NATIONAL QUALITY FORUM
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END STAGE RENAL DISEASE QUALITY MEASURES
STEERING COMMITTEE
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WEDNESDAY,
JANUARY 12, 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 8:00 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, P.C.

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

STAFF PRESENT:

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, Centers for Medicare & Medicaid Services (by teleconference)
RENEE HENRY, CMS (by teleconference)
LISA McGONIGAL, Kidney Care Partner
JOE MESSANA, Arbor Research Collaborative for Health
ROBYN NISHIMI, MD, Kidney Care Partners
PRITI PATEL, MD, MPH, Centers for Disease Control and Prevention (by teleconference)
DALE SINGER, Renal Physicians Association
ROBERT WOLFE, Arbor Research Collaborative for Health

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

C-O-N-T-E-N-T-S (Cont'd)

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

(8:11 a.m.)

WELCOME, RECAP OF DAY ONE

DR. PACE: Thank you all for getting here bright and early. We have a lot to do. And I'm just going to recap kind of a tally board for you. And then Peter and Kristine will make some comments. And then we're going to decide how to move through our agenda.

So yesterday we reviewed 14 measures. We have 18 to go. So we'll keep moving through these. What I put up here -- and I know that it's a little bit difficult to see, but I'll try to just show you. If you look in the -- should I enlarge this some or let me see. I don't know if it will -- oh, sorry.

So 1418 is -- now my whole thing went kabooey. Fourteen eighteen is -- let me tell you what measure that is. Yes. Okay. And that one was recommended. And if you see

in the right-hand yellow column, that's the vote, the final vote, on the recommendation.

Fourteen twenty-one was also recommended. And, Lauren, would you highlight the cell with this measure name and number? Okay. There. We should see it in this formula bar. Okay. Oh, I see. All right. Method of adequacy measurement. And that one was recommended.

Fourteen twenty-three is -- here. I'll just read them off -- minimum spKv/T for pediatric modal, this patient. That was recommended.

Fourteen twenty-five, measurement of nPCR for pediatric patients was recommended.

Fourteen twenty-six was assessment of iron stores. That one did not pass the importance criteria. That's why I have the "no I." That's my little shorthand there.

Fourteen thirty-one was measurement of iron stores for pediatric

patients. That one did not pass.

And then 1428, use of iron therapy when indicated, that one also was not recommended. It did not pass the importance criteria.

Fourteen thirty-three was use of iron therapy for pediatric patients. And that one was recommended.

Fourteen twenty-nine, avoidance of iron therapy and iron overload. That one was not recommended, did not pass the importance criterion.

Then we go to 1424, monthly hemoglobin measurement for pediatric patients. That one was recommended.

Fourteen thirty is lower limit of hemoglobin for pediatric patients. That one was recommended with conditions. And those conditions were exclude sickle cell anemia patients and the numerator to be the number of patients who were below that level for the three months out of the three-month study

period.

Okay. Fourteen fifty-four was proportion of patients with hypercalcemia. And that one was recommended with condition. And, again, the condition was for that one to change from average to the percentage of patients above the value for the three months, for each of the three months.

Fourteen twenty-seven was adult dialysis patients, serum phosphorous greater than six. That one did not pass the importance criterion, did not recommended.

And the same with 1461, proportion of patients with hypophosphatemia, same thing, did not pass importance. Okay.

CO-CHAIR CROOKS: Okay. So we would just like to provide an opportunity to make some comments on any concerns you have, any concern about inconsistencies or other issues with the metrics from yesterday before we move on to the new work. Anybody have any comments?

DR. VASSALOTTI: In the interest of time, it would be better at the end for this and we've looked at everything or maybe offline in a subsequent phone call. It may be better in the context of looking at all the measures that have been approved to assess what we think.

CO-CHAIR CROOKS: That is fine. I have been notified that Bob Wolfe and his group want to ask us to reconsider the recommended change on the anemia, pediatric anemia, metric. And I think maybe it is best if you address it when you do your --

DR. PACE: When we have a period for the measure developers to --

CO-CHAIR CROOKS: Yes.

DR. PACE: -- make some comments.

CO-CHAIR CROOKS: Let's do that then.

DR. PACE: All right.

CO-CHAIR CROOKS: Okay. Any other comments, something that you must say? Okay.

DR. PACE: Is CMS on the line? Because we will have that time for CMS to -- I know they said that they were going to be able to join us. What we'll do, then -- and I guess we just wanted to check, not so much to rehash things, but if there are any questions that we need to make any clarifications for review of the rest of your measures, we should do that now. And I think that's a fine idea that we can, you know, look at all of the recommendations after they are finished.

Also, in terms of any of the recommendations with conditions, the measure developers have an opportunity to make a response to you one way or the other and provide their rationale. So it's not like this is the final take on that. We'll need to see what their response is. And I think, as pointed out, we have a lot to do.

So have we heard from CDC? Okay. So I think what we'll do --

DR. DUDLEY: Karen?

DR. PACE: Yes?

DR. DUDLEY: It's Tom Dudley. I'm on the line. I just wanted to let you know.

DR. PACE: Okay. Great.

MS. HENRY: Renee Henry here, too.

DR. PACE: Who?

MS. HENRY: Renee Henry from CMS.

DR. PACE: Okay. Great. Okay. So what we're going to do is we are going to finish up. We are going to do fluid management measures that we didn't get to yesterday. And then we will proceed with our agenda for today, which will begin with introductory remarks or brief introductions by the measure developers and stewards and then the measures that we were scheduled to do today.

We may have to do infection before hospitalization depending on CDC's availability on the phone. So we will have a little flexibility there.

But shall we just get into it?

CO-CHAIR CROOKS: Okay. So let's move to the measures for fluid weight management. And we will start with 1432, "Dietary Sodium Reduction Advice." Myra Kleinpeter, primary reviewer, are you ready to take it away?

DR. KLEINPETER: Yes.

CO-CHAIR CROOKS: Do you need a minute to kind of jump?

CONSIDERATION OF CANDIDATE MEASURES

FLUID WEIGHT MANAGEMENT

1432, DIETARY SODIUM REDUCTION ADVICE

DR. KLEINPETER: This measure was the dietary sodium reduction advice. The information that is summarized by the staff indicates that it's a process measure. And the requested measure submission information was complete.

Testing has not been completed yet, but there is no data to support this performance among ESRD patients, but the

general recommendations from both Institute of Medicine Committee, the Salt Committee in terms of looking at overall reduction in cardiovascular disease to the general population. It's assumed that it corresponds to the ESRD population. This information is part of the dietary instructions for patients.

Some of the benefits are improvement in quality. The excessive salt intake stimulates thirst that leads to the fluid excess in patients. And it's almost entirely dependent on the dialysis for providing an important function.

And the restriction of the dietary sodium has been widely recognized in recent times as a big public health priority. And it remains a critical part of the management of hypertension in patients overall on dialysis and not on dialysis.

So in terms of the summary of the information, I had six reviewers, seven now. So one yes, four nos for the second. In terms

of acceptability, it's all over the place. We had two completely, two partially, two minimally; in terms of usability, one completely, two partially, two minimally, and three not at all; feasibility, three completely, two minimally, and one not at all.

