

NATIONAL QUALITY FORUM
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END STAGE RENAL DISEASE QUALITY MEASURES
STEERING COMMITTEE

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TUESDAY
JANUARY 11, 2011

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The Steering Committee met in Salon B in
the Marriott Metro Center 775 12th Street,
N.W., Washington, D.C., at 9:00 a.m., Peter
Crooks and Kristine Schonder, Co-Chairs,
presiding.

PRESENT:

PETER CROOKS, MD, Co-Chair
KRISTINE SCHONDER, PharmD, Co-Chair
CONSTANCE ANDERSON, BSN, MBA, Northwest
Kidney Centers
SUE BARNES, RN, BSN, CIC, Kaiser Permanente

National Office
JEFFREY BERNS, MD, University of
Pennsylvania School of Medicine
BARBARA FIVUSH, MD, Johns Hopkins University
School of Medicine
JERRY JACKSON, MD, Nephrology Associates, PC
FREDERICK KASKEL, MD, PhD, Children's

Hospital at Montefiore
MYRA KLEINPETER, MD, MPH, Tulane University
School of Medicine
ALAN KLIGER, MD, Hospital of St. Raphael/
Yale University School of Medicine
LISA LATTS, MD, MSPH, MBA, WellPoint, Inc.
KATHE LeBEAU, Renal Support Network

JOSEPH V. NALLY, JR., MD, Cleveland Clinic
Foundation

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

ROBERT PROVENZANO, MD, FACP, DaVita

JOSEPH VASSALOTTI, MD, FASN, National Kidney
Foundation

RUBEN VELEZ, MD, Dallas Nephrology
Associates

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

HARVEY WELLS, Dialysis Patient Advocate,
Euless, Texas

ANDREW NARVA, MD, (ex officio), National
Institute of Diabetes and Digestive and
Kidney Diseases, NIH

NQF STAFF:

HELEN BURSTIN, MD, MPH, Vice President of
Performance Measurement

TENEE DAVENPORT

ANN HAMMERSMITH, General Counsel

KAREN PACE, PhD, RN, Senior Program Director

LAUREN RICHIE, MA, Project Manager

ALSO PRESENT:

TOM DUDLEY, Center for Medicare & Medicaid
Services (by teleconference)

LISA MCGONIGAL, Kidney Care Partner

JOSE MENOYO, Genzyme

JOE MESSANA, Arbor Research Collaborative
for Health

ROBYN NISHIMI, MD, Kidney Care Partners

SYLVIA RAMIREZ, Arbor Research Collaborative
for Health

DALE SINGER, Renal Physicians Association
(by teleconference)

BRADLEY WARADY, MD, University of Missouri,
Kansas City School of Medicine

ROBERT WOLFE, Arbor Research Collaborative
for Health

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

9:00 a.m.

Welcome and Introductions

CO-CHAIR CROOKS: Okay, good morning everyone. Welcome to the National Quality Forum's ESRD Steering Committee meeting. I'm Peter Crooks, and this is Kristine Schonder.

We're your co-chairs for the next two days, and we'd like to welcome you to our two-day meeting, and to take this opportunity to thank you all for your participation, and for devoting some of your holiday time to this important work.

Karen and I were just talking about this. It seems that we had very good responses and maybe the fact that a lot of us were not working and were on vacation actually gave us more time to work on it than we might have otherwise. But in any case, thank you for figuring out how to get this important work done.

1 So just to review a couple of
2 items before we get started. First of all,
3 the purpose of our meeting, just to remind
4 everybody, is to evaluate the submitted
5 measures according to NQF criteria, to
6 determine if suitable to recommend for
7 endorsement as voluntary consensus standards.

8 Secondly, to review related and
9 competing measures to facilitate measure
10 harmonization and select the best measure from
11 among competing measures.

12 I might just point out that in
13 some cases, just reviewing some of the stuff
14 that came in, people might say I'm not
15 recommending this one because I prefer
16 another, and one of our procedures is to look
17 at each measure as a stand-alone measure and
18 not try to -- not look at it in comparison to
19 others. That's a separate process that will
20 come on Day 2. So please keep that in mind.

21 Our third purpose is to identify
22 gaps in performance measures for ESRD care,

1 and we do have some time devoted tomorrow to
2 that issue, because as when we met as a
3 Steering Committee by phone a few weeks ago,
4 it became evident that a lot of people had
5 ideas about metrics that weren't available for
6 us to be evaluating.

7 So that's the purpose of the
8 meeting, and the agenda for today has been
9 distributed, and I think the version you have
10 is the latest, and I'd like to ask the
11 Committee to take a quick look at it and let
12 me know now if you see a need to change
13 anything or have any concerns about the
14 agenda, or questions about the agenda.
15 Anyone?

16 And while you're looking, I will
17 just remind you too that this meeting is open
18 to the public, and we are being audiotaped.
19 We have participants on the telephone. It
20 would be a good time now to find out who's --

21 CO-CHAIR SCHONDER: Why don't you
22 do that later?

1 CO-CHAIR CROOKS: We can do that
2 later. We'll have a chance to find out who's
3 listening in, and you know, as you've all been
4 members of committees in the past, I don't
5 need to give you a lecture on how to behave as
6 a Committee member.

7 But I'd just remind you that we
8 listen respectfully and we keep our remarks
9 cogent and brief, and we try to follow the
10 agenda and not get off track. So any other
11 additions or questions about the agenda right
12 now? Okay.

13 The measure developers will be
14 present. They have a chance for a brief
15 statement today, this morning and also
16 tomorrow morning before we dive into
17 evaluating individual measures. They will
18 often stay here for the, especially during the
19 time that their measures are being considered.

20 They can answer questions, but
21 they should not take part in Committee
22 discussions. Kristine and I will be dividing

1 the chair time. Basically, I guess, I'll do
2 mornings and you'll do afternoons. But we're
3 going to work together to support each other
4 and try to keep the Committee on track.

5 We expect to finish the work in
6 two days, but we may not, and we're not going
7 to rush and not do a good job. So we have the
8 options of some further phone calls if needed.
9 But our intention is to try to finish up the
10 work while we're all together.

11 Since our phone call, we've had a
12 couple of -- several additions to the
13 Committee, and just to acknowledge them and
14 they'll have a chance to introduce themselves
15 too.

16 But Robert Provenzano has joined
17 the group. Roberta Wagner, Wager. I'm sorry
18 Roberta. Harvey Wells and Jessie Pavlinac,
19 who's not here yet but will be coming in a
20 while.

21 So okay. So at this point, do you
22 want to add anything right now, Kristine?

1 CO-CHAIR SCHONDER: No. I'll just
2 welcome everybody.

3 CO-CHAIR CROOKS: And so is Helen
4 -- there she is. Hi Helen. I remember you
5 now. Helen is here to give us a hello and
6 some other information.

7 DR. BURSTIN: Good morning,
8 everybody. I'm Helen Burstin, Senior Vice
9 President of Performance Measures at NQF.
10 Welcome back to some of you from last time.
11 I'm actually going to take the --

12 I'll do it after Karen's slides.
13 I just want to emphasize a couple of key
14 things that are a little different about this
15 project, particularly for some of you who were
16 with us the last round, some of the changes in
17 our guidelines and parameters.

18 But I'll let the process proceed
19 first and then move back to me.

20 CO-CHAIR CROOKS: Okay, thank you
21 Helen. So before we go into the
22 introductions, we'll have Ann Hammersmith,

1 who's the general counsel, to review for us
2 disclosure of interest issues.

3 Disclosure of Interest

4 MS. HAMMERSMITH: Good morning,
5 everyone. Thank you for participating. What
6 we're going to do now is combine introductions
7 with the disclosure of interests. If you
8 recall, several weeks ago we asked you to
9 complete a disclosure of interest form, and
10 with some of you we had some follow-up
11 questions.

12 What we'd like to do now, and this
13 is part of NQF's openness and transparency, is
14 have you go around the table, introduce
15 yourselves, tell us who you are with. Karen,
16 do you want people to follow what's on --

17 DR. PACE: Yes.

18 MS. HAMMERSMITH: Okay. So it's
19 your name, your organization, your ESRD and
20 quality experience, your hobbies, other than
21 going to NQF meetings, and then the disclosure
22 of interest. I want to emphasize that we are

1 not asking you to recount your CV to us. We
2 know you're all quite experienced and
3 qualified and distinguished and so on.

4 What we would like you to do in
5 the disclosures is reveal anything to your
6 fellow Committee members that you believe is
7 important to your service on this Committee,
8 or that they should know. So I'm going to
9 start with Kristine Schonder.

10 CO-CHAIR SCHONDER: Okay. Again,
11 I want to echo Peter's comments to welcome
12 everybody. My name is Kristine Schonder. I'm
13 a clinical pharmacist with the Thomas E.
14 Starzl Transplant Institute in Pittsburgh,
15 Pennsylvania, and I'm an assistant professor
16 at the University of Pittsburgh School of
17 Pharmacy. I have to look at my cheat sheet
18 for what I need to do.

19 My experience with ESRD is
20 primarily in the area of kidney
21 transplantation, and work both pre- and post-
22 kidney transplant. So I've dealt quite a bit

1 with patients on both sides of the spectrum,
2 as far as ESRD is concerned.

3 I was a member of the last NQF
4 Quality Forum as well. So I have some ideas
5 of what the process is as far as what we're
6 doing today.

7 As far as my hobbies, I really
8 don't have a whole lot of time for hobbies any
9 more. I'm a new mother of two adopted boys
10 from Russia. So that pretty much takes up all
11 my time right now. So that's my main hobby,
12 and I have no disclosures today.

13 CO-CHAIR CROOKS: Okay. I'm Peter
14 Crooks. I'm a nephrologist. I'm with Kaiser
15 Permanente in Southern California.

16 As a nephrologist, I've been in
17 practice for close to 30 years, hard to
18 believe, and have been involved in quality in
19 a number of ways over the years, through
20 disease management organizations within Kaiser
21 Permanente, quality efforts related to an ESRD
22 Medicare demonstration project, and then I

1 also was fortunate to serve with this group a
2 couple of years ago.

3 So I have the sincere belief that
4 delivering quality of care to patients is also
5 the most -- brings value, and that is the most
6 cost-effective way to deliver care.

7 For hobbies, I'd just like to
8 mention that I'm actually really a musician
9 and not a physician, and one day in the not-
10 too-distant future I look forward to getting
11 back to my song writing career.

12 My disclosures of interest are
13 brief, I think. I serve on the board of
14 directors of the California Dialysis Council,
15 which represents the interest of dialysis
16 providers and nephrologists to the California
17 state legislature, and to some degree to
18 Washington, D.C. lobbying.

19 Kaiser Permanente is involved in
20 metric development, but we don't sell them and
21 they're freely available to all the Kaiser
22 Permanente regions, and freely shared with the

1 renal community.

2 As a partner physician in the
3 medical group, I also have a direct
4 relationship with Kaiser Health Plan, Kaiser
5 health care facilities and all the various
6 services. But I'm not an owner of these
7 services, pharmacy, imaging, et cetera.

8 With Fresenius medical care, my
9 partner physicians are medical directors at 17
10 units in Southern California, one DaVita unit
11 and one Renal Advantage unit. Within the last
12 years, I was a member of the medical advisory
13 board for Renaissance, a renal disease
14 management company.

15 I have to tell you that my son
16 Christopher is in the industry as a dialysis
17 technician, and I think that's -- okay. Thank
18 you.

19 DR. PACE: I'm Karen Pace. I'm
20 NQF staff, and I'm the senior director on this
21 project, and besides NQF, when I'm not
22 commuting, because I live on Kent Island, my

1 interests are just being outside, walking,
2 reading. So just kind of run-of-the-mill down
3 time things.

4 MS. RICHIE: And I am Lauren
5 Richie. I'm sure you all recognize me from my
6 flood of emails that come to you all. I am
7 the project manager. I've been with NQF for
8 about six months now. My background is in
9 performance measurement and research in the
10 areas of quality improvement, and outside of
11 NQF I enjoy bike riding and a lot of outdoor
12 activities.

13 DR. BURSTIN: I'm still Helen
14 Burstin. I have, I seem to have absolutely no
15 hobbies at the moment. I have a six year-old
16 and an eight year-old and a new puppy, a very
17 bad idea. I'm already overtaxed, but he's
18 coming along, and no disclosures.

19 DR. LATTIS: Good morning. I'm
20 Lisa Latts. I have a new title actually. I'm
21 Vice President for Public Health Policy with
22 WellPoint, which is a large health insurer,

1 for those you who are not familiar with us.

2 At WellPoint, I'm responsible for
3 quality programs, health disparities, public
4 health programs obviously and several other
5 things that we can talk about.

6 I'm an internist, have a
7 subspecialty in high risk pregnancy. Also a
8 health services researcher and my area of
9 research was in tobacco cessation.

10 Thirteen months ago now, I was
11 pregnant with twins when I developed hemolytic
12 uremic syndrome, developed end stage renal
13 disease as a result of that. I was on
14 dialysis until two and a half months ago, when
15 I got a kidney transplant. So this is very
16 personal to me as well. So that's my
17 background.

18 Disclosure-wise, only that I work
19 for a health insurance company, WellPoint.

20 MR. WELLS: Hi. My name is Harvey
21 Wells. I'm a 58 year-old dialysis patient,
22 and I've survived PD, a transplant, in center

1 thrice weekly, hemodialysis and now I tell
2 people I thrive on the frequent short daily
3 home dialysis.

4 My mission over the last three
5 years has been to educate and promote home
6 dialysis, because of the difference that it
7 made in my life. In completing the disclosure
8 form, I think I probably should have said that
9 my most vested interest here is because I want
10 to live an active, purposeful and healthy
11 life, and that's really why I'm involved in
12 the renal community.

13 While there are tons of things
14 that can be measured, I think not all of them
15 make a tangible difference in the patient's
16 life or that of his family. I remember the
17 ESRD Boston Conference in 2009, that showed
18 that for all the clinical hoops that providers
19 have to go through, there's been very little
20 improvement in patient outcomes and mortality
21 over the years.

22 That conference had experts from

1 around the world, and they found that the best
2 hope for improving outcomes is to improve
3 fluid management, infections and cardiac care.
4 Their recommendation in brief for how to
5 accomplish is more dialysis and better access
6 management, and this I agree.

7 I'm thankful and excited to
8 participate, and I hope my patient perspective
9 will be useful and valuable, and reading over
10 the materials that I've got since last week,
11 I realize how woefully uneducated I am, and I
12 thought I knew a lot.

13 But it makes, it reminds me of how
14 much that a lot of renal patients just don't
15 know about the disease that we have to deal
16 with on a daily basis.

17 I'd just, I want to be a part of
18 changing that. The disclosure, I work for --
19 well, I'm a paid consultant, a paid speaker
20 for Next Stage Medical, which manufactures the
21 machine that I use. I've traveled. Over the
22 last three years, my hobby has been traveling

1 all over the country, speaking to dialysis
2 patients.

3 I've traveled over 60,000 miles in
4 my motor home over the last three years, been
5 to over 150 dialysis centers in 38 states. I
6 enjoy speaking to patients and just letting
7 them know that life -- or dialysis is not a
8 death sentence. Thanks very much.

9 MS. LeBEAU: Very tough to go
10 after, Harvey, and I think it's interesting we
11 have a little block of patients right here.
12 So we're all sticking together with our --
13 yes. The renal community is small.

14 My name is Kathe LeBeau. I am a
15 home hemodialysis patient of about three and
16 a half years now, diagnosed seven years ago.
17 My husband is my care partner. I am a waiting
18 transplant candidate as well. I work for, for
19 those of you who know here, Lori Hartwell of
20 the Renal Support Network.

21 I primarily do patient support and
22 education, and legislation and regulatory

1 advocacy through a number of channels, all
2 voluntary. But this is sort of by way of my
3 disclosure.

4 I participate in the ESRD
5 Network's Patient Affairs Committee, the UNOS
6 Organization Patient Affairs Committee, hang
7 on, the National Kidney Foundation of
8 Northeastern New York, and the PEAK
9 Initiative, for those of you who are familiar
10 with that as well on the technical and
11 curriculum guidance.

12 I also have a disclaimer. I
13 obviously am not a clinical expert, but I do
14 know what it's like to live with this. I'm
15 delighted I have fellow patients on this
16 Committee for all of your clinical expertise,
17 I do think our voice is important, and I'm
18 really pleased that you all have acknowledged
19 that as well.

20 In terms of hobbies, not what
21 everyone would do the first year on dialysis,
22 but a year in I went to clown school. Most of

1 my friends wondered what took me so long. So
2 I am a certified card-carrying organization
3 belonging clown.

4 I largely entertain at hospice
5 walks, kidney events, diabetes events. I do -
6 - my niche was going into dialysis centers.
7 I know what it's like to sit in the chair. I
8 go in with my red nose and I help people. I
9 did that Christmas Eve; it was terrific. So
10 great for me. A really fun hobby. I suggest
11 everyone give it a try. Thank you so much.

12 MS. WAGER: Hi. My name is Bobbi
13 Wager. I'm immediate past president of the
14 American Association of Kidney Patients. My
15 experience with ESRD is I am a nurse. I was
16 a peritoneal dialysis nurse, hemo nurse, staff
17 educator, and now I am a nurse educator with
18 Fresenius Medical Care.

19 I'm very proud of my lifetime
20 experience with ESRD, with Kathe, Harvey and
21 Helen who lived it, and we are living it and
22 will continue to live it. I'm so excited to

1 be on this Committee, to give the patient's
2 point of view on this. Thank you.

3 MS. HAMMERSMITH: Do you have any
4 disclosures?

5 MS. WAGER: I wish I did, but I
6 don't.

7 MS. HAMMERSMITH: Okay, thank you.

8 MS. ANDERSON: I'm Connie
9 Anderson. I'm the Vice President of Clinical
10 Operations of the Northwest Kidney Centers in
11 Seattle, and I have been, belong to many
12 quality Committees over my 37 years in the
13 ESRD field, and as a hobby, I'm a new
14 grandmother. So I spend a lot of time being
15 a grandma, which is great fun, and ski through
16 the winters. Seattle and ski and just
17 enjoying the snow.

18 As part of disclosures, I'm a
19 member of the Quality Committee for KCP and
20 KCC. I'm also on the Quality Committee of the
21 NRAA and I sit on the Quality Committee of the
22 Northwest Kidney Centers, which is a board

1 quality committee.

2 DR. VASSALOTTI: Hi, good morning.
3 I'm Joe Vassalotti. I'm a nephrologist at the
4 National Kidney Foundation. I'm the chief
5 medical officer. I also am associate clinical
6 professor of Medicine at Mount Sinai School of
7 Medicine.

8 In terms of my experience with
9 ESRD, I've had dialysis experience directing
10 programs here in D.C. and in Manhattan at
11 Mount Sinai School of Medicine. Quality
12 improvement experience is with the official
13 first initiative, both as a Network 2
14 consultant and a national consultant.

15 I've worked with the Quality
16 Improvement organizations with chronic kidney
17 disease, and I was part of the last iteration
18 of this Committee. I'm looking forward to
19 this. I think it's very important. In terms
20 of my hobbies, I have a six and eight year-old
21 and all I do is not that much.

22 My son would like me to spend my

1 time in indoor skate parks these days, and I
2 have nothing to disclose, although I also
3 would like to have things to disclose.

4 DR. KLEINPETER: Hi. I'm Myra
5 Kleinpeter. I'm associate professor of
6 Clinical Medicine at Tulane University. I
7 also served on this Committee, the previous
8 iteration of this. My quality experience, I'm
9 on the QIO for Network 13 for Louisiana,
10 Oklahoma and Arkansas.

11 I have served on the PEAK
12 Committee most recently and also have served
13 on various quality committees for the charity
14 hospital system in the state of Louisiana
15 public hospitals.

16 My disclosures, I'm on the
17 Speaker's Bureau for Pfizer, Gilead, Glaxo and
18 Berringer, mostly for hypertension and all the
19 honoraria go to the University actually, and
20 member of the National Kidney Foundation. I'm
21 the president of the Louisiana affiliate, and
22 also on the Board of Trustees for the American

1 Kidney Fund.

2 In terms of hobbies, I normally
3 like to travel, but yesterday was quite
4 taxing. So warm weather travel is my
5 qualifier.

6 DR. VELEZ: Good morning. I'm
7 Ruben Velez. I'm a practicing nephrologist in
8 the Dallas area for about 28 years. I am
9 president-elect of the RPA, Renal Physicians
10 Association, and on the board of the NKF.

11 Experience-wise, at least in Teas,
12 I've been part of the Texas Ad Hoc Committee
13 for the rules and regulations for about 15
14 years, part of the Network 14 of Texas. And
15 the hobbies, I would say any kind of sport.
16 If I'm not playing it, I'll be there watching
17 it.

18 Disclosure, I would like to
19 mention again the RPA. I'm medical director
20 in our company as medical directorships, with
21 multiple FMC dialysis facilities. And with
22 the local NKF chapter and various national,

1 the NKF.

2 DR. KLIGER: Hi. I'm Alan Kliger.
3 I'm a nephrologist in New Haven, Connecticut.
4 I'm the chief medical officer and chief
5 quality officer for the Hospital of St.
6 Raphael's, one of the Yale teaching hospitals,
7 and a clinical professor of Medicine at Yale.

8 My experience in quality goes back
9 many years. I was on the steering Committee
10 for the original DOQI and KDOQI. I served as
11 chair and then member of the Quality
12 Committees for the Forum of ESRD networks, and
13 then with the Renal Physicians Association as
14 well.

15 We had several projects over the
16 last dozen years, organizing nationally
17 efforts to define quality initiatives and
18 eventually quality measures, such as we're
19 measuring here.

20 My only significant disclosure is
21 that I have an investigator-directed research
22 grant from Amgen, and I also am the immediate

1 past president of the Renal Physicians
2 Association.

3 DR. PROVENZANO: I'm Bob
4 Provenzano. I'm a practicing clinical
5 nephrologist from Detroit. I am a clinical
6 professor of Medicine at Wayne State in
7 Detroit. Much like Alan, I am a past
8 president of the RPA and currently serves as
9 their counselor.

10 I'm a past president of the Renal
11 Network 11 of the Upper Midwest, and at the
12 National Kidney Foundation of Michigan. I
13 currently serve as a chief strategy officer
14 for DaVita, and as a medical director in
15 several DaVita facilities.

16 Disclosures, I am on a board of
17 directors of Vasc-Alert, which is a
18 surveillance company for dialysis accesses.
19 I do consulting work for Hemosphere, who
20 produces the HeRO catheters, and personal
21 disclosures. My son is a nephrologist,
22 practicing nephrologist, and I have six family

1 members on dialysis. I've only been
2 practicing 22 years, as opposed to Velez.

3 DR. NARVA: I'm Andy Narva. I am
4 a federal employee so I don't get a
5 microphone.

6 (Laughter.)

7 I am Director of the National
8 Kidney Disease Education Program at NIDDK.
9 Prior to that I worked for the Indian Health
10 Service and established the kidney disease
11 program for Indian health.

12 I still continue to function as
13 the chief clinical consultant for nephrology
14 for the Indian Health Service. My experience
15 in quality, I learned most about quality
16 improvement as a member of the Medical Review
17 Board of Network 15 for about 20 years.

18 As well, the Indian Health Service
19 is a fairly coherent and fairly large health
20 care system that has an excellent health data
21 system and has for many years, and is very
22 focused on using data to leverage improved

1 outcomes, and I was involved in that.

2 In my current job at NKDP, we're
3 very interested in promoting sort of systems
4 change to improve care for people with CKD,
5 and so we've collaborated closely with the
6 QIOs and a variety of other organizations,
7 many of which are represented here.

8 I have -- it's illegal for me to
9 have something to disclose. Although I serve
10 on a number of Committees that develop
11 guidelines, including JNC-8, the KDOQI Work
12 Group on Kidney Disease and Diabetes, and I
13 work as a member of the ABM Work Group, to
14 develop a practice improvement model for
15 nephrology.

16 My hobbies are I have a two year-
17 old, as a 31, 29 and 25 year-old, and other
18 than that, I'm a big game hunter and I guest
19 conduct for the National Symphony. I just
20 made that up.

21 (Laughter.)

22 DR. JACKSON: I'm Jerry Jackson.

1 I'm a practicing nephrologist in Birmingham,
2 Alabama, and I was the co-founder of our group
3 over 33 years ago. We care for approximately
4 just under 1,000 dialysis patients.

5 I'm the medical director of two
6 Fresenius clinics and I average taking care of
7 personally over about 65 to 70 patients, many
8 of whom I'm very close to and feel very
9 compassionate for what they have to go
10 through.

11 I'm also medical director of our
12 Outpatient Vascular Access Center and work
13 part-time there as an interventional
14 nephrologist, and that is managed by a DaVita
15 subsidiary called RNS Lifeline. I'm chairman
16 of the Medical Review Board of Network 8, and
17 we're very much engaged in external quality
18 improvement, and that's Mississippi,
19 Tennessee, Alabama. I'm very involved in
20 internal quality improvement for my group,
21 after taking training at the Institute for
22 Health Care Improvement.

1 As far, I'm on the -- I'm the NQF
2 voting member for the Forum of ESRD Networks.
3 I'm on the RPA Quality and Safety and
4 Accountability Committee, and as far as
5 hobbies, I like to read, I like photography
6 and we have four grandchildren between eight
7 months and six years that we're very involved
8 in.

9 DR. FIVUSH: I'm very impressed to
10 be in a room with so many interesting and
11 diverse people. My name is Barbara Fivush.
12 I'm the Division Chief of Pediatric Nephrology
13 at Johns Hopkins. Additionally, I wear a
14 totally different hat. I direct the Office of
15 Women there. I look at gender equity.

16 I'm a Professor of Pediatrics and
17 I'm a lifer at Hopkins. I've been there since
18 1978. There aren't that many lifers there,
19 but I'm one of them. I've had a long interest
20 in quality, and I tried to write it down to be
21 complete.

22 I think I probably started back in

1 the 90's. I was the pediatric representative
2 to the ESRD CPM project, with my friend Alan
3 who was involved in that. That was quite a
4 while ago, and we had a very active Committee
5 at that time.

6 I'm a member of the American
7 Society of Pediatric Nephrology and I am their
8 representative to the AMA PCPI, which is a
9 developer of pediatric physician-level
10 measures. We're in the process, we recently
11 developed two and we're in the process of
12 trying to develop a number more.

13 We work closely, as a
14 representative of ASPN, with KCP, Kidney Care
15 Partner. I'm on their KCQI Committee as well
16 as on their PEAK Committee, as well as on
17 their MIPPA Committee, so I do quite a bit of
18 quality work with them.

19 I also, and have been for a long
20 time, the clinical co-chair at the American
21 Society of Pediatric Nephrology. I was a
22 board member of the RPA, which was a wonderful

1 experience, and now I continue on their
2 Quality Committee and am head of the Pediatric
3 Committee, looking at shared decision and
4 dialysis, initiation and withdrawal.

5 I'm a member of the International
6 Pediatric Nephrology Association and was a
7 counselor for six years, and now am working
8 closely to look at their development agenda
9 and where they need to go. I'm a member of
10 the American Academy of Pediatrics and am on
11 their Quality Committee.

12 I also work with the network. I
13 helped our network to develop a Five Diamond
14 safety program, and I'm the pediatric
15 representative to the network. On the
16 National Kidney Foundation level, I'm on the
17 KDOQI grant review Committee, and I'm on our
18 local medical review board.

19 I think that's most of my quality
20 experience. I also have no disclosures at
21 this time, or probably have never had
22 disclosure, and I don't anticipate any

1 disclosures.

2 In terms of hobbies, I have two
3 children who are really large children, 24 and
4 27. They are great. I'm waiting for
5 grandchildren. I'm jealous of everybody in
6 the room who has them. I do love to travel
7 and have had a real opportunity to see lots of
8 parts of the world.

9 I also bike and exercise as much
10 as I can, and I probably -- one surprising
11 thing about me is I'm addicted to mahjong,
12 which is a tile game, and I try and play that
13 at least once a week. So I'm just sharing
14 with everybody.

15 Lastly, I'm a very, very big
16 sports fan and excited about the Ravens
17 playing Saturday. That's all I have.

18 DR. KASKEL: Rick Kaskel. I'm
19 Barbara's friend.

20 (Laughter.)

21 DR. KASKEL: I too am honored to
22 be in the room and to be one of the two

1 pediatric nephrologists on the panel with
2 Barbara. So I'm Vice Chairman and Director of
3 the Pediatric Nephrology Program at Einstein
4 and monitor in the Dialysis Unit and the NIH
5 Training Program.

6 I've served multiple capacities
7 with the American Society of Pediatric
8 Nephrology and the International Association
9 of Pediatric Nephrology, former president of
10 the ASPN. In terms of quality issues, I've
11 worked with KDOQI on the growth guidelines.
12 I've been with Andy as the pediatric
13 representative on the NKDEP Initiative.

14 I've served on mostly joint
15 services. I was with the FDA Cardiovascular
16 Renal Advisory Committee, especially when they
17 were dealing with the media.

18 So I could go on, but I think
19 representing pediatric nephrology along with
20 Barbara in the interest of children is an
21 honor. Thank you. I have no disclosures,
22 except my wife, four children, two

1 grandchildren, and I like things outside, and
2 I sail including in the winter.

3 DR. NALLY: I'm Joe Nally, and I
4 think I'm smarter than sailing in the winter.
5 I am impressed. I am a nephrologist at the
6 Cleveland Clinic, where I'm a Clinical
7 Professor of Medicine. I am also the Director
8 of the Center for CKD.

9 In terms of other interests
10 related to quality, I joined the Medical
11 Advisory Board for KDOQI in 2002 through the
12 National Kidney Foundation, went through that
13 process, sat on a few writing Committees, and
14 I'm also currently a vice chair for KDOQI
15 Public Policy.

16 At home I am a PI on our new CKD
17 registry, which actually will be published
18 this week, I hope, in CJASN, and outside
19 hobbies, golfer, racquetball, a sports guy,
20 but importantly, I have two granddaughters,
21 three and a half and one and a half.
22 Unfortunately, they live in Philadelphia,

1 closer to Jeffrey than me. But he has
2 visitation rights on weekends.

3 (Laughter.)

4 DR. NALLY: Thank you.

5 MS. BARNES: I'm Sue Barnes with
6 Kaiser Permanente's National Office,
7 supporting infection prevention and control
8 throughout our program, and I'm representing
9 APIC, which is the Association for Prevention
10 of Infections.

11 My experience in hemodialysis is
12 really restricted to my -- I facilitated the
13 development of the APIC guideline on
14 prevention of infections in hemodialysis, and
15 I worked with a lot of your colleagues and I
16 learned so much. Mostly, I learned what a
17 complex discipline this is. So I'm really
18 excited to be part of this.

19 My disclosures are that I'm a
20 member of the board of directors of national,
21 or it's actually International APIC now. I
22 was a TAP member for the NQF Patient Safety

1 Measure Development, focused on health care-
2 associated infections last year.

3 I am a Kaiser Permanente employee,
4 and Med Mind, which was listed on the list of
5 organizations, which is an automated infection
6 surveillance software program. Two of our
7 Kaiser facilities have implemented that, and
8 I've been consequently involved in
9 implementing that in a number of meetings
10 relative to it.

11 Epic is our, Kaiser's form of
12 electronic medical record. Oh, hobby is I
13 still play soccer. I think I have about a
14 year and a half left in my old Kaiser, in my
15 old geezer bones. Thank you.

16 DR. NALLY: I was so excited about
17 my granddaughters that I forgot about my
18 disclosures. I'm a medical director for a
19 Fresenius unit, and I also have the
20 development and infrastructure support of the
21 registry from an unrestricted grant partly
22 from Amgen. Thank you.

1 DR. BERNES: I'm Jeff Berns. I'm a
2 nephrologist in Philadelphia. I've been
3 practicing nephrology for 20 some-odd years.
4 I spent my formative years learning from Alan
5 Kliger, who was an attending of mine when I
6 was young.

7 I'm a Professor of Medicine and
8 Pediatrics at the University of Pennsylvania,
9 associate dean for Graduate Medical Education,
10 and run our Renal Fellowship Program. My
11 principle disclosures are that I served until
12 about six or nine months ago on the Data
13 Safety Monitoring Board for a clinical trial
14 run by Affymax, which is now closed.

15 I currently serve as an executive
16 Committee member on an advisory capacity to
17 Amgen for a clinical trial that they are
18 developing with the FDA, but has not been
19 launched. I'm on the advisory board for
20 Litholink, which is developing or has
21 developed a CKD lab testing organization, and
22 they are owned by LabCorp.

1 I currently serve as the Vice
2 Chair for Guidelines and Commentaries for
3 National Kidney Foundation KDOQI. I was on
4 the original KDOQI and then KDOQI Anemia Work
5 Group and currently serve on the KDIGO Anemia
6 Work Group.

7 Although I'm not a medical
8 director and actually don't see dialysis
9 patients right now, the University's dialysis
10 facilities are owned by DaVita. My hobby is
11 that I run.

12 MS. PAVLINAC: Good morning. Yes,
13 and my friend Ann told me how not to fail. So
14 I apologize for being late, but I did do a
15 redeye from the west coast or the left coast,
16 but I'm glad I'm here. I'm Jessie Pavlinac.
17 I work at Oregon Health and Science University
18 in Portland, Oregon as the Director of
19 Clinical Nutrition Services, and a renal
20 dietitian.

21 Have worked in ESRD transplant
22 pediatric hemodialysis before our University

1 sold their dialysis unit for over 30 years.
2 Immediate past president of the American
3 Dietetic Association. Has just recently
4 worked on the end stage, the chronic kidney
5 disease non-dialysis practice guidelines for
6 that organization, and involved in National
7 Kidney Foundation Council on Renal Nutrition.

8 Hobbies. Well, my husband and I
9 are charter members of the One More Time
10 Around Again Marching Band in Portland,
11 Oregon. We're an adult marching band. We've
12 been doing it for 25 years, and I suppose
13 that's our hobby. I don't think I have any
14 disclosures, and thank you very much.

15 MS. HAMMERSMITH: Are there any
16 Committee members on the phone?

17 (No response.)

18 MS. HAMMERSMITH: Okay, all right.
19 Do any of you have any questions of each other
20 or anything you would like to discuss
21 regarding the disclosures?

22 (No response.)

1 MS. HAMMERSMITH: Okay. I'll take
2 that as a no. Thank you all for
3 participating. You all did very well as far
4 as disclosures, and have a good meeting.

5 CO-CHAIR CROOKS: Okay. Thank
6 you, Ann. The public members and submitters
7 of metrics will be able to introduce
8 themselves briefly when they do their
9 presentation. They don't need to follow this
10 format.

11 Dinner reservations, we're
12 supposed to let Lauren know by, during our
13 morning break. If you'd like to join us for
14 dinner tonight at the Fire and Sage up the
15 street a little bit.

16 PARTICIPANT: It's right here.

17 CO-CHAIR CROOKS: It's right here
18 in this building, okay. Hey, you don't have
19 to go out in the snow. And just one other
20 thing.

21 You know, for the chair's
22 convenience, we'd like to be on a first name

1 basis with the Committee. We may call you by
2 your first name, we may call you by your last
3 name. We may say "hey you," but please
4 respond in a kindly manner, thank you.

5 If that's all right, I'd just like
6 to have your permission to use first names.
7 If anybody isn't comfortable, let me know.
8 Okay. I'll turn it over to Karen and Lauren
9 now to give us a project introduction and
10 overview.

11 Project Introduction and Overview

12 MS. RICHIE: Well, we will try to
13 keep the overview as brief as we possibly can.
14 I know we have a full agenda before us today.
15 But we just wanted to provide a really brief
16 high level summary of the project, for those
17 that are new to the Committee as well as our
18 developers that are here in person and on the
19 phone.

20 So with that, my computer. There
21 we go. So of course we are here to, for the
22 Committee, to recommend endorsement for

1 additional measures on ESRD care. As you all
2 know, there are currently 25 endorsed measures
3 were endorsed back in 2008, and again this
4 project is limited to that of ESRD care only
5 and does not encompass CKD.

6 However, there is an endorsement
7 maintenance project that will begin in a
8 couple of months here. We're able to look at
9 all things renal, including ESRD as well as
10 CKD.

11 Again, the Committee is asked to
12 act as a proxy for our multi-stakeholder
13 membership here and work with us to achieve
14 the goals of evaluating the candidate
15 standards against our evaluation criteria, and
16 ultimately make recommendations for
17 endorsement, as well as respond to comments
18 received on your recommendations.

19 Again, this is just our consensus
20 development process or our CDP, as we like to
21 refer to it, and we are about halfway through.

22 After we adjourn tomorrow, we will

1 immediately begin the process of compiling all
2 the recommendations and beginning a draft
3 report, in which you all will have a hand in
4 creating the draft report, as well as
5 responding to the comments received on the
6 report, and then we'll move on to voting and
7 ultimately to the CSAC decision and to the
8 board and an appeals process if necessary.

9 Again, this is just a visual
10 schematic of our CDP, again with the next
11 hurdle being creating the draft report and
12 posting that for member and public comment.

13 Objectives for today and tomorrow,
14 again, to evaluate the measures for
15 recommendation for endorsement. Tomorrow we
16 will -- tomorrow afternoon, I believe it is,
17 we will move into reviewing related and
18 competing measures to facilitate
19 harmonization, as well as measures for best in
20 class, and identify any remaining gaps in
21 performance for ESRD care.

22 Just a quick breakdown of the

1 measures. As I'm sure you all know, there are
2 32, with seven subtopics, and the bulk of
3 those being in anemia, fluid weight and
4 infection. I'm going to turn it over to Karen
5 briefly, so we can go over our measure
6 evaluation criteria, and then I will come back
7 again to go over the format for the evaluation
8 process today, as well as our voting
9 procedures.

10 DR. PACE: Okay. First of all, I
11 want to compliment this Committee. You were
12 just stellar in reviewing the measures as we
13 asked you to, and entering your evaluations on
14 line.

15 So I'm going to just quickly go
16 through our evaluation criteria, and then see
17 if there are any questions or issues that you
18 identified in terms of understanding the
19 criteria as you were working through the
20 measures, so that we can address those before
21 we get into discussion of the measures.

22 We have certain conditions before

1 we will even consider measures. I won't go
2 through those today, because we can staff
3 review these before we send the measures on to
4 you. We have four major criteria, and we look
5 at these in a hierarchy.

6 First, we look at importance to
7 measure and report. We really want to endorse
8 performance measures for those aspects of care
9 with the greatest potential of driving
10 improvements. Next is scientific
11 acceptability of the measure properties. This
12 has to do with making, you know, reliable and
13 ultimately valid conclusions about the quality
14 of care based on the scores from the measures.

15 We want the measures to be
16 useable, so that people can use them regarding
17 decisions related to selection and
18 improvement, and then finally feasible.
19 Ideally, we want measures that have the least
20 burden in terms of data collection and
21 reporting.

22 If we have competing measures, NQF

1 prefers to endorse one measure, the best
2 weighted measure. We will talk more about
3 that, as Warren said, tomorrow. So we have
4 the four major criteria. As you know, each of
5 those criteria have subcriteria, and that's
6 what you look at to determine if a measure
7 actually meets our criteria.

8 We think that those subcriteria
9 parallel best practices for measure
10 development. For example, if you begin with
11 identifying what is important to measure and
12 later what is feasible. Most criteria involve
13 a matter of degree rather than an all or
14 nothing determination.

15 However, importance to measure
16 report is a threshold criterion where we ask
17 you to identify either yes or no that it has
18 been met.

19 Importance to measure and report.
20 Again, the focus here is on those, measuring
21 those aspects of care that are most likely to
22 really drive improvements in the quality of

1 care and achievement of desired outcomes.

2 There's three components of this.
3 We want to really endorse measures that have
4 a high impact, and this can be that it affects
5 a large volume of patients. It could be high
6 consequences and poor quality. It could be
7 high resource use. So ESRD care fits a lot of
8 those areas of high impact.

9 Gap in performance. Here, we're
10 looking at wanting to endorse measures that,
11 where there is variation in quality across
12 providers, or that there's overall poor
13 quality. So again, we want to endorse
14 measures where actually it's going to help
15 drive improvements.

16 The third aspect of this is that
17 there's evidence that supports the measure
18 focus. So we really want to endorse those,
19 especially when we're talking about structures
20 and processes, those things where there is
21 strong evidence that they lead to the desired
22 outcomes.

1 I'd just make a couple of notes
2 here. In the evaluation criteria, and I think
3 you have a pamphlet that was distributed just
4 for your reference today, we have a Footnote
5 14, and that is that all things being equal,
6 NQF would prefer to endorse measures of
7 aspects of care that are most proximal to the
8 desired outcomes.

9 So you all know that in your
10 practice, there's many steps in a process. We
11 start with assessment, then diagnosis. Then
12 we identify the treatment options, selected
13 treatment, administer the treatment. Usually
14 the evidence is for that treatment to the
15 desired outcomes.

16 So one of the things that we'll
17 ask you to think about as we're looking at
18 importance on measures that are more distal to
19 that desired outcome is, is that something
20 that we really should invest resources into
21 performance measurement, when there are other
22 things that are more proximal to the desired

1 outcome that perhaps we would get more bang
2 for our buck.

3 The other thing that I think we
4 try to emphasize here is that there are many
5 things that are important to delivering care.
6 That doesn't necessarily always translate that
7 we want a performance measure for every single
8 thing that it's important to happen in
9 clinical care practices.

10 We'd have thousands and thousands
11 of measures if we went down that road. So
12 we'll ask you to be thinking about that as we
13 talk about important to measuring report.

14 Scientific acceptability of
15 measure properties. What this really boils
16 down to is reliability and validity of the
17 measures as they are specified. So importance
18 to measure and report is more at the concept
19 level of what you're intending to measure.

20 Reliability and validity really is
21 related to the measure as it's specified. So
22 you can have a good idea to measure something

1 for quality, but if the way the measure's
2 constructed really doesn't achieve that,
3 because you end up with unreliable or invalid
4 results, and so we'll certainly be addressing
5 this as we go through.

6 For outcome measures, risk
7 adjustment is a big component of looking at
8 whether you have a valid, that you can make
9 valid conclusions about quality from a
10 particular measure.

11 Usability. You know, I think this
12 is something that all of you will have
13 experience with, in terms of thinking about
14 these measures and is this, if you have the
15 information on this measure for a particular
16 facility, if you're a consumer or a payor,
17 will that help you make a determination of
18 whether you'd want to receive care there.

19 Contract with that facility for
20 care. If you are a provider or a facility, is
21 that information that will help you look at
22 your own care and make improvements. So

1 that's what we're really looking for under
2 usability.

3 And lastly, feasibility.
4 Certainly, data that is electronically
5 collected. Ultimately, we're moving toward
6 really wanting to have measures that are based
7 in electronic health records, so that quality
8 measurement can be a byproduct of care and the
9 documentation that you're already doing.

10 But obviously that's not a
11 widespread reality at this point in time. But
12 again, an assessment of how feasible is it to
13 collect the data that's needed for the
14 particular performance measure that's
15 proposed.

16 So as Peter mentioned earlier, we
17 really will try to get you to look at these
18 measures individually first, even though you
19 know that there are other measures competing.
20 We really want to make sure that each measure
21 is reviewed and evaluated against the
22 criteria.

