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

C-O-N-T-E-N-T-S

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.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Disclosure of Interest

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

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

DR. PACE: Yes.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

renal community.

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

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

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

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

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

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

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

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

for those you who are not familiar with us.

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

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

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

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

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

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

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

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

That conference had experts from

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

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

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

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

all over the country, speaking to dialysis patients.

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

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

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

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

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

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

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

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

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

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

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

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

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

MS. HAMMERSMITH: Do you have any disclosures?

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

MS. HAMMERSMITH: Okay, thank you.

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

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

quality committee.

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

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

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

My son would like me to spend my

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

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

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

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

Kidney Fund.

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

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

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

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

the NKF.

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

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

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

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

past president of the Renal Physicians Association.

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

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

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

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

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

(Laughter.)

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

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

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

outcomes, and I was involved in that.

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

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

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

(Laughter.)

DR. JACKSON: I'm Jerry Jackson.

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

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

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

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

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

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

I think I probably started back in

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

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

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

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

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

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

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

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

disclosures.

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

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

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

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

(Laughter.)

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

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

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

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

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

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

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

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

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

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

(Laughter.)

DR. NALLY: Thank you.

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

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

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

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

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

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

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

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

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

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

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

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

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

Have worked in ESRD transplant pediatric hemodialysis before our University

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

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

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

(No response.)

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

(No response.)

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

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

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

PARTICIPANT: It's right here.

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

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

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

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

Project Introduction and Overview

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

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

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

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

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

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

After we adjourn tomorrow, we will

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

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

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

Just a quick breakdown of the

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

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

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

We have certain conditions before

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

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

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

If we have competing measures, NQF

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

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

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

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

care and achievement of desired outcomes.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

DR. PACE: Thank you.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

to us?

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

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

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

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

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

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

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

DR. LATTS: Oh, and if the

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(Laughter.)

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

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

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

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

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

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

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

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

advance.

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

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

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

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

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

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

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

DR. LATTS: Yes, yes.

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

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

difficult there. Yes.

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

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

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

That is correct. So any measure

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

DR. PACE: And just to clarify, NQF does not have unlimited endorsement. Endorsement is for three years, and then all the measures are reviewed again. And that's, we've moved into a new process, which we call endorsement maintenance cycles by topic, and that's what the next phase of this project is really going to be, the renal endorsement maintenance.

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

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

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

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

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

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

CO-CHAIR CROOKS: Okay. It's time

for us to --

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

CO-CHAIR CROOKS: Yes.

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

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

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

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

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

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

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

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

CO-CHAIR CROOKS: After the break.

DR. PACE: After the break, sorry.

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

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

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

OPERATOR: Dale Singer's on the

line.

DR. PACE: Okay.

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

DR. PACE: Okay, thank you.

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

(No response.)

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

Public Comment

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

renal disease.

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

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

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

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

eight proposed pediatric consensus standards. We support all eight measures for use in public reporting and for payment purposes.

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

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

First, we feel the requirement for a simultaneous ferritin and TSAT collection date should be removed from both the numerator and denominator in all three of the measures. There are several reasonable scenarios where simultaneous values might not be reported that

outside the facility's realm of control.

For example, lab errors and so on. In these instances, the facility would be unfairly penalized. KCP is also concerned about the potential for unintended consequences, specifically increased cost with this requirement. Facilities might end up having to repeat testing to get the required simultaneous values.

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

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

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

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

Finally, KCP recommends that an exclusion be added to Measure 1429, Avoidance of Iron Therapy and Iron Overload. Specifically, as many nephrologists typically obtain a TSAT value and then act on it one to two months later, requiring avoidance of iron for three months is inappropriate and out of sync with current practices.

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

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

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

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

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

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

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

CO-CHAIR CROOKS: Okay, thank you. Any other public or NQF members care to comment? Would you like to comment? Okay.

(No response.)

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

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

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

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

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

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

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

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

The preliminary evaluations, the

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

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

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

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

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

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

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

Introduction of Measure Developers

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

tracked for the benefit associated with achieving that level.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

dialysis community.

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

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

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

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

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

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

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

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

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

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

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

Consideration of Candidate Measures

Measure 1418

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(Off mic comment.)

DR. PACE: Microphone.

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

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

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

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

DR. PACE: Yes, right.

DR. KLIGER: Well, I have three. Okay.

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

CO-CHAIR CROOKS: Are those primary reviewers?

DR. PACE: Yes.

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

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

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

really thinking ahead to tomorrow.

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

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

DR. PACE: Right, right.

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

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

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

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

DR. KLIGER: Correct, right.

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

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

DR. PACE: Okay.

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

But I gather that the data behind a

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

DR. WOLFE: Yes. I can speak, I can speak to the fact that we do have the dose of dialysis on the claims for all patients, whether they're at the hospital or not. However, if they don't submit a bill while the patient is in the hospital, then they are not in the denominator.

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

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

DR. BERNS: Yes.

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

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

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

DR. KLIGER: No, it's not.

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

CO-CHAIR CROOKS: Barbara.

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

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

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

But NQF I think has, and if you look

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

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

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

that would take a life of its own.

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

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

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

CO-CHAIR CROOKS: Go ahead, Sylvia.

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

However, one of the considerations

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

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

MS. RAMIREZ: Yes.

CO-CHAIR CROOKS: Thank you. Barbara was next.

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

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

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

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

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

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

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

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

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

CO-CHAIR CROOKS: Okay, Jerry?

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

a family of measures for internal quality improvement.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

CO-CHAIR CROOKS: Lisa?

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

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

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

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

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

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

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

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

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

the patients were ever getting their adequacy measured.

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

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

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

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

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

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

But looking at the CPM data years back, when I worked on that project, and I guess we're hearing there's a 20 percent -- there has been a persistent, and I would be interested in what Arbor has seen recently. But we did demonstrate over time a continued gap in measurement.

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

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

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

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

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

But when it comes to pediatric

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

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

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

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

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

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

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

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

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

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

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

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

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

(Committee voting.)

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

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

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

(Committee voting.)

DR. PACE: Pardon me?

(Off-mic comment.)

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

(Off-mic comment.)

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

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

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

(Committee voting.)

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

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

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

(Committee voting.)

DR. PACE: And then feasibility.

(Committee voting.)

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

(Committee voting.)

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

(Laughter.)

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

CO-CHAIR CROOKS: Congratulations,

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

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

Measure No. 1421

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

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

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

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

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

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

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

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

I looked at all the comments during, you know, throughout all the subcategories, and there really wasn't anything substantive about why we wouldn't accept this measure. The reviewer who felt that we shouldn't, I think, felt, in looking through the comments, that it should be combined and harmonized with another measure, and therefore it would be more valuable if it was a linked measure rather than a stand-alone measure, to look at the method of adequacy measurement, that perhaps it should have been linked with the frequency of adequacy measurement.

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

CO-CHAIR CROOKS: Okay, thank you.

Other assigned reviewers now? Robert.

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

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

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

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

the adult populations.

CO-CHAIR CROOKS: Barbara.

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

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

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

that's four times a week.

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

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

DR. FIVUSH: Right, right.

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

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

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

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

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

is specified in terms of the frequency.

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

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

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

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

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

CO-CHAIR CROOKS: Joseph.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

DR. WOLFE: Or URR.

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

CO-CHAIR CROOKS: Other comments?

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

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

take frequency into account.

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

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

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

making the recommendation.

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

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

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

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

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

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

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

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

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

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

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

DR. FIVUSH: So that would be --

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

DR. KLIGER: I would suggest instead

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

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

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

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

method to assess a dialysis session's adequacy.

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

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

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

So I guess I don't know procedurally

where the group is.

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

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

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

CO-CHAIR CROOKS: Okay, Barb.

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

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

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

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

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

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

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

this one?

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

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

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

DR. KLIGER: Exactly.

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

DR. PACE: Well, we could vote on it

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

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

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

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

That's for the minimum threshold.

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

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

DR. FIVUSH: It's irrespective of frequency.

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

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

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

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

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

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

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

DR. MESSANA: That's the specification.

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

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

this?

DR. FIVUSH: Yes.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

not in the facility the entire calendar month.

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

(Off mic comments.)

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

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

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

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

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

(Committee voting.)

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

(Committee voting.)

DR. PACE: Next question, usability.

(Committee voting.)

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

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

(Committee voting.)

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

(Committee voting.)

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

(Committee voting.)

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

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

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

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

CO-CHAIR CROOKS: Time check. 12:10, we're at lunch break time.

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

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

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

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

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

(Whereupon, the above-entitled matter went of the record at 12:12 p.m., and 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.

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

DR. DUDLEY: Yes, I can hear you.

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

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

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

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

DR. PACE: His what?

OPERATOR: His line did disconnect.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

do nothing.

DR. LATTS: I would argue that your obligation, though, is to do what needs to be done to encourage adherence among your patient population.

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

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

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

patients in-center.

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

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

(Laughter.)

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

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

I just think that that should be

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

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

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

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

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

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

DR. PACE: Okay.

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

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

MS. LeBEAU: I just, as the risk of

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

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

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

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

justified really.

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

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

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

MS. ANDERSON: Coming from a large

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

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

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

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

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

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

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

DR. FIVUSH: There you go.

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

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

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

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

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

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

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

pediatric patients who are home hemo.

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

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

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

What I'm talking about here, the

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

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

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

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

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

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

DR. PACE: Right, yes, exactly.

CO-CHAIR CROOKS: And the next level can say well then we shouldn't do it or that's okay, you know, or --

DR. PACE: Right.

CO-CHAIR CROOKS: Is that okay with the Committee we do it that way? I don't think we need to revote.

DR. BURSTIN: I'd just be a little worried that perhaps there are some mixed bags on the way people voted. Some people may have

voted based on that issue; some people may have voted based on other issues.

So just for the sake of clarity, it might just be nice. And the question would be if this issue's going to come up every single time, do you want to be constantly clouding the vote every single time on this issue, and do we somehow --

I mean it's just going to come up every single time apparently. Or do we somehow make that a discussion item we'll have separately, maybe even put out for comment as a general issue?

DR. PACE: Right. But if the -- so I guess the question is if the Committee can reach consensus on that. Otherwise, it is going to come up on every vote, because people are going to have to vote the way they feel about that issue. So and I know it applies to more than just the measure we're talking about.

CO-CHAIR CROOKS: Some measures may

be more appropriate to include home hemo than others. I think that's another complicating thing. Do you think so, Alan or others? This one seems pretty straightforward. Yes, measure adequacy. There's as much evidence for home as there is for not doing it at home.

But if it comes to maybe vascular access or an infection, it may not be applicable. They're self-cannulating versus in-center. You know, there's differences in the way the treatment is accomplished.

DR. PACE: So does anyone have a way out of this or around this that we should proceed, or discuss it with each measure?

CO-CHAIR CROOKS: I think we're going to have to.

DR. PACE: Okay, okay. Given our discussion about the past measure, is there any need to revisit that, with the caveat of making a recommendation for home hemodialysis, or do you want to just move on?

(Off mic comment.)

DR. PACE: Okay. So why don't we just do a show of hands of who would like to revote on the method measure?

DR. BURSTIN: Why don't we just revote, in case -- why don't we just revote?

DR. PACE: The question is whether someone wants to suggest the Committee that the measure should be voted on, with the condition of adding home hemodialysis patients, or do you --

DR. PROVENZANO: So the revote would be -- well, nobody's made any --

(Off mic comment.)

DR. PACE: Okay. Let me do it this way. The measure you voted on excludes home hemodialysis patients. So it sounds like your vote took that into account. So if the measure stays as it is, is there any need to do a revote?

DR. FIVUSH: Again, I'm not the measure developer. I'm the measure explainer, I guess, or the measure presenter. But as a

pediatrician, I really think it's critical that we have a measure that is about how we measure adequacy.

I mean, I think I'm using the word "measure" twice in the sentence, but I think we do have to have it. My concern is that I understand the exclusion of home hemodialysis patients. I think it's a very, very small and very poorly understood population in pediatrics, much more so even than in adults.

And again, we have such small numbers over many sites, and I think it was probably the intent of the TEP was to exclude that population, not because they don't care about the population, but because they simply, it's such a new process.

But I also am concerned that there was some confusion about frequency tied into this measure, that also may have worked against the measure, that I'd actually like a revote. If it's positive, that's great. If it's negative because of that exclusion, then

I think it would be very important to go back to the TEP and say that's why there's an exclusion. That's why there's a problem.

DR. PACE: All right. Let's do this. We'll ask you to revote just on recommendation, yes or no, if that's --

DR. RAMIEREZ: May I interrupt for a second, just to respond to the question asked of us earlier, with regards to the percent of pediatric patients on home hemodialysis. That is 1.1 percent.

DR. FIVUSH: So and again, to couch that in 1,600 patients, it's just -- it's a small number that I think we're struggling with even understanding. That doesn't mean they should be excluded.

CO-CHAIR CROOKS: Let me propose that we just let it go and just put a little note in there saying that the reason -- some Committee members were hesitant to vote for this because it excluded home hemodialysis patients. But it passed. I mean, it passed

and let's move on. I don't see that we're going to gain anything by revoting or dissecting it further.

We have agreed, I think it was important to agree that the home issue, we're going to have to look at it measure by measure, that we can't make a sweeping statement for all the metrics. So I think that's where we're at. Is that okay with the Committee?

CO-CHAIR SCHONDER: Should we check to see if Tom is on the line?

CO-CHAIR CROOKS: Oh Tom, did you -- yes. Go ahead.

CO-CHAIR SCHONDER: Is Tom on the line again?

DR. DUDLEY: Yes, I'm back on. Sorry. My phone died right mid-statement. I'm not sure how much you heard when I spoke before.

CO-CHAIR SCHONDER: We really didn't hear a whole lot. Just go ahead and start

from the beginning again.

DR. DUDLEY: Okay. Shari actually touched on this in the morning. There was a comment made earlier today about the possible use of other endorsed measures for payment.

I just wanted to reiterate what Shari said, that CMS is held to the rulemaking process before you use any measurements, any new measures for the purpose of the quality incentive program.

So hopefully, that is the concerns about the use for payment is kind of taken out of the equation when talking about the possible measures. Just a simple statement.

CO-CHAIR CROOKS: Okay. Thank you for that reassurance, and with that, we'll move on to the next metric.

CO-CHAIR SCHONDER: Yes, okay. We'll move on to the next metric, which is No. 1423, which Barbara is also our presenter for that as well.

Measure No. 1423

DR. FIVUSH: So hopefully this will follow in line with the last measure. This measure is dialysis adequacy. It's minimum single pool Kt/V for pediatric hemodialysis patients.

The numerator statement is number of patients, and the denominator is delivered dose of hemodialysis, calculated from the last measurements of the month using the UKM or the Daugirdas formula was greater than or equal to 1.2.

The denominator statement is number of pediatric patients in-center hemo, and again that's less than 18, who have been on hemodialysis for 90 days or more, dialyzing three or four times weekly. So the exclusions are patients receiving dialysis less than three times a week or more than three times a week, and not in a facility for the entire calendar month.

So in terms of what the, there were five evaluators of this measure, and when we

-- when the evaluators looked at the criteria for importance of the measure for measurement and reporting, all five said yes, that there was a lack of pediatric data, and that there was some comment that there was a reliability of this standard on adult data, but it was still accepted that we should go forth with it.

The scientific criteria met. Two said it was completely, 3 said partially. One commented on the exclusion of home hemo patients in this. But again, this is a very narrow spectrum measure, because we're determining a level of adequacy, which we really don't have evidence for in that home population at this point.

And to what extent was criteria feasibility met? Four said completely, one evaluator said partially. And was the criteria feasibility met all five said completely. Everybody that reviewed the measure, at least that entered data on it,

recommended that we go through with the measure.

There was some discussion not of the home hemo patients, because again, of the lack of data understanding not that we either should or shouldn't measure adequacy in them, but that we knew exactly what it was, that we don't have evidence of what that standard Kt/V would be.

But that if we're going to do three or four times a week, that that may lead to the issue that we ended up discussing the last go-round, that perhaps we're not calculating it correctly using the single pool Kt/V in a patient who has dialyzed more than three times a week.

Looking at further into the specifications of that measure, that was taken into great consideration by the CTEP that recommended this measure, and they felt that although it's a small percent of patients that are actually dialyzed, we said about 5-1/2

percent, and again we're talking about a small pool, we were afraid of continuing to pull patients out of the denominator, inability to really look at all patients, that they wanted to keep as many patients in the denominator as they could.

They felt very comfortable that many of the patients, and I don't have the number; maybe Arbor does, of that 5-1/2 percent, what age are we looking at? Their sense was it as the much smaller patients, the younger patients, that needed to be done four times a week, and that we would achieve that minimal adequacy level in even those younger pediatric patients.

So that was the recommendation that came forth from this group.

CO-CHAIR SCHONDER: Any comments from the other reviewers?

(Off mic comment.)

DR. FIVUSH: We know who you are.

(Laughter.)

DR. FIVUSH: I know who you are.

CO-CHAIR SCHONDER: Any other discussions? Alan.

DR. KLIGER: I'm not going to repeat it all again, but here's where it matters. So here, I would submit that if you don't want to eliminate people in the denominator who dialyze less or more than three times a week, that the numerator can't be what it is now. It needs to be standard Kt/V.

DR. BERNS: Might I ask a question or raise a concern? Again, it gets back to the issue that I talked about, about the wide age range. Is there a risk that this is -- that a Kt/V is inadequate dialysis for a baby, for instance? Is there some spectrum of people for whom this would not be appropriate and shouldn't be an acceptable performance measure?

CO-CHAIR SCHONDER: Barbara, go ahead.

DR. FIVUSH: I would -- this is a

minimum level, and I think the concern is that there is a minimum standard. I think you're exactly correct. We're going to find out when we really can look at this data that perhaps younger children do need more dialysis. They have much more rapid growth. They have much more rapid cognitive development.

But this is again a minimum adequacy level, and the concern in the pediatric community, from reading the specifications and from practicing in that community is that there's not even a minimum standard, and there needs to at least be that.

But I don't think this is the maximum standard, and I don't think this is suggesting that this is the best standard. I guess the concern would be that if we say this is okay, does this become okay. But with the gap in care that we're seeing, I think the thought is we have to, the pediatric community has to start some place in looking at this data, and seeing that there are minimum

standards.

We may be able to link this later and find out that we need to do much better. So it's just, I think, being seen as a first line. If we -- and I think if we looked at the numbers, and again I don't have the number, the patients that are getting it more than four times a week, my suspicion is that they're our youngest patients.

So therefore I think that was why the CTEP felt comfortable keeping this in there, that they were knowing that the younger patients may be getting a single pool Kt/V of 1.2, but they were getting it more frequently.

DR. BERNS: There's two issues here, one of which is a need, from the pediatric nephrology community, to collect data, and then analyze that data and come up with some answers for us.

The other is the establishment of performance measures that are going to influence care, influence payment, you know,

and as we're hearing, that setting this Kt/V of 1.2 is going to be the standard of care until somebody proves otherwise.

It may be that this an appropriate standard of care or a minimum dose of dialysis for a teenager, an adolescent and above, and maybe we should treat them as adults and not children. But there is a risk that we have to - this is the unintended consequences, that we're going to do a bad thing for children.

The mandate ought to be measure in the population for whom we have absolutely no data about what to do or what that number should be. Where we do have information, let's be very directive about that population.

This is going to come up probably when we talk about anemia too, is we have anemia outcomes data on a very specific patient population, and we're applying it to everybody who dialyzes. I think it's just really inappropriate to do so.

CO-CHAIR SCHONDER: Joe.

DR. NALLY: Jeffrey stole most of my thoughts, but we would be - I think we were of the understanding that it would be a good thing to start measuring. It's a different question to arbitrarily pick a standard, and it sounds like from the measure, that it was 1.2 because that was the lowest for adults, lowest minimum for adults, and kids may be higher.

So when you don't have any outcomes connected to the various Kt/V's, that makes me uncomfortable setting a standard. Then when I read that the Kt/V can be influenced by patient's age, size and ethnicity, and you start introducing several variables along the equations without outcomes to use as the gold standard, I think it may be premature to set a target or a standard when I think is what you really want to be doing is just data collecting, to determine what those future standards will be arrived at.

DR. KLIGER: Can we ask the measure

developers their responses to that? I'm sure that the CTEP discussed this. I'm curious what their thoughts were about this.

DR. MESSANA: If Bianca or Sylvia Ramirez is on the phone, she was there. She might be able to comment most accurately.

CO-CHAIR SCHONDER: Sylvia?

DR. RAMIREZ: Yes. Could you just repeat the specific question?

CO-CHAIR CROOKS: The issue is the potential danger of kind of a single prescription for all ages and sizes and did the Committee, were they concerned about that or think about that?

DR. RAMIREZ: Yes absolutely, and in fact, in the formal report for the clinical performance measures, as Dr. Fivush stated in the beginning, there were certain considerations that the TEP discussed in the pediatric population as a whole.

The first is the general acceptance of the limited data. The second is the

importance of growth, and the third for sure is the wide variation in physiology by age and clinical needs. I think that in general, the approach of the TEP was to develop at least a minimum standard, and not to set an ideal standard, because there's no measurement whatsoever.