And in terms of recommendation of this measure, on this one, there are five nos and one yes. And above, it has I guess one yes and six nos on the more completed one, five and two. Okay.

And that is pretty much all.

DR. PACE: So what were the issues?

DR. KLEINPETER: Some of the big issues were it's part of the regular counseling, but there was no evidence. There's minimal evidence in ESRD population in terms of what this outcome would be. We have inference information that it's a good thing to do for hypertension management, but we have no hard data to show where the

morbidity/mortality reduction is.

They cite on page 4 of the summary some studies from 2003-2009 from Tassin, France showing diligent use of dietary restriction does decrease the amount of fluid gained between sessions, but there is no other long-term outcome data. And that is the big problem that the reviewers had in terms of making this recommendation overall.

Any other discussion from other reviewers?

DR. KLIGER: Yes. Myra, maybe I could add over here. I think there are two ways to look at this. First of all, if you look at the science, the science doesn't have the adequate links. That is, there is no data on performance gap. There is insufficient data linking dietary advice given by the dietician to actual sodium intake and its consequences or volume and its consequences. That link is missing.

And so there is a problem with

this, but I would look at this the other way. And, actually, Karen had suggested this in here notes. And I think it's very wise for us to consider this, that this is a measure that perhaps is best assessed, dietary advice is best assessed, perhaps by patients and not by professionals. And a measure that is designed around patients' hearing and understanding of advice is something that would make more sense to me than this measure as it's currently presented.

CO-CHAIR CROOKS: Jessie?

MS. PAVLINAC: I agree with all of that. The other issue I thought was problematic was within 90 days, which says to me that every patient within whatever this 90-day period was going to have that specific advice, which made no sense from a practical standpoint.

CO-CHAIR CROOKS: Okay. Other comments by those who reviewed it?

MS. WAGER: Yes. I was one of the

reviewers. And being a patient, I am for it. The reason is patients -- when I started on dialysis, there was, of course, a fluid problem. I learned early on that there was a link between my salt intake and my fluid intake. And that also dictated how well I dialyzed.

A lot of the patients today that are starting on dialysis have no idea about that link. And, as Dr. Kliger and the physicians say, there is really no scientific, but as a patient, I can tell you I have been there and it does make a difference. The patients that do not -- that come in fluid-overloaded are branded as non-compliant.

We worry about phosphorous. We worry about anemia. But we do not emphasize the fluid management. I talked to -- I visit 28 clients in the San Antonio and the valley region. I met with 14 dieticians about this. Hardly any of them talk about or document salt restriction or salt intake. What they do if

someone is overloaded is they give them a sodium sheet that tells them what foods to watch out for. They don't sit down and talk to them and try to explain to them the relationship between the salt and the food then.

So, although this measure may not be written quite right, I think it's something that we really should consider for the patient.

Thank you.

CO-CHAIR CROOKS: Thank you.

Alan?

DR. KLIGER: I think Bobbi is exactly right. And I think that a measure that has the ability to measure what dieticians say to patients and patients' assessment of that advice is the measure that I would love to see.

CO-CHAIR CROOKS: Myra or Joe?

DR. VASSALOTTI: Do you want to propose how that would be constructed?

DR. KLIGER: I think that that has to go to the measure developer. I mean, it's not this measure.

DR. KLEINPETER: So I was one of the ones that voted yes for it. I am in an area where the average New Orleanian salt intake is 10 to 15 grams of salt a day. And it's not unheard of that I see people coming in with eight to ten kilos of fluid between a two-day session.

We make the recommendation, but we need to figure out a better measure to actually capture the data. I recommend that yes, we have to start with something. There is nothing now. And perhaps over time develop something that is a little bit more precise to measure what we are trying to get at in terms of acceptance of the advice given by the dieticians.

MS. ANDERSON: I was also one of the reviewers. And I agree. Actually, what Myra said is exactly what I was going to say.

I think we need a better measure with more specific standards that are more objectively being able to be measured. I think it is a critical measure that we should look at, but this isn't the right language. It's too vague and I think needs to go back to the developers for better language.

CO-CHAIR CROOKS: For those of us who haven't studied it, how is the numerator collected? Is it just a check box on some CROWNWeb screen or something that it was done? How is the documentation requirement here?

DR. KLEINPETER: So in terms of the calculator algorithm, it is basically at the 90-day period of the reporting month, it's all patients that are admitted to that facility over that 90-day period who receive dialysis through that 90-day period. And it's basically they have no exclusions and everyone who is there in that 90-day period is part of the numerator from the way I see it. And the reliability and validity testing has not been

completed as of yet.

CO-CHAIR CROOKS: But the date that a patient has received instruction is just a check, check it off?

DR. KLEINPETER: It is patient education or sodium restriction from CROWNWeb data --

CO-CHAIR CROOKS: From CROWNWeb.

DR. KLEINPETER: -- is all they say. It doesn't specific how it's -- what that means.

CO-CHAIR CROOKS: Thank you.

DR. FIVUSH: Is that in CROWNWeb? Is that collected in CROWNWeb? So is it a data element that gets back to -- is it just a check box that says, "Diet" --

DR. MESSANA: It is a data element.

DR. FIVUSH: That just says --

DR. MESSANA: I don't know the form, but it is a data element that says, "Patient received dietary sodium education."

DR. FIVUSH: Right.

DR. PACE: Lauren has put the specifications. So it says basically there's going to be a data element recording the date of the most recent patient education on sodium restriction.

And then there is some comment about formal documentation of dietary advice counseling should be signed by the registered dietician at the facility, but it's unclear how that relates to the data element. It seems like the data element is going to be just the date.

And, Helen, you want to make a --

DR. BURSTIN: I want to make a comment as a matter of policy over the last year or so. We have for the most part rejected all measures as a matter of course that reflect what a provider says about what a patient learned, that the appropriate approach is you go to the patient to find out "Did you get that counseling?" because

otherwise it does just become a check box.

CO-CHAIR CROOKS: I would like to just comment that just the fact that this is on there is something. You know, they are going to be asking for that. And that is going to influence behavior to some extent probably as much as if we had this metric pass, which we see, you know, has these flaws.

So other comments before we get to voting? Bob?

DR. WOLFE: Thank you.

The measure was not intended to be a measure of the information that the patient received. The measure was a process measure of whether advice was given.

CO-CHAIR CROOKS: And that is good, but, you know, one could question whether that needs to be a national voluntary consensus standard. So okay.

Other comments?

MS. RICHIE: Just a reminder that this says, "Eligible for time-limited." In

fact, all of the fluid weight measures are time-limited.

CO-CHAIR CROOKS: Only time-limited? Because they haven't been tested. Okay. So this is eligible only for time-limited endorsement. Okay.

So I think we are ready to vote. Do we have, everybody have, your voting tablet?

DR. PACE: So we will start with is this measure important to measure and report?

(Pause.)

CO-CHAIR SCHONDER: We have 5 yeses and 15 nos. So it doesn't pass the importance criteria.

CO-CHAIR CROOKS: Okay. Very good. We will move to the next one. Next in line --

CO-CHAIR SCHONDER: Fourteen thirty-four.