1 Then tomorrow, we'll really look
2 at comparison of measures, to see if there are
3 issues with measure harmonization and
4 specifications, or if we have multiple
5 measures on the same topics that will start
6 addressing is there one that's really superior
7 to the others, and what would be the reason
8 that we would need multiple measures if we
9 can't make that determination.

10 Okay. I'll let Lauren pick up
11 there. Oh, yes, go ahead.

12 DR. BERNES: Just to clarify, our
13 role here is to evaluate the measures as
14 written. There's no opportunity or room for
15 editing or revising or coming up with a
16 slightly tweaked measure?

17 DR. PACE: I'll modify that. You
18 know, pretty much we have to deal with the
19 measures as they have been provided to us.
20 There is some room for suggestions to the
21 measure developers, you know. It's kind of a
22 fine line.

1 If you are suggesting lots of
2 changes, it actually becomes a new measure and
3 we're crossing the line into measure
4 development versus tweaking the measures. So
5 you know, certainly bring those issues up, and
6 we'll help navigate that. So there are some
7 potential opportunities.

8 DR. FIVUSH: The other measures
9 that have previously been endorsed by NQF,
10 they will be looked at again by NQF. But at
11 this point, we won't be discussing those
12 measures or potentials for harmonizations
13 backwards to those measures or --

14 DR. PACE: Yes, actually we will,
15 and tomorrow what we'll do is we -- it's on
16 your flash drive actually.

17 We put together some comparison
18 tables, so that if we have a measure from the
19 last project that is similar to or related,
20 we'll look at those side by side and see if
21 there are any harmonization, or whether it
22 should be one measure, those kinds of issues.

1 But we will have an opportunity to
2 look at those in relation to the new measures.

3 DR. PACE: Thank you.

4 DR. NALLY: Question as a new
5 member, because this has been a very daunting
6 task, looking at all this. But when you use
7 those criteria and assume that most questions
8 are important, then you get down to the
9 specifics, say, of scientific acceptability,
10 whereby there is information presented.

11 But when other groups have looked
12 at it, they might have said since, let's use
13 bone mineral as an example. There is some
14 evidence here, but it's all Level 2 and there
15 are Committee suggestions out there that, you
16 know, that needs more discussion and
17 investigation.

18 So what exactly would the criteria
19 be in that circumstance when there's Level 2
20 evidence, and then another area where there's
21 also important questions, but maybe the
22 feasibility or methodology of either using

1 data that's a couple of years ago for Medicare
2 claims forms and then transitioning to a
3 CROWNWeb.

4 In other words, the methodology is
5 not in place. What is the approach to those
6 things, where you don't know what CROWNWeb has
7 to offer about hospitalization and infections
8 down the road?

9 DR. PACE: Let me talk about the
10 first question, about the evidence. Just to
11 clarify, we look at the evidence, the clinical
12 evidence for whatever you're suggesting to be
13 measured under importance to measure and
14 report.

15 So we really want a strong
16 clinical evidence foundation, because
17 otherwise, why do we want it? If we don't
18 know that something really improves patient
19 outcomes, do we want to invest time and effort
20 into measuring it?

21 Under scientific acceptability of
22 measure properties, that's where we look at

1 the reliability and validity of the specific
2 measure that's being provided.

3 So all of these criteria, as I
4 mentioned, you know, it's not a black and
5 white thing, and that's why we assemble this
6 group of experts with different perspectives
7 and different areas of expertise, to help us
8 go through this, because there are trade-offs
9 at times, you know. There are different ways
10 of look at it.

11 So there's not one answer usually,
12 and that's why we need your collective
13 knowledge to kind of wade through this.

14 In terms of measures that are
15 untested and I'll have Helen make some
16 comments here in a moment too, generally we're
17 trying to get away from endorsing untested
18 measures, and we'll talk about this a little
19 bit more.

20 So the issue with moving into a
21 new data platform with CROWNWeb, they may have
22 done some pilot testing and that's perfectly

1 acceptable for us to have pilot testing
2 results on a small sample.

3 If there's absolutely no testing,
4 I think that's something we'll have to
5 discuss. Sometimes when moving to a different
6 data platform, they're really going to use
7 exactly the same specifications that they did
8 for their prior data collection.

9 So it will vary depending on the
10 particular measure. So I'll stop there and
11 see if that has answered at least some of your
12 questions.

13 DR. NALLY: Yes, thank you, and I
14 suspect we'll get into this, dig a little
15 deeper within each measure.

16 DR. KLIGER: Karen, among the
17 criteria that you described, you did not
18 include unintended consequences, and in the
19 field of measure development, it's become very
20 clear that unintended consequences have a
21 major, negative effect on approved or endorsed
22 measures. Might you say something about that

1 to us?

2 DR. PACE: Right. I actually
3 skipped over that. It is one of the
4 subcriteria under feasibility. If, you know,
5 we ask the measure developer to discuss, and
6 something we ask you then to look at is are
7 there particular issues with potential for
8 inaccuracies, errors and unintended
9 consequences.

10 So it is certainly something that
11 you can bring up and discuss. The difficulty,
12 we often have difficulty in this area, because
13 it's more theoretical than actual having data
14 to support that. So but it's certainly an
15 issue that can be discussed and deliberated
16 over as you review the measures here.

17 CO-CHAIR CROOKS: Karen, are you
18 going to discuss now or fill us in a bit on
19 the time-limited issue, you know. I think
20 looking at many of the metrics we have before
21 us, whether they were identified as only
22 eligible for time-limited, or not and whether

1 we can recommend time-limited. How does all
2 that play out?

3 DR. PACE: That really is a -- we
4 make that determination of which measures are
5 eligible, only eligible for time-limited
6 endorsement, based on whether there has been
7 any testing.

8 So we do sometimes get into the
9 discussion with Committees that, you know,
10 even though the measure has been tested, they
11 have some questions, and they would feel more
12 comfortable recommending it for time-limited
13 endorsement.

14 But we really have only specific
15 requirements, and that is that there's been no
16 testing. So if the measure has been tested
17 and you don't think the testing results
18 indicate that it's really going to result in
19 reliable and valid measurement, then you
20 really need to think about not recommending
21 it. But okay.

22 DR. LATTIS: Oh, and if the

1 Committee does recommend a time-limited
2 approval, does the Committee then get back
3 together in a year and review the data, to say
4 yes, okay, now we can go ahead to a three-year
5 approval? Or CSAC does that?

6 DR. PACE: Yes. Measure
7 developers have to submit the testing results
8 within 12 months of the endorsement, and that
9 does go back to the consensus. Yes.

10 DR. BURSTIN: I knew this would
11 come up, as it always does. So we are
12 definitely at a point, I think, in the whole
13 measurement enterprise, where there is both an
14 appetite for new measures as fast as possible,
15 and at the same time high stakes measurements
16 and lots of concerns about untested measures.

17 So we're kind of really in that
18 middle vortex, I think, which makes this a bit
19 difficult. We discussed this in great detail
20 with the board of directors last year, and we
21 made a determination, and this project is
22 actually under the new guidance.

1 So the new guidance from the board
2 is that we will only accept time-limited
3 measures in three, if all three of the
4 following criteria are met. The first is that
5 there's a clear gap in the portfolio, and
6 there are some areas, like perhaps some of the
7 ESRD infection measures, where we don't
8 actually have any measures like that in the
9 portfolio. So that's the first requirement.

10 The second is that there's a time-
11 sensitive legislative mandate. Now we know
12 there are payment rules for ESRD, but we also
13 need to understand from the developers in CMS
14 when in fact there is that opportunity to
15 allow the six months for testing, and really
16 revisit it when the measure has been tested,
17 and that is the second one.

18 The third is that the measures
19 can't be what we call complex. They can't
20 have a risk adjustment methodology attached to
21 them, they can't be composites, things that
22 really -- they're not sort of the basic

1 process measures. It's hard to envision
2 anybody wanting to use a complex measure
3 that's not been tested.

4 So all three of those are in fact
5 required for a time-limited measure to move
6 forward. This is one of the first projects
7 that's initiated since that board policy went
8 into effect.

9 So the third, the final piece of
10 that is it used to be we would say time-
11 limited testing, that measures had to come
12 back within 12 to 24 months. Clearly people
13 think that's too long. They now must come
14 back within 12 months, and the developers have
15 to present to us a plan that demonstrates to
16 the Committee that you really think they're
17 capable, that they have the resources and the
18 plan to actually test the measures within that
19 time period.

20 So clearly this is a significant
21 narrowing of this funnel. I suspect within,
22 I don't know, X period of time, within a

1 couple of years, I think time-limited measures
2 will probably go away. But I think because of
3 the, you know, the need to continually add
4 measures for many areas for which there aren't
5 measures, the board left it in place for now.
6 I don't know how long that will persist.

7 DR. PACE: When we get to review
8 of the measures that are recommended for time-
9 limited, can you just write those three
10 criterias so we can --

11 DR. BURSTIN: Yes, absolutely.
12 We'd be happy to do that. Yes, we will.

13 MS. LeBEAU: Just to go back to
14 our December 2nd conference call, there was a
15 lot of consensus among this group that while
16 looking at all the measures that are proposed
17 at the clinical profile of the patient, that
18 it was important to bring it back to the
19 patient and look at other measures that are
20 very significant in the quality of care, but
21 that we really haven't yet identified or
22 talked about or certainly tested.

1 Is there an opportunity during
2 this two-day meeting to look at those kinds of
3 things?

4 DR. PACE: Yes, and one of the
5 things that we put on your flash drive is kind
6 of expanded the table that we started with,
7 and added some of the discussion, and we'll go
8 back to that tomorrow to get your feedback on
9 that, identify where there are measurement
10 gaps, because we do want this Committee to
11 make those recommendations.

12 Hopefully, measure developers will
13 take that to heart and start working on those
14 kinds of measures.

15 DR. VASSALOTTI: I just wanted to
16 follow up on Alan's comment about the
17 unintended consequences, especially since
18 there are patients here. We want to serve the
19 patients as best as we possibly can. I just
20 want to make the point that there may be
21 measures here that we believe clinically we
22 should do, that we feel strongly they may have

1 an impact, that they're important to patient
2 care, that they should potentially be part of
3 quality improvement processes.

4 But because this is potentially
5 incentive-based, there will be a financial
6 incentive to these measures, these measures
7 will have a huge impact on care. I just want
8 to be very careful about what we do here.

9 I wonder if you had any comments
10 about that, that really the measure that have
11 the highest-quality evidence, that we really
12 confident in, because we will focus physician
13 and dialysis facility behavior toward these
14 measures, which could potentially take their
15 behavior away from other activities that are
16 important.

17 There also may be unintended
18 consequences of some of these measures that we
19 don't even understand. So I just wanted to
20 make that point, and I want to serve the
21 patients and the dialysis community as best as
22 we possibly can here today.

1 DR. BURSTIN: Just a couple of
2 comments, and I think that's a really
3 important point, and it's something that's
4 going to continue to come up. I think the
5 difficulty is for a lot of the measures you're
6 looking at, that they have been tested, pilot-
7 tested, but not in use.

8 It's oftentimes difficult to know
9 what the unintended consequences will be. So
10 we actually put, you know, emphasis on it at
11 the initial endorsement, but in fact it's a
12 much larger consideration for measures when
13 they're up for maintenance.

14 We also have what's called ad hoc
15 maintenance, so that, for example, if there's
16 an unintended consequence identified in the
17 community, it can be brought to NQF at any
18 time, and we'll convene an ad hoc panel to
19 look at it.

20 But again, oftentimes it's sort of
21 theoretically. We just had a discussion
22 yesterday on our call about a perceive

1 unintended consequence. The immediate
2 question was well, what's the level? How many
3 people would this affect? Again, it's often
4 very difficult to know for a measure that's
5 not in use.

6 The other sort of big picture
7 issue I want to raise, and I know Karen did
8 earlier as well, is harmonization. We have
9 now got over 600 measures in the NQF
10 portfolio. A good number of them are there
11 because they in fact cover lots of different
12 clinical areas, settings, et cetera.

13 We also have a lot of, I think as
14 our Harmonization Committee called it,
15 unintentional disharmony, where measures are
16 just sort of put --

17 (Laughter.)

18 DR. BURSTIN: I love that term --
19 where measures are put forward without
20 consideration of how the measures relate to
21 other settings of care, how they relate to
22 patients. Patients is all this little row

1 knows. Patients flow through different
2 settings of care. It's not always a single
3 setting of care or a single provider who takes
4 care of them.

5 And so we really need your help
6 here. We want you to both focus within the
7 portfolio of measures that you're being
8 presented in ESRD, but in some of the
9 instances, and I'm glad Sue's here on the
10 infection side, there are measures.

11 We've already got HAI-related
12 measures that are broader than dialysis, and
13 I think one question we'd really like you to
14 think about is how much can you use, for
15 example, you know, at least make sure we
16 harmonize with the existing measures, so we
17 don't avoid people having different
18 requirements. If it's a bloodstream infection
19 in a hospital versus a identification of a
20 bloodstream infection in a dialysis facility.

21 So we really will need your help
22 here, and as much as possible, if measures are

1 not harmonious, if there are differences,
2 you've got to be able to indicate there's a
3 justification for that lack of harmony. That
4 was a really important finding out of the
5 committee that Karen just led for us, on
6 harmonization.

7 As much as possible, we want
8 measures that are harmonized across settings
9 and providers and patient groups, but if
10 they're not harmonized, we've got to have a
11 justification saying the lack of harmony is
12 justified because if it's really important,
13 this is an important strategy, it will drive
14 improvement, et cetera.

15 So just really thanking you in
16 advance for this. And again, if you can
17 identify the unintended consequences for us,
18 it will be great for us to try to ask the
19 developers to actually do some analyses for
20 you, to be more quantitative about it. But
21 it's, you know, something we recognize we
22 won't always have the capacity to do in

1 advance.

2 DR. VASSALOTTI: Lisa's point was
3 if we recommend something for time-limited
4 testing, would that be part of the QIP and
5 incentive-based?

6 DR. PACE: Well, NQF endorses
7 measures, and then other people use them. But
8 once it's endorsed, even if it's time-limited
9 endorsement, it could be used by those that
10 are required to use endorsed measures.

11 DR. BURSTIN: And just important
12 to remember that really you would only put
13 through a measure for time-limited endorsement
14 if it otherwise meets all of the NQF criteria.
15 You think it's completely fine; you just don't
16 have pilot testing data yet.

17 So you really have to feel very
18 comfortable that that measure's ready to move
19 into prime time.

20 DR. LATTS: So if we really have
21 methodologic recommendations, we should not do
22 a time-limited endorsement, methodologic

1 changes. If we want them to change something
2 and do a testing, it should not be endorsed.
3 It should only be if it's perfect, we think
4 it's perfect; we just don't have the proof
5 it's perfect.

6 DR. BURSTIN: If you think it
7 meets the overall criteria. Perfect is a --
8 we live in a world of gray. I don't know what
9 perfect is, but I think it's got to meet the
10 other criteria otherwise.

11 DR. LATTS: Yes, yes.

12 DR. BURSTIN: But it does not, it
13 does not yet have testing data.

14 DR. PACE: On the other hand,
15 measures that haven't yet been tested, there's
16 more room potentially to make some
17 recommendations for the measure because, you
18 know, it's more difficult for a measure that's
19 already been tested, to say "Oh now we want
20 you to change it this way," because then at
21 what point does the testing become invalid,
22 based on the changes? So it's a little

1 difficult there. Yes.

2 DR. FIVUSH: I'm sorry. To just
3 understand this, there's room for time-limited
4 measures, although we're not really looking
5 for those. But there are opportunities for
6 those measures that have not been previously
7 tested? When there's a need, when it's
8 evaluated.

9 But I just want to understand one
10 more time. Can measures that are previously
11 untested be given full endorsement, or will
12 they have to be given time-limited? I mean is
13 there a circumstance with which without
14 previous testing.

15 I understand we don't want, we
16 don't want measures that are time-limited, but
17 we know there may be circumstances when that
18 may happen. Does that mean that time-limited
19 measures, that untested measures will never
20 get endorsement without first getting time-
21 limited endorsement?

22 That is correct. So any measure

1 that we consider that's not been previously
2 tested, but is important, could potentially
3 get time-limited, but will never get unlimited
4 endorsement?

5 DR. PACE: And just to clarify,
6 NQF does not have unlimited endorsement.

7 Endorsement is for three years, and then all
8 the measures are reviewed again. And that's,
9 we've moved into a new process, which we call
10 endorsement maintenance cycles by topic, and
11 that's what the next phase of this project is
12 really going to be, the renal endorsement
13 maintenance.

14 So we'll be looking at all of
15 those measures that were previously endorsed,
16 as well as new measures. So you know, just
17 like everything else, there are advances in
18 measurement, there are changes in clinical
19 practice, et cetera.

20 So measures need to be updated as
21 well, and make sure that they still meet our
22 criteria. A measure that was endorsed, you

1 know, three years ago may no longer be
2 important for us to be endorsing again.

3 DR. LATTIS: Sorry. One last
4 question. So if we don't approve something
5 and say it needs whatever changes, when -- is
6 that then the next opportunity for the measure
7 submitter to resubmit for consideration?

8 DR. PACE: That's a possibility.
9 We have a couple of things. If the Committee
10 really feels that they can't recommend a
11 measure for endorsement unless some change is
12 made, again it will depend on what that change
13 is. It could be something that could be
14 accommodated within this project.

15 After this meeting, if there are
16 any of those kinds of things, we will go back
17 to the measure developers, have a discussion
18 with them about what your recommendation is,
19 see if that can be accommodated or not. They
20 will respond to the Committee, and then you
21 will decide where to go from there. Okay.

22 CO-CHAIR CROOKS: Okay. It's time

1 for us to --

2 DR. PACE: Lauren has a couple of
3 things, sorry.

4 MS. RICHIE: Before we actually
5 dive into the measures, just a couple of
6 logistics.

7 As you all notice on the agenda,
8 there is a designated place for member and
9 public comment, and that will actually begin.
10 The first one will be -- I know we're a little
11 bit behind, but we'll have one in the morning
12 and again one this afternoon, and then twice
13 again on tomorrow.

14 The measure developers will do a
15 brief introduction of their measures starting
16 here shortly, and they are available to you
17 for questions or clarifications throughout the
18 day as you discuss the measures. Then we will
19 take each measure discussed and then vote on
20 them separately.

21 As you all know, we -- everyone
22 had their assigned measures, which I'm sure

1 you're well-versed in by now. One committee
2 member will begin a discussion by just
3 providing the group with a summary from the
4 evaluations that you provided in the Excel
5 file, and each -- from then, the full
6 committee will discuss the measures.

7 We will vote and we will save
8 related and competing measures until tomorrow.
9 And speaking of voting, does everyone have a
10 little remote control here? We can pass one
11 to Jessie and Lisa. One more around to Andrew
12 please.

13 So the measure number and title
14 will be displayed on the second screen here,
15 and you will see a question for each of the
16 major criteria, as well as the subcriteria.
17 So what you'll do is enter your response on
18 their remote control there, and you will --
19 it's either be 1 through 4, and you will enter
20 1 and then send to indicate your response.

21 So for example, Measure No. 1418,
22 Frequency of Adequacy Measurement, does the

1 measure meet NQF criteria for importance? 1
2 yes, 2 no. So you hit 1, then send or 2, then
3 send. The caveat here is that once you hit
4 send, you cannot change your response.

5 So if you would like to change
6 your response before you hit send, it's 1,
7 then the exclamation point here, the caution
8 symbol, and then your changed response. So if
9 you want to change your answer from 1 to 2,
10 it's 1, caution symbol 2, and then send, and
11 et cetera.

12 So once we have a question up and
13 we've discussed the measure until we're blue
14 in the face, we will then be ready to vote,
15 and you'll have 60 seconds. There will be a
16 timer in the lower right-hand corner there.
17 Then the results will be displayed. We'll
18 have the total number of votes, and the co-
19 chairs will kind of summarize the votes and
20 we'll move from there. So --

21 CO-CHAIR CROOKS: All right. It's
22 time to meet the public, and NQF members who

1 are attending first by phone. Who's on the
2 phone with us? I invite you to introduce
3 yourself and make any comments you'd like to.
4 Do we have somebody on the phone? The phone
5 line's open, but apparently there's nobody on
6 right now.

7 MR. DUDLEY: Actually I'm on.
8 This is Tom Dudley from CMS.

9 CO-CHAIR CROOKS: Yes.

10 MS. LING: And this is Shari Ling
11 from CMS.

12 MR. PEARSON: And this is Jeff
13 Pearson with a group from Arbor Research
14 Collaborative for Health and the University of
15 Michigan.

16 MS. RAMIREZ: This is Sylvia
17 Ramirez for the Arbor Research Collaborative
18 for Health.

19 CO-CHAIR CROOKS: Okay. Those of
20 you who are not, who are attending not as
21 measure developers on the phone, do you have
22 any comments for us?

1 OPERATOR: And this is the
2 Operator. They can press Star 1 if they have
3 a question or comment at this time.

4 DR. PACE: Could you repeat that
5 again? Who just spoke?

6 OPERATOR: This is the Operator.
7 If a person on the phone has a question or
8 comment, they can press Star 1.

9 DR. PACE: Right, and this is for
10 NQF member and public comment? We'll go to
11 the measure developers and stewards in a
12 minute, make sure --

13 CO-CHAIR CROOKS: After the break.

14 DR. PACE: After the break, sorry.

15 OPERATOR: We do have Dale Singer
16 that has a question.

17 MS. SINGER: No, I just wanted to
18 get --

19 DR. PACE: Operator, we're having
20 trouble understanding you. Could you say that
21 again?

22 OPERATOR: Dale Singer's on the

1 line.

2 DR. PACE: Okay.

3 MS. SINGER: I just wanted to say
4 hello. I'm Dale Singer with the Renal
5 Physicians Association.

6 DR. PACE: Okay, thank you.

7 CO-CHAIR CROOKS: Okay. Any other
8 comments from those on the telephone?

9 (No response.)

10 CO-CHAIR CROOKS: Okay, and in
11 person, we have several people in the back.
12 Can you stand up and identify yourselves, make
13 any comments you'd like to. Please use a
14 microphone.

15 Public Comment

16 MS. MCGONIGAL: All right. Can you
17 hear me? I am Lisa McGonigal from Kidney Care
18 Partners. Kidney Care Partners is a national
19 coalition of patient advocates, health care
20 professionals and providers and suppliers,
21 working together to improve care for patients
22 with chronic kidney disease and end stage

1 renal disease.

2 KCP appreciates this opportunity to
3 comment on the measures that will be before
4 this Steering Committee this morning. I'd
5 like to preface my remarks about specific
6 measures by noting that as KCP reviewed the
7 detailed specifications over the past two
8 months.

9 We felt that it was important to do
10 so in the regulatory context faced by the ESRD
11 committee. Specifically, Medicare ESRD
12 program is unique, in that it is the federal
13 government's only true pay for performance
14 program. Thus, our review of the measures
15 focused on their appropriateness for public
16 reporting, but also for payment.

17 We also noted that the vast majority
18 of the measures had not been tested for
19 reliability and validity, and so also express
20 our concerns in that regard.

21 So starting first with the pediatric
22 measures, KCP has no objections to any of the

1 eight proposed pediatric consensus standards.

2 We support all eight measures for use in
3 public reporting and for payment purposes.

4 We also wanted to state that given
5 the dearth of existing pediatric ESRD
6 measures, KCP notes that it's important to
7 begin building the portfolio across additional
8 measurement topics in pediatrics.

9 Next, turning to adult anemia
10 management measures, KCP only supports these
11 measures for public reporting if the
12 specifications are modified. We don't support
13 any of the measures for payment purposes.
14 We'd also like to recommend a few
15 modifications to the anemia management
16 measures.

17 First, we feel the requirement for a
18 simultaneous ferritin and TSAT collection date
19 should be removed from both the numerator and
20 denominator in all three of the measures.

21 There are several reasonable scenarios where
22 simultaneous values might not be reported that

1 outside the facility's realm of control.

2 For example, lab errors and so on.

3 In these instances, the facility would be
4 unfairly penalized. KCP is also concerned
5 about the potential for unintended
6 consequences, specifically increased cost with
7 this requirement. Facilities might end up
8 having to repeat testing to get the required
9 simultaneous values.

10 KCP instead believes that the test
11 should be required within the same reporting
12 month, rather than on the same day.

13 Next, for Measure 1428, use of iron
14 therapy when indicated, KCP believes that the
15 exclusion should be brought in from patients
16 with hemoglobin greater than 12, to patients
17 with hemoglobin greater than 10.

18 KCP is concerned that there are
19 clinically stable patients with hemoglobin
20 values between 10 and 12 for IVR would do
21 nothing to improve their care, their clinical
22 status or their outcomes. We believe that

1 excluding patients with hemoglobin values
2 between 10 and 12 would resolve this issue.

3 Finally, KCP recommends that an
4 exclusion be added to Measure 1429, Avoidance
5 of Iron Therapy and Iron Overload.

6 Specifically, as many nephrologists typically
7 obtain a TSAT value and then act on it one to
8 two months later, requiring avoidance of iron
9 for three months is inappropriate and out of
10 sync with current practices.

11 We believe that this concern could
12 be alleviated by adding an exclusion for
13 patients in whom confirmatory or follow-up
14 TSATs are less than 50 percent. That's it.
15 Thank you.

16 CO-CHAIR CROOKS: Thank you. Next.
17 Come on up and use the microphone.

18 MS. NISHIMI: Thank you. I'm Robin
19 Nishimi, representing KCP today, and as a NQF
20 member, we appreciate the opportunity to
21 comment on this project. As Lisa has just
22 noted, KCP's review of the proposed consensus

1 standards was done with an eye toward their
2 final use for public reporting only, or public
3 reporting and payment.

4 So with that mind now, I'd like
5 provide KCP's comments now on some measures
6 that you're not going to review until the
7 afternoon. But since there's no public
8 comment period just before that, we're going
9 to comment now.

10 For the fluid weight management
11 measures, KCP opposed No. 1438, Periodic
12 Assessment of Post-Dialysis Weight by
13 Nephrologists. Since we do not think it is
14 appropriate to evaluate at the facility level,
15 because it's a clinician responsibility. We
16 also oppose all of the other proposed fluid
17 weight management measures in this area.

18 For the three mineral and bone
19 measures, KCP supports these three measures
20 for public reporting and payment, and has no
21 recommended modifications to the
22 specifications. Thanks.

1 CO-CHAIR CROOKS: Okay, thank you.

2 Any other public or NQF members care to
3 comment? Would you like to comment? Okay.

4 (No response.)

5 CO-CHAIR CROOKS: Then I think we've
6 reached a break time. We'll take ten minutes.
7 That will get us back in our chairs about
8 shortly after the half hour, and we'll move on
9 from there.

10 (Whereupon, the above-entitled
11 matter went off the record at 10:22 a.m. and
12 resumed at 10:37 a.m.)

13 CO-CHAIR CROOKS: Coming back to the
14 table, please. All right. Please take your
15 seats, and while you're coming to your seat,
16 anybody like to join us for supper tonight who
17 hasn't told us? Speak now. Alan Kliger, Dr.
18 Kliger. Okay, good. Anybody else?

19 Now that Alan's coming, everybody
20 will want to come. Any cancellations? Okay.
21 Lauren, just before we move on, Lauren will
22 take a minute or two just to describe the

1 flash drive that you have all with computers
2 have been given, to just let you know what's
3 on there and how to use it.

4 MS. RICHIE: For those of you with
5 laptops, just so that you all know.
6 Everything that you have received from myself
7 in the last couple of months, all those copies
8 are on the flash drives.

9 So we've broken it out by topics for
10 the measures. So there's an anemia folder,
11 dialysis adequacy and nutrition folder, a
12 fluid weight, mineral metabolism, infection,
13 et cetera.

14 Also, there are the additional
15 attachments that are for the measures.
16 They're going to be at the end of the
17 measures. So for anything related to
18 CROWNWeb, you will find that at the end of the
19 measure. We have some additional CMS data
20 documentation folders. Those are in there as
21 well.

22 The preliminary evaluations, the

1 Excel file and the Word file that was sent to
2 you with all the preliminary findings are in
3 the folder called "Preliminary Evals." Then
4 just all the supplemental material to the
5 steering committee is in the folder entitled
6 "Steering Committee."

7 Just a few other additional memos
8 that you have received from myself is there.
9 So just as a backup, anything that you
10 remember seeing, it's more than likely on this
11 flash drive and we can pull it up really
12 quickly for you for all to see.

13 DR. FIVUSH: Lauren, I'm sorry.
14 Where did you say the actual measures, the
15 measure list was which file was that?

16 MS. RICHIE: So we're going to start
17 by topic. So for instance, we're going to
18 start with Dialysis Adequacy and Nutrition,
19 and that folder is Dialysis Adequate Nutrition
20 Pediatric, dated December 16th, 2010.

21 DR. PACE: So for those of you who
22 don't have your laptop, we can also display on

1 the projector any particular information. If
2 an issue comes up, we can find it, and we'll,
3 you know, so speak up if you can't find
4 something or you need us to project something.
5 We'll try to do that.

6 CO-CHAIR CROOKS: Okay. Now it's
7 time for brief introduction of measures by
8 developers, and we don't have any particular
9 order here. So any volunteers to go first?
10 Jose, okay.

11 Introduction of Measure Developers

12 MR. MENOYO: Good morning. It's a
13 pleasure to be here today. My name is Jose
14 Menoyo. I'm a Nephrologist Vice President for
15 Global Medical Affairs for Genzyme
16 Corporation.

17 Genzyme Corporation is the developer
18 for Measure No. 1427, a measure to report the
19 proportion of patients with serum phosphorous
20 greater than six milligrams per deciliters.

21 Like many of you know,
22 cardiovascular mortality is the leading cause

1 of death among end stage dialysis patients on
2 dialysis. High serum phosphorous has been
3 identified as a significant risk factor for
4 cardiovascular morbidity and mortality.

5 An analysis of more than 40,000 end
6 stage renal disease patients on dialysis has
7 showed above minimum mortalities were
8 associated with 1-1/2 times the mortality risk
9 of anemia, and three times the mortality risk
10 of inefficient end dialysis.

11 The Kidney Disease Improvement
12 Global Outcomes organization has published
13 clinical practice guidelines for kidney
14 disorder, that recommends that decisions
15 target a phosphorous level towards normal and
16 end stage renal disease patients on dialysis,
17 as well as maintaining a serum calcium level
18 within the normal range.

19 These guidelines also rate the
20 presence and severity of cardiovascular
21 calcification, that strongly predicts
22 cardiovascular morbidity and mortality in

1 patients with chronic kidney disease. They
2 agree that dialysis patients be considered at
3 the highest cardiovascular risk.

4 The dialysis community has utilized
5 these guidelines, as well as previous
6 guidelines, to guide the care of end stage
7 renal disease patients in the U.S. for almost
8 a decade, and many studies have examined the
9 impact on outcomes related to these
10 guidelines.

11 Considering evidence from numerous
12 scores and observational trials consistently
13 demonstrate that serum phosphorous greater
14 than six milligrams per deciliter is strongly
15 associated with adverse cardiovascular
16 outcomes and mortality. The dialysis outcomes
17 and practice patterns study is a prospective
18 cohort study of hemodialysis practices based
19 on the correlation of observational and
20 latitudinal data from a representative random
21 sample of patients from 12 countries,
22 including the U.S.

1 Those have demonstrated the
2 correlation of serum phosphorous levels to
3 increase mortality and cardiovascular outcomes
4 at phosphorous levels greater than six
5 milligrams per deciliter. The patient
6 characteristics in U.S. facilities mirror the
7 patient characteristics of the patients for
8 which CMS is the primary payor, which is 70
9 percent of the U.S. dialysis populations.

10 Given this, the results from that
11 can be viewed as a valid representation to the
12 screening the performance and assess outcomes.

13 Additionally, CMS has collected data
14 from the ESRD Disease Management Demonstration
15 Program from 2006 to 2009, that included
16 performance measures for the reporting of
17 serum phosphorous greater than six milligrams
18 per deciliter.

19 The demonstration project tested the
20 effectiveness of managing various quality
21 performance parameters, while containing costs
22 under a capitated payment system. The recent

1 technical expert panel for blood disorder
2 agreed that serum phosphorous is an important
3 biomarker strongly associated with adverse
4 cardiovascular outcomes.

5 As we reviewed the minutes from the
6 technical expert panel, we were disappointed
7 that although the panel agreed on the
8 detrimental consequences of elevated
9 phosphorous, they could not agree on an upper
10 limit of phosphorous, in part because the
11 specific method to level phosphorous by itself
12 would present a risk to the patient, such as
13 increased risks for calcium binding
14 association with detrimental calcium loading
15 and calcification.

16 We believe that clinical evidence
17 demonstrates that there is a potential for
18 high positive impact based on decreased
19 cardiovascular morbidity and mortality when
20 phosphorous levels are maintained under six
21 milligrams per deciliter, and that the method
22 on how that level is achieved should not be

1 tracked for the benefit associated with
2 achieving that level.

3 Clinicians are expected to balance
4 risks to ensure optimal treatment for their
5 patients.

6 To summarize, the data show that at
7 the facility level, phosphorous of less than
8 six milligrams per deciliter is associated
9 with improvement in cardiovascular morbidity
10 and mortality in end stage renal disease
11 patients. Serum phosphorous are routinely
12 measured, and has been demonstrated to be a
13 reliable test.

14 Additionally, the interventions to
15 treat high serum phosphorous levels have been
16 proven to be safe and efficacious. Thank you.

17 CO-CHAIR CROOKS: Okay, thank you
18 Jose. We have the CMS Work Group and on the
19 phone? On the phone.

20 MS. LING: Hi. This is Shari Ling.
21 I'm a medical officer with the Quality
22 Measurement and Health Assessment Group, and

1 I'd like to just provide a framing for the
2 CMS, for the measures that will be presented,
3 for which CMS is a measure steward.

4 Just as an important start, I think
5 we need to keep in mind that the measures that
6 you will be hearing about today are aligned
7 with the goals of the Department and of CMS,
8 to improve the health and well-being of
9 Medicare beneficiaries, and in this case,
10 patients with ESRD at any age and at all ages.

11 Our objective is to achieve better
12 health of the population in general, to better
13 care and also at lower cost through improved
14 care efficiency. As you will see, the
15 measures that will be presented to you
16 represent clinically important concepts that
17 speak to Department goals that will be aligned
18 across all care settings eventually, and that
19 the measures presented today are intended to
20 move care in the direction.

21 But we hesitate that in your review,
22 please do not be fearful of the specter of

1 public reporting or inclusion in the quality
2 incentive program. It's important to keep in
3 mind, in response to one of the comments heard
4 earlier, that measures must go through
5 rulemaking in order to be included in the
6 incentive program.

7 Now with that said, I want to
8 sincerely thank the Steering Committee for
9 your diligent review of each proposed quality
10 measure in the context of the goal that we
11 share, and also thank the NQF staff for their
12 tireless effort towards achieving this common
13 goal. With that said, I'd like to turn this
14 over to Arbor Research Group.

15 DR. WOLFE: Thanks Shari. I'm Bob
16 Wolfe. I'm a statistician working at Arbor
17 Research as a contractor to CMS for support of
18 measure development. It is on here, perhaps
19 it's not active. I can use this one?

20 Okay, I'm sorry. I'm Bob Wolfe.
21 I'm a statistician working at Arbor Research
22 as a contractor to support CMS in measure

1 development. I've been working as a
2 statistician in organ failure research for 35
3 years.

4 I'm not a committee member, so I
5 won't tell you that I sing on a chorus and
6 love to ride my bicycle and cross-country ski
7 and have two grandchildren and read and love
8 genealogy, and consequently my TV is
9 unplugged.

10 Instead, I'll say that Claudia
11 Dahlerus and Joe Messana and I are here to
12 provide details, if you have questions, about
13 the TEP deliberations, and also to provide
14 information, backup information about our
15 substantial experience with the data flow,
16 both through claims and through the prototype
17 CROWNWeb data, which may be of interest to
18 you.

19 I'm going to turn this over to Joe
20 with more details about the substantial
21 process we had for bringing these measures to
22 you.

1 DR. MESSANA: Thanks, Bob. As Dr.
2 Wolfe mentioned, my name is Joe Messina. I'm
3 a clinical nephrologist at the University of
4 Michigan, by training and by experience. But
5 I've worked at TEP for the last several years
6 on a number of projects under contract at CMS,
7 including the measures development projects in
8 2006 and again this past year, year and a
9 half.

10 We really appreciate the opportunity
11 to be here and to listen to your deliberations
12 and to assist you in this.

13 I would like to recognize that we
14 represent two organizations, with a large
15 number of dedicated staff with intellectual
16 diversity, many of whom are listening on the
17 phone, who put a lot of hours in to develop
18 the numerous CMS measures under contract to
19 CMS with our project officer, Tom Dudley.

20 Excuse me. I'm just going to
21 provide a brief overview of the global
22 methodology that we used in measures

1 development, with a significant number of
2 measures we assisted CMS in presenting. We
3 can't talk about the specifics in a couple of
4 minutes.

5 So these comments do not pertain to
6 the non-CMS measures that were submitted. So
7 I believe there are four other measures in
8 the ESRD realm that these comments are not
9 pertinent to.

10 So we started approximately a year
11 and a half ago, in identifying clinical
12 performance guidelines, both through the
13 National Kidney Foundation's KDOQI and the
14 international guidelines as a foundation or as
15 a basis for development of information to
16 assist our TEPs.

17 Subsequently, we did structured
18 literature searches in all of the topic areas
19 that CMS identified as being important to them
20 prior to convening the TEP, and identified
21 nearly 2,300 articles that would be
22 potentially relevant to these topics.

1 We screened those. All of our
2 investigators with our two organizations
3 screened those, and identified about 650
4 articles that were presented to the TEPs based
5 on topic.

6 Subsequently, the TEPs were convened
7 in March and then in April for the follow-up
8 data TEP, and because of time limitations, I
9 will just mention the chairs of the six TEPs
10 that were convened for CMS.

11 The Bone and Mineral TEP, the chair
12 was Stuart Sprague from Chicago and Francesca
13 Tentori from Arbor Research was our
14 facilitator. David Van Wyck chaired the
15 Anemia Iron Committee or TEP, with Bruce
16 Robinson from Arbor Research as the
17 facilitator and kind of lead reviewer of
18 literature. The Vascular Access Infection
19 Clinical TEP was led by Michael Allon from
20 UAV. Ron Pisoni from Arbor Research was the
21 facilitator. Brad Warady, Warady, I always
22 mispronounce his name; I apologize if he's

1 listening in, but he was the chair for the
2 Pediatric Hemodialysis Adequacy and Anemia
3 TEPs with Sylvia Ramirez being the facilitator
4 from Arbor Research.

5 The Fluid TEP, which had a number of
6 leaders in the dialysis community on the
7 committee, was chaired by Rajiv Agarawal from
8 the University of Indiana, and Rajiv Saran was
9 the facilitator for U of M KECC.

10 I had the opportunity to sit through
11 the deliberations of the clinical TEP and then
12 help with Dr. Wolfe to facilitate the Data TEP
13 a month later. It was an extraordinary
14 experience watching the distillation of all of
15 this information by these clinical, you know,
16 experts and ESRD data technical experts to
17 develop these numerous measures.

18 There was some difference of opinion
19 between Clinical and Data TEP in some cases,
20 but they were generally resolved, and our
21 measures, I think, reflect a fairly broad-
22 based consensus by some of the leaders in the

1 dialysis community.

2 I'd like to finish by mentioning a
3 couple of things about data sources. All of
4 our measures either -- our proposed measures
5 either use Medicare claims or CROWNWeb as
6 potential data sources, and we have a long
7 experience at UM KECC and Arbor Research in
8 calculating measures based on Medicare claims.

9 Although as Dr. Nally points out,
10 there is often a lag between Medicare claims
11 availability and the clinical events, the lag
12 is often very short-lived. It's generally
13 about nine months after the close of the year.

14 The three- to four-year lag that you
15 see with some measures is related to a
16 volitional choice, to look at longer-term
17 averages for some measures over multiple
18 years. So generally we're talking about nine-
19 month lag for claims data at a minimum.

20 In terms of CROWNWeb, I think it's
21 interesting to note, let me just pull up. So
22 as of September 2010, we have experience with

1 reviewing the CROWNWeb data that's available.
2 As of September 2010, approximately 80 percent
3 of U.S. ESRD patients have data being reported
4 into CROWNWeb, and 64 percent of facilities
5 are represented in this CROWNWeb data.

6 And we have had the opportunity to
7 look at measures, previously NQF-endorsed ESRD
8 measures, calculations, and compare those to
9 calculations based on the five percent sample
10 CPM data from 2006 and 2007, and there's a
11 remarkable degree of concordance between the
12 two.

13 So we're quite confident that as
14 CROWNWeb is rolled out, the data calculations
15 are going to be validated. Thank you.

16 CO-CHAIR CROOKS: Okay, thank you.
17 The other group with us today for CDC. Oh,
18 they're not --

19 DR. PACE: I think they're just
20 going to be here tomorrow.

21 CO-CHAIR CROOKS: Oh, they're going
22 to be here tomorrow, because their measures

1 are only under consideration. Okay. So that
2 would complete. Okay. So we're ready to
3 begin looking at our first measures, and we're
4 going to start with the Pediatric Group of
5 Adequacy and Fluid. So Karen, you're going to
6 kick off Measure 1418.

7 Consideration of Candidate Measures

8 Measure 1418

9 DR. PACE: Right. We thought I
10 would do the introduction to the measure, just
11 to start us off and give you all a little
12 breathing room, and then we'll go from there.
13 So our idea is that the person who starts us
14 off is really to help begin the discussion by
15 summarizing the preliminary evals and
16 specifically highlighting if there were any
17 areas of concern or areas of differences of
18 opinion.

19 And then we'll be open to full
20 discussion by the entire Committee, and
21 followed by a vote. So we'll vote on each
22 measure before we move on, so that it's fresh

1 in your mind, and we'll be asking you to vote
2 on the rating of the major criteria and then
3 finally whether you would recommend the
4 measure for endorsement.

5 Lauren will let us know at the
6 beginning of the discussion if it's a measure
7 that's only eligible for time-limited, and
8 we'll also mention that when you begin voting.
9 So if we neglect to do that, please ask us.
10 Okay.

11 So obviously there were committee
12 members assigned to do in-depth evaluation,
13 and I know that most of you have become
14 familiar with these measures. But this is
15 Measure No. 1418. The title is Frequency of
16 Adequacy Measurement for Pediatric
17 Hemodialysis Patients.

18 The brief description is this is a
19 measure about the percentage of all pediatric
20 patients less than 18 years, receiving in-
21 center hemodialysis, irrespective of frequency
22 of dialysis, with documented monthly adequacy

1 measurements, spKt/V or its components in the
2 calendar month.

3 So we had several people that did
4 preliminary evals. I'll just kind of
5 summarize those, and then we'll have a
6 discussion. Basically, the group that
7 reviewed this measure thought that it did meet
8 the importance criterion, but I will just
9 throw out a question for you all in light of
10 our discussion about evidence and measures,
11 measuring topics proximal to desired outcome.

12 This is an assessment frequency
13 measure, and so we also have measures more
14 directly related to the outcomes. So I'll ask
15 you to at least mull that over. It's not
16 saying that you can't recommend this measure,
17 but just something for you to discuss.

18 In terms of scientific acceptability
19 of measure properties, this measure was
20 tested, and basically the group that reviewed
21 it, there was -- felt that it either partially
22 or completely met the criteria.

