for you to bring it up here. That,
8 you know, where's the evidence that doing a
9 measure like this will work for the group
10 uniformly and not just --

11 DR. DALRYMPLE: I understand the
12 rationale of wanting to report on more units.

13 CO-CHAIR CROOKS: Right.

14 DR. DALRYMPLE: But what I worry is we
15 actually lose useful measures of quality.
16 Especially for the pediatric population.

17 CO-CHAIR CROOKS: Yes. And it's
18 better than not measuring those kids at all
19 because they don't have 11 kids in the unit.

20 DR. ANDRESS: So, that's what I was
21 referring to on that. So, you have the minimum
22 case requirements are for two reasons.

1 On the one hand, you know, there's a
2 concern -- there's a -- it's a policy concern at
3 CMS about the reliability of the assessment.

4 On the second hand, there's the issue
5 of -- there's the issue of patient
6 identification. If you get to a point where you
7 have too few patients, it's potentially possible
8 that a patient could be identified based off of
9 the performance. Or something about the patient
10 could be identified.

11 And so this is a policy that's in
12 place at CMS in general. And I think you would
13 be hard pressed to find any quality measures that
14 we report where a denominator is under 11.

15 I wanted to hit on your point a little
16 bit about the -- you know, the risk of, you know,
17 pediatric patients being subsumed in the whole
18 and lost.

19 I think, you know, there is certainly
20 some reasonable concern with regard to that.
21 Certainly the vast majority of patients in the
22 combined measure for instance are in center adult

1 hemodialysis patients. And they drive much of
2 the performance.

3 The alternative is not that we have a
4 measure or an assessment of the pediatric
5 patients separately. The alternative is that we
6 have no assessment whatsoever because they don't
7 have enough numbers within the facility.

8 And the number of facilities again, in
9 total, that get assessed by the QIP is something
10 like 30. Certainly there are many more
11 facilities with pediatric patients. But they are
12 not currently assessed at all for the quality --
13 for the adequacy of dialysis that their pediatric
14 patients receive.

15 CO-CHAIR CROOKS: Okay. Thanks. I
16 think we understand the logic there.

17 So, before we vote on evidence, any
18 other comments or questions? Oh, Lori's first.
19 I'm sorry.

20 MS. HARTWELL: I just have a quick
21 question, just being new to this process.
22 Because we're missing so many pediatric patients,

1 is there a way to measure like regional? Or
2 citywide?

3 Or something to basically capture the
4 patients that aren't being measured? The
5 pediatric patients? It's just a question.

6 DR. ANDRESS: You could. You would
7 not be able to attribute responsibility to a
8 particular dialysis facility.

9 So, for reporting programs or payment
10 programs that are dependent upon attribution to
11 the facility level, you would not be able
12 specifically to say that that facility was
13 responsible. And then say adjust their payment
14 as a consequence of it.

15 Something where you have a situation
16 like what -- the demonstration that's coming out
17 of the Innovation Center right now with the ESCO
18 project might be a circumstance in which you
19 could have something like that more broadly
20 applicable to the population as a whole.

21 But that's not something that we
22 currently have those as an option.

1 CO-CHAIR CROOKS: Okay. Michael?

2 DR. FISCHER: So just to fall back to
3 Lorien's point. So to me it's less about
4 evidence, more about validity.

5 Because, is the measure going to
6 really be a valid or true measure of quality, of
7 adequacy, of dialysis care? For adults, yes.
8 For kids, maybe not as it's currently written.

9 And that means that it may not be a
10 valid measure when, you know, pediatrics are
11 included in this as it's currently written.

12 And then I guess my question back to
13 the Developer is then about stratification. I
14 mean, to me it seems like the way to resolve some
15 of that is required of the measure.

16 And just in an aggregate report, help
17 stratify reporting by adults and pediatric
18 patients.

19 CO-CHAIR CROOKS: So, what you're
20 asking the Developer if it would be -- even if
21 there are less than 11 patients could stratify it
22 in their reports to the --

1 DR. FISCHER: Precisely. I mean, if
2 that's a concern, that's one potential option.

3 CO-CHAIR CROOKS: Is that a
4 possibility? Is that in the plan?

5 DR. MESSANA: So if you stratify it
6 for adults and children, if you have less than 11
7 children in that facility, you run into the same
8 problem with potentially identifiable
9 information.

10 CO-CHAIR CROOKS: Well, if you're not
11 adjusting payment, but you're just giving them
12 the data so they can -- to let them know if
13 you're not --

14 DR. MESSANA: If I know the geographic
15 location of a facility and there are five kids in
16 that facility, that's the potentially
17 identifiable information issue. That's why we
18 always suppress.

19 In the DFRs, we suppress for small
20 cells for that very reason. So it's a fairly
21 widespread practice.

22 And I think with the -- the

1 stratification would fulfil the concern about
2 losing some of the pediatric information. But it
3 doesn't address the concern about potentially
4 identifiable information for very small cells.

5 CO-CHAIR CROOKS: Okay. That's the
6 answer. Mahesh is next I think.

7 DR. KRISHNAN: Just I'm thinking more
8 about this. So you're saying if there's a
9 facility that has 100 adult patients and three
10 pediatric patients, I'm just wondering how you
11 can -- what the clinic would do?

12 Why the clinic would -- the
13 performance in the adult patients would overwhelm
14 any under-performance by the pediatric patients.
15 It just seems to me like I -- I get -- it almost
16 feels like, well Peter, this is a check the box.

17 We want to have something to cover
18 pediatrics. We have this 11 cell problem. But
19 from a practical reality standpoint, I don't know
20 how to deal with that.

21 CO-CHAIR CROOKS: Don't ask the
22 Developers. Let's ask the Committee. I think

1 what the -- yes, what we're hearing is that it's
2 better than not measuring them at all.

3 And I accept that. I see it's not
4 perfect. I'm not going to let the perfect be the
5 enemy of the good in this case, in my vote.

6 I think it's good that the kids are
7 going to be included in the measure. Hopefully
8 each unit has their own quality improvement
9 program. And we'll want everybody to hit the
10 target.

11 DR. KRISHNAN: But do we think it will
12 actually improve care for pediatric patients?

13 CO-CHAIR CROOKS: I hope so. I can
14 only hope. I can't make -- the granularity isn't
15 there. Until we have larger PD units for kids, I
16 guess.

17 Go ahead.

18 DR. ZARITSKY: Just a technical
19 question. It might also get to reliability. But
20 so, if you have a unit that has 50 adult patients
21 and five pediatric patients, those five patients
22 are still reported in this kind of algorithm,

1 right.

2 So in some senses, by adding them you
3 are encouraging the dialysis unit to at least
4 make those measurements. Because if they don't,
5 that's going to show up on their bottom line.

6 So, I mean, there is a little bit --
7 you are getting that data out. Whereas if you
8 said there is a -- I mean that goes more to your
9 -- I don't know if that goes to reliability or
10 the evidence. But I do see that advantage of
11 those limited circumstances.

12 CO-CHAIR CROOKS: Okay. Rick, one
13 more comment.

14 DR. KASKEL: Even though the numbers
15 are low, each unit, and I think we can fairly say
16 that in the States anyway, we'll look at this
17 data very closely on the monthly basis. And they
18 will change therapy, the dialysis prescription
19 accordingly if they're not making the measure.

20 There's no question that the team will
21 look at that value and determine why they're not
22 making it.

1 CO-CHAIR CROOKS: Okay. Are we ready
2 to vote on the evidence?

3 (No response)

4 CO-CHAIR CROOKS: All right. Let's do
5 it.

6 MS. OGUNGBEMI: The Committee is
7 voting on evidence. This is an intermediate
8 outcome measure. So the options are one high,
9 two moderate, three low and four insufficient.
10 This is for Measure 2704. And voting is open.

11 Results are one vote for high, 18
12 votes moderate, one vote low, and three votes for
13 insufficient. Measure 2704 passes on evidence.