CO-CHAIR CROOKS: -- 1434, "Sodium

Profiling Practice" and "Hemodialysis. Connie Anderson was asked to review.

1434, SODIUM PROFILING PRACTICE FOR HEMODIALYSIS

MS. ANDERSON: This measure is the proportion of patients who were not prescribed sodium profiling in a reporting month. This is a process measure. This measure has not been tested.

The numerator is the number of patients in the denominator who were not prescribed sodium profiling in a reporting month. And the denominator is the number of patients in an outpatient dialysis facility undergoing chronic maintenance hemodialysis.

There has been no reliability or validity testing. There are no exclusions. The measure, there is no gap analysis or performance. And the measure, there has been no testing of the measure.

In looking at the importance, there were two yeses and three nos. In terms

of -- and I'm having to read it from up there.

DR. PACE: Okay. In terms of importance, there were two that said yes and three no. And then for scientific acceptability, spread out, one completely, two partially, two minimally, one not at all; and then usability, one completely, three minimally, two not at all; and usability -- oh, that was -- feasibility, one completely, two partially, three minimally; and then for recommendation, one yes and five no.

MS. ANDERSON: And I think some of the comments were it's uncertain of its widespread use, uncertain that the public can use the information or even if the information is reliable.

Sodium restriction is an important but limited data on the use of sodium modeling, whether or not this was even an issue. Also consider hypertonic saline at facilities. And it is susceptible to unintended consequences; for example,

increased intradialytic hypotension, in a subpopulation of the susceptible patients, but it's not been tested.

CO-CHAIR CROOKS: Okay. Comments from other reviewers? Yes?

DR. FIVUSH: Jerry just pointed out to me that although it's in the specifications, this is intended for adults or patients over 18. It's not clear in the measure in either the numerator or the denominator. So I --

DR. JACKSON: It says "Target population 18 and over."

DR. FIVUSH: Right.

DR. JACKSON: But in the "Exclusion" section, it says, "None."

CO-CHAIR CROOKS: That is not really an exclusion if it's defined in the --

DR. FIVUSH: But usually the measures are defined in either the numerator, number of patients over the age of 18. So just that, in and of itself --

DR. PACE: That is something that we could ask them to do.

DR. FIVUSH: Right.

DR. PACE: That is a minor thing. I mean, I think that's -- yes.

DR. FIVUSH: I would just say as we go forward, that it's clear that nobody think that they should be included because it's not clearly stated in the numerator or denominator.

CO-CHAIR CROOKS: Is there an assumption, then, by those submitting this that sodium profiling is a good thing and that everybody should be on it? I'm not clear what the intent is.

DR. KLIGER: No. The intent is the opposite. There is conjecture and reasonably good hypothesis suggesting that sodium modeling results in increased sodium delivery and, therefore, increased volume -- and we will talk about this with the next measure as well -- consequences of excess

sodium transfer into patients.

I was one of the reviewers as well. The hypothesis is a very strong one. And I, for one, would love to see more evidence examining this hypothesis, but it's not ready for prime time as a measure as yet. There are no sufficient data that would support that hypothesis.

CO-CHAIR CROOKS: The hypothesis that this is not good for anyone, is that --

DR. KLIGER: The hypothesis that sodium modeling ends up causing excessive sodium transfer to patients and the bad consequences of that.

CO-CHAIR CROOKS: Okay. Other comments?

(No response.)

CO-CHAIR CROOKS: Are we ready to vote? Okay. Let's do it.

DR. PACE: All right. Fourteen thirty-four, importance to measure and report.

(Pause.)

CO-CHAIR SCHONDER: So we have So we have 4 yeses and 16 nos. And it does not meet the importance criteria.

CO-CHAIR CROOKS: Okay. Let's move on to 1435, "Restriction of Dialysate Sodium." Alan? 1435, RESTRICTION OF DIALYSATE SODIUM

DR. KLIGER: Okay. Well, this is the measure, as described, which is intended to measure the proportion of patients who are prescribed a dialysate sodium concentration of less than 138 milliequivalents per liter for all sessions in the reporting month.

The definition with a numerator being the number of patients who were prescribed a dialysate sodium of less than or equal to 138 and the denominator is all patients -- and I don't remember. It doesn't say adult or not, but it says, "all patients in any session month that is being reported."

The overall intent here again is the hypothesis that when the sodium

concentration is greater than some number -- and they have picked in this proposed measure 138 -- that there will be excessive sodium transfer into patients and negative consequences of that, again I think a very attractive hypothesis and one that many clinicians are using and thinking about now. But, unfortunately, the data for the utility of that hypothesis is not present.

Developers themselves say that there have been no formal studies on the dialysate sodium concentrations of facilities in the United States and that disparities for sodium by population group have not been reported in the literature.

The measure is really based on the 2006 publication of DOPPS that does show some correlation. I'm sorry. I apologize. That's the next measure.

I would like to again quote Karen. Karen Pace, for those of you who haven't paid attention to it, did a spectacular job, I

think -- and I just want to publicly acknowledge that -- in helping us reviewers point out what some of the potential weaknesses and issues were in the measures. And Karen really nailed this one because -- let me just quote, if I may, some of the concerns that she had about this review.

Karen, I don't mean to put you on the spot that way, but Karen points out that there was no data on the performance gap in this one, that the developers' summary of the evidence did not identify a specific value associated with outcomes; in other words, why 138. There is evidence that the high sodiums are a problem; lower are not, but no evidence in the literature at all about what is high and what is low and why that particular cutoff.

Testing has not been conducted. And so that was the overall sense of this. And, Karen, could I ask you to run through the voting on this one? My old eyes don't get up

there.

DR. PACE: On this one, importance to measure and report, two said yes and four said no; on scientific acceptability, one partially, three minimally, two not at all; on usability, three minimally, three not at all; on feasibility, one completely, three partially, two minimally; and on the recommendation, one yes, five no.

DR. KLIGER: Do any of the other primary reviewers want to add anything to that?

(No response.)

DR. KLIGER: I guess my take-away after reading the reports is that I think this is, you know, a really attractive possibility and, again, an hypothesis very worthy of appropriate study. And it wouldn't surprise me one tad if this ends up being important and at the next round turns out to be one we should look at carefully, but I think it's premature.

CO-CHAIR CROOKS: Okay. Any other comments before we vote?

(No response.)

CO-CHAIR CROOKS: Good. Let's get to it.

DR. PACE: Fourteen thirty-five, importance to measure and report?

(Pause.)

CO-CHAIR SCHONDER: We have 2 yeses and 18 nos, again does not meet the importance criteria.

DR. FIVUSH: Can I ask one question? I am trying to look through the specifications about the age, the intent of the target population here. And I'm not sure. I just couldn't go through it quickly enough during the conversation.

DR. PACE: Okay.

DR. FIVUSH: But when we get back to the measure developers with these, I think the issue of the way salt is handled in small children is distinctly different than in

adults and we do use different dialysis bath. And we do because of blood pressure issues use different -- we may have to use sodium profiling. And I think in growing children and many of our patients actually lose salt in their urine.

My point is only I would like to get back to them and state if they haven't excluded pediatric, that would be an important --

DR. PACE: This one also says the target population --

DR. FIVUSH: Right.