1 Just one comment about this measure
2 in regards to testing. We're most interested
3 in reliability and validity testing, and
4 certainly for outcome measures the risk
5 adjustment model or risk adjustment method
6 could be stratification.

7 So most of the measures, including
8 this one, talk about face validity. Our
9 criteria do allow for face validity if it's
10 systematically assessed, and we don't have
11 enough information to know how that was
12 assessed, other than that the TEP agreed to
13 move forward with this particular measure.

14 Okay, usability. Basically the
15 preliminary evaluations felt that this was a
16 measure that would be usable, and then
17 feasibility, again, the group felt that this
18 measure would be feasible to measure.

19 There was, in terms of whether this
20 measure -- preliminary analysis, whether this
21 measure should be recommended for endorsement,
22 most of the preliminary evaluations were yes,

1 but there was one no, and the comments about
2 that was combining the measure for frequency
3 of measurement of dialysis, and that's for the
4 method of measurement of dialysis, might be a
5 better way to address both of these topics.
6 So I'm going to stop there. Yes.

7 (Off mic comment.)

8 DR. PACE: Microphone.

9 DR. KLIGER: The thumb drive that I
10 got provided only has three reviewers.
11 There's two additional ones up here.

12 MS. RICHIE: Yes. Oh, okay. So the
13 version that you have is from last Friday on
14 the 7th, and since then, we've had additional
15 --

16 DR. PACE: Right. But that's what
17 you were going to put on the drive.

18 DR. KLIGER: I thought that's why we
19 had the thumb drive.

20 DR. PACE: Yes, right.

21 DR. KLIGER: Well, I have three.

22 Okay.

1 DR. PACE: Okay, well sorry. Then
2 that was a problem; the wrong file got copied
3 to your thumb drive. So we'll project it and
4 we can get those to you. Okay. Sorry about
5 that. Okay. So --

6 CO-CHAIR CROOKS: Are those primary
7 reviewers?

8 DR. PACE: Yes.

9 CO-CHAIR CROOKS: Okay. Other
10 primary reviewers have additional comments?
11 Do you want -- well, comment on any part of
12 it, I guess, at this point. Yes.

13 MS. PAVLINAC: I don't disagree with
14 the comment by Joseph that perhaps combining
15 the frequency in measurement into one. I
16 rated this one independent, which I thought
17 was how we're supposed to do it. But I don't
18 disagree.

19 DR. VASSALOTTI: I want to say that
20 I would probably, if I redid this now, I would
21 say yes to that, and I didn't -- I thought we
22 were evaluating just the face value. I'm

1 really thinking ahead to tomorrow.

2 MS. PAVLINAC: Okay, yes. Okay,
3 thank you.

4 CO-CHAIR CROOKS: Any other comments
5 from the primary reviewers? I'll just use
6 that term to indicate people who were
7 assigned. Assigned reviewers maybe would be
8 a better term.

9 DR. PACE: Right, right.

10 CO-CHAIR CROOKS: So at this point,
11 all of the assigned reviewers are recommending
12 yes then. Is that -- he was the only one that
13 -- he's kind of switched. Okay. So Karen, do
14 you want to step us through the next steps

15 DR. PACE: Well, what about the rest
16 of the Committee? What are your thoughts? Do
17 you have any questions about the measure, any
18 thoughts about the measure?

19 DR. KLIGER: Yes. For those who
20 reviewed it more thoroughly, can you again
21 review for me the evidence that the frequency
22 of measurement makes a difference to outcome?

1 DR. PACE: So one of the things, if
2 you look at the evidence section of the
3 measure submission form, and Lauren will pull
4 that up, most of the evidence that was
5 presented was about the adequacy of the dose.

6 DR. KLIGER: Correct, right.

7 DR. PACE: And then also the
8 guideline was about the method of measurement.
9 So it --

10 DR. KLIGER: Right. That's the
11 reason for my question, Karen.

12 DR. PACE: Okay.

13 DR. BERNS: Maybe it's a somewhat
14 related question. This measure really looks
15 at just obtaining a lab value, and doesn't
16 make any assessment of what anybody does with
17 that lab value, which to me, you know, I mean
18 it's a part of care. It's a process of care
19 that we could agree might be the right thing
20 or not. It depends upon how much we believe
21 in frequency.

22 But I gather that the data behind a

1 specific -- of evaluating children is not that
2 robust; it's not even that robust in adults.
3 But that, you know, there's no requirement
4 here for anybody to do anything with the
5 information once it's obtained, which I find
6 to be a problem. It comes through many of the
7 measures that I reviewed as well.

8 CO-CHAIR CROOKS: For the adults, we
9 approved a parallel measure, I believe, and
10 went through that process. I think the
11 thinking is just basically that we may not
12 know what to do with the data, but at least it
13 should be being measured and available to the
14 clinician, and that was sort of the
15 justification.

16 DR. PACE: And I'll just say that
17 you're not held to that, to go along that same
18 path. Those measures will be up for review
19 again in the next phase of this project.

20 DR. BERNS: If I can ask one more
21 question. The performance gap, I guess, you
22 have indicated as being about 20 percent of

1 children who didn't have the lab test, and I
2 just wonder whether that excludes children who
3 were hospitalized during a given month, and
4 whether --

5 So I guess questioning whether there
6 is in fact a performance gap in this at all.
7 If you expect about -- it wouldn't surprise me
8 if 20 percent of kids are in the hospital at
9 any given time.

10 CO-CHAIR CROOKS: Dr. Wolfe or I'm
11 sorry, Jeff. Yes. You have any information
12 on that question?

13 DR. WOLFE: Yes. Maybe Barbara
14 Fivush can jump, because she's waving her arm
15 and she has more direct experience in this
16 than just about anybody.

17 DR. FIVUSH: No. I would say as a
18 pediatrician I think one of the things we're
19 coming to the table with is the fact that we
20 don't have any measures, and we don't have any
21 guidelines for documentation or measurement of
22 what we do.

1 I think just saying well, it doesn't
2 seem important to measure this, because we
3 don't have evidence that it's important to
4 measure this, and we have a documented gap;
5 the concern of the pediatric community is that
6 people are not measuring adequacy, and they're
7 not measuring it routinely.

8 So this is an instance where we
9 don't have evidence, as Alan suggested. We
10 need to measure it monthly, but there is a
11 parallel measure in the adult world, and we
12 would think that at least that standard should
13 be met in pediatrics.

14 Now it is possible that we'll find
15 out that measurement of adequacy is less
16 important than we think. But we think it is
17 a starting point. We understand that it's
18 low-hanging fruit. But I think as a group, we
19 feel very strongly that people should at least
20 be measuring it.

21 I mean we will get to talk about the
22 method with which they measure it, and the

1 minimal adequacy. But we think that -- the
2 pediatric community has felt strongly that it
3 should be looked at at least monthly.

4 Now whether we harmonize that with
5 an adult measure, or we harmonize that, as Joe
6 suggested, with measurement at a minimal
7 level, or measurement and a way that we
8 measure it, I don't think we would argue with.

9 But I think the suggestion that it
10 be measured monthly, I think that to me, it's
11 a minimal standard of care that we measure
12 adequacy in pediatric patients. I think we
13 don't really understand that gap, and I'm not
14 sure that we will understand that gap, because
15 if you look at hospitalization records in
16 USRDS, that a lot of those patients are
17 Medicare patients.

18 You know, you don't have information
19 on Medicaid patients, and we're really not
20 sure, when we look at our populations, we
21 think about 40 percent are Medicare. We know
22 that CPM and Arbor collect 100 percent data,

1 but when that's merged with morbidity and
2 mortality data, we're not sure that we even
3 understand the gap of where patients are and
4 why they're not getting adequacy measurements.

5 CO-CHAIR CROOKS: Let me see if we
6 can get an answer to Jeffrey's question first.

7 DR. WOLFE: Yes. I can speak, I can
8 speak to the fact that we do have the dose of
9 dialysis on the claims for all patients,
10 whether they're at the hospital or not.

11 However, if they don't submit a bill while the
12 patient is in the hospital, then they are not
13 in the denominator.

14 So if they're in the hospital for
15 the entire month, they would not be counted in
16 the denominator as a statistic for that
17 facility. That's potentially a limitation of
18 the data available, but it is the fact of the
19 data availability.

20 CO-CHAIR CROOKS: Jeffrey, does that
21 answer your concern?

22 DR. BERNS: Yes.

1 CO-CHAIR CROOKS: Okay. Let's go to
2 Alan and then back to Barbara.

3 DR. KLIGER: So again just for the
4 developers, as you reviewed all the data, were
5 there any data suggesting that the frequency
6 of once a month for an adequacy measure,
7 whatever that measure is, is based in any
8 helpful frame? Is there anything in the
9 literature that says that once a month, once
10 every six months, once every two weeks? Is
11 there anything that would guide us?

12 DR. MESSANA: I think that's a
13 rhetorical question, Alan.

14 DR. KLIGER: No, it's not.

15 DR. MESSANA: We did not identify
16 any specific information that validated the
17 once a month. It is a, I would say as a
18 practicing clinician, it's a generally
19 accepted practice in the adult community. I
20 won't speak as a pediatric nephrologist.
21 Others may.

22 CO-CHAIR CROOKS: Barbara.

1 DR. FIVUSH: But there is data, and
2 I think Alan, your point is well taken. But
3 there's data that suggest that adequacy is
4 related to outcome, at least in, you know, in
5 the very little bit of data that we have.
6 There is data to suggest that adequacy --

7 But you're right. I don't know if
8 once a month or every six months is important,
9 except that we do need to look at adequacy
10 measures and adjust it. I don't want to say
11 it's rhetorical. I think we don't know the
12 answer, so --

13 DR. KLIGER: See, I guess I'm trying
14 to, in my mind, set the stage for all of the
15 measures that we look at in this exercise of
16 ours, because every clinician around the table
17 will say that our practice is, and the best
18 practice, as we understand it, is to get
19 measurements at some reasonably frequent
20 intervals, and in adults we do it once a
21 month.

22 But NQF I think has, and if you look

1 at the criteria that we have, the
2 responsibility of being very focused and
3 precise about those measures that are NQF-
4 endorsed. So I'm raising the issue, and it's
5 not rhetorical. But you know, I'm raising a
6 real question about when you have something
7 that has face validity, that says yes, we
8 should probably be getting at some frequent
9 measure, but nobody knows how frequently, a
10 measure of adequacy, how are we to respond?

11 There are thousands of measures out
12 there, my guess is, that don't have the basis
13 to say that there's a best practice or a best
14 way of doing something. How does the NQF
15 respond to that?

16 DR. BERNS: I think the follow-on,
17 and I think part of this is if it's maybe
18 those of us who are new to this, grappling
19 with the difference between a clinical
20 practice guideline or a clinical practice
21 recommendation, which this might be very
22 reasonable for, versus a performance measure

1 that would take a life of its own.

2 DR. PROVENZANO: And let me just
3 build on Alan's point, because we fall into
4 this trap, particularly for the patients. In
5 the 70's, it was common clinical practice to
6 get labs every week or at every treatment, and
7 we've devolved away from that.

8 In the changing financial and
9 regulatory environment, frequency becomes a
10 much bigger issue than it ever had before. So
11 I think Alan is spot-on trying to set the
12 stage for truly how we rethink all of these
13 issues, based on what data's available.

14 MS. RAMIREZ: This is Sylvia from --
15 oh sorry.

16 CO-CHAIR CROOKS: Go ahead, Sylvia.

17 MS. RAMIREZ: Yes. I was part of
18 the TEP panel that discussed this, and one of
19 the key points, I think in general we agreed
20 that there's no specific testing in regards to
21 the interval for the measurement of adequacy.

22 However, one of the considerations

1 was the fact that the children are in a growth
2 phase, and therefore there may be ongoing or
3 continuous need to modify dose, or the dose of
4 dialysis. I think that's an important aspect
5 for pediatric patients in general.

6 CO-CHAIR CROOKS: Okay. I would
7 just remind the developers that they're not on
8 the Committee and unless you're specifically
9 asked a question, you should hold back.

10 MS. RAMIREZ: Yes.

11 CO-CHAIR CROOKS: Thank you.

12 Barbara was next.

13 DR. FIVUSH: I would actually
14 support that point that, you know, I
15 understand that we have to look at all the
16 measures the same way. But I'm going to step
17 away from that for one second, and say that we
18 have no pediatric measures at all in ESRD, and
19 we really do need a starting point.

20 The adults have had an adequacy and
21 frequency measure for multiple years. I think
22 whether this is an area where we need a time-

1 limited endorsement, I think the reality is we
2 have to start looking at data in pediatrics.

3 The reason we haven't had measures
4 before is because we haven't had evidence
5 before. We're not going to get evidence
6 unless we get measures. This is a very
7 straightforward measure. I think we all --
8 well, I hope we will agree there is a minimal
9 dose of dialysis adequacy.

10 So that would indicate we have to
11 measure it some time. I think children are in
12 a phase of growth, and it's not only growth
13 but neurocognitive development. So adequacy
14 may even be more critical -- how often we
15 measure it.

16 But I definitely understand
17 unintended consequences, measures taking on a
18 life of their own. So with both hats on and
19 thinking as an NQF member, thinking as a
20 pediatrician, I still feel this is -- it's
21 critically important that we measure adequacy
22 in children. I think we're going to keep

1 going back to the fact that we don't have the
2 same kind of evidence base.

3 I would just remind everybody that
4 if we combine HD and PD patients under the age
5 of 18 in this country, we're probably looking
6 at 1,600 patients. So it's a very, very small
7 number, and those patients are distributed, we
8 know, over at least 40 sites.

9 So our largest hemo unit, our
10 largest hemo unit, we think, is about 37
11 patients. We can't really do the same kinds
12 of studies. Hopefully, when we start
13 collecting the data reliably, we will have a
14 much better idea, and maybe we will see in two
15 years that we don't need to look at it
16 monthly. That's all.

17 CO-CHAIR CROOKS: Okay, Jerry?

18 DR. JACKSON: This is a question
19 about our overall process that will relate to
20 all of our measure considerations. But when
21 I've gone through some quality improvement
22 training, we try to look at, try to develop

1 a family of measures for internal quality
2 improvement.

3 I know that we're looking at each
4 measure separately on its own merits, as
5 separate, its own individual specifications.
6 But in terms of eventual usability, they're
7 going to be, in pragmatic terms, linked
8 together to look at different parts of the
9 care process.

10 So in terms of this measure, this
11 would be the frequency of just obtaining the
12 laboratory data. Another measure would
13 probably be linked with this later. Karen,
14 can you comment on how that works here?

15 DR. PACE: Right. Well, I'll make a
16 few comments, and again, as I said, there's no
17 black and white answer here, but just a couple
18 of things.

19 One is that we had a task force that
20 looked at evidence last year, and they have a
21 whole set of recommendations that we're not
22 implementing here. But I'll just give you a

1 little bit of their thinking about the
2 evidence base for a measure, because we've
3 always had this criterion about evidence.

4 Basically, I think as someone
5 mentioned, once you get into using,
6 developing, endorsing measures for performance
7 measurement, that then might be used in public
8 reporting; it may be used in incentive
9 programs and other things, that you'd end up
10 incentivizing, developing structures or
11 implementing these structures in your
12 organization. Their thinking was that you
13 should have pretty good evidence for that.

14 The other thing is this whole idea
15 of measuring processes that are most proximal
16 to the desired outcome, and that, as someone
17 already mentioned, if you measure -- taking
18 the lab test requires someone to look at the
19 results, interpret the results, then identify
20 the appropriate response to the results, then
21 to deliver that response according to, you
22 know, best practices.

1 So there's a whole set of things
2 that need to happen before you actually
3 influence the outcome. So since our
4 perspective is to really measure, you know,
5 put resources into measuring those things that
6 are going to most drive improvement in patient
7 health and patient outcomes, that trying to
8 measure those things most proximal would be
9 the way to go, and that's also where the
10 evidence is.

11 As we've already mentioned, the
12 evidence that you're citing is about the
13 adequacy of the dose. So that's the thinking
14 that that's the preference. That's not to say
15 that we can't endorse assessment measures. As
16 someone else mentioned, though, there are
17 thousands of those if you start looking at all
18 of the things that you should be doing in
19 clinical practice.

20 The other thing is, is when you have
21 the process that's most proximal or the
22 intermediate outcome or the health outcome,

1 this may be something that you would look at
2 for internal quality improvement in terms of
3 well, if you're not achieving the outcomes,
4 maybe you're not even measuring.

5 So you know, there's no one that's
6 saying that it's not important to measure
7 this, that it's not important to measure it
8 frequently and use this information to manage
9 care. The question before you is whether this
10 rises to the level of something that should be
11 a performance measure.

12 And again, there's no right or wrong
13 answer. It's for your collective discussion.
14 But I think you're right, that it affects many
15 of the measures that you'll be looking at.
16 And Helen, do you want to weigh in?

17 DR. BURSTIN: I think Karen really
18 captured it. The only thing I'd add is that
19 I think, you know, oftentimes depending on
20 where a given area is in its level of measure
21 development, we tend to see measures along
22 that continuum.

1 So if pediatric dialysis is at a
2 much earlier stage of development, it's not
3 surprising we're seeing some assessment
4 measures. We're starting to see, as we move
5 towards, for example, areas like diabetes,
6 much more emphasis on the actual outcome, as
7 opposed to did you check the A1c.

8 But again, I think some of that may
9 be evolutionary in terms of where the field
10 is. I think you need to consider that. But
11 again, there's just nothing black and white
12 here.

13 I would also probably point out that
14 I was just Googling, you know, what's the
15 evidence for the frequency of A1c testing, for
16 example. There's a lot of instances where
17 there's not a huge evidence base for some of
18 what we sort of do as clinical dictum.

19 I think the hope would be as you
20 begin to get more experience around the
21 outcomes, will that help us drive towards the
22 better process measures, as well?

1 CO-CHAIR CROOKS: Lisa?

2 DR. LATTIS: Yes. I have a question
3 that's probably for staff. Many of the
4 measures that we're going to be reviewing over
5 the next two days are CMS-focused measures
6 from CROWNWeb, is where they've been tested.

7 I guess from a private payer
8 perspective, does that mean that these
9 measures are only for CMS, with CROWNWeb as
10 the substrate, if you will, or can we as
11 private payers also use these measures from
12 our own databases with access to data?

13 Because you know, especially for the
14 pediatric measures, we have the Medicaid data.
15 So unless they're dual-eligibles, you know,
16 the data is not going to be in Medicare
17 databases.

18 DR. PACE: Yes. Once NQF endorses
19 the measure, they can be used by any party.

20 DR. LATTIS: I mean it's something to
21 consider, because for example, for the outcome
22 measures that are risk-adjusted, do we have

1 access to the risk-adjustment methodology, or
2 is it something that's embedded in CROWNWeb
3 that we don't have access to?

4 DR. BURSTIN: Everything is fully
5 open. So it should be. But again, I think
6 the one consideration is for the measures that
7 have been tested, they may have only been
8 tested on a Medicare-only population, an
9 elderly population.

10 So in this case, probably not, since
11 dialysis can be any aged patient. But I think
12 that would be the only consideration. Does
13 the testing done to date on the population of
14 the measure apply to the commercial
15 population?

16 CO-CHAIR CROOKS: I'd just like to
17 comment that part of the importance of the
18 evaluation is the performance gap too. We
19 started, we kind of touched on that here. It
20 would make a difference to me if there's a big
21 gap. Only half the patients are ever getting
22 their -- if that was the case, that only half

1 the patients were ever getting their adequacy
2 measured.

3 I would feel it's important that
4 they start measuring it. Do we have
5 information on the gap here? It was 20
6 percent. Wasn't that your -- it was stated?

7 DR. WOLFE: They were citing a 20
8 percent data gap on one month.

9 CO-CHAIR CROOKS: And we've
10 established it's probably not because of
11 hospitalizations, right? So is that a
12 realistic number, and to me, that's quite
13 worrisome.

14 DR. FIVUSH: I think that there are,
15 and I was using the example of the Medicare,
16 Medicaid-Medicare hospitalization in terms of
17 impact of adequacy, and linking it to
18 morbidity and mortality, when many of our
19 patients aren't -- they're in the CPM or the
20 CROWNWeb system, but they may not --

21 Their morbidity and mortality,
22 because if they're hospitalized, there's not

1 a Medicare claim. We sometimes have a harder
2 time establishing what the long-term outcome
3 is or an intermediate outcome, so we can
4 record intermediate outcomes like adequacy.

5 But looking at the CPM data years
6 back, when I worked on that project, and I
7 guess we're hearing there's a 20 percent --
8 there has been a persistent, and I would be
9 interested in what Arbor has seen recently.

10 But we did demonstrate over time a continued
11 gap in measurement.

12 My second, my question in that,
13 getting back to the gap question is, and this
14 is a procedural question. If we don't approve
15 a frequency measure, and I'm just again new to
16 this myself. If we don't approve a frequency
17 measure, but we approve a minimal level of
18 adequacy, then we've approved something that
19 doesn't have to be measured.

20 In any frequency, how do we -- do we
21 have to reconcile that? That's a question I'm
22 just thinking how do we do that then?

1 DR. PACE: I think that's a good
2 question, and I'm not going to be doing
3 measure development here, but there are ways
4 to build that into a measure, so that you kind
5 of get a negative, if there's no measurement.
6 Rather than being excluded from missing
7 information.

8 So there are ways to work that into
9 measures, but we don't have that measure. So
10 for just for future. I mean that's how some
11 people have addressed it. That's not the only
12 away.

13 DR. NARVA: I don't think Alan was
14 really objecting to this measure, so much as
15 trying to set a standard for the discussion,
16 which I think is really important, because the
17 more important the measures are, the more
18 bearing they have on -- the more evidence-
19 based they are, the more bearing they have on
20 improving care, the more credible they'll all
21 be.

22 But when it comes to pediatric

1 measures, it's a little bit different. You
2 know, if there's --- it's a vulnerable
3 population, and if there's not a lot of
4 pediatric evidence, I think it's more
5 obligated to identify if there's data to
6 suggest that it's not equally applicable to
7 the pediatric population, rather than that
8 there is pediatric data.

9 So really, I think the point you're
10 making is extremely important, and the
11 pediatric population is really different, I
12 think. So we probably need to err more on the
13 side of making measurements than we would,
14 say, in an adult population, where we might
15 just be adding to the burden of measurement
16 without improvement.

17 DR. KLIGER: So it's an interesting
18 question methodologically here, because we're
19 being asked to look at these measures
20 independent of others, with a later
21 harmonization plan. I personally have a
22 problem with looking at this single measure

1 standing alone as a frequency measure that is
2 not harmonized and is not brought together
3 with other potential measures.

4 So you know, I'd want to give -- I
5 mean to be honest with you, this is the one I
6 want to give sort of provisional yes to, with
7 the presumption that we can make it a better
8 measure with harmonization.

9 DR. PACE: So that's an excellent
10 point. So let me clarify, because we've gone
11 back and forth on how to look at related and
12 competing measures and, you know, our most
13 recent best guess is that we should look at
14 individual measures first, and then look at
15 related and competing measures.

16 So having said that, all of the
17 recommendations that you make today before we
18 address that will be provisional, meaning that
19 once we do the comparison, you can change that
20 particular recommendation. So the point right
21 now is, you know, does this measure meet the
22 criteria when you look at it alone.

1 Tomorrow when we look at related and
2 competing measures, we can revisit that
3 recommendation. But the reason we're doing
4 that is we don't really want to spend your
5 time comparing measure specifications if the
6 measure's going to fail on some other
7 criterion.

8 So it's kind of -- it's probably a
9 chicken-and-egg kind of thing, and maybe some
10 people would prefer to start one way than the
11 other. But we were just trying to think of,
12 in terms of the amount of materials, that we
13 want to make sure measures should go forward
14 before we start spending time comparing them
15 to other measures.

16 So you know, we'll certainly learn
17 from your experience again and see if there's
18 other things we should be considering.

19 CO-CHAIR CROOKS: Any other comments
20 right now? Okay. So we're ready to start
21 going through the vote. So we're going to
22 vote on importance straight up and down, or

1 are we going to do each of the -- is it going
2 to be the three subcriteria?

3 DR. PACE: No, we won't do the
4 subcriteria. So today you want to address the
5 first question. So this is the measure, and
6 the first question is just on the major
7 criterion of importance to measure and report.
8 If you say yes, you press 1 and then send. If
9 you say no, you press 2 and then send, and we
10 will go ahead and start the timer.

11 (Committee voting.)

12 DR. PACE: We'll give Tenee a
13 second. We wanted to give you 60 seconds.
14 This program defaults to ten seconds, and we
15 think that's not enough time. So what we will
16 be doing, and I'll just kind of tell you again
17 what we're going to be doing, is we'll put up
18 each of the major criterion.

19 So important to measure and report
20 is a yes/no. The other three, scientific
21 acceptability, usability and feasibility is
22 that completely, partially, minimally or not

1 at all, and then we'll end with would you
2 recommend the measure for endorsement, and
3 we'll keep it in mind that it's with the
4 caveat that if there are related and competing
5 measures, we will be looking at that tomorrow
6 and, you know, that may change things once you
7 look at it in that light.

8 (Committee voting.)

9 DR. PACE: Pardon me?

10 (Off-mic comment.)

11 DR. PACE: Oh, just the whole major
12 criterion. Not, yes. Right, right, right.
13 You should be thinking about the subcriteria
14 as you vote on it, but we're just going to
15 have you vote on the major criterion. Yes.

16 (Off-mic comment.)

17 DR. PACE: Yes. It hasn't
18 registered yet. Okay, we're going to try this
19 again. Okay. So we had a mix-up with the
20 program, so we're starting over. So we're on
21 that same measure, importance to measure and
22 report.

1 DR. LATTS: Does it only record it
2 when the clock is ready?

3 DR. PACE: Okay. There's your
4 clock.

5 (Committee voting.)

6 DR. PACE: We'll give you up to a
7 minute, but if everyone gets their votes in,
8 then we can stop it and we will go to tally,
9 okay. Yes.

10 DR. BURSTIN: This is fairly new for
11 us, so thank you for being guinea pigs. We've
12 used this once before, but it will be so much
13 easier -- we would literally just walk around
14 just counting hands for an hour a meeting. So
15 this should be a little easier.

16 DR. PACE: The next criterion,
17 scientific acceptability. So Tenee, you'll
18 choose your response. Okay, go ahead. Okay.
19 Okay, and we'll go on to the next one,
20 usability. Same thing, vote.

21 (Committee voting.)

22 DR. PACE: And then feasibility.

1 (Committee voting.)

2 DR. PACE: And then finally your
3 vote on recommending that it move forward for
4 consideration for endorsement, with the caveat
5 that we will look at this with related and
6 competing measures.

7 (Committee voting.)

8 DR. PACE: We'll just wait until the
9 end, when everyone thinks they have their vote
10 in. Okay. All right. Okay. All right. So
11 this one, 17 yes and 3 no. Okay. So now
12 we've got one measure under our belt --

13 (Laughter.)

14 DR. BURSTIN: And just in case you
15 guys are nervous, it routinely -- just having
16 sat through, having hunched through these in
17 the last four years, the first measure always
18 takes an hour and a half, so you guys are
19 ahead of schedule. It will speed up
20 significantly now, especially if the
21 technology cooperates.

22 CO-CHAIR CROOKS: Congratulations,

1 Committee. Okay. Let's, if we're able to
2 stay on schedule, have three more done in the
3 next 35 minutes or so.

4 Barbara, you are the chosen person
5 for 1421 and 1423. So let's go to 1421.
6 Method of Adequacy Measures of Pediatric Hemo
7 Patients.

8 Measure No. 1421

9 DR. FIVUSH: Okay. So I'm going to
10 try and do this as briefly and as wonderfully
11 as Karen did it. So this measure is entitled
12 Method of Adequacy Measurement for Pediatric
13 HD.

14 The description is the percent of
15 pediatric in-center hemodialysis patients for
16 whom the delivered dose of adequacy was
17 measured by a single pool, Kt/V , as calculated
18 using the urea kinetic method or the Daugirdas
19 during the reporting period.

20 The numerator statement is the
21 number of patients, and the denominator, with
22 monthly adequacy measures using this

1 methodology, and the denominator is number of
2 pediatric patients less than 18 on in-center
3 hemodialysis, irrespective of frequency of
4 dialysis.

5 In looking at the categories that
6 were commented on, there were five evaluators
7 of this measure that were in the program, and
8 the first one was the criteria for importance
9 in measure of report. Of the reviewers, five
10 said yes for that category. There were no
11 substantive comments.

12 The second category was of
13 scientific acceptability. The criteria were
14 met. Two people felt there was partial
15 criteria met, and three felt that this measure
16 completely met the acceptability criteria. To
17 what extent was the criteria of usability met?
18 Four felt that it was completely met. One
19 felt that it was partially met.

20 To what extent was the criteria of
21 feasibility met? Four felt it was completely
22 met, and one felt it was partially met. The

1 overall recommendation of this measure was, of
2 the five evaluators, was to approve it, and
3 four of the evaluators felt to approve it and
4 one felt not to.

5 I looked at all the comments during,
6 you know, throughout all the subcategories,
7 and there really wasn't anything substantive
8 about why we wouldn't accept this measure.

9 The reviewer who felt that we shouldn't, I
10 think, felt, in looking through the comments,
11 that it should be combined and harmonized with
12 another measure, and therefore it would be
13 more valuable if it was a linked measure
14 rather than a stand-alone measure, to look at
15 the method of adequacy measurement, that
16 perhaps it should have been linked with the
17 frequency of adequacy measurement.

18 So I couldn't find any substantive
19 comments. I think this is an important --
20 well, I'm going to leave it. That's my
21 presentation on that, Karen.

22 CO-CHAIR CROOKS: Okay, thank you.

1 Other assigned reviewers now? Robert.

2 DR. PROVENZANO: I just want to
3 comment on the Daugirdas methodology. It is
4 related to frequency, as opposed to what's
5 stated. So is that going to vary in pediatric
6 patients? I'm not quite --

7 DR. KLIGER: Maybe I can clarify.
8 If we're not using standard Kt/V, if you're
9 using just the standard Daugirdas, the only
10 way that you can compare is for everyone to be
11 at the same frequency. So that if you're
12 looking at everyone on three times a week,
13 yes, it would make sense to look at Kt/V of a
14 sampling of --

15 But if you're looking at, as you
16 write here independent of frequency, then you
17 cannot compare a patient done five times a
18 week to a patient done three times a week,
19 without using standard Kt/V.

20 DR. PROVENZANO: Right, and again,
21 there's somewhere in here that I saw the
22 frequency varies a great deal, as opposed to

1 the adult populations.

2 CO-CHAIR CROOKS: Barbara.

3 DR. FIVUSH: I would comment that I
4 think I might have actually put that comment
5 in there, or might have put it in the next
6 one, with minimal -- when they look at minimal
7 levels of Kt/V, that the pattern in pediatrics
8 is somewhat different than in adults.

9 It can be either three or four times
10 a week, and that is not uncommon, as opposed
11 to nightly or daily dialysis. This is just a
12 pattern for our regular three to four hour
13 treatment patients. The younger patients seem
14 to benefit from having more frequent dialysis,
15 and it doesn't fit into any category that
16 generally is a pattern seen in internal
17 medicine.

18 So I understand the concern, that
19 -- I understand the concern that if we measure
20 a Kt/V, and we're looking at it in a patient
21 who gets it four times a week versus three
22 times a week, it will be lower in a patient

1 that's four times a week.

2 But that be -- the pediatric
3 community spoke about this at great length.
4 I was not on the CTEP, but the thought was
5 that many of the patients that are receiving
6 dialysis four times a week are very young
7 infants and children, and they're going to
8 meet a minimal Kt/V target, and that was how,
9 reading through these comments, how that
10 measure was constructed. But I understand the
11 concerns.

12 DR. KLIGER: And if I may, again,
13 the issue isn't that it isn't important to do.
14 But Kt/V is not additive. You can't simply
15 add up the Kt/V of each dialysis session to
16 come up with a dose.

17 DR. FIVUSH: Right, right.

18 DR. KLIGER: So if the measure is
19 intended to measure a dose of dialysis, and
20 it's varying frequency of those dialyses, I
21 would submit you really cannot use Kt/V. You
22 need to use standard Kt/V.

1 DR. FIVUSH: So you're talking about
2 more of a weekly number. I think that -- now
3 when I think that that may be more important
4 in the next measurement, when we talk about
5 minimum levels. But I think you're correct.
6 It does impact this measure as well, in the
7 methodology which is suggested.

8 If you're going to use or take into
9 account anybody that has more than three times
10 a week, we should not be looking at single
11 pool Kt/V.

12 CO-CHAIR CROOKS: Do we have any
13 data from the developer, as far as the
14 frequency? How common is more than three
15 times a week or four times a week or more in
16 pediatric populations?

17 DR. WOLFE: Some of that information
18 is covered in the next measure, which does
19 have to do with the actual threshold value
20 that should be achieved. I believe that that
21 addresses some of the concerns that Alan is
22 raising, that the criterion for achieving 1.2

1 is specified in terms of the frequency.

2 Right now the measure, if I
3 understand it, that's being considered is the
4 method of measurement, and the method of
5 measurement did consider whether the
6 standardized Kt/V would be appropriate
7 standardized. Standard, thank you.

8 And they also considered the surface
9 area normalized, and both of them were
10 considered as being worthy and important to
11 consider in the future. But there wasn't
12 adequate data yet to consider them.

13 For the frequency, what we do know
14 is that about 20 percent of patients don't
15 have any Kt/V measured, or it's not measured
16 by Kt/V. So this has the same evidence base
17 as the first measure, where the frequency and
18 the method are missing in about 20 percent of
19 the patients.

20 There's another documentation you
21 have on your thumb drive under specifications,
22 where it points out in a particular facility

1 they found, which is well known and they had
2 about 40 percent of the patients with
3 pediatric patients without measures, and in
4 that substudy there were a large number of
5 facilities that just didn't measure it at all.
6 Not a large number, but not insignificant
7 numbers that just didn't measure it at all.

8 CO-CHAIR CROOKS: Joseph.

9 DR. NALLY: I'm not a pediatric
10 nephrologist, but I wonder if there are kind
11 of practice variations, whereby those that
12 dialyze say four times a week use a Daugirdas
13 formulation, versus maybe others with
14 different frequencies use a UKM. Do those
15 associate in terms of what types of
16 measurements are used, as opposed to the
17 frequency of dialysis per week?

18 DR. WOLFE: I'm sorry. Could you
19 repeat the question?

20 DR. BERNS: Since there are
21 relatively small numbers of pediatric patients
22 in practices, perhaps different practices

1 could have patterns whereby you dialyze a
2 certain frequency, and say you dialyze four
3 times a week and have selected the Daugirdas
4 as your way to follow people, as other people
5 might be more likely to dialyze three times a
6 week and use UKM.

7 So are there trackings whereby
8 frequency and methodology of measurement,
9 either associated or not?

10 DR. WOLFE: I don't know the answer
11 to that question. It's a good question. I
12 don't know the answer.

13 DR. FIVUSH: I think that's a very
14 good question. I think that people are not
15 saying, if I understand your question
16 correctly, people are not saying I'm dialyzing
17 four times a week. I'm going to use this
18 methodology, versus I'm dialyzing three times
19 a week, I'm going to use this methodology to
20 calculate Kt/V.

21 I think people are dialyzing and
22 using a methodology for calculating Kt/V.

1 DR. BERNES: Because it has potential
2 also for the next measure that we talk about,
3 relating to what targets you set.

4 DR. KLIGER: So again, if they're
5 not independent of each other, that is John
6 Daugirdas and his method, for example, is
7 what's used to calculate the standard Kt/V
8 over a week. So we're not talking about a
9 difference, but rather the conceptual issue of
10 the relationship of frequency to dose.

11 That's why I would strongly
12 recommend that if we're talking about a method
13 for dose, that if frequency is somehow in that
14 method and it is in this one, that it not be
15 just the Daugirdas but either the Daugirdas or
16 any other method that is -- that has a way of
17 standardizing for the time period.

18 DR. BERNES: Just a question. It
19 says in the documents here that only 76
20 percent of patients have delivered if you're
21 recalculating using either one of these two
22 methods. What was used in the other quarter,

1 and is there evidence -- what is the evidence
2 that that's an inferior method of determining
3 Kt/V.

4 If it doesn't say it wasn't
5 measured; it was just, it says a different
6 measure was utilized.

7 DR. FIVUSH: I suspect that it was
8 not measured. Is that --

9 DR. WOLFE: Or URR.

10 DR. FIVUSH: Right, or URR, which --
11 okay.

12 CO-CHAIR CROOKS: Other comments?

13 DR. FIVUSH: So is this a time when
14 if this group felt that that was a concern,
15 that we could modify the measure, or is that -
16 -

17 CO-CHAIR CROOKS: We can't modify.
18 We can ask the developers to consider. Well,
19 we're trying not to harmonize or think of
20 multiple measures that in my mind it seems
21 difficult to justify this, especially if we
22 might the consider the next one, which does

1 take frequency into account.

2 And why do we care, and why should
3 we endorse a measure that probably isn't the
4 right calculation at this, you know, in the
5 present state of knowledge, is my synthesis of
6 it at this point?

7 DR. PACE: So it is within your
8 purview to recommend a measure on the
9 condition that, in this case, the method be
10 specified as you've been talking about. That
11 would be something that we would then go back
12 to the measure developer for their response,
13 and we would bring their response back to you
14 to determine whether it met your condition, or
15 if they submit a rationale of why they can't,
16 and you could accept their rationale.

17 Or you could say okay, we're not
18 going to move forward with the measure then.
19 So it is something that you can do, especially
20 we want those kinds of things to be well-
21 grounded in evidence and guidelines and, you
22 know, have a good basis in our criteria for

1 making the recommendation.

2 CO-CHAIR CROOKS: And any testing
3 they've done, though, might not be applicable
4 anymore, if they weren't testing that method.

5 DR. PACE: Right. So then there's
6 the consideration, does that in any way negate
7 some of the testing. So you know, I can't
8 answer that offhand, but I think the -- I
9 guess I would say that we would want to be
10 most closely aligned with the evidence, and we
11 could deal with the testing issues, you know,
12 rather than saying --

13 And what's why we have importance,
14 which includes evidence as kind of the top of
15 the hierarchies. So I think we can probably
16 deal with that. So I think, you know, really,
17 based on your clinical expertise and the
18 evidence that you know for these, how this
19 testing should be done, that's what should
20 guide you.

21 DR. BERNS: If I can just return to
22 my earlier question then, I just don't know

1 the answer to this, whether URR has been shown
2 to be as, you know, inferior in any way in
3 children, as an assessment of dialysis
4 adequacy.

5 And then second, and it probably
6 relates to several of these measures,
7 pediatric patients encompasses little tiny
8 babies and elementary school kids and
9 teenagers, and we're applying the same
10 measures to all of them. I think we should
11 think about whether that's appropriate or
12 inappropriate for some portions of that
13 patient population.

14 DR. FIVUSH: I think that the
15 limited evidence that we have is Kt/V and it's
16 not URR. I can't think of a good study where
17 we've looked at URR and even any kind of
18 morbidity and mortality. So I don't think the
19 pediatric community would think that that was
20 actually a good measure.

21 I just, I want to clarify, because I
22 think this will come up again, that the

1 concern, I believe, is that we're letting the
2 denominator include patients that are having
3 dialysis at different frequency, and we're
4 trying to use a single pool Kt -- we're
5 allowing a single pool Kt/V rather than a
6 standard Kt/V.

7 The thought that I heard from Arbor
8 is that method, the developing group or the
9 CTEP that developed this measure, was
10 concerned that we have very limited experience
11 using a standard.

12 DR. KLIGER: Yes. There's a way
13 around that, and that's to define the method
14 of the method of measuring a single dialysis'
15 adequacy. If you call it that as the method,
16 and then later aggregate it according to
17 frequency, then you've solved your problem.

18 DR. FIVUSH: So that would be --

19 CO-CHAIR CROOKS: So you're
20 recommending renaming it to a different,
21 giving it a different --

22 DR. KLIGER: I would suggest instead

1 of calling it, with anything about frequency
2 at all in this measure, to define this as a
3 method of measuring pediatric hemodialysis
4 adequacy for a single dialysis session.

5 DR. FIVUSH: So to clarify, I think,
6 I mean I'm trying to -- what Alan is saying is
7 that we just talked about the last measure
8 that we have to measure that dialysis
9 adequacy, and in this measure we're saying we
10 have to measure it using a certain
11 methodology. That methodology is difficult.

12 So the measure would then become --
13 that it's not that you had to just measure it,
14 but you'd have to measure it each single
15 treatment using a standardized methodology?

16 DR. KLIGER: I'm just saying that if
17 you're defining the methodology for measuring
18 a treatment's adequacy, and so you don't have
19 to deal with the frequency piece at all. When
20 you do indeed do the frequency piece, you know
21 you'll have to use standard Kt/V. But you can
22 eliminate that problem by just calling this

1 method to assess a dialysis session's
2 adequacy.

3 CO-CHAIR CROOKS: But then is that
4 important, especially in view of other metrics
5 coming up?

6 DR. FIVUSH: Well, I think it is
7 additive to the fact that it has to be
8 measured. I think it's going to say, if I
9 understand what the suggestion would be to the
10 developers, would be that you have to state,
11 irregardless of frequency, there would be a
12 standardized methodology for calculating
13 adequacy.

14 The first one is that you calculate
15 adequacy. So I think this would give us the
16 same -- Alan's suggestion seems to give us the
17 same thing that this measure gives us, but
18 takes the frequency question, which you know,
19 I know we're not supposed to go forward, which
20 was an issue with the next measure in this
21 measure set.

22 So I guess I don't know procedurally

1 where the group is.

2 CO-CHAIR CROOKS: Well, I think if
3 the Committee agreed with Alan's suggestion,
4 then we would submit that back to the
5 developer, rather than approve the metric as
6 it is.

7 DR. PROVENZANO: Yes. I would
8 support Alan, because after all, this is going
9 to deal with harmonization down the road, and
10 this is the direction that adult adequacy is
11 moving, because of more frequent dialysis and
12 home dialysis.

13 So rather than have to go through
14 this painful process, I would support Alan's
15 suggestion.

16 CO-CHAIR CROOKS: Okay, Barb.

17 DR. FIVUSH: So would an alternative
18 suggestion to the Committee then be, and I'm
19 just trying to think of alternative
20 suggestions, that the denominator would
21 exclude any patients other than receiving
22 three times a week, if you're going to use --

1 DR. KLIGER: That's not what I'm
2 suggesting.

3 DR. FIVUSH: No, I understand. I'm
4 just saying is that an alternative?

5 DR. KLIGER: The other alternative
6 is to leave it as is, but specify a common
7 frequency, like three times a week. Those
8 are, in my mind, those are the two
9 scientifically valid alternatives.

10 DR. KASKEL: As mentioned before,
11 this is a composite-type score when you
12 evaluate an internal QI, your assessment of
13 each patient. This comes into play with the
14 other factors, and Alan mentioned that before
15 as did Barb.

16 So I think you have to look at this
17 in the big picture, and it adds to our
18 understanding, although somewhat immature at
19 this point in time, because we don't have the
20 data. That's what we need to accumulate.

21 CO-CHAIR CROOKS: Okay. Other
22 comments? Are we ready to start voting on

1 this one?