You can see the high percentage. I think there's at least 20 percent without Kt/V measurement, that it's thought that given the evidence linking Kt/V greater than 1.2 even in the pediatric population, in terms of reducing hospitalization and mortality, that even if this may not be the ideal standard, we have sufficient data to suggest that a standard of 1.2 or a target of 1.2 may be of clinical benefit.

DR. NALLY: But Sylvia, wasn't that 1.2 in an adolescent population, and you know, how would that compare to the younger children, et cetera.

DR. FIVUSH: I actually had the

opportunity to participate in looking at some of that data, and actually there is a minimum standard. It's sort of -- I think it may be like the hemoglobin data. We don't know what the best target is. We know below which there are problems.

So if you look at the data, even in younger kids, less than 1.2 is a problem, and associated with increased morbidity and mortality. That is one of the few things we do have data on.

The problem is, and Arbor again may comment on this, there are so few pediatric patients under the age of two in this country that the data has been censored in any reports, because the boxes are too small.

I think when we looked at it, we guessed that there are less than ten patients under the age of two on hemodialysis in the country. So it's very hard to draw general conclusions about optimal Kt/V's when you're talking about populations that are this small.

And I mean I think that's why our concern is that we do have a minimal level. We could try and exclude all those very young infants, but then we think we're excluding a particularly vulnerable population. We're not learning anything about them that may in the future allow us to achieve better targets.

That's why this is not a target Kt/V. This is a minimum, and I think the word is pretty clear. It starts with minimum. But again I'm --

CO-CHAIR CROOKS: Well, I listened. I think you kind of made an argument against the importance of it, in the sense that this is a very small population. We're going to set a national consensus, voluntary national consensus standard and apply it across this whole population, and it, you know, makes me wonder is it important enough to be a standard, especially if you're going to include --

Then you also have the possibility

of unintended consequences. Now what we say is a minimum has a way of becoming a maximum in the health care world, and also you are setting it for kids, and is there really enough data.

It worries me, if I was a father of a small child on dialysis, you don't really know what the right thing to do. I'm not sure that this would reassure me that the quality is improved now because this metric was put in place.

DR. FIVUSH: I could tell you from a data point of view, we may not be able to tell you what the optimal is. I think certainly pediatricians could tell you that less than 1.2 would be problematic.

So you know, I understand that everybody, I understand the concerns around the table. I happen to feel strongly that we need to have a minimum Kt/V. We need to have a minimum adequacy measure. We shouldn't throw out the small children.

Just like we didn't want to throw out the home hemo patients in the last measure, we need to take them into account. We can't just ignore them because there aren't that many of them. Again, I understand how -- I can understand the concern about unintended consequences. I still feel quite strongly that we should have a minimum adequacy measure in children.

CO-CHAIR SCHONDER: Jerry has a question.

DR. JACKSON: Question. Is this a facility level measure? The reason I ask this is that if you have a target, call it minimum but it's a target, you're going to have a distribution of outcomes around that.

So if it's a normal distribution that's going to be named, you're going to have a substantial number. You might have 20 percent who fall below this and still have your minimum target met by that facility.

We've recently moved our target in

an adult facility up to 1.4 because of this issue, in order to get the lower end of the curve up to a better minimum. My question would be is the 1.2 the right number, or should it be higher?

DR. KASKEL: To emphasize what Barbara was saying again, these measures are taken in a composite. You have small numbers. You have an infant who you're looking at this as a measure of adequacy. You also look at growth. You look at anemia and you look at development. It's all taken in a package.

If the patient's value is not what we expect it to be and they're not doing well with the other factors, we have an assessment that the prescription is not adequate. That's what we come up with.

So this piece of that, this factor adds to the composite score of the evaluation of dialysis in that young infant.

DR. PROVENZANO: I was going to say, I'm beginning to better understand why there's

no measures in pediatrics. I mean it is a diverse population.

You have a bunch of people here, adult nephrologists. We feel your pain. I guess my simple question is it seems like there's a rush to pick a number with little data.

Help me better understand why must we, if what we can do is approve just measurement, and then use that data to select something that's more scientifically valid?

DR. FIVUSH: This measure actually has the, as I said, the validity more than any of the other measures. Alan asked about frequency or methodology. But this one, actually there are studies in pediatrics using the CPM data, and looking at morbidity and mortality linked to low Kt/V.

So I think again, you know, the concern is we have a gap. There are 20 percent of patients that aren't even having Kt/V measured, and then you know, our concern

is that if you have a minimal level in adults, wouldn't it be natural to assume a child who's having growth and development would at least need that same level, at least, at least.

So I would -- I think we have been talking about measure development for ten years in pediatrics, and we can't seem to get over this, the hump of actually saying it's, you know, it's time to say there's minimum standards for children.

Yes, we don't know the optimal. But there are minimum standards, and we should abide by those. I think the pediatric community would say to you loud and clear yes, we understand our lack of ability to look at these patients critically. We don't have that many.

But I think, you know, the CPM project was in 1999 it started out. I'm trying to go back. It has been a long time of data collection, with people continuing to inadequately dialyze children because we've

never taken that step.

So understanding this process is not in place for that, I think, you know, and the Committee has to -- and I'm not the measure developer. I think the pediatric community feels that it is important, that there be a minimum level of hemodialysis adequacy in children, understanding all of the concerns at the table.

If the group feels that this measure, that we don't have data on the youngest infants and children, then I would at least ask that we, and I guess it depends on what the vote is, that we consider talking to the developers about at least changing this to an adolescent measure for hemodialysis.

I think as a starting point, there needs to be minimal levels of adequacy in pediatric patients, in some population of pediatrics. So and I know we can't change the measure. I would just --

CO-CHAIR SCHONDER: Any other

discussion?

DR. VASSALOTTI: You said the gap in care 20 percent. We've already addressed that with the previous measure, a gap in care for this measure, in terms of --

DR. FIVUSH: You know, as I said, we aren't allowed to report on it. We have been able to report on it in the youngest patients, because of the consequences of having outliers. So I'd have to go back to Arbor to even see if they could tell us.

DR. VASSALOTTI: I see a facility, 90 percent of the patients have a Kt/V of more than 1.2 in 68 percent of facilities?

DR. WOLFE: So that's fairly comparable to the adult population, but there are patients that are not receiving that level of dialysis. The TEP's thinking on this was while they, and I'm including here, this is from page 92 of the synthesis report.

The TEP agreed the initial pediatric target should be set to ensure delivery of at

least the minimum required care for this population, if not optimal care.

In addition, these adequacy targets should be no lower than existing adult hemodialysis targets, since generally pediatric patients' greater metabolic demands require higher hemodialysis adequacy targets, in terms of small solute clearance.

It is, and this is an intent, rather than the measure. I understand that. "It is the intent that over time, the initial measurements will be improved, and additional targets established, resulting in improved quality of care for pediatric patients."

So the TEP did recognize that this was and proposed it as a starting point, rather than an ending point. There was discussion, and it's not summarized here, of a concern generally by several of the TEPs, that setting a requirement for measuring something, without setting any requirement at all for achieving a threshold, seemed strange.

So this was their approach towards that, resolving that problem, to at least set it at a minimum level, as opposed to an ideal level.

DR. BERNS: Just to further complicate this issue about the performance gap, one must wonder, at least, whether some of that 20 percent that's not measuring this is not measuring it because they're not convinced that there's a value to doing so, and they don't know what to do with the number once they have it.

MS. ANDERSON: Just a point of clarification. In the information I think you provided, Barbara, is that in the infants, there's evidence that less than, a Kt/V less than 1.2 was problematic for morbidity and mortality. Did I understand that correctly?

DR. FIVUSH: Yes. I think the -- you know, again, a lot of this is -- I don't want to say it's very small sizes, but it's been linked to also cognitive development in

children, in the youngest patients. But not in any large study, not in any kind of randomized control trial, and that's -- we just don't have the numbers for that.

DR. KLEINPETER: Well one thing, perhaps we should consider time limitations on this, and when we would want more data to look at this again. Because as Barbara mentioned, this hasn't been looked at in over 15 years, and there's been no follow-up over that time period for when this first was done for the initial CPM project.

DR. PACE: This measure has been tested, so it's not one that we would put under time-limited endorsement. But keep in mind that any measure we endorse is reviewed at least every three years, where we would ask them for data on the actual measure, plus we solicit comments on unintended consequences, plus we have an ad hoc review process.

So if new evidence emerges that shows that this is the wrong value, that can

be, you know, taken into consideration before that three years. So our testing is about the reliability and validity, and they've presented, you know, you can decide that that was inadequate and that it's not reliable and valid.

But it technically doesn't meet a criteria for time-limited endorsement.

DR. KLIGER: I don't want to beat a dead horse, but let me propose two children sitting next to each other in a hemodialysis unit, one dialyzed three times a week and one dialyzed four times a week.

The three times a week has a measured spKt/V of 1.2, and the four times a week child has an spKt/V measured at 1.05. That 1.05 fails. When you measure standard Kt/V, the one who fails has better urea removal and better kinetics than the one who passed. This is a flawed measure, because it does not consider frequency in spKt/V.

CO-CHAIR SCHONDER: Any other

comments? Okay. I think we're calling for a vote.

DR. PACE: So just to clarify then, you want to put up -- so the denominator is what you're talking about, that is the problem. If it includes, let me just find it, right there.

CO-CHAIR CROOKS: To rephrase it, if I may, that it's a flawed measure, you know, in the way it's constructed and conceived, you know, because you can't adjust it by doing something to the denominators.

DR. PACE: Because the denominator --

CO-CHAIR CROOKS: It's the wrong, it's the wrong measure, to use this Kt/V rather than a standard.

DR. PACE: Right. So what you're saying is that the denominator includes patients dialyzing three or four times. So if they want to keep that denominator, then they need to change the numerator to the standard,

or if they want to keep the numerator, then the denominator needs to pick probably three times, because that's most frequent. Okay.

DR. FIVUSH: It's not a flawed measure. This was the intent of the measure developers, because I read the entire measure. It was their intent. It's not flawed. They clearly understood. We're talking about under-dialysis. We had a whole conversation about not being adequate.

They feel that the patients that get it four times a week are the younger patients who need it, the measure developers felt very strongly that this was the correct measure, that patients dialyzed four times a week should additionally meet the single pool of 1.2 with each treatment.

Now I'm not -- I'm just saying that's what the measure developers felt, they clearly understood that they were using four times a week in this measure though. When you read through the whole text, and they felt

that if that were true, they would still want those patients who were sicker or smaller to get more dialysis, and each time to reach 1.2.

So I think the flawed part is that we may not think that that's true. But the measure developers felt that that was true. So --

DR. LATTS: So can I just ask our pediatric experts, for those of us who are not pediatricians and nephrologists. Based on Alan's comments and based on your understanding then, are you recommending acceptance of this measure?

DR. FIVUSH: Well, the answer, and there are other pediatric people in the room and other people with experience. I feel that this is a good and adequate measure for pediatrics, and a starting point. I believe that those patients dialyzed four times a week will have a single pool Kt/V over 1.2.

I don't think it's a flawed measure. I think it's an unusual measure, because I

don't think the adult population generally dialyzes their patients four times a week, for the reasons that we dialyze our babies four times a week.

But I just am trying to separate myself from again, as I sit here, I'm not the measure developer. I'm the measure presenter. I don't know --

DR. KASKEL: I think we have to consider it as a subjective feeling about neurocognitive development that you cannot put into an equation and growth. Growth you can make up for with some extra help. Not neurocog.

We're very cognizant ourselves as to the adverse effects of uremia and under-dialysis in the infants and toddler's brain. It may not be strong evidence. There's suggestive evidence. There are some reports, very under-studied. We also know that this doesn't improve when you identify it.

So based on that, we work

aggressively to follow some guidelines, to make sure we're doing adequate dialysis, just like we do providing adequate nutrition. This is all we have right now. That's it. That's the measure, be it good or bad.

DR. VELEZ: Barbara, what happens if we don't put a number and this measure fails? I mean what harm have we done?

DR. FIVUSH: Well, I think if we have a measure that says you have to measure adequacy, but we haven't told them what the minimal acceptance is, we're not fixing anything. You're now measuring something, but again, they may be now measuring in children, but they still -- maybe they're not measuring that because they don't know what to do with it.

But at least if we know that it's 1.2 as a minimum, and they're not achieving it, then they have to do something about it. So I think that the risk is that we're going to continue to under-dialyze some children.

DR. VELEZ: Even though we have to look at each measure by itself, and we all agree with that. My word of caution is also when we go to the next one, nPCR, the statement is made differently. We don't have a good target; we're just going to measure.

DR. FIVUSH: But thankfully I'm not presenting that measure.

(Laughter.)

DR. NALLY: But Barbara, if they're going to collect data and measure things, it might be possible, say, to have a clinical guideline of 1.2. But I think there's a difference between having this as a should guideline, as opposed to a CPM. I think that's the concern of some of the audience.

DR. FIVUSH: I would say, and I know Karen and Peter, everybody's done a great job keeping this contained, and I appreciate everybody's time. I think I can only state again that the pediatric community feels critically strongly about having a minimal

Kt/V. I think every comment has been important, thoughtful, and I think we need to think about that as pediatricians.

Understanding everything, I still think -- my feeling is still that we should still have the minimum. But I absolutely think every point is critically valid, I think. So I guess I'm saying --

MS. PAVLINAC: This doesn't really address whether it should be a CPM or not. But I've been on the medical review board for my network for years. This is the same conversation we had in adult populations, whether or not to even start measuring Kt/V, whether it should be 1.0, whether it should be 1.2.

It may, yes. But in kids who are in adult units, and there are no guidelines for adult nephrologists to follow, I think that's where those of us that work in pediatrics are concerned. Just because, and we do know that we're following adult guidelines. We don't

have great data. But --

DR. PACE: So the first question is does it meet the criteria for importance to measure and report.

(Committee voting.)

CO-CHAIR CROOKS: Okay. We have 13 yes and 7 no.

DR. PACE: Okay. Moving on to scientific acceptability of measure properties.

(Committee voting.)

CO-CHAIR CROOKS: 4 completely, 6 partially, 6 minimally and 4 not at all. We have symmetry.

(Laughter.)

DR. PACE: Okay. Next, usability.

(Committee voting.)

CO-CHAIR CROOKS: 4 completely, 12 partially, 4 minimally. Symmetry is again achieved.

DR. PACE: Okay, and next is feasibility.

(Committee voting.)

CO-CHAIR CROOKS: Results for feasibility, 7 completely, 10 partially and 3 minimally. DR. PACE: Okay, and lastly, do you recommend for endorsement?

(Committee voting.)

DR. PACE: Okay.

CO-CHAIR CROOKS: Another close one, 11 yes, 9 no.

DR. PACE: Okay.

CO-CHAIR SCHONDER: All right then. We'll move on to the next measure, 1425. Jessie?

Measure No. 1425

MS. PAVLINAC: I can hardly wait for this one. The title of this measure is "Measurement of Normalized Protein Catabolic Rate or nPCR for Pediatric Hemodialysis Patients." Brief description, percentage of pediatric patients less than 18 years old, in-center hemodialysis. Irrespective of frequency of dialysis, with documented monthly

nPCR measurements.

Let's see if I can go back. I lost the --

CO-CHAIR SCHONDER: Right, sorry. We have a temporary glitch in the connection to the screen, but you can go on.

MS. PAVLINAC: Okay, thank you. So no testing has been done on this particular measure, and the measure developers are saying testing will be completed within 12 months. So that means this would only be eligible for time-limited endorsement.

To comment on the, that there is no recommended value for nPCR, there is none, in the data that is being presented, is that there are recommended levels for protein intake for different ages of children. nPCR is a documented measurement of dietary protein intake. So they're making the assumption that if you know what the protein should be and you get a low nPCR, then the child is not getting adequate protein and that there is a relation

to nutritional intake and going along with adequacy.

Let me go to my spreadsheet, because I can at least talk about it. There are six of us that evaluated. We're on the team that looked at this more intensely. Out of that, five out of six rated it as met the importance testing, with one saying no.

Under scientific -- oh, what's the -- I can't read, acceptability, 3 completely, 3 partially. So we were evenly divided on that. Under usability, 1 partially, 5 completely; and under feasibility, 1 partially 5 completely; and the recommendation was split. 5 yes, 1 no. What else should we, do you guys want to know? We're trying to shorten this one. Okay, cool.

CO-CHAIR SCHONDER: Okay. Any other comments from the assigned reviewers? Okay. Dare we open this up to the floor?

DR. KLIGER: I'd love to hear from the no, why the no was a no.

DR. VASSALOTTI: I'm not a pediatric nephrologist, and I wasn't, I reviewed as many of these as I possibly could, because I wanted to review them before I voted, and I didn't think that the level of data was robust enough to let this rise to the level of a performance measurement.

That was my thought. I thought this is more of a nutritional measure and not an adequacy measure in the sense this is something -- what about measuring serum albumin, other potential things. So that was my sense as an adult nephrologist who doesn't have the experience that the others in the room do. That was my sense.

MS. PAVLINAC: If you'd look at the 2006 KDOQI adequacy and the newly-revised 2008 pediatric nutritional DOQI, there was discussion and some cited articles that albumin was not an effective measurement, that nPCR was. More, there was more evidence for that.

DR. VASSALOTTI: I know that in the previous iterations, we talked about serum albumin for adults and that perhaps not being actionable. So I understand that. But still I was concerned about the level of that threshold. I guess I would ask you in that KDOQI guideline, what was the level of evidence, you know, that was reviewed. To be honest, I don't remember.

MS. PAVLINAC: I don't either.

DR. VASSALOTTI: But was that a high level of evidence or was that --

MS. PAVLINAC: I'm sure it wasn't, for the same very reason, and please people from, that reviewed this, jump in. The same very reason that many of the other pediatric recommendations are not, because there haven't been adequate -- there have not been an extensive amount of study.

DR. WOLFE: It is observational data. It is Level 2 data supporting it.

MS. PAVLINAC: Yes, yes.

DR. WOLFE: And the TEP's recommendation was not that this was a stand-alone measure, but it would be used in conjunction with Kt/V, to help improve the appropriate targeting of Kt/V. I'm a statistician, so I really don't know what I just said, but that's what the TEP said.

MS. PAVLINAC: Yes, and --

DR. RAMIREZ: And Bob, maybe I can add to that, because I was part of that. I was in the TEP. Basically the rationale for this by the TEP, first of all, this was the most divided measure amongst all the adequacy measures.

But the thinking of pediatricians was that adequacy of dialysis in the pediatric population is more than just solute clearance. Given that nPCR is readily available from urea kinetics, it's not that difficult to collect this piece of information.

DR. PACE: Any other comments from the group?

DR. FIVUSH: I would just say to Joseph's point, I think it is the level of evidence was not first-line. But I think albumin is really not panning out in pediatrics, for a multitude of reasons, besides a lot of our kids are nephrotic.

There's so many reasons why we can't seem to use albumin in a way that tells us about nutrition. So I think the intent was to have something that would help us with that.

DR. KLIGER: So if I'm running a dialysis unit, and I'm now urged by the quality measure to be measuring nPCR, what do I do with that?

DR. KASKEL: We usually look at that in combination with the other variables. That's what we do. Again, a composite score, overall assessment of what we think is good or not good prescription.

DR. BERNS: I really have the same problem. I was not certain what's actionable when you have that measurement, and what the

standard is, and the impact of Kt/V. It gets back to what we talked about. You're asking somebody to measure and it's not the same measure, but nothing beyond that.

DR. KASKEL: I think because nutrition is such an important part of some of these growing or not growing patients, that we use it with the other factors, to determine if overall we're providing adequate nutrition. We don't use the albumin in and by itself. We know we can't.

We have to assess chronological parameters. They take three to six months to determine any significant change in length or weight that's significant. That's just another added factor, without a strong evidence-based support, that this is the major determinant.

CO-CHAIR CROOKS: I have a little concern about usability. You know, I think as a nephrology fellow and as a nephrologist, it took me a while to get my head around nPCR,

you know, what it really means, and what --

You know, and so if this is going to be a national voluntary consensus standard, and I'm in Lisa's chair and I hear that my patients, the patients who are paying for it are getting an inadequate nPCR, what does that mean, you know. Does it, you know. So on the usability by the public, I think it may not meet the test.

DR. LATTS: Although I do like the idea, you know, as Fred sort of suggested, of starting with this and maybe moving to a composite measure down the road, that sort of gives an adequacy of dialysis composite measure.

CO-CHAIR CROOKS: So you're not all that uncomfortable with it, as long as you know it's related to nutrition and adequacy. Okay.

MS. PAVLINAC: From a renal dietician perspective, hanging your hat on an nPCR versus an albumin, you're going to get

beat up on that you can't effect at all with nutrition or dietary protein intake. It makes some sense.

DR. JACKSON: We've been doing an internal quality improvement project on nutrition, and the more I've read about this, the more nPCR becomes important in our adult population, not only for low levels but also high level. I think we're over-promoting protein. We give them extra phosphorous and sometimes their albumin is low for other reasons.

But there is data in the adult population that protein catabolic rate correlates with mortality, whereas albumin does not. This measure makes a lot of sense to me, whether -- it's going to be debatable whether it's a level of performance measure.