DR. PACE: -- is 18 and older. So that is the group. But we can certainly ask them to put that --

DR. FIVUSH: To put that in the --

DR. PACE: -- also in the denominator statement, yes.

DR. MESSANA: We will definitely reconfirm this with the CTEP, but my recollection from being there for much of the

deliberations and follow-up was that they were looking specifically at adults 18 and above with all of the measures in this fluid group.

CO-CHAIR CROOKS: Okay. Shall we move on, Karen? Okay.

The next metric is 1437, "Utilization of Dialysis Duration of Four Hours or Longer for Patients New to Dialysis." Bobbi?

1437, UTILIZATION OF DIALYSIS DURATION OF FOUR HOURS OR LONGER FOR PATIENTS NEW TO DIALYSIS

MS. WAGER: Okay. As you read, the description of the measure, the proportion of patients new to dialysis, the prescribed dialysis session length is at least 240 minutes.

Type of measure is a process. Testing/no testing has been done, but testing should be completed within 12 months. No data on performance gap was provided. The summary of the evidence does not provide the steady

results that suggest that longer treatment time is associated with improved outcomes.

The title indicates patients new to dialysis, but the denominator seems to include all patients undergoing chronic maintenance hemodialysis.

As you can see from the top, I have importance to measure. Out of the committee, there were three yes and three nos. So there was a split.

Scientific acceptability. Let me see if I can -- two complete?

DR. PACE: Two completely, two partially, and two minimally.

MS. WAGER: So we are all over the place with that. Usability?

DR. PACE: Was two completely, two minimally, two not at all.

MS. WAGER: And feasibility?

DR. PACE: Four completely, two partially. Okay. And then the recommendation was two yes, four no of the initial reviewers.

MS. WAGER: Okay. Some of the comments the reviewers had were shorter dialysis times have been associated with poor outcomes, increased dialysis times have been associated with improved outcomes, dependence of dose is measured by Kt/V, time on dialysis very important, more data needed on frequency versus time.

By the time, the denominator described is wrong. The denominator described all dialysis patients and not just the new dialysis patients.

While it is clear that several outcomes are better, when more dialysis is compared with less treatment and also there is a wide variation in dialysis prescription across dialysis facilities, the specific link to longer dialysis sessions prescribed three times a week has less support.

More frequent hemodialysis treatments may improve some outcomes. More removal of solute measured by Kt/V may improve

some outcomes, and longer dialysis may improve some outcomes.

There is little convincing evidence that a cutoff of four hours of treatment provides better outcomes and particularly little evidence in subsets of patients, small patients, large patients, who may have different metabolic requirements for dialysis.

And the last comment, "Numerator of measure is unclear. Incident patients only or prevalent patients?"

CO-CHAIR CROOKS: Thank you. That is excellent.

Other reviewers want to comment? I think she said it all. Please go ahead.

MS. WAGER: I would like to give my comment again as why I voted yes. This may not be again a written measure, written well. I remember when I dialyzed 28 years ago, we all dialyzed the same amount of time, 4 to 5 hours. At the time there was no three and a

half. I felt better. I did better.

We all know maybe conception in regards to scientific, maybe, you know, things haven't been proven, but I can tell you conceptually in the way I feel and other patients feel, there is a big difference.

I am tired of seeing patients only lasting three to five years on dialysis. I want patients to live longer. And I think living longer, better quality of life, better outcomes has to do with longer dialysis. Whether it's frequent dialysis four or five times, six times a week, I just think we're under-dialyzing the patients.

Thank you.

CO-CHAIR CROOKS: Thanks.

Alan?

DR. KLIGER: Bobbi, I think you are exactly right. My prejudice is that we're under-dialyzing patients. My concern about this particular measure is that I don't think it captures what you're looking for, which is

clear evidence that more dialysis is doing more.

You all know the FHM study that we just looked at recently in which we really did show nicely for the first time that more frequent treatments, which did indeed include increasing urea clearance, increasing volume removal and a whole variety of other things, and some increase in time, although each session was shorter, resulted in clear evidence of improvement.

This measure really concentrates on time for standard three times a week dialysis. And I am afraid we don't have clear evidence that increasing the time in that limited three times a week is linked to the better outcomes that you are looking for.

MS. LeBEAU: I'm sorry. I would just like to offer a couple of things. I was not one of the primary reviewers but some conversation. Sometimes important things are talked about outside of this room. And last

night we talked a little bit about this is an evolutionary process without a revolution. We have steps.

I actually think the better way for this measure to be written is not so much for new patients but for all patients. And I think the other piece that is really important -- and this is from a lay person -- is sometimes -- and I wasn't the only one who said this -- I wasn't the first person who said this last night -- we sacrifice good on the altar of perfect. So I think it's very important to think about the steps we need to move towards for improving patient mortality.

CO-CHAIR CROOKS: Fortunately, this is much like the hemo studies. The thesis behind the hemo study was to increase time on a three times a week in center typical therapy and compare shorter versus longer times. And there was no difference in mortality.

So that's what's even a bit

surprising about this to me it says here is an hypothesis that we can prove things by supporting more time per session, but a major NIH-funded study showed that is not the case.

Does anybody disagree with that or --

DR. KLIGER: They didn't look at more than four hours. So I would be careful about making that inference.

CO-CHAIR CROOKS: Okay.

DR. KLIGER: But there isn't good evidence that three times a week.

CO-CHAIR CROOKS: Right.

DR. PACE: The issue here is people getting less than four hours, right, I mean, that this measure is trying to address, that people are getting even less than four hours?

DR. KLIGER: Yes.

DR. PACE: Is there evidence that people should be getting at least four hours?

DR. KLIGER: No.

DR. PACE: But is there evidence that more is better?

DR. KLIGER: It depends on how you define more. Again, we just published some data for randomized controlled trial looking at more as more frequent and clearly showed that that was better. More as in adding four or more hours to the standard three times a week treatment has not been shown to be effective.

DR. LATTS: So how did four hours become the standard?

DR. KLIGER: That is what the proposers of this measure are proposing. There is nothing in the literature to support that.

DR. PROVENZANO: Let me just complicate it a little more since you're needing an exact number. There is now more data coming out of nocturnal dialysis, which is generally in center three times a week six to eight hours and showing improved outcomes.

But the difference between four hours and eight hours stratified, nobody knows where that benefit comes.

The data is very, very weak, as Alan pointed out. Four hours is good. The data is getting much better, that eight hours is better. But to pick a number in there right now I think doesn't help anybody.

DR. PACE: But is there a number that is bad? I mean, so, you know, like with -- I'm just asking if there's anything comparable to, for example, the hemoglobin, that maybe we don't know the right range or the upper limit, but there seems to be consensus around the less than ten. So is there a less than something hours that is supported?

DR. KLIGER: Not for time. There are data looking at other measures of adequacy that do suggest some minimums but not for time.

Now, again, having said that, if

you ask the clinicians around the room, we all do believe that one hour of treatment is not adequate and two hours is not adequate and that four or more hours probably is.

There are many patients between three and four now and little to support that moving above three to five is going to make a difference.

DR. JACKSON: I want to ask the group about the DOPPS data that was presented a couple of months ago. And from multiple countries, they showed a correlation between longer dialysis and survival. In Australia, the standard time is four and a half hours. And that was presented there. But what is the feeling about the validity, if you will, of that data and the power of their studies?