14 CO-CHAIR CROOKS: Okay. Is there a
15 gap?

16 CO-CHAIR ANDERSON: In the analysis of
17 the CROWNWeb and Medicare claims data, 78.1
18 percent had met the adequacy target in the four-
19 month period for adults and the six-month period
20 for pediatrics.

21 Approximately 18 percent of the
22 patients do not reach the target Kt/V. So it

1 looks like moderate performance gap. And the
2 percent of patient PD adequacy numbers falls way
3 below where the hemodialysis adequacy numbers
4 are.

5 There was no disparities in care
6 noted. And I guess that's it. Do you have
7 anything Beth?

8 MS. EVANS: No. The only thing I had
9 thought was really you explained. I had concern
10 over that clinic size less than 11. And were we
11 missing a lot? And actually you answered that.
12 So that took care of a lot of my concerns.

13 CO-CHAIR CROOKS: So there appears to
14 be a performance gap that could be improved on
15 this Measure. Are there other comments about
16 performance gap? Alan?

17 DR. KLIGER: Just a question. When it
18 says -- when you record 18 percent of patients
19 fell below compared to hemo, do you mean failed
20 the test? Is that what you mean by that?

21 CO-CHAIR ANDERSON: Approximately 18
22 percent don't reach that 1.7 as adult.

1 DR. KLIGER: Okay.

2 CO-CHAIR CROOKS: Okay. All right,
3 let's vote.

4 MS. OGUNGBEMI: The Committee is now
5 voting for Measure 2704 on performance gap. The
6 options are one high, two moderate, three low and
7 four insufficient. Voting is open.

8 The results are for performance gap,
9 five votes high, 18 votes moderate, zero low and
10 zero insufficient. Measure 2704 passes on
11 performance gap.

12 CO-CHAIR CROOKS: Okay.
13 Specifications and reliability. Connie?

14 CO-CHAIR ANDERSON: Okay. The data
15 elements are clearly defined. Again, clinics
16 with less than 11 PD patients are excluded. And
17 if the Kt/V is not measured, it's still included
18 in the denominator.

19 The logic and the algorithm is clear.
20 And again, I think you've answered the question
21 about if it's not collected every four months, is
22 it going to start skewing the results.

1 So, I would say that this has a
2 moderate reliability.

3 CO-CHAIR CROOKS: Okay. Other
4 comments? Specifications, reliability, testing?

5 CO-CHAIR ANDERSON: Oh, the other
6 comment I might use is out of 46,307 PD patients
7 in 1,557 units, the inter unit reliability was at
8 91 percent.

9 CO-CHAIR CROOKS: Okay. Other
10 comments?

11 (No response)

12 CO-CHAIR CROOKS: Okay. Let's vote on
13 specifications and reliability.

14 MS. OGUNGBEMI: I need to reset the
15 slide. One moment.

16 The Committee is now voting on
17 reliability. The options are one high, two
18 moderate, three low, and four insufficient. This
19 is for Measure 2704. Voting is now open.

20 MS. BAL: All right. We're hand
21 voting. Okay. So, we're going to have to go old
22 school because now there are more people than

1 voting is possible.

2 So, for reliability for 2704, put your
3 hands up really high for high. If you're voting
4 high on reliability. Please high. So I have
5 five.

6 Okay. So for moderate? Okay, I have
7 18.

8 Okay. And then low? Yes. No need to
9 actually count for the other ones.

10 Okay. So the results are five high,
11 18 moderate, zero low, zero insufficient for
12 reliability for 2704. And we can move forward to
13 validity.

14 CO-CHAIR ANDERSON: All right. In
15 terms of validity. There were no exclusions and
16 there's no need for risk adjustment because there
17 was no disparities.

18 Noted, the measure specs are
19 consistent with the evidence provided. For
20 pediatrics the validity was established on face
21 value validity.

22 This measure is included in the 2015

1 QIP which is a pay for performance. It's also
2 reported in the Dialysis Facility Compare. On
3 the peds it will be reported in QIP in 2018 as a
4 measure.

5 The magnitude in correlation between
6 SHR and SMR is low. In terms of meaningful
7 difference, 82.5 percent achieves the expected
8 Kt/V. 17.4 percent were worse than expected.

9 CO-CHAIR CROOKS: I think you jumped
10 ahead of us on that.

11 CO-CHAIR ANDERSON: Oh, did I jump
12 ahead? Sorry.

13 CO-CHAIR CROOKS: But the validity
14 testing, I see that they had -- they did Spearman
15 --

16 CO-CHAIR ANDERSON: Correlation.

17 CO-CHAIR CROOKS: Or they did the TEP
18 too, yes.

19 CO-CHAIR ANDERSON: Yes.

20 CO-CHAIR CROOKS: So they correlated
21 with hospital ratios and mortality.

22 CO-CHAIR ANDERSON: Right.

1 CO-CHAIR CROOKS: It's a low
2 correlation with the TEP. Okay. So let's vote
3 on validity.

4 CO-CHAIR ANDERSON: We need to have a
5 discussion first.

6 CO-CHAIR CROOKS: I'm sorry. I forgot
7 to open the discussion.

8 CO-CHAIR ANDERSON: Beth? Do you have
9 anything more?

10 CO-CHAIR CROOKS: Jump in.

11 DR. DALRYMPLE: I don't want to
12 belabor this point. But I think this is actually
13 the right place to talk about combining a
14 pediatric and adult measure.

15 And so I think it's worth the
16 Committee maybe just rehashing this one last
17 time. Because I am trying to think, if I'm a
18 parent, and I want to know about performance for
19 my child at a dialysis unit, would I rather see
20 something that says we don't have enough
21 information to tell you anything useful?

22 Or do I want to see something that

1 looks really good, and oh, by the way, this is
2 all being driven by the adults. And do you
3 understand that as a consumer of healthcare?

4 So, I know perfect is the enemy of
5 good. But at the end of the day, if this is
6 going to be publically reported, as a parent, I'm
7 not sure which of those two I would rather have
8 available to me to understand.

9 CO-CHAIR CROOKS: Okay. So, I don't
10 think we're -- and we've kind of gone over that.
11 And I don't think we have a perfect solution for
12 it.

13 DR. KLIGER: I mean, a solution as
14 Andy says, is that we have both. So you'll be
15 able to tell your parents that when you look at a
16 whole unit, including adults and children, the
17 numbers look really good. We can't separate out
18 the kids.

19 But when we look at the kids
20 specifically with the kids measure, we really
21 don't have sufficient numbers to make a
22 meaningful comment. So you'll have both.

1 CO-CHAIR CROOKS: You have a -- and on
2 one you can say, and your child is reaching 1.8
3 or higher. Or we're working on getting them
4 there.

5 DR. DALRYMPLE: And maybe the
6 Developers can weigh in. Because perhaps I
7 misunderstood. I thought that there was a
8 possibility this measure was going to overtake
9 the individual measures we've had in the past of
10 a pediatric one and an adult one.

11 So that would be more reassuring if
12 all three are being kept.

13 DR. ANDRESS: So Joe is here throwing
14 me under the bus. Thanks Joe.

15 So, that is the initial intent. That
16 is not to say of course that it has to be the
17 course of the measures.

18 I think we have that intent in mind
19 with the thought that we didn't want to have, you
20 know, 10 million dialysis adequacy measures that
21 we're, you know, maintaining for no purpose
22 whatsoever.

1 I think it probably makes more sense
2 in this case to have something like the more, you
3 know, composited measure. And that you can
4 report on.

5 And then, you know, investigate ways
6 that we can report more granularly on the
7 detailed data within that measure. Then to have
8 multiple measures.

9 Because I think the comment earlier
10 was right. You can take the peritoneal dialysis
11 measure and then break down reporting by adults
12 and children where that seems like it's feasible
13 and then simply not report anything on the
14 children where it is.

15 That's not something that we've done
16 in the past. So I don't want to pretend like,
17 you know, we've figured this all out.

18 But, I mean, it's certainly something
19 that we can consider doing. I guess the -- you
20 know, we're okay doing it either way. I mean,
21 you know, we're going to be here no matter what.