But I think, I would think if I were a pediatric nephrologist, that this would be a very important thing to know about in a patient in a composite sense.

CO-CHAIR SCHONDER: Any other comments? Are we ready for a vote? Okay.

DR. PACE: All right. We'll start with importance to measure and report.

(Committee voting.)

CO-CHAIR CROOKS: 14 yes, 6 no.

DR. PACE: Okay. Next is scientific acceptability of measure properties.

(Committee voting.)

DR. PACE: Okay. Voted? Push again, I guess.

(Off mic comments.)

DR. PACE: Well, we can't force people to vote, but we --

(Laughter.)

CO-CHAIR CROOKS: But we know who you are.

DR. PACE: All right.

CO-CHAIR CROOKS: So 3 completely, 13 partially, 4 minimally. That's a 13, that's right.

(Off mic comments.)

DR. PACE: Yes, okay, all right. Next is usability.

(Committee voting.)

CO-CHAIR CROOKS: 6 completely, 7 partially, 6 minimally, and one not at all. That's 21. No, that's right. Sorry.

DR. PACE: Okay. Next is feasibility.

(Committee voting.)

CO-CHAIR CROOKS: 7 completely, 11 partially and 2 minimally.

DR. PACE: Okay, and finally do you recommend the measure.

(Committee voting.)

CO-CHAIR CROOKS: We have 12 yes and 8 no.

DR. WOLFE: There's a trend. They're going to be smart.

(Laughter; off mic comments.)

CO-CHAIR SCHONDER: All right. So moving to the next category of measures, starting with anemia, and we'll start with

Measure No. 1426, "Assessment of Iron Stores," and Jeffrey will present that.

Measure No. 1426

DR. BERNS: So the description of the measure is a percentage of all adult dialysis patients for whom serum ferritin and transferrin saturation percentage are measured simultaneously at once during a three-month study period.

Just to give you a sense of the vote's importance, there were five evaluations. I'm sorry. Five evaluations. Three said it was important, two did not. On scientific acceptability, one was completely, two partially and two not at all.

Usability, two completely, one partially, two not at all. Feasibility, five completely, and recommendations were three yes and two no. There were only three specific comments, one of which was this does not meet the importance and scientific acceptability criteria.

While the recommendation may be good practice, it's not supported by meaningful evidence and there's no evidence linking this process with improvement in clinical outcomes, or even intermediate outcomes such as iron or ESA utilization or hemoglobin levels.

The other comment much more succinctly said this measure adds no value. The third suggested that maintaining hemoglobin and static iron levels within certain ranges helps reduce negative events, but can result in more intensive care and resource utilization.

The evidence that was proposed in support of this measure really had much more to do, or actually had only to do with hemoglobin level measurement and hemoglobin levels, and had very little to do with the impact of measuring TSAT and ferritin levels.

CO-CHAIR SCHONDER: Any other comments from the assigned reviewers? Any from the floor? Good.

CO-CHAIR CROOKS: That's easy.

CO-CHAIR SCHONDER: Wow. I guess we're getting tired. Okay. Well, I guess we'll call for a vote.

DR. PACE: Going once, going twice. Well, I guess there just is a lack of consensus among the measure reviewers. I would think there would be more discussion.

CO-CHAIR CROOKS: Can we hear from one pro and one con maybe, or a little more about the -- I'd like to hear more about the evidence, their assessment of the science supporting this or not supporting it.

DR. BERNS: I'll address the con side, and make a couple of points. One, that the inter-patient month to month variability in these measures is high. The use of these to accurately predict iron stores in patients is low, and this doesn't specify any ranges. It just simply says "measure." So we get sort of maybe back to the issue that we talked about before. We could have a different

debate about specific numbers. But since there's a lack of clarity as to what the numbers ought to be, to have a performance measure simply saying "measure" didn't seem to make a whole lot of sense to me.

It's feasible. It's obviously doable. It's easy to do, to assess this. But I think it's very difficult to translate this into any meaningful clinical practice outcome.

This isn't measuring hemoglobin, it's not measuring ESA utilization, and the impact of therapy positively, giving more iron, and negatively, giving less iron, all have implications that I think make this a very nuanced issue.

CO-CHAIR SCHONDER: Ruben.

DR. VELEZ: I'm one of the yes, but I think Jeffrey summarized it very well. This is a process measure, and it just talks about measuring, measuring something that in the clinical world we've been measuring for a long time.

There's no clinical strong data about having to do them both on the same day. We heard some comments earlier today about that. But it's a practice that is being done out there quite frequently, and again, this is a process measure and we're just measuring. It's not assigned to any kind of outcome at this point.

MS. ANDERSON: I think my concern, and I was one of the no voters, was because of the simultaneously. I don't think that adds any benefit to the measure whatsoever. There's no evidence that says that they have to be simultaneous. So I didn't support the measure.

CO-CHAIR CROOKS: While this has to be evaluated on its own, just a reminder that there is an endorsed measure for iron sufficiency, and that is the 0252 from last go-round, Assessment of Iron Stores.

I think this is based on a TSAT value, I don't want to be -- I don't want to

take time to read it all for you now, but my point being that this is, if you looked at this alone, you might say well, there's no other way -- there's no other metric related to iron stores for adults, and in fact there already exists one. One already exists.

DR. KLIGER: Can I raise a broader issue? We're looking here at each individual proposed measure, and looking at the characteristics of that measure. I want to raise a broader question. Do we really need more measures in anemia in ESRD?

I'm not sure how we factor that into our thinking and voting here. There have been many in nephrology who believe that our focus on anemia has been large and time has passed that by.

That is that there are many more important areas for dialysis providers and patients and others to be focused and spending time on, particularly given recent data that in many ways turns on its ear the way we

thought about the treatment of anemia.

So I'm not sure how to factor that in as I'm diving into this particular measure. Do we really need more anemia measures at all?

CO-CHAIR SCHONDER: Well, I think one thing is that this measure was intended to replace the 0252; is that correct? Is that correct?

CO-CHAIR CROOKS: Yes, that's correct.

CO-CHAIR SCHONDER: 0252 is an assessment of iron stores. This is the approved measure from 2008 that looks at the percentage of adult hemodialysis, HDPD patients prescribed in ESA at any time period who have, or who have a hemoglobin less than 11 in a one month study period.

So it actually put some parameters on either ESAs or a hemoglobin.

CO-CHAIR CROOKS: Well, that's how you define who's to measure. But the numerator is that patients have either a serum

ferritin and percentage transferrin saturation or a reticulocyte hemoglobin content, are measured at least once in a three month period. So that was the numerator.

DR. PACE: So the intention is that this replaces the measure that we just talked about. They're both about measuring versus actual levels.

DR. NALLY: The question then I don't understand, is the implication then that they are removing ferritin from the metrics of iron assessment?

CO-CHAIR SCHONDER: This one's talking simultaneous measurement of ferritin and TSAT.

DR. BERNS: Again, somebody made the comment that there's no proven value of measuring ferritin and TSAT simultaneously. This lumps everybody together. So a patient who's getting IV iron and a patient who's not on an ESA, although it's not very common, but he's not getting iron, has had stable iron

parameters for months and months.

I think we're seeing in clinical practice and in other guidelines more of an emphasis on evaluating trends, and the entire picture of what's going on.

So this is what's happened in the hemoglobin, the ESA dose, the iron dose, and trends in ferritin, trends in TSAT, and this doesn't get at any of that. It just says measure it and you've met the standard, which I think is not where we should be going personally with standards at this point.

DR. PROVENZANO: Yes. Let me just follow-up on what Jeff said, because it gets to the process of what we're doing. The necessity to replace one measure for another, as we're doing here, has to take into consideration the additional data and knowledge, like Alan said, in anemia and how we manage this. It has really changed in the last 24 months.

So again, it gets back to do we

really need to replace what's out there now? You know, maybe some of these things should expire.

DR. PACE: From NQF's standpoint, there's no requirement that, and that was part of our discussion earlier, that as we get more to intermediate clinical outcomes and outcomes, do you need these measures at the very distal end of assessment?

CO-CHAIR SCHONDER: Any other comments?

DR. LATTS: Well, I was just going to say, this measure doesn't seem to be closer to an outcome than the current measure. Maybe farther away even, I would argue.

CO-CHAIR SCHONDER: I just wanted to bring up the comment about the simultaneous. Is there any motion to put that caveat out there? Will that change votes?

Okay, all right then. I think now we can call for a vote.

DR. PACE: Okay. So we'll start

with importance to measure and report. Be sure you hit your send button, because that's what the tally's based on. If you registered a response at all, it will come up in the tally. Oh, okay. All right, go ahead.

(Committee voting.)

CO-CHAIR CROOKS: Well, our work is done on this one. Is that right? We have 5 yes and 13 no.

DR. PACE: So, since it didn't pass the threshold criterion, we will move on.

CO-CHAIR SCHONDER: Okay. So next is Measure 1431, and Jeffrey's also going to present that?

Measure No. 1431

DR. BERNS: Measurement of Iron Stores for Pediatric Patients. The description of the measure is the percentage of all pediatric less than 18 years old, hemodialysis and peritoneal dialysis patients, prescribed in ESA at any time during the study period, or who have a hemoglobin less than 11

gram per deciliter in at least one month of the study period, for whom serum ferritin concentration and percent transferrin saturation are measured at least once in a three month period.

There were five comments or evaluations. Importance, three said yes, two said no. Scientific acceptability, two completely, two partially and one minimally. Usability, two completely, one partially, two minimally. Feasibility, three completely, one partially, one minimally, and recommended there were three yeses and two nos.

Some of the comments. One was that since iron stores are involved in anemia management along with ESA dosing, monitoring the iron studies will improve quality of care. Another comment was similar. It's easy to report on the data readily available, and this will have a dramatic impact on care of these patients. The third comment was very similar.

Another comment was the current

description of the measure is misleading and confusing. New, lower hemoglobin target and not all patients tested, only ones with ESA. Iron deficiency may be missed in other patients.

Then the final comment was this is a complex measure statement with unproven value of the underlying parameters, i.e., value of quarterly iron testing in this population, and a hemoglobin level of 11 gram per deciliter. Mixes patients on PD and hemodialysis, as well as those who are on and off of ESA.

Iron therapy is not addressed, nor trends in any of the lab tests. It's not clear what fraction of all pediatric patients would be included in the or statements. As with other measures, the more important response to measurement of ferritin and TSAT levels is not part of the measure. You may be able to guess who's comment that was.

And again, the evidence that was used in support of this is primarily based

upon hemoglobin data and guidelines pertinent to adult patients, or based upon evidence from adult patients. Just frankly, I had a hard time understanding what the numbers were here, because it's such a complex measure of ands and ors.

DR. VELEZ: On the information I have, I have three nos and three yes. Is that --

DR. PACE: Right, exactly. There's -- we've updated this since we sent it out last week, based on getting some new evaluations. So the one you have on your drive should be the most up to date.

CO-CHAIR SCHONDER: So it was divided among the reviewers, so we should probably -- if we can open this up like we did for the last one. Somebody from the pro, somebody from the con to speak to it.

DR. PACE: Could we hear from our pediatricians again?

DR. KASKEL: We know that the

response to the ESA is going to be very dependent on what we're dealing with. So we try to avoid what we've learned also in the adults, that we don't want to give too much ESA if we can avoid it.

So we're looking to see adequate assessment of stores or responses, so that we can assess our response. If indeed, based on what the stores are we don't see an adequate response over time, then we have to reassess. So it has a direct relationship to how we manage the anemia.

DR. FIVUSH: I would just say there's some, I think, fascinating new data and thought that ESAs in and of themselves have some pretty significant unintended consequences in patients and particularly we're seeing it, perhaps, in pediatric patients.

There's some new data that suggests that in terms of disparities, certain ethnicities and races may respond less to ESAs

than others in pediatrics. And we're just concerned that if you're going to be using an ESA, that there's monitoring of the iron stores.

I think it is a complex measure. I think that's sort of the conceptual process, that nobody really should be on, at least the thought is in pediatrics, that no one should be on an ESA unless we're assessing the iron status, because perhaps we could minimize the use of ESA if we adequately --

And there's also, I will tell you, an aversion in pediatrics to using IV iron in peritoneal dialysis patients, and there is a lot of peritoneal dialysis patients in pediatrics. The proportions are higher, and the aversion is that those patients would be getting, would not be able to get it through the hemodialysis procedure.

So the concern is just that the people are paying attention to the iron status in pediatric patients. But it is a complex

measure. That's sort of just, I think, some of the philosophically why.

DR. BERNS: Just a comment, that this measure includes patients, pediatric patients who are not on an ESA, as well as those who are, and so somebody who had a hemoglobin of less than 11 grams per deciliter, at least one month. So that a hemoglobin of 12, 12 and 10.9 and not an ESA would fail this performance measure?

DR. FIVUSH: Only if you didn't measure their iron stores. I mean there's nothing, it's not about --

DR. BERNS: So there'd be no reason for this. You could argue that there's no reason for iron, to measure the iron stores.

DR. FIVUSH: I guess, I sort of think one of the things that comes up in this debate, which we haven't really -- which is really hard to debate, is what the optimal level of hemoglobin is in pediatric patients.

Maybe if we assume that in adults

it's between 10 and 12, we haven't assumed that in pediatrics. I'm a little biased in that, because we think that probably between 10 and 11 is very murky in pediatrics, again because of growth and development and cognitive issues.

So I think the concept of using the 11 here is that we would be considering that to be low for a pediatric patient. So maybe you would liken that, I'm still thinking about this measure when I thought about it. You would liken that in an adult to less than 10, should they have their iron stores checked. I think the way this TEP was going forward, that under 11 they're still assuming those same recommendations for 11 to 13, even though there's guidance in the adults that perhaps over 12 is problematic.

We have not really seen that in children, because of access differences and stroke problems. We haven't seen the issues in over 12, and we're not sure of that because

of school performance, for example. So I think there are two things in this measure that are --

I think it's important in our peritoneal dialysis patients, who I think that they're addressing in part, that the anemia guidance is unclear as well. I don't know, I don't know how to address it as a group, but I think that's --

DR. BERNS: Let me make one last comment. Just in terms of the, I guess, feasibility of this, I had a little bit of a worry, which may or may not be correct, about putting this data together. So you have to collect data on ESA use during a three month period, hemoglobin levels over three months, iron use during three months.

Or not iron use, and then laboratory tests. I'm not sure that all comes from the same database. So there may be some concerns about the reliability of the data, when somebody has to start doing some of this by

hand, which I suspect in some facilities anyway would be necessary.

DR. PROVENZANO: All right. Let me just play devil's advocate. I mean obviously we have more and more sophisticated IT systems, and I don't know what it's like in pediatrics. But I do remember 15 years ago, as they pushed ESA levels right through the ceiling, and you find out the iron saturation is two and, you know, there's no ferritin.

Now we all sit amongst this room of very high-performing individuals. I guess my question is, except for Andy, the question is is this a -- what's the problem right now in pediatrics? Is this a problem? I mean --

DR. KASKEL: We have data, evidence data showing both in CKD and ESRD that anemia is quite prevalent in 30 to 40 percent of patients under dialysis, if not more will be anemic at the time. So it would be -- and that CPD is not adequate.

Two, greater hospitalizations. We

have data on that. These are sicker patients. There are gender and race effects that Barbara mentioned coming out, disparities. There's a gap of information that there's a gap in knowledge, of very important information regarding to outcome.

In order to manage the anemia more appropriately and know what we're doing, it can only come from these measures. If you look at iron stores and this as a guideline. I'll emphasize again that in the CKD population, getting this treatment together appropriately has a lot of difficulties.

CO-CHAIR CROOKS: Well, with due respect, that's all important. But that's not relating to the iron therapy, and even in the submission itself, it says is there a benefit from proving this, and 92 percent of patients met the requirements.

So you know, what it says to me is that most of the time, iron is being measured anyway, so there's not really a gap. Then

when it comes down then to the 1C, which is outcome to support the measure focus, they don't even address that. They talked about it's important to treat anemia. Well yes.

So even in their own application, they're not supporting that this is important. It's just not convincing at all, that there's evidence to support that this is important enough to merit a national voluntary consensus standard.

DR. FIVUSH: I was just going to go back to what the CTEP was -- were they thinking it was the gap in the ten percent of patients that weren't getting iron, or was it more that they were thinking about the number of patients. I know ones that entered dialysis anemic or after 90 days were still anemic. Do you have a sense?

DR. MESSANA: Both Bianca and Dr. Warady are on the line. So if you'd like them to address it, they could.

DR. RAMIREZ: I'll go a couple of

sentences and I'll turn it over to you. One of the points that there's a study, at least one or two studies in the pediatric population, that showed that ESA therapy will not result in an increase in hemoglobin, if iron stores are deficient.

So basically that's one point. So it's the leading cause of non-response to ESA therapy. So I think that's one reason why the TEP felt it was important to measure iron stores in this population. The cut-off of 11, it's a little bit complex, and it's related to later on we'll talk about the proposed cut-off for hemoglobin level.

The thought for 11 actually was partly based on the NHANES cut-off point for normal hemoglobin levels in the normal pediatric population. But I'll turn it over to Brad, if you have something else to add. Dr. Warady?

(No response.)

DR. RAMIREZ: He may have hung up.

But in essence, the TEP felt that to be effectively able to manage anemia, you need to ensure adequate iron stores.

CO-CHAIR SCHONDER: I did want to point out Jeffrey's comment about the feasibility. Going back to Measure 0252, it's an endorsed measure where we are actually looking for all three of those parameters in that measure. So I don't know how feasible it is in the pediatric population, but there is an adult measure that does look at all of those.

DR. MESSANA: All the data elements required to calculate this measure are in the CROWNWeb business requirements document, moving forward. So all the data elements are available.

DR. BERNS: Just maybe reflecting my ignorance here. What percentage of pediatric dialysis patients are going to be in CROWNWeb?

DR. MESSANA: Well, my understanding is that pediatrics are included.

DR. FIVUSH: Full. It's 100 percent of the pediatric universe under the age of 18. In the adults, it has up to date been, at least with the CPM project, a random sample.

But it's always been 100 percent of pediatric patients. I guess what the intent as CROWNWeb emerges, it will be 100 percent of all patients. But pediatrics data has been entered for years.

DR. WARADY: Hello.

CO-CHAIR SCHONDER: Dr. Warady.

DR. WARADY: Yes.

DR. RAMIREZ: Yes. So I called on you earlier. I think we'll have to --

DR. WARADY: Oh yes. I heard you. They couldn't hear me.

DR. RAMIREZ: Okay.

CO-CHAIR SCHONDER: Go ahead and comment. On the phone, if you want to go ahead and comment?

DR. WARADY: Yes. This is Dr. Warady. Can you hear me?

CO-CHAIR SCHONDER: Yes.

CO-CHAIR CROOKS: Yes.

DR. WARADY: Okay. Just a couple of things to amplify what Sylvia said. One, the target of 11 that's incorporated into the measure, is based on NHANES. If one looks at NHANES for all the different pediatric age groups, that virtually all of them, the fifth percentile for hemoglobin is above 11.

So I think sort of like Barbara suggested, that 11, a value of 11 for children really truly does define anemia, and that's supported by the recommendations from KDOQI. So that's where 11 comes from.

Then if one looks at hemoglobin in the children, a paper by Amy Staples, which looks at all the NAPRTCS data, has demonstrated in the CKD population many of the children are anemic. Now I can't tell you whether it's due to lack of epo or lack of iron, but many of them are anemic. As many as 70 percent of kids with CKD are anemic, which

is again defined by hemoglobin less than 11.

If you look at the USRDS data from 2009, which is actually the 2009 report, which is the 2007 data, the mean hemoglobin for children starting hemodialysis is 10. So again, a substantial percentage of these kids are anemic going in and starting dialysis.

So that's the issue and, you know, as we all know, epo is iron. So we have a lot to address in pediatrics to optimize anemia management, and thus the measure was trying to address the important issue of iron to that.

CO-CHAIR CROOKS: At the risk of repeating myself though, this is all well and good, and this is an important issue, and it's important, that there is anemia, it needs to be managed.

But there's nothing that's been presented here or really much in the discussion about this particular metric, that to measure this iron levels has an impact, or that there's a gap. It's being done in most

patients, and I presume if it's being done, it's being used in management.

I have not been convinced that there's importance to this, that it's going to either improve care, that there's a gap or that they're even able to bring to bear any evidence that this is the right thing to focus on.

DR. LATTS: I just have a question about CROWNWeb and apologize for my ignorance. Are all dialysis patients entered in CROWNWeb, or only those on Medicare?

DR. FIVUSH: So in pediatrics, even though we're predominantly not a Medicare population, 100 percent of pediatric patients are entered, regardless of their insurer.

DR. LATTS: How do get around HIPAA for that, in terms of using the data?

DR. PACE: Is there someone from CMS that's on the line that can answer that question, about are facilities required to enter all patients, or only those covered by

Medicare in the CROWNWeb? Okay.

DR. NARVA: I'm a little confused, because we seem to have different criteria for different measures, and whether -- I understand there's no point in having a measure if there's no gap. But then the other issue that we seem to be sort of ambivalent about is whether we measure things for which there's not an evidence-based target.