DR. KLIGER: Again, DOPPS is a wonderful retrospective review. And the correlations are not just to time, but there are many other correlations as well to better outcomes.

So there again I think that that is an important observation. I think that it is an important hypothesis-generating observation that we need to look at more critically.

Here is where Peter's comment before I think is appropriate. You similarly had multiple observational studies done back in the late 1990s talking about adequacy of dialysis that spawned the prospective randomized trial that was hemo, suggesting that in three-hour sessions, more treatment is better with a measure being Kt/V, rather than time. And that prospective randomized trial failed to show that there was indeed that effect.

So I think that the DOPPS are very important observational data that needs to generate appropriate hypotheses. Indeed, it's just those that spawned our FHM study. That's where that came from. So I think it's important to look at that.

DR. NALLY: I want to point out, too -- oh, I'm sorry.

DR. LATTS: Go ahead.

CO-CHAIR CROOKS: Well, at least I called your --

DR. LATTS: So here is what I am struggling with, and this is what I struggled with yesterday, is that if we only have performance measures where we have prospective randomized trials and there is unequivocal evidence that this is 100 percent the right thing to do, we're going to have 40 performance measures across all of medicine, most in cardiovascular medicine.

It's just not -- you know, for us as patients, for us as payers, for the employers that aren't here in the room today, they're going to demand more. Frankly, they're demanding more. And they're demanding more of us as payers. They're demanding more of the NQF. And Helen can speak to this or Karen. And it's not going to be acceptable to

only have performance measures where the science is 100 percent unequivocal.

I'll tell you when I was on dialysis, if I, you know, God forbid, had to leave a few minutes early because I had to catch a plane, I had to sign an against medical advice waiver if I dialyzed less than four hours. So it really puzzles me.

You know, again, I don't care. If four hours is controversial, let's say three and a half hours. If three and a half hours is controversial, pick a number. Let's say three hours. Let's pick a number that is something that is so like we did with hemoglobin, so noncontroversial that it gives us a starting place. But we've got to start somewhere.

And we can't wait for those trials to be done. I'm telling you this is the purchaser perspective, and this is what we're hearing from our employers. We can't wait. And we're pressuring NQF to get us more

measures faster.

DR. NALLY: My concern with that is that if you use general broad-stroke concepts, rather than science, and you go back a decade ago or more, when it was thought that taking a hemoglobin to normal would be a good thing, you did not help. And you clearly resulted in harm, strokes and death, to patients.

So if you're going to have a process -- and this was the reason for my questions right out of the chute -- what are the criteria for a performance measure?

It's different than offering a broad-stroke clinical guideline of a should. A CPM is going to be a recommend and a must. And there has to be a science behind that process or the debacle of the high hemoglobin thing will be revisited.

And there are morbidity/mortality implications. There are payer implications. There are lots of implications of giving the

imprimatur of an NQF-endorsed measure that we have to consider.

And that's why criteria of that measure need to be adhered to strictly, rather than if I were the doctor, I would probably do this at the chair-side. That's a big different question than an NQF endorsement. That's one man's opinion.

CO-CHAIR CROOKS: Alan?

DR. KLIGER: Lisa, I think you are right that we can't wait for the 100 percent certainty, absolutely right about that. That is not what I am arguing for, what I hear others arguing for.

We do have a measure that is out there and is now active in terms of adequacy of dialysis. It is based on urea modeling, rather than time. So we have a clear measure that says there is a minimum.

I do think time may in the long term prove to be as effective and maybe even more than urea modeling. We just don't have

the evidence that that is the case right now.

So I think it is correct that we shouldn't be looking for 100 percent for something, but we do need the sufficient evidence. And in the one prospective randomized trial that was done looking at time for three-hour standard three times a week treatments that Peter referenced before. It turned out that increased time did not improve outcomes.

CO-CHAIR CROOKS: I would just point out for Lisa, too, that there is a minimum standard here in Kt/V or urea kinetics from the last batch. Two four seven is that patients have that measurement done. Then 248, delivered dose, that is measured. I don't know.

DR. LATTS: Yes.

CO-CHAIR CROOKS: Yes. Here's a 249, that the minimum single pool Kt/V is greater than or equal to 1.2. So there is an NQF standard for a minimum.

And I also wanted to make the comment, when it comes to information about improving dialysis, we have information how to improve dialysis. And Alan was a PI of a two-arm study that has shown the way. And the answer is not extending time, at least just the four hours on a three-times-a-week basis. It's more frequency and more time.

There are two models of care that they use in that study. That shows the way. That improves outcomes. So I would argue that there is science and that NQF, if anything, should be figuring out metrics to looking for metrics to push the industry in the right direction.

I think there is a great danger of approving this. Industry is going to say, "Well, NQF said four hours three times a week is enough. And that is the way to go." And it takes us away from creating new solutions. The new solutions have to be individualized dialysis prescription for each patient.

If more frequent is better, what fits your lifestyle? What fits your work? What fits your social situation? How many times a week do you want to do it? And how can the dialysis industry providers accommodate you?

That is where I think things need to move, not to say four times a week, four hours per treatment is the right thing, NQF stamp of approval.

DR. NALLY: And, just to expand, Lisa, not only is the issue of giving adequate dialysis important. As we are facing all the bundling aspects now, there is a quality improvement project that only involves three things, one of which is a marker of the adequacy of dialysis.

So nobody debates the issue that it is an important thing, but there is a standard out there. And time hasn't met that level of evidence. So we are sticking with the existing standard.

DR. VASSALOTTI: Yes. I just wanted to add that I think fluid and weight management in the dialysis community is a really important problem. And I'm not sure this measure is the way to do it.

You know, I can certainly think of a fatigued patient where four hours might be more than adequate possibly clinically. I could certainly think of a person, maybe like me or maybe 100 kilos or something, who, you know, might -- four hours wouldn't even be close to being adequate for that. So it's really about individualized care.

So I would say, instead of let's just pick a measure because we want to measure, let's think about all these measures in total when we're done. They're all time-limited.

To me it sounds like the TEP really was kind of just casting, you know, doing --

DR. MESSANA: No.

DR. VASSALOTTI: What?

DR. MESSANA: I just --

DR. VASSALOTTI: Okay.

DR. MESSANA: If you are asking a question of us --

DR. VASSALOTTI: No, I'm not asking a question.

DR. MESSANA: -- that is not the case.

DR. VASSALOTTI: I'm sorry. I didn't --

DR. MESSANA: That is not the case.

DR. VASSALOTTI: Thank you. I am sorry.

DR. MESSANA: Okay.

DR. VASSALOTTI: I'm sorry. I apologize for saying that.

And then I think we should --

DR. MESSANA: I could give the rationale if you would like to hear it.

DR. VASSALOTTI: We could come

back to the TEP and ask what or perhaps suggest, ask of the TEP which is the measure they think is the best or try to address this in some way if that's what we really wanted, was to have a fluid and a weight management.

I guess now that I spoke, I will ask you to provide a rationale.