22 But I think it's -- we'd certainly

1 appreciate your input in what the best way is to
2 manage the measures in terms of how we're, you
3 know, moving forward with this.

4 You know, and at the end the day I
5 think we'll have the information we need. But if
6 we don't have the broader -- the like larger
7 measure constructs, then we have limitations in
8 terms of the extent to which we can report on the
9 composited data.

10 It's easier I think to break those
11 down and provide reporting on them at a lower
12 level. If that's something that we should, you
13 know, choose to do.

14 DR. MESSANA: With the caveat about
15 the small cell size. So, but you would have data
16 at the facility level. And for a subset of
17 facilities you would have data stratified.

18 CO-CHAIR CROOKS: Okay. We're bumping
19 up against our mandatory public input time.
20 Should we try to vote through this measure? Or
21 should we stop here?

22 MS. BAL: Well, we try to keep the

1 public commenting on time. So I would say vote
2 on this and then let's go to public comment and
3 then continue.

4 CO-CHAIR CROOKS: Okay. Are they on
5 the phone or are they behind me?

6 MS. BAL: Oh, vote on validity first.

7 CO-CHAIR CROOKS: Oh, we're going to
8 vote first. I heard you guys -- I heard you say
9 exactly the opposite.

10 (Laughter)

11 CO-CHAIR CROOKS: Okay. Let's vote on
12 the evidence then. I mean, not the evidence,
13 we're going to vote on validity. Validity at
14 this point.

15 MS. OGUNGBEMI: The Committee is now
16 voting on validity for Measure 2704. The options
17 are one high, two moderate, three low and four
18 insufficient. Voting is open.

19 The results are zero votes for high,
20 18 votes moderate, four votes low and one vote
21 insufficient. Measure 2704 passes on validity.

22 CO-CHAIR CROOKS: Okay. Poonam and I

1 have put our heads decided and we've decided to
2 pause for public comment.

3 We're going to -- I know we really
4 want to try to stop at 5:00. We need to stop at
5 5:00. And I know at least one member has to
6 leave at 5:00.

7 But, we're going to have to go ahead
8 a little.

9 MS. BAL: Yes. So, unfortunately we
10 have gone way past where we should be. We should
11 have done with these at 3:30. And it's almost
12 5:00 now.

13 So, due to that, we will have to stay
14 a little later. We're trying not to go too much
15 further. But there are a couple of measures that
16 we do need to get done today before we can leave.

17 So if we can quickly get through
18 public and member commenting, quickly go through
19 the rest of the measures. Hopefully we can get
20 that done and get you guys out of here quickly.

21 CO-CHAIR CROOKS: Okay. The phones
22 are open.

1 OPERATOR: Okay. At this time if you
2 would like to make a comment, please press star
3 then the number one.

4 There are no public comments at this
5 time.

6 MS. BAL: Are there any comments in
7 the room?

8 CO-CHAIR CROOKS: On site?

9 MS. BAL: Okay. We're good. Let's
10 continue.

11 CO-CHAIR CROOKS: We're good. Okay.
12 Thank you.

13 So that gets up to feasibility I
14 believe.

15 CO-CHAIR ANDERSON: Feasibility is
16 based on CROWNWeb data and claims data. And
17 appears high.

18 CO-CHAIR CROOKS: Other opinions,
19 thoughts, comments? On feasibility?

20 Okay. Let's vote on feasibility.

21 MS. OGUNGBEMI: The Committee is now
22 voting for feasibility on Measure 2704. Options

1 are one high, two moderate, three low and four
2 insufficient. Voting is open.

3 Results are 15 votes high, eight votes
4 moderate, zero votes low and zero votes
5 insufficient. Measure 2704 passes on
6 feasibility.

7 CO-CHAIR CROOKS: Okay. Usability and
8 use.

9 CO-CHAIR ANDERSON: Okay. For
10 usability and use, this is a new measure. It's
11 not currently in use. Although if you look at
12 the existing NQF endorsed adult PD Kt/V measure,
13 0318, it's currently publicly reported.

14 And the pediatric PD Kt/V measure is
15 under NQF review. And has been finalized
16 actually for payment year 2018 for the ESRD QIP.

17 CO-CHAIR CROOKS: Dr. Kliger looks
18 about --

19 DR. KLIGER: Just a question for the
20 pediatricians. Do you have any concerns about
21 usability of this?

22 DR. KASKEL: I don't. Because most of

1 the families that we would take care of, would
2 ask us and talk to us.

3 So public information, to answer your
4 question, it doesn't matter what their social or
5 economic background is. Our experience has been
6 they are a parent. They will talk to us.

7 And they will look at data. We can
8 explain data. And it's a one on one or a team
9 approach. That's the best we can do with these
10 numbers.

11 CO-CHAIR CROOKS: Okay. Other
12 comments on usability and use?

13 Okay. Let's vote then.

14 MS. OGUNGBEMI: The Committee is now
15 voting on usability and use for Measure 2704.
16 Options are one high, two moderate, three low,
17 four insufficient information. Voting is open.

18 Results are eight votes high, 12 votes
19 moderate, one vote low and one insufficient
20 information. Measure 2704 passes on usability
21 and use.

22 CO-CHAIR CROOKS: Okay. And now

1 before voting on recommending endorsement, are
2 there any other comments before we vote? General
3 comments?

4 Let me know when we're ready.

5 MS. OGUNGBEMI: The Committee is now
6 voting on overall suitability for endorsement of
7 Measure 2704. Options are one yes, two no.
8 Voting is open.

9 The results are 21 votes yes and one
10 vote no. The Measure passes. That's 2704 on the
11 overall suitability for endorsement.

12 CO-CHAIR CROOKS: Okay. Thank you.
13 Now, what we'd like to do is guarantee you a 5:30
14 exit and get through measure 2706, which may not
15 take so long because it's got a lot of the same--

16 (Off microphone comment)

17 Yes, good idea. So, 2706. Take it
18 away.

19 DR. MESSANA: Really quick. Same
20 typographical errors in this submission. And one
21 thing that is -- needs to be brought up.

22 In the workgroup discussion there was

1 a question raised about residual renal function
2 being measured using combined creatinine
3 clearance and urea clearance. And I wasn't the
4 measure developer or I wasn't the clinician
5 involved in this measure development.

6 So I had to do a little digging. It
7 turns out that the TEP report from the pediatric
8 TEP held in 2013 included a statement that said,
9 we recommend use of combined creatinine and urea
10 clearance to measure residual kidney function
11 because that comports with, and I'm paraphrasing
12 it, because that is consistent with how it's done
13 in adults, which is not the case.

14 So, my interpretation of that was that
15 they intended the residual renal function
16 assessment to comport with the adult approach,
17 which is measuring your urea clearance.

18 And that would be consistent with the
19 clinical performance recommendations for
20 pediatric measures. I throw it up to you.
21 That's what I know.

22 CO-CHAIR CROOKS: Okay. Andrew?

1 Thanks for staying around.

2 DR. NARVA: My pleasure. So this
3 measure bears a haunting resemblance to the
4 previous one except it pertains only to the
5 pediatric population.

6 The evidence is largely based on the
7 inference from adults that adequate --
8 measurement of adequate peritoneal dialysis
9 results in better outcomes.

10 Along with the consensus that when no
11 pediatric specific data exists, performance
12 measures for adults should serve as the minimum
13 of standard.

14 The one thing that's not in here, it
15 doesn't really specify how often adequacy is
16 supposed to be measured, or I couldn't find it.

17 DR. MESSANA: For consistency's sake,
18 you know, again, I didn't write it. But it
19 should be consistent with the pediatric portion
20 of the last measure. So, within six months to be
21 consistent with the KDOQI CPRs.

22 CO-CHAIR CROOKS: Okay. Karilynne?

1 MS. LENNING: No further comment.

2 CO-CHAIR CROOKS: Any other comments?

3 Okay. Any other discussion about the review of
4 the evidence? Alan?

5 DR. KLIGER: So, I just want to be
6 clear. Are we again making a change to the
7 document?

8 When we calculate the combined Kt/V
9 for either kids or adults, we're using urea.
10 We're not using any other solutes.