So we just pretty relatively enthusiastically endorsed the NPCR for kids, but we're not looking at this. I have no idea what we're going to do when we get to phosphorous. So you know, we have to be consistent, or at least have some philosophy, I think.

The other thing which is, maybe it's because I'm kind of jaded, but it seems -- it's interesting that at the same time that funding has occurred, we're using much different standards than we did three years ago, in terms of measuring things.

That may or may not have to do with the bundling process. But I think if we withdraw on some of these measures that we previously endorsed, we probably need to explain to the public that we're just not, that there's no connection, or if there's some other explanation.

DR. PACE: And I'll just mention that, just within the scientific world, in terms of clinical science, our measurement world has also evolved, and we're becoming more stringent on actually applying the criteria that we have.

So I mean and basically all the decisions about recommending or not recommending measures should be grounded in the criterion. There should be a justification for that, as well as continuing endorsement or withdrawing endorsement.

I think your point about perhaps looking at things inconsistently, I think you know, it's something the Committee should

think about, and you know, certainly have more discussion on.

CO-CHAIR CROOKS: Yes. If I can just comment too. What you're talking about is the importance issue, you know, the very first thing.

Is it important enough to make a standard on, and if you read and think about what they're asking for, they really are asking for some science to support it, that it's not just something that everybody does or everybody should do, but there's some rationale for making this a national voluntary consensus standard. This is an important pedestal to hit.

And you know, we can all sit around and say we agree. But on the other hand, it's written in such a way that if we as a committee say well maybe we recognize there's not enough science. But we think it's so important, it meets the importance criteria. Okay. Then they'll let us get away with it,

you know, for now.

But you know, I'm trying to, as a -- maybe it's because I'm chairman of the steering committee, co-chair of the Steering Committee, but I want us to try to go for a higher level, and say this is not just something we all think is a nice thing to do or something we all do. I think it's the right thing to do.

But let's really base it more and more on evidence. We were guilty through the KDOQI process, perhaps, of publishing too many guidelines that were not evidence-based, and we paid a price and we're still kind of thinking that was a mistake. I don't want to repeat history.

We should really be trying to get, you know, more and more science-based in our decision of is it important enough, in my opinion.

DR. LATTS: I guess the way I'm thinking about this though, frankly is that

for me, the bar is lower in the pediatric population. Given the state of the science, given the state of performance measurement in pediatrics, which is, my understanding is minimal, and given the need for performance measurement, I am, as I look through these, holding the adult measurements to a higher standard than the pediatric measurements.

DR. JACKSON: In looking at the endorsed measure, 0252, and comparing it to this one, it seems that the differences are that the new proposed measure omits the use of reticulocyte hemoglobin content and changes, takes out the -- I think it takes out the peritoneal dialysis population. Are those the two major differences?

DR. PACE: That's an adult measure.

DR. JACKSON: Oh, I'm sorry correct. You're right, you're right.

DR. PACE: That's an adult measure.

DR. JACKSON: But if we don't have this measure, then there would be, there's no

other existing measure about measurement of iron stores in pediatrics; correct? I'm just asking a question for clarification. Okay.

DR. KASKEL: I will just add that although it's not part of the measure, the concept of epo resistance is not brought up here. We do have potentially some unique risk factors for resistance to epo, even with adequate levels.

So there's a whole host of factors that may account for the presence of anemia that we haven't understood yet. We are obviously not measuring the resistance factors yet, but one identifiable one is the iron store.

DR. BERNS: Again, if I can comment. Again, I think the issue may be you need something around anemia, hemoglobin monitoring, hemoglobin measurement or ideally responses to hemoglobin that you're unhappy with. This is something very different, and again -- I'm sensitive to the issue about

pediatrics. I was a child once and had some of my own.

(Laughter.)

DR. KLIGER: I am not so sure.

DR. BERNS: I'll bring a picture next time. But again, I'm struggling with this issue about these are performance measures. These are setting standards of care, and this is very different than an opinion-based, clinical practice recommendation or a wishy-washy, partially evidence-based clinical practice guideline.

I think there is a value for those, and I think that what we went through with KDOQI and we're going through now with KDIGO has value. But it's a very different piece of work, and it has a very different impact on the community, I think, than this does, if it's branded as a performance measure.

CO-CHAIR SCHONDER: Any other comments? Oh Karen.

DR. PACE: Yes. I just want to

maybe restate some of the comments another way, and that is I don't think anyone here is saying that in clinical practice, people shouldn't be measuring these things, and then assessing it and determining how that factors into treatment.

But all the comments that people have made is, you know, we have kids with anemia. We need to treat the anemia. There are treatments for anemia. But that's not what this measure is about. So I think the comment about yes, you need to have measures of anemia and treatment of anemia. The question is do you need this as a performance measure. So I think that's maybe just another way of saying the same thing.

DR. FIVUSH: I think, you know again, it's a complex measure and I think these comments are important. But I do think there are two themes, and I think one is yes, there are children that are anemic. There's a gap in care of ten percent. We want to be

sure that at least in those patients, we're at the very least checking iron stores.

But I think this idea of having children on erythropoietin who are not having their iron stores checked is of more concern to me as a physician. But even if it's ten percent, that's a substantive number of patients who are receiving an ESA.

Again, I think another unusual part of this measure is that it has peritoneal dialysis patients. I again would just caution, that I think we're, and I think people, physicians may be less willing to give these patients IV iron infusion, and I think we all know that there are many patients that get oral iron supplementation. It just doesn't -- it's just not enough.

But there's still a hesitation. It's just I think sometimes in practice, people continue to give ESAs. So I think that's just one part of the measure that's interesting, and it's important.

CO-CHAIR CROOKS: Call for a vote.

CO-CHAIR SCHONDER: Call for a vote? Okay.

DR. PACE: All right. So we'll start out with importance to measure and report.

(Committee voting.)

CO-CHAIR CROOKS: 11 yes, 9 no.

DR. PACE: So we'll go on to scientific acceptability of measure properties.

(Committee voting.)

CO-CHAIR CROOKS: 3 completely, 12 partially, 5 minimally.

DR. PACE: Next is usability. Hit your send button.

(Committee voting.)

CO-CHAIR CROOKS: 5 completely, 10 partially, 5 minimally.

DR. PACE: Feasibility.

(Committee voting.)

CO-CHAIR CROOKS: 7 completely, 10

partially, 2 minimally, 1 not at all.

DR. PACE: All right, and finally do you recommend for endorsement?

(Committee voting.)

CO-CHAIR CROOKS: 9 yes and 11 no.

CO-CHAIR SCHONDER: We will, are we close to our break time? Okay.

DR. PACE: Yes. Do you want to take the break now?

CO-CHAIR SCHONDER: Do we take the break now?

DR. PACE: Okay.

CO-CHAIR SCHONDER: I'm getting some yeses. Okay. So we'll convene here in --

DR. PACE: Ten minutes.

CO-CHAIR SCHONDER: Ten minutes.

(Whereupon, the above-entitled matter went off the record at 2:33 p.m. and resumed at 2:48 p.m.)

DR. PACE: We're going to reconvene and get started on Measure 1428. Is that where we're at?

CO-CHAIR SCHONDER: Yes, we are on 1428, if we can come to order. Okay. So start back up again on 1428, and Ruben will present that for us.

Measure No. 1428

DR. VELEZ: We're going to present a couple of measures, one on the high side and one on the low side, that I know there's absolutely 100 percent consistency, and we all would agree with them hopefully.

Let's go first on the low side, 1428, Use of Iron Therapy When Indicated. This is essentially the description as percent of adult over 18 years old, dialysis patients, and I have to add that they're both hemo and PD, with ferritin of less than 100 TSATs or less than 50 percent, again on simultaneous measurements, who have received IV iron in the following three months. This is a rolling three-month study period.

I will add that there's a couple of exclusions in the denominator. Patients have

to be present in the three-months study period. Of course, patients who are allergic to the IV iron products, and the other exclusion is patients with a hemoglobin of over 12, who did not receive ESA during the three-month study period.

On the responses on the importance of measurement and reporting, we have four yes and one no. On the science, we have one, two partially, two complete and one minimal.

On the usability, we have one minimal, two partially, one complete and one not at all. On the feasibility, we have two complete, two partial, one not at all. On the recommendations, we have four yes and one no.

If I may summarize some of the statements, on the positive side everybody agreed that yes, appropriate use of iron was important, especially in its relationship with the use of ESAs, and that a significant amount of this data should be and can be collected in the CROWNWeb system.

On the negative side, and this one is half positive, half negative, said measure has limited impact, but reasonable. Testing has been mentioned to be completed but not available for review, so really we didn't have, it wasn't tested for reliability, at least in the information we had.

A comment about the combination of lab tests. I suspect on CROWNWeb and the iron administration, that that has not been tested or documented, a collection of this data together.

Concern about the unintended consequence of iron overload. Then a comment about the reliability of ferritin and TSAT from different labs have not been tested.

The no evaluation for the causes of potential iron deficiencies, there was a comment about the concern over the poor evidence on peritoneal dialysis patients. There was a question about collecting all this data may be somewhat problematic, and again

the comment about the simultaneous testing of both ferritin and TSAT on the same day.

CO-CHAIR CROOKS: Ruben or Kristine, we should mention this only for time-limited approval, because like I said, the data is there to test for reliability, but it wasn't done, and there's no validity testing.

DR. VELEZ: Right.

CO-CHAIR SCHONDER: Any comments from the assigned reviewers? In general, anyone?

MS. LeBEAU: I was one of the assigned reviewers, and I'd just like to share with the group, we talked a lot about anemia, and just during the break, a couple of us patients were talking.

You know, anemia is one of the things that really affects how we feel. So if we're coming back to how are we feeling, if that's an important measure, it is critical that we pay attention to this. Just from a very practical standpoint, I'm a great epo

responder. My iron stores suck the basement.

So if I don't get continual IV iron, my hemoglobin's going to drop. With iron, I need it once maybe every six months. So I do think, I think the way I have looked at these as we've talked, it's hard not to do comparative when you're thinking about this and that.

So I think there were better ones than some of the earlier ones we've talked about. But I really do think that yes, it is still important to pay attention to these things. I think the things that make a difference of how patients feel are three big things: comorbidities, anemia management, doing that well, and all the things that's in there.

I know practicing nephrologists who really don't a good job with iron therapy, but they dose and dose and dose the epo and, you know, how well dialyzed are people or how well is their transplant managed. So there's my

soapbox, and thank you.

CO-CHAIR SCHONDER: Any other comments?

DR. BERNS: I'll make a couple. One is that there's no hemoglobin content in this measure at all. So obviously the need to give IV iron in this setting should be somehow linked to what the hemoglobin level is.

So a TSAT of 90 percent or, I'm sorry, a ferritin of 90 nanograms -- and a hemoglobin of 13, you know, should -- probably the patient shouldn't be getting IV iron. It would in fact potentially be dangerous.

The inclusion of the transferrin saturation of less than 50 percent is really meaningless, because nobody has -- almost nobody has a transferrin saturation above 50 percent. So it really doesn't exclude anybody.

I'm a little unclear as to whether this is picking out people who do a good thing or a bad thing, right. So that, you know, you

could look at it and say if the ferritin's below a 100, then it's a good thing because they're getting IV iron, or they're getting IV iron. If ferritin's below 100, they're not getting enough iron and it's a bad thing.

So I'm not exactly sure what end of the spectrum we're looking at or how this is going to impact what we're doing with patients, because it's going to identify people who are doing a good thing and people who are doing a bad thing potentially.

CO-CHAIR CROOKS: If I could comment. I think the inclusion or exclusion of hemoglobin is important, because if a patient has a hemoglobin of 13, and a transferrin sat or, I mean, a ferritin of 90 and TSAT of 45 percent, are we saying they have to have IV iron? Is that what this is implying? I have some trouble with that.

DR. FIVUSH: I would agree that the exclusion of the hemoglobin level doesn't make sense in this measure, in no way.

CO-CHAIR CROOKS: That doesn't make sense?

DR. FIVUSH: No, there should -- there doesn't. There should be some reason besides the level of iron to use them.

DR. BERNS: This is one of those unintended consequences of performance measures.

DR. MESSANA: There is a denominator exclusion for hemoglobin.

CO-CHAIR CROOKS: Oh, there is a denominator exclusion.

DR. MESSANA: This is 1428, correct?

(Off mic comments.)

DR. MESSANA: Correct. But I heard the statement that there was no hemoglobin exclusion.

(Off mic comments.)

DR. PACE: Lauren's going to put it up on the screen. It's 2A.9 and 10.

DR. BERNS: It doesn't change my comment.

DR. VASSALOTTI: So it's both mean hemoglobin greater than 12 and did not receive an ESA in the three month study period, is that right?

DR. BERNS: That's the way I read it.

DR. PROVENZANO: Yes. I think, just to be succinct and getting back to Jeff, I'm not quite sure what this is, what are we trying to accomplish with this. With only a denominator exclusion, it is unclear as to what the goal of this measure is going to be, and whether it's necessary in view of -- I presume this is about anemia management, I presume.

So question whether or not this is really a necessary measure, considering the other measures for anemia.

CO-CHAIR CROOKS: And also the choice of 12, which is sort of kind of an upper range for pushing it. Now is this pediatric? No, this is adults. Yes. Maybe

it if was less than 10.

If somebody's less than 10, and their indices indicate iron deficiency, yes, they need IV iron. But if they're 11.5 and they're just barely deficient or deficient in one, not the other, I don't think it's an open and shut case.

DR. PACE: So are there any recommendations in terms of what would make it a better measure in terms of the evidence for these measures and what the indications are for iron therapy?

CO-CHAIR CROOKS: Well, this is for a limited time anyway, which maybe we shouldn't loosen our criteria because of that. But I think if the focus was to treat anemic patients who are iron deficient with iron, that would make more sense to me than to treat patients who are in the treatment target range, have to get iron.

DR. KLIGER: You know, it's confounded obviously, because of I'm very

aware and listen carefully to what Kathe is telling us, and for patients who are prescribed ESAs, and where ESAs are being pushed aggressively. Now with the bundle, it's likely that that's going to change, but that's at least the way it's been.

Assuring that iron deficiency anemia, as liberally defined, makes some sense to me. But I have a problem, as you do, with the definitions that are here, and were this a guideline that was really focused on the treatment of clear iron deficiency anemia, I would have an easier time approving that.

DR. JACKSON: Can you imagine explaining this measure to your anemia management nurse? I mean it's --

CO-CHAIR CROOKS: That goes to the issue of usability too. In other words, can you imagine explaining this to health plan executives, why this is a national standard?

DR. JACKSON: As the developer, why the TSAT of less than 50 was chosen, as

opposed to a lower number.

DR. MESSANA: I can tell you that during the CTEP deliberations, they tried to define the zones of iron deficiency that would be unequivocal, that not even NQF would argue with, and zones of iron overload that not even the NQF would argue with.

The definition of a -- is ferritin less than 100, with a TSAT below 50 percent. They all agree with iron deficiency, because of the ferritin less than 100.

Because of the ferritin less than 100, the fact that some people, as the discussion, that some people who were receiving IV iron or have recently received IV iron, may have a high TSAT falsely elevated, and the ferritin is still reflect a reduced body iron store within the limits of that test.

So that was, this was the CTEP decision. This was how they defined iron deficiency.

DR. BERNS: And having just reviewed this literature, I think the only number that I think is partially justifiable is a ferritin less than 30, is virtually -- is synonymous with iron deficiency, and anything above that is not.

So that's probably the only defensible number, I think, that one could use in a performance measurement that is absolutely iron deficient. But all bets are off otherwise, I think, with every other number of ferritin and TSAT.

DR. WOLFE: Thank you. That's very useful feedback to us, because I think that we were relying on the CTEP's evaluation, and they did their evaluations and getting further evaluations is useful.

It is -- in terms of the importance in a cross-section from CROWN Web, there were 10,000 people in this deficient criterion with the simultaneous being less than 50 and the other criterion.

6,300 of them were being treated with iron. 3,700 were not. So that's the level of importance. There were 3,700 people in the United States in this quadrant of iron measurements, who were not receiving any iron.

DR. BERNS: But again, in the absence of knowing what their hemoglobin levels were, it's impossible -- that may have been perfectly appropriate care.

DR. WOLFE: With hemoglobins five or less.

DR. BERNS: Yes, but that may have been perfectly appropriate to do that.

DR. WOLFE: Sure, and that's all I know.

DR. LATTS: So if it had been less than ten, would that be more meaningful to you or not?

DR. BERNS: Again, I've changed a lot in my thinking about this. I think trends are important, and I think individualization of care is important, and none of that comes

into play here.

I think if you have a patient who has a hemoglobin that's below ten but a ferritin of 90, does not mean that they're iron deficient, and we have to remember that exposing that patient to intravenous iron, which this would sort of force us to do, has a risk of bad events including death.

DR. LATTS: That actually was going to be another one of my questions, because this does seem to force you into IV iron, which you know again, from the non-dialysis, we do IV iron, you know, in someone who's at extremis from anemia. We're very afraid of IV iron. So it seems much more obviously common in the dialysis population.

You'd never use oral iron. I mean obviously in the hemo population, it's very easy to do IV iron. But in the PD population, do you do oral iron first or you just go right to IV iron?

DR. BERNS: It probably -- Alan's

probably got a bigger --

DR. KLIGER: Well, I mean we started looking at that, and probably half of chronic PD patients do not respond adequately to oral iron. Correct.

CO-CHAIR SCHONDER: Any other comments? Call for a vote?

DR. PACE: Okay. We'll start with importance to measure and report. Oh, this is for a time-limited measure, remember, time-limited endorsement.

(Committee voting.)

CO-CHAIR CROOKS: Well, we have only 5 yes and 15 no.

CO-CHAIR SCHONDER: All right. So we'll move on then to 1433, Dr. Kaskel. 1433. Measure No. 1433

DR. KASKEL: Description of all pediatric patients less than 18 years old on hemodialysis and peritoneal dialysis, with hemoglobins less than 11 grams per deciliter, and in whom simultaneous values assume

ferritin concentration was less than 100 nanograms per mL, and TSATs less than 20 percent, who received IV iron or were prescribed oral iron within the following three months.

The numerator statement is the number of patients in the denominator who received IV iron or were prescribed oral iron in the three months following the first occurrence of serum ferritin, less than 100 nanograms per mL, and transferrin, TSAT less than 20 percent during the study period.

The denominator statement was all pediatric patients, 18 years or less, on hemo and PD, in the facility for the entire three month period, with hemoglobin less than 11 grams per deciliter and in whom simultaneous values of serum ferritin of less than 100 nanograms per mL, and TSATs less than 20 percent during the three month period.

The data source was CROWNWeb data, obviously electronically obtained. So we have

the review here, and just to start off overall, we had two in favor and three against. So this will be an interesting discussion.

The importance to measure and report, we had basically some comments from the no regarding the confusing data, and difficulty in measuring this, as well as in monitoring oral iron therapy or adherence to oral iron therapy.

As far as the scientific acceptability of the measure, we had one no and it involved minimum value, how we're going to measure this oral iron administration or adherence. For usability, there was one partial, the rest were complete. For feasibility, we had again an issue of no, the ability to measure the iron intake.

So we're left with overall, in summary then, it looks like we had some issues regarding a complicated measure to follow. However, balanced by others that were in favor

of it, in terms of the importance of this measure to evaluate outcome of anemia management.

CO-CHAIR SCHONDER: Okay. So any comments from the other assigned reviewers, specifically regarding the differences in opinions?

MS. RICHIE: Just to remind you, this is a time-limited measure.

DR. FIVUSH: So, I reviewed the measure. I would just say again the rationale for the 11, again in pediatrics is that we think that that may be anemia. We think it does reflect anemia in a pediatric population. So it's really, in looking at patients that we think that are anemic, that are being evaluated for their iron levels and being treated appropriately.

And again, in our peritoneal dialysis patients, and you had asked this question, we really do push oral iron. We -- often it doesn't work. But we do really in

the younger kids I think sometimes do use more oral iron than the adults, simply in terms of percentages, because more of our patients are on PD than in the adult population.

So use of oral iron is complicated. I know there's some question about how do you monitor that using oral iron? I think that gets back to comments that were raised earlier about adherence. You have to monitor that, because if you're going to prescribe it, you should be monitoring it.

So that doesn't bother me, that there's a notation that that's part of the measure. That's therapeutic iron, whether it's IV or oral. So I think it is -- this gets to comments about anemia, and again, just making sure that patients that are anemic, that are iron deficient, are being treated for their iron deficiency.

Whether they're on an ESA or not, they should be treated for their iron deficiency. They should also potentially be

treated with an ESA, but they should certainly be treated for their iron deficiency.

CO-CHAIR CROOKS: As opposed to the last measure, where the criteria for who is iron deficient and needing therapy was arguable, I think in this case, this group of patients that the measure is saying should be treated, is a group of patients who should be treated.

So I like that. I don't think there's much scientific support for it, and unfortunately there's not evidence for a performance gap either. But I think, in my mind, this is more important than the last one.