DR. MESSANA: Okay. So the clinical TEP was charged with trying to develop measures or recommend measures in an area that was of great importance. Okay? I don't think anybody around this table would debate the rates of congestive heart failure in the ESRD populations, the rates of hospitalization for said consequences, the cardiovascular mortalities, which the leading members of the TEP, which included the chief medical officers of the two large dialysis organizations, and a number of other esteemed senior nephrologists, many of whom were participants in the Boston conference last year, which highlighted the issue of

congestive heart failure in cardiomyopathy, felt very strongly that there is data that may not be represented in each of these measures.

But if you look in toto at all of the references, there is data about hibernating myocardium with rapid ultrafiltration rates and the issue of time as a potential major effector of total body salt and water. Okay? And they felt there was a starting point that needed to be made. They carefully deliberated the available evidence. And it's all level 2.

But I don't think anybody debates the issue of inadequate volume control in the dialysis population.

DR. VASSALOTTI: Yes.

DR. MESSANA: And you all are talking about Kt/V and adequacy of small solute clearance excluding adequacy of sodium clearance. And that's where the TEP was going with this. They were not focusing on --

DR. KLIGER: I take exception to

that. That's not --

DR. VASSALOTTI: The TEP's intent with this measure --

DR. KLIGER: I'm talking to that. Don't characterize what I am saying, please.

DR. MESSANA: Then I am mistaken, Alan.

DR. WOLFE: The TEP's intention with this measure had to do with volume control and getting adequate experience with the patient so that care could be individualized.

And the TEP's recommendation was that the initial period of identifying the appropriate volume for the patient was a crucial part of developing an appropriate care plan for each patient. They were oriented towards individualized care. And they recommend that the best way to do that is to assure that you have adequate dialysis at the beginning so you can find out what the appropriate fluid level management is.

I again apologize. And I will say something that some people laughed at yesterday. I'm a statistician. I don't know all of the arguments and all of the understanding of the model, but I can at least understand what they were talking about. It certainly sounded important.

DR. VASSALOTTI: I just want to say obviously this is a very important issue. And we're very devoted to doing the best we can for the patient. And I'm not implying that fluid and weight management is not important. The issue is, is this going to be a measure that is going to be impactful for the patients and serve the patients best?

DR. KLIGER: I just need to say something, if I may, because I don't think we should be characterized as only looking at urea or Kt/V and that we're not interested in volume because it is quite the opposite.

I think that it is clear the more we understand about adequacy, that adequacy

has to do with time. It has to do with volume control. It has to do with what happens to the left ventricle. It has to do with urea movement. It has to do with large molecule movement. We're understanding a whole lot more about what's defining adequacy.

My comments and some that I have heard around the table are focused on the appropriateness of this particular measure and this particular time requirement, for which there is no convincing evidence. And I do think we need to continue to be paying more attention to volume and to time and to the other measures other than Kt/V.

I'm just saying once again sometimes it's prime time for measures. And sometimes more data has to stand underneath that before you can know what that means.

I'm reminded again of the hemo study, I think a very important lesson for all of us.

DR. MESSANA: Thank you, Alan. I

apologize if I misconstrued your earlier comments.

DR. NALLY: So how might we move this forward? I think in our hearts of hearts, we all tend to think the same thing. We may have some disagreements, you know, Alan and I with the science and of a given issue, but then how in Joe's and Bob's, how do we move the field forward as an NQF committee?

So I don't see that we're charged to solve the world's problems. I mean, if we ran the NIH or whatever, you know, we might have an RFA for this. But I'm not sure how we're going to extricate ourselves from this box. And that's the question.

CO-CHAIR CROOKS: Well, our job, first of all, is to deal with the measures that are presented to us. And we're not writing measures. But we do have the opportunity later today -- and we want to do this today while we are all together -- to do some brainstorming about where metric

development needs to go, where evidence might be useful to help develop better standards and to list out areas of care that are not addressed by the current NQF standards. So that's the way we can impact that. We're not the NIH.

DR. MESSANA: This is a technical comment. In the initial presentation, I believe that it was stated that there had not been testing of this. These data about duration of dialysis are currently collected in CROWNWeb and had been evaluated. And I think they are in the measures evaluation form under 2.b.c, I think, or 2.b.2 and 2.b.3.

So, as you consider them, if you get to the point of feasibility, these data have been collected.

CO-CHAIR CROOKS: Okay. Lisa?

DR. LATTS: You know, I look forward to the discussion later today. And I very much hope we can get to it because I think that it is critically important that we

have some recommendations for the measure developers on where there is an opportunity to improve some of the global assessment of dialysis care.

I think we are all quite acutely aware of the issues around mortality and morbidity among end-stage renal disease patients and how we compare to some other nations of the world.

I think that there is very good -- you know, again, I don't know the dialysis data very well, but, you know, there is certainly very good data within medicine about the importance of under-used measures. And this is an under-used measure. This is measuring whether dialysis is being under-used.

We might not know what the right number is. And, again, I don't particularly -- I am fine with starting somewhere. Maybe three hours is the right. And maybe this whole measure is bad and maybe there is good

data. But I have been fairly -- without having in-depth reading the data, I have been fairly convinced that we need to on average dialyze our patients more than they are getting dialyzed currently.

And I think that there are probably some financial incentives that are leading us to under-dialyze our patients, which is, again, the elephant in the room. But a lot of what we do in medicine is based on financial incentives. So I think that is why under-used measures are so critically important to counteract some of those financial incentives.

DR. PROVENZANO: Lisa, I think we need to be very careful not to go down that path. This is a very sophisticated industry. It is reported on a monthly basis, our measures of dialysis. Every dialysis unit must report them.

So to comment that people are under-dialyzed I just think is incorrect,

absolutely no doubt that there are broader understandings of issues, such as hospitalization for volume management.

And there is no doubt that many of the things that we have been touching on get to that, you know, sodium restriction, time on dialysis for ultrafiltration, educational aspects, et cetera.

But to say that we doctors consider financial issues and that we're under-dialyzing patients I just think is really not true and offensive.

MS. WAGER: I would like to comment. As a nurse, I truly understand evidence-based and how we practice. But as a patient, I am very frustrated because there isn't a measure in regards to a time.

I lost my train of thought when we were talking about the -- lost. I don't think that there is -- maybe there isn't financial incentive, but there is something wrong if our morbidity and mortality rate is as high as it

is for patients, where a patient with diabetes, the average time of life on dialysis is three to five years. To me, that is uncalled for in 2011 as a patient.

How do I educate the patients when they ask "If I choose hemodialysis, how long will I live?"

"Let me tell you you are a diabetic. Maybe three to five years."

No one 28 years ago could tell me how long I would live as a dialysis patient or how long I would live as a transplant patient. Okay? I worked with my physician and learned as much as I could, became a nurse, maybe didn't have to do it but got educated. And I am here 28, 29 years later. But I think a lot of that is maybe an exception because a lot of my friends are dying around me. So we are not doing something right.

Thank you.

MS. LeBEAU: I would just like to piggyback on that a little bit. I do

understand the inadequacies of scientific evidence that we are looking at here and that we don't fully understand this, but intuitively it seems to me that when you are talking about what is a continuous body function, replacing it with intermittent treatment 12 hours a week compared to 24/7 is not the same thing.