2 DR. PACE: So well, I guess before
3 we go to voting, let's -- we'll do a hand vote
4 on this, to see if -- Alan do you want to make
5 a motion, state what you're suggesting, and
6 then we'll have the Committee weigh in on that
7 and then decide how we proceed with the rest
8 of the voting on this measure.

9 DR. KLIGER: Well, I would move that
10 the measure be entitled "Method of Adequacy
11 Measurement in a Single Dialysis Session for
12 Pediatric Hemodialysis Patients," and that the
13 discussion of the denominator exclude
14 frequency.

15 DR. PACE: Okay. So the denominator
16 then would just be pediatric hemodialysis
17 patients?

18 DR. KLIGER: Exactly.

19 CO-CHAIR CROOKS: As a point of
20 clarification, would this then not be eligible
21 for voting? We would send it back?

22 DR. PACE: Well, we could vote on it

1 with that condition. So I think this is what
2 we'll do. We'll first vote on the, whether
3 you agree with that condition, and if you do,
4 then we'll proceed with the voting, and your
5 vote would be -- does that make sense? Okay.

6 DR. FIVUSH: Can we throw back to
7 Arbor just one time, do you -- and this might
8 have been asked and I might have missed it,
9 and I think Jeffrey might have asked this. Do
10 we know how many patients are getting four
11 times versus three times a week?

12 DR. WOLFE: It's about five percent.
13 That's on page 37 of the recommendations
14 report to the staff.

15 5.6 percent, and the test conclusion
16 was, and I'll just quote it here, "Given at
17 this is not" -- and this is having to do with
18 the next measure for the minimum criterion --
19 "Given that this is not an insignificant
20 proportion, these patients should be included
21 in this measure."

22 That's for the minimum threshold.

1 The definition of the measure having to do
2 with method of hemodialysis, has a denominator
3 which is irrespective of frequency. And Alan,
4 so I'm not sure why you're saying it should be
5 irrespective of frequency, because that's what
6 it is. Are you proposing a change or not? I
7 don't --

8 DR. KLIGER: I mean, I apologize.
9 I'm not as familiar with -- in the discussion
10 that I saw and heard, there was a discussion
11 of frequency, three or more times. That's all
12 I -- if the definition clearly has no, nothing
13 about frequency, then I would --

14 DR. FIVUSH: It's irrespective of
15 frequency.

16 CO-CHAIR CROOKS: So now we're
17 looking at just a matter of retitling it so
18 that it's clear. This is just single session
19 Kt/V, that if you're going to measure, you
20 should use one of these two metrics, one of
21 these two methods. Is that -- so it's not a
22 matter of changing anything else about the --

1 DR. KLIGER: I mean, again, I
2 apologize for making a tempest in a teapot
3 here. But if indeed this is independent of
4 frequency, then I think it can stand as it's
5 proposed. The trouble has to do with the
6 frequency of measurement. So if this is
7 simply methodology and it has nothing to do
8 with frequency --

9 CO-CHAIR CROOKS: Do you want to
10 clarify something we'd asked before?

11 DR. MESSANA: Just numerator and
12 denominator definition for 1421, Method of
13 Adequacy Measurement. The numerator states,
14 and if I'm reading it correctly, that the
15 number of patients in the denominator for whom
16 delivered hemodialysis dose was calculated
17 using urea kinetics measurements or Daugirdas
18 II during the reporting period, and for whom
19 the frequency of hemodialysis per week is
20 specified.

21 So it asks for information about
22 frequency. The denominator says irrespective

1 of frequency of dialysis. So I think that it
2 is asking for information that would allow for
3 more meaningful calculations based on
4 frequency.

5 CO-CHAIR CROOKS: So to make the
6 numerator, you have to have both the -- it was
7 done by a certain method and the frequency of
8 treatment given a week or some such has to
9 also be in there, or they're not included in
10 the numerator.

11 DR. MESSANA: That's the
12 specification.

13 DR. WOLFE: So it does assure that
14 we get the information that Alan is concerned
15 about, and it's necessary for the next measure
16 also, to be able to define the next measure,
17 which is based upon --

18 CO-CHAIR CROOKS: Right. But if
19 this measure is not approved, the next measure
20 still stands on its own, right? Or do you
21 need the data from this metric to do the next
22 metric? You can do the next metric without

1 this?

2 DR. FIVUSH: Yes.

3 CO-CHAIR CROOKS: You know, as a
4 non-primary reviewer, I am having trouble
5 seeing the importance of doing this,
6 particularly if we're going to look at, you
7 know, I think it may add more confusion to
8 help to the whole situation. This is my
9 comment.

10 DR. PACE: One other question, and
11 this applies to a lot of the measures, that
12 they specify these are for in-center
13 hemodialysis. I mean, they don't explicitly
14 say excluding home hemodialysis. But I think
15 it's a question that you all need to consider.

16 So am I correct that this would
17 exclude any home hemodialysis?

18 DR. WOLFE: Yes. The denominator is
19 among patients less than 18 years old,
20 receiving in-center hemodialysis.

21 DR. PACE: And I know many of the
22 measures do that. So I just want to throw

1 that out to the Committee also to be thinking
2 about, whether that's necessary.

3 MS. PAVLINAC: And a question about
4 that. So if you have kids in acute dialysis
5 centers in a hospital, that would exclude them
6 too, because they would not be considered in-
7 center? That's not -- and I may be wrong, but
8 at least in the population I know it's not an
9 insignificant number.

10 DR. FIVUSH: Theoretically, there
11 are chronic patients dialyzed in acute units.
12 But they wouldn't have a 27-28 form. So that
13 they wouldn't be considered ESRD, so they
14 wouldn't be in the pool.

15 So theoretically, you would not be
16 dealing with patients that were, although you
17 could be dealing with patients that were sick
18 and acutely dialyzed in a chronic ESRD, that
19 were in the hospital for more than a month,
20 could be captured in this measure.

21 DR. WOLFE: That's correct. The
22 definitions here were driven, to a large

1 extent, by the medical criteria that, just as
2 Alan was concerned with, assuring that we have
3 the right information to come up with the
4 right measure.

5 But also the practical data flow
6 that truly is available and the CTEP is trying
7 to come up with measures which are useful for
8 a large number of patients for whom we have
9 data, and our ability to bring in other
10 patients who might be important is certainly
11 important. But we're dealing with what's
12 available right now.

13 CO-CHAIR CROOKS: And data on home
14 hemodialysis patients, which I guess is still
15 a very small fraction of pediatric
16 hemodialysis patients, right? But that's not
17 collected under this metric?

18 DR. WOLFE: It has not been yet to
19 date.

20 DR. PACE: But I guess that's my
21 question. Just because you don't currently
22 have the data, my question is, is there some

1 clinical reason that those patients should not
2 be included in the measure? If you don't have
3 the data, they're not going to be included in
4 the performance score.

5 But do we need to limit the measure
6 to exclude them, when maybe a year down the
7 line -- so that's just a question. Is it
8 strictly a matter of there's a few numbers and
9 the data aren't available, or is it driven by
10 the clinical --

11 CO-CHAIR CROOKS: Or in other words,
12 maybe what you're saying is if we pass this
13 metric, are you saying you don't need to
14 measure it in home hemodialysis patients.

15 I think the answer is of course, we
16 think it should be measured in home
17 hemodialysis patients too. But that would
18 require again, another rewrite of the
19 statement.

20 DR. FIVUSH: But it is excluded,
21 right? It is an exclusion. I mean, it says
22 exclusions are patients on home hemo, patients

1 not in the facility the entire calendar month.

2 DR. PACE: Right. What's the
3 justification for excluding patients on home
4 hemodialysis?

5 (Off mic comments.)

6 DR. KLEINPETER: One question. Once
7 it's adopted, any home program can still use
8 the measure. So we're not precluding them
9 from measuring the data at some point. But
10 it's not a requirement at this point.

11 DR. PACE: Right. But because
12 you're saying they're excluded, it could lead
13 people to believe that maybe it's not relevant
14 to --

15 CO-CHAIR CROOKS: Okay. Are we
16 ready? Any more comments? I think we're
17 ready to start voting on this metric.

18 DR. PACE: So we're going to vote on
19 the metric as it is. I'm sorry, in the future,
20 when there's a question about the numerator
21 and denominator, we can display it so that we
22 can make sure we're all on the same page.

1 All right. So we're on this measure
2 as it's stated, and the first question is
3 about to measure and report, and go ahead and
4 --

5 (Committee voting.)

6 DR. PACE: Okay, the next question
7 then, scientific acceptability of measure
8 properties.

9 (Committee voting.)

10 DR. PACE: Next question, usability.

11 (Committee voting.)

12 CO-CHAIR CROOKS: Karen pointed out
13 to me the people on the phone aren't able to
14 see the results of the voting, and might like
15 to know. We were going to announce, but then
16 when we saw what's on the screen, we decided
17 not to. So from now on, why don't you -- one
18 of us will go ahead and --

19 DR. PACE: Okay. So the results
20 were that six completely, 11 partially, 2
21 minimally and one not at all. Feasibility.

22 (Committee voting.)

1 DR. PACE: Okay. So for
2 feasibility, we have 7 completely, 11
3 partially, 2 minimally and that's all.

4 (Committee voting.)

5 DR. PACE: Okay, and then finally
6 recommend for endorsement?

7 (Committee voting.)

8 DR. PACE: You hear the "oohs". We
9 have 11 for yes and 9 nos.

10 CO-CHAIR CROOKS: Is that enough of
11 a consensus to --

12 DR. PACE: Well, generally what we
13 would do is when we put out the draft report,
14 we will note that the Steering Committee was
15 more divided on their recommendation for this
16 particular measure.

17 We'll ask for comments, and it's
18 something that you could, depending on the
19 comments, revisit at that point. But that's
20 generally what we would do. Time check.

21 CO-CHAIR CROOKS: Time check.

22 12:10, we're at lunch break time.

1 DR. PACE: Okay. So lunch is out
2 there. So we have two options. We can break
3 for lunch and we'll take a half hour, and then
4 come back and resume this. We're a little bit
5 behind schedule but I think, you know, as we
6 get into a groove here, we'll do okay.

7 Or we can try to push through the
8 two more measures. What do you guys think?

9 CO-CHAIR CROOKS: You don't want to
10 eat and work at the same time.

11 DR. PACE: No. Well, some people
12 will be leaving, that we could work through
13 lunch. So we could go ahead and get lunch and
14 come back, and resume in about 15 minutes. Do
15 you want to try that?

16 CO-CHAIR CROOKS: So unless there's
17 objections, let's break. Get your food.
18 Let's try to resume at about 12:30, and we'll
19 see how that works out. Okay. Thank you.

20 (Whereupon, the above-entitled
21 matter went of the record at 12:12 p.m., and
22 resumed at 12:38 p.m.)

A-F-T-E-R-N-O-O-N S-E-S-S-I-O-N

12:38 p.m.

1
2
3 DR. PACE: Anybody from CMS wanted
4 to get in a comment? We kind of missed them
5 because they're on the phone. Tom, can you
6 hear me?

7 DR. DUDLEY: Yes, I can hear you.

8 DR. PACE: Okay. Do you want to go
9 ahead and give us your comments?

10 DR. DUDLEY: Well, actually, Shari
11 already hit it with her comment earlier today.
12 I appreciate the opportunity. I just wanted
13 to reassure everyone that with regards to any
14 measures that are used for public reporting,
15 or more importantly for payment purposes, we
16 need to go through the rulemaking. So I think
17 there was a comment earlier today about the --

18 DR. PACE: I think we lost you.
19 Operator, can you hear me?

20 OPERATOR: Yes, I can. His line did
21 disconnect.

22 DR. PACE: His what?

1 OPERATOR: His line did disconnect.

2 DR. PACE: Okay, all right. Well,
3 we will see if he has anything else to say
4 when he comes back on. And before we resume
5 the measures, several Committee members came
6 up and wanted to discuss the vote on the prior
7 measure. So we want to clarify a couple of
8 things, and then if need be, we can revote on
9 that.

10 But one of the questions that came
11 up was about whether you can recommend any
12 changes, and I think we maybe didn't clarify
13 that sufficiently. So for example, someone
14 mentioned that they voted down the measure
15 because it didn't include home hemodialysis
16 patients.

17 So let me just clarify that the
18 Committee can make recommendations to change
19 a measure. But we want you to be very
20 cautious about this and there's a line at
21 which you're making so many changes that it's
22 a different measure.

1 But you know, the guiding thing is
2 what the evidence calls for. So in that
3 particular case, the Committee could have made
4 a recommendation that the -- that all
5 pediatric hemodialysis patients be included,
6 and so we just wanted to bring that up, but
7 also because it is an issue that crosses many
8 of the measures, it may be more efficient to
9 talk about it across the board, to see if
10 there are any of the topics where home
11 hemodialysis patients should be excluded,
12 based on the clinical evidence.

13 If not, is that something that you
14 want to recommend across the board. So if we
15 could just take a minute to get your sense of
16 that, if that was the issue for some of you
17 that voted no on the measure. I mean, and
18 it's fine. Your vote is fine. We just wanted
19 to make sure if there were any things we
20 needed to clarify that we got those out before
21 we moved on.

22 MS. LeBEAU: I'm assuming, I'm

1 sorry. I'm assuming the reason that that was
2 excluded, and I'd have to go back and look
3 through, is simply because of the difference
4 in frequency, because, you know, as an adult
5 home hemo patient, I know that my adequacy is
6 not properly or accurately represented, unless
7 it's accounted for. So since we did discuss
8 that, anyway, I just wanted to offer that up.

9 DR. PROVENZANO: My only comment is
10 if we get into the realm of home measurements,
11 it's a completely different can of worms,
12 because although you are correct, Kathleen,
13 the ability for a physician or a facility to
14 be responsible for any therapy which they
15 don't have direct oversight of is just
16 problematic.

17 So if we broach that issue with
18 pediatrics, I think we're going to open a can
19 of worms, and I would suggest that we don't
20 lump it in here.

21 MS. PAVLINAC: I was part of the
22 whatever we're calling ourselves, the assigned

1 reviewers, thank you. I didn't want to have
2 any more or less importance. I raised the
3 question of home hemodialysis.

4 I ended up voting yes because of
5 what Robert just said, because I don't know
6 how you can hold them, facilities responsible
7 because it's hard enough when people don't
8 come in on time, and leave when it's in the
9 facility.

10 But I think it is a hugely important
11 issue, as far as quality of care in our
12 population, what is done with our home
13 patients.

14 DR. LATTI: I don't know that much
15 about home hemo, but I mean who's responsible
16 then. If the facility isn't responsible, who
17 is responsible?

18 DR. PROVENZANO: Yes. I mean again,
19 we're going down that path already. I as a
20 doctor and I as a facility can provide you
21 with the equipment, the training, the
22 expertise, and you can go home and choose to

1 do nothing.

2 DR. LATTIS: I would argue that your
3 obligation, though, is to do what needs to be
4 done to encourage adherence among your patient
5 population.

6 DR. PROVENZANO: Again, we can have
7 this conversation, but the point is the
8 processes necessary to hold an individual
9 accountable for something that they have --
10 that little direct impact on is problematic.
11 I'm not saying it's whose responsibility it
12 is, whether it's the right thing to do.

13 But although even in a facility,
14 where there is much more ability to monitor
15 impact, processes that are measurable, home
16 dialysis is a whole different realm. That's
17 my only point. I'm not taking sides.

18 DR. LATTIS: And I would argue this
19 is no different than holding a primary care
20 physician responsible for their patient's
21 cholesterol. Yes. I mean, the dialysis
22 setting, you have the luxury of having

1 patients in-center.

2 But most physicians, it's all about
3 encouraging your patients to follow your
4 treatment recommendations when they're not in
5 front of you. That's what medicine is about.

6 DR. PROVENZANO: Yes, I know you
7 agree. Jeff, get on your mic and agree.

8 (Laughter.)

9 DR. BERNS: Yes. I guess I'll ask
10 the rhetorical question. We can then assume
11 that you won't support any measures that have
12 patient compliance as a component of meeting
13 that performance measure, because we're really
14 not that much different from that.

15 DR. PROVENZANO: Even Kliger can't
16 guess what I'm thinking. No, no. My point is
17 I think this is a separate issue that
18 shouldn't be lumped together. I'm not taking
19 a position whether we do it or don't. But if
20 we start lumping it in right now, we will be
21 here until June.

22 I just think that that should be

1 addressed independently, because it isn't
2 -- you know, home pediatric is different than
3 home adult. Home nocturnal is different than
4 in-center.

5 I mean, there's a whole bunch of
6 parameters that I just think we will dilute
7 the nuances of what is required to measure
8 outcomes in different sites of service than we
9 do when we're talking about in-center. That's
10 all.

11 DR. FIVUSH: Can I bring up another
12 point about the last measure? I read the
13 numerator statement and the denominator
14 statement, because you know we have three
15 minutes to present a measure. I feel that
16 there was confusion that arose potentially
17 because of 1423, where we talk about
18 frequency.

19 I really just want to make it clear
20 that this 1421 is a stand-alone measure, and
21 I hope people voted on it in the spirit with
22 which it was put forth. Because when we

1 looked at the specifications and the
2 measurement, it really actually seems that
3 nobody actually objected to it in the fashion.

4 But we were sort of somehow linking
5 it to frequency, which it wasn't linked to.
6 So I just want to put that out again, because
7 I think it is an important measure, that we
8 specify that not only do we measure adequacy,
9 but that there are correct ways to measure
10 adequacy.

11 DR. PACE: Okay.

12 DR. KLIGER: Real quickly. My whole
13 objection and concern before has to do with
14 1423, and again, an apology.

15 The method, I'm concerned, I guess,
16 looking at the vote, that if anyone had shared
17 my concerns about assuring appropriate
18 measurement dealing with varying frequency,
19 that actually has to do with the one we're
20 about to talk about, and not the one we talked
21 about before.

22 MS. LeBEAU: I just, as the risk of

1 opening a can of worms, then we have to
2 acknowledge that there's a gap in care if we
3 are not coming up with any adequacy measure
4 for home pediatric patients. So what do we do
5 about that?

6 DR. PACE: And I guess again, the
7 question, and I think we need to hear from
8 more of the Committee, because if the evidence
9 is no different for patients on home
10 hemodialysis versus in-center, what is the
11 justification for not, for excluding them from
12 the measure?

13 CO-CHAIR CROOKS: I would like to
14 comment on that. Does subtleties and
15 differences in dialysis at home or more
16 frequent? But this isn't subtle. I mean,
17 either you got Kt/V measure or you didn't.

18 There's not anything too subtle
19 about that, and for us to not acknowledge
20 that, you know, there's no scientific reason
21 to exclude the requirement to measure Kt/V for
22 home patients, and I don't think it's

1 justified really.

2 DR. FIVUSH: So then I just want to
3 be -- I mean, I know the vote on the measure,
4 but I think in terms of feedback, I think the
5 -- I want to be clear, not to me, because I
6 think this group is clear why people may or
7 may not have voted on it.

8 But I think to the measure
9 developers, I'm now hearing a conversation
10 that a lot of it was due to the exclusion of
11 home hemodialysis patients, which I think is
12 very, is a valid concern. Rather than that
13 it's tied into a frequency of dialysis.

14 So that when we give the measure
15 developers any kind of feedback or Arbor
16 feedback, that in fact it's not, that what the
17 concern is, is I'm understanding it now, and
18 again, I'm not the measure developer, just
19 that it is related to the lack of -- that the
20 exclusion in fact is of concern to this group.
21 Is that -- thank you.

22 MS. ANDERSON: Coming from a large

1 home program, hemodialysis program, I voted no
2 because of the exclusion of the home dialysis.
3 I think you can measure Kt/V. It's not a
4 burden, and that's what I was thinking, would
5 this add an additional burden on.

6 I think I voted no because of the
7 exclusion for the home hemo. They should be
8 treated the same as the in-center population
9 for care, to be able to measure care.

10 DR. FIVUSH: Thank you. Can we just
11 ask Arbor, I know you told us there was less
12 than six percent, something like five percent
13 getting in-center four times a week. Did you
14 give us a number of how many pediatric home
15 hemo patients? We're just, I think it's, you
16 know, just for us to move forward through the
17 process. Do we actually know that number?

18 DR. WOLFE: I don't know that right
19 now. It may be that someone at Arbor who is
20 on the telephone can answer that in a moment.

21 But I will say that the TEP did
22 consider very thoughtfully the issue of home

1 hemodialysis on all of these measures, and it
2 was not because they wanted to exclude home
3 hemo.

4 It was because of the lack of data
5 and there was a concern that, this seems so
6 ironic to me, was a concern that this
7 Committee would vote it down because there was
8 no data to support the measure for home hemo,
9 that we didn't put it in.

10 DR. FIVUSH: There you go.

11 DR. WOLFE: So, I do suspect, and it
12 is telling that there was a question. So
13 what's the evidence for pediatrics that
14 measuring it monthly is important? The answer
15 is we don't have any evidence for that, but
16 that's the evidence for the adults, and
17 there's no reason to think that they're
18 different.

19 So the question did arise. When we
20 had a measure for a subgroup, of whether to
21 bring it in and the question came up and it
22 was, it sounded to me like it was very

1 threatening to the frequency of pediatric
2 assessment, on the lack of data for it.

3 So our concern was real. If we had
4 put them in, I suspect there would have been
5 a question saying so what's the evidence that
6 it works for home?

7 The question is is there a measure
8 which is useful for a large segment? It's a
9 very large number of people, and it's very
10 important for the in-center hemo patients.

11 It's a large number of people,
12 we're proposing a measure for it. We aren't
13 worrying about people in India. I'm sorry.
14 There are some people who are left out. But
15 we know that there are a large number of
16 people who are impacted by this measure, and
17 for whom this would be beneficial.

18 We're trying to craft measures which
19 this Committee will approve on the basis of
20 there being evidence for it, and there is
21 evidence for the in-center patients. Perhaps
22 Sylvia knows the number of patients, the

1 pediatric patients who are home hemo.

2 MS. RAMIREZ: Bob, I'm actually
3 asking someone from Arbor to calculate that as
4 we speak, if they can do that. However, while
5 I have the microphone, I'd like to also say
6 that the intent of the TEP to not include home
7 hemo goes along with somebody's comment, that
8 this population should be treated differently.

9 The thinking of the TEP was that
10 there may be a separate technical expert panel
11 to specifically look at measures for the home
12 hemo population. It was not meant to exclude
13 the group.

14 DR. PACE: All right, and just one
15 comment from NQF's perspective about measures,
16 and it relates to a comment about
17 harmonization and competing measures, that if
18 a measure, if the evidence supports the
19 measure being applied to more than a narrow
20 population, the measure should be based on the
21 evidence.

22 What I'm talking about here, the

1 clinical evidence that that's the particular
2 structure or process that's relevant to that
3 population.

4 So, I mean, and it's something that
5 you're going to have to address tomorrow, is
6 if the parameters are exactly the same, do we
7 need a separate measure for pediatric patients
8 versus adult patients, or can you have one
9 measure that you could stratify the results by
10 those populations, rather than having multiple
11 measures that then introduce the possibility,
12 you know, as they morph, to become different.

13 So there is again no standard answer
14 to that, but it is something that you're going
15 to have to address. So the idea that we would
16 have, you know, a measure with exactly the
17 same specifications, but now say that it's
18 only for the home pediatric dialysis patients,
19 you know, is that helpful or is that more
20 confusing?

21 But we can move on? Maybe what we
22 want to do is just vote on these measures as

1 they are, as you did on the last one, and can
2 revisit this issue later on, if someone wants
3 to bring it up again, about whether home --

4 CO-CHAIR CROOKS: Well, couldn't you
5 -- wouldn't you make a comment with, in our
6 forwarding this to the next level up, the
7 process that in discussion about this measure,
8 the reason quite a few people voted no, was
9 concern that home hemodialysis patients
10 weren't included, and just leave it at that,
11 you know.

12 DR. PACE: Right, yes, exactly.

13 CO-CHAIR CROOKS: And the next level
14 can say well then we shouldn't do it or that's
15 okay, you know, or --

16 DR. PACE: Right.

17 CO-CHAIR CROOKS: Is that okay with
18 the Committee we do it that way? I don't
19 think we need to revote.

20 DR. BURSTIN: I'd just be a little
21 worried that perhaps there are some mixed bags
22 on the way people voted. Some people may have

1 voted based on that issue; some people may
2 have voted based on other issues.

3 So just for the sake of clarity, it
4 might just be nice. And the question would
5 be if this issue's going to come up every
6 single time, do you want to be constantly
7 clouding the vote every single time on this
8 issue, and do we somehow --

9 I mean it's just going to come up
10 every single time apparently. Or do we
11 somehow make that a discussion item we'll have
12 separately, maybe even put out for comment as
13 a general issue?

14 DR. PACE: Right. But if the -- so
15 I guess the question is if the Committee can
16 reach consensus on that. Otherwise, it is
17 going to come up on every vote, because people
18 are going to have to vote the way they feel
19 about that issue. So and I know it applies to
20 more than just the measure we're talking
21 about.

22 CO-CHAIR CROOKS: Some measures may

1 be more appropriate to include home hemo than
2 others. I think that's another complicating
3 thing. Do you think so, Alan or others? This
4 one seems pretty straightforward. Yes,
5 measure adequacy. There's as much evidence
6 for home as there is for not doing it at home.

7 But if it comes to maybe vascular
8 access or an infection, it may not be
9 applicable. They're self-cannulating versus
10 in-center. You know, there's differences in
11 the way the treatment is accomplished.

12 DR. PACE: So does anyone have a way
13 out of this or around this that we should
14 proceed, or discuss it with each measure?

15 CO-CHAIR CROOKS: I think we're
16 going to have to.

17 DR. PACE: Okay, okay. Given our
18 discussion about the past measure, is there
19 any need to revisit that, with the caveat of
20 making a recommendation for home hemodialysis,
21 or do you want to just move on?

22 (Off mic comment.)

1 DR. PACE: Okay. So why don't we
2 just do a show of hands of who would like to
3 revote on the method measure?

4 DR. BURSTIN: Why don't we just
5 revote, in case -- why don't we just revote?

6 DR. PACE: The question is whether
7 someone wants to suggest the Committee that
8 the measure should be voted on, with the
9 condition of adding home hemodialysis
10 patients, or do you --

11 DR. PROVENZANO: So the revote would
12 be -- well, nobody's made any --

13 (Off mic comment.)

14 DR. PACE: Okay. Let me do it this
15 way. The measure you voted on excludes home
16 hemodialysis patients. So it sounds like your
17 vote took that into account. So if the
18 measure stays as it is, is there any need to
19 do a revote?

20 DR. FIVUSH: Again, I'm not the
21 measure developer. I'm the measure explainer,
22 I guess, or the measure presenter. But as a

1 pediatrician, I really think it's critical
2 that we have a measure that is about how we
3 measure adequacy.

4 I mean, I think I'm using the word
5 "measure" twice in the sentence, but I think
6 we do have to have it. My concern is that I
7 understand the exclusion of home hemodialysis
8 patients. I think it's a very, very small and
9 very poorly understood population in
10 pediatricics, much more so even than in adults.

11 And again, we have such small
12 numbers over many sites, and I think it was
13 probably the intent of the TEP was to exclude
14 that population, not because they don't care
15 about the population, but because they simply,
16 it's such a new process.

17 But I also am concerned that there
18 was some confusion about frequency tied into
19 this measure, that also may have worked
20 against the measure, that I'd actually like a
21 revote. If it's positive, that's great. If
22 it's negative because of that exclusion, then

1 I think it would be very important to go back
2 to the TEP and say that's why there's an
3 exclusion. That's why there's a problem.

4 DR. PACE: All right. Let's do
5 this. We'll ask you to revote just on
6 recommendation, yes or no, if that's --

7 DR. RAMIEREZ: May I interrupt for a
8 second, just to respond to the question asked
9 of us earlier, with regards to the percent of
10 pediatric patients on home hemodialysis. That
11 is 1.1 percent.

12 DR. FIVUSH: So and again, to couch
13 that in 1,600 patients, it's just -- it's a
14 small number that I think we're struggling
15 with even understanding. That doesn't mean
16 they should be excluded.

17 CO-CHAIR CROOKS: Let me propose
18 that we just let it go and just put a little
19 note in there saying that the reason -- some
20 Committee members were hesitant to vote for
21 this because it excluded home hemodialysis
22 patients. But it passed. I mean, it passed

1 and let's move on. I don't see that we're
2 going to gain anything by revoting or
3 dissecting it further.

4 We have agreed, I think it was
5 important to agree that the home issue, we're
6 going to have to look at it measure by
7 measure, that we can't make a sweeping
8 statement for all the metrics. So I think
9 that's where we're at. Is that okay with the
10 Committee?

11 CO-CHAIR SCHONDER: Should we check
12 to see if Tom is on the line?

13 CO-CHAIR CROOKS: Oh Tom, did you --
14 yes. Go ahead.

15 CO-CHAIR SCHONDER: Is Tom on the
16 line again?

17 DR. DUDLEY: Yes, I'm back on.
18 Sorry. My phone died right mid-statement.
19 I'm not sure how much you heard when I spoke
20 before.

21 CO-CHAIR SCHONDER: We really didn't
22 hear a whole lot. Just go ahead and start

1 from the beginning again.

2 DR. DUDLEY: Okay. Shari actually
3 touched on this in the morning. There was a
4 comment made earlier today about the possible
5 use of other endorsed measures for payment.

6 I just wanted to reiterate what
7 Shari said, that CMS is held to the rulemaking
8 process before you use any measurements, any
9 new measures for the purpose of the quality
10 incentive program.

11 So hopefully, that is the concerns
12 about the use for payment is kind of taken out
13 of the equation when talking about the
14 possible measures. Just a simple statement.

15 CO-CHAIR CROOKS: Okay. Thank you
16 for that reassurance, and with that, we'll
17 move on to the next metric.

18 CO-CHAIR SCHONDER: Yes, okay.
19 We'll move on to the next metric, which is No.
20 1423, which Barbara is also our presenter for
21 that as well.
22 Measure No. 1423

1 DR. FIVUSH: So hopefully this will
2 follow in line with the last measure. This
3 measure is dialysis adequacy. It's minimum
4 single pool Kt/V for pediatric hemodialysis
5 patients.

6 The numerator statement is number of
7 patients, and the denominator is delivered
8 dose of hemodialysis, calculated from the last
9 measurements of the month using the UKM or the
10 Daugirdas formula was greater than or equal to
11 1.2.

12 The denominator statement is number
13 of pediatric patients in-center hemo, and
14 again that's less than 18, who have been on
15 hemodialysis for 90 days or more, dialyzing
16 three or four times weekly. So the exclusions
17 are patients receiving dialysis less than
18 three times a week or more than three times a
19 week, and not in a facility for the entire
20 calendar month.

21 So in terms of what the, there were
22 five evaluators of this measure, and when we

1 -- when the evaluators looked at the criteria
2 for importance of the measure for measurement
3 and reporting, all five said yes, that there
4 was a lack of pediatric data, and that there
5 was some comment that there was a reliability
6 of this standard on adult data, but it was
7 still accepted that we should go forth with
8 it.

9 The scientific criteria met. Two
10 said it was completely, 3 said partially. One
11 commented on the exclusion of home hemo
12 patients in this. But again, this is a very
13 narrow spectrum measure, because we're
14 determining a level of adequacy, which we
15 really don't have evidence for in that home
16 population at this point.

17 And to what extent was criteria
18 feasibility met? Four said completely, one
19 evaluator said partially. And was the
20 criteria feasibility met all five said
21 completely. Everybody that reviewed the
22 measure, at least that entered data on it,

1 recommended that we go through with the
2 measure.

3 There was some discussion not of the
4 home hemo patients, because again, of the lack
5 of data understanding not that we either
6 should or shouldn't measure adequacy in them,
7 but that we knew exactly what it was, that we
8 don't have evidence of what that standard Kt/V
9 would be.

10 But that if we're going to do three
11 or four times a week, that that may lead to
12 the issue that we ended up discussing the last
13 go-round, that perhaps we're not calculating
14 it correctly using the single pool Kt/V in a
15 patient who has dialyzed more than three times
16 a week.

17 Looking at further into the
18 specifications of that measure, that was taken
19 into great consideration by the CTEP that
20 recommended this measure, and they felt that
21 although it's a small percent of patients that
22 are actually dialyzed, we said about 5-1/2

1 percent, and again we're talking about a small
2 pool, we were afraid of continuing to pull
3 patients out of the denominator, inability to
4 really look at all patients, that they wanted
5 to keep as many patients in the denominator as
6 they could.

7 They felt very comfortable that many
8 of the patients, and I don't have the number;
9 maybe Arbor does, of that 5-1/2 percent, what
10 age are we looking at? Their sense was it as
11 the much smaller patients, the younger
12 patients, that needed to be done four times a
13 week, and that we would achieve that minimal
14 adequacy level in even those younger pediatric
15 patients.

16 So that was the recommendation that
17 came forth from this group.

18 CO-CHAIR SCHONDER: Any comments
19 from the other reviewers?

20 (Off mic comment.)

21 DR. FIVUSH: We know who you are.

22 (Laughter.)

1 DR. FIVUSH: I know who you are.

2 CO-CHAIR SCHONDER: Any other
3 discussions? Alan.

4 DR. KLIGER: I'm not going to repeat
5 it all again, but here's where it matters. So
6 here, I would submit that if you don't want to
7 eliminate people in the denominator who
8 dialyze less or more than three times a week,
9 that the numerator can't be what it is now.
10 It needs to be standard Kt/V.

11 DR. BERNS: Might I ask a question
12 or raise a concern? Again, it gets back to
13 the issue that I talked about, about the wide
14 age range. Is there a risk that this is --
15 that a Kt/V is inadequate dialysis for a baby,
16 for instance? Is there some spectrum of
17 people for whom this would not be appropriate
18 and shouldn't be an acceptable performance
19 measure?

20 CO-CHAIR SCHONDER: Barbara, go
21 ahead.

22 DR. FIVUSH: I would -- this is a

1 minimum level, and I think the concern is that
2 there is a minimum standard. I think you're
3 exactly correct. We're going to find out when
4 we really can look at this data that perhaps
5 younger children do need more dialysis. They
6 have much more rapid growth. They have much
7 more rapid cognitive development.

8 But this is again a minimum adequacy
9 level, and the concern in the pediatric
10 community, from reading the specifications and
11 from practicing in that community is that
12 there's not even a minimum standard, and there
13 needs to at least be that.

14 But I don't think this is the
15 maximum standard, and I don't think this is
16 suggesting that this is the best standard. I
17 guess the concern would be that if we say this
18 is okay, does this become okay. But with the
19 gap in care that we're seeing, I think the
20 thought is we have to, the pediatric community
21 has to start some place in looking at this
22 data, and seeing that there are minimum

1 standards.

2 We may be able to link this later
3 and find out that we need to do much better.
4 So it's just, I think, being seen as a first
5 line. If we -- and I think if we looked at
6 the numbers, and again I don't have the
7 number, the patients that are getting it more
8 than four times a week, my suspicion is that
9 they're our youngest patients.

10 So therefore I think that was why
11 the CTEP felt comfortable keeping this in
12 there, that they were knowing that the younger
13 patients may be getting a single pool Kt/V of
14 1.2, but they were getting it more frequently.

15 DR. BERNIS: There's two issues here,
16 one of which is a need, from the pediatric
17 nephrology community, to collect data, and
18 then analyze that data and come up with some
19 answers for us.

20 The other is the establishment of
21 performance measures that are going to
22 influence care, influence payment, you know,

1 and as we're hearing, that setting this Kt/V
2 of 1.2 is going to be the standard of care
3 until somebody proves otherwise.

4 It may be that this an appropriate
5 standard of care or a minimum dose of dialysis
6 for a teenager, an adolescent and above, and
7 maybe we should treat them as adults and not
8 children. But there is a risk that we have to
9 - this is the unintended consequences, that
10 we're going to do a bad thing for children.

11 The mandate ought to be measure in
12 the population for whom we have absolutely no
13 data about what to do or what that number
14 should be. Where we do have information,
15 let's be very directive about that population.

16 This is going to come up probably
17 when we talk about anemia too, is we have
18 anemia outcomes data on a very specific
19 patient population, and we're applying it to
20 everybody who dialyzes. I think it's just
21 really inappropriate to do so.

22 CO-CHAIR SCHONDER: Joe.

1 DR. NALLY: Jeffrey stole most of my
2 thoughts, but we would be - I think we were of
3 the understanding that it would be a good
4 thing to start measuring. It's a different
5 question to arbitrarily pick a standard, and
6 it sounds like from the measure, that it was
7 1.2 because that was the lowest for adults,
8 lowest minimum for adults, and kids may be
9 higher.

10 So when you don't have any outcomes
11 connected to the various Kt/V's, that makes me
12 uncomfortable setting a standard. Then when
13 I read that the Kt/V can be influenced by
14 patient's age, size and ethnicity, and you
15 start introducing several variables along the
16 equations without outcomes to use as the gold
17 standard, I think it may be premature to set
18 a target or a standard when I think is what
19 you really want to be doing is just data
20 collecting, to determine what those future
21 standards will be arrived at.

22 DR. KLIGER: Can we ask the measure

1 developers their responses to that? I'm sure
2 that the CTEP discussed this. I'm curious
3 what their thoughts were about this.

4 DR. MESSANA: If Bianca or Sylvia
5 Ramirez is on the phone, she was there. She
6 might be able to comment most accurately.

7 CO-CHAIR SCHONDER: Sylvia?

8 DR. RAMIREZ: Yes. Could you just
9 repeat the specific question?

10 CO-CHAIR CROOKS: The issue is the
11 potential danger of kind of a single
12 prescription for all ages and sizes and did
13 the Committee, were they concerned about that
14 or think about that?

15 DR. RAMIREZ: Yes absolutely, and in
16 fact, in the formal report for the clinical
17 performance measures, as Dr. Fivush stated in
18 the beginning, there were certain
19 considerations that the TEP discussed in the
20 pediatric population as a whole.

21 The first is the general acceptance
22 of the limited data. The second is the

1 importance of growth, and the third for sure
2 is the wide variation in physiology by age and
3 clinical needs. I think that in general, the
4 approach of the TEP was to develop at least a
5 minimum standard, and not to set an ideal
6 standard, because there's no measurement
7 whatsoever.

8 You can see the high percentage. I
9 think there's at least 20 percent without Kt/V
10 measurement, that it's thought that given the
11 evidence linking Kt/V greater than 1.2 even in
12 the pediatric population, in terms of reducing
13 hospitalization and mortality, that even if
14 this may not be the ideal standard, we have
15 sufficient data to suggest that a standard of
16 1.2 or a target of 1.2 may be of clinical
17 benefit.

18 DR. NALLY: But Sylvia, wasn't that
19 1.2 in an adolescent population, and you know,
20 how would that compare to the younger
21 children, et cetera.

22 DR. FIVUSH: I actually had the

1 opportunity to participate in looking at some
2 of that data, and actually there is a minimum
3 standard. It's sort of -- I think it may be
4 like the hemoglobin data. We don't know what
5 the best target is. We know below which there
6 are problems.

7 So if you look at the data, even in
8 younger kids, less than 1.2 is a problem, and
9 associated with increased morbidity and
10 mortality. That is one of the few things we
11 do have data on.

12 The problem is, and Arbor again may
13 comment on this, there are so few pediatric
14 patients under the age of two in this country
15 that the data has been censored in any
16 reports, because the boxes are too small.

17 I think when we looked at it, we
18 guessed that there are less than ten patients
19 under the age of two on hemodialysis in the
20 country. So it's very hard to draw general
21 conclusions about optimal Kt/V's when you're
22 talking about populations that are this small.

1 And I mean I think that's why our
2 concern is that we do have a minimal level.
3 We could try and exclude all those very young
4 infants, but then we think we're excluding a
5 particularly vulnerable population. We're not
6 learning anything about them that may in the
7 future allow us to achieve better targets.

8 That's why this is not a target
9 Kt/V. This is a minimum, and I think the word
10 is pretty clear. It starts with minimum. But
11 again I'm --

12 CO-CHAIR CROOKS: Well, I listened.
13 I think you kind of made an argument against
14 the importance of it, in the sense that this
15 is a very small population. We're going to
16 set a national consensus, voluntary national
17 consensus standard and apply it across this
18 whole population, and it, you know, makes me
19 wonder is it important enough to be a
20 standard, especially if you're going to
21 include --

22 Then you also have the possibility

1 of unintended consequences. Now what we say
2 is a minimum has a way of becoming a maximum
3 in the health care world, and also you are
4 setting it for kids, and is there really
5 enough data.

6 It worries me, if I was a father of
7 a small child on dialysis, you don't really
8 know what the right thing to do. I'm not sure
9 that this would reassure me that the quality
10 is improved now because this metric was put in
11 place.

12 DR. FIVUSH: I could tell you from a
13 data point of view, we may not be able to tell
14 you what the optimal is. I think certainly
15 pediatricians could tell you that less than
16 1.2 would be problematic.

17 So you know, I understand that
18 everybody, I understand the concerns around
19 the table. I happen to feel strongly that we
20 need to have a minimum Kt/V. We need to have
21 a minimum adequacy measure. We shouldn't
22 throw out the small children.

1 Just like we didn't want to throw
2 out the home hemo patients in the last
3 measure, we need to take them into account.
4 We can't just ignore them because there aren't
5 that many of them. Again, I understand how --
6 I can understand the concern about unintended
7 consequences. I still feel quite strongly
8 that we should have a minimum adequacy measure
9 in children.

10 CO-CHAIR SCHONDER: Jerry has a
11 question.

12 DR. JACKSON: Question. Is this a
13 facility level measure? The reason I ask this
14 is that if you have a target, call it minimum
15 but it's a target, you're going to have a
16 distribution of outcomes around that.

17 So if it's a normal distribution
18 that's going to be named, you're going to have
19 a substantial number. You might have 20
20 percent who fall below this and still have
21 your minimum target met by that facility.

22 We've recently moved our target in

1 an adult facility up to 1.4 because of this
2 issue, in order to get the lower end of the
3 curve up to a better minimum. My question
4 would be is the 1.2 the right number, or
5 should it be higher?

6 DR. KASKEL: To emphasize what
7 Barbara was saying again, these measures are
8 taken in a composite. You have small numbers.
9 You have an infant who you're looking at this
10 as a measure of adequacy. You also look at
11 growth. You look at anemia and you look at
12 development. It's all taken in a package.

13 If the patient's value is not what
14 we expect it to be and they're not doing well
15 with the other factors, we have an assessment
16 that the prescription is not adequate. That's
17 what we come up with.

18 So this piece of that, this factor
19 adds to the composite score of the evaluation
20 of dialysis in that young infant.

21 DR. PROVENZANO: I was going to say,
22 I'm beginning to better understand why there's

1 no measures in pediatrics. I mean it is a
2 diverse population.

3 You have a bunch of people here,
4 adult nephrologists. We feel your pain. I
5 guess my simple question is it seems like
6 there's a rush to pick a number with little
7 data.

8 Help me better understand why must
9 we, if what we can do is approve just
10 measurement, and then use that data to select
11 something that's more scientifically valid?

12 DR. FIVUSH: This measure actually
13 has the, as I said, the validity more than any
14 of the other measures. Alan asked about
15 frequency or methodology. But this one,
16 actually there are studies in pediatrics using
17 the CPM data, and looking at morbidity and
18 mortality linked to low Kt/V.

19 So I think again, you know, the
20 concern is we have a gap. There are 20
21 percent of patients that aren't even having
22 Kt/V measured, and then you know, our concern

1 is that if you have a minimal level in adults,
2 wouldn't it be natural to assume a child who's
3 having growth and development would at least
4 need that same level, at least, at least.