11 So I just want to be clear about what
12 we're doing here?

13 DR. MESSANA: Well, we have three
14 pediatric members of the group. We would be
15 interesting in making sure that they're in
16 agreement with that.

17 But I think that would be a
18 stipulation that we would be very comfortable
19 making. Assuming we didn't get any push back
20 from the pediatricians.

21 That the -- I believe that the intent
22 of the technical expert panel was to be

1 consistent with the adult measure. And that the
2 information they had at the TEP may not have been
3 accurate.

4 That's my interpretation.

5 DR. KLIGER: I mean, even more to the
6 point thought, I don't know how you'd use a
7 clearance. Since we're talking about a combined
8 urea measure, Kt/V.

9 DR. ZARITSKY: It's kind of
10 nonsensical because the Kt/V is your urea
11 kinetics. So you're, you know, and so you're in
12 steady state. You have to use the urea for the
13 residual Kt/V.

14 So I don't even know how you would
15 factor in creatinine. I don't know what
16 calculated it.

17 DR. KASKEL: If you're saying that the
18 TEP modeled this to be comparable, at least
19 partly with the adult analyses, and the adults
20 are not doing that combined. Then we have a
21 problem to go back to them next time.

22 It's too late to change now. But

1 that's what you're indicating. That you think
2 there was a misunderstanding at that level?

3 DR. MESSANA: The information that I
4 just shared with you was in one sentence
5 essentially, it said we recommend using combined
6 creatinine in the urea clearance because that's
7 consistent or that's to be consistent with how
8 it's done in adults.

9 So, my interpretation is they were
10 intending to comport with the adult approach.
11 And that they were misinformed.

12 That's my best interpretation.

13 DR. KLIGER: Just again so I
14 understand. So you're suggesting that you make a
15 clarification and change the document now.
16 Right?

17 DR. MESSANA: Correct. We would
18 recommend urea clearance to measure residual
19 kidney function be consistent with 2704 and 0318,
20 the adult measure.

21 CO-CHAIR CROOKS: So we'll consider it
22 a typo, but you'll get back to us if it's not?

1 DR. MESSANA: Yes.

2 CO-CHAIR CROOKS: Okay. Other --

3 DR. ZARITSKY: I think we're all in
4 agreement that you have to do this. It doesn't
5 make any sense. It's a urea clearance, so, but
6 you can't throw it out.

7 CO-CHAIR CROOKS: Okay. Other
8 comments on evidence?

9 Okay. I think we're ready to vote.

10 MS. OGUNGBEMI: The Committee is now
11 voting on evidence. It will come up on the
12 screen soon. There we go.

13 This is for Measure 2706. The options
14 are one high, two moderate, three low and four
15 insufficient. Voting is open.

16 The results are zero votes for high,
17 18 votes for moderate, two votes for low and one
18 vote insufficient. The Measure 2704 passes on
19 evidence.

20 CO-CHAIR CROOKS: Gap, Andrew?

21 DR. NARVA: Okay. Again, there's less
22 data. They site CROWNWeb data from 2013 showing

1 that only about 50 percent of pediatric patients
2 had a measure of PD adequacy during the six
3 months which was looked at.

4 Data on disparities, there's not
5 enough data to identify disparities.

6 CO-CHAIR CROOKS: Okay. Other
7 considerations in the performance gap? They're
8 hitting about 50 percent, so it sounds like
9 there's a ways to go. Alan?

10 DR. KLIGER: It was 50 percent that
11 had no measure. Not that had an inadequate
12 measure.

13 CO-CHAIR CROOKS: I wrote down the
14 mean of hitting the measure was 49 percent.

15 DR. KLIGER: Forty-nine percent had a
16 measure.

17 CO-CHAIR CROOKS: Oh. Well, --

18 DR. NARVA: Percentage of pediatric
19 patients with PD adequacy measurements that
20 achieved the target at least once in six months.

21 CO-CHAIR CROOKS: Okay. On gap, other
22 comments, thoughts?

1 All right. Let's get ready to vote.

2 MS. OGUNGBEMI: The Committee is
3 voting on performance gap for Measure 2706.
4 Options are one high, two moderate, three low and
5 four insufficient. Voting is open.

6 Results are 14 votes high, eight votes
7 moderate, one vote low and zero votes
8 insufficient. Measure 2706 passes on performance
9 gap.

10 CO-CHAIR CROOKS: Thank you.
11 Specifications and reliability. Andrew?

12 DR. NARVA: This is well specified.
13 Except for this particular version of it doesn't
14 specify the interval. But presumably it's the
15 same. And it's well defined for CROWNWeb
16 purposes.

17 CO-CHAIR CROOKS: Okay. Any other
18 concerns about the specifications or the
19 reliability? Lorien?

20 DR. DALRYMPLE: Just a very small
21 comment. Occasionally in this document, I think
22 1.7 shows up when the numerator and other things

1 are specified.

2 So if just for consistency, it can be
3 changed to 1.8 throughout.

4 DR. NARVA: Thank you.

5 CO-CHAIR CROOKS: Frederick --
6 Franklin?

7 DR. MADDUX: Was their intent to have
8 a time frame on this that it would be tested?

9 DR. MESSANA: Yes. I think Dr. Narva
10 brought that up. Within six months to be
11 consistent with the prior measure. Yes, we are.

12 Again, this was left over from a prior
13 year and the clinician who was involved is not
14 available. So we will clean that stuff up.

15 CO-CHAIR CROOKS: Okay. Other
16 comments?

17 We're clear on the specifications and
18 the reliability. Let's go.

19 MS. OGUNGBEMI: The Committee is now
20 voting on reliability for Measure 2706. The
21 options are one high, two moderate, three low and
22 four insufficient. Voting is open.

1 Results are three votes high, 19 votes
2 moderate, zero low and zero insufficient.

3 Measure 2706 passes on reliability.

4 CO-CHAIR CROOKS: Validity Andrew?

5 DR. NARVA: This is put forward on the
6 basis of face validity.

7 CO-CHAIR CROOKS: Nice and succinct.
8 Other thoughts on the validity testing or lack
9 thereof?

10 (No response)

11 CO-CHAIR CROOKS: Okay. Well, let's
12 vote. Are we going to accept the TEP's validity?

13 MS. OGUNGBEMI: The Committee is now
14 voting on validity for Measure 2706. The options
15 are one high, two moderate, three low and four
16 insufficient. The voting is open.

17 MS. BAL: Okay. Hand vote it is. So,
18 for validity, please put your hand up very high
19 for high. I see no hands.

20 Okay. For moderate. I don't even
21 need to count because that's everybody. Okay.
22 So 23 it is. Thank you.

1 So we have zero high, 23 moderate,
2 zero low, zero insufficient for validity for
3 2706. And we can move forward to feasibility.

4 CO-CHAIR CROOKS: Andrew?

5 DR. NARVA: This is meant to be
6 implemented through CROWNWeb. And appears well
7 adapted for that.

8 CO-CHAIR CROOKS: Okay. Any other
9 comments on feasibility?

10 Will we be hand voting or machine
11 voting?

12 Okay. Let's vote on feasibility.

13 MS. OGUNGBEMI: The Committee is now
14 voting on feasibility of Measure 2706. The
15 options are one high, two moderate, three low and
16 four insufficient. Voting is open.

17 Results are 16 votes high, six votes
18 moderate, zero votes low and zero votes
19 insufficient. Measure 2706 passes on
20 feasibility.

21 CO-CHAIR CROOKS: Thank you. So
22 Andrew, is it in use or usable?

1 DR. NARVA: It's definitely usable.
2 My only -- and it's meant to -- it's planned to
3 be reported in the ESRD QIP for 2018.

4 My only concern would be what is it --
5 what percentage of dialysis units have too few
6 patients to report what's in the cell? I mean
7 less than 11 patients. Is that half of the
8 dialysis units?