DR. FIVUSH: Can I just say that I know that it says that I voted no, and Rick asked me if I voted no. I was doing so many measures. I might have voted no, but I did not mean to vote no.

(Laughter.)

DR. KASKEL: This is my friend.

DR. FIVUSH: No, no, because Jerry asked me that as well, so I --

DR. KASKEL: Barbara, can I ask a question? We have limited data in adults about the sensitivity and specificity of the TSAT and ferritin levels. What is the data in children?

DR. FIVUSH: I think that's a great question. I'm not sure that -- I'm not sure that we know that. I think there's more and more evidence, because we talked about the use of albumin and what that really means.

I think definitions of iron deficiency and what's a marker of inflammation and what's not, in a patient who's transfused, what does that mean.

But I think that if this measure uses numbers as opposed to the 50 percent, the 20 percent that is more standardly accepted, your comments on the last measure were very interesting, that you reviewed the data and that was your comment on what you felt would

be iron deficiency. That was new data to me.

So I can only say that this is sort of the data that has been generally -- generally, 120 has been generally accepted as a lower limit, and that -- simultaneously, and that I don't have -- I think there's provocative data to suggest that it's hard to really understand iron and measurements of iron.

But I still think those are acceptable in this measure, understanding your comments before.

DR. KASKEL: Okay, and can I add that there is some early data on the score number of pediatric patients looking at cytokines, various cytokines in ESKD, and less so in CKD.

One of the concerns that the community has is that the cytokines interfere with a number of important factors that are accountable for anemia management, as well as in areas of growth.

So we are just beginning to understand the role of cytokines, and again it's without a lot of data. But it's provocative and it may even place more emphasis on all these values, why we need to be careful and proactive in the treatment of the anemia.

DR. KLIGER: Jeff, I was just wondering in reading the ferritin in particular, if there was any discussion of children and ferritin levels?

DR. BERNS: No.

DR. KASKEL: There is some data on age-dependent changes in ferritins, and we do know that, in well children. I'm not aware of data in the ESKD population. But it seems to go up early on and then drops down and levels off, and then peaks again during adolescence.

DR. KLIGER: So then one would presume its predictive value in ESRD is pretty poor?

DR. KASKEL: I know that you can say

that, that it's a poor measure in the population. I mean you have again, a lot of factors affecting it in the uremic patients, and the role of cytokines and responsiveness in the management of the anemia is unknown. It's another marker. It's a marker.

It's just like proteinuria. It's a biomarker. Is it a good one or bad one?

DR. FIVUSH: And I would say it's really interesting, because there's now some really provocative data that maybe Vitamin D deficiency impacts inflammation, it may impact iron levels and hepacidin may impact iron reabsorption. But and I think those things, we'll know more about them in several years.

But I think in this state, where we are now, this looks like iron deficiency, and this looks like we should treat it. I don't think we know enough.

As a time-limited measure, you know, as Karen's pointed out to us, I think for right now we're not going to know that answer,

I don't think, for a couple more years. There's just a lot, you know, the thought about iron and how it's transported and how it's affected by inflammation and I don't know.

DR. BERNS: Just one more word of caution. One could satisfy this performance measure by prescribing oral iron and watching a patient be iron deficient on that month after month after month. That would still look like a good guy in terms of this performance measure. So we have to be careful about that unintended consequence.

DR. LATTS: Well, just to comment on that, and I agree, and I think, you know, if we look through the NQF armamentarium we'd find many measures where they're process measures, and there's ways to game the measure. I think that's part of the evolution of measurement, is that we start with a process measure that is imperfect and subject to -- yes.

I was trying to think of a maybe less manipulative word, but yes, and then eventually we want to look, I would assume, at the outcome, and really want to look at if we're, you know, anemia, you know. But you've got to start somewhere.

DR. BERNS: I'm not suggesting that it was intentional manipulation. It just would not ever be picked up as being bad practice.

DR. LATTS: Yes, and I think that's a problem with a process measure.

CO-CHAIR SCHONDER: Any other comments? I just want to clarify again. With the time-limited measurements, if the measure developers do the testing, then that meets the requirement. Then they automatically get the three-year endorsement if they were to be endorsed?

DR. PACE: Yes. Well, they would get two more years. So it's not they'd get three years from that point. They would stay

on the regular maintenance review cycle.

But in order to continue beyond one year, as endorsed, they would have to submit testing results that were acceptable, and the testing in this case is primarily that it's a reliable and valid measure, and that's what we would want, and then they would continue the endorsement for the remaining two years.

CO-CHAIR SCHONDER: Okay. But it wouldn't necessarily -- the outcomes wouldn't necessarily affect that, that if we found out that we're measuring the wrong thing or something?

DR. PACE: In what regards are you referring to?

CO-CHAIR SCHONDER: I guess I'm going to go back to Barb's comment, that this would be a time-limited measurement. So we're trying to figure out if this is -- at least this is starting point, to build off of that.

DR. PACE: Right. The time-limited endorsement is really to get that testing that

hasn't been done. The issues that you're talking about in terms of if it's making a difference, that's something that we would look more at during the endorsement maintenance review.

So, you know, to speak to some of your comments, is that if we have measures where, you know, the performance on this measure is great, but we still have lots of anemic kids, then maybe this measure isn't what we need. But that's something that would be accepted, that endorsement maintenance.

CO-CHAIR SCHONDER: All right.

DR. PACE: So any further comments? Call for the vote. All right. So we'll start with importance to measure and report.

(Committee voting.)

CO-CHAIR CROOKS: Okay. We have 13 yes and 7 no.

DR. PACE: And next will be scientific acceptability of measure properties.

(Committee voting.)

CO-CHAIR CROOKS: 4 completely, I'm sorry. 11 partially and 4 minimally.

DR. PACE: Okay. Next will be usability.

DR. LATTS: Now if the testing hasn't been done, what about that criteria? Even if the testing hasn't been done -

DR. PACE: Well, on usability, okay. I'll go back to that in a minute, but I don't want to interfere with people. That's a good question.

(Committee voting.)

CO-CHAIR CROOKS: We have 3 completely, 14 partially and 3 minimally.

DR. PACE: Before we go to the next one, there was a question about if it hasn't been tested, what were we asking you to rate on scientific acceptability.

So the other big component of that would be the measure specifications, that the measure specifications are precise enough to

actually move to testing, you know, that it could be. So precise specifications are kind of your basic foundation for having a reliable measures. So that's what --

All right. I think we're up to -- are we up to the final question? And this would be for a time-limited endorsement, or I'm sorry, feasibility. I'm sorry, feasibility first.

(Committee voting.)

CO-CHAIR CROOKS: 7 completely, 11 partially and 2 minimally.

DR. PACE: And finally do you recommend, and this would be time-limited endorsement.

(Committee voting.)

DR. PACE: There is an abstain option, so did people hit their send button? We'll go ahead and let this run out, since it seems like -

CO-CHAIR CROOKS: Okay. We have 14 yes, 6 no.

CO-CHAIR SCHONDER: Okay. So we're back to Ruben for 1429.

DR. VELEZ: 1429.

CO-CHAIR SCHONDER: Microphone please.

Measure No. 1429

DR. VELEZ: This is an outcome measure. Again, a rolling three month starting period, and it's "The Avoidance of Iron and Iron Overload." The definition is the percent of adult hemo and peritoneal dialysis patients with ferritin over 1,200, TSAT over 50 percent on simultaneous measured during -- and who did not receive IV iron in the three months after this measurement. There's no exclusion on this measurement.

On the results, from the assigned members, on the importance, four said yes, one said no. On the science, there was three partially, one complete and one minimal. On the usability, we have three complete, one partial, and one not at all.

On the feasibility, we have three complete, two partials, and on the recommendation, recommended, we have four yes and one no. Summary of some of the comments on the positive side. The importance of the iron, critically important to avoid iron overdose, and the potential consequence with the new bundling.

On the negative side, lack of data on at least mentioned on the response to ferritin to illness or inflammation. Lack of evidence-based information for the definition of why we're calling iron overload. Reliability of collecting some of the data, and has to do with scheduling between the blood work that will be done and the iron administration.

CO-CHAIR SCHONDER: Any comments from the other assigned reviewers? From the committee in general?

DR. KLIGER: Can I just ask the data on a performance gap of this measure?

DR. WOLFE: That's on page 25 of the synthesis report, and the sample from CROWNWeb 2009, there are 40,000 patients that were high on both of that, the iron compliments, and 40,000 who were high, and 10,000 of them did not receive iron. 30,000 were continuing to receive iron.

So if I'm understanding the definition, there were 30,000 who were inappropriately treated even though they were high on both criteria, out of the 40,000 who were high.

DR. KLIGER: And can I just -- may I just ask another technical question, which is shortly after the administration of intravenous iron, the numbers not yet in equilibrium, often are high.

Do we have any information about how many of those 30,000 were judged that way because the numbers were measured within a month of receiving intravenous iron?

DR. WOLFE: I don't think I know

that. I'm not sure. I don't know it right now. Let me just give an antidotal answer, because in DaVita, we have looked at that, because so many patients are on standing doses of iron, either weekly or at some other parameter, and we found that when you isolate out similar criteria, the majority of them were on some standing iron. So that there was no stabilization of the ferritin, and therefore it was suspect.

CO-CHAIR CROOKS: I'd like to ask those, my colleagues with a little more academic background and more knowledge of the literature, what is the incidence of liver biopsy-proven iron overload in hemodialysis patients? I'm asking this because I'm concerned about the importance of this.

Even though there were 40,000 who met that criteria, you know, what is the evidence that this is really doing damage, and are we setting up a national standard to treat one in a thousand or a one in ten thousand

kind of case? Does anybody have any information about the incidence of biopsy-proven hemochromatosis?

DR. BERNS: Yes. That's not really been studied. There's one or two reports, I guess, looking at imaging of hepatic iron deposition, and one showed a relationship with ferritin, that it had to be pretty high, and the other did not show a direct relationship with ferritin, but more of a relationship with the amount of iron that had been given and the duration of time, the length of the time the patient had been on dialysis.

Again, if we're looking at evidence basis for ferritin level, and it's very hard to do. Virtually everybody who has a ferritin above 300 has iron in their bone marrow. So defining adequate iron is done two different ways.

One is do you have iron in your bone marrow. Everybody with ferritin, most people actually about 100, but certainly above 300.

That's different than saying will you respond with a higher hemoglobin if you've got more iron.

That looks at sort of an artificial measure. It looks at hemoglobin, but it doesn't look at whether patients are better or worse for having had their hemoglobin level raised by being given IV iron.

But the answer to your question is that we don't really have any, in the modern era, any data that shows that there's a precise link between high ferritin levels and either liver deposition or any other adverse outcome.

DR. VASSALOTTI: Those studies were non-contrast CT to see if the liver lights up, is that right?

DR. BERNS: MRI.

DR. VASSALOTTI: That's MRI, okay. And what level of ferritin was that?

DR. BERNS: I don't remember the specific numbers, but as I recall, both

studies were very high, went up to very high ferritin levels. Typically, they don't look at people who have ferritins of 100 and 200 in these studies. But it would be at the higher end of, you know, the higher hundreds. I actually have them. I can look.

DR. FIVUSH: Jeff, can you go back? In the last measure discussion, you said after you reviewed the literature. Can you just remind us what do you think, based on your review in the adult literature, what would you use as a definition for iron deficiency? What did you say you felt comfortable with? I just want to hear it.

DR. BERNS: So if you're looking at bone marrow iron, virtually everybody who has a ferritin below 30 is iron deficient.

DR. FIVUSH: Below 30.

DR. BERNS: Or who has no, virtually no or very little bone marrow iron by iron -- some measures. There's different ways people look at this. Most studies actually would

show that in CKD and hemo, and there's really no data in PD patients, that almost everybody who has a ferritin above 100 has adequate bone marrow iron.

Now that's again very different than saying will they respond with an increase in hemoglobin and/or a decrease in ESA dose, assuming either one of those are good outcomes by getting more iron. But if you're really focusing on is there iron deficiency, sufficiency or overload, probably the best number is 30 and below is really iron deficient, 100 and above is probably iron sufficient, based upon bone marrow iron.

DR. FIVUSH: And for TSAT? I mean because we're talking about ferritin, which is so confusing.

DR. BERNS: I have no idea. Nobody really knows. It's really not very well studied. Because remember, TSAT is really a reflection of available iron for erythropoiesis.

DR. FIVUSH: Right.

DR. BERNS: It's not a useful measure of tissue iron stores.

DR. FIVUSH: Right.

DR. KLIGER: I just want to again show my concern that without knowing the relationship of these measures to intravenous iron therapies, I don't know what we're really measuring here.

DR. VELEZ: One last comment. Again, looking at unintended consequences, we look at everybody the same way. When you look at subset of patients, especially now with our percent of patients with chronic Hepatitis C, the way you would look at the iron on them might be somewhat different than some of the initial studies have shown, that you can cause more damage in the liver feeding them more irons.

DR. FIVUSH: But to my adult colleagues, this measure seems to me, I know we've talked about anemia, the consequences of

anemia. But this to me by most standards, would really be -- these are very high levels of both TSAT and ferritin. But Alan, you're saying you still --

DR. KLIGER: The measure of those values the day after or the week after administering intravenous iron, you get tremendous variability and high numbers.

DR. FIVUSH: So I guess I think I'm thinking conceptually the concept of iron overuse is important, because we sort of talked about unintended consequences of iron overuse.

So would this measure be more acceptable if somehow it was changed, so that the iron, that the level of -- when you drew the level or when you checked the iron level of the ferritin or transferrin sat, was 30 days after the transfusion?

I'm just trying to figure out, because I think the concept of overuse of iron therapy, I think it's important.

DR. KLIGER: So I mean Barbara, I agree with you. I think it would be useful to have some way of measuring and decreasing the overuse of iron. My concern is that as this measure now stands, I'm afraid it will not do that. And yes, some period of time, and I'll defer to the experts about how long after intravenous iron.

I mean the standard that we've commonly used in New Haven has been a month later. But my guess is it can be backed up to a shorter period than that.

CO-CHAIR SCHONDER: Any other comments?

DR. PACE: So do we need the developer to explain the, if there's any parameters around that data collection period, or have they discussed that?

DR. VELEZ: I would like to ask. I mean you're using a combination here now of CROWNWeb and what, billing data, is that correct? Or --

DR. WOLFE: The numbers that I reported about the fraction of patients are all from CROWNWeb, because I don't think, we certainly don't have it from the claims. I don't believe it's in the CPM either. But this was from CROWNWeb that I was just reporting.

So these are mostly people who are at a large dialysis chains, for whom we have the -

DR. VELEZ: So you're saying the CROWNWeb will include if I gave iron or not?

DR. WOLFE: It knows right now, yes.

DR. VELEZ: Okay, got it.

DR. WOLFE: And it includes these other two measures as well.

CO-CHAIR CROOKS: To me, it feels like this is a metric that evolved because there's certain numbers that are going to be coming across on CROWNWeb, and there's a desire to avoid iron overload. And some fear that we might cause hemochromatosis or liver

damage to some patients.

But we see that the time that these numbers are being collected are, in other words, there's not a break. Iron therapy patients are getting it all the time. This is just coming off the monthly lab data report, I presume.

So we are not going to be able to successfully impose a restriction. You have a wait a month and then do an iron level. We're going to have to use what they're saying. This is the data we got. This is the best you could come up with.

I think it's up to us to say well, that's nice, but it's not good enough, because it doesn't meet the importance criteria in my view. This is a lot of work, and setting up a national standard to treat a condition that is rare or almost never happens, and that is actual iron overload disease these days.

So that's my take on it, you know, that they've got these numbers that are coming

across. They're looking for things to do with them, and this is a, you know, a nice goal to try to go for, but I don't think this one hits the mark.

DR. BERNS: I also think that there's a credibility issue. I think if we're going to put a number in a performance measure, it needs to be defensible, or very, very important in the absence of an ability to defend that number. I'm not sure that this meets either of those criteria.

CO-CHAIR SCHONDER: We're getting the call to vote.

DR. PACE: Right. So we will start with importance to measure and report, and again, this is a time-limited measure. So when we get, if we get to scientific acceptability. Okay.

(Committee voting.)

CO-CHAIR CROOKS: 9 yes, 11 no. DR. PACE: Okay, move on.

CO-CHAIR SCHONDER: We'll move right

along then to Kathe for Measure No. 1424.

Measure No. 1424

MS. LeBEAU: This is the monthly hemoglobin measure for pediatric patients. It is a process measure. It is defined as the percentage of all pediatric patients, that is younger than 18 years of age, receiving hemodialysis or peritoneal dialysis, who have a monthly measure for hemoglobin.

In terms of the assessment of the evaluators, the evaluators agreed that it was -- that a method criteria, that it was a demonstrated gap in care, and it could potentially significantly improve the care of pediatric patients.

Citing the standard and not editorialize, but I thought this was a staggering number. The NAPRTCS study, that 68 percent of pediatric patients are anemic, even given the small sample size. So and I'm sorry. I did my numbers before the update and the evaluation.

Well, okay, well, do you want me to use?

DR. PACE: You don't have to. I mean basically we can just see that --.

MS. LeBEAU: Okay, okay. A scientific acceptability of the measure was divided. There was agreement that it was precise and had face validity. There was some question about the identification of meaningful differences in performance as in current use. Only 65 percent of the 317 facilities with pediatric patients reported a hemoglobin value currently.

In usability, most of the evaluators felt that it was meaningful, understandable and useful to the needs of the intended audience for decision-making, public reporting and quality improvement.

But there was concern, because this measure was only discernible, I'm sorry. I can't read my own writing. Only described percentage of tests done, not actions.

Feasibility, most of the evaluators felt that it met the criteria, that there was a concern that -- oh no, I'm sorry. Not a concern. Most felt that it would be able to collect the data electronically. I'm sorry. As of my writing, all of the evaluators did recommend the measure for endorsement.

The rationale for the measure, it's generally well-based scientifically and has great potential to be reliably reportable, as it's a familiar data set and could result in identification of those at risk for morbidity associated with anemia.

CO-CHAIR SCHONDER: Any comments from assigned reviewers or the Committee?

DR. KLIGER: Sorry. Can I just ask again about specifically the performance gap here? What percentage of pediatric patients who are anemic do not have monthly readings or any actual, I'm sorry probably any pediatric dialysis patients, don't have monthly hemoglobins measured?

MS. LeBEAU: Thirty-five percent.

DR. KLIGER: Thirty-five percent.

MS. LeBEAU: Yes, and that's across the 317 facilities.

DR. LATTS: No. Wasn't that the percent of patients that were anemic? That was the percent of patients that did not have a hemoglobin?

MS. LeBEAU: No. That was only 65 percent of the 317 -- I'm sorry. That's not a percentage of patients of the facilities reporting.

DR. KLIGER: Yes. I'm wondering about the number of -- does the developers know that?

DR. FIVUSH: I think that's from NAPRTCS.

MS. LeBEAU: Yes.

DR. FIVUSH: So that's not the CPM data. That's a great collaborative group study centers that submit data on a voluntary basis. But it's only pediatric nephrologists.

It doesn't have adult nephrology input. So it would be nice to validate. That's a pretty staggering gap to validate and see what the gap is in the Arbor database.

DR. PACE: All right. Lauren's putting up what was in the measure submission under 1B, Opportunities for Improvement, the summary of the data. Hemoglobin was reported in less than three of the six.

DR. WOLFE: So I'm not sure I understood the question then. On page 39 of the recommendations report, in a six month period, 29 percent of pediatric ESRD patients had fewer than three hemoglobin values, and 11 percent had none.

DR. LATTS: That's unbelievable.

DR. FIVUSH: Right. Six months.

CO-CHAIR SCHONDER: Call the question. Any other comments? Okay. I think we'll call for a vote.

DR. PACE: Okay. So we will start with importance to measure and report.

(Committee voting.)

DR. PACE: Has everyone voted? All right, go.

CO-CHAIR CROOKS: 19 yes, zero no.

DR. PACE: Okay. So we'll move on to scientific acceptability of measure properties.

(Committee voting.)

CO-CHAIR CROOKS: 15 responded completely, 5 partially.

DR. PACE: All right, usability.

(Committee voting.)

CO-CHAIR CROOKS: 18 completely, two partially.

DR. PACE: Okay, then feasibility.

(Committee voting.)

CO-CHAIR CROOKS: 18 completely, one partially.

DR. PACE: And the last is recommend for endorsement or not.

(Committee voting.)

CO-CHAIR CROOKS: It is -- it's

unanimous. 20 yeses. You won't see that very often.

CO-CHAIR SCHONDER: All right. We're on a roll now. Good momentum. So we're down to our last anemia measure, Measure No. 1430, and Rick will present that.

Measure No. 1430

DR. KASKEL: So this is the percentage of pediatric patients less than 18 years of age on hemodialysis and peritoneal dialysis with ESRD of less than three months, who have had a mean hemoglobin less than 10 grams per deciliter for a three month reporting period, irrespective of ESA use.

The hemoglobin value reported at the end of each reporting month, at the end of the month, hemoglobin is used for the calculation. The numerator, again was the number of pediatric patients in this criteria, irrespective of ESA use, and the denominator again is all pediatric hemo and PD patients with PSKD in the three months.