5 So I would -- I think we have been
6 talking about measure development for ten
7 years in pediatrics, and we can't seem to get
8 over this, the hump of actually saying it's,
9 you know, it's time to say there's minimum
10 standards for children.

11 Yes, we don't know the optimal. But
12 there are minimum standards, and we should
13 abide by those. I think the pediatric
14 community would say to you loud and clear yes,
15 we understand our lack of ability to look at
16 these patients critically. We don't have that
17 many.

18 But I think, you know, the CPM
19 project was in 1999 it started out. I'm
20 trying to go back. It has been a long time of
21 data collection, with people continuing to
22 inadequately dialyze children because we've

1 never taken that step.

2 So understanding this process is not
3 in place for that, I think, you know, and the
4 Committee has to -- and I'm not the measure
5 developer. I think the pediatric community
6 feels that it is important, that there be a
7 minimum level of hemodialysis adequacy in
8 children, understanding all of the concerns at
9 the table.

10 If the group feels that this
11 measure, that we don't have data on the
12 youngest infants and children, then I would at
13 least ask that we, and I guess it depends on
14 what the vote is, that we consider talking to
15 the developers about at least changing this to
16 an adolescent measure for hemodialysis.

17 I think as a starting point, there
18 needs to be minimal levels of adequacy in
19 pediatric patients, in some population of
20 pediatrics. So and I know we can't change the
21 measure. I would just --

22 CO-CHAIR SCHONDER: Any other

1 discussion?

2 DR. VASSALOTTI: You said the gap in
3 care 20 percent. We've already addressed that
4 with the previous measure, a gap in care for
5 this measure, in terms of --

6 DR. FIVUSH: You know, as I said, we
7 aren't allowed to report on it. We have been
8 able to report on it in the youngest patients,
9 because of the consequences of having
10 outliers. So I'd have to go back to Arbor to
11 even see if they could tell us.

12 DR. VASSALOTTI: I see a facility,
13 90 percent of the patients have a Kt/V of more
14 than 1.2 in 68 percent of facilities?

15 DR. WOLFE: So that's fairly
16 comparable to the adult population, but there
17 are patients that are not receiving that level
18 of dialysis. The TEP's thinking on this was
19 while they, and I'm including here, this is
20 from page 92 of the synthesis report.

21 The TEP agreed the initial pediatric
22 target should be set to ensure delivery of at

1 least the minimum required care for this
2 population, if not optimal care.

3 In addition, these adequacy targets
4 should be no lower than existing adult
5 hemodialysis targets, since generally
6 pediatric patients' greater metabolic demands
7 require higher hemodialysis adequacy targets,
8 in terms of small solute clearance.

9 It is, and this is an intent, rather
10 than the measure. I understand that. "It is
11 the intent that over time, the initial
12 measurements will be improved, and additional
13 targets established, resulting in improved
14 quality of care for pediatric patients."

15 So the TEP did recognize that this
16 was and proposed it as a starting point,
17 rather than an ending point. There was
18 discussion, and it's not summarized here, of
19 a concern generally by several of the TEPs,
20 that setting a requirement for measuring
21 something, without setting any requirement at
22 all for achieving a threshold, seemed strange.

1 So this was their approach towards
2 that, resolving that problem, to at least set
3 it at a minimum level, as opposed to an ideal
4 level.

5 DR. BERNS: Just to further
6 complicate this issue about the performance
7 gap, one must wonder, at least, whether some
8 of that 20 percent that's not measuring this
9 is not measuring it because they're not
10 convinced that there's a value to doing so,
11 and they don't know what to do with the number
12 once they have it.

13 MS. ANDERSON: Just a point of
14 clarification. In the information I think you
15 provided, Barbara, is that in the infants,
16 there's evidence that less than, a Kt/V less
17 than 1.2 was problematic for morbidity and
18 mortality. Did I understand that correctly?

19 DR. FIVUSH: Yes. I think the --
20 you know, again, a lot of this is -- I don't
21 want to say it's very small sizes, but it's
22 been linked to also cognitive development in

1 children, in the youngest patients. But not
2 in any large study, not in any kind of
3 randomized control trial, and that's -- we
4 just don't have the numbers for that.

5 DR. KLEINPETER: Well one thing,
6 perhaps we should consider time limitations on
7 this, and when we would want more data to look
8 at this again. Because as Barbara mentioned,
9 this hasn't been looked at in over 15 years,
10 and there's been no follow-up over that time
11 period for when this first was done for the
12 initial CPM project.

13 DR. PACE: This measure has been
14 tested, so it's not one that we would put
15 under time-limited endorsement. But keep in
16 mind that any measure we endorse is reviewed
17 at least every three years, where we would ask
18 them for data on the actual measure, plus we
19 solicit comments on unintended consequences,
20 plus we have an ad hoc review process.

21 So if new evidence emerges that
22 shows that this is the wrong value, that can

1 be, you know, taken into consideration before
2 that three years. So our testing is about the
3 reliability and validity, and they've
4 presented, you know, you can decide that that
5 was inadequate and that it's not reliable and
6 valid.

7 But it technically doesn't meet a
8 criteria for time-limited endorsement.

9 DR. KLIGER: I don't want to beat a
10 dead horse, but let me propose two children
11 sitting next to each other in a hemodialysis
12 unit, one dialyzed three times a week and one
13 dialyzed four times a week.

14 The three times a week has a
15 measured $spKt/V$ of 1.2, and the four times a
16 week child has an $spKt/V$ measured at 1.05.
17 That 1.05 fails. When you measure standard
18 Kt/V , the one who fails has better urea
19 removal and better kinetics than the one who
20 passed. This is a flawed measure, because it
21 does not consider frequency in $spKt/V$.

22 CO-CHAIR SCHONDER: Any other

1 comments? Okay. I think we're calling for a
2 vote.

3 DR. PACE: So just to clarify then,
4 you want to put up -- so the denominator is
5 what you're talking about, that is the
6 problem. If it includes, let me just find it,
7 right there.

8 CO-CHAIR CROOKS: To rephrase it, if
9 I may, that it's a flawed measure, you know,
10 in the way it's constructed and conceived, you
11 know, because you can't adjust it by doing
12 something to the denominators.

13 DR. PACE: Because the denominator -
14 -

15 CO-CHAIR CROOKS: It's the wrong,
16 it's the wrong measure, to use this Kt/V
17 rather than a standard.

18 DR. PACE: Right. So what you're
19 saying is that the denominator includes
20 patients dialyzing three or four times. So if
21 they want to keep that denominator, then they
22 need to change the numerator to the standard,

1 or if they want to keep the numerator, then
2 the denominator needs to pick probably three
3 times, because that's most frequent. Okay.

4 DR. FIVUSH: It's not a flawed
5 measure. This was the intent of the measure
6 developers, because I read the entire measure.
7 It was their intent. It's not flawed. They
8 clearly understood. We're talking about
9 under-dialysis. We had a whole conversation
10 about not being adequate.

11 They feel that the patients that get
12 it four times a week are the younger patients
13 who need it, the measure developers felt very
14 strongly that this was the correct measure,
15 that patients dialyzed four times a week
16 should additionally meet the single pool of
17 1.2 with each treatment.

18 Now I'm not -- I'm just saying
19 that's what the measure developers felt, they
20 clearly understood that they were using four
21 times a week in this measure though. When you
22 read through the whole text, and they felt

1 that if that were true, they would still want
2 those patients who were sicker or smaller to
3 get more dialysis, and each time to reach 1.2.

4 So I think the flawed part is that
5 we may not think that that's true. But the
6 measure developers felt that that was true.

7 So --

8 DR. LATTIS: So can I just ask our
9 pediatric experts, for those of us who are not
10 pediatricians and nephrologists. Based on
11 Alan's comments and based on your
12 understanding then, are you recommending
13 acceptance of this measure?

14 DR. FIVUSH: Well, the answer, and
15 there are other pediatric people in the room
16 and other people with experience. I feel that
17 this is a good and adequate measure for
18 pediatrics, and a starting point. I believe
19 that those patients dialyzed four times a week
20 will have a single pool Kt/V over 1.2.

21 I don't think it's a flawed measure.
22 I think it's an unusual measure, because I

1 don't think the adult population generally
2 dialyzes their patients four times a week, for
3 the reasons that we dialyze our babies four
4 times a week.

5 But I just am trying to separate
6 myself from again, as I sit here, I'm not the
7 measure developer. I'm the measure presenter.
8 I don't know --

9 DR. KASKEL: I think we have to
10 consider it as a subjective feeling about
11 neurocognitive development that you cannot put
12 into an equation and growth. Growth you can
13 make up for with some extra help. Not
14 neurocog.

15 We're very cognizant ourselves as to
16 the adverse effects of uremia and under-
17 dialysis in the infants and toddler's brain.
18 It may not be strong evidence. There's
19 suggestive evidence. There are some reports,
20 very under-studied. We also know that this
21 doesn't improve when you identify it.

22 So based on that, we work

1 aggressively to follow some guidelines, to
2 make sure we're doing adequate dialysis, just
3 like we do providing adequate nutrition. This
4 is all we have right now. That's it. That's
5 the measure, be it good or bad.

6 DR. VELEZ: Barbara, what happens if
7 we don't put a number and this measure fails?
8 I mean what harm have we done?

9 DR. FIVUSH: Well, I think if we
10 have a measure that says you have to measure
11 adequacy, but we haven't told them what the
12 minimal acceptance is, we're not fixing
13 anything. You're now measuring something, but
14 again, they may be now measuring in children,
15 but they still -- maybe they're not measuring
16 that because they don't know what to do with
17 it.

18 But at least if we know that it's
19 1.2 as a minimum, and they're not achieving
20 it, then they have to do something about it.
21 So I think that the risk is that we're going
22 to continue to under-dialyze some children.

1 DR. VELEZ: Even though we have to
2 look at each measure by itself, and we all
3 agree with that. My word of caution is also
4 when we go to the next one, nPCR, the
5 statement is made differently. We don't have
6 a good target; we're just going to measure.

7 DR. FIVUSH: But thankfully I'm not
8 presenting that measure.

9 (Laughter.)

10 DR. NALLY: But Barbara, if they're
11 going to collect data and measure things, it
12 might be possible, say, to have a clinical
13 guideline of 1.2. But I think there's a
14 difference between having this as a should
15 guideline, as opposed to a CPM. I think
16 that's the concern of some of the audience.

17 DR. FIVUSH: I would say, and I know
18 Karen and Peter, everybody's done a great job
19 keeping this contained, and I appreciate
20 everybody's time. I think I can only state
21 again that the pediatric community feels
22 critically strongly about having a minimal

1 Kt/V. I think every comment has been
2 important, thoughtful, and I think we need to
3 think about that as pediatricians.

4 Understanding everything, I still
5 think -- my feeling is still that we should
6 still have the minimum. But I absolutely
7 think every point is critically valid, I
8 think. So I guess I'm saying --

9 MS. PAVLINAC: This doesn't really
10 address whether it should be a CPM or not.
11 But I've been on the medical review board for
12 my network for years. This is the same
13 conversation we had in adult populations,
14 whether or not to even start measuring Kt/V,
15 whether it should be 1.0, whether it should be
16 1.2.

17 It may, yes. But in kids who are in
18 adult units, and there are no guidelines for
19 adult nephrologists to follow, I think that's
20 where those of us that work in pediatrics are
21 concerned. Just because, and we do know that
22 we're following adult guidelines. We don't

1 have great data. But --

2 DR. PACE: So the first question is
3 does it meet the criteria for importance to
4 measure and report.

5 (Committee voting.)

6 CO-CHAIR CROOKS: Okay. We have 13
7 yes and 7 no.

8 DR. PACE: Okay. Moving on to
9 scientific acceptability of measure
10 properties.

11 (Committee voting.)

12 CO-CHAIR CROOKS: 4 completely, 6
13 partially, 6 minimally and 4 not at all. We
14 have symmetry.

15 (Laughter.)

16 DR. PACE: Okay. Next, usability.

17 (Committee voting.)

18 CO-CHAIR CROOKS: 4 completely, 12
19 partially, 4 minimally. Symmetry is again
20 achieved.

21 DR. PACE: Okay, and next is
22 feasibility.

1 (Committee voting.)

2 CO-CHAIR CROOKS: Results for
3 feasibility, 7 completely, 10 partially and 3
4 minimally. DR. PACE: Okay, and
5 lastly, do you recommend for endorsement?

6 (Committee voting.)

7 DR. PACE: Okay.

8 CO-CHAIR CROOKS: Another close one,
9 11 yes, 9 no.

10 DR. PACE: Okay.

11 CO-CHAIR SCHONDER: All right then.
12 We'll move on to the next measure, 1425.

13 Jessie?

14 Measure No. 1425

15 MS. PAVLINAC: I can hardly wait for
16 this one. The title of this measure is
17 "Measurement of Normalized Protein Catabolic
18 Rate or nPCR for Pediatric Hemodialysis
19 Patients." Brief description, percentage of
20 pediatric patients less than 18 years old, in-
21 center hemodialysis. Irrespective of
22 frequency of dialysis, with documented monthly

1 nPCR measurements.

2 Let's see if I can go back. I lost
3 the --

4 CO-CHAIR SCHONDER: Right, sorry.
5 We have a temporary glitch in the connection
6 to the screen, but you can go on.

7 MS. PAVLINAC: Okay, thank you. So
8 no testing has been done on this particular
9 measure, and the measure developers are saying
10 testing will be completed within 12 months.
11 So that means this would only be eligible for
12 time-limited endorsement.

13 To comment on the, that there is no
14 recommended value for nPCR, there is none, in
15 the data that is being presented, is that
16 there are recommended levels for protein
17 intake for different ages of children. nPCR
18 is a documented measurement of dietary protein
19 intake. So they're making the assumption that
20 if you know what the protein should be and you
21 get a low nPCR, then the child is not getting
22 adequate protein and that there is a relation

1 to nutritional intake and going along with
2 adequacy.

3 Let me go to my spreadsheet, because
4 I can at least talk about it. There are six
5 of us that evaluated. We're on the team that
6 looked at this more intensely. Out of that,
7 five out of six rated it as met the importance
8 testing, with one saying no.

9 Under scientific -- oh, what's the
10 -- I can't read, acceptability, 3 completely,
11 3 partially. So we were evenly divided on
12 that. Under usability, 1 partially, 5
13 completely; and under feasibility, 1 partially
14 5 completely; and the recommendation was
15 split. 5 yes, 1 no. What else should we, do
16 you guys want to know? We're trying to
17 shorten this one. Okay, cool.

18 CO-CHAIR SCHONDER: Okay. Any other
19 comments from the assigned reviewers? Okay.
20 Dare we open this up to the floor?

21 DR. KLIGER: I'd love to hear from
22 the no, why the no was a no.

1 DR. VASSALOTTI: I'm not a pediatric
2 nephrologist, and I wasn't, I reviewed as many
3 of these as I possibly could, because I wanted
4 to review them before I voted, and I didn't
5 think that the level of data was robust enough
6 to let this rise to the level of a performance
7 measurement.

8 That was my thought. I thought this
9 is more of a nutritional measure and not an
10 adequacy measure in the sense this is
11 something -- what about measuring serum
12 albumin, other potential things. So that was
13 my sense as an adult nephrologist who doesn't
14 have the experience that the others in the
15 room do. That was my sense.

16 MS. PAVLINAC: If you'd look at the
17 2006 KDOQI adequacy and the newly-revised 2008
18 pediatric nutritional DOQI, there was
19 discussion and some cited articles that
20 albumin was not an effective measurement, that
21 nPCR was. More, there was more evidence for
22 that.

1 DR. VASSALOTTI: I know that in the
2 previous iterations, we talked about serum
3 albumin for adults and that perhaps not being
4 actionable. So I understand that. But still
5 I was concerned about the level of that
6 threshold. I guess I would ask you in that
7 KDOQI guideline, what was the level of
8 evidence, you know, that was reviewed. To be
9 honest, I don't remember.

10 MS. PAVLINAC: I don't either.

11 DR. VASSALOTTI: But was that a high
12 level of evidence or was that --

13 MS. PAVLINAC: I'm sure it wasn't,
14 for the same very reason, and please people
15 from, that reviewed this, jump in. The same
16 very reason that many of the other pediatric
17 recommendations are not, because there haven't
18 been adequate -- there have not been an
19 extensive amount of study.

20 DR. WOLFE: It is observational
21 data. It is Level 2 data supporting it.

22 MS. PAVLINAC: Yes, yes.

1 DR. WOLFE: And the TEP's
2 recommendation was not that this was a stand-
3 alone measure, but it would be used in
4 conjunction with Kt/V, to help improve the
5 appropriate targeting of Kt/V. I'm a
6 statistician, so I really don't know what I
7 just said, but that's what the TEP said.

8 MS. PAVLINAC: Yes, and --

9 DR. RAMIREZ: And Bob, maybe I can
10 add to that, because I was part of that. I
11 was in the TEP. Basically the rationale for
12 this by the TEP, first of all, this was the
13 most divided measure amongst all the adequacy
14 measures.

15 But the thinking of pediatricians
16 was that adequacy of dialysis in the pediatric
17 population is more than just solute clearance.
18 Given that nPCR is readily available from urea
19 kinetics, it's not that difficult to collect
20 this piece of information.

21 DR. PACE: Any other comments from
22 the group?

1 DR. FIVUSH: I would just say to
2 Joseph's point, I think it is the level of
3 evidence was not first-line. But I think
4 albumin is really not panning out in
5 pediatrics, for a multitude of reasons,
6 besides a lot of our kids are nephrotic.

7 There's so many reasons why we can't
8 seem to use albumin in a way that tells us
9 about nutrition. So I think the intent was to
10 have something that would help us with that.

11 DR. KLIGER: So if I'm running a
12 dialysis unit, and I'm now urged by the
13 quality measure to be measuring nPCR, what do
14 I do with that?

15 DR. KASKEL: We usually look at that
16 in combination with the other variables.
17 That's what we do. Again, a composite score,
18 overall assessment of what we think is good or
19 not good prescription.

20 DR. BERNS: I really have the same
21 problem. I was not certain what's actionable
22 when you have that measurement, and what the

1 standard is, and the impact of Kt/V. It gets
2 back to what we talked about. You're asking
3 somebody to measure and it's not the same
4 measure, but nothing beyond that.

5 DR. KASKEL: I think because
6 nutrition is such an important part of some of
7 these growing or not growing patients, that we
8 use it with the other factors, to determine if
9 overall we're providing adequate nutrition.
10 We don't use the albumin in and by itself. We
11 know we can't.

12 We have to assess chronological
13 parameters. They take three to six months to
14 determine any significant change in length or
15 weight that's significant. That's just
16 another added factor, without a strong
17 evidence-based support, that this is the major
18 determinant.

19 CO-CHAIR CROOKS: I have a little
20 concern about usability. You know, I think as
21 a nephrology fellow and as a nephrologist, it
22 took me a while to get my head around nPCR,

1 you know, what it really means, and what --

2 You know, and so if this is going to
3 be a national voluntary consensus standard,
4 and I'm in Lisa's chair and I hear that my
5 patients, the patients who are paying for it
6 are getting an inadequate nPCR, what does that
7 mean, you know. Does it, you know. So on the
8 usability by the public, I think it may not
9 meet the test.

10 DR. LATTS: Although I do like the
11 idea, you know, as Fred sort of suggested, of
12 starting with this and maybe moving to a
13 composite measure down the road, that sort of
14 gives an adequacy of dialysis composite
15 measure.

16 CO-CHAIR CROOKS: So you're not all
17 that uncomfortable with it, as long as you
18 know it's related to nutrition and adequacy.
19 Okay.

20 MS. PAVLINAC: From a renal
21 dietician perspective, hanging your hat on an
22 nPCR versus an albumin, you're going to get

1 beat up on that you can't effect at all with
2 nutrition or dietary protein intake. It makes
3 some sense.

4 DR. JACKSON: We've been doing an
5 internal quality improvement project on
6 nutrition, and the more I've read about this,
7 the more nPCR becomes important in our adult
8 population, not only for low levels but also
9 high level. I think we're over-promoting
10 protein. We give them extra phosphorous and
11 sometimes their albumin is low for other
12 reasons.

13 But there is data in the adult
14 population that protein catabolic rate
15 correlates with mortality, whereas albumin
16 does not. This measure makes a lot of sense
17 to me, whether -- it's going to be debatable
18 whether it's a level of performance measure.

19 But I think, I would think if I were
20 a pediatric nephrologist, that this would be
21 a very important thing to know about in a
22 patient in a composite sense.

1 CO-CHAIR SCHONDER: Any other
2 comments? Are we ready for a vote? Okay.

3 DR. PACE: All right. We'll start
4 with importance to measure and report.

5 (Committee voting.)

6 CO-CHAIR CROOKS: 14 yes, 6 no.

7 DR. PACE: Okay. Next is scientific
8 acceptability of measure properties.

9 (Committee voting.)

10 DR. PACE: Okay. Voted? Push
11 again, I guess.

12 (Off mic comments.)

13 DR. PACE: Well, we can't force
14 people to vote, but we --

15 (Laughter.)

16 CO-CHAIR CROOKS: But we know who
17 you are.

18 DR. PACE: All right.

19 CO-CHAIR CROOKS: So 3 completely,
20 13 partially, 4 minimally. That's a 13,
21 that's right.

22 (Off mic comments.)

1 DR. PACE: Yes, okay, all right.

2 Next is usability.

3 (Committee voting.)

4 CO-CHAIR CROOKS: 6 completely, 7
5 partially, 6 minimally, and one not at all.
6 That's 21. No, that's right. Sorry.

7 DR. PACE: Okay. Next is
8 feasibility.

9 (Committee voting.)

10 CO-CHAIR CROOKS: 7 completely, 11
11 partially and 2 minimally.

12 DR. PACE: Okay, and finally do you
13 recommend the measure.

14 (Committee voting.)

15 CO-CHAIR CROOKS: We have 12 yes and
16 8 no.

17 DR. WOLFE: There's a trend.
18 They're going to be smart.

19 (Laughter; off mic comments.)

20 CO-CHAIR SCHONDER: All right. So
21 moving to the next category of measures,
22 starting with anemia, and we'll start with

1 Measure No. 1426, "Assessment of Iron Stores,"
2 and Jeffrey will present that.

3 Measure No. 1426

4 DR. BERNS: So the description of
5 the measure is a percentage of all adult
6 dialysis patients for whom serum ferritin and
7 transferrin saturation percentage are measured
8 simultaneously at once during a three-month
9 study period.

10 Just to give you a sense of the
11 vote's importance, there were five
12 evaluations. I'm sorry. Five evaluations.
13 Three said it was important, two did not. On
14 scientific acceptability, one was completely,
15 two partially and two not at all.

16 Usability, two completely, one
17 partially, two not at all. Feasibility, five
18 completely, and recommendations were three yes
19 and two no. There were only three specific
20 comments, one of which was this does not meet
21 the importance and scientific acceptability
22 criteria.

1 While the recommendation may be good
2 practice, it's not supported by meaningful
3 evidence and there's no evidence linking this
4 process with improvement in clinical outcomes,
5 or even intermediate outcomes such as iron or
6 ESA utilization or hemoglobin levels.

7 The other comment much more
8 succinctly said this measure adds no value.

9 The third suggested that maintaining
10 hemoglobin and static iron levels within
11 certain ranges helps reduce negative events,
12 but can result in more intensive care and
13 resource utilization.

14 The evidence that was proposed in
15 support of this measure really had much more
16 to do, or actually had only to do with
17 hemoglobin level measurement and hemoglobin
18 levels, and had very little to do with the
19 impact of measuring TSAT and ferritin levels.

20 CO-CHAIR SCHONDER: Any other
21 comments from the assigned reviewers? Any
22 from the floor? Good.

1 CO-CHAIR CROOKS: That's easy.

2 CO-CHAIR SCHONDER: Wow. I guess
3 we're getting tired. Okay. Well, I guess
4 we'll call for a vote.

5 DR. PACE: Going once, going twice.
6 Well, I guess there just is a lack of
7 consensus among the measure reviewers. I
8 would think there would be more discussion.

9 CO-CHAIR CROOKS: Can we hear from
10 one pro and one con maybe, or a little more
11 about the -- I'd like to hear more about the
12 evidence, their assessment of the science
13 supporting this or not supporting it.

14 DR. BERNS: I'll address the con
15 side, and make a couple of points. One, that
16 the inter-patient month to month variability
17 in these measures is high. The use of these
18 to accurately predict iron stores in patients
19 is low, and this doesn't specify any ranges.
20 It just simply says "measure." So we get sort
21 of maybe back to the issue that we talked
22 about before. We could have a different

1 debate about specific numbers. But since
2 there's a lack of clarity as to what the
3 numbers ought to be, to have a performance
4 measure simply saying "measure" didn't seem to
5 make a whole lot of sense to me.

6 It's feasible. It's obviously
7 doable. It's easy to do, to assess this. But
8 I think it's very difficult to translate this
9 into any meaningful clinical practice outcome.

10 This isn't measuring hemoglobin,
11 it's not measuring ESA utilization, and the
12 impact of therapy positively, giving more
13 iron, and negatively, giving less iron, all
14 have implications that I think make this a
15 very nuanced issue.

16 CO-CHAIR SCHONDER: Ruben.

17 DR. VELEZ: I'm one of the yes, but
18 I think Jeffrey summarized it very well. This
19 is a process measure, and it just talks about
20 measuring, measuring something that in the
21 clinical world we've been measuring for a long
22 time.

1 There's no clinical strong data
2 about having to do them both on the same day.
3 We heard some comments earlier today about
4 that. But it's a practice that is being done
5 out there quite frequently, and again, this is
6 a process measure and we're just measuring.
7 It's not assigned to any kind of outcome at
8 this point.

9 MS. ANDERSON: I think my concern,
10 and I was one of the no voters, was because of
11 the simultaneously. I don't think that adds
12 any benefit to the measure whatsoever.
13 There's no evidence that says that they have
14 to be simultaneous. So I didn't support the
15 measure.

16 CO-CHAIR CROOKS: While this has to
17 be evaluated on its own, just a reminder that
18 there is an endorsed measure for iron
19 sufficiency, and that is the 0252 from last
20 go-round, Assessment of Iron Stores.

21 I think this is based on a TSAT
22 value, I don't want to be -- I don't want to

1 take time to read it all for you now, but my
2 point being that this is, if you looked at
3 this alone, you might say well, there's no
4 other way -- there's no other metric related
5 to iron stores for adults, and in fact there
6 already exists one. One already exists.

7 DR. KLIGER: Can I raise a broader
8 issue? We're looking here at each individual
9 proposed measure, and looking at the
10 characteristics of that measure. I want to
11 raise a broader question. Do we really need
12 more measures in anemia in ESRD?

13 I'm not sure how we factor that into
14 our thinking and voting here. There have been
15 many in nephrology who believe that our focus
16 on anemia has been large and time has passed
17 that by.

18 That is that there are many more
19 important areas for dialysis providers and
20 patients and others to be focused and spending
21 time on, particularly given recent data that
22 in many ways turns on its ear the way we

1 thought about the treatment of anemia.

2 So I'm not sure how to factor that
3 in as I'm diving into this particular measure.
4 Do we really need more anemia measures at all?

5 CO-CHAIR SCHONDER: Well, I think
6 one thing is that this measure was intended to
7 replace the 0252; is that correct? Is that
8 correct?

9 CO-CHAIR CROOKS: Yes, that's
10 correct.

11 CO-CHAIR SCHONDER: 0252 is an
12 assessment of iron stores. This is the
13 approved measure from 2008 that looks at the
14 percentage of adult hemodialysis, HDPD
15 patients prescribed in ESA at any time period
16 who have, or who have a hemoglobin less than
17 11 in a one month study period.

18 So it actually put some parameters
19 on either ESAs or a hemoglobin.

20 CO-CHAIR CROOKS: Well, that's how
21 you define who's to measure. But the
22 numerator is that patients have either a serum

1 ferritin and percentage transferrin saturation
2 or a reticulocyte hemoglobin content, are
3 measured at least once in a three month
4 period. So that was the numerator.

5 DR. PACE: So the intention is that
6 this replaces the measure that we just talked
7 about. They're both about measuring versus
8 actual levels.

9 DR. NALLY: The question then I
10 don't understand, is the implication then that
11 they are removing ferritin from the metrics of
12 iron assessment?

13 CO-CHAIR SCHONDER: This one's
14 talking simultaneous measurement of ferritin
15 and TSAT.

16 DR. BERNS: Again, somebody made the
17 comment that there's no proven value of
18 measuring ferritin and TSAT simultaneously.
19 This lumps everybody together. So a patient
20 who's getting IV iron and a patient who's not
21 on an ESA, although it's not very common, but
22 he's not getting iron, has had stable iron

1 parameters for months and months.

2 I think we're seeing in clinical
3 practice and in other guidelines more of an
4 emphasis on evaluating trends, and the entire
5 picture of what's going on.

6 So this is what's happened in the
7 hemoglobin, the ESA dose, the iron dose, and
8 trends in ferritin, trends in TSAT, and this
9 doesn't get at any of that. It just says
10 measure it and you've met the standard, which
11 I think is not where we should be going
12 personally with standards at this point.

13 DR. PROVENZANO: Yes. Let me just
14 follow-up on what Jeff said, because it gets
15 to the process of what we're doing. The
16 necessity to replace one measure for another,
17 as we're doing here, has to take into
18 consideration the additional data and
19 knowledge, like Alan said, in anemia and how
20 we manage this. It has really changed in the
21 last 24 months.

22 So again, it gets back to do we

1 really need to replace what's out there now?
2 You know, maybe some of these things should
3 expire.

4 DR. PACE: From NQF's standpoint,
5 there's no requirement that, and that was part
6 of our discussion earlier, that as we get more
7 to intermediate clinical outcomes and
8 outcomes, do you need these measures at the
9 very distal end of assessment?

10 CO-CHAIR SCHONDER: Any other
11 comments?

12 DR. LATTS: Well, I was just going
13 to say, this measure doesn't seem to be closer
14 to an outcome than the current measure. Maybe
15 farther away even, I would argue.

16 CO-CHAIR SCHONDER: I just wanted to
17 bring up the comment about the simultaneous.
18 Is there any motion to put that caveat out
19 there? Will that change votes?

20 Okay, all right then. I think now
21 we can call for a vote.

22 DR. PACE: Okay. So we'll start

1 with importance to measure and report. Be
2 sure you hit your send button, because that's
3 what the tally's based on. If you registered
4 a response at all, it will come up in the
5 tally. Oh, okay. All right, go ahead.

6 (Committee voting.)

7 CO-CHAIR CROOKS: Well, our work is
8 done on this one. Is that right? We have 5
9 yes and 13 no.

10 DR. PACE: So, since it didn't pass
11 the threshold criterion, we will move on.

12 CO-CHAIR SCHONDER: Okay. So next
13 is Measure 1431, and Jeffrey's also going to
14 present that?

15 Measure No. 1431

16 DR. BERNS: Measurement of Iron
17 Stores for Pediatric Patients. The
18 description of the measure is the percentage
19 of all pediatric less than 18 years old,
20 hemodialysis and peritoneal dialysis patients,
21 prescribed in ESA at any time during the study
22 period, or who have a hemoglobin less than 11

1 gram per deciliter in at least one month of
2 the study period, for whom serum ferritin
3 concentration and percent transferrin
4 saturation are measured at least once in a
5 three month period.

6 There were five comments or
7 evaluations. Importance, three said yes, two
8 said no. Scientific acceptability, two
9 completely, two partially and one minimally.
10 Usability, two completely, one partially, two
11 minimally. Feasibility, three completely, one
12 partially, one minimally, and recommended
13 there were three yeses and two nos.

14 Some of the comments. One was that
15 since iron stores are involved in anemia
16 management along with ESA dosing, monitoring
17 the iron studies will improve quality of care.
18 Another comment was similar. It's easy to
19 report on the data readily available, and this
20 will have a dramatic impact on care of these
21 patients. The third comment was very similar.

22 Another comment was the current

1 description of the measure is misleading and
2 confusing. New, lower hemoglobin target and
3 not all patients tested, only ones with ESA.
4 Iron deficiency may be missed in other
5 patients.

6 Then the final comment was this is a
7 complex measure statement with unproven value
8 of the underlying parameters, i.e., value of
9 quarterly iron testing in this population, and
10 a hemoglobin level of 11 gram per deciliter.
11 Mixes patients on PD and hemodialysis, as well
12 as those who are on and off of ESA.

13 Iron therapy is not addressed, nor
14 trends in any of the lab tests. It's not
15 clear what fraction of all pediatric patients
16 would be included in the or statements. As
17 with other measures, the more important
18 response to measurement of ferritin and TSAT
19 levels is not part of the measure. You may be
20 able to guess who's comment that was.

21 And again, the evidence that was
22 used in support of this is primarily based

1 upon hemoglobin data and guidelines pertinent
2 to adult patients, or based upon evidence from
3 adult patients. Just frankly, I had a hard
4 time understanding what the numbers were here,
5 because it's such a complex measure of ands
6 and ors.

7 DR. VELEZ: On the information I
8 have, I have three nos and three yes. Is that
9 --

10 DR. PACE: Right, exactly. There's
11 -- we've updated this since we sent it out
12 last week, based on getting some new
13 evaluations. So the one you have on your
14 drive should be the most up to date.

15 CO-CHAIR SCHONDER: So it was
16 divided among the reviewers, so we should
17 probably -- if we can open this up like we did
18 for the last one. Somebody from the pro,
19 somebody from the con to speak to it.

20 DR. PACE: Could we hear from our
21 pediatricians again?

22 DR. KASKEL: We know that the

1 response to the ESA is going to be very
2 dependent on what we're dealing with. So we
3 try to avoid what we've learned also in the
4 adults, that we don't want to give too much
5 ESA if we can avoid it.

6 So we're looking to see adequate
7 assessment of stores or responses, so that we
8 can assess our response. If indeed, based on
9 what the stores are we don't see an adequate
10 response over time, then we have to reassess.
11 So it has a direct relationship to how we
12 manage the anemia.

13 DR. FIVUSH: I would just say
14 there's some, I think, fascinating new data
15 and thought that ESAs in and of themselves
16 have some pretty significant unintended
17 consequences in patients and particularly
18 we're seeing it, perhaps, in pediatric
19 patients.

20 There's some new data that suggests
21 that in terms of disparities, certain
22 ethnicities and races may respond less to ESAs

1 than others in pediatrics. And we're just
2 concerned that if you're going to be using an
3 ESA, that there's monitoring of the iron
4 stores.

5 I think it is a complex measure. I
6 think that's sort of the conceptual process,
7 that nobody really should be on, at least the
8 thought is in pediatrics, that no one should
9 be on an ESA unless we're assessing the iron
10 status, because perhaps we could minimize the
11 use of ESA if we adequately --

12 And there's also, I will tell you,
13 an aversion in pediatrics to using IV iron in
14 peritoneal dialysis patients, and there is a
15 lot of peritoneal dialysis patients in
16 pediatrics. The proportions are higher, and
17 the aversion is that those patients would be
18 getting, would not be able to get it through
19 the hemodialysis procedure.

20 So the concern is just that the
21 people are paying attention to the iron status
22 in pediatric patients. But it is a complex

1 measure. That's sort of just, I think, some
2 of the philosophically why.

3 DR. BERNES: Just a comment, that
4 this measure includes patients, pediatric
5 patients who are not on an ESA, as well as
6 those who are, and so somebody who had a
7 hemoglobin of less than 11 grams per
8 deciliter, at least one month. So that a
9 hemoglobin of 12, 12 and 10.9 and not an ESA
10 would fail this performance measure?

11 DR. FIVUSH: Only if you didn't
12 measure their iron stores. I mean there's
13 nothing, it's not about --

14 DR. BERNES: So there'd be no reason
15 for this. You could argue that there's no
16 reason for iron, to measure the iron stores.

17 DR. FIVUSH: I guess, I sort of
18 think one of the things that comes up in this
19 debate, which we haven't really -- which is
20 really hard to debate, is what the optimal
21 level of hemoglobin is in pediatric patients.

22 Maybe if we assume that in adults

1 it's between 10 and 12, we haven't assumed
2 that in pediatrics. I'm a little biased in
3 that, because we think that probably between
4 10 and 11 is very murky in pediatrics, again
5 because of growth and development and
6 cognitive issues.

7 So I think the concept of using the
8 11 here is that we would be considering that
9 to be low for a pediatric patient. So maybe
10 you would liken that, I'm still thinking about
11 this measure when I thought about it. You
12 would liken that in an adult to less than 10,
13 should they have their iron stores checked.
14 I think the way this TEP was going forward,
15 that under 11 they're still assuming those
16 same recommendations for 11 to 13, even though
17 there's guidance in the adults that perhaps
18 over 12 is problematic.

19 We have not really seen that in
20 children, because of access differences and
21 stroke problems. We haven't seen the issues
22 in over 12, and we're not sure of that because

1 of school performance, for example. So I
2 think there are two things in this measure
3 that are --

4 I think it's important in our
5 peritoneal dialysis patients, who I think that
6 they're addressing in part, that the anemia
7 guidance is unclear as well. I don't know, I
8 don't know how to address it as a group, but
9 I think that's --

10 DR. BERNS: Let me make one last
11 comment. Just in terms of the, I guess,
12 feasibility of this, I had a little bit of a
13 worry, which may or may not be correct, about
14 putting this data together. So you have to
15 collect data on ESA use during a three month
16 period, hemoglobin levels over three months,
17 iron use during three months.

18 Or not iron use, and then laboratory
19 tests. I'm not sure that all comes from the
20 same database. So there may be some concerns
21 about the reliability of the data, when
22 somebody has to start doing some of this by

1 hand, which I suspect in some facilities
2 anyway would be necessary.

3 DR. PROVENZANO: All right. Let me
4 just play devil's advocate. I mean obviously
5 we have more and more sophisticated IT
6 systems, and I don't know what it's like in
7 pediatrics. But I do remember 15 years ago,
8 as they pushed ESA levels right through the
9 ceiling, and you find out the iron saturation
10 is two and, you know, there's no ferritin.

11 Now we all sit amongst this room of
12 very high-performing individuals. I guess my
13 question is, except for Andy, the question is
14 is this a -- what's the problem right now in
15 pediatrics? Is this a problem? I mean --

16 DR. KASKEL: We have data, evidence
17 data showing both in CKD and ESRD that anemia
18 is quite prevalent in 30 to 40 percent of
19 patients under dialysis, if not more will be
20 anemic at the time. So it would be -- and
21 that CPD is not adequate.

22 Two, greater hospitalizations. We

1 have data on that. These are sicker patients.
2 There are gender and race effects that Barbara
3 mentioned coming out, disparities. There's a
4 gap of information that there's a gap in
5 knowledge, of very important information
6 regarding to outcome.

7 In order to manage the anemia more
8 appropriately and know what we're doing, it
9 can only come from these measures. If you
10 look at iron stores and this as a guideline.
11 I'll emphasize again that in the CKD
12 population, getting this treatment together
13 appropriately has a lot of difficulties.

14 CO-CHAIR CROOKS: Well, with due
15 respect, that's all important. But that's not
16 relating to the iron therapy, and even in the
17 submission itself, it says is there a benefit
18 from proving this, and 92 percent of patients
19 met the requirements.

20 So you know, what it says to me is
21 that most of the time, iron is being measured
22 anyway, so there's not really a gap. Then

1 when it comes down then to the 1C, which is
2 outcome to support the measure focus, they
3 don't even address that. They talked about
4 it's important to treat anemia. Well yes.

5 So even in their own application,
6 they're not supporting that this is important.
7 It's just not convincing at all, that there's
8 evidence to support that this is important
9 enough to merit a national voluntary consensus
10 standard.

11 DR. FIVUSH: I was just going to go
12 back to what the CTEP was -- were they
13 thinking it was the gap in the ten percent of
14 patients that weren't getting iron, or was it
15 more that they were thinking about the number
16 of patients. I know ones that entered
17 dialysis anemic or after 90 days were still
18 anemic. Do you have a sense?

19 DR. MESSANA: Both Bianca and Dr.
20 Warady are on the line. So if you'd like them
21 to address it, they could.

22 DR. RAMIREZ: I'll go a couple of

1 sentences and I'll turn it over to you. One
2 of the points that there's a study, at least
3 one or two studies in the pediatric
4 population, that showed that ESA therapy will
5 not result in an increase in hemoglobin, if
6 iron stores are deficient.

7 So basically that's one point. So
8 it's the leading cause of non-response to ESA
9 therapy. So I think that's one reason why the
10 TEP felt it was important to measure iron
11 stores in this population. The cut-off of 11,
12 it's a little bit complex, and it's related to
13 later on we'll talk about the proposed cut-off
14 for hemoglobin level.

15 The thought for 11 actually was
16 partly based on the NHANES cut-off point for
17 normal hemoglobin levels in the normal
18 pediatric population. But I'll turn it over
19 to Brad, if you have something else to add.
20 Dr. Warady?

21 (No response.)

22 DR. RAMIREZ: He may have hung up.

1 But in essence, the TEP felt that to be
2 effectively able to manage anemia, you need to
3 ensure adequate iron stores.

4 CO-CHAIR SCHONDER: I did want to
5 point out Jeffrey's comment about the
6 feasibility. Going back to Measure 0252, it's
7 an endorsed measure where we are actually
8 looking for all three of those parameters in
9 that measure. So I don't know how feasible it
10 is in the pediatric population, but there is
11 an adult measure that does look at all of
12 those.

13 DR. MESSANA: All the data elements
14 required to calculate this measure are in the
15 CROWNWeb business requirements document,
16 moving forward. So all the data elements are
17 available.

18 DR. BERNS: Just maybe reflecting my
19 ignorance here. What percentage of pediatric
20 dialysis patients are going to be in CROWNWeb?

21 DR. MESSANA: Well, my understanding
22 is that pediatrics are included.

1 DR. FIVUSH: Full. It's 100 percent
2 of the pediatric universe under the age of 18.
3 In the adults, it has up to date been, at
4 least with the CPM project, a random sample.

5 But it's always been 100 percent of
6 pediatric patients. I guess what the intent
7 as CROWNWeb emerges, it will be 100 percent of
8 all patients. But pediatrics data has been
9 entered for years.

10 DR. WARADY: Hello.

11 CO-CHAIR SCHONDER: Dr. Warady.

12 DR. WARADY: Yes.

13 DR. RAMIREZ: Yes. So I called on
14 you earlier. I think we'll have to --

15 DR. WARADY: Oh yes. I heard you.
16 They couldn't hear me.

17 DR. RAMIREZ: Okay.

18 CO-CHAIR SCHONDER: Go ahead and
19 comment. On the phone, if you want to go
20 ahead and comment?

21 DR. WARADY: Yes. This is Dr.
22 Warady. Can you hear me?

1 CO-CHAIR SCHONDER: Yes.

2 CO-CHAIR CROOKS: Yes.

3 DR. WARADY: Okay. Just a couple of
4 things to amplify what Sylvia said. One, the
5 target of 11 that's incorporated into the
6 measure, is based on NHANES. If one looks at
7 NHANES for all the different pediatric age
8 groups, that virtually all of them, the fifth
9 percentile for hemoglobin is above 11.

10 So I think sort of like Barbara
11 suggested, that 11, a value of 11 for children
12 really truly does define anemia, and that's
13 supported by the recommendations from KDOQI.
14 So that's where 11 comes from.