9 It would just make it less usable for
10 the, you know, the public understanding of
11 quality of dialysis. But do any of the
12 pediatricians have an idea of ---

13 DR. ZARITSKY: That's the nature of
14 the beast, right?

15 DR. NARVA: Yes. I'm just curious,
16 you know. If, you know, the way is, is that most
17 dialysis -- most units serving dialysis --
18 pediatric dialysis patients have less than 11
19 then it is what it is, but it's not going to be
20 as usable as if most pediatric patients are seen
21 in units that have more than 11.

22 CO-CHAIR CROOKS: Okay. That is a

1 limitation. But we've talked about that. Would
2 you like to --

3 DR. MESSANA: So, Dr. Narva, 27
4 facilities met the criteria for minimum of 11
5 patients. So, we lose the majority of the kids
6 from the measure because of the combination of
7 small size and maybe half or so of the kids are
8 distributed through adult facilities.

9 So, it's a significant step down in
10 terms of the number of kids that are actually
11 reported with a pediatric-only measure.

12 CO-CHAIR CROOKS: But don't we know
13 from the last measure that some of those kids
14 will get caught in the -- picked up in the other
15 broader measure?

16 DR. SOMERS: Now with CROWNWeb you
17 actually capture more potential children within
18 the measure than previously.

19 DR. MESSANA: I think that analysis of
20 27 facilities is using CROWNWeb data. So it's --
21 yes, it's better than ten facilities, yes.

22 CO-CHAIR CROOKS: Okay. So we vote on

1 usability and use?

2 MS. OGUNGBEMI: The Committee is now
3 voting on usability and use for Measure 2706.
4 Options are one high, two moderate, three low and
5 four insufficient. Voting is open.

6 Results are six for high, 15 votes
7 moderate, one low and one insufficient. Measure
8 2706 passes on usability and use.

9 CO-CHAIR CROOKS: Okay. And so before
10 we vote on endorsing this or recommending it for
11 endorsement, I just want to warn you that we have
12 one more measure we have to do because the
13 Developers are here in person for this day.

14 So, we will hang on. Don't just get
15 up and walk away after this last vote. Any other
16 comments before we vote?

17 Okay.

18 MS. OGUNGBEMI: The Committee is now
19 voting on overall suitability for endorsement for
20 Measure 2706. Options are one yes, two no.
21 Voting is open.

22 Results are unanimous. 23 votes yes

1 and zero no. The Measure passes. That's 2706,
2 meeting NQF criteria for endorsement.

3 CO-CHAIR CROOKS: Okay.

4 DR. MESSANA: Can I -- thank you all
5 very much. And I'd like to thank the NQF staff
6 and the Committee for fighting through the brief
7 period of anarchy created by upper bound-gate.

8 CO-CHAIR CROOKS: Okay. The measure
9 that we're going to finish the day with is
10 Measure 0323 sponsored by RPA. It's a
11 maintenance on the measure of Adult Kidney
12 Disease, Hemodialysis Adequacy: Solute.

13 MS. SINGER: Thank you all for hanging
14 with us. And actually you will see Amy and I
15 tomorrow. But more critical, Paul Palevsky is on
16 the line and we won't have him tomorrow. So,
17 we're going to let Paul introduce this.

18 DR. PALEVSKY: Hi. And I am probably
19 fortunate I missed some of the discussion between
20 the RPD measure and now.

21 But, this is the physician level
22 hemodialysis adequacy solute measure. Which is

1 the percentage of calendar months within a 12-
2 month period, during which patients age 12 years
3 and older with a diagnosis of end stage renal
4 disease receiving hemodialysis three times a week
5 for greater than or equal to 90 days, have a
6 single pool Kt/V greater than or equal to 1.2.

7 The rationale adequate dialysis dose
8 is strongly associated with better outcomes,
9 including decreased mortality, fewer
10 hospitalizations, decreased length of
11 hospitalizations, decreased hospital costs.

12 This is an intermediate outcome
13 measure. We are presenting this as a physician-
14 level measure as contrasted with the CMS
15 facility-level measure.

16 The measure is currently in use in
17 PQRS. And included in the RPA kidney quality
18 improvement registry.

19 The issue of performance gap, the
20 measure, this is an area where the performance
21 has steadily improved. And from the USRDS data,
22 we're now at 97 percent of patients obtaining a

1 single pool Kt/V of greater than or equal to 1.2.
2 So, the performance gap is very small.

3 Although I would point out that
4 meeting an adequacy measure is still required per
5 the conditions for coverage. And I'm sure you've
6 discussed this in the discussions of the other
7 adequacy measures. And as with the PD, we were
8 unable to retrieve specific disparities data.

9 And in the interest of your time, I
10 will turn things back over to you.

11 CO-CHAIR CROOKS: Thank you very much.
12 Mahesh is one of the primary reviewers. And
13 Michael, are you going to do it? Okay.

14 DR. FISCHER: So, Paul gave a nice
15 summary. I'm not going to repeat the basic
16 definitions of the measure. So I'll just go --
17 no, it's greater than or equal to 18. This is
18 adults. So it's greater or equal to 18.

19 And the only other -- originally this
20 in everyone's packet, it was an outcome measure.
21 But in the revised document that was sent
22 separately, it's an intermediate outcome measure

1 that as Paul indicated, the analysis level is
2 clinician.

3 The only thing else that I would add
4 is that it was endorsed originally in 2007 and
5 reendorsed in 2012.

6 So getting the evidence, our
7 conclusion, I'm summarizing not only just my
8 reflections, but those of the working group call
9 we had. Mahesh can chime in to add what I have
10 to say.

11 But, I think we all thought that it
12 was moderate to high. KDOQI gives it an A
13 rating, albeit that's from 2006. And the
14 application details data that was reviewed by
15 KDOQI from 1999 to 2005.

16 They acknowledge the data is old.
17 They also spent a lot of time discussing the
18 results of the hemo trial and some of the
19 relevant issues, particularly around V in smaller
20 patients and women. I thought they did a very
21 nice job.

22 But they also said that, you know,

1 despite some limitations, they didn't think they
2 were compelling enough to change the
3 specifications of the measure. And the evidence-
4 based remains as is.

5 And there's a related measure, just to
6 conclude the conversation about evidence 249,
7 that goes into greater detail about the
8 observational trials and randomized control
9 studies.

10 So with that, I'll conclude the
11 comments about evidence. As I said, I think our
12 feeling was it was moderate to high. And I'll
13 stop there.

14 CO-CHAIR CROOKS: All right. So open
15 to the Committee. Discussions, comments,
16 thoughts about the evidence?

17 Alan? I thought you just keep it in
18 the upright position all the time. That's right.

19 Okay. So I think we -- it seems like
20 we found the evidence compelling. Shall we vote
21 on the evidence?

22 MS. OGUNGBEMI: The Committee is now

1 voting on evidence for Measure 0323. The options
2 are one high, two moderate, three low and four
3 insufficient. Voting is open.

4 Results are nine votes high, 12 votes
5 moderate, zero votes low and zero votes
6 insufficient. Measure 0323 passes on evidence.

7 CO-CHAIR CROOKS: Okay. Gap?

8 DR. FISCHER: So the performance gap,
9 so Paul presented more recent data then I believe
10 was in the application. So just to reiterate, he
11 said that 97 percent of the patients were meeting
12 the measure. They don't have disparity data.

13 In the application there was data from
14 USRDS and PQRI from 2008 where they mentioned
15 that the performance and they had looked prior to
16 2008 where 99 percent of the patients were
17 meeting the measure.

18 More relevant I think, is that they
19 did comment a little bit about disparities. They
20 did not notice any gender or sex-based
21 disparities, although they then went on to say
22 that the male and female gap had closed to less

1 than ten percent by 2000.

2 They also commented that the
3 performance difference between whites and
4 African-Americans was about three percent. The
5 last comment I'll mention that this data, once
6 again, was largely focused around patients and
7 this is a clinician or physician level measure.

8 So this is obviously indirect evidence
9 supporting the performance gap just based on the
10 level -- the target level that the evidence was
11 presented in. It's a bit old, although Paul gave
12 much more recent data.

13 I think our conclusion was that we
14 thought that there was a moderate performance
15 gap. I think that was the consensus of the
16 working group.