This is CROWNWeb electronic data. So if we can look at the overall review for importance, we had a unanimous group, I believe, with one partial and all complete, all yes, and in terms of scientific acceptability of the measure, we had a total here of three partial. The rest were complete. Is that right?

And in terms of the usability, everybody was complete usability. Feasibility, only one partial, the rest were complete. As we move to the final one, we had uniformity of acceptance. There was a comment, and I agree with it, by one of the reviewers.

Jeffrey mentioned about quality of life data, and certainly we need to think about having more quality of life data reported or at least determined in this population.

CO-CHAIR SCHONDER: Any comments from the Committee? Your microphone.

DR. VASSALOTTI: Well, this is consistent with the package insert for ESAs, lower hemoglobin target, and is it Jeff, the KDOQI review. Can you comment on that with pediatric hemoglobin target?

DR. BERNS: I don't actually know what the pediatric target is going to be in KDIGO. I'm not even sure what the adult target's going to be. But certainly I have the pediatric target.

DR. KLIGER: I'm not sure how it's related to ESAs. This is really identifying patients who persistently are anemic. That's the action items.

DR. FIVUSH: You know, when I -- right. When I reviewed it originally, I think it is critically important to identify patients who have hemoglobins of less than ten. I guess I'm going to ask my adult colleagues something I've heard many times about unintended consequences.

What about a patient with a

hemoglobin of less than ten, who's getting IV iron, who's getting ESAs, whose hemoglobin is less than ten? So I guess the question is, so there's nothing actionable. It's just reporting.

So Alan, I mean tell me about unintended consequences. In small populations, when we're talking about standards and measures which may impact payment to facilities, I'm just --

I'm just trying to figure out, because they'll probably use some set of the population, both in the adult and the pediatric world, who despite our best efforts, maybe we just need to get smarter about how to treat them. Is that true?

DR. KLIGER: I'll give you my take on that. I mean right now in dialysis facilities, there's autopilot with respect to several therapies for anemia, and what I see this measure doing, which I think is a good idea, is to despite those measures, to pick

out those patients with persistent anemia that need individualized focused attention, to understand what's going on.

DR. KLEINPETER: So one other thing, I guess, in the pediatric adolescent sickle cell patient, where you want a lower hemoglobin, you have an unintended consequence of potentially doing harm if you try to achieve a higher hemoglobin.

DR. KASKEL: That's a very good point, and we have very few of those patients. Fortunately, we have few, but there are some, and we have a couple where I am. But they're not on dialysis.

DR. KLEINPETER: We have a couple where I am, and they're on dialysis, and the pediatrician sees them infrequently in the unit. But they see them regularly in the office, and those of us that are doing the reviews on these patients, we also need to make an exception for those, and then justify that.

DR. BERNS: That's the key, I think. You make an exception, and I think clinical performance measures can't trump good medical care. This is applied to the bulk of our patients, and there's always going to be exceptions, and getting to the point that you made, the patient who you're thrashing with iron and epo and that's the wrong thing. But you still need to identify that group of patients that's at risk.

DR. KASKEL: I think what Alan said, and I want to go back to this resistance as -- resistance to something, as opposed to anemia, has not been well-studied. Whether it's adults or peds, it has not been studied. This opens up a whole area for investigation.

DR. KLIGER: I would answer you, Myra, in saying that the actions that you must get the hemoglobin up, right, this is an identification CPM, that says what's going on here? So for those patients who you know are sicklers, it's easy. But how about those that

you didn't know were sicklers? DR. KLEINPETER: Well, the thing that I'm concerned about in the, I guess, in the autopilot world, where you have an anemia management nurse that's coming into a unit once a month, and just sees these numbers and makes these decisions with the medical director in the absence of knowing that individual patient, to supercede what the individual nephrologist is doing, because of the, I guess the CMS guidance for medical directors to have more of an input with their units, this can be a potential problem.

CO-CHAIR CROOKS: And for a unit, a facility that has a high population of sickle cell patients, it could be significant, especially if this gets adapted for a payment somehow, you know. Is it impossible or a good idea to put it as a denominator exclusion? Is that a recommendation we can make back?

I mean you can always come up with more and more and smaller, smaller groups and

you can't go on endlessly. But this may be a significant enough problem that it deserves a denominator exclusion.

CO-CHAIR SCHONDER: Jerry.

DR. JACKSON: Question on the numerator specification. For a three-month reporting period, since we just passed the previous measure of monthly hemoglobins, how is that going to be scored? It looks like you have one month of 10.1 and the others are less, maybe fall out of this.

So the intent is to identify people with resistant hemoglobin, with resistant anemia.

I'm not reading that right?

DR. WOLFE: So it's the mean hemoglobin. So you'd take the average of those three, if I understood your question.

DR. KLIGER: I wonder if it might be wiser for this read persistently under ten, rather than average of under ten.

DR. JACKSON: I think that would be

more consistent with the intent.

DR. BERNS: I've tended to look at these performance measures by wanting to know which patient is below ten for each of the last three months, and maybe that's a way of getting -

DR. KLIGER: I think we're saying the same thing.

DR. PROVENZANO: Can vote to amend that piece to reflect what is done in clinical practice, or at least what we view as having more meaning in clinical practice?

DR. PACE: You can make that recommendation, and before you do that, perhaps we want to see if the developer, if they had any discussion around that, and if there was any rationale for the average versus the suggestion of persistent.

DR. WOLFE: None of us were at that particular TEP, so we don't know if they had considered it and made a judgment.

DR. RAMIREZ: Bob, we did not

discuss that in particular. So we did not discuss persistently lower hemoglobins below ten.

DR. WOLFE: So we're glad for feedback.

DR. RAMIREZ: So I think that's a valid suggestion.

CO-CHAIR SCHONDER: Okay. So do we want to take a vote on whether to include that as a suggestion?

DR. PACE: So you need to state that as a motion, and then be very specific about what that would mean. So we have monthly measures. Are you saying two out of three or what is it?

DR. KLIGER: No. I mean I would move that the numerator reflect those patients who in each of the three month study periods have hemoglobins of less than ten.

DR. PACE: Okay. So just to be clear, in a three-month study period, all three have to be less than ten is what the

intent is here?

DR. KLIGER: Correct.

DR. PACE: All right.

CO-CHAIR CROOKS: Just to note, this is actually the adult measure that's already approved says "who have a mean hemoglobin less than ten grams for a three month study period."

Oh, mean for a three month, right. So that was like it was originally proposed. Is it of concern to anybody that it's kind of different than the adult one, I guess?

DR. MESSANA: I have a technical question. What if there were more than three hemoglobins in the three month period?

DR. PACE: Microphone.

CO-CHAIR CROOKS: Microphone on please.

DR. MESSANA: What if there were more than three hemoglobins in the three month period? I just want to know how to handle it, if the numerator statement should deal with

that.

DR. BERNS: Isn't one of each monthly hemoglobin the one that's used for billing purposes?

DR. MESSANA: The last.

DR. BERNS: Yes, is really how I would use it.

DR. MESSANA: Okay. But if you're talking about CROWNWeb as a data source, you may have all the hemoglobins. We can define it. But you want to put that in the numerator statement then. Bianca, go ahead.

DR. RAMIREZ: I just wanted to add then, that the pediatric measure would then be more stringent in defining anemia than the adult measure, because we're requiring it for all three month versus just the mean.

DR. PACE: Is it appropriate, I mean so there's a couple of things to think about here. Is there a difference in pediatric and adults in regards to this?

Perhaps when we look at them side by

side, you would say the same thing about the adult measure, and when that's reviewed in the next project, that would be an issue that would need to be addressed.

So again, let's focus on what's, you know, indicated based on the evidence of what we should be measuring.

DR. PROVENZANO: Yes. I think what you're seeing here is again an update of what, how clinical practice has interpreted what we do in adult analysis, applying it to pediatrics, and I would guess that when the opportunity comes up to harmonize the adults, you may see a shift.

DR. PACE: Is everyone in agreement? Should we first -- is there anyone that objects to voting on the measure with that condition, that we suggest to the developer that they make the change, that it's in all three, in each of the three study months, the load?

DR. KASKEL: I have an objection. I

think that the effect, the adverse effect of the hemoglobin below a target value has more profound effects in a pediatric patient than in adults, and I don't know why we have to do this three times in a row.

If we have a patient that has a value on one time that low, we're not waiting to repeat it. We will act on it. We might repeat it the next week, but we're doing something. To wait three months, I want to see why we need to wait.

DR. KLIGER: So if I may say Rick, if that were the case, then why have three months in your measure at all? Just make it any given measure under ten.

DR. KASKEL: I didn't develop the measure.

DR. PROVENZANO: And let me, if I may comment. There is an assumption that if there's a low hemoglobin, let's just say on Month 1, but there is some intervention, and so rather than having a cyclic sort of

situation where oh my gosh, I've got to get this up by next week, this is an opportunity to allow the clinician to impact that hemoglobin. So I would look at it more from the positive side than the negative side.

CO-CHAIR CROOKS: I think you're losing something, though, from public reporting. We're talking, kind of focusing on how we manage patients and stuff. But you know, if I'm a payor, I'd like to know in general why are you keeping my patients above ten, you know, as a mean hemoglobin usually above ten, you know.

I don't really care. I'm not as interested in the number of patients who have had three months in a row with a low hemoglobin. Those are outliers, but it doesn't really give me a mean of how we're doing.

DR. LATTS: You know, I would agree, and I would think from a usability point of view, the mean is easier to understand, and I

would question why we would deliberately do something different than the measure that's already been approved in the adult, that was clearly good enough for the adults.

DR. JACKSON: I brought this up as a question, because I didn't understand the collection methodology. But if the word "rolling average" were in there, it would harmonize with a lot of the other measures we're going to consider either today or tomorrow. I think that's the intent, isn't it? It's a rolling average.

DR. WOLFE: It is a rolling average.

DR. JACKSON: And it makes more sense, especially with what Frederick said. You're not waiting three months, but you're always looking at the current month. But the measure is for the average of the previous three months. So I think based on my better understanding of what the intent they have is, I would be okay with the way it's specified now.

DR. KLIGER: Here's the way I'd argue it, Lisa. When the hemoglobin is less than ten, the clinician and the patient should be taking some action. The reason for having these measures is to see, I believe, where the action has been inappropriate or absent.

So looking at patients who persistently are anemic says to me that whatever action has been taken, if any, is inadequate. If there is a rolling average that is low, it says nothing about the method in between, the clinician -- it could be on the way up. The hemoglobin could be rising, and rising appropriately and still have a rolling average that's low.

So my argument would be as a clinician working with patients, that what you want a measure to do is to catch when the action by the patient and the physician has not been adequate.

DR. PROVENZANO: And let me, Lisa, let me just add to Alan's comments. When we

round with our nurse, we don't say what's the rolling average last month? I look at the hemoglobin this month, what was it last month. I look at what I've been doing.

So if somebody had a hemoglobin typically 8.8, and now it's 9.2 and 9.5, the rolling average is going to be below. I'm going to see what I was doing, so that I'm trending in the right direction.

So practically speaking, it is a process to us, you know, are our doctors doing anything, or are they just ignoring this?

DR. LATTS: I think, though, the reality is, and again check my math here, but from a methodologic perspective, if the rolling average is less than ten, you're going to have three measures that are less than ten, right? Pretty much, unless you have a drastic drop.

DR. BERNS: No. You can have an 8.5, a 9.2 and a 10.3 and fail this measure.

DR. LATTS: So yes. So why is it

good enough for the adults and not good enough for the pediatric --

DR. KLIGER: It should be changed in the adults.

CO-CHAIR CROOKS: Well, I still have not been persuaded by your arguments. You're looking at it as a doctor managing an individual patient. As a payor, I want to know how a group of patients is doing. And yes, some are going down but some are going up and it balances out.

What I'd like to know is what's the mean hemoglobin or how many patients that I'm paying for the care of, are hitting the target most of the time? I'm looking for a population average. You can manage it however you see fit as a doctor, but you should be producing mean hemoglobins over ten.

DR. LATTS: I would agree, and I would think that the -- that's the reason that I won't want one month at a time, is because the one month you haven't had a chance to do

anything, whereas three months, you've had a chance to affect it. So that's why I like the three month as opposed to a single month.

CO-CHAIR CROOKS: And three-month rolling averages to, you know, decrease variability from month to month. That's the real reason for it.

That's why we don't do a month at a time too, is to realize that there is some biologic variability and we don't have to overreact to a 9.9. If they've been 11, you might wait and see what happens next month.

DR. KLIGER: Peter, I would argue to you that as a payor, you don't want only to know about what the averages are. You want to know about the direction and the evidence of improvement. That's why I believe that a measure looking at evidence of inadequate action is a better measure.

CO-CHAIR CROOKS: Well, you sort of get into the outlier kind of thing, means versus looking at outliers. What we're

defining now is an outlier group, a group that needs -- you have to respond to this. Here's an issue. The quality plan sends you a letter, doctor, this patient's had a hemoglobin under ten for three months in a row. What are you doing about it? What's your explanation for it?

That's an outlier approach, as opposed to looking at means, and population means.

DR. LATTS: I would also argue that the outcome, the mean is a better true outcome measure, because that is the average of the population, whereas the three month level is more of a process measuring what you're doing. What's the process that you're doing to increase your hemoglobin, whereas the true outcome is what's the level.

DR. PROVENZANO: Let me just comment, because obviously if you look at what we've been focusing on in anemia the last ten years, we're right now in a situation where

there is a great fear out there, both clinically and legally, of over-utilization of ESAs.

So we're ratcheting down overshoots, right? I'm not going to go into all the data that we all know. Most protocols and most focused care goes to the process of incrementally moving hemoglobins into a much tighter target.

So although I appreciate what you're saying, and if we're talking about individualized care, because I appreciate that payers look at the global picture, I have to look at one person in the eye, and I would suggest that in the current environment, that the process of monitoring and treating anemia is better reflected by a monthly hemoglobin trend, in the face of the current environment.

DR. JACKSON: We trend our -- we look at individual month and three-month rolling average on a number of parameters, doing quality assessment in the clinic, and

you can trend three-month rolling averages. Wouldn't you agree? I mean it changes every month, and it reflects that month and the two previous months. So you can get a trend every three months.

DR. WOLFE: That's right, and what Peter said is correct, that if you use the three-month rolling average, you end up with more compliance in the 10 to 12 range. That is if you look at just a fraction of individual values, sometimes one will bounce out. But on average, they will be within.

So we've done several analyses looking at using a one month value, using a three-month average. We haven't looked at all three months being low. We just truly haven't done that. But if you compare having the three-month average in range, it's a much higher fraction to have the three-month average in range than it is to have all individual values in range.

So this sounds cheap, but it makes

it look better. But I suspect it also truly reflects the attempt to control the hemoglobin levels, of keeping them within range. A three-month average just does better reflect the chronic care, at least that's my understanding.

DR. FIVUSH: I just, you know, I'm just thinking about unintended consequences in the other direction now, because really ten, as Rick pointed out, we don't think we're going to have the same guidance with hemoglobin as the adult targets are.

We think we're not going to be 10 to 12. We think we're going to -- we think what is best in our population, and we talked about it earlier, is 11 to 13. So less than 10 in a pediatric patient is probably less than 10 in an adult patient.

So I think if we -- I think when I think about this intent of this measure is really to identify those patients who are particularly either resistant to epo or just

not being treated appropriately, or there's another reason which should be identified and defined.

If we do this rolling average and look for patients who are sometimes under 10 on three months, and as you said, it's an 8.9 and a 9.5 and then an 11, we're going to miss the patients that are not in pediatrics, that probably should really -- which was your point in the first place, that really should have been identified in the beginning, who are lower than they should be most of the time, but on an average may not be less than 10.

So I actually, just having gone full circle, I think that the intent of this measure was to really identify those patients, as you said, that clearly are falling out of what we think is good guidance for anemia in children. I think less than 10 has clearly been associated in pediatrics with bad outcomes.

I think there's no pediatric

nephrologist who would say well maybe 10 to 11 is okay. I think most pediatric nephrologists would tell you we think it should be 11 to 13. So less than 10 is pretty substantive in our age group, because the school attendance, physical activity, you know, all the things we talked about, quality of life issues.

But so I would not want it to be masked by a rolling average. I just, I wouldn't want it be sort of rolled up and one time the kid was 11 but the other two times they were less than 10, and then we don't see it.

CO-CHAIR CROOKS: Well, but you're going to be managing that patient, looking at those values every month.

DR. FIVUSH: Yes, you are correct.

CO-CHAIR CROOKS: You're not going to miss on this. It's not going to change what you do, except to help you, you know, be aware that those who are watching you want you to, you know, keep it above a certain level.

DR. FIVUSH: Right.

CO-CHAIR CROOKS: You know, I just wanted to say that the number one, the first intended use of this measure is public reporting and then second, internal quality improvement. So this is meant for public reporting, and again, it's sort of looking at the mean versus the outlier.

When you're looking at the mean, all patients are accounted for in the metric. If you're looking at the outlier, you're looking at a smaller group of patients that need attention, but you're not learning what the mean value is, which is what the public presumably wants to know.

DR. KLIGER: I'm not sure that's what the public wants to know. The public wants to know who's getting adequately treated and who's not.

DR. VASSALOTTI: But this isn't the mean of the overall population, right. This is the number of patients that you have a mean

value --

CO-CHAIR CROOKS: Right. Well, but it's the number, it's the percent of patients who are hitting a goal of at least 10 is what it is. But all patients are accounted for in the metric, as opposed to smaller number.

DR. LATTS: Yes, and I think that's exactly the difference, is you're looking at this as how is it going to help me measure the individual patient, when this is a population-based outcome measure.

So it's how is your whole population being managed overall, which is a very different way of looking at it, which is why I think the mean is probably, you know, good enough and --

DR. PACE: This discussion just makes me want to kind of clarify.

(Laughter.)

DR. PACE: No. I just want to clarify again, you know. NQF endorses measures that are intended for both public

reporting and quality improvement. So we want measures that do both, and we are talking about measures, performance measures. So we're talking about data that are aggregated to whatever entity level we're measuring.

So in this case, we're talking about dialysis facilities. Sometimes we're talking about health plans, sometimes about physician practices. But we are, I think as Peter said, you know, it's not -- you know, in your individual practice you're still looking at every value, and treating.

But this is intended to be a performance score on overall, how well are you keeping your patients above a certain target value. But just, you know, a couple of things.

MS. LeBEAU: Just, I don't want to get into the clinical statistical debate here, but what I think, and please correct me if I'm wrong, the adult measure here is weighted more in its use, because there's such a serious

consequence for lower hemoglobins, poorly managed anemia at that end.

So I'm thinking that the group very particularly that they're trying to identify, are the people who are falling below consistently. I don't know.

CO-CHAIR CROOKS: Whether the measure will pick that up.

CO-CHAIR SCHONDER: Okay. So I'll go back to the motion that's on the floor, to make the amendment that it's each of three, each of the three months is less than 10. Do we want to take a formal vote or --

DR. PACE: I think we'll do a hand vote on that, and then -- so then that will decide for the formal vote which version we're voting on.

CO-CHAIR SCHONDER: Okay, okay. So this is a vote in favor of making the amendment, that each of the three months is less than 10.

DR. FIVUSH: This is the mean?

CO-CHAIR SCHONDER: No, no. This is to make the change that each of the three months has to be less than 10, hemoglobin less than 10.

(Show of hands.)

CO-CHAIR CROOKS: Thirteen, okay. How many want to leave it as it is?

CO-CHAIR SCHONDER: Leave it as it is?

(Show of hands.)

CO-CHAIR CROOKS: Eight.

(Off mic comments.)

CO-CHAIR CROOKS: Who voted twice? Alan? No. He's sitting on his hands. Okay.

DR. PACE: Okay, so --

CO-CHAIR CROOKS: The count is 14. Let's say 12 and 8. I think I probably counted wrong.

DR. PACE: Revote, okay.

(Simultaneous speaking.)

DR. PACE: Those who voted to leave the measure as it's currently specified, as

was submitted to us, raise your hand again?

(Show of hands.)

DR. PACE: Seven, okay. So 13 and 7. Okay, all right. So we'll move on then to -- okay. Why don't we go ahead then, through the evaluation --

CO-CHAIR SCHONDER: I do want to bring up one, because there was a question about the sickle cell that Myra brought up, in changing the denominator.

CO-CHAIR CROOKS: If we're going to send stuff back to them, can we vote on that, whether to recommend -- I move that we recommend a denominator exclusion for sickle cell patients.

CO-CHAIR SCHONDER: We have a second.

CO-CHAIR CROOKS: All in favor?

(Show of hands.)

CO-CHAIR CROOKS: I think we can say that one passed.

CO-CHAIR SCHONDER: That looks like

unanimous.

CO-CHAIR CROOKS: Unanimously, or close to it.

DR. FIVUSH: So Peter -- so Karen. Karen, will this now go back?

DR. PACE: Pardon me?

DR. FIVUSH: This is not -- now what's happened is this is not denied or approved. It goes back -- this is the first time we've done this today. So it goes back to the measure developers now?