15 Then if one looks at hemoglobin in
16 the children, a paper by Amy Staples, which
17 looks at all the NAPRTCS data, has
18 demonstrated in the CKD population many of the
19 children are anemic. Now I can't tell you
20 whether it's due to lack of epo or lack of
21 iron, but many of them are anemic. As many as
22 70 percent of kids with CKD are anemic, which

1 is again defined by hemoglobin less than 11.

2 If you look at the USRDS data from
3 2009, which is actually the 2009 report, which
4 is the 2007 data, the mean hemoglobin for
5 children starting hemodialysis is 10. So
6 again, a substantial percentage of these kids
7 are anemic going in and starting dialysis.

8 So that's the issue and, you know,
9 as we all know, epo is iron. So we have a lot
10 to address in pediatrics to optimize anemia
11 management, and thus the measure was trying to
12 address the important issue of iron to that.

13 CO-CHAIR CROOKS: At the risk of
14 repeating myself though, this is all well and
15 good, and this is an important issue, and it's
16 important, that there is anemia, it needs to
17 be managed.

18 But there's nothing that's been
19 presented here or really much in the
20 discussion about this particular metric, that
21 to measure this iron levels has an impact, or
22 that there's a gap. It's being done in most

1 patients, and I presume if it's being done,
2 it's being used in management.

3 I have not been convinced that
4 there's importance to this, that it's going to
5 either improve care, that there's a gap or
6 that they're even able to bring to bear any
7 evidence that this is the right thing to focus
8 on.

9 DR. LATTS: I just have a question
10 about CROWNWeb and apologize for my ignorance.
11 Are all dialysis patients entered in CROWNWeb,
12 or only those on Medicare?

13 DR. FIVUSH: So in pediatrics, even
14 though we're predominantly not a Medicare
15 population, 100 percent of pediatric patients
16 are entered, regardless of their insurer.

17 DR. LATTS: How do get around HIPAA
18 for that, in terms of using the data?

19 DR. PACE: Is there someone from CMS
20 that's on the line that can answer that
21 question, about are facilities required to
22 enter all patients, or only those covered by

1 Medicare in the CROWNWeb? Okay.

2 DR. NARVA: I'm a little confused,
3 because we seem to have different criteria for
4 different measures, and whether -- I
5 understand there's no point in having a
6 measure if there's no gap. But then the other
7 issue that we seem to be sort of ambivalent
8 about is whether we measure things for which
9 there's not an evidence-based target.

10 So we just pretty relatively
11 enthusiastically endorsed the NPCR for kids,
12 but we're not looking at this. I have no idea
13 what we're going to do when we get to
14 phosphorous. So you know, we have to be
15 consistent, or at least have some philosophy,
16 I think.

17 The other thing which is, maybe it's
18 because I'm kind of jaded, but it seems --
19 it's interesting that at the same time that
20 funding has occurred, we're using much
21 different standards than we did three years
22 ago, in terms of measuring things.

1 That may or may not have to do with
2 the bundling process. But I think if we
3 withdraw on some of these measures that we
4 previously endorsed, we probably need to
5 explain to the public that we're just not,
6 that there's no connection, or if there's some
7 other explanation.

8 DR. PACE: And I'll just mention
9 that, just within the scientific world, in
10 terms of clinical science, our measurement
11 world has also evolved, and we're becoming
12 more stringent on actually applying the
13 criteria that we have.

14 So I mean and basically all the
15 decisions about recommending or not
16 recommending measures should be grounded in
17 the criterion. There should be a
18 justification for that, as well as continuing
19 endorsement or withdrawing endorsement.

20 I think your point about perhaps
21 looking at things inconsistently, I think you
22 know, it's something the Committee should

1 think about, and you know, certainly have more
2 discussion on.

3 CO-CHAIR CROOKS: Yes. If I can
4 just comment too. What you're talking about
5 is the importance issue, you know, the very
6 first thing.

7 Is it important enough to make a
8 standard on, and if you read and think about
9 what they're asking for, they really are
10 asking for some science to support it, that
11 it's not just something that everybody does or
12 everybody should do, but there's some
13 rationale for making this a national voluntary
14 consensus standard. This is an important
15 pedestal to hit.

16 And you know, we can all sit around
17 and say we agree. But on the other hand, it's
18 written in such a way that if we as a
19 committee say well maybe we recognize there's
20 not enough science. But we think it's so
21 important, it meets the importance criteria.
22 Okay. Then they'll let us get away with it,

1 you know, for now.

2 But you know, I'm trying to, as a
3 -- maybe it's because I'm chairman of the
4 steering committee, co-chair of the Steering
5 Committee, but I want us to try to go for a
6 higher level, and say this is not just
7 something we all think is a nice thing to do
8 or something we all do. I think it's the
9 right thing to do.

10 But let's really base it more and
11 more on evidence. We were guilty through the
12 KDOQI process, perhaps, of publishing too many
13 guidelines that were not evidence-based, and
14 we paid a price and we're still kind of
15 thinking that was a mistake. I don't want to
16 repeat history.

17 We should really be trying to get,
18 you know, more and more science-based in our
19 decision of is it important enough, in my
20 opinion.

21 DR. LATTS: I guess the way I'm
22 thinking about this though, frankly is that

1 for me, the bar is lower in the pediatric
2 population. Given the state of the science,
3 given the state of performance measurement in
4 pediatrics, which is, my understanding is
5 minimal, and given the need for performance
6 measurement, I am, as I look through these,
7 holding the adult measurements to a higher
8 standard than the pediatric measurements.

9 DR. JACKSON: In looking at the
10 endorsed measure, 0252, and comparing it to
11 this one, it seems that the differences are
12 that the new proposed measure omits the use of
13 reticulocyte hemoglobin content and changes,
14 takes out the -- I think it takes out the
15 peritoneal dialysis population. Are those the
16 two major differences?

17 DR. PACE: That's an adult measure.

18 DR. JACKSON: Oh, I'm sorry correct.
19 You're right, you're right.

20 DR. PACE: That's an adult measure.

21 DR. JACKSON: But if we don't have
22 this measure, then there would be, there's no

1 other existing measure about measurement of
2 iron stores in pediatrics; correct? I'm just
3 asking a question for clarification. Okay.

4 DR. KASKEL: I will just add that
5 although it's not part of the measure, the
6 concept of epo resistance is not brought up
7 here. We do have potentially some unique risk
8 factors for resistance to epo, even with
9 adequate levels.

10 So there's a whole host of factors
11 that may account for the presence of anemia
12 that we haven't understood yet. We are
13 obviously not measuring the resistance factors
14 yet, but one identifiable one is the iron
15 store.

16 DR. BERNS: Again, if I can comment.
17 Again, I think the issue may be you need
18 something around anemia, hemoglobin
19 monitoring, hemoglobin measurement or ideally
20 responses to hemoglobin that you're unhappy
21 with. This is something very different, and
22 again -- I'm sensitive to the issue about

1 pediatrics. I was a child once and had some
2 of my own.

3 (Laughter.)

4 DR. KLIGER: I am not so sure.

5 DR. BERNS: I'll bring a picture
6 next time. But again, I'm struggling with
7 this issue about these are performance
8 measures. These are setting standards of
9 care, and this is very different than an
10 opinion-based, clinical practice
11 recommendation or a wishy-washy, partially
12 evidence-based clinical practice guideline.

13 I think there is a value for those,
14 and I think that what we went through with
15 KDOQI and we're going through now with KDIGO
16 has value. But it's a very different piece of
17 work, and it has a very different impact on
18 the community, I think, than this does, if
19 it's branded as a performance measure.

20 CO-CHAIR SCHONDER: Any other
21 comments? Oh Karen.

22 DR. PACE: Yes. I just want to

1 maybe restate some of the comments another
2 way, and that is I don't think anyone here is
3 saying that in clinical practice, people
4 shouldn't be measuring these things, and then
5 assessing it and determining how that factors
6 into treatment.

7 But all the comments that people
8 have made is, you know, we have kids with
9 anemia. We need to treat the anemia. There
10 are treatments for anemia. But that's not
11 what this measure is about. So I think the
12 comment about yes, you need to have measures
13 of anemia and treatment of anemia. The
14 question is do you need this as a performance
15 measure. So I think that's maybe just another
16 way of saying the same thing.

17 DR. FIVUSH: I think, you know
18 again, it's a complex measure and I think
19 these comments are important. But I do think
20 there are two themes, and I think one is yes,
21 there are children that are anemic. There's
22 a gap in care of ten percent. We want to be

1 sure that at least in those patients, we're at
2 the very least checking iron stores.

3 But I think this idea of having
4 children on erythropoietin who are not having
5 their iron stores checked is of more concern
6 to me as a physician. But even if it's ten
7 percent, that's a substantive number of
8 patients who are receiving an ESA.

9 Again, I think another unusual part
10 of this measure is that it has peritoneal
11 dialysis patients. I again would just
12 caution, that I think we're, and I think
13 people, physicians may be less willing to give
14 these patients IV iron infusion, and I think
15 we all know that there are many patients that
16 get oral iron supplementation. It just
17 doesn't -- it's just not enough.

18 But there's still a hesitation.
19 It's just I think sometimes in practice,
20 people continue to give ESAs. So I think
21 that's just one part of the measure that's
22 interesting, and it's important.

1 CO-CHAIR CROOKS: Call for a vote.

2 CO-CHAIR SCHONDER: Call for a vote?

3 Okay.

4 DR. PACE: All right. So we'll
5 start out with importance to measure and
6 report.

7 (Committee voting.)

8 CO-CHAIR CROOKS: 11 yes, 9 no.

9 DR. PACE: So we'll go on to
10 scientific acceptability of measure
11 properties.

12 (Committee voting.)

13 CO-CHAIR CROOKS: 3 completely, 12
14 partially, 5 minimally.

15 DR. PACE: Next is usability. Hit
16 your send button.

17 (Committee voting.)

18 CO-CHAIR CROOKS: 5 completely, 10
19 partially, 5 minimally.

20 DR. PACE: Feasibility.

21 (Committee voting.)

22 CO-CHAIR CROOKS: 7 completely, 10

1 partially, 2 minimally, 1 not at all.

2 DR. PACE: All right, and finally do
3 you recommend for endorsement?

4 (Committee voting.)

5 CO-CHAIR CROOKS: 9 yes and 11 no.

6 CO-CHAIR SCHONDER: We will, are we
7 close to our break time? Okay.

8 DR. PACE: Yes. Do you want to take
9 the break now?

10 CO-CHAIR SCHONDER: Do we take the
11 break now?

12 DR. PACE: Okay.

13 CO-CHAIR SCHONDER: I'm getting some
14 yeses. Okay. So we'll convene here in --

15 DR. PACE: Ten minutes.

16 CO-CHAIR SCHONDER: Ten minutes.

17 (Whereupon, the above-entitled
18 matter went off the record at 2:33 p.m. and
19 resumed at 2:48 p.m.)

20 DR. PACE: We're going to reconvene
21 and get started on Measure 1428. Is that
22 where we're at?

1 CO-CHAIR SCHONDER: Yes, we are on
2 1428, if we can come to order. Okay. So
3 start back up again on 1428, and Ruben will
4 present that for us.

5 Measure No. 1428

6 DR. VELEZ: We're going to present a
7 couple of measures, one on the high side and
8 one on the low side, that I know there's
9 absolutely 100 percent consistency, and we all
10 would agree with them hopefully.

11 Let's go first on the low side,
12 1428, Use of Iron Therapy When Indicated. This
13 is essentially the description as percent of
14 adult over 18 years old, dialysis patients,
15 and I have to add that they're both hemo and
16 PD, with ferritin of less than 100 TSATs or
17 less than 50 percent, again on simultaneous
18 measurements, who have received IV iron in the
19 following three months. This is a rolling
20 three-month study period.

21 I will add that there's a couple of
22 exclusions in the denominator. Patients have

1 to be present in the three-months study
2 period. Of course, patients who are allergic
3 to the IV iron products, and the other
4 exclusion is patients with a hemoglobin of
5 over 12, who did not receive ESA during the
6 three-month study period.

7 On the responses on the importance
8 of measurement and reporting, we have four yes
9 and one no. On the science, we have one, two
10 partially, two complete and one minimal.

11 On the usability, we have one
12 minimal, two partially, one complete and one
13 not at all. On the feasibility, we have two
14 complete, two partial, one not at all. On the
15 recommendations, we have four yes and one no.

16 If I may summarize some of the
17 statements, on the positive side everybody
18 agreed that yes, appropriate use of iron was
19 important, especially in its relationship with
20 the use of ESAs, and that a significant amount
21 of this data should be and can be collected in
22 the CROWNWeb system.

1 On the negative side, and this one
2 is half positive, half negative, said measure
3 has limited impact, but reasonable. Testing
4 has been mentioned to be completed but not
5 available for review, so really we didn't
6 have, it wasn't tested for reliability, at
7 least in the information we had.

8 A comment about the combination of
9 lab tests. I suspect on CROWNWeb and the iron
10 administration, that that has not been tested
11 or documented, a collection of this data
12 together.

13 Concern about the unintended
14 consequence of iron overload. Then a comment
15 about the reliability of ferritin and TSAT
16 from different labs have not been tested.

17 The no evaluation for the causes of
18 potential iron deficiencies, there was a
19 comment about the concern over the poor
20 evidence on peritoneal dialysis patients.
21 There was a question about collecting all this
22 data may be somewhat problematic, and again

1 the comment about the simultaneous testing of
2 both ferritin and TSAT on the same day.

3 CO-CHAIR CROOKS: Ruben or Kristine,
4 we should mention this only for time-limited
5 approval, because like I said, the data is
6 there to test for reliability, but it wasn't
7 done, and there's no validity testing.

8 DR. VELEZ: Right.

9 CO-CHAIR SCHONDER: Any comments
10 from the assigned reviewers? In general,
11 anyone?

12 MS. LeBEAU: I was one of the
13 assigned reviewers, and I'd just like to share
14 with the group, we talked a lot about anemia,
15 and just during the break, a couple of us
16 patients were talking.

17 You know, anemia is one of the
18 things that really affects how we feel. So if
19 we're coming back to how are we feeling, if
20 that's an important measure, it is critical
21 that we pay attention to this. Just from a
22 very practical standpoint, I'm a great epo

1 responder. My iron stores suck the basement.

2 So if I don't get continual IV iron,
3 my hemoglobin's going to drop. With iron, I
4 need it once maybe every six months. So I do
5 think, I think the way I have looked at these
6 as we've talked, it's hard not to do
7 comparative when you're thinking about this
8 and that.

9 So I think there were better ones
10 than some of the earlier ones we've talked
11 about. But I really do think that yes, it is
12 still important to pay attention to these
13 things. I think the things that make a
14 difference of how patients feel are three big
15 things: comorbidities, anemia management,
16 doing that well, and all the things that's in
17 there.

18 I know practicing nephrologists who
19 really don't a good job with iron therapy, but
20 they dose and dose and dose the epo and, you
21 know, how well dialyzed are people or how well
22 is their transplant managed. So there's my

1 soapbox, and thank you.

2 CO-CHAIR SCHONDER: Any other
3 comments?

4 DR. BERNS: I'll make a couple. One
5 is that there's no hemoglobin content in this
6 measure at all. So obviously the need to give
7 IV iron in this setting should be somehow
8 linked to what the hemoglobin level is.

9 So a TSAT of 90 percent or, I'm
10 sorry, a ferritin of 90 nanograms -- and a
11 hemoglobin of 13, you know, should -- probably
12 the patient shouldn't be getting IV iron. It
13 would in fact potentially be dangerous.

14 The inclusion of the transferrin
15 saturation of less than 50 percent is really
16 meaningless, because nobody has -- almost
17 nobody has a transferrin saturation above 50
18 percent. So it really doesn't exclude
19 anybody.

20 I'm a little unclear as to whether
21 this is picking out people who do a good thing
22 or a bad thing, right. So that, you know, you

1 could look at it and say if the ferritin's
2 below a 100, then it's a good thing because
3 they're getting IV iron, or they're getting IV
4 iron. If ferritin's below 100, they're not
5 getting enough iron and it's a bad thing.

6 So I'm not exactly sure what end of
7 the spectrum we're looking at or how this is
8 going to impact what we're doing with
9 patients, because it's going to identify
10 people who are doing a good thing and people
11 who are doing a bad thing potentially.

12 CO-CHAIR CROOKS: If I could
13 comment. I think the inclusion or exclusion
14 of hemoglobin is important, because if a
15 patient has a hemoglobin of 13, and a
16 transferrin sat or, I mean, a ferritin of 90
17 and TSAT of 45 percent, are we saying they
18 have to have IV iron? Is that what this is
19 implying? I have some trouble with that.

20 DR. FIVUSH: I would agree that the
21 exclusion of the hemoglobin level doesn't make
22 sense in this measure, in no way.

1 CO-CHAIR CROOKS: That doesn't make
2 sense?

3 DR. FIVUSH: No, there should --
4 there doesn't. There should be some reason
5 besides the level of iron to use them.

6 DR. BERNS: This is one of those
7 unintended consequences of performance
8 measures.

9 DR. MESSANA: There is a denominator
10 exclusion for hemoglobin.

11 CO-CHAIR CROOKS: Oh, there is a
12 denominator exclusion.

13 DR. MESSANA: This is 1428, correct?
14 (Off mic comments.)

15 DR. MESSANA: Correct. But I heard
16 the statement that there was no hemoglobin
17 exclusion.

18 (Off mic comments.)

19 DR. PACE: Lauren's going to put it
20 up on the screen. It's 2A.9 and 10.

21 DR. BERNS: It doesn't change my
22 comment.

1 DR. VASSALOTTI: So it's both mean
2 hemoglobin greater than 12 and did not receive
3 an ESA in the three month study period, is
4 that right?

5 DR. BERNS: That's the way I read
6 it.

7 DR. PROVENZANO: Yes. I think, just
8 to be succinct and getting back to Jeff, I'm
9 not quite sure what this is, what are we
10 trying to accomplish with this. With only a
11 denominator exclusion, it is unclear as to
12 what the goal of this measure is going to be,
13 and whether it's necessary in view of -- I
14 presume this is about anemia management, I
15 presume.

16 So question whether or not this is
17 really a necessary measure, considering the
18 other measures for anemia.

19 CO-CHAIR CROOKS: And also the
20 choice of 12, which is sort of kind of an
21 upper range for pushing it. Now is this
22 pediatric? No, this is adults. Yes. Maybe

1 it if was less than 10.

2 If somebody's less than 10, and
3 their indices indicate iron deficiency, yes,
4 they need IV iron. But if they're 11.5 and
5 they're just barely deficient or deficient in
6 one, not the other, I don't think it's an open
7 and shut case.

8 DR. PACE: So are there any
9 recommendations in terms of what would make it
10 a better measure in terms of the evidence for
11 these measures and what the indications are
12 for iron therapy?

13 CO-CHAIR CROOKS: Well, this is for
14 a limited time anyway, which maybe we
15 shouldn't loosen our criteria because of that.
16 But I think if the focus was to treat anemic
17 patients who are iron deficient with iron,
18 that would make more sense to me than to treat
19 patients who are in the treatment target
20 range, have to get iron.

21 DR. KLIGER: You know, it's
22 confounded obviously, because of I'm very

1 aware and listen carefully to what Kathe is
2 telling us, and for patients who are
3 prescribed ESAs, and where ESAs are being
4 pushed aggressively. Now with the bundle,
5 it's likely that that's going to change, but
6 that's at least the way it's been.

7 Assuring that iron deficiency
8 anemia, as liberally defined, makes some sense
9 to me. But I have a problem, as you do, with
10 the definitions that are here, and were this
11 a guideline that was really focused on the
12 treatment of clear iron deficiency anemia, I
13 would have an easier time approving that.

14 DR. JACKSON: Can you imagine
15 explaining this measure to your anemia
16 management nurse? I mean it's --

17 CO-CHAIR CROOKS: That goes to the
18 issue of usability too. In other words, can
19 you imagine explaining this to health plan
20 executives, why this is a national standard?

21 DR. JACKSON: As the developer, why
22 the TSAT of less than 50 was chosen, as

1 opposed to a lower number.

2 DR. MESSANA: I can tell you that
3 during the CTEP deliberations, they tried to
4 define the zones of iron deficiency that would
5 be unequivocal, that not even NQF would argue
6 with, and zones of iron overload that not even
7 the NQF would argue with.

8 The definition of a -- is ferritin
9 less than 100, with a TSAT below 50 percent.
10 They all agree with iron deficiency, because
11 of the ferritin less than 100.

12 Because of the ferritin less than
13 100, the fact that some people, as the
14 discussion, that some people who were
15 receiving IV iron or have recently received IV
16 iron, may have a high TSAT falsely elevated,
17 and the ferritin is still reflect a reduced
18 body iron store within the limits of that
19 test.

20 So that was, this was the CTEP
21 decision. This was how they defined iron
22 deficiency.

1 DR. BERNS: And having just reviewed
2 this literature, I think the only number that
3 I think is partially justifiable is a ferritin
4 less than 30, is virtually -- is synonymous
5 with iron deficiency, and anything above that
6 is not.

7 So that's probably the only
8 defensible number, I think, that one could use
9 in a performance measurement that is
10 absolutely iron deficient. But all bets are
11 off otherwise, I think, with every other
12 number of ferritin and TSAT.

13 DR. WOLFE: Thank you. That's very
14 useful feedback to us, because I think that we
15 were relying on the CTEP's evaluation, and
16 they did their evaluations and getting further
17 evaluations is useful.

18 It is -- in terms of the importance
19 in a cross-section from CROWN Web, there were
20 10,000 people in this deficient criterion with
21 the simultaneous being less than 50 and the
22 other criterion.

1 6,300 of them were being treated
2 with iron. 3,700 were not. So that's the
3 level of importance. There were 3,700 people
4 in the United States in this quadrant of iron
5 measurements, who were not receiving any iron.

6 DR. BERNS: But again, in the
7 absence of knowing what their hemoglobin
8 levels were, it's impossible -- that may have
9 been perfectly appropriate care.

10 DR. WOLFE: With hemoglobins five or
11 less.

12 DR. BERNS: Yes, but that may have
13 been perfectly appropriate to do that.

14 DR. WOLFE: Sure, and that's all I
15 know.

16 DR. LATTS: So if it had been less
17 than ten, would that be more meaningful to you
18 or not?

19 DR. BERNS: Again, I've changed a
20 lot in my thinking about this. I think trends
21 are important, and I think individualization
22 of care is important, and none of that comes

1 into play here.

2 I think if you have a patient who
3 has a hemoglobin that's below ten but a
4 ferritin of 90, does not mean that they're
5 iron deficient, and we have to remember that
6 exposing that patient to intravenous iron,
7 which this would sort of force us to do, has
8 a risk of bad events including death.

9 DR. LATTS: That actually was going
10 to be another one of my questions, because
11 this does seem to force you into IV iron,
12 which you know again, from the non-dialysis,
13 we do IV iron, you know, in someone who's at
14 extremis from anemia. We're very afraid of IV
15 iron. So it seems much more obviously common
16 in the dialysis population.

17 You'd never use oral iron. I mean
18 obviously in the hemo population, it's very
19 easy to do IV iron. But in the PD population,
20 do you do oral iron first or you just go right
21 to IV iron?

22 DR. BERNS: It probably -- Alan's

1 probably got a bigger --

2 DR. KLIGER: Well, I mean we started
3 looking at that, and probably half of chronic
4 PD patients do not respond adequately to oral
5 iron. Correct.

6 CO-CHAIR SCHONDER: Any other
7 comments? Call for a vote?

8 DR. PACE: Okay. We'll start with
9 importance to measure and report. Oh, this is
10 for a time-limited measure, remember, time-
11 limited endorsement.

12 (Committee voting.)

13 CO-CHAIR CROOKS: Well, we have only
14 5 yes and 15 no.

15 CO-CHAIR SCHONDER: All right. So
16 we'll move on then to 1433, Dr. Kaskel. 1433.
17 Measure No. 1433

18 DR. KASKEL: Description of all
19 pediatric patients less than 18 years old on
20 hemodialysis and peritoneal dialysis, with
21 hemoglobins less than 11 grams per deciliter,
22 and in whom simultaneous values assume

1 ferritin concentration was less than 100
2 nanograms per mL, and TSATs less than 20
3 percent, who received IV iron or were
4 prescribed oral iron within the following
5 three months.

6 The numerator statement is the
7 number of patients in the denominator who
8 received IV iron or were prescribed oral iron
9 in the three months following the first
10 occurrence of serum ferritin, less than 100
11 nanograms per mL, and transferrin, TSAT less
12 than 20 percent during the study period.

13 The denominator statement was all
14 pediatric patients, 18 years or less, on hemo
15 and PD, in the facility for the entire three
16 month period, with hemoglobin less than 11
17 grams per deciliter and in whom simultaneous
18 values of serum ferritin of less than 100
19 nanograms per mL, and TSATs less than 20
20 percent during the three month period.

21 The data source was CROWNWeb data,
22 obviously electronically obtained. So we have

1 the review here, and just to start off
2 overall, we had two in favor and three
3 against. So this will be an interesting
4 discussion.

5 The importance to measure and
6 report, we had basically some comments from
7 the no regarding the confusing data, and
8 difficulty in measuring this, as well as in
9 monitoring oral iron therapy or adherence to
10 oral iron therapy.

11 As far as the scientific
12 acceptability of the measure, we had one no
13 and it involved minimum value, how we're going
14 to measure this oral iron administration or
15 adherence. For usability, there was one
16 partial, the rest were complete. For
17 feasibility, we had again an issue of no, the
18 ability to measure the iron intake.

19 So we're left with overall, in
20 summary then, it looks like we had some issues
21 regarding a complicated measure to follow.
22 However, balanced by others that were in favor

1 of it, in terms of the importance of this
2 measure to evaluate outcome of anemia
3 management.

4 CO-CHAIR SCHONDER: Okay. So any
5 comments from the other assigned reviewers,
6 specifically regarding the differences in
7 opinions?

8 MS. RICHIE: Just to remind you,
9 this is a time-limited measure.

10 DR. FIVUSH: So, I reviewed the
11 measure. I would just say again the rationale
12 for the 11, again in pediatrics is that we
13 think that that may be anemia. We think it
14 does reflect anemia in a pediatric population.
15 So it's really, in looking at patients that we
16 think that are anemic, that are being
17 evaluated for their iron levels and being
18 treated appropriately.

19 And again, in our peritoneal
20 dialysis patients, and you had asked this
21 question, we really do push oral iron. We --
22 often it doesn't work. But we do really in

1 the younger kids I think sometimes do use more
2 oral iron than the adults, simply in terms of
3 percentages, because more of our patients are
4 on PD than in the adult population.

5 So use of oral iron is complicated.
6 I know there's some question about how do you
7 monitor that using oral iron? I think that
8 gets back to comments that were raised earlier
9 about adherence. You have to monitor that,
10 because if you're going to prescribe it, you
11 should be monitoring it.

12 So that doesn't bother me, that
13 there's a notation that that's part of the
14 measure. That's therapeutic iron, whether
15 it's IV or oral. So I think it is -- this
16 gets to comments about anemia, and again, just
17 making sure that patients that are anemic,
18 that are iron deficient, are being treated for
19 their iron deficiency.

20 Whether they're on an ESA or not,
21 they should be treated for their iron
22 deficiency. They should also potentially be

1 treated with an ESA, but they should certainly
2 be treated for their iron deficiency.

3 CO-CHAIR CROOKS: As opposed to the
4 last measure, where the criteria for who is
5 iron deficient and needing therapy was
6 arguable, I think in this case, this group of
7 patients that the measure is saying should be
8 treated, is a group of patients who should be
9 treated.

10 So I like that. I don't think
11 there's much scientific support for it, and
12 unfortunately there's not evidence for a
13 performance gap either. But I think, in my
14 mind, this is more important than the last
15 one.

16 DR. FIVUSH: Can I just say that I
17 know that it says that I voted no, and Rick
18 asked me if I voted no. I was doing so many
19 measures. I might have voted no, but I did
20 not mean to vote no.

21 (Laughter.)

22 DR. KASKEL: This is my friend.

1 DR. FIVUSH: No, no, because Jerry
2 asked me that as well, so I --

3 DR. KASKEL: Barbara, can I ask a
4 question? We have limited data in adults
5 about the sensitivity and specificity of the
6 TSAT and ferritin levels. What is the data in
7 children?

8 DR. FIVUSH: I think that's a great
9 question. I'm not sure that -- I'm not sure
10 that we know that. I think there's more and
11 more evidence, because we talked about the use
12 of albumin and what that really means.

13 I think definitions of iron
14 deficiency and what's a marker of inflammation
15 and what's not, in a patient who's transfused,
16 what does that mean.

17 But I think that if this measure
18 uses numbers as opposed to the 50 percent, the
19 20 percent that is more standardly accepted,
20 your comments on the last measure were very
21 interesting, that you reviewed the data and
22 that was your comment on what you felt would

1 be iron deficiency. That was new data to me.

2 So I can only say that this is sort
3 of the data that has been generally --
4 generally, 120 has been generally accepted as
5 a lower limit, and that -- simultaneously, and
6 that I don't have -- I think there's
7 provocative data to suggest that it's hard to
8 really understand iron and measurements of
9 iron.

10 But I still think those are
11 acceptable in this measure, understanding your
12 comments before.

13 DR. KASKEL: Okay, and can I add
14 that there is some early data on the score
15 number of pediatric patients looking at
16 cytokines, various cytokines in ESKD, and less
17 so in CKD.

18 One of the concerns that the
19 community has is that the cytokines interfere
20 with a number of important factors that are
21 accountable for anemia management, as well as
22 in areas of growth.

1 So we are just beginning to
2 understand the role of cytokines, and again
3 it's without a lot of data. But it's
4 provocative and it may even place more
5 emphasis on all these values, why we need to
6 be careful and proactive in the treatment of
7 the anemia.

8 DR. KLIGER: Jeff, I was just
9 wondering in reading the ferritin in
10 particular, if there was any discussion of
11 children and ferritin levels?

12 DR. BERNIS: No.

13 DR. KASKEL: There is some data on
14 age-dependent changes in ferritins, and we do
15 know that, in well children. I'm not aware of
16 data in the ESKD population. But it seems to
17 go up early on and then drops down and levels
18 off, and then peaks again during adolescence.

19 DR. KLIGER: So then one would
20 presume its predictive value in ESRD is pretty
21 poor?

22 DR. KASKEL: I know that you can say

1 that, that it's a poor measure in the
2 population. I mean you have again, a lot of
3 factors affecting it in the uremic patients,
4 and the role of cytokines and responsiveness
5 in the management of the anemia is unknown.
6 It's another marker. It's a marker.

7 It's just like proteinuria. It's a
8 biomarker. Is it a good one or bad one?

9 DR. FIVUSH: And I would say it's
10 really interesting, because there's now some
11 really provocative data that maybe Vitamin D
12 deficiency impacts inflammation, it may impact
13 iron levels and hepcidin may impact iron
14 reabsorption. But and I think those things,
15 we'll know more about them in several years.

16 But I think in this state, where we
17 are now, this looks like iron deficiency, and
18 this looks like we should treat it. I don't
19 think we know enough.

20 As a time-limited measure, you know,
21 as Karen's pointed out to us, I think for
22 right now we're not going to know that answer,

1 I don't think, for a couple more years.
2 There's just a lot, you know, the thought
3 about iron and how it's transported and how
4 it's affected by inflammation and I don't
5 know.

6 DR. BERNS: Just one more word of
7 caution. One could satisfy this performance
8 measure by prescribing oral iron and watching
9 a patient be iron deficient on that month
10 after month after month. That would still
11 look like a good guy in terms of this
12 performance measure. So we have to be careful
13 about that unintended consequence.

14 DR. LATTS: Well, just to comment on
15 that, and I agree, and I think, you know, if
16 we look through the NQF armamentarium we'd
17 find many measures where they're process
18 measures, and there's ways to game the
19 measure. I think that's part of the evolution
20 of measurement, is that we start with a
21 process measure that is imperfect and subject
22 to -- yes.

1 I was trying to think of a maybe
2 less manipulative word, but yes, and then
3 eventually we want to look, I would assume, at
4 the outcome, and really want to look at if
5 we're, you know, anemia, you know. But you've
6 got to start somewhere.

7 DR. BERNES: I'm not suggesting that
8 it was intentional manipulation. It just
9 would not ever be picked up as being bad
10 practice.

11 DR. LATTS: Yes, and I think that's
12 a problem with a process measure.

13 CO-CHAIR SCHONDER: Any other
14 comments? I just want to clarify again. With
15 the time-limited measurements, if the measure
16 developers do the testing, then that meets the
17 requirement. Then they automatically get the
18 three-year endorsement if they were to be
19 endorsed?

20 DR. PACE: Yes. Well, they would
21 get two more years. So it's not they'd get
22 three years from that point. They would stay

1 on the regular maintenance review cycle.

2 But in order to continue beyond one
3 year, as endorsed, they would have to submit
4 testing results that were acceptable, and the
5 testing in this case is primarily that it's a
6 reliable and valid measure, and that's what we
7 would want, and then they would continue the
8 endorsement for the remaining two years.

9 CO-CHAIR SCHONDER: Okay. But it
10 wouldn't necessarily -- the outcomes wouldn't
11 necessarily affect that, that if we found out
12 that we're measuring the wrong thing or
13 something?

14 DR. PACE: In what regards are you
15 referring to?

16 CO-CHAIR SCHONDER: I guess I'm
17 going to go back to Barb's comment, that this
18 would be a time-limited measurement. So we're
19 trying to figure out if this is -- at least
20 this is starting point, to build off of that.

21 DR. PACE: Right. The time-limited
22 endorsement is really to get that testing that

1 hasn't been done. The issues that you're
2 talking about in terms of if it's making a
3 difference, that's something that we would
4 look more at during the endorsement
5 maintenance review.

6 So, you know, to speak to some of
7 your comments, is that if we have measures
8 where, you know, the performance on this
9 measure is great, but we still have lots of
10 anemic kids, then maybe this measure isn't
11 what we need. But that's something that would
12 be accepted, that endorsement maintenance.

13 CO-CHAIR SCHONDER: All right.

14 DR. PACE: So any further comments?
15 Call for the vote. All right. So we'll start
16 with importance to measure and report.

17 (Committee voting.)

18 CO-CHAIR CROOKS: Okay. We have 13
19 yes and 7 no.

20 DR. PACE: And next will be
21 scientific acceptability of measure
22 properties.

1 (Committee voting.)

2 CO-CHAIR CROOKS: 4 completely, I'm
3 sorry. 11 partially and 4 minimally.

4 DR. PACE: Okay. Next will be
5 usability.

6 DR. LATTIS: Now if the testing
7 hasn't been done, what about that criteria?
8 Even if the testing hasn't been done -

9 DR. PACE: Well, on usability, okay.
10 I'll go back to that in a minute, but I don't
11 want to interfere with people. That's a good
12 question.

13 (Committee voting.)

14 CO-CHAIR CROOKS: We have 3
15 completely, 14 partially and 3 minimally.

16 DR. PACE: Before we go to the next
17 one, there was a question about if it hasn't
18 been tested, what were we asking you to rate
19 on scientific acceptability.

20 So the other big component of that
21 would be the measure specifications, that the
22 measure specifications are precise enough to

1 actually move to testing, you know, that it
2 could be. So precise specifications are kind
3 of your basic foundation for having a reliable
4 measures. So that's what --

5 All right. I think we're up to --
6 are we up to the final question? And this
7 would be for a time-limited endorsement, or
8 I'm sorry, feasibility. I'm sorry,
9 feasibility first.

10 (Committee voting.)

11 CO-CHAIR CROOKS: 7 completely, 11
12 partially and 2 minimally.

13 DR. PACE: And finally do you
14 recommend, and this would be time-limited
15 endorsement.

16 (Committee voting.)

17 DR. PACE: There is an abstain
18 option, so did people hit their send button?
19 We'll go ahead and let this run out, since it
20 seems like -

21 CO-CHAIR CROOKS: Okay. We have 14
22 yes, 6 no.

1 CO-CHAIR SCHONDER: Okay. So we're
2 back to Ruben for 1429.

3 DR. VELEZ: 1429.

4 CO-CHAIR SCHONDER: Microphone
5 please.

6 Measure No. 1429

7 DR. VELEZ: This is an outcome
8 measure. Again, a rolling three month
9 starting period, and it's "The Avoidance of
10 Iron and Iron Overload." The definition is
11 the percent of adult hemo and peritoneal
12 dialysis patients with ferritin over 1,200,
13 TSAT over 50 percent on simultaneous measured
14 during -- and who did not receive IV iron in
15 the three months after this measurement.
16 There's no exclusion on this measurement.

17 On the results, from the assigned
18 members, on the importance, four said yes, one
19 said no. On the science, there was three
20 partially, one complete and one minimal. On
21 the usability, we have three complete, one
22 partial, and one not at all.

1 On the feasibility, we have three
2 complete, two partials, and on the
3 recommendation, recommended, we have four yes
4 and one no. Summary of some of the comments
5 on the positive side. The importance of the
6 iron, critically important to avoid iron
7 overdose, and the potential consequence with
8 the new bundling.

9 On the negative side, lack of data
10 on at least mentioned on the response to
11 ferritin to illness or inflammation. Lack of
12 evidence-based information for the definition
13 of why we're calling iron overload.
14 Reliability of collecting some of the data,
15 and has to do with scheduling between the
16 blood work that will be done and the iron
17 administration.

18 CO-CHAIR SCHONDER: Any comments
19 from the other assigned reviewers? From the
20 committee in general?

21 DR. KLIGER: Can I just ask the data
22 on a performance gap of this measure?

1 DR. WOLFE: That's on page 25 of the
2 synthesis report, and the sample from CROWNWeb
3 2009, there are 40,000 patients that were high
4 on both of that, the iron compliments, and
5 40,000 who were high, and 10,000 of them did
6 not receive iron. 30,000 were continuing to
7 receive iron.

8 So if I'm understanding the
9 definition, there were 30,000 who were
10 inappropriately treated even though they were
11 high on both criteria, out of the 40,000 who
12 were high.

13 DR. KLIGER: And can I just -- may I
14 just ask another technical question, which is
15 shortly after the administration of
16 intravenous iron, the numbers not yet in
17 equilibrium, often are high.

18 Do we have any information about how
19 many of those 30,000 were judged that way
20 because the numbers were measured within a
21 month of receiving intravenous iron?

22 DR. WOLFE: I don't think I know

1 that. I'm not sure. I don't know it right
2 now. Let me just give an antidotal answer,
3 because in DaVita, we have looked at that,
4 because so many patients are on standing doses
5 of iron, either weekly or at some other
6 parameter, and we found that when you isolate
7 out similar criteria, the majority of them
8 were on some standing iron. So that there was
9 no stabilization of the ferritin, and
10 therefore it was suspect.

11 CO-CHAIR CROOKS: I'd like to ask
12 those, my colleagues with a little more
13 academic background and more knowledge of the
14 literature, what is the incidence of liver
15 biopsy-proven iron overload in hemodialysis
16 patients? I'm asking this because I'm
17 concerned about the importance of this.

18 Even though there were 40,000 who
19 met that criteria, you know, what is the
20 evidence that this is really doing damage, and
21 are we setting up a national standard to treat
22 one in a thousand or a one in ten thousand

1 kind of case? Does anybody have any
2 information about the incidence of biopsy-
3 proven hemochromatosis?

4 DR. BERNES: Yes. That's not really
5 been studied. There's one or two reports, I
6 guess, looking at imaging of hepatic iron
7 deposition, and one showed a relationship with
8 ferritin, that it had to be pretty high, and
9 the other did not show a direct relationship
10 with ferritin, but more of a relationship with
11 the amount of iron that had been given and the
12 duration of time, the length of the time the
13 patient had been on dialysis.

14 Again, if we're looking at evidence
15 basis for ferritin level, and it's very hard
16 to do. Virtually everybody who has a ferritin
17 above 300 has iron in their bone marrow. So
18 defining adequate iron is done two different
19 ways.

20 One is do you have iron in your bone
21 marrow. Everybody with ferritin, most people
22 actually about 100, but certainly above 300.

1 That's different than saying will you respond
2 with a higher hemoglobin if you've got more
3 iron.

4 That looks at sort of an artificial
5 measure. It looks at hemoglobin, but it
6 doesn't look at whether patients are better or
7 worse for having had their hemoglobin level
8 raised by being given IV iron.

9 But the answer to your question is
10 that we don't really have any, in the modern
11 era, any data that shows that there's a
12 precise link between high ferritin levels and
13 either liver deposition or any other adverse
14 outcome.

15 DR. VASSALOTTI: Those studies were
16 non-contrast CT to see if the liver lights up,
17 is that right?

18 DR. BERNS: MRI.

19 DR. VASSALOTTI: That's MRI, okay.
20 And what level of ferritin was that?

21 DR. BERNS: I don't remember the
22 specific numbers, but as I recall, both

1 studies were very high, went up to very high
2 ferritin levels. Typically, they don't look
3 at people who have ferritins of 100 and 200 in
4 these studies. But it would be at the higher
5 end of, you know, the higher hundreds. I
6 actually have them. I can look.

7 DR. FIVUSH: Jeff, can you go back?
8 In the last measure discussion, you said after
9 you reviewed the literature. Can you just
10 remind us what do you think, based on your
11 review in the adult literature, what would you
12 use as a definition for iron deficiency? What
13 did you say you felt comfortable with? I just
14 want to hear it.

15 DR. BERNS: So if you're looking at
16 bone marrow iron, virtually everybody who has
17 a ferritin below 30 is iron deficient.

18 DR. FIVUSH: Below 30.

19 DR. BERNS: Or who has no, virtually
20 no or very little bone marrow iron by iron --
21 some measures. There's different ways people
22 look at this. Most studies actually would

1 show that in CKD and hemo, and there's really
2 no data in PD patients, that almost everybody
3 who has a ferritin above 100 has adequate bone
4 marrow iron.

5 Now that's again very different than
6 saying will they respond with an increase in
7 hemoglobin and/or a decrease in ESA dose,
8 assuming either one of those are good outcomes
9 by getting more iron. But if you're really
10 focusing on is there iron deficiency,
11 sufficiency or overload, probably the best
12 number is 30 and below is really iron
13 deficient, 100 and above is probably iron
14 sufficient, based upon bone marrow iron.

15 DR. FIVUSH: And for TSAT? I mean
16 because we're talking about ferritin, which is
17 so confusing.

18 DR. BERNS: I have no idea. Nobody
19 really knows. It's really not very well
20 studied. Because remember, TSAT is really a
21 reflection of available iron for
22 erythropoiesis.

1 DR. FIVUSH: Right.

2 DR. BERNS: It's not a useful
3 measure of tissue iron stores.

4 DR. FIVUSH: Right.

5 DR. KLIGER: I just want to again
6 show my concern that without knowing the
7 relationship of these measures to intravenous
8 iron therapies, I don't know what we're really
9 measuring here.

10 DR. VELEZ: One last comment.
11 Again, looking at unintended consequences, we
12 look at everybody the same way. When you look
13 at subset of patients, especially now with our
14 percent of patients with chronic Hepatitis C,
15 the way you would look at the iron on them
16 might be somewhat different than some of the
17 initial studies have shown, that you can cause
18 more damage in the liver feeding them more
19 irons.

20 DR. FIVUSH: But to my adult
21 colleagues, this measure seems to me, I know
22 we've talked about anemia, the consequences of

1 anemia. But this to me by most standards,
2 would really be -- these are very high levels
3 of both TSAT and ferritin. But Alan, you're
4 saying you still --

5 DR. KLIGER: The measure of those
6 values the day after or the week after
7 administering intravenous iron, you get
8 tremendous variability and high numbers.

9 DR. FIVUSH: So I guess I think I'm
10 thinking conceptually the concept of iron
11 overuse is important, because we sort of
12 talked about unintended consequences of iron
13 overuse.

14 So would this measure be more
15 acceptable if somehow it was changed, so that
16 the iron, that the level of -- when you drew
17 the level or when you checked the iron level
18 of the ferritin or transferrin sat, was 30
19 days after the transfusion?

20 I'm just trying to figure out,
21 because I think the concept of overuse of iron
22 therapy, I think it's important.

1 DR. KLIGER: So I mean Barbara, I
2 agree with you. I think it would be useful to
3 have some way of measuring and decreasing the
4 overuse of iron. My concern is that as this
5 measure now stands, I'm afraid it will not do
6 that. And yes, some period of time, and I'll
7 defer to the experts about how long after
8 intravenous iron.

9 I mean the standard that we've
10 commonly used in New Haven has been a month
11 later. But my guess is it can be backed up to
12 a shorter period than that.

13 CO-CHAIR SCHONDER: Any other
14 comments?

15 DR. PACE: So do we need the
16 developer to explain the, if there's any
17 parameters around that data collection period,
18 or have they discussed that?

19 DR. VELEZ: I would like to ask. I
20 mean you're using a combination here now of
21 CROWNweb and what, billing data, is that
22 correct? Or --

1 DR. WOLFE: The numbers that I
2 reported about the fraction of patients are
3 all from CROWNWeb, because I don't think, we
4 certainly don't have it from the claims. I
5 don't believe it's in the CPM either. But
6 this was from CROWNWeb that I was just
7 reporting.

8 So these are mostly people who are
9 at a large dialysis chains, for whom we have
10 the -

11 DR. VELEZ: So you're saying the
12 CROWNWeb will include if I gave iron or not?

13 DR. WOLFE: It knows right now, yes.

14 DR. VELEZ: Okay, got it.

15 DR. WOLFE: And it includes these
16 other two measures as well.

17 CO-CHAIR CROOKS: To me, it feels
18 like this is a metric that evolved because
19 there's certain numbers that are going to be
20 coming across on CROWNWeb, and there's a
21 desire to avoid iron overload. And some fear
22 that we might cause hemochromatosis or liver

1 damage to some patients.

2 But we see that the time that these
3 numbers are being collected are, in other
4 words, there's not a break. Iron therapy
5 patients are getting it all the time. This is
6 just coming off the monthly lab data report,
7 I presume.

8 So we are not going to be able to
9 successfully impose a restriction. You have
10 a wait a month and then do an iron level.
11 We're going to have to use what they're
12 saying. This is the data we got. This is the
13 best you could come up with.

14 I think it's up to us to say well,
15 that's nice, but it's not good enough, because
16 it doesn't meet the importance criteria in my
17 view. This is a lot of work, and setting up
18 a national standard to treat a condition that
19 is rare or almost never happens, and that is
20 actual iron overload disease these days.

21 So that's my take on it, you know,
22 that they've got these numbers that are coming

1 across. They're looking for things to do with
2 them, and this is a, you know, a nice goal to
3 try to go for, but I don't think this one hits
4 the mark.

5 DR. BERNES: I also think that
6 there's a credibility issue. I think if we're
7 going to put a number in a performance
8 measure, it needs to be defensible, or very,
9 very important in the absence of an ability to
10 defend that number. I'm not sure that this
11 meets either of those criteria.

12 CO-CHAIR SCHONDER: We're getting
13 the call to vote.

14 DR. PACE: Right. So we will start
15 with importance to measure and report, and
16 again, this is a time-limited measure. So
17 when we get, if we get to scientific
18 acceptability. Okay.

19 (Committee voting.)

20 CO-CHAIR CROOKS: 9 yes, 11 no. DR.

21 PACE: Okay, move on.

22 CO-CHAIR SCHONDER: We'll move right

1 along then to Kathe for Measure No. 1424.

2 Measure No. 1424

3 MS. LeBEAU: This is the monthly
4 hemoglobin measure for pediatric patients. It
5 is a process measure. It is defined as the
6 percentage of all pediatric patients, that is
7 younger than 18 years of age, receiving
8 hemodialysis or peritoneal dialysis, who have
9 a monthly measure for hemoglobin.

10 In terms of the assessment of the
11 evaluators, the evaluators agreed that it was
12 -- that a method criteria, that it was a
13 demonstrated gap in care, and it could
14 potentially significantly improve the care of
15 pediatric patients.

16 Citing the standard and not
17 editorialize, but I thought this was a
18 staggering number. The NAPRTCS study, that 68
19 percent of pediatric patients are anemic, even
20 given the small sample size. So and I'm
21 sorry. I did my numbers before the update and
22 the evaluation.

1 Well, okay, well, do you want me to
2 use?

3 DR. PACE: You don't have to. I
4 mean basically we can just see that --.

5 MS. LeBEAU: Okay, okay. A
6 scientific acceptability of the measure was
7 divided. There was agreement that it was
8 precise and had face validity. There was some
9 question about the identification of
10 meaningful differences in performance as in
11 current use. Only 65 percent of the 317
12 facilities with pediatric patients reported a
13 hemoglobin value currently.

14 In usability, most of the evaluators
15 felt that it was meaningful, understandable
16 and useful to the needs of the intended
17 audience for decision-making, public reporting
18 and quality improvement.

19 But there was concern, because this
20 measure was only discernible, I'm sorry. I
21 can't read my own writing. Only described
22 percentage of tests done, not actions.

1 Feasibility, most of the evaluators
2 felt that it met the criteria, that there was
3 a concern that -- oh no, I'm sorry. Not a
4 concern. Most felt that it would be able to
5 collect the data electronically. I'm sorry.
6 As of my writing, all of the evaluators did
7 recommend the measure for endorsement.

8 The rationale for the measure, it's
9 generally well-based scientifically and has
10 great potential to be reliably reportable, as
11 it's a familiar data set and could result in
12 identification of those at risk for morbidity
13 associated with anemia.

14 CO-CHAIR SCHONDER: Any comments
15 from assigned reviewers or the Committee?

16 DR. KLIGER: Sorry. Can I just ask
17 again about specifically the performance gap
18 here? What percentage of pediatric patients
19 who are anemic do not have monthly readings or
20 any actual, I'm sorry probably any pediatric
21 dialysis patients, don't have monthly
22 hemoglobins measured?

1 MS. LeBEAU: Thirty-five percent.

2 DR. KLIGER: Thirty-five percent.

3 MS. LeBEAU: Yes, and that's across
4 the 317 facilities.

5 DR. LATTS: No. Wasn't that the
6 percent of patients that were anemic? That
7 was the percent of patients that did not have
8 a hemoglobin?

9 MS. LeBEAU: No. That was only 65
10 percent of the 317 -- I'm sorry. That's not
11 a percentage of patients of the facilities
12 reporting.

13 DR. KLIGER: Yes. I'm wondering
14 about the number of -- does the developers
15 know that?

16 DR. FIVUSH: I think that's from
17 NAPRTCS.

18 MS. LeBEAU: Yes.

19 DR. FIVUSH: So that's not the CPM
20 data. That's a great collaborative group
21 study centers that submit data on a voluntary
22 basis. But it's only pediatric nephrologists.

1 It doesn't have adult nephrology input. So it
2 would be nice to validate. That's a pretty
3 staggering gap to validate and see what the
4 gap is in the Arbor database.

5 DR. PACE: All right. Lauren's
6 putting up what was in the measure submission
7 under 1B, Opportunities for Improvement, the
8 summary of the data. Hemoglobin was reported
9 in less than three of the six.

10 DR. WOLFE: So I'm not sure I
11 understood the question then. On page 39 of
12 the recommendations report, in a six month
13 period, 29 percent of pediatric ESRD patients
14 had fewer than three hemoglobin values, and 11
15 percent had none.

16 DR. LATTIS: That's unbelievable.

17 DR. FIVUSH: Right. Six months.

18 CO-CHAIR SCHONDER: Call the
19 question. Any other comments? Okay. I think
20 we'll call for a vote.

21 DR. PACE: Okay. So we will start
22 with importance to measure and report.

1 (Committee voting.)

2 DR. PACE: Has everyone voted? All
3 right, go.

4 CO-CHAIR CROOKS: 19 yes, zero no.

5 DR. PACE: Okay. So we'll move on
6 to scientific acceptability of measure
7 properties.

8 (Committee voting.)

9 CO-CHAIR CROOKS: 15 responded
10 completely, 5 partially.

11 DR. PACE: All right, usability.

12 (Committee voting.)

13 CO-CHAIR CROOKS: 18 completely, two
14 partially.

15 DR. PACE: Okay, then feasibility.

16 (Committee voting.)

17 CO-CHAIR CROOKS: 18 completely, one
18 partially.

19 DR. PACE: And the last is recommend
20 for endorsement or not.

21 (Committee voting.)

22 CO-CHAIR CROOKS: It is -- it's

1 unanimous. 20 yeses. You won't see that very
2 often.

3 CO-CHAIR SCHONDER: All right.
4 We're on a roll now. Good momentum. So we're
5 down to our last anemia measure, Measure No.
6 1430, and Rick will present that.
7 Measure No. 1430

8 DR. KASKEL: So this is the
9 percentage of pediatric patients less than 18
10 years of age on hemodialysis and peritoneal
11 dialysis with ESRD of less than three months,
12 who have had a mean hemoglobin less than 10
13 grams per deciliter for a three month
14 reporting period, irrespective of ESA use.

15 The hemoglobin value reported at the
16 end of each reporting month, at the end of the
17 month, hemoglobin is used for the calculation.
18 The numerator, again was the number of
19 pediatric patients in this criteria,
20 irrespective of ESA use, and the denominator
21 again is all pediatric hemo and PD patients
22 with PSKD in the three months.

1 This is CROWNWeb electronic data.
2 So if we can look at the overall review for
3 importance, we had a unanimous group, I
4 believe, with one partial and all complete,
5 all yes, and in terms of scientific
6 acceptability of the measure, we had a total
7 here of three partial. The rest were
8 complete. Is that right?

9 And in terms of the usability,
10 everybody was complete usability.
11 Feasibility, only one partial, the rest were
12 complete. As we move to the final one, we had
13 uniformity of acceptance. There was a
14 comment, and I agree with it, by one of the
15 reviewers.

16 Jeffrey mentioned about quality of
17 life data, and certainly we need to think
18 about having more quality of life data
19 reported or at least determined in this
20 population.

21 CO-CHAIR SCHONDER: Any comments
22 from the Committee? Your microphone.

1 DR. VASSALOTTI: Well, this is
2 consistent with the package insert for ESAs,
3 lower hemoglobin target, and is it Jeff, the
4 KDOQI review. Can you comment on that with
5 pediatric hemoglobin target?

6 DR. BERNS: I don't actually know
7 what the pediatric target is going to be in
8 KDIGO. I'm not even sure what the adult
9 target's going to be. But certainly I have
10 the pediatric target.

11 DR. KLIGER: I'm not sure how it's
12 related to ESAs. This is really identifying
13 patients who persistently are anemic. That's
14 the action items.

15 DR. FIVUSH: You know, when I --
16 right. When I reviewed it originally, I think
17 it is critically important to identify
18 patients who have hemoglobins of less than
19 ten. I guess I'm going to ask my adult
20 colleagues something I've heard many times
21 about unintended consequences.

22 What about a patient with a

1 hemoglobin of less than ten, who's getting IV
2 iron, who's getting ESAs, whose hemoglobin is
3 less than ten? So I guess the question is, so
4 there's nothing actionable. It's just
5 reporting.

6 So Alan, I mean tell me about
7 unintended consequences. In small
8 populations, when we're talking about
9 standards and measures which may impact
10 payment to facilities, I'm just --

11 I'm just trying to figure out,
12 because they'll probably use some set of the
13 population, both in the adult and the
14 pediatric world, who despite our best efforts,
15 maybe we just need to get smarter about how to
16 treat them. Is that true?

17 DR. KLIGER: I'll give you my take
18 on that. I mean right now in dialysis
19 facilities, there's autopilot with respect to
20 several therapies for anemia, and what I see
21 this measure doing, which I think is a good
22 idea, is to despite those measures, to pick

1 out those patients with persistent anemia that
2 need individualized focused attention, to
3 understand what's going on.

4 DR. KLEINPETER: So one other thing,
5 I guess, in the pediatric adolescent sickle
6 cell patient, where you want a lower
7 hemoglobin, you have an unintended consequence
8 of potentially doing harm if you try to
9 achieve a higher hemoglobin.

10 DR. KASKEL: That's a very good
11 point, and we have very few of those patients.
12 Fortunately, we have few, but there are some,
13 and we have a couple where I am. But they're
14 not on dialysis.

15 DR. KLEINPETER: We have a couple
16 where I am, and they're on dialysis, and the
17 pediatrician sees them infrequently in the
18 unit. But they see them regularly in the
19 office, and those of us that are doing the
20 reviews on these patients, we also need to
21 make an exception for those, and then justify
22 that.

1 DR. BERNS: That's the key, I think.
2 You make an exception, and I think clinical
3 performance measures can't trump good medical
4 care. This is applied to the bulk of our
5 patients, and there's always going to be
6 exceptions, and getting to the point that you
7 made, the patient who you're thrashing with
8 iron and epo and that's the wrong thing. But
9 you still need to identify that group of
10 patients that's at risk.

11 DR. KASKEL: I think what Alan said,
12 and I want to go back to this resistance as --
13 resistance to something, as opposed to anemia,
14 has not been well-studied. Whether it's
15 adults or peds, it has not been studied. This
16 opens up a whole area for investigation.

17 DR. KLIGER: I would answer you,
18 Myra, in saying that the actions that you must
19 get the hemoglobin up, right, this is an
20 identification CPM, that says what's going on
21 here? So for those patients who you know are
22 sicklers, it's easy. But how about those that

1 you didn't know were sicklers? DR.

2 KLEINPETER: Well, the thing that I'm
3 concerned about in the, I guess, in the
4 autopilot world, where you have an anemia
5 management nurse that's coming into a unit
6 once a month, and just sees these numbers and
7 makes these decisions with the medical
8 director in the absence of knowing that
9 individual patient, to supercede what the
10 individual nephrologist is doing, because of
11 the, I guess the CMS guidance for medical
12 directors to have more of an input with their
13 units, this can be a potential problem.

14 CO-CHAIR CROOKS: And for a unit, a
15 facility that has a high population of sickle
16 cell patients, it could be significant,
17 especially if this gets adapted for a payment
18 somehow, you know. Is it impossible or a good
19 idea to put it as a denominator exclusion? Is
20 that a recommendation we can make back?

21 I mean you can always come up with
22 more and more and smaller, smaller groups and

1 you can't go on endlessly. But this may be a
2 significant enough problem that it deserves a
3 denominator exclusion.

4 CO-CHAIR SCHONDER: Jerry.

5 DR. JACKSON: Question on the
6 numerator specification. For a three-month
7 reporting period, since we just passed the
8 previous measure of monthly hemoglobins, how
9 is that going to be scored? It looks like you
10 have one month of 10.1 and the others are
11 less, maybe fall out of this.

12 So the intent is to identify people
13 with resistant hemoglobin, with resistant
14 anemia.

15 I'm not reading that right?

16 DR. WOLFE: So it's the mean
17 hemoglobin. So you'd take the average of
18 those three, if I understood your question.

19 DR. KLIGER: I wonder if it might be
20 wiser for this read persistently under ten,
21 rather than average of under ten.

22 DR. JACKSON: I think that would be

1 more consistent with the intent.

2 DR. BERNS: I've tended to look at
3 these performance measures by wanting to know
4 which patient is below ten for each of the
5 last three months, and maybe that's a way of
6 getting -

7 DR. KLIGER: I think we're saying
8 the same thing.

9 DR. PROVENZANO: Can vote to amend
10 that piece to reflect what is done in clinical
11 practice, or at least what we view as having
12 more meaning in clinical practice?

13 DR. PACE: You can make that
14 recommendation, and before you do that,
15 perhaps we want to see if the developer, if
16 they had any discussion around that, and if
17 there was any rationale for the average versus
18 the suggestion of persistent.

19 DR. WOLFE: None of us were at that
20 particular TEP, so we don't know if they had
21 considered it and made a judgment.

22 DR. RAMIREZ: Bob, we did not

1 discuss that in particular. So we did not
2 discuss persistently lower hemoglobins below
3 ten.

4 DR. WOLFE: So we're glad for
5 feedback.

6 DR. RAMIREZ: So I think that's a
7 valid suggestion.

8 CO-CHAIR SCHONDER: Okay. So do we
9 want to take a vote on whether to include that
10 as a suggestion?

11 DR. PACE: So you need to state that
12 as a motion, and then be very specific about
13 what that would mean. So we have monthly
14 measures. Are you saying two out of three or
15 what is it?

16 DR. KLIGER: No. I mean I would
17 move that the numerator reflect those patients
18 who in each of the three month study periods
19 have hemoglobins of less than ten.

20 DR. PACE: Okay. So just to be
21 clear, in a three-month study period, all
22 three have to be less than ten is what the

1 intent is here?

2 DR. KLIGER: Correct.

3 DR. PACE: All right.

4 CO-CHAIR CROOKS: Just to note, this
5 is actually the adult measure that's already
6 approved says "who have a mean hemoglobin less
7 than ten grams for a three month study
8 period."

9 Oh, mean for a three month, right.
10 So that was like it was originally proposed.
11 Is it of concern to anybody that it's kind of
12 different than the adult one, I guess?

13 DR. MESSANA: I have a technical
14 question. What if there were more than three
15 hemoglobins in the three month period?

16 DR. PACE: Microphone.

17 CO-CHAIR CROOKS: Microphone on
18 please.

19 DR. MESSANA: What if there were
20 more than three hemoglobins in the three month
21 period? I just want to know how to handle it,
22 if the numerator statement should deal with

1 that.

2 DR. BERNS: Isn't one of each
3 monthly hemoglobin the one that's used for
4 billing purposes?

5 DR. MESSANA: The last.

6 DR. BERNS: Yes, is really how I
7 would use it.

8 DR. MESSANA: Okay. But if you're
9 talking about CROWNWeb as a data source, you
10 may have all the hemoglobins. We can define
11 it. But you want to put that in the numerator
12 statement then. Bianca, go ahead.

13 DR. RAMIREZ: I just wanted to add
14 then, that the pediatric measure would then be
15 more stringent in defining anemia than the
16 adult measure, because we're requiring it for
17 all three month versus just the mean.

18 DR. PACE: Is it appropriate, I mean
19 so there's a couple of things to think about
20 here. Is there a difference in pediatric and
21 adults in regards to this?

22 Perhaps when we look at them side by

1 side, you would say the same thing about the
2 adult measure, and when that's reviewed in the
3 next project, that would be an issue that
4 would need to be addressed.

5 So again, let's focus on what's, you
6 know, indicated based on the evidence of what
7 we should be measuring.

8 DR. PROVENZANO: Yes. I think what
9 you're seeing here is again an update of what,
10 how clinical practice has interpreted what we
11 do in adult analysis, applying it to
12 pediatrics, and I would guess that when the
13 opportunity comes up to harmonize the adults,
14 you may see a shift.

15 DR. PACE: Is everyone in agreement?
16 Should we first -- is there anyone that
17 objects to voting on the measure with that
18 condition, that we suggest to the developer
19 that they make the change, that it's in all
20 three, in each of the three study months, the
21 load?

22 DR. KASKEL: I have an objection. I

1 think that the effect, the adverse effect of
2 the hemoglobin below a target value has more
3 profound effects in a pediatric patient than
4 in adults, and I don't know why we have to do
5 this three times in a row.

6 If we have a patient that has a
7 value on one time that low, we're not waiting
8 to repeat it. We will act on it. We might
9 repeat it the next week, but we're doing
10 something. To wait three months, I want to
11 see why we need to wait.

12 DR. KLIGER: So if I may say Rick,
13 if that were the case, then why have three
14 months in your measure at all? Just make it
15 any given measure under ten.

16 DR. KASKEL: I didn't develop the
17 measure.

18 DR. PROVENZANO: And let me, if I
19 may comment. There is an assumption that if
20 there's a low hemoglobin, let's just say on
21 Month 1, but there is some intervention, and
22 so rather than having a cyclic sort of

1 situation where oh my gosh, I've got to get
2 this up by next week, this is an opportunity
3 to allow the clinician to impact that
4 hemoglobin. So I would look at it more from
5 the positive side than the negative side.

6 CO-CHAIR CROOKS: I think you're
7 losing something, though, from public
8 reporting. We're talking, kind of focusing on
9 how we manage patients and stuff. But you
10 know, if I'm a payor, I'd like to know in
11 general why are you keeping my patients above
12 ten, you know, as a mean hemoglobin usually
13 above ten, you know.

14 I don't really care. I'm not as
15 interested in the number of patients who have
16 had three months in a row with a low
17 hemoglobin. Those are outliers, but it
18 doesn't really give me a mean of how we're
19 doing.

20 DR. LATTS: You know, I would agree,
21 and I would think from a usability point of
22 view, the mean is easier to understand, and I

1 would question why we would deliberately do
2 something different than the measure that's
3 already been approved in the adult, that was
4 clearly good enough for the adults.

5 DR. JACKSON: I brought this up as a
6 question, because I didn't understand the
7 collection methodology. But if the word
8 "rolling average" were in there, it would
9 harmonize with a lot of the other measures
10 we're going to consider either today or
11 tomorrow. I think that's the intent, isn't
12 it? It's a rolling average.

13 DR. WOLFE: It is a rolling average.

14 DR. JACKSON: And it makes more
15 sense, especially with what Frederick said.
16 You're not waiting three months, but you're
17 always looking at the current month. But the
18 measure is for the average of the previous
19 three months. So I think based on my better
20 understanding of what the intent they have is,
21 I would be okay with the way it's specified
22 now.

1 DR. KLIGER: Here's the way I'd
2 argue it, Lisa. When the hemoglobin is less
3 than ten, the clinician and the patient should
4 be taking some action. The reason for having
5 these measures is to see, I believe, where the
6 action has been inappropriate or absent.

7 So looking at patients who
8 persistently are anemic says to me that
9 whatever action has been taken, if any, is
10 inadequate. If there is a rolling average
11 that is low, it says nothing about the method
12 in between, the clinician -- it could be on
13 the way up. The hemoglobin could be rising,
14 and rising appropriately and still have a
15 rolling average that's low.

16 So my argument would be as a
17 clinician working with patients, that what you
18 want a measure to do is to catch when the
19 action by the patient and the physician has
20 not been adequate.

21 DR. PROVENZANO: And let me, Lisa,
22 let me just add to Alan's comments. When we

1 round with our nurse, we don't say what's the
2 rolling average last month? I look at the
3 hemoglobin this month, what was it last month.
4 I look at what I've been doing.

5 So if somebody had a hemoglobin
6 typically 8.8, and now it's 9.2 and 9.5, the
7 rolling average is going to be below. I'm
8 going to see what I was doing, so that I'm
9 trending in the right direction.

10 So practically speaking, it is a
11 process to us, you know, are our doctors doing
12 anything, or are they just ignoring this?

13 DR. LATTS: I think, though, the
14 reality is, and again check my math here, but
15 from a methodologic perspective, if the
16 rolling average is less than ten, you're going
17 to have three measures that are less than ten,
18 right? Pretty much, unless you have a drastic
19 drop.

20 DR. BERNS: No. You can have an
21 8.5, a 9.2 and a 10.3 and fail this measure.

22 DR. LATTS: So yes. So why is it

1 good enough for the adults and not good enough
2 for the pediatric --

3 DR. KLIGER: It should be changed in
4 the adults.

5 CO-CHAIR CROOKS: Well, I still have
6 not been persuaded by your arguments. You're
7 looking at it as a doctor managing an
8 individual patient. As a payor, I want to
9 know how a group of patients is doing. And
10 yes, some are going down but some are going up
11 and it balances out.

12 What I'd like to know is what's the
13 mean hemoglobin or how many patients that I'm
14 paying for the care of, are hitting the target
15 most of the time? I'm looking for a
16 population average. You can manage it however
17 you see fit as a doctor, but you should be
18 producing mean hemoglobins over ten.

19 DR. LATTS: I would agree, and I
20 would think that the -- that's the reason that
21 I won't want one month at a time, is because
22 the one month you haven't had a chance to do

1 anything, whereas three months, you've had a
2 chance to affect it. So that's why I like the
3 three month as opposed to a single month.

4 CO-CHAIR CROOKS: And three-month
5 rolling averages to, you know, decrease
6 variability from month to month. That's the
7 real reason for it.

8 That's why we don't do a month at a
9 time too, is to realize that there is some
10 biologic variability and we don't have to
11 overreact to a 9.9. If they've been 11, you
12 might wait and see what happens next month.

13 DR. KLIGER: Peter, I would argue to
14 you that as a payor, you don't want only to
15 know about what the averages are. You want to
16 know about the direction and the evidence of
17 improvement. That's why I believe that a
18 measure looking at evidence of inadequate
19 action is a better measure.

20 CO-CHAIR CROOKS: Well, you sort of
21 get into the outlier kind of thing, means
22 versus looking at outliers. What we're

1 defining now is an outlier group, a group that
2 needs -- you have to respond to this. Here's
3 an issue. The quality plan sends you a
4 letter, doctor, this patient's had a
5 hemoglobin under ten for three months in a
6 row. What are you doing about it? What's
7 your explanation for it?

8 That's an outlier approach, as
9 opposed to looking at means, and population
10 means.

11 DR. LATTS: I would also argue that
12 the outcome, the mean is a better true outcome
13 measure, because that is the average of the
14 population, whereas the three month level is
15 more of a process measuring what you're doing.
16 What's the process that you're doing to
17 increase your hemoglobin, whereas the true
18 outcome is what's the level.

19 DR. PROVENZANO: Let me just
20 comment, because obviously if you look at what
21 we've been focusing on in anemia the last ten
22 years, we're right now in a situation where

1 there is a great fear out there, both
2 clinically and legally, of over-utilization of
3 ESAs.

4 So we're ratcheting down overshoots,
5 right? I'm not going to go into all the data
6 that we all know. Most protocols and most
7 focused care goes to the process of
8 incrementally moving hemoglobins into a much
9 tighter target.

10 So although I appreciate what you're
11 saying, and if we're talking about
12 individualized care, because I appreciate that
13 payers look at the global picture, I have to
14 look at one person in the eye, and I would
15 suggest that in the current environment, that
16 the process of monitoring and treating anemia
17 is better reflected by a monthly hemoglobin
18 trend, in the face of the current environment.

19 DR. JACKSON: We trend our -- we
20 look at individual month and three-month
21 rolling average on a number of parameters,
22 doing quality assessment in the clinic, and

1 you can trend three-month rolling averages.
2 Wouldn't you agree? I mean it changes every
3 month, and it reflects that month and the two
4 previous months. So you can get a trend every
5 three months.

6 DR. WOLFE: That's right, and what
7 Peter said is correct, that if you use the
8 three-month rolling average, you end up with
9 more compliance in the 10 to 12 range. That
10 is if you look at just a fraction of
11 individual values, sometimes one will bounce
12 out. But on average, they will be within.

13 So we've done several analyses
14 looking at using a one month value, using a
15 three-month average. We haven't looked at all
16 three months being low. We just truly haven't
17 done that. But if you compare having the
18 three-month average in range, it's a much
19 higher fraction to have the three-month
20 average in range than it is to have all
21 individual values in range.

22 So this sounds cheap, but it makes

1 it look better. But I suspect it also truly
2 reflects the attempt to control the hemoglobin
3 levels, of keeping them within range. A
4 three-month average just does better reflect
5 the chronic care, at least that's my
6 understanding.

7 DR. FIVUSH: I just, you know, I'm
8 just thinking about unintended consequences in
9 the other direction now, because really ten,
10 as Rick pointed out, we don't think we're
11 going to have the same guidance with
12 hemoglobin as the adult targets are.

13 We think we're not going to be 10 to
14 12. We think we're going to -- we think what
15 is best in our population, and we talked about
16 it earlier, is 11 to 13. So less than 10 in
17 a pediatric patient is probably less than 10
18 in an adult patient.

19 So I think if we -- I think when I
20 think about this intent of this measure is
21 really to identify those patients who are
22 particularly either resistant to epo or just

1 not being treated appropriately, or there's
2 another reason which should be identified and
3 defined.

4 If we do this rolling average and
5 look for patients who are sometimes under 10
6 on three months, and as you said, it's an 8.9
7 and a 9.5 and then an 11, we're going to miss
8 the patients that are not in pediatrics, that
9 probably should really -- which was your point
10 in the first place, that really should have
11 been identified in the beginning, who are
12 lower than they should be most of the time,
13 but on an average may not be less than 10.

14 So I actually, just having gone full
15 circle, I think that the intent of this
16 measure was to really identify those patients,
17 as you said, that clearly are falling out of
18 what we think is good guidance for anemia in
19 children. I think less than 10 has clearly
20 been associated in pediatrics with bad
21 outcomes.

22 I think there's no pediatric

1 nephrologist who would say well maybe 10 to 11
2 is okay. I think most pediatric nephrologists
3 would tell you we think it should be 11 to 13.
4 So less than 10 is pretty substantive in our
5 age group, because the school attendance,
6 physical activity, you know, all the things we
7 talked about, quality of life issues.

8 But so I would not want it to be
9 masked by a rolling average. I just, I
10 wouldn't want it be sort of rolled up and one
11 time the kid was 11 but the other two times
12 they were less than 10, and then we don't see
13 it.

14 CO-CHAIR CROOKS: Well, but you're
15 going to be managing that patient, looking at
16 those values every month.

17 DR. FIVUSH: Yes, you are correct.

18 CO-CHAIR CROOKS: You're not going
19 to miss on this. It's not going to change
20 what you do, except to help you, you know, be
21 aware that those who are watching you want you
22 to, you know, keep it above a certain level.

1 DR. FIVUSH: Right.

2 CO-CHAIR CROOKS: You know, I just
3 wanted to say that the number one, the first
4 intended use of this measure is public
5 reporting and then second, internal quality
6 improvement. So this is meant for public
7 reporting, and again, it's sort of looking at
8 the mean versus the outlier.

9 When you're looking at the mean, all
10 patients are accounted for in the metric. If
11 you're looking at the outlier, you're looking
12 at a smaller group of patients that need
13 attention, but you're not learning what the
14 mean value is, which is what the public
15 presumably wants to know.

16 DR. KLIGER: I'm not sure that's
17 what the public wants to know. The public
18 wants to know who's getting adequately treated
19 and who's not.

20 DR. VASSALOTTI: But this isn't the
21 mean of the overall population, right. This
22 is the number of patients that you have a mean

1 value --

2 CO-CHAIR CROOKS: Right. Well, but
3 it's the number, it's the percent of patients
4 who are hitting a goal of at least 10 is what
5 it is. But all patients are accounted for in
6 the metric, as opposed to smaller number.

7 DR. LATTS: Yes, and I think that's
8 exactly the difference, is you're looking at
9 this as how is it going to help me measure the
10 individual patient, when this is a population-
11 based outcome measure.

12 So it's how is your whole population
13 being managed overall, which is a very
14 different way of looking at it, which is why
15 I think the mean is probably, you know, good
16 enough and --

17 DR. PACE: This discussion just
18 makes me want to kind of clarify.

19 (Laughter.)

20 DR. PACE: No. I just want to
21 clarify again, you know. NQF endorses
22 measures that are intended for both public

1 reporting and quality improvement. So we want
2 measures that do both, and we are talking
3 about measures, performance measures. So
4 we're talking about data that are aggregated
5 to whatever entity level we're measuring.

6 So in this case, we're talking about
7 dialysis facilities. Sometimes we're talking
8 about health plans, sometimes about physician
9 practices. But we are, I think as Peter said,
10 you know, it's not -- you know, in your
11 individual practice you're still looking at
12 every value, and treating.

13 But this is intended to be a
14 performance score on overall, how well are you
15 keeping your patients above a certain target
16 value. But just, you know, a couple of
17 things.

18 MS. LeBEAU: Just, I don't want to
19 get into the clinical statistical debate here,
20 but what I think, and please correct me if I'm
21 wrong, the adult measure here is weighted more
22 in its use, because there's such a serious

1 consequence for lower hemoglobins, poorly
2 managed anemia at that end.

3 So I'm thinking that the group very
4 particularly that they're trying to identify,
5 are the people who are falling below
6 consistently. I don't know.

7 CO-CHAIR CROOKS: Whether the
8 measure will pick that up.

9 CO-CHAIR SCHONDER: Okay. So I'll
10 go back to the motion that's on the floor, to
11 make the amendment that it's each of three,
12 each of the three months is less than 10. Do
13 we want to take a formal vote or --

14 DR. PACE: I think we'll do a hand
15 vote on that, and then -- so then that will
16 decide for the formal vote which version we're
17 voting on.

18 CO-CHAIR SCHONDER: Okay, okay. So
19 this is a vote in favor of making the
20 amendment, that each of the three months is
21 less than 10.

22 DR. FIVUSH: This is the mean?

1 CO-CHAIR SCHONDER: No, no. This is
2 to make the change that each of the three
3 months has to be less than 10, hemoglobin less
4 than 10.

5 (Show of hands.)

6 CO-CHAIR CROOKS: Thirteen, okay.
7 How many want to leave it as it is?

8 CO-CHAIR SCHONDER: Leave it as it
9 is?

10 (Show of hands.)

11 CO-CHAIR CROOKS: Eight.

12 (Off mic comments.)

13 CO-CHAIR CROOKS: Who voted twice?
14 Alan? No. He's sitting on his hands. Okay.

15 DR. PACE: Okay, so --

16 CO-CHAIR CROOKS: The count is 14.
17 Let's say 12 and 8. I think I probably
18 counted wrong.

19 DR. PACE: Revote, okay.

20 (Simultaneous speaking.)

21 DR. PACE: Those who voted to leave
22 the measure as it's currently specified, as

1 was submitted to us, raise your hand again?

2 (Show of hands.)

3 DR. PACE: Seven, okay. So 13 and
4 7. Okay, all right. So we'll move on then to
5 -- okay. Why don't we go ahead then, through
6 the evaluation --

7 CO-CHAIR SCHONDER: I do want to
8 bring up one, because there was a question
9 about the sickle cell that Myra brought up, in
10 changing the denominator.

11 CO-CHAIR CROOKS: If we're going to
12 send stuff back to them, can we vote on that,
13 whether to recommend -- I move that we
14 recommend a denominator exclusion for sickle
15 cell patients.

16 CO-CHAIR SCHONDER: We have a
17 second.

18 CO-CHAIR CROOKS: All in favor?

19 (Show of hands.)

20 CO-CHAIR CROOKS: I think we can say
21 that one passed.

22 CO-CHAIR SCHONDER: That looks like

1 unanimous.

2 CO-CHAIR CROOKS: Unanimously, or
3 close to it.

4 DR. FIVUSH: So Peter -- so Karen.
5 Karen, will this now go back?

6 DR. PACE: Pardon me?

7 DR. FIVUSH: This is not -- now
8 what's happened is this is not denied or
9 approved. It goes back -- this is the first
10 time we've done this today. So it goes back
11 to the measure developers now?

12 DR. PACE: Right. Let's, I think
13 what we'll do, what we do, so the Committee
14 has voted to put a condition on this. I guess
15 what we need to do now is take a vote.

16 We'll go through the criteria. I'm
17 trying to think if that makes sense, given the
18 changes. A lot of that probably is okay, but
19 the reliability and validity would be
20 different. It's a different measure.

21 Why don't we take a vote? We'll
22 just have you vote up and down on -- okay.

1 Let's start with I think importance to measure
2 and report is still something you can vote on.
3 We want to make sure that we pass that
4 criterion, and then we'll take a vote on the
5 measure, as you've specified the condition.

6 What will happen, if you approve it
7 that way, we will go back to the measure
8 developer, tell them what the condition is,
9 ask them to respond to that. They can either
10 say yes, we agree or no, we don't agree for
11 these reasons. They'll come back to you to
12 review their response and see how you want to
13 move forward after that.

14 Okay. So let's at least do
15 importance to measure and report, and then
16 we'll do on the vote, on the measure as you're
17 suggesting the change. So importance to
18 measure and report. No, no, no. Okay.

19 (Off mic comments.)

20 CO-CHAIR CROOKS: We're missing one.

21 (Committee voting.)

22 DR. PACE: Okay. Does everyone

1 think they've registered their vote? Okay, go
2 ahead. You can --

3 CO-CHAIR CROOKS: 19 yeses and no
4 nos.

5 DR. PACE: Okay. So let's go
6 forward to the recommend flag. We'll get --
7 okay. So what you're voting on here is
8 recommending the measure with the two
9 conditions.

10 One is that it's percentage of
11 patients with all three in the three-month
12 study period that are below ten, and adding
13 the exclusion for sickle cell anemia patients.

14 Any question about what you're
15 voting on? So it's both. Okay. All right.
16 Go ahead.

17 (Committee voting.)

18 CO-CHAIR CROOKS: 18 yes and 2 no.

19 (Off mic comment.)

20 DR. PACE: We'll send that back to
21 the measure developer, ask for their response,
22 that they can provide to you either yes/no and

1 reasons why or why not. Okay.

2 DR. WOLFE: Thank you.

3 CO-CHAIR SCHONDER: Okay. So in
4 case you're not keeping up with us, we are a
5 little bit behind schedule. We do have one of
6 our measure developers who's here for one
7 measure only. So actually we're going to go
8 out of order right now and skip to the minimum
9 metabolism measures at this point.

10 So flip over your sheets to page
11 three, and we'll move to Measure No. 1454, and
12 Joe, I'll ask you to --

13 DR. PACE: Actually, it's 1427.

14 CO-CHAIR SCHONDER: I'm sorry. Oh,
15 1427, I'm sorry. Okay. So the other Joe. If
16 you can -- they're out of order on our list.
17 Go ahead. So we're going with 1427.

18 DR. PACE: Right. That's fine.
19 We'll do the whole group on mineral
20 metabolism, but we'll go ahead and do that one
21 first.
22 Measure No. 1427

1 DR. VASSALOTTI: Okay. So 1427 is
2 the proportion of adult patients with a serum
3 phosphorous greater than six milligrams per
4 deciliter. The numerator is the average CM
5 phosphorous greater than six milligrams per
6 deciliter, the number of patients with that
7 over a three-month rolling average.

8 The denominator is adults greater
9 than or equal to 18 years of age, who were
10 treated with, it says outpatient PD or HD. I
11 guess that means PD associated with an
12 outpatient facility, for at least 30 days at
13 that facility, who have been treated with
14 dialysis for more than 90 days, who have at
15 least one phosphorous measure during the 90-
16 day study period.

17 Now I think I may need glasses, but
18 I'm looking at the review there, and I see
19 maybe Karen, it looks like we have one
20 complete and four partial.

21 DR. PACE: Yes. I can read them if
22 you'd like.

1 DR. VASSALOTTI: Yes, thanks.

2 DR. PACE: Okay. So for -- oh,
3 let's go back to importance. Okay.
4 Importance, all five said it was important,
5 and then on scientific acceptability, one
6 completely, four partially. Usability, one
7 completely, four partially. Feasibility, the
8 same, one and four. In terms of recommending,
9 four yes and one no.

10 DR. VASSALOTTI: Okay. So this, I
11 think just to briefly summarize, this measure
12 has a lot of attractive qualities, in terms of
13 it's something that's easily measured and
14 captured electronically. We think it's
15 reliable, it's useable, it's something
16 clinicians think about all the time.

17 So I think it's certainly valuable
18 in that sense. It's clearly associated with
19 increased mortality, both all cause and
20 cardiovascular mortality. It may address some
21 of the disparities in care, in terms of racial
22 and ethnic minorities and poverty, and we

1 think conceptually that reducing serum
2 phosphorous could improve patient outcomes.

3 I think I would say clearly to me,
4 this is the best potentially in the class of
5 the three measures that we've been asked to
6 review in mineral metabolism. I think the
7 down side of this is that most of the data
8 that we have are retrospective studies or
9 observational studies.

10 We don't have any interventional
11 studies that prove a benefit to, you know,
12 that reducing phosphorous improves outcomes.
13 Unfortunately, we don't really know what the
14 optimal intervention is. I think I know the
15 optimal intervention. Let's put everybody on
16 long nocturnal hemodialysis.

17 But that's not going to happen
18 probably any time soon. So given that, and I
19 would also this is one of the most
20 controversial areas in all of nephrology,
21 calcium-based binders versus non-calcium based
22 binders.

1 If we lower our serum phosphorous
2 with calcium-based binders, does that have
3 unintended consequences that are potentially
4 detrimental to patients? So I want to make a
5 distinction between what I think is important
6 and what I would do everyday with a patient in
7 front of me.

8 That, I think, is a very important
9 thing for me as an individual and for my
10 patients. What I think is important is a
11 quality improvement initiative, which I think
12 is potentially great. This is a very
13 important area in terms of quality
14 improvement.

15 But I guess I'm not so sure this
16 rises to the level of a performance measure
17 for public reporting and for potentially for
18 incentive-based health care. I would just
19 point out that the CMS TEP on page 37 did
20 consider this to be a very important
21 biomarker, but for some other reasons I just
22 outlined, did not agree or could not agree on

1 the threshold, you know. Is it 5, is it 7.

2 So that was their reason that they
3 didn't bring this forward, and that the KDOQI
4 commentary groups. So these are a group of
5 experts published in 2010, based on the KDIGO
6 guideline. I think Jeff was one of the
7 authors of this, has a conclusion here, which
8 I won't read in entirety.

9 But basically, it does not recommend
10 performance measures in this area, because of
11 some of the reasons that I just outlined. But
12 I voted no. But you know, I think that this
13 is something that's really up to -- I was the
14 only vote, I think, no.

15 I think this is -- everybody else
16 said yes. This is open to discussion, and
17 again, I think this is something that's very
18 important, but I'm just not so sure it rises
19 to the level of performance measurement.

20 DR. NALLY: There's been several
21 discussions in the last 48 hours or so along
22 the lines of evidence and the distinction

1 between, as you put it Joe, what you might do
2 versus rising to the level of a performance
3 measure.

4 I think the concern is that
5 threshold, because clearly having, be it high
6 calcium, high phosphorous, high PPHs, one can
7 associate in observational trials that there
8 are adverse outcomes, increased mortality with
9 those.

10 Unfortunately, we don't have
11 randomized control trials in this arena to
12 really inform us into the optimal management
13 of things. So we're in this quandary of the
14 associations being translated into practice
15 measures.

16 I think, after discussions that Joe
17 and I had through the weekend, it made me go
18 back and look at who else has examined the
19 issue. So KDOQI had looked at this six or
20 eight years ago, and issued some very specific
21 evidence, or excuse me, opinion-based
22 guidelines.

1 Then more recently we had KDIGO have
2 a panel of experts examine the questions, and
3 they pointed up some of the limitations and
4 need for more information. As I went back and
5 read this through on the plane coming here,
6 most of the evidence is Level 2, which tends
7 to be not at a level where you would want to
8 have performance measures based here.