I don't think it's a coincidence that home patients who tend to have access to in every way we define more frequent, longer dialysis tend to do better, anecdotally speaking. So I am frustrated as well.

And while, you know, we look at some of the reasons why that is such an entrenched 12 hours a week 3 times a week, Monday, Wednesday, Friday, Tuesday, Thursday, Saturday person, why that is, it's largely because that is what we have done and because that works in scheduling. And it is often very hard to tell patients it is a better thing to sit in the chair longer. It really

is. And I am the first one to say that is true. It is tough to tell people that.

DR. FIVUSH: Yes. I think there is a tension in the room that I think clearly everybody in this room is invested in providing the absolute best outcomes for patients an I think in every corner of this room, not just at the table. I think we are all here for the same purpose.

And in listening to this conversation -- and, again, I am a pediatric nephrologist. And mostly my dialysis does pertain to the smaller patients. We certainly dialyze patients over 18.

I think the concern -- understanding we all want to get to the same place, which is better outcomes, if we look at this and we say every new patient, for example, has to have 4 hours, I can tell you I have 18 patients that have cardiomyopathies that simply will not tolerate that.

So the question is, is this the

right measure to get to the outcome you want, not is it do we want to get to that outcome? An I'm concerned because I can actually see times when this would not serve my patients.

And I think that we all agree that there is a minimum adequacy and there probably needs to be an optimal adequacy. We don't know what that is. But a measure that just increases length for new patients really may have -- if you are talking about unintended consequence for patients simply that that is not the right thing for them, maybe they need to have more frequent dialysis, instead of longer dialysis. And I just hope this isn't the kind of measure that might box people in the corner and end up being more problematic but clearly hearing it's the intent that we all want to do the same thing and the frustration that we're not as far along as we should be. And I'm understanding that the measure group that looked at this was clearly trying to identify measures that were

actionable. I think we have to put more thought into this.

CO-CHAIR CROOKS: We have Jerry next.

DR. JACKSON: I am really conflicted over this measure. I would like to say that I have recently issued standing orders in both of my clinics that every new patient start at four hours if they have a graft or fistula and four and a half hours if they have a catheter, in part because I want to try to incentivize patients to get their catheters out sooner.

(Laughter.)

DR. JACKSON: But I believe in the concepts behind this. And I think maybe one distinction that we haven't brought out clearly enough is this measure is intended for the incident patient. And we have been for a number of years working on an internal QF project to try to reduce first 90-day mortality rate.

I think it is intended for the new patient coming in, trying to get them stabilized, and find out what they really need and then try to fine-tune their prescription. And it's much easier to go down on time than it is to go up as far as the patient acceptance.

However, I am swayed by all the comments made on the side having concern about this measure because of the concept of what are we trying to accomplish with a performance measure, as opposed to a guideline.

I think this would be a great thing for KDOQI to take up as a revised or additional guideline; whereas, perhaps it has not reached evidence-based enough to become a performance measure that then takes on a life of its own. I realize this would be time-limited.

So, again, I can see both sides of it. I like the measure, but I would like to get feedback from Karen about, again, the

difference between a performance measure and a guideline. Maybe this will help reduce some of the tension in the room.

DR. BERNS: KDOQI should have a clinical practice guideline out on hemodialysis by the end of this calendar year. And KDIQO should have an international guideline on dialysis within another probably 18 months after that. So that is coming. It's in the pipeline.

DR. PACE: Guidelines on the time?

DR. BERNS: We haven't even put the workgroup together yet, but it's really going to be an update of the current KDOQI going on. So it will look at when to initiate dialysis, adequacy of dialysis.

And I'll just remind everybody that the original KDOQI discussion about adequacy of dialysis used urea kinetics as only a tiny fraction of that, that it was volume control, adequacy of nutrition, adequacy of blood pressure, phosphorous,

anemia, all of those things, not having cramping, not having vomiting on dialysis. That's an adequate dialysis treatment. You know, just mandating four hours I think leads us away from really thinking about what is adequate.

DR. PROVENZANO: Right. And let me focus because we may be looking at this the wrong way. Individualized care is what we're talking about. There are some people -- and most nephrologists do start at four hours, but there are some people where it actually can be quite harmful. And so the availability of more frequent dialysis, both in center or at home, nocturnal dialysis in the last ten years has really skyrocketed.

So we're looking at individualized prescribed care. A wiser way of looking at it may be for a minimum, you know, weekly time or some broader view to address separately the volume issue.

And, I mean, obviously we all have

personalized stories. I joke with people that you haven't lived until you've had a bunch of Sicilians on dialysis, my family calling because they're cramping.

(Laughter.)

DR. PROVENZANO: It's really bad. But I think we need to look at this broadly because the issue here is volume that in most physicians' minds is separated from adequacy. Some people can get adequate dialysis in two and a half hours. Years ago that's a problem we had.

But I do think that for us to not accept unintended consequences of this mandate might be short-sighted and we should look at this in a broader context.

DR. VELEZ: Not to delay this a lot more, but after having this wonderful educational experience today, I realize we are all talking about the same thing. We all want the same thing. It's how to get there. So I think we're really a lot closer than what we

think we are.

Going to the specifics, this measure does not get us there. And that's what we need to look at.

CO-CHAIR CROOKS: Okay. So are we getting close to being able to vote? I think, as the Chair, I would like to stipulate that everybody here wants the best outcomes for patients. In one way or another, we have all devoted our careers to doing that. And we all wish the NIH would have given us millions of dollars 30 years ago and we could have gotten this thing right by now.

So I would like to move to voting if we can. Okay.

DR. PACE: Okay. This is on number 1437, importance to measure and report.

(Pause.)

CO-CHAIR SCHONDER: We have 6 yes and 14 no. So it does not meet the importance criteria.

CO-CHAIR CROOKS: Okay, then. All

right. Let's move on, then, to the next metric, number 1439, "Utilization of High Ultrafiltration Rate for Fluid Removal." Alan?

1439, UTILIZATION OF HIGH ULTRAFILTRATION RATE FOR FLUID REMOVAL

DR. KLIGER: This is a measure in the spirit that Joe mentioned before of the series that intends to try to address volume for patients on dialysis. And this is one that specifically looks at the rate of ultrafiltration, the rate that fluid is removed from patients during the course of a hemodialysis.

The measure itself is -- the numerator is the number of patients who did not receive an ultrafiltration rate of greater than or equal to 15 milliliters per kilogram per hour. And the denominator is, again, all patients in that particular time interval.

The steward indicated that the measure was not tested. The reliability of

weights -- sorry. Let me just go back again to the rationale, where this really comes from.

There are now several studies, one that does come from DOPPS. That's what I mentioned before. I apologize I mentioned it with the wrong measure. The DOPPS study was done and did show a clear correlation between mortality and rates of ultrafiltration. That is, in people in whom fluid was removed very quickly, they had worse outcomes than people who had more gradual removal of fluid.

There also were then subsequently several other studies, again, all observational studies, that looked at the effect of rapid ultrafiltration in terms of its effect on the heart and, again, evidence that rapid ultrafiltration rates have potentially negative consequences.