17 DR. KRISHNAN: I think if you were to
18 use the CMS technician it would be even smaller.

19 CO-CHAIR CROOKS: Well, 97 percent is
20 right up there. It's close to the top and then
21 you have to -- and the disparities gaps are all
22 closed.

1 There were some disparities gaps with
2 all, at least the ones that were presented in the
3 closing.

4 DR. FISCHER: I think some of the
5 sentiment was that given the critical nature
6 about the clinical importance of adequacy of
7 dialytic clearance that even this kind of --
8 Michael kind of touched upon this, that given the
9 clinical relevance of it, that provided it's
10 three or four percent, but of not meeting that,
11 the consequences could be quite negative for
12 patient care.

13 DR. BHAN: I guess the question is, is
14 there really room for improvement? You know for
15 a 97 percent now, regardless of putting a measure
16 in place, are we really ever going to get --
17 we're never going to get to 100 percent.

18 There's always circumstances which are
19 beyond our control. You know, putting an
20 emphasis on this, where we're already doing
21 nearly perfect. That's my thought.

22 CO-CHAIR CROOKS: Josh?

1 DR. ZARITSKY: Another technical
2 thing. For the analysis here --

3 CO-CHAIR CROOKS: Can you get closer
4 to your mic please?

5 DR. ZARITSKY: Yes. The analysis
6 here, what does this gap in here -- what is this
7 41 percent of patients reported, did not receive
8 the optimal care.

9 What is that? Is that just a typo
10 there?

11 DR. KRISHNAN: I interpreted that to
12 be based on 2008 data that the percentage of
13 patients who did not meet the Kt/V target was
14 41.36 percent. It seemed high to me, but that's
15 what I interpreted it to be.

16 CO-CHAIR CROOKS: Okay other --

17 DR. KRISHNAN: Although as was pointed
18 out now, that's tiny.

19 CO-CHAIR CROOKS: Frank?

20 DR. MADDUX: So, in my view, as I
21 think about the portfolio of how we look at doses
22 of dialysis and the granularity of some of the

1 other measures that are being proposed to look at
2 related to this, this looks to me more like a
3 candidate for reserve measure because of the fact
4 that I think the gap's pretty small at this
5 point.

6 And just to answer his point, the
7 ability to improve doesn't mean that we don't
8 need to create a high threshold that people need
9 to achieve. But I think it's going to be very
10 hard to make the gains between 2008 and now that
11 are being gained in the future with this.

12 CO-CHAIR CROOKS: I am in agreement
13 with you Frank. But I think, in my opinion,
14 there's been maybe overemphasis on Kt/V over the
15 years. And now, we're going to start turning
16 more attention to ultra-filtration and maybe
17 other components of what makes dialysis good.

18 So, I would support seeing this is a
19 reserve measure. I wouldn't support not having
20 it.

21 Okay. So are we ready to vote on gap?

22 MS. OGUNGBEMI: The Committee is now

1 voting on performance gap for Measure 0323.

2 Options are one high, two moderate, three low and
3 four insufficient. Voting is open.

4 Results are zero votes high, four
5 votes moderate, 14 votes low and three votes
6 insufficient. Measure 0323 does not pass on
7 performance gap.

8 CO-CHAIR CROOKS: Okay. So in this
9 case we continue our evaluation of the other
10 criteria. And then we'll see at the end whether
11 it meets criteria for being a reserve measure.
12 Okay?

13 MS. SAMPSEL: Actually, hold on a
14 minute. We actually need the Committee, you
15 know, I know Committee Member indicated it looks
16 like a great candidate for reserve status. We
17 should do a hand vote on that, because
18 technically if it doesn't pass performance gap,
19 the vote should stop in a normal review.

20 CO-CHAIR CROOKS: So, to move on we
21 need to have a hand vote about this being a
22 potentially reserve measure. If we do not get a

1 majority of, what 16's a majority? Then the
2 measure will end right here. And it won't be
3 endorsed.

4 So, I put the question. So, if you're
5 in favor of considering this for reserve status,
6 raise your hand high.

7 Okay. I think it's unanimous within
8 zero or one. Okay. Thank you.

9 All right. So let's go on and look at
10 specifications and reliability.

11 DR. FISCHER: So I thought we -- I
12 thought the specifications were pretty well
13 defined and consistent with the evidence.

14 Just to be clear, there are no
15 exclusions, no risk adjustment or stratification.
16 However, they do kind of encourage reporting to
17 be stratified by race, sex and primary language
18 is in the application, which seemed not
19 unreasonable.

20 One concern with there was no mention
21 made of minimum number of measurements per
22 clinician to be meaningful. That was something

1 one of the people on the working group had
2 raised.

3 And I think that was kind of our
4 summary. And I'll just stop and we'll talk about
5 reliability testing but just continues its
6 specifications. And we just stopped there.

7 I don't know if Mahesh, if you have
8 anything to add?

9 CO-CHAIR CROOKS: Just for the record,
10 there's no -- or correction if I'm wrong.
11 There's no taking into account residual renal
12 function on this measure. Correct?

13 DR. FISCHER: That's correct.

14 DR. PALEVSKY: That is correct.

15 CO-CHAIR CROOKS: And the guideline
16 that it's based on does talk about residual
17 kidney function as being a part of the calculus I
18 believe, no? Am I wrong?

19 DR. KLIGER: It actually doesn't
20 although I was going to raise that later.
21 Because in all of the hemodialysis measures,
22 currently we do not take residual kidney function

1 into account.

2 But in the year 2015, many of us
3 believe we should be. And so I think it's
4 important question to raise.

5 CO-CHAIR CROOKS: Lorien?

6 DR. DALRYMPLE: I actually do have a
7 question on that. Because my interpretation of
8 the E specifications was that residual kidney
9 function was a denominator exception.

10 At least based on the last page with
11 the E's where there were medical exceptions. And
12 then two residual kidney function conditions
13 showing. So I actually interpreted the
14 specification did have denominator exceptions.
15 But is that incorrect?

16 CO-CHAIR CROOKS: Let's ask the
17 developer. So, to restate her question, I think
18 is, if a patient has significant residual
19 function, then they're not eligible to be in the
20 measure? Is that what you're asking?

21 DR. DALRYMPLE: I'm looking at the
22 first page of the PCPIE specification, AKD 10.

1 And for denominator exceptions it states
2 documentation of medical reasons for not having a
3 single pool Kt/V greater than/or equal to one,
4 such as residual kidney functions and other
5 medical reasons.

6 And then on the very last page where
7 we have the column of IPP and, in E, residual
8 kidney function shows up in there.

9 MS. SINGER: Paul, I'm going to defer
10 to you.

11 DR. PALEVSKY: I could not hear. You
12 broke up completely. I gathered you were asking
13 whether the measure includes an exception for
14 residual -- again, I'm trying to get the --

15 CO-CHAIR CROOKS: That was the gist of
16 it. Yes.

17 DR. PALEVSKY: Okay. I'm trying a
18 little --

19 DR. DALRYMPLE: Yes. And I'm sorry.
20 I can speak up. I know it's hard on the phone.

21 But on our E specifications, there are
22 denominator exceptions that appear to include

1 residual kidney function and medical reasons for
2 not achieving a single pool Kt/V of 1.2.

3 DR. PALEVSKY: I have to admit that I
4 do not have that. I'm trying to pull up all of
5 the pages. And unfortunately that was not -- I
6 don't see that forwarded to me from --

7 DR. DALRYMPLE: I think there is
8 inconsistency between the E specifications and
9 the measure information form so. I mean, I think
10 we just need some clarification.

11 Do you mean for those exceptions to be
12 there? Or not mean for, you know, just for
13 consistency where CMS in the last version said,
14 you know, we had some issues with how we -- with
15 edits, et cetera in their form.

16 You know, is that a similar situation
17 or do you really need to check on it? If you
18 really need to check on it, then, you know, I
19 might suggest we not vote. Or we vote and you
20 come back with public comment.