DR. PACE: Right. Let's, I think what we'll do, what we do, so the Committee has voted to put a condition on this. I guess what we need to do now is take a vote.

We'll go through the criteria. I'm trying to think if that makes sense, given the changes. A lot of that probably is okay, but the reliability and validity would be different. It's a different measure.

Why don't we take a vote? We'll just have you vote up and down on -- okay.

Let's start with I think importance to measure and report is still something you can vote on. We want to make sure that we pass that criterion, and then we'll take a vote on the measure, as you've specified the condition.

What will happen, if you approve it that way, we will go back to the measure developer, tell them what the condition is, ask them to respond to that. They can either say yes, we agree or no, we don't agree for these reasons. They'll come back to you to review their response and see how you want to move forward after that.

Okay. So let's at least do importance to measure and report, and then we'll do on the vote, on the measure as you're suggesting the change. So importance to measure and report. No, no, no. Okay.

(Off mic comments.)

CO-CHAIR CROOKS: We're missing one.

(Committee voting.)

DR. PACE: Okay. Does everyone

think they've registered their vote? Okay, go ahead. You can --

CO-CHAIR CROOKS: 19 yeses and no nos.

DR. PACE: Okay. So let's go forward to the recommend flag. We'll get -- okay. So what you're voting on here is recommending the measure with the two conditions.

One is that it's percentage of patients with all three in the three-month study period that are below ten, and adding the exclusion for sickle cell anemia patients.

Any question about what you're voting on? So it's both. Okay. All right. Go ahead.

(Committee voting.)

CO-CHAIR CROOKS: 18 yes and 2 no.

(Off mic comment.)

DR. PACE: We'll send that back to the measure developer, ask for their response, that they can provide to you either yes/no and

reasons why or why not. Okay.

DR. WOLFE: Thank you.

CO-CHAIR SCHONDER: Okay. So in case you're not keeping up with us, we are a little bit behind schedule. We do have one of our measure developers who's here for one measure only. So actually we're going to go out of order right now and skip to the minimum metabolism measures at this point.

So flip over your sheets to page three, and we'll move to Measure No. 1454, and Joe, I'll ask you to --

DR. PACE: Actually, it's 1427.

CO-CHAIR SCHONDER: I'm sorry. Oh, 1427, I'm sorry. Okay. So the other Joe. If you can -- they're out of order on our list. Go ahead. So we're going with 1427.

DR. PACE: Right. That's fine. We'll do the whole group on mineral metabolism, but we'll go ahead and do that one first.

Measure No. 1427

DR. VASSALOTTI: Okay. So 1427 is the proportion of adult patients with a serum phosphorous greater than six milligrams per deciliter. The numerator is the average CM phosphorous greater than six milligrams per deciliter, the number of patients with that over a three-month rolling average.

The denominator is adults greater than or equal to 18 years of age, who were treated with, it says outpatient PD or HD. I guess that means PD associated with an outpatient facility, for at least 30 days at that facility, who have been treated with dialysis for more than 90 days, who have at least one phosphorous measure during the 90-day study period.

Now I think I may need glasses, but I'm looking at the review there, and I see maybe Karen, it looks like we have one complete and four partial.

DR. PACE: Yes. I can read them if you'd like.

DR. VASSALOTTI: Yes, thanks.

DR. PACE: Okay. So for -- oh, let's go back to importance. Okay. Importance, all five said it was important, and then on scientific acceptability, one completely, four partially. Usability, one completely, four partially. Feasibility, the same, one and four. In terms of recommending, four yes and one no.

DR. VASSALOTTI: Okay. So this, I think just to briefly summarize, this measure has a lot of attractive qualities, in terms of it's something that's easily measured and captured electronically. We think it's reliable, it's useable, it's something clinicians think about all the time.

So I think it's certainly valuable in that sense. It's clearly associated with increased mortality, both all cause and cardiovascular mortality. It may address some of the disparities in care, in terms of racial and ethnic minorities and poverty, and we

think conceptually that reducing serum phosphorous could improve patient outcomes.

I think I would say clearly to me, this is the best potentially in the class of the three measures that we've been asked to review in mineral metabolism. I think the down side of this is that most of the data that we have are retrospective studies or observational studies.

We don't have any interventional studies that prove a benefit to, you know, that reducing phosphorous improves outcomes. Unfortunately, we don't really know what the optimal intervention is. I think I know the optimal intervention. Let's put everybody on long nocturnal hemodialysis.

But that's not going to happen probably any time soon. So given that, and I would also this is one of the most controversial areas in all of nephrology, calcium-based binders versus non-calcium based binders.

If we lower our serum phosphorous with calcium-based binders, does that have unintended consequences that are potentially detrimental to patients? So I want to make a distinction between what I think is important and what I would do everyday with a patient in front of me.

That, I think, is a very important thing for me as an individual and for my patients. What I think is important is a quality improvement initiative, which I think is potentially great. This is a very important area in terms of quality improvement.

But I guess I'm not so sure this rises to the level of a performance measure for public reporting and for potentially for incentive-based health care. I would just point out that the CMS TEP on page 37 did consider this to be a very important biomarker, but for some other reasons I just outlined, did not agree or could not agree on

the threshold, you know. Is it 5, is it 7.

So that was their reason that they didn't bring this forward, and that the KDOQI commentary groups. So these are a group of experts published in 2010, based on the KDIGO guideline. I think Jeff was one of the authors of this, has a conclusion here, which I won't read in entirety.

But basically, it does not recommend performance measures in this area, because of some of the reasons that I just outlined. But I voted no. But you know, I think that this is something that's really up to -- I was the only vote, I think, no.

I think this is -- everybody else said yes. This is open to discussion, and again, I think this is something that's very important, but I'm just not so sure it rises to the level of performance measurement.

DR. NALLY: There's been several discussions in the last 48 hours or so along the lines of evidence and the distinction

between, as you put it Joe, what you might do versus rising to the level of a performance measure.

I think the concern is that threshold, because clearly having, be it high calcium, high phosphorous, high PPHs, one can associate in observational trials that there are adverse outcomes, increased mortality with those.

Unfortunately, we don't have randomized control trials in this arena to really inform us into the optimal management of things. So we're in this quandary of the associations being translated into practice measures.

I think, after discussions that Joe and I had through the weekend, it made me go back and look at who else has examined the issue. So KDOQI had looked at this six or eight years ago, and issued some very specific evidence, or excuse me, opinion-based guidelines.

Then more recently we had KDIGO have a panel of experts examine the questions, and they pointed up some of the limitations and need for more information. As I went back and read this through on the plane coming here, most of the evidence is Level 2, which tends to be not at a level where you would want to have performance measures based here.

Then finally last May, we had the commentary on the KDIGO guidelines, with the first author who actually ran the evidence-based team for KDIGO on the subject. Jeff was an author and some others, and they came away with a conclusion specifically stating that levels of increased phosphorous would not reach the status of a performance measure.

So that type of conflict was exactly what I was inferring this morning, when I asked the questions about the actual criteria for a performance measure, because we have now an international panel weighing in on the subject, suggesting that it hasn't reached

that level.

I think that for me is the conflict and the angst here, is that we've had some different standards as we've marched through the day, in terms of translating or our thoughts and wishes in a performance measure or not.

And so the dichotomy to me right now is what an international panel recommends, that it doesn't reach a level and what some of us might have said in our processing through this exercise.

DR. LATTS: Well, I'm confused, and if you guys could maybe explain. In the last measure we talked a lot about how it's important to take what we do with individual patient level and transfer that to the measure, and that not looking at the population level was not as important as looking at how does it translate into what you do for the individual patient.

So if you had an individual patient,

and again, I just truly don't understand. If you had an individual patient who consistently had a phos greater than six, you wouldn't try to lower it. Or is it that you just don't know what to do?

DR. KLIGER: Can I just take a quick crack at this? The difference between the two has to do with the quality of the supporting data. In anemia, there is a clear -- there is clear evidence that intervention makes a difference to outcomes. In phosphorous control, there is no evidence for that.

DR. VASSALOTTI: If I can make --

DR. LATTS: So you would still, you would try to do things, but you don't know that what you would do is successful.

DR. BERNS: One of the risks that I would worry about with a performance measure like this is that we do more harm than good, and that this quashes any motivation for the studies to be done, that show there's a benefit. Really what we're saying is you

should keep everybody below six, there's very little motivation then for anybody to prove that that's the right to do.

That's what we're desperately in need of, and I don't think it's a secret to anybody that this particular performance measure is industry-supported.

That's the industry that needs to help us find out whether or not we should be lowering phosphorous levels, and how we should be lowering phosphorous levels below six, because we don't have answers to those questions.

But we desperately need the research to get that answer, and I'm afraid this performance measure would make that less likely to happen.

DR. PACE: So I just want to give you a little information on some of the thinking behind our Consensus Standards Approval Committee, and our Evidence Task Force, and actually very much recently

reinforced by the board in terms of outcome measures versus process and structure measures.

So, and this is kind in the middle. It's intermediate outcome measures. So what we would be looking for here, is there evidence that that level is linked to health outcomes. So is there evidence that, you know, phosphorous level is related to morbidity-mortality.

DR. KLIGER: That's not the question, because the question is whether intervening has an effect on morbidity and mortality.

DR. PACE: That's what I'm saying. We don't have that as a requirement, that you have to know exactly what to do to change the outcome, and I'll just go through some of the thinking behind that.

The reason is that, and this may not apply to this particular outcome, so I'm talking more in general, is that if we measure

that kind of outcome and we start seeing variability across facilities in terms of their ability to get that level to a reasonable place, then we start seeing that, you know, some people have figured out what to do.

So that you actually may facilitate identifying ways to influence an outcome that maybe we don't know. So that's one reason, and the other aspect is if we -- if it's something that no one can influence, then it's not going to put any one provider at a disadvantage, because it's going to stay at a certain level across patients.

So I'm talking in general about outcomes and outcome measurement and some of the thinking of our board and consensus standards approval and Evidence Task Force. You need to look at the specifics of this particular measure.

But there's a lot of interest in measuring outcomes, even if we can't identify

one particular treatment or intervention that's going to change it at this point in time.

MR. WELLS: I'm a little confused, and that happens easy for me. Is the intervention you're talking about, is that prescribing a binder, or are we talking about better therapy?

DR. KLIGER: All and any of those. There's no evidence that prescribing binders or giving fancy drugs or any of the things that have been done and that we do, has an effect on outcomes.

DR. LATTS: How about dietary adherence?

DR. KLIGER: I don't know the answer in relationship to diet. I haven't seen any of the evidence for that. I don't know if anyone else has.

DR. FIVUSH: So I'm getting a little lost in the conversation. So are we saying that there's no evidence that there's -- that

we can drop phosphate levels below six, or are we saying there's no evidence that dropping levels of phosphate below six matters?

So the question of dietary. So I guess that's not really coming into play, whether that does or doesn't drop it, because all you're saying is there's no evidence of doing it, the dropping it. There are many ways to drop it, but there's no evidence that lowering it below six results in a better outcome for patients. Is that --

DR. VASSALOTTI: Okay. I mean Joe really said it very articulately, I thought, very articulately, which is that it's clear that there is a correlation between the levels and a variety of outcomes, absolute clarity about that. But no evidence that trying to affect or change a phosphorous level impacts outcomes.

DR. FIVUSH: So then is it not -- so this -- so it's important to know if we have patients whose phosphorous is over six, but --

so is this something you'd say would be better for quality improvement than public reporting?

I mean I'm just trying to -- because you're clearly saying this is critical. We've been talking about phosphorous for years. We know that it's difficult to lower. We know that we haven't done a good job. But we don't think it's yet ready to be measured for, to be measured in this standard?

DR. VASSALOTTI: It's very important. I would address it. I wouldn't ignore a phosphorous over six. As an individual, I think it's an important quality improvement initiative. But I don't think the level -- we don't know the best intervention.

We don't have interventional data that shows that there is an improvement. We don't have good data that shows the threshold of six is any better than five or seven of, you know, I could go on about the last iteration, some of the things we talked about, unintended consequences.

So you have urban dialysis facilities which my colleague here is, I think, very familiar with, who are financially strapped, who have struggled to survive, who are in areas where patients live in food deserts. They might not have access to fresh foods, so they have to eat processed foods.

So those facilities are going to have patients that are going to be very, very difficult to treat without frequent dialysis or the therapies that may be difficult for them to implement. So there are all kinds of consequences potentially of this. Those were raised in the last iteration of this.

You know, we could -- and also, this is not you mentioned consistently above six. So this is a mean. So this is not consistently above six. This is a rolling mean. So you could potentially have a patient who has a level of let's say seven, five and four or something, and has a mean that's above six. So those are other issues that are

raised.

I think again, I want to make the distinction with what we do clinically, what's important, with what we think should be at the level of a performance measure.

I also think that there's a chance, if we really -- if the group thinks this is important, and we want to do something with this, I think we can go back to the developers and say maybe we're willing -- Jeff says we want more data.

Certainly, that would be great to have the outcomes data. That's one thing we could ask, to try to address some of these research questions. What about a more stringent measure, you know, higher levels of phosphorous, maybe consistent levels.

But I think the problem, the concern is picking a particular level, and implementing that in a community.

DR. LATTS: I've got to tell you I'm struggling with this, and I know I'm one of

the non-nephrologists here, I'm unpopular. But this is important, and this is --

You know, you're telling me this is important clinically, and this is something you spend a lot of times with your patients, working to get their hemoglobin, I'm sorry, their phoses down, and therefore it's an important thing to measure.

I don't really care frankly if the number is five, six or seven. You know, if six is controversial, then I'd be okay with seven. I think if it's important to measure and lower is better, you know, I don't buy that just because it's hard to lower it in an urban population, we shouldn't measure it. I really have a problem with that.

If this is clinically important, then it should be measured, and it's important for your patients and the population to see performance at a facility level.

DR. KLIGER: I'd agree with you, and then the measure is not a threshold measure.

What you're suggesting is like some of the others we've had, is a frequency measure rather than a threshold measure.

DR. BERNS: Can I make a case to, and I think this is important from not only the nephrologist perspective but maybe even more so from the patient perspective, which is not only do we not have evidence of benefit of lowering phosphorous below six; we don't have evidence that it's safe to do so.

Often, the response to that elevated phosphorous is dietary manipulation, which may be disadvantageous to the patient, or phosphate binders, which have an expense issue, maybe a quality of life issue, and maybe a medical risk issue.

So I think we have to be aware that we also need to be thoughtful about avoiding risk when we think about some of these therapeutic interventions, and whether they're important or necessary.

MS. WAGER: I've got a question.

Dr. Vassalotti, as a patient and my phosphorous was over six, and you said clinically that you would treat it. I was a patient would then ask you why are you doing this? What do you want my phosphorous at then? If there's no -- what are you going on that, okay?

DR. VASSALOTTI: Well you know certainly I would shoot for the normal range. I would target the normal range, and I would look at all of the, you know, all the aspects of your care that I thought were relevant, whether you were on dialysis, the type of dialysis, your dialysis regime or diet, and then address the phosphate binders. But I think this, you know --

DR. NARVA: When you talk to patients, it's perfectly okay to say you know, I can't prove this, but I know that having this value is really associated with a lot of bad things, and I think we really should pay attention to it.

I can't prove that to you, and that's an individual decision. This is a very different thing then to say you're bad; your unit or your practice is inadequate if you don't meet this. It's a really different standard. It acknowledges the fact that we're not, things aren't quite as certain as we might advertise, or as many people might think.

DR. NALLY: And not only are those two different and distinct conversations, but if you do not require more rigor in your granting a performance measure, then you tend to stifle research into that area. So I mean maybe a reasonable randomized control trial might have three different levels of phosphate as a target, and might have different ways to get there.

If that type of information really has been needed over the past decade, and it's been an embarrassment that those type of studies have not been done.

MS. ANDERSON: Just a couple of comments. First of all, there's no evidence that a phosphorous level of six, and I think we've all discussed that. But of more concern, and I think the industry is moving more towards looking at hypercalcemia as a more serious and safety measure versus high phosphorous.

Also, if this is a facility-level standard or measure, there's too many variables involved with setting the level of six, whether it be lab variability, facilities may not necessarily have control over adherence to phosphate binders and whatever.

So to have it as a standard, there's too many variables right now to be able to identify it. I think there's more significant and more serious values with hypercalcemia that we could look at instead.

CO-CHAIR CROOKS: I agree with the majority here. I think that to put this out as a public reporting standard, that your

unit, Myra, has an average phosphorous level, or let's say only, let's say 30 percent of your patients are exceeding that.

Down at Alan's unit in Connecticut, he only has ten percent of the patients exceeding it, that they would conclude that your practice is, your patients is at higher risk and you're practicing worse than Alan.

I think that's a wrong interpretation, and we cannot. But that's what we'd be saying by passing this.

DR. PACE: So is the evidence that was suggested, that values greater than six are associated with higher morbidity and mortality -- they are?

CO-CHAIR CROOKS: They are.

DR. KLIGER: There's a continuum. Right. You could use this for any of the things we'll talk about. 5 to 7 would be a ballpark, you know; calcium kind of high 9's to 11-1/2, the same thing. But now we're setting a specific number on this of 6, which

I believe is in the middle, yet arbitrary.

DR. BERNS: I also point out that observational studies have shown that hemoglobin levels above 13 are better for patients than lower hemoglobins. When we actually got the right information, we found that that maybe wasn't the right to do.

MR. WELLS: I just want to say, I mean the reason I'm piping up now is this is something that's very personal to me. I struggled with phosphorous when I was in-center, and I mean I had some very, very high numbers that were alarming to those around me. Since I thought I wasn't going to be around that long, it didn't bother me.

After I started on frequent dialysis and doing it at home, they started coming down, and I found that, you know, the longer I did my treatments, the better my numbers got. My thinking here, and I could be wrong; that's happened one or two times in my life, but that we are looking at establish measures

for quality care, and we know what will bring phosphorous down.

Obviously, my goal is to see more people doing more frequent dialysis. I'm not going to deny that. If that is our goal, I mean to me, I mean I think we should establish a standard somewhere.

I mean I honestly think 5.5 and 6 is higher than what it should be. I mean that's for, that's within range for a dialysis patient, and I think, you know, the real goal should be what normal levels are, and we should work for that.

That's why -- I mean there is a solution to bringing it down without intervening with medications or what have you, and you know.

DR. KLIGER: So I might caution you, as you think about getting everything to normal, we used to think that, for example, about hemoglobin. We used to think that getting patients' hemoglobin to normal is an

obvious goal. We now know that our efforts to do that ended up killing more people than helping them. So I'd be careful about setting a standard at what normal is.

MR. WELLS: Oh yes. I don't think we should set the standard there. I'm just saying my feeling is that when I was in-center, and knowing the rates of phosphorous that I had and then when I started, I guess my point comes back to is the discussion around setting it at 6.

We don't want to do it because we don't want to impede research into that, which you know, I think that's a valid objection. I mean I'm not saying it's not. Or is it because we don't want to prescribe phosphate binders because of the issues involved there.

I mean those things -- I mean I'm not saying I think it should be set at 6. I guess I'm trying to figure out, you know, is the discussion because, you know, there's no adequate way of treating it, or is it because

I mean that's what I --

DR. PROVENZANO: Let me try to use Alan's analogy, which is I think the right one. The answer is we don't, we just don't know, and we didn't know in hemoglobin, and when we went down the path of thinking, as you mentioned, normal is better, theoretically, depending upon who you want to believe, patients suffered.

Therefore, the only argument is here is we do not have the science to suggest that this number is the right number, and until we do, until that data becomes available, it would be unwise to approve this. I just think that's where we're coming down at.

CO-CHAIR CROOKS: Also Harvey, I think if we believe that adopting this as a national standard would encourage a blossoming of home and long nocturnal dialysis, I'd be the first one to go for it.

Because you're right. We do have a good treatment, and we do have a treatment

that will improve outcomes, and that is lowering it by more dialysis. I believe that's true.

Again, that hasn't been proven per se. But the truth is, if we approve this as a national standard, phosphorous will get pushed down, but it won't be by giving more dialysis, for the most part. It will be by giving more drugs, giving more calcium-related binders and so on and all these issues we talked about.

So I agree with you in theory, but I think the practical answer is approving it won't get the result that you want.

CO-CHAIR SCHONDER: Okay. Any more discussion? Yes. Okay. We're going to -- oh okay. to make a comment.

MR. MENOYO: Sure. I would like to make some remarks. I think that, you know, as we sit here through the discussions of the day, it seems to me, number one, that we are looking at the evidence of the measures that

have been approved, and setting different standards in terms of the level of evidence for the measures that have been endorsed by the NQF, versus this particular measure.

When we look at the number of studies, and may not be randomly controlled trials, for the quantity of associated studies and observational studies are there all point in the direction that lower phosphorous is better than not. How we lower it, either by more dialysis, binders, diet, is a whole different issue.

When we look at some of the data, it's certainly observational for example DOPPS, and you look at facility level of facilities that have phosphorous greater than 6, versus facilities that have a phosphorous between 3-1/2 and 5, facilities that have levels greater than 6 have worse outcomes for patients than facilities that do not.

So already, going back to maybe an urban facility versus not, there's already a

standard in terms of the level of 6, or the number of 6 is actually worse for those patients than not.