9 Then finally last May, we had the
10 commentary on the KDIGO guidelines, with the
11 first author who actually ran the evidence-
12 based team for KDIGO on the subject. Jeff was
13 an author and some others, and they came away
14 with a conclusion specifically stating that
15 levels of increased phosphorous would not
16 reach the status of a performance measure.

17 So that type of conflict was exactly
18 what I was inferring this morning, when I
19 asked the questions about the actual criteria
20 for a performance measure, because we have now
21 an international panel weighing in on the
22 subject, suggesting that it hasn't reached

1 that level.

2 I think that for me is the conflict
3 and the angst here, is that we've had some
4 different standards as we've marched through
5 the day, in terms of translating or our
6 thoughts and wishes in a performance measure
7 or not.

8 And so the dichotomy to me right now
9 is what an international panel recommends,
10 that it doesn't reach a level and what some of
11 us might have said in our processing through
12 this exercise.

13 DR. LATTS: Well, I'm confused, and
14 if you guys could maybe explain. In the last
15 measure we talked a lot about how it's
16 important to take what we do with individual
17 patient level and transfer that to the
18 measure, and that not looking at the
19 population level was not as important as
20 looking at how does it translate into what you
21 do for the individual patient.

22 So if you had an individual patient,

1 and again, I just truly don't understand. If
2 you had an individual patient who consistently
3 had a phos greater than six, you wouldn't try
4 to lower it. Or is it that you just don't
5 know what to do?

6 DR. KLIGER: Can I just take a quick
7 crack at this? The difference between the two
8 has to do with the quality of the supporting
9 data. In anemia, there is a clear -- there is
10 clear evidence that intervention makes a
11 difference to outcomes. In phosphorous
12 control, there is no evidence for that.

13 DR. VASSALOTTI: If I can make --

14 DR. LATTI: So you would still, you
15 would try to do things, but you don't know
16 that what you would do is successful.

17 DR. BERNS: One of the risks that I
18 would worry about with a performance measure
19 like this is that we do more harm than good,
20 and that this quashes any motivation for the
21 studies to be done, that show there's a
22 benefit. Really what we're saying is you

1 should keep everybody below six, there's very
2 little motivation then for anybody to prove
3 that that's the right to do.

4 That's what we're desperately in
5 need of, and I don't think it's a secret to
6 anybody that this particular performance
7 measure is industry-supported.

8 That's the industry that needs to
9 help us find out whether or not we should be
10 lowering phosphorous levels, and how we should
11 be lowering phosphorous levels below six,
12 because we don't have answers to those
13 questions.

14 But we desperately need the research
15 to get that answer, and I'm afraid this
16 performance measure would make that less
17 likely to happen.

18 DR. PACE: So I just want to give
19 you a little information on some of the
20 thinking behind our Consensus Standards
21 Approval Committee, and our Evidence Task
22 Force, and actually very much recently

1 reinforced by the board in terms of outcome
2 measures versus process and structure
3 measures.

4 So, and this is kind in the middle.
5 It's intermediate outcome measures. So what
6 we would be looking for here, is there
7 evidence that that level is linked to health
8 outcomes. So is there evidence that, you
9 know, phosphorous level is related to
10 morbidity-mortality.

11 DR. KLIGER: That's not the
12 question, because the question is whether
13 intervening has an effect on morbidity and
14 mortality.

15 DR. PACE: That's what I'm saying.
16 We don't have that as a requirement, that you
17 have to know exactly what to do to change the
18 outcome, and I'll just go through some of the
19 thinking behind that.

20 The reason is that, and this may not
21 apply to this particular outcome, so I'm
22 talking more in general, is that if we measure

1 that kind of outcome and we start seeing
2 variability across facilities in terms of
3 their ability to get that level to a
4 reasonable place, then we start seeing that,
5 you know, some people have figured out what to
6 do.

7 So that you actually may facilitate
8 identifying ways to influence an outcome that
9 maybe we don't know. So that's one reason,
10 and the other aspect is if we -- if it's
11 something that no one can influence, then it's
12 not going to put any one provider at a
13 disadvantage, because it's going to stay at a
14 certain level across patients.

15 So I'm talking in general about
16 outcomes and outcome measurement and some of
17 the thinking of our board and consensus
18 standards approval and Evidence Task Force.
19 You need to look at the specifics of this
20 particular measure.

21 But there's a lot of interest in
22 measuring outcomes, even if we can't identify

1 one particular treatment or intervention
2 that's going to change it at this point in
3 time.

4 MR. WELLS: I'm a little confused,
5 and that happens easy for me. Is the
6 intervention you're talking about, is that
7 prescribing a binder, or are we talking about
8 better therapy?

9 DR. KLIGER: All and any of those.
10 There's no evidence that prescribing binders
11 or giving fancy drugs or any of the things
12 that have been done and that we do, has an
13 effect on outcomes.

14 DR. LATTIS: How about dietary
15 adherence?

16 DR. KLIGER: I don't know the answer
17 in relationship to diet. I haven't seen any
18 of the evidence for that. I don't know if
19 anyone else has.

20 DR. FIVUSH: So I'm getting a little
21 lost in the conversation. So are we saying
22 that there's no evidence that there's -- that

1 we can drop phosphate levels below six, or are
2 we saying there's no evidence that dropping
3 levels of phosphate below six matters?

4 So the question of dietary. So I
5 guess that's not really coming into play,
6 whether that does or doesn't drop it, because
7 all you're saying is there's no evidence of
8 doing it, the dropping it. There are many
9 ways to drop it, but there's no evidence that
10 lowering it below six results in a better
11 outcome for patients. Is that --

12 DR. VASSALOTTI: Okay. I mean Joe
13 really said it very articulately, I thought,
14 very articulately, which is that it's clear
15 that there is a correlation between the levels
16 and a variety of outcomes, absolute clarity
17 about that. But no evidence that trying to
18 affect or change a phosphorous level impacts
19 outcomes.

20 DR. FIVUSH: So then is it not -- so
21 this -- so it's important to know if we have
22 patients whose phosphorous is over six, but --

1 so is this something you'd say would be better
2 for quality improvement than public reporting?

3 I mean I'm just trying to -- because
4 you're clearly saying this is critical. We've
5 been talking about phosphorous for years. We
6 know that it's difficult to lower. We know
7 that we haven't done a good job. But we don't
8 think it's yet ready to be measured for, to be
9 measured in this standard?

10 DR. VASSALOTTI: It's very
11 important. I would address it. I wouldn't
12 ignore a phosphorous over six. As an
13 individual, I think it's an important quality
14 improvement initiative. But I don't think the
15 level -- we don't know the best intervention.

16 We don't have interventional data
17 that shows that there is an improvement. We
18 don't have good data that shows the threshold
19 of six is any better than five or seven of,
20 you know, I could go on about the last
21 iteration, some of the things we talked about,
22 unintended consequences.

1 So you have urban dialysis
2 facilities which my colleague here is, I
3 think, very familiar with, who are financially
4 strapped, who have struggled to survive, who
5 are in areas where patients live in food
6 deserts. They might not have access to fresh
7 foods, so they have to eat processed foods.

8 So those facilities are going to
9 have patients that are going to be very, very
10 difficult to treat without frequent dialysis
11 or the therapies that may be difficult for
12 them to implement. So there are all kinds of
13 consequences potentially of this. Those were
14 raised in the last iteration of this.

15 You know, we could -- and also, this
16 is not you mentioned consistently above six.
17 So this is a mean. So this is not
18 consistently above six. This is a rolling
19 mean. So you could potentially have a patient
20 who has a level of let's say seven, five and
21 four or something, and has a mean that's above
22 six. So those are other issues that are

1 raised.

2 I think again, I want to make the
3 distinction with what we do clinically, what's
4 important, with what we think should be at the
5 level of a performance measure.

6 I also think that there's a chance,
7 if we really -- if the group thinks this is
8 important, and we want to do something with
9 this, I think we can go back to the developers
10 and say maybe we're willing -- Jeff says we
11 want more data.

12 Certainly, that would be great to
13 have the outcomes data. That's one thing we
14 could ask, to try to address some of these
15 research questions. What about a more
16 stringent measure, you know, higher levels of
17 phosphorous, maybe consistent levels.

18 But I think the problem, the concern
19 is picking a particular level, and
20 implementing that in a community.

21 DR. LATTS: I've got to tell you I'm
22 struggling with this, and I know I'm one of

1 the non-nephrologists here, I'm unpopular.

2 But this is important, and this is --

3 You know, you're telling me this is
4 important clinically, and this is something
5 you spend a lot of times with your patients,
6 working to get their hemoglobin, I'm sorry,
7 their phoses down, and therefore it's an
8 important thing to measure.

9 I don't really care frankly if the
10 number is five, six or seven. You know, if
11 six is controversial, then I'd be okay with
12 seven. I think if it's important to measure
13 and lower is better, you know, I don't buy
14 that just because it's hard to lower it in an
15 urban population, we shouldn't measure it. I
16 really have a problem with that.

17 If this is clinically important,
18 then it should be measured, and it's important
19 for your patients and the population to see
20 performance at a facility level.

21 DR. KLIGER: I'd agree with you, and
22 then the measure is not a threshold measure.

1 What you're suggesting is like some of the
2 others we've had, is a frequency measure
3 rather than a threshold measure.

4 DR. BERNIS: Can I make a case to,
5 and I think this is important from not only
6 the nephrologist perspective but maybe even
7 more so from the patient perspective, which is
8 not only do we not have evidence of benefit of
9 lowering phosphorous below six; we don't have
10 evidence that it's safe to do so.

11 Often, the response to that elevated
12 phosphorous is dietary manipulation, which may
13 be disadvantageous to the patient, or
14 phosphate binders, which have an expense
15 issue, maybe a quality of life issue, and
16 maybe a medical risk issue.

17 So I think we have to be aware that
18 we also need to be thoughtful about avoiding
19 risk when we think about some of these
20 therapeutic interventions, and whether they're
21 important or necessary.

22 MS. WAGER: I've got a question.

1 Dr. Vassalotti, as a patient and my
2 phosphorous was over six, and you said
3 clinically that you would treat it. I was a
4 patient would then ask you why are you doing
5 this? What do you want my phosphorous at
6 then? If there's no -- what are you going on
7 that, okay?

8 DR. VASSALOTTI: Well you know
9 certainly I would shoot for the normal range.
10 I would target the normal range, and I would
11 look at all of the, you know, all the aspects
12 of your care that I thought were relevant,
13 whether you were on dialysis, the type of
14 dialysis, your dialysis regime or diet, and
15 then address the phosphate binders. But I
16 think this, you know --

17 DR. NARVA: When you talk to
18 patients, it's perfectly okay to say you know,
19 I can't prove this, but I know that having
20 this value is really associated with a lot of
21 bad things, and I think we really should pay
22 attention to it.

1 I can't prove that to you, and
2 that's an individual decision. This is a very
3 different thing then to say you're bad; your
4 unit or your practice is inadequate if you
5 don't meet this. It's a really different
6 standard. It acknowledges the fact that we're
7 not, things aren't quite as certain as we
8 might advertise, or as many people might
9 think.

10 DR. NALLY: And not only are those
11 two different and distinct conversations, but
12 if you do not require more rigor in your
13 granting a performance measure, then you tend
14 to stifle research into that area. So I mean
15 maybe a reasonable randomized control trial
16 might have three different levels of phosphate
17 as a target, and might have different ways to
18 get there.

19 If that type of information really
20 has been needed over the past decade, and it's
21 been an embarrassment that those type of
22 studies have not been done.

1 MS. ANDERSON: Just a couple of
2 comments. First of all, there's no evidence
3 that a phosphorous level of six, and I think
4 we've all discussed that. But of more
5 concern, and I think the industry is moving
6 more towards looking at hypercalcemia as a
7 more serious and safety measure versus high
8 phosphorous.

9 Also, if this is a facility-level
10 standard or measure, there's too many
11 variables involved with setting the level of
12 six, whether it be lab variability, facilities
13 may not necessarily have control over
14 adherence to phosphate binders and whatever.

15 So to have it as a standard, there's
16 too many variables right now to be able to
17 identify it. I think there's more significant
18 and more serious values with hypercalcemia
19 that we could look at instead.

20 CO-CHAIR CROOKS: I agree with the
21 majority here. I think that to put this out
22 as a public reporting standard, that your

1 unit, Myra, has an average phosphorous level,
2 or let's say only, let's say 30 percent of
3 your patients are exceeding that.

4 Down at Alan's unit in Connecticut,
5 he only has ten percent of the patients
6 exceeding it, that they would conclude that
7 your practice is, your patients is at higher
8 risk and you're practicing worse than Alan.

9 I think that's a wrong
10 interpretation, and we cannot. But that's
11 what we'd be saying by passing this.

12 DR. PACE: So is the evidence that
13 was suggested, that values greater than six
14 are associated with higher morbidity and
15 mortality -- they are?

16 CO-CHAIR CROOKS: They are.

17 DR. KLIGER: There's a continuum.
18 Right. You could use this for any of the
19 things we'll talk about. 5 to 7 would be a
20 ballpark, you know; calcium kind of high 9's
21 to 11-1/2, the same thing. But now we're
22 setting a specific number on this of 6, which

1 I believe is in the middle, yet arbitrary.

2 DR. BERNS: I also point out that
3 observational studies have shown that
4 hemoglobin levels above 13 are better for
5 patients than lower hemoglobins. When we
6 actually got the right information, we found
7 that that maybe wasn't the right to do.

8 MR. WELLS: I just want to say, I
9 mean the reason I'm piping up now is this is
10 something that's very personal to me. I
11 struggled with phosphorous when I was in-
12 center, and I mean I had some very, very high
13 numbers that were alarming to those around me.
14 Since I thought I wasn't going to be around
15 that long, it didn't bother me.

16 After I started on frequent dialysis
17 and doing it at home, they started coming
18 down, and I found that, you know, the longer
19 I did my treatments, the better my numbers
20 got. My thinking here, and I could be wrong;
21 that's happened one or two times in my life,
22 but that we are looking at establish measures

1 for quality care, and we know what will bring
2 phosphorous down.

3 Obviously, my goal is to see more
4 people doing more frequent dialysis. I'm not
5 going to deny that. If that is our goal, I
6 mean to me, I mean I think we should establish
7 a standard somewhere.

8 I mean I honestly think 5.5 and 6 is
9 higher than what it should be. I mean that's
10 for, that's within range for a dialysis
11 patient, and I think, you know, the real goal
12 should be what normal levels are, and we
13 should work for that.

14 That's why -- I mean there is a
15 solution to bringing it down without
16 intervening with medications or what have you,
17 and you know.

18 DR. KLIGER: So I might caution you,
19 as you think about getting everything to
20 normal, we used to think that, for example,
21 about hemoglobin. We used to think that
22 getting patients' hemoglobin to normal is an

1 obvious goal. We now know that our efforts to
2 do that ended up killing more people than
3 helping them. So I'd be careful about setting
4 a standard at what normal is.

5 MR. WELLS: Oh yes. I don't think
6 we should set the standard there. I'm just
7 saying my feeling is that when I was in-
8 center, and knowing the rates of phosphorous
9 that I had and then when I started, I guess my
10 point comes back to is the discussion around
11 setting it at 6.

12 We don't want to do it because we
13 don't want to impede research into that, which
14 you know, I think that's a valid objection.
15 I mean I'm not saying it's not. Or is it
16 because we don't want to prescribe phosphate
17 binders because of the issues involved there.

18 I mean those things -- I mean I'm
19 not saying I think it should be set at 6. I
20 guess I'm trying to figure out, you know, is
21 the discussion because, you know, there's no
22 adequate way of treating it, or is it because

1 I mean that's what I --

2 DR. PROVENZANO: Let me try to use
3 Alan's analogy, which is I think the right
4 one. The answer is we don't, we just don't
5 know, and we didn't know in hemoglobin, and
6 when we went down the path of thinking, as you
7 mentioned, normal is better, theoretically,
8 depending upon who you want to believe,
9 patients suffered.

10 Therefore, the only argument is here
11 is we do not have the science to suggest that
12 this number is the right number, and until we
13 do, until that data becomes available, it
14 would be unwise to approve this. I just think
15 that's where we're coming down at.

16 CO-CHAIR CROOKS: Also Harvey, I
17 think if we believe that adopting this as a
18 national standard would encourage a blossoming
19 of home and long nocturnal dialysis, I'd be
20 the first one to go for it.

21 Because you're right. We do have a
22 good treatment, and we do have a treatment

1 that will improve outcomes, and that is
2 lowering it by more dialysis. I believe
3 that's true.

4 Again, that hasn't been proven per
5 se. But the truth is, if we approve this as
6 a national standard, phosphorous will get
7 pushed down, but it won't be by giving more
8 dialysis, for the most part. It will be by
9 giving more drugs, giving more calcium-related
10 binders and so on and all these issues we
11 talked about.

12 So I agree with you in theory, but I
13 think the practical answer is approving it
14 won't get the result that you want.

15 CO-CHAIR SCHONDER: Okay. Any more
16 discussion? Yes. Okay. We're going to -- oh
17 okay. to make a comment.

18 MR. MENOYO: Sure. I would like to
19 make some remarks. I think that, you know, as
20 we sit here through the discussions of the
21 day, it seems to me, number one, that we are
22 looking at the evidence of the measures that

1 have been approved, and setting different
2 standards in terms of the level of evidence
3 for the measures that have been endorsed by
4 the NQF, versus this particular measure.

5 When we look at the number of
6 studies, and may not be randomly controlled
7 trials, for the quantity of associated studies
8 and observational studies are there all point
9 in the direction that lower phosphorous is
10 better than not. How we lower it, either by
11 more dialysis, binders, diet, is a whole
12 different issue.

13 When we look at some of the data,
14 it's certainly observational for example
15 DOPPS, and you look at facility level of
16 facilities that have phosphorous greater than
17 6, versus facilities that have a phosphorous
18 between 3-1/2 and 5, facilities that have
19 levels greater than 6 have worse outcomes for
20 patients than facilities that do not.

21 So already, going back to maybe an
22 urban facility versus not, there's already a

1 standard in terms of the level of 6, or the
2 number of 6 is actually worse for those
3 patients than not.

4 In terms of the guidelines, yes,
5 there's not really necessarily consensus in
6 terms of what the numbers should be. The
7 reason that we submitted 6 is based on the
8 evidence that is there for DOPPS and the
9 evidence from the demonstration project.

10 I think at the end of the day,
11 everybody in this room that's a nephrologist
12 will treat their patients and try to keep the
13 phosphorous under 6. I think that at the end
14 of the day, if there's not a standard measure
15 to try to continue to improve that moving
16 forward, we're probably doing a disservice to
17 the patients.

18 CO-CHAIR SCHONDER: Any other
19 comments? Okay. Move to vote.

20 DR. PACE: Importance to measure and
21 report.

22 (Committee voting.)

1 CO-CHAIR CROOKS: We have 13 no and
2 7 yes.

3 DR. PACE: All right. So we'll move
4 on to the next one. Is there another
5 phosphorous one? Maybe we should do that one.

6 CO-CHAIR SCHONDER: Yes, okay. So
7 we'll stick with the mineral metabolism and
8 move to 1461, since we're already out of
9 order.

10 Measure No. 1461

11 DR. VASSALOTTI: This is
12 hypophosphatemia. So thank you for assigning
13 me with phosphorous measures.

14 (Laughter.)

15 DR. VASSALOTTI: Wherever that came
16 from. So I think this is a little bit more
17 straightforward. This is the proportion of
18 patients with a three-month rolling average of
19 serum phosphorous, less than 2.5 milligrams
20 per deciliter.

21 I think that's the numerator. I
22 think the denominator is pretty similar. It's

1 all -- I think it's both PD and hemodialysis
2 patients that are treated in an outpatient
3 facility. The same kind of adults 18 years or
4 older.

5 They have to be at the facility for
6 at least 90 days. They have to have been
7 treated with dialysis for greater than 90
8 days, and have at least one phosphorous
9 measurement during the 90-day study period.

10 Okay. So my visual acuity test
11 rolling. I failed again. Snelling chart.

12 DR. PACE: Right. Just a second.

13 CO-CHAIR SCHONDER: There's four nos
14 and one yes.

15 DR. VASSALOTTI: Okay. So four nos
16 and one yes for importance.

17 DR. PACE: Right.

18 DR. VASSALOTTI: For scientific
19 acceptability of measure properties, we have -
20 -

21 DR. PACE: We have a spread. One
22 completely, one partially, two minimally and

1 one not at all.

2 DR. VASSALOTTI: Okay. For
3 usability?

4 DR. PACE: And then usability, two
5 partially, three minimally.

6 DR. VASSALOTTI: Feasibility?

7 DR. PACE: Feasibility, two
8 completely, two partially, one minimally and
9 then recommend, one yes and four no.

10 DR. VASSALOTTI: Okay. So this has
11 the same kind of -- it's attractive in the
12 sense that it's easily measured. It's
13 electronic data capture. It's reliable, it's
14 understandable. There is a strong association
15 with serum phosphorous less than 2.5
16 milligrams per deciliter in all cause and
17 cardiovascular mortality.

18 Those are the pluses. Again, we
19 have no interventional data. I think this is
20 a little bit of a misnomer to me at least. I
21 think this is not how I think about patients
22 and calcium phosphorous metabolism. This is

1 not a mineral metabolism measure. This is
2 more a nutritional measure to me.

3 So I'm not sure this really belongs
4 here. In my experience, and I'm curious to
5 hear what everybody else thinks, but the kinds
6 of patients I've seen with this, who don't
7 have the obvious causes, are very sick
8 patients who have, you know, probably have an
9 incredibly high mortality, and I'm not sure
10 that feeding patients who are malnourished,
11 have atherosclerosis, inflammation, maybe
12 something I don't always understand, I don't
13 know if feeding them actually helps. I don't
14 even know if this is actionable, to be honest.

15 The gap in care for these patients,
16 I'm not sure what an impact this will have.
17 This is 0.6 percent of the population, I
18 think, according to the performance gap that
19 I read, and please, developers please correct
20 me if I misspoke about that.

21 I think that's really all I have to
22 say about that. Any comments from the other

1 reviewers?

2 CO-CHAIR SCHONDER: I know I was the
3 one yes. Up there, you can see that. But I
4 actually would change my vote if I was doing
5 that today.

6 DR. NALLY: I was a reviewer also,
7 and I agree with everything you say, but also
8 emphasizing the fact of picking out a measure
9 that affects less than one percent of the
10 population, and trying to make that a
11 performance measure detracts attention from
12 other very important areas that we'll be
13 talking about.

14 CO-CHAIR SCHONDER: Any other
15 discussion? We'll move this one to vote
16 quickly.

17 DR. PACE: Okay. Are we ready?

18 CO-CHAIR SCHONDER: Yes.

19 DR. PACE: Okay, all right.

20 Importance to measure and report?

21 (Committee voting.)

22 DR. PACE: Everyone thinks they've

1 hit send? Okay.

2 MS. RICHIE: Just a reminder not to
3 hit the send button before we actually start
4 the timer, because it won't capture your
5 votes.

6 CO-CHAIR CROOKS: We have 2 yes and
7 17 no.

8 DR. PACE: Right. So that's
9 probably what happened. Someone may have hit
10 their response before we actually -- yes. I
11 know you're anxious.

12 CO-CHAIR SCHONDER: Okay. We will
13 finish the mineral metabolisms and go back to
14 the first one then, 1454. Joe.
15 Measure No. 1454

16 DR. NALLY: I would like to thank
17 anybody that selected the other Joe for the
18 phosphorous.

19 (Laughter.)

20 DR. NALLY: However, this is in the
21 same category, but I think it will take a
22 little more thought than the last one we just

1 went through, with a little more discussion.

2 This measure looks at the proportion
3 of patients with three-month rolling average
4 of total uncorrected serum calcium greater
5 than 10.2. That being the numerator, the
6 denominator being, as Joe mentioned before,
7 the people in the unit. It's data that's
8 readily available and easy to collect.

9 In terms of, I guess we could go to
10 the evaluation process, and now there's an
11 update here. I only had five observers, but
12 I think we get a sixth, and in this case, the
13 importance, five of six said that this was an
14 important issue.

15 In terms of the scientific
16 acceptability, here you see a smattering
17 ranging from a couple completes to one minimal
18 and the other is partially. This, I think, is
19 where some of the discussion that we've
20 already had about this area of bone mineral
21 disease being important.

22 The idea is that calcium

1 phosphorous, Vitamin D, PTH are very common,
2 but we really lack data making for compelling
3 information to guide our judgments in this
4 impact. But I think there's a different spin
5 with the high calcium here.

6 If we could go on to the usability.
7 Here we have all partials except the one
8 minimal, and feasibility, here we have four
9 completes and two partial. Then one pause
10 before we get to the recommendations. There
11 were some observations as part of the
12 evaluation process.

13 Again, the concept that the 10.2 was
14 an arbitrary number. As I may have alluded to
15 before, having high calcium confers increased
16 risk, but that spread goes from roughly 9-1/2
17 to 11-1/2. So this is an arbitrary number.
18 It does in fact use total calcium that's not
19 corrected, and more recent data would suggest
20 that the uncorrected calcium is probably a
21 reasonable way to go. And finally there
22 was concern that there wasn't any information

1 given about the level of a high calcium and
2 how that translates into the number and types
3 of adverse events. So those were most of the
4 concerns there. We've already heard about
5 issues of potential management as it affects
6 phosphorous.

7 In this case, having a high calcium
8 may more likely be a consequence of therapy,
9 such that the behavioral pattern might be to
10 reduce therapy as opposed to the phosphorous
11 issue, the high phosphorous, where it might
12 impact more therapy.

13 I think that's an important
14 distinction to make, that the hypercalcemia,
15 and again, in terms of the gap measures, I
16 looked at this. There was a survey done
17 twice, and I'll ask our measure developers to
18 comment here, whereby in almost 14,000
19 patients, there was about 4-1/2 percent that
20 would meet this measure.

21 Then when they looked at a facility
22 level, that number went up to about 13

1 percent. So there seemed to be a threefold
2 difference in the data there, and I would like
3 to request an explanation, if that's a correct
4 statement.

5 DR. MESSANA: We're working on
6 pulling those data up for you.

7 DR. NALLY: It's in the 1B, Summary
8 of the Data Demonstrating the Performance Gap.
9 Pull that up there, Lauren. 1B, page four.

10 DR. PACE: I guess one simple
11 explanation is that it's showing that
12 facilities have variability in how well
13 they're managing it. So if you looked at just
14 the population, but those are concentrated in
15 maybe facilities that aren't doing well. That
16 would be one hypothesis.

17 DR. NALLY: But it didn't say 13
18 percent of facilities. It said 13 percent of
19 patients.

20 So I don't know if that was a typo
21 or if that was a true --

22 DR. PACE: Yes, you're right.

1 DR. WOLFE: We believe that that's
2 right. We are checking that to make sure that
3 that's not a typo. It is possible that that
4 is still consistent, but nationally they are
5 4-1/2 percent above the cutoff.

6 But at 95 percent of facilities,
7 there are 13 percent or more with -- that are
8 above there, and that five percent of the
9 facilities have very good management. But we
10 will check that. In either event, it's one or
11 two of those.

12 DR. NALLY: So somewhere between 4
13 and 13 percent, rather than the 18 percent
14 with high phosphorous and the 0.6 percent with
15 low phosphorous. So it's a problem of note.

16 DR. BERNS: This is again one of
17 those performance measures that may be every
18 month for the last three might be a better way
19 of looking at this, than a rolling average, if
20 it's going to be made into a performance
21 measure at all.

22 The other thing I think that speaks

1 to this, which is different than the other
2 ones that we just addressed, that this does
3 provide opportunities to address toxicities of
4 therapy, whether it's calcium containing
5 phosphate binders or Vitamin D or Vitamin D
6 analog.

7 So there is a potential value to
8 doing that, not so much to give more
9 treatment, but to reassess what treatment the
10 patient's getting.

11 DR. KLIGER: Yes. If it's meant to
12 specifically address overtreatment, or
13 treatment, then I would think that the
14 denominator should be those patients on
15 treatment, because I'm concerned about that
16 population of people with hypercalcemia, that
17 has nothing to do with treatment.

18 We obviously have people who have
19 metastatic bone disease or Paget's Disease or
20 a variety of other reasons why the calcium
21 might be elevated.

22 DR. NALLY: I understand and very

1 much appreciate that concept. But it would be
2 difficult to sort that out in the denominator,
3 when all you know for sure is their calcium is
4 12-1/2. Once you stop therapies that might
5 affect calcium, the Vitamin D's and et cetera,
6 et cetera, then you still have to go through
7 the drill of whether or not they do have the
8 malignancy or the sarcoid or tertiary
9 hyperpara or those other things.

10 But I think that would be a very
11 difficult exclusion to build into the measure.

12 DR. KLIGER: Why would it be hard to
13 know as a denominator who's on treatment and
14 who's not? I'm just saying --

15 DR. NALLY: Or you're saying do it
16 from the other way around.

17 DR. KLIGER: Yes, yes. I'm saying
18 just look only at those people on calcium-
19 containing binders.

20 DR. NALLY: Well, yes. You'd have
21 to go the whole gamut. Calcium-containing
22 binders, Vitamin D. That would make it

1 reasonably complex. But I understand what
2 you're saying.

3 DR. PROVENZANO: I mean I think the
4 reality here, as opposed to the other -- and
5 Jeff's hit on this, is this is a marker that
6 doctors use for toxicity, you know. Vitamin
7 D, binders, right? We naturally say --

8 DR. NALLY: Go through that
9 differential.

10 DR. PROVENZANO: Right, and then
11 once that's eliminated, we say tertiary
12 hyperparathyroidism, metastatic disease, et
13 cetera. It's a trigger to us for toxicity,
14 and it should be viewed as that.

15 DR. NALLY: And therefore in my
16 judgment has some benefit, as opposed to
17 another arbitrary level that might invoke more
18 therapy and toxicity.

19 CO-CHAIR SCHONDER: Any other
20 comments? Barbara.

21 DR. FIVUSH: So I know we had a lot
22 of question about the 6.0 level with the

1 phosphorous. We're pretty certain about the
2 10.2? That would be --

3 DR. NALLY: The short answer is no.

4 DR. FIVUSH: That's my only
5 question. Do we have better --

6 DR. BERNS: Uncorrected calcium
7 level. It's probably reasonable, you know, as
8 uncorrected calcium, because then corrected
9 would be actually higher calcium in most
10 patients. So this is probably a relatively
11 conservative number, but not defensible other
12 than that.

13 CO-CHAIR CROOKS: While this is a
14 nice tool for individual patient management,
15 what does it mean as a public reporting
16 measure? There's going to be a certain
17 instance of patients that have high calcium,
18 you know. Is this telling the payers that a
19 unit with high calciums, these doctors are
20 mismanaging the patients?

21 Or does it mean, you know, how do
22 they interpret it? Is it important in that

1 sense? I don't have the answer. I'm
2 questioning that it's of value for that
3 purpose. Does anybody defend that, that it
4 has good public reporting usefulness?

5 DR. KLIGER: Yes.

6 CO-CHAIR CROOKS: And how would you
7 advise a research company to interpret a unit
8 that has a high proportion of patients with
9 hypercalcemia?

10 DR. KLIGER: Again, in my mind, if
11 the denominator is the appropriate one. So
12 you're talking about people with hypercalcemia
13 who are on drugs that can induce that
14 toxicity, it's telling the company that that
15 unit is not appropriately assessing patients
16 for toxicity of their medications. CO-

17 CHAIR CROOKS: And even if the denominator's
18 the same, you still might kind of come to that
19 conclusion. That would be a not unreasonable
20 conclusion. Okay. Well, that sort of answers
21 my concern. Other thoughts on usefulness as
22 a public reporting measure?

1 DR. FIVUSH: Can we, can I just go
2 back to -- so if you believe it has to be --
3 you said it has to be corrected, right?

4 DR. NALLY: This is uncorrected
5 calcium.

6 DR. FIVUSH: So I'm saying is
7 uncorrected 10.2, is that right? You said --

8 DR. NALLY: That it's a 10.2
9 uncorrected.

10 DR. KLIGER: I mean again, you
11 know. When you're talking about toxicity, I
12 think Bob's point is really very pertinent
13 here. There's a difference between talking
14 about biologic variation in an illness, and
15 talking about recognizing toxicity of our
16 therapies.

17 When we're coming up with a measure
18 that's intended to find the toxicity of our
19 therapies, we want to have a sensitive and not
20 specific measure. You want to have a measure
21 that takes in more patients than less. You
22 want to be conservative in that.

1 So while we don't have data on it,
2 on the face of it, 10.2 to me would seem like
3 a very reasonable number.

4 DR. VASSALOTTI: And I can tell you
5 from last time when we discussed the corrected
6 formulas, there was questions about the
7 validity of those formulas for correction.
8 There were issues of bromcresol green, of
9 bromcresol purple measurements of serum
10 albumin.

11 Those are, give you different serum
12 albumin levels, so that your corrected calcium
13 will depend on which technique your lab uses
14 for measuring the serum albumin. So there are
15 a lot of concerns, that the corrected calcium
16 was a very problematic measure to use.

17 DR. NALLY: So if then we could come
18 full circle and go to the evaluation page
19 under the recommendations. So these were some
20 of the excellent points brought out during the
21 discussion of this measure that was, I think,
22 thoughtfully reviewed.

1 Now we have a total of six measure,
2 five, four and one against recommendation,
3 just to complete things. Thank you.

4 CO-CHAIR SCHONDER: Any other
5 discussion? I just want to clarify --

6 DR. NALLY: Should we consider this
7 with an amendment then?

8 CO-CHAIR SCHONDER: I was going to
9 ask that. Is there any motion to consider
10 this with an amendment, to look at patients
11 who are on treatments, to make this more of a
12 toxicity measure?

13 DR. BERNS: And I would add that
14 each of the prior three months, rather than
15 rolling average would be my preference.

16 CO-CHAIR SCHONDER: So can I have a
17 motion for -- with a specific statement.

18 DR. BERNS: So I'll make a motion
19 that we consider this with the revisions that
20 it would be each of the three previous months
21 for calcium above 10.2, and the denominator be
22 limited to patients who are on calcium or

1 Vitamin D products of any sort, calcium-
2 containing Vitamin D products.

3 DR. KLIGER: Can I just ask the
4 measure developers about the feasibility of
5 those proposed amendments?

6 DR. WOLFE: The data, if I
7 understand it, that would be feasible. Mr.
8 Chairman, the committee, TEP did have some
9 discussion which may not have made it into the
10 write-up, having to do with the choice of the
11 denominator not being limited to those who are
12 treated, and it had -- they were concerned
13 about, and I may not get the words right,
14 people getting calcium from other sources when
15 they didn't have the ability to pay for the
16 drugs, perhaps by having calcium carbonate.

17 So we can't get that through the
18 data, and I don't know if that's an important
19 thing or not. But it is a consideration that
20 --

21 DR. BERNES: But you would know --
22 wouldn't you know if it was prescribed, oral

1 calcium or prescribed oral Vitamin D?

2 PARTICIPANT: What if they're taking
3 a ton of Tums?

4 DR. MESSANA: Yes. Oral calcium
5 carbonate is not prescription. So you'd have
6 to put a data element in that the physician or
7 facility prescribed an OTC.

8 DR. PROVENZANO: I think it gets to
9 Peter's overall point, that even without these
10 revisions, this would be viewed as a toxicity
11 measure, and then we would just go through the
12 stratification of what was just discussed. So
13 I think just to keep it clean.

14 DR. KLIGER: But I'm moved by that.
15 It is indeed true that there are patients who
16 are using products that we know nothing about,
17 and we would miss those toxicities if we
18 included the denominator, as you and I have
19 suggested. So I would suggest that we remove
20 that proposal.

21 CO-CHAIR SCHONDER: Okay. So we'll
22 remove the calcium.

1 DR. NALLY: I have a proposal for
2 you.

3 CO-CHAIR SCHONDER: Okay.

4 DR. NALLY: Are you willing to
5 retract, Jeffrey?

6 DR. BERNS: I'll retract and revise.
7 So then the only change --

8 DR. NALLY: Let the record -- he
9 does retract, and he was a child once.

10 (Laughter.)

11 DR. BERNS: Apparently there's some
12 debate about this, but then my only suggested
13 change would be that it should be each of the
14 last three months, rather than a rolling
15 average for calcium above 10.2.

16 CO-CHAIR SCHONDER: Okay. So we
17 still have the motion to change this to a
18 rolling average? No, no. From rolling
19 average to each month.

20 DR. NALLY: Can I ask just the
21 measure people, is that much work, or is that
22 an easy thing to do? It's not a problem?

1 DR. WOLFE: That's not hard to do in
2 terms of implementation.

3 DR. NALLY: Thank you.

4 DR. PACE: Are there any other
5 discussion? Is there anyone opposed to that
6 condition, to change --

7 CO-CHAIR CROOKS: I am, for the same
8 reason as before. I think we're --

9 DR. PACE: So we first vote then,
10 like we did before, on the condition, the
11 proposal that was put forward. We'll vote on
12 that first, and then we'll -- yes.

13 MS. PAVLINAC: If I could have an
14 explanation why you think that that is a
15 significant change, just so that I'm clear
16 about it please?

17 DR. BERNS: Well, I guess what we're
18 trying to do is identify the outlier, and the
19 provider of bad care and the patient at
20 greatest risk. And again, when you look at
21 what happens over trends, you know, a 10.8, a
22 10.3 and a 9.8, because the doctor did the

1 right thing, would still be triggered as not
2 complying with this performance measure.

3 There's so much clinical variability
4 in patients and labs and so forth, that you
5 really want to identify, focus on those who
6 are persistently out of whack.

7 DR. PACE: So that's -- and the
8 negative side of -- I mean those who advocate
9 for continuing with the rolling average, you
10 want to make a few comments?

11 CO-CHAIR CROOKS: Well, you're
12 moving away from addressing all the patients,
13 and you've moved from an average to an outlier
14 measure, as you said yourself. Now focusing
15 on outliers rather than on what's normally
16 publicly reported to payers. So I think
17 that's a nice tool. I think when you see
18 those high calciums, you're going to roll into
19 that outlier mode automatically, whether
20 there's a consensus standard or not.

21 But what we're not -- what we're
22 doing is we're denying the information or

1 preventing the information that the health
2 care industry can use from getting to them, in
3 my opinion.

4 DR. JACKSON: Generally, any
5 performance grading is not at 100 percent.
6 It's going to be at a certain population and
7 you can trend. Again, you can trend the
8 rolling average and it's going to identify the
9 patients that you need to focus on, and you
10 can still get a one-month number for somebody
11 that's jumped, you know, gone from 9.8 to
12 10.3.

13 You can still jump on that patient
14 and figure out what's going on. So it's, I
15 don't feel strongly one way or the other. But
16 I don't see the need.

17 DR. PACE: So let's, this time let's
18 vote on importance first, and then we'll, if
19 it passes importance, then we'll vote on the
20 amendment before we vote, okay. So importance
21 to measure and report.

22 (Committee voting.)

1 CO-CHAIR CROOKS: We have 16 yes and
2 4 no.

3 DR. PACE: All right. So before we
4 proceed, we will vote on the proposal to
5 suggest to the developer to change it from
6 rolling average to each of the three
7 measurements in that period, and those that
8 are in favor of the proposed change, raise
9 your hand?

10 (Show of hands.)

11 DR. PACE: Those opposed to the
12 change?

13 (Show of hands.)

14 DR. PACE: I think what we'll do
15 then, just as we did for the other one,
16 because that has some implications for the
17 measure construction, and we'll get the
18 developer's response. But let's go to the
19 vote on recommending.

20 So this vote will be on recommending
21 the measure, with the condition going back to
22 the developer, to change it to each of the

1 three months, versus the rolling average, and
2 then we'll get their response. Okay. Go
3 ahead and start.

4 (Committee voting.)

5 CO-CHAIR CROOKS: We have 18 yes and
6 2 no.

7 CO-CHAIR SCHONDER: Okay. So I
8 believe we'll break there as far as the
9 measure evaluations for today. But we do want
10 to take the opportunity to ask for any NQF
11 members or public comment that we may have now
12 at the end of the day.

13 Public Comment - Afternoon

14 MS. MCGONIGAL: Can you hear me?
15 Okay. I'm Lisa McGonigal again from Kidney
16 Care Partners. Like this morning, we would
17 like to take the opportunity to comment on the
18 measure groups that are going through
19 tomorrow, just because there won't be the
20 chance in the morning.

21 So first, for the hospitalization
22 measures, KCP supports Measure 1463, which is

1 the standardized hospitalization ratio for
2 admissions. We support it for public
3 reporting only and not for payment purposes,
4 as hospitalization can occur multiple times
5 for a single patient.

6 This measure could have a
7 substantially greater impact on a facility
8 score than the standardized mortality ratio
9 measure in dialysis facility compare, after
10 which it was largely modeled.

11 So because of this, unlike the
12 mortality ratio, the hospitalization ratio
13 should be limited to hospitalizations, for
14 reasons specific to CKD. Specifically,
15 hospitalizations for appropriate DRGs for
16 dialysis access related infections, and for
17 cardiovascular fluid overload admissions.

18 We don't support Measure 1464, which
19 is the hospitalization ratio for days, for
20 either public reporting or payment, because
21 hospital length of stay is affected by many
22 factors that are entirely outside the

1 facility's realm of control.

2 So moving to the vascular access-
3 related infection measures, KCP supports all
4 three of the CDC's National Health Care Safety
5 Network measures. That's measures 1460, 77
6 and 78. We support them for the purposes of
7 public reporting only, and not for payment
8 purposes at this time.

9 KCP reviewed all of the infection
10 measures first, with an eye towards
11 identifying the best in class, pursuant to
12 NQF's policies, and then second with an eye
13 towards recommending a parsimonious set, based
14 on objective criteria and not subject to
15 interpretation.

16 So we believe the CDC measures are
17 superior to similar measures that were
18 submitted for consideration, because the CDC
19 measures have been fully tested.

20 Moreover, many facilities are
21 already familiar with and are reporting the
22 data related to these measures, and they

1 receive reports that are useful for their
2 internal quality improvement purposes.

3 That's it. Thank you for the
4 opportunity to comment.

5 CO-CHAIR SCHONDER: Thank you. Are
6 there any other public comments?

7 CO-CHAIR CROOKS: On the phone?

8 CO-CHAIR SCHONDER: Are there any
9 comments from the phone?

10 (No response.)

11 CO-CHAIR SCHONDER: And measure
12 developers can also comment at this point as
13 well.

14 (No response.)

15 CO-CHAIR SCHONDER: Hearing none,
16 then I think we'll adjourn for the evening.

17 For those you that are -- tomorrow,
18 we will meet -- breakfast will be at 8:00
19 a.m., and then we'll do the welcome. We'll
20 begin our proceedings at 8:30 a.m.

21 (Off mic comments.)

22 DR. PACE: I think that's a good

1 suggestion. Why don't we have you, I mean
2 we'll have you come down here, get your
3 breakfast at eight and we'll start as quickly
4 as possible afterwards.

5 CO-CHAIR SCHONDER: Okay, okay.
6 Then we'll do that. We'll plan to start at
7 8:00 a.m. or shortly thereafter, okay. For
8 those of you traveling, have a safe trip
9 tonight.

10 (Whereupon, at 5:28 p.m., the above-
11 entitled matter went off the record.)
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C E R T I F I C A T E

This is to certify that the foregoing transcript

In the matter of: End-Stage Renal Disease
Steering Committee

Before: National Quality Forum

Date: 01-11-11

Place: Washington, DC

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