21 MS. SAMPSEL: I think we can just
22 double check the consistency.

1 DR. PALEVSKY: I need to double check
2 it. I --

3 CO-CHAIR CROOKS: Thank you. Yes,
4 Item S-10, denominator exclusions. There are no
5 denominator exceptions. If there's another
6 section saying what it does?

7 MS. SINGER: At the E specifications.

8 CO-CHAIR CROOKS: At the E
9 specification. Okay.

10 MS. SINGER: We need to go back and
11 correct.

12 DR. PALEVSKY: I don't have the E --
13 a copy of the E specifications. I only have the
14 other specs where there are no denominator
15 exclusions.

16 MS. SINGER: I'm comfortable with the
17 E specifications. We just need to go back and
18 make everything consistent in the documents.

19 CO-CHAIR CROOKS: Let's put the
20 question to the Committee. What's your comfort
21 level with not having any accounting for residual
22 kidney function on this measure? Somebody must

1 have some thoughts on this?

2 DR. PALEVSKY: I believe that the
3 discussion in past NQF reviews on this measure
4 was that since this is patient after three months
5 on dialysis, that the vast majority of patients
6 do not have residual kidney function.

7 And that's why it was not apt.

8 CO-CHAIR CROOKS: I think that's old
9 data. I don't know that that's actually true.
10 Franklin?

11 DR. MADDUX: Yes, I think the only
12 other thing that sort of gets into this is the
13 basic definitions for how we calculate this are
14 not perfectly concordant if you're using your
15 kinetic model and you're using a prepost and pre-
16 BUN, you're getting interdialytic, urea
17 generation included. In the Daugirdas II
18 standard there is two standards, pre and post.
19 You're not including that.

20 So, it's one of those areas where I
21 spoke previously to where we're not granular
22 enough about the detailed specification to

1 account for inter-organizational variability that
2 might occur if one organization chooses an
3 equilibrated Kt/V and they take the single pooled
4 component of that.

5 Or a -- just a standard pre and post
6 single pooled Kt/V calculated off of a pre- and
7 post-BUN.

8 CO-CHAIR CROOKS: But at the same
9 time, everybody's hitting it. So, maybe that's
10 less important now that the gap is so small.

11 DR. MADDUX: It may be irrelevant to
12 some degree, but it just gets to the point that I
13 think for some of these measures, we've got to be
14 a little bit careful about source data that might
15 not actually be the same.

16 DR. KRISHNAN: Yes,
17 microspecifications.

18 DR. MADDUX: Yes.

19 CO-CHAIR CROOKS: To the issue of not
20 including residual kidney function, is the
21 Committee okay with that? Or do we --

22 DR. KRISHNAN: I read this as not

1 including residual renal function. Because I
2 just went with what was in the measure
3 specification.

4 I guess the question is, what is the
5 measure? Is the measure as stated in the form?
6 Or is the measure as stated in the E
7 specification? Because if it's different, I
8 don't know how to vote other than what's in the
9 form.

10 CO-CHAIR CROOKS: Yes, it may be more
11 important that there's an inconsistency perhaps
12 in the two places where it gives specifications
13 and the measure is the measure.

14 DR. KRISHNAN: The endorsed measure --
15 the endorsed measure doesn't have residual renal
16 function. Is that correct? The prior endorsed
17 version? Correct?

18 DR. PALEVSKY? Correct.

19 CO-CHAIR CROOKS: That's my
20 understanding.

21 DR. KRISHNAN: So then technically the
22 E specification is inconsistent if we're renewing

1 this measure.

2 CO-CHAIR CROOKS: Yes.

3 DR. KRISHNAN: So, that's the way I
4 think about it.

5 CO-CHAIR CROOKS: Lori?

6 MS. HARTWELL: I just have a question
7 for the Committee. Would this disincentivize to
8 try to keep the renal function? Because there's
9 technologies, I believe, out there that can help
10 keep the patients' renal function on
11 hemodialysis.

12 So, given the fact, I just wanted to
13 ask the experts on the Committee if that would
14 deincentivize -- I can't even talk anymore. If
15 that was not included?

16 DR. KRISHNAN: I don't think it makes
17 a difference one way or another. It's just the
18 way it's supported.

19 Right, so today, as he's pointed out,
20 Kt/V as on the claims form is reported without
21 because there's no renal function. That's -- we
22 went to this -- that was the data error --- the

1 data issue without -- despite the specification
2 we had in 2010.

3 So it's just the way it is right now.
4 I don't think it makes a difference one way or
5 another.

6 CO-CHAIR CROOKS: Alan?

7 DR. KLIGER: Right. I agree. It is
8 not a disincentive. But I do want to raise the
9 question, I mean the majority of hemodialysis
10 patients don't have sufficient urine for it to
11 make any difference.

12 But, in the incident population where
13 there are many who do, and because we know that
14 residual kidney function is one of the biggest
15 predictors of health and survival in dialysis
16 patients, I wonder if the time has come for us to
17 do with hemodialysis what we've done with
18 peritoneal dialysis, and urge developers to
19 include endogenous kidney function when there is
20 some.

21 Now it doesn't -- you know, what I
22 mean. You can specify it in a way that's not too

1 burdensome for facilities. Because it would be
2 very burdensome if we asked them to be collecting
3 urine on everybody.

4 But I do think that there is a small
5 subpopulation of patients that does have
6 substantial residual kidney function that would
7 be useful to include in these measures as we do
8 with peritoneal dialysis.

9 DR. KRISHNAN: For this measure,
10 right, because as submitted, it just doesn't have
11 it.

12 DR. KLIGER: Well, this doesn't have
13 it. Nor do any of the others we're going to
14 consider later. So I'm just raising that
15 question for the Committee.

16 DR. KRISHNAN: Yes. It's an awesome
17 suggestion, Peter. Could we vote?

18 DR. PALEVSKY: As the Developer, can
19 I speak up to Alan's comment?

20 CO-CHAIR CROOKS: In this one
21 instance, you may make a brief comment.

22 DR. PALEVSKY: So, the one thought

1 that I would offer, Alan, is that in PD it is
2 often difficult to get over the 1.7 threshold in
3 the absence of residual function. And it becomes
4 a far greater factor in establishing adequacy.

5 Where that is much less of a case in
6 hemodialysis where it is much easier to achieve
7 the 1.2 threshold even in the absence of residual
8 function.

9 CO-CHAIR CROOKS: Okay. Alan?

10 DR. KLIGER: I guess just briefly. In
11 the interest of having patient focused care, we
12 would indeed be doing less hemodialysis on
13 patients that have substantial residual kidney
14 function.

15 And I think tailoring the therapy
16 appropriately when we can count endogenous kidney
17 function is a patient oriented and patient
18 specific opportunity.

19 CO-CHAIR CROOKS: Okay. So we need to
20 -- I'm hearing extraneous noise over the phone.
21 Kind of -- Paul? Can you mute your phone when
22 you're not speaking please? Thank you.

1 DR. PALEVSKY: That's not me. My
2 phone is muted.

3 (Laughter)

4 CO-CHAIR CROOKS: Okay, thank you.
5 Whoever it be. All right. I think we're ready
6 to vote on the evidence.

7 DR. FISCHER: We're on reliability.

8 CO-CHAIR CROOKS: You're right.

9 DR. FISCHER: And I should just say
10 one thing about reliability testing for due
11 diligence, all right?

12 CO-CHAIR CROOKS: Yes, please.

13 DR. FISCHER: I'll make it brief. I
14 know it's getting late.

15 So the sources of the data are claims
16 electronic records. They -- in 2008 they did
17 reliability testing by examining four different
18 nephrology practices participating in the PQRI
19 program with hemodialysis/peritoneal dialysis
20 patients.

21 This included multiple visits at
22 multiple sites across the country. It was

1 several hundred patient records that were
2 examined.

3 And the calculated the kappa for
4 inter-rater reliability. And the kappa values
5 were exceptionally high, one or nearing one.

6 So based on that, and we think we
7 agreed in our working group discussion, the
8 reliability testing seemed to be sound. And
9 demonstrated very high reliability.