The specific issues around this are that as the developers themselves say there is a paucity of studies examining

long-term outcomes associated with high ultrafiltration rates, the developers say it is uncontroversial that an ultrafiltration rate above 15 milliliters per kilogram per hour is potentially harmful for patients. But that statement is made without any support in the literature. I'm not sure that it's uncontroversial because there are no data showing, again, that there is any cutoff.

And I think it is important to note that most of the data on the high rates of ultrafiltration are in patients who are getting short dialysis. And so the two; that is, short dialysis and high ultrafiltration rates, are inexorably confounded. And separating them is not possible based on the data that is available right now.

Again I want to, if I may, Karen, with apologies to you, quote some of the issues that you raised because, again, I think they are right on line. The measure was not tested. The summary of the evidence does not

provide the study results that the higher odds of our bad outcomes are with this very high level of 15 milliliters per kilogram per hour So that's not been sort of the cutoff. And why that was selected is not clear from what the literature shows.

And so maybe I can then ask, Karen, if you could run through for us the feeling of all of the reviewers.

DR. PACE: And let me just make a comment about some of these measures and the testing. There was some inconsistent information, I think, on the submission. Some of these were checked as not being tested. But then there was some reliability and validity information presented. So this is one where it was checked as not tested, but there was reliability and validity information provided.

So let me go to the table. Just one second. Okay. So the initial reviewers on importance, three said yes and three said

no; -- okay -- on scientific acceptability, two completely, four partially; on usability, one completely, one partially, three minimally, one not at all; feasibility, five completely, one partially; and on recommendation, two yes, four no.

DR. KLIGER: So maybe I can invite others of the primary reviewers to make some comments.

MS. WAGER: I originally had voted yes, and I am now voting no. So no comment.

DR. VASSALOTTI: I mean, my concern was what are the gaps in care, how will this impact care, what is the evidence level, is this a measure that really is going to accomplish what we all want to accomplish.

MS. ANDERSON: My concern was that there were no demonstrated gaps in care and there was no evidence to support this.

CO-CHAIR CROOKS: Okay. Comments from the wider -- Alan?

DR. KLIGER: I'm sorry. Just one

last thing from a reviewer, which is that in my mind, this is again one of those very attractive hypotheses. I think that it is likely we are going to be able to show that rapid rates of ultrafiltration is probably not a good thing. We just don't have sufficient evidence to make this a clinical performance measure right now.

CO-CHAIR CROOKS: Okay. Comments from non-reviewers or those who were not assigned to review? Karen?

DR. PACE: And I just want to also clarify that the comments that we as staff put in for the reviewers' consideration; for example, the questions about the evidence, are questions that occurred to us that you all, knowing the field and the evidence more, perhaps it just wasn't put in the submission form. And you might know that it's there.

So just because it's not in the submission form, that's why we asked you as experts of the area, is there evidence here

or, you know, are we dismissing something in the form?

CO-CHAIR CROOKS: Okay. Jerry?

DR. JACKSON: Sort of a contrarian position, since we have not yet endorsed any volume-related measures, could this not be since it's time-limited a way of promoting attention to the volume area in practice without over-committing to a longer period of time?

DR. PACE: I will just mention this particular one actually does have testing information on reliability. And then they reported face validity. So I guess we would need to look at that testing information. So technically --

DR. JACKSON: Not available for time-limited.

DR. PACE: -- it wouldn't be for time-limited endorsement.

DR. JACKSON: And then I withdraw my comment.

DR. PACE: But is there something about the -- well, I'll let you finish your discussion.

CO-CHAIR CROOKS: What you were saying doesn't obviate what he was saying, does it? You were saying that maybe we should do one of these to have a metric related to volume.

DR. JACKSON: Yes.

CO-CHAIR CROOKS: And you're just saying that it has had some testing.

DR. JACKSON: I realize that we are charged with looking at these individually, but this is almost the last one in this section. Knowing that we have rejected or not endorsed, rather, the others, this would be a way of getting some measure in this arena that could be addressed later.

And, like Myra had said, we have patients, too, that getting seven, eight, ten kilos and addressing those patients, you have to do it through multiple directions of either

adding time or talking to them about sodium and pleading with them, you know, so all of those things. But this does give a measure where that patient would be highlighted.

CO-CHAIR CROOKS: All right. Jeffrey?

DR. BERNS: I am having a hard time understanding this physiology behind this measure, quite honestly. Neither the plasma volume nor the fluid volume go up commensurate with body weight in somebody who is obese. So that the ultrafiltration rate in terms of plasma volume or the CF volume is really not all that weight-based. It is lean body mass weight-based but not total body weight-based.

And, of course, we measure dialysis patients when they're wearing their winter boots and their jacket and their sweater or just their shorts and t-shirt depending upon the season of the year.

So I'm not sure that even having a weight-based ultrafiltration rate makes sense

physiologically to me before we even get to think about whether having a rate-based performance measure is the right thing at all.

Am I thinking correctly or incorrectly?

CO-CHAIR CROOKS: Alan?

DR. KLIGER: Yes. I mean, I guess again the only comment is the DOPPS data are very robust in this regard. If you look at the DOPPS data, they are robust.

The question then has to be what explains it. And, again, I think there is so much confounding just the ultrafiltration rate, but it is impossible to know that.

So yes, I think you raise a good point. It's just that in my heart of hearts, I do think that rapid ultrafiltration rate when confounded with time the way we have done it is a problem. But this measure ain't going to help us with that.

And, Jerry, if I just may quickly, the other thing about just selecting one, I

mean, we've got to pick one, let's get one. And let's get it and make it time-limited. We haven't talked about the unintended consequences of having your patient or your patient who comes in with a ten-kilo weight gain and, despite increasing dialysis time for that patient, if you use strict ultrafiltration rate to low rates, which is what this would urge us to do, you're going to have patients with far more congestive heart failure and pulmonary edema. So the unintended consequences of this I think are substantial.

CO-CHAIR CROOKS: You are saying that the response won't be to increase the time to achieve dry weight or the patient won't sit there long enough to achieve dry weight if we limit the ultrafiltration rates? Yes, Andrew?

DR. NARVA: It is really disappointing that we have gotten to the end of the volume measures and we don't have a

measure and we're probably not going to. Well, we'll see, but it sounds like we don't recommend a measure.

I don't really see how this issue can be addressed without addressing patients' health management a little bit. And, you know, this is true in this issue. This is true in dialysis. It is true in chronic disease. And the idea that somehow performance measures simply that look at objective interventions that the physician or the provider makes are not going to be adequate to improve outcomes in dialysis or other kinds of chronic disease. And we don't have good tools for assessing self-management. I mean, I can barely describe it, but I know when I see it. I see it in four people here for sure.

So that's going to have to be a different paradigm when you set quality measures in the future because there's no way to get people to avoid huge volume gains

without actively enlisting their participation. And none of these measures sort of get at that.

CO-CHAIR CROOKS: Okay. Other comments?

(No response.)

CO-CHAIR CROOKS: Okay. I guess we're ready to vote, then.

DR. PACE: This is measure 1439. We need to go back. Oh, no. You're on the wrong one. Okay. Fourteen thirty-nine, importance to measure and report.

(Pause.)

DR. PACE: Everybody think they voted? Oh, one. Okay. All right. Yes