In terms of the guidelines, yes, there's not really necessarily consensus in terms of what the numbers should be. The reason that we submitted 6 is based on the evidence that is there for DOPPS and the evidence from the demonstration project.

I think at the end of the day, everybody in this room that's a nephrologist will treat their patients and try to keep the phosphorous under 6. I think that at the end of the day, if there's not a standard measure to try to continue to improve that moving forward, we're probably doing a disservice to the patients.

CO-CHAIR SCHONDER: Any other comments? Okay. Move to vote.

DR. PACE: Importance to measure and report.

(Committee voting.)

CO-CHAIR CROOKS: We have 13 no and 7 yes.

DR. PACE: All right. So we'll move on to the next one. Is there another phosphorous one? Maybe we should do that one.

CO-CHAIR SCHONDER: Yes, okay. So we'll stick with the mineral metabolism and move to 1461, since we're already out of order.

Measure No. 1461

DR. VASSALOTTI: This is hypophosphatemia. So thank you for assigning me with phosphorous measures.

(Laughter.)

DR. VASSALOTTI: Wherever that came from. So I think this is a little bit more straightforward. This is the proportion of patients with a three-month rolling average of serum phosphorous, less than 2.5 milligrams per deciliter.

I think that's the numerator. I think the denominator is pretty similar. It's

all -- I think it's both PD and hemodialysis patients that are treated in an outpatient facility. The same kind of adults 18 years or older.

They have to be at the facility for at least 90 days. They have to have been treated with dialysis for greater than 90 days, and have at least one phosphorous measurement during the 90-day study period.

Okay. So my visual acuity test rolling. I failed again. Snelling chart.

DR. PACE: Right. Just a second.

CO-CHAIR SCHONDER: There's four nos and one yes.

DR. VASSALOTTI: Okay. So four nos and one yes for importance.

DR. PACE: Right.

DR. VASSALOTTI: For scientific acceptability of measure properties, we have --

DR. PACE: We have a spread. One completely, one partially, two minimally and

one not at all.

DR. VASSALOTTI: Okay. For usability?

DR. PACE: And then usability, two partially, three minimally.

DR. VASSALOTTI: Feasibility?

DR. PACE: Feasibility, two completely, two partially, one minimally and then recommend, one yes and four no.

DR. VASSALOTTI: Okay. So this has the same kind of -- it's attractive in the sense that it's easily measured. It's electronic data capture. It's reliable, it's understandable. There is a strong association with serum phosphorous less than 2.5 milligrams per deciliter in all cause and cardiovascular mortality.

Those are the pluses. Again, we have no interventional data. I think this is a little bit of a misnomer to me at least. I think this is not how I think about patients and calcium phosphorous metabolism. This is

not a mineral metabolism measure. This is more a nutritional measure to me.

So I'm not sure this really belongs here. In my experience, and I'm curious to hear what everybody else thinks, but the kinds of patients I've seen with this, who don't have the obvious causes, are very sick patients who have, you know, probably have an incredibly high mortality, and I'm not sure that feeding patients who are malnourished, have atherosclerosis, inflammation, maybe something I don't always understand, I don't know if feeding them actually helps. I don't even know if this is actionable, to be honest.

The gap in care for these patients, I'm not sure what an impact this will have. This is 0.6 percent of the population, I think, according to the performance gap that I read, and please, developers please correct me if I misspoke about that.

I think that's really all I have to say about that. Any comments from the other

reviewers?

CO-CHAIR SCHONDER: I know I was the one yes. Up there, you can see that. But I actually would change my vote if I was doing that today.

DR. NALLY: I was a reviewer also, and I agree with everything you say, but also emphasizing the fact of picking out a measure that affects less than one percent of the population, and trying to make that a performance measure detracts attention from other very important areas that we'll be talking about.

CO-CHAIR SCHONDER: Any other discussion? We'll move this one to vote quickly.

DR. PACE: Okay. Are we ready?

CO-CHAIR SCHONDER: Yes.

DR. PACE: Okay, all right. Importance to measure and report?

(Committee voting.)

DR. PACE: Everyone thinks they've

hit send? Okay.

MS. RICHIE: Just a reminder not to hit the send button before we actually start the timer, because it won't capture your votes.

CO-CHAIR CROOKS: We have 2 yes and 17 no.

DR. PACE: Right. So that's probably what happened. Someone may have hit their response before we actually -- yes. I know you're anxious.

CO-CHAIR SCHONDER: Okay. We will finish the mineral metabolisms and go back to the first one then, 1454. Joe.

Measure No. 1454

DR. NALLY: I would like to thank anybody that selected the other Joe for the phosphorous.

(Laughter.)

DR. NALLY: However, this is in the same category, but I think it will take a little more thought than the last one we just

went through, with a little more discussion.

This measure looks at the proportion of patients with three-month rolling average of total uncorrected serum calcium greater than 10.2. That being the numerator, the denominator being, as Joe mentioned before, the people in the unit. It's data that's readily available and easy to collect.

In terms of, I guess we could go to the evaluation process, and now there's an update here. I only had five observers, but I think we get a sixth, and in this case, the importance, five of six said that this was an important issue.

In terms of the scientific acceptability, here you see a smattering ranging from a couple completes to one minimal and the other is partially. This, I think, is where some of the discussion that we've already had about this area of bone mineral disease being important.

The idea is that calcium

phosphorous, Vitamin D, PTH are very common, but we really lack data making for compelling information to guide our judgments in this impact. But I think there's a different spin with the high calcium here.

If we could go on to the usability. Here we have all partiallys except the one minimal, and feasibility, here we have four completes and two partial. Then one pause before we get to the recommendations. There were some observations as part of the evaluation process.

Again, the concept that the 10.2 was an arbitrary number. As I may have alluded to before, having high calcium confers increased risk, but that spread goes from roughly 9-1/2 to 11-1/2. So this is an arbitrary number. It does in fact use total calcium that's not corrected, and more recent data would suggest that the uncorrected calcium is probably a reasonable way to go. And finally there was concern that there wasn't any information

given about the level of a high calcium and how that translates into the number and types of adverse events. So those were most of the concerns there. We've already heard about issues of potential management as it affects phosphorous.

In this case, having a high calcium may more likely be a consequence of therapy, such that the behavioral pattern might be to reduce therapy as opposed to the phosphorous issue, the high phosphorous, where it might impact more therapy.

I think that's an important distinction to make, that the hypercalcemia, and again, in terms of the gap measures, I looked at this. There was a survey done twice, and I'll ask our measure developers to comment here, whereby in almost 14,000 patients, there was about 4-1/2 percent that would meet this measure.

Then when they looked at a facility level, that number went up to about 13

percent. So there seemed to be a threefold difference in the data there, and I would like to request an explanation, if that's a correct statement.

DR. MESSANA: We're working on pulling those data up for you.

DR. NALLY: It's in the 1B, Summary of the Data Demonstrating the Performance Gap. Pull that up there, Lauren. 1B, page four.

DR. PACE: I guess one simple explanation is that it's showing that facilities have variability in how well they're managing it. So if you looked at just the population, but those are concentrated in maybe facilities that aren't doing well. That would be one hypothesis.

DR. NALLY: But it didn't say 13 percent of facilities. It said 13 percent of patients.

So I don't know if that was a typo or if that was a true --

DR. PACE: Yes, you're right.

DR. WOLFE: We believe that that's right. We are checking that to make sure that that's not a typo. It is possible that that is still consistent, but nationally they are 4-1/2 percent above the cutoff.

But at 95 percent of facilities, there are 13 percent or more with -- that are above there, and that five percent of the facilities have very good management. But we will check that. In either event, it's one or two of those.

DR. NALLY: So somewhere between 4 and 13 percent, rather than the 18 percent with high phosphorous and the 0.6 percent with low phosphorous. So it's a problem of note.

DR. BERNS: This is again one of those performance measures that may be every month for the last three might be a better way of looking at this, than a rolling average, if it's going to be made into a performance measure at all.

The other thing I think that speaks

to this, which is different than the other ones that we just addressed, that this does provide opportunities to address toxicities of therapy, whether it's calcium containing phosphate binders or Vitamin D or Vitamin D analog.

So there is a potential value to doing that, not so much to give more treatment, but to reassess what treatment the patient's getting.

DR. KLIGER: Yes. If it's meant to specifically address overtreatment, or treatment, then I would think that the denominator should be those patients on treatment, because I'm concerned about that population of people with hypercalcemia, that has nothing to do with treatment.

We obviously have people who have metastatic bone disease or Paget's Disease or a variety of other reasons why the calcium might be elevated.

DR. NALLY: I understand and very

much appreciate that concept. But it would be difficult to sort that out in the denominator, when all you know for sure is their calcium is 12-1/2. Once you stop therapies that might affect calcium, the Vitamin D's and et cetera, et cetera, then you still have to go through the drill of whether or not they do have the malignancy or the sarcoid or tertiary hyperpara or those other things.

But I think that would be a very difficult exclusion to build into the measure.

DR. KLIGER: Why would it be hard to know as a denominator who's on treatment and who's not? I'm just saying --

DR. NALLY: Or you're saying do it from the other way around.

DR. KLIGER: Yes, yes. I'm saying just look only at those people on calcium-containing binders.

DR. NALLY: Well, yes. You'd have to go the whole gamut. Calcium-containing binders, Vitamin D. That would make it

reasonably complex. But I understand what you're saying.

DR. PROVENZANO: I mean I think the reality here, as opposed to the other -- and Jeff's hit on this, is this is a marker that doctors use for toxicity, you know. Vitamin D, binders, right? We naturally say --

DR. NALLY: Go through that differential.

DR. PROVENZANO: Right, and then once that's eliminated, we say tertiary hyperparathyroidism, metastatic disease, et cetera. It's a trigger to us for toxicity, and it should be viewed as that.

DR. NALLY: And therefore in my judgment has some benefit, as opposed to another arbitrary level that might invoke more therapy and toxicity.

CO-CHAIR SCHONDER: Any other comments? Barbara.

DR. FIVUSH: So I know we had a lot of question about the 6.0 level with the

phosphorous. We're pretty certain about the 10.2? That would be --

DR. NALLY: The short answer is no.

DR. FIVUSH: That's my only question. Do we have better --

DR. BERNS: Uncorrected calcium level. It's probably reasonable, you know, as uncorrected calcium, because then corrected would be actually higher calcium in most patients. So this is probably a relatively conservative number, but not defensible other than that.

CO-CHAIR CROOKS: While this is a nice tool for individual patient management, what does it mean as a public reporting measure? There's going to be a certain instance of patients that have high calcium, you know. Is this telling the payers that a unit with high calciums, these doctors are mismanaging the patients?

Or does it mean, you know, how do they interpret it? Is it important in that

sense? I don't have the answer. I'm questioning that it's of value for that purpose. Does anybody defend that, that it has good public reporting usefulness?

DR. KLIGER: Yes.

CO-CHAIR CROOKS: And how would you advise a research company to interpret a unit that has a high proportion of patients with hypercalcemia?

DR. KLIGER: Again, in my mind, if the denominator is the appropriate one. So you're talking about people with hypercalcemia who are on drugs that can induce that toxicity, it's telling the company that that unit is not appropriately assessing patients for toxicity of their medications. CO-CHAIR CROOKS: And even if the denominator's the same, you still might kind of come to that conclusion. That would be a not unreasonable conclusion. Okay. Well, that sort of answers my concern. Other thoughts on usefulness as a public reporting measure?

DR. FIVUSH: Can we, can I just go back to -- so if you believe it has to be -- you said it has to be corrected, right?

DR. NALLY: This is uncorrected calcium.

DR. FIVUSH: So I'm saying is uncorrected 10.2, is that right? You said --

DR. NALLY: That it's a 10.2 uncorrected.

DR. KLIGER: I mean again, you know. When you're talking about toxicity, I think Bob's point is really very pertinent here. There's a difference between talking about biologic variation in an illness, and talking about recognizing toxicity of our therapies.

When we're coming up with a measure that's intended to find the toxicity of our therapies, we want to have a sensitive and not specific measure. You want to have a measure that takes in more patients than less. You want to be conservative in that.

So while we don't have data on it, on the face of it, 10.2 to me would seem like a very reasonable number.

DR. VASSALOTTI: And I can tell you from last time when we discussed the corrected formulas, there was questions about the validity of those formulas for correction. There were issues of bromcresol green, of bromcresol purple measurements of serum albumin.

Those are, give you different serum albumin levels, so that your corrected calcium will depend on which technique your lab uses for measuring the serum albumin. So there are a lot of concerns, that the corrected calcium was a very problematic measure to use.

DR. NALLY: So if then we could come full circle and go to the evaluation page under the recommendations. So these were some of the excellent points brought out during the discussion of this measure that was, I think, thoughtfully reviewed.

Now we have a total of six measure, five, four and one against recommendation, just to complete things. Thank you.

CO-CHAIR SCHONDER: Any other discussion? I just want to clarify --

DR. NALLY: Should we consider this with an amendment then?

CO-CHAIR SCHONDER: I was going to ask that. Is there any motion to consider this with an amendment, to look at patients who are on treatments, to make this more of a toxicity measure?

DR. BERNS: And I would add that each of the prior three months, rather than rolling average would be my preference.

CO-CHAIR SCHONDER: So can I have a motion for -- with a specific statement.

DR. BERNS: So I'll make a motion that we consider this with the revisions that it would be each of the three previous months for calcium above 10.2, and the denominator be limited to patients who are on calcium or

Vitamin D products of any sort, calcium-containing Vitamin D products.

DR. KLIGER: Can I just ask the measure developers about the feasibility of those proposed amendments?

DR. WOLFE: The data, if I understand it, that would be feasible. Mr. Chairman, the committee, TEP did have some discussion which may not have made it into the write-up, having to do with the choice of the denominator not being limited to those who are treated, and it had -- they were concerned about, and I may not get the words right, people getting calcium from other sources when they didn't have the ability to pay for the drugs, perhaps by having calcium carbonate.

So we can't get that through the data, and I don't know if that's an important thing or not. But it is a consideration that --

DR. BERNS: But you would know -- wouldn't you know if it was prescribed, oral

calcium or prescribed oral Vitamin D?

PARTICIPANT: What if they're taking a ton of Tums?

DR. MESSANA: Yes. Oral calcium carbonate is not prescription. So you'd have to put a data element in that the physician or facility prescribed an OTC.

DR. PROVENZANO: I think it gets to Peter's overall point, that even without these revisions, this would be viewed as a toxicity measure, and then we would just go through the stratification of what was just discussed. So I think just to keep it clean.

DR. KLIGER: But I'm moved by that. It is indeed true that there are patients who are using products that we know nothing about, and we would miss those toxicities if we included the denominator, as you and I have suggested. So I would suggest that we remove that proposal.

CO-CHAIR SCHONDER: Okay. So we'll remove the calcium.

DR. NALLY: I have a proposal for you.

CO-CHAIR SCHONDER: Okay.

DR. NALLY: Are you willing to retract, Jeffrey?

DR. BERNS: I'll retract and revise. So then the only change --

DR. NALLY: Let the record -- he does retract, and he was a child once.

(Laughter.)

DR. BERNS: Apparently there's some debate about this, but then my only suggested change would be that it should be each of the last three months, rather than a rolling average for calcium above 10.2.

CO-CHAIR SCHONDER: Okay. So we still have the motion to change this to a rolling average? No, no. From rolling average to each month.

DR. NALLY: Can I ask just the measure people, is that much work, or is that an easy thing to do? It's not a problem?

DR. WOLFE: That's not hard to do in terms of implementation.

DR. NALLY: Thank you.

DR. PACE: Are there any other discussion? Is there anyone opposed to that condition, to change --

CO-CHAIR CROOKS: I am, for the same reason as before. I think we're --

DR. PACE: So we first vote then, like we did before, on the condition, the proposal that was put forward. We'll vote on that first, and then we'll -- yes.

MS. PAVLINAC: If I could have an explanation why you think that that is a significant change, just so that I'm clear about it please?

DR. BERNS: Well, I guess what we're trying to do is identify the outlier, and the provider of bad care and the patient at greatest risk. And again, when you look at what happens over trends, you know, a 10.8, a 10.3 and a 9.8, because the doctor did the

right thing, would still be triggered as not complying with this performance measure.

There's so much clinical variability in patients and labs and so forth, that you really want to identify, focus on those who are persistently out of whack.

DR. PACE: So that's -- and the negative side of -- I mean those who advocate for continuing with the rolling average, you want to make a few comments?

CO-CHAIR CROOKS: Well, you're moving away from addressing all the patients, and you've moved from an average to an outlier measure, as you said yourself. Now focusing on outliers rather than on what's normally publicly reported to payers. So I think that's a nice tool. I think when you see those high calciums, you're going to roll into that outlier mode automatically, whether there's a consensus standard or not.

But what we're not -- what we're doing is we're denying the information or

preventing the information that the health care industry can use from getting to them, in my opinion.

DR. JACKSON: Generally, any performance grading is not at 100 percent. It's going to be at a certain population and you can trend. Again, you can trend the rolling average and it's going to identify the patients that you need to focus on, and you can still get a one-month number for somebody that's jumped, you know, gone from 9.8 to 10.3.

You can still jump on that patient and figure out what's going on. So it's, I don't feel strongly one way or the other. But I don't see the need.

DR. PACE: So let's, this time let's vote on importance first, and then we'll, if it passes importance, then we'll vote on the amendment before we vote, okay. So importance to measure and report.

(Committee voting.)

CO-CHAIR CROOKS: We have 16 yes and 4 no.

DR. PACE: All right. So before we proceed, we will vote on the proposal to suggest to the developer to change it from rolling average to each of the three measurements in that period, and those that are in favor of the proposed change, raise your hand?

(Show of hands.)

DR. PACE: Those opposed to the change?

(Show of hands.)

DR. PACE: I think what we'll do then, just as we did for the other one, because that has some implications for the measure construction, and we'll get the developer's response. But let's go to the vote on recommending.

So this vote will be on recommending the measure, with the condition going back to the developer, to change it to each of the

three months, versus the rolling average, and then we'll get their response. Okay. Go ahead and start.

(Committee voting.)

CO-CHAIR CROOKS: We have 18 yes and 2 no.

CO-CHAIR SCHONDER: Okay. So I believe we'll break there as far as the measure evaluations for today. But we do want to take the opportunity to ask for any NQF members or public comment that we may have now at the end of the day.

Public Comment - Afternoon

MS. McGONIGAL: Can you hear me? Okay. I'm Lisa McGonigal again from Kidney Care Partners. Like this morning, we would like to take the opportunity to comment on the measure groups that are going through tomorrow, just because there won't be the chance in the morning.

So first, for the hospitalization measures, KCP supports Measure 1463, which is

the standardized hospitalization ratio for admissions. We support it for public reporting only and not for payment purposes, as hospitalization can occur multiple times for a single patient.

This measure could have a substantially greater impact on a facility score than the standardized mortality ratio measure in dialysis facility compare, after which it was largely modeled.

So because of this, unlike the mortality ratio, the hospitalization ratio should be limited to hospitalizations, for reasons specific to CKD. Specifically, hospitalizations for appropriate DRGs for dialysis access related infections, and for cardiovascular fluid overload admissions.

We don't support Measure 1464, which is the hospitalization ratio for days, for either public reporting or payment, because hospital length of stay is affected by many factors that are entirely outside the

facility's realm of control.

So moving to the vascular access-related infection measures, KCP supports all three of the CDC's National Health Care Safety Network measures. That's measures 1460, 77 and 78. We support them for the purposes of public reporting only, and not for payment purposes at this time.

KCP reviewed all of the infection measures first, with an eye towards identifying the best in class, pursuant to NQF's policies, and then second with an eye towards recommending a parsimonious set, based on objective criteria and not subject to interpretation.

So we believe the CDC measures are superior to similar measures that were submitted for consideration, because the CDC measures have been fully tested.

Moreover, many facilities are already familiar with and are reporting the data related to these measures, and they

receive reports that are useful for their internal quality improvement purposes.

That's it. Thank you for the opportunity to comment.

CO-CHAIR SCHONDER: Thank you. Are there any other public comments?

CO-CHAIR CROOKS: On the phone?

CO-CHAIR SCHONDER: Are there any comments from the phone?

(No response.)

CO-CHAIR SCHONDER: And measure developers can also comment at this point as well.

(No response.)

CO-CHAIR SCHONDER: Hearing none, then I think we'll adjourn for the evening.

For those you that are -- tomorrow, we will meet -- breakfast will be at 8:00 a.m., and then we'll do the welcome. We'll begin our proceedings at 8:30 a.m.

(Off mic comments.)

DR. PACE: I think that's a good

suggestion. Why don't we have you, I mean we'll have you come down here, get your breakfast at eight and we'll start as quickly as possible afterwards.

CO-CHAIR SCHONDER: Okay, okay. Then we'll do that. We'll plan to start at 8:00 a.m. or shortly thereafter, okay. For those of you traveling, have a safe trip tonight.

(Whereupon, at 5:28 p.m., the above-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

was duly recorded and accurately transcribed under my direction; further, that said transcript is a true and accurate record of the proceedings.

Neal R. Gross

Court Reporter