10 CO-CHAIR CROOKS: Okay. If there's no
11 objections, let's vote.

12 MS. OGUNGBEMI: The Committee is now
13 voting on reliability for Measure 0323. The
14 options are one high, two moderate, three low and
15 four insufficient. Voting is open.

16 Results are three high, 17 moderate,
17 two low and zero insufficient. Measure 0323
18 passes on reliability.

19 CO-CHAIR CROOKS: All right. Next up,
20 validity.

21 DR. FISCHER: So face validity as some
22 of the other measures we've examined, they had a

1 21 member TEP.

2 And on this Likert scale from zero to
3 five with agreeing with the strength of the
4 evidence of this measure in terms of reflecting
5 dialytic adequacy was a mean of 4.63. Which, I
6 think as we've seen elsewhere, suggests high face
7 validity as determined by this expert panel.

8 They then, once again, looking at
9 practices somewhere to the reliability testing
10 that were in the PQRI program in 2008, they
11 looked at physician level performance to see if
12 you could detect significant differences in
13 physician level performance.

14 So they provided some inter-quartile
15 -- they provided some percentile range of range
16 of performance. Inter-quartile range is around
17 49 percent, suggesting that there's a reasonable
18 spread in physician performance around this
19 measure.

20 Again, this is back in 2008. Things
21 have changed. But that's what was in the
22 submission packet.

1 So that suggested that there was an
2 important validity from both the face and then
3 also from detect -- being able to detect
4 meaningful performance differences at the
5 physician level.

6 A couple of things, there wasn't
7 really a comment on missing data. So presumably,
8 you're, you know, if there's missing data, that
9 means you're in the denominator and not in the
10 numerator as there are for some measures, but
11 that wasn't really explicitly stated other than
12 they don't make any exceptions for it. And I
13 think I'll end my comments there. I don't know
14 if Mahesh has anything to add.

15 DR. KRISHNAN: No. I think again,
16 they did that based on the manual system
17 according to that electronic. And we don't know
18 how close to the gap -- how much the gap has
19 closed, but we just have to vote on what we have.

20 CO-CHAIR CROOKS: All right. Can we
21 vote on validity?

22 MS. OGUNGBEMI: The Committee is now

1 ready to vote on validity for Measure 0323.

2 Options are one high, two moderate, three low and
3 four insufficient. Voting is open.

4 Results are zero votes high, 19 votes
5 moderate, zero votes low and two insufficient.
6 Measure 0323 passes on validity.

7 CO-CHAIR CROOKS: So TEP panels don't
8 tend to get high validity votes. But they're
9 moderate.

10 Okay. Finally we're into feasibility
11 -- almost finally.

12 DR. FISCHER: It's feasible.

13 (Laughter)

14 DR. FISCHER: I mean, it's being --
15 well, no, I mean it's -- I mean, it's late. This
16 is already being used in CROWNweb.

17 CO-CHAIR CROOKS: If CROWNweb is
18 feasible, then it's as feasible as CROWNweb.

19 DR. FISCHER: This was PQRS --

20 MS. SINGER: It's being used in PQRS
21 actually.

22 CO-CHAIR CROOKS: Okay.

1 DR. FISCHER: Right.

2 CO-CHAIR CROOKS: Okay. Any other
3 comments on feasibility before we vote?

4 Let's vote.

5 MS. OGUNGBEMI: The Committee is now
6 voting on feasibility for Measure 0323. Options
7 are one high, two moderate, three low and four
8 insufficient. Voting is open.

9 Results are 11 votes high, 11 votes
10 moderate, zero votes low and zero votes
11 insufficient. Measure 0323 passes on
12 feasibility.

13 CO-CHAIR CROOKS: Okay. Use and
14 usability. Michael?

15 DR. FISCHER: We thought it was high.
16 I mean, it's already currently in use in the PQRS
17 program. We didn't believe there were any
18 unintended consequences.

19 And kind of circling back to our other
20 comments about the closure of the performance gap
21 further corroborates that it's been useful, used
22 in improving performance. Which in some ways I

1 guess has been the demise of this measure now
2 perhaps going to reserve status, but, yes, very
3 usable.

4 CO-CHAIR CROOKS: Okay. Other
5 thoughts to share? Comments?

6 Okay. Let's vote.

7 MS. OGUNGBEMI: The Committee is now
8 voting on usability and use for Measure 0323.
9 Options are one high, two moderate, three low and
10 four insufficient. Voting is open.

11 Results are 15 votes high, five votes
12 moderate, two votes low and zero votes
13 insufficient. Measure 0323 passes on usability
14 and use.

15 CO-CHAIR CROOKS: Okay. Thank you.
16 So before vote on suitability for endorsement or
17 recommendation for endorsement, any other general
18 comments? Michael?

19 DR. FISCHER: So just one. So we'll
20 probably talk about this then tomorrow, the
21 harmonization aspect. Just so I'm clear. Is
22 that correct?

1 CO-CHAIR CROOKS: Right.

2 DR. FISCHER: Okay.

3 CO-CHAIR CROOKS: That will have to be
4 tomorrow.

5 MS. SAMPSEL: Actually we're -- and
6 remember, we're voting on reserve status.

7 CO-CHAIR CROOKS: We're voting on
8 reserve status. Okay. So we've done all the
9 preliminary work?

10 MS. SAMPSEL: Yes.

11 CO-CHAIR CROOKS: Right. Yes, that's
12 -- because that's the way it is. Okay.

13 So, --

14 MS. SAMPSEL: No, that was to consider
15 it.

16 CO-CHAIR CROOKS: That was to consider
17 it for a -- and to look at the rest of the
18 evidence, which we've done. The rest of the
19 criteria.

20 So now having looked at all the
21 criteria, we're going to vote. And if we vote
22 yes, we're voting for reserve status. A vote no

1 means that you don't want it endorsed at all.

2 MS. BAL: And just a reminder, reserve
3 status means that you feel that if the measure
4 does not -- if we don't continue to have the
5 measure, it will have a negative effect on
6 performance. And that you also think that
7 reliability and validity are strong enough to
8 maintain this measure.

9 So those are the stipulations I want
10 to remind everyone of.

11 MS. OGUNGBEMI: The Committee is now
12 voting on Measure 0323's endorsement, maintenance
13 potential for reserve status. You heard Poonam's
14 wonderful explanation of it. So, please vote.
15 The options are one yes, two no.

16 Results are 21 votes yes and zero
17 votes no. The Measure 0323 is -- has a potential
18 for reserve status. Yes.

19 CO-CHAIR CROOKS: Okay. Thank you
20 all. We're --

21 MS. BAL: We're going to start at like
22 behind.

1 CO-CHAIR CROOKS: Yes. We're three
2 measures behind our target. And believe it or
3 not, we're going to make it up by starting a half
4 hour early tomorrow.

5 So instead of opening at 9:00, we'll
6 start at 8:30 as we did today. And we have to
7 end at 3:00.

8 MS. BAL: I think it's 8:00

9 CO-CHAIR CROOKS: Oh, well continental
10 breakfast at 8:00 and gavel at 8:30.

11 DR. KLIGER: So can I suggest --

12 CO-CHAIR CROOKS: I'll gavel earlier.
13 I'm --

14 DR. KLIGER: Let's suggest 8:00? Can
15 we suggest starting it --

16 CO-CHAIR CROOKS: It's easy for you
17 east coast people to say but -- yes. I'm going
18 to bed.

19 DR. LATTS: It's up to the Committee
20 to upset the day. It always works out.

21 CO-CHAIR CROOKS: Let's start at 8:00.
22 I'd like to start at 8:00. I think that would

1 give us a little more time to consider things.

2 Okay. Can we have the food here
3 before 8:00? Or --

4 MS. BAL: Yes. We can have it at
5 7:30. We just need to know now.

6 CO-CHAIR CROOKS: Okay. Doors open
7 7:30.

8 MS. BAL: Yes.

9 CO-CHAIR CROOKS: Gavel at 8:00.
10 Okay.

11 (Whereupon, the above-entitled matter
12 went off the record at 5:43 p.m.)
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Date: 05-06-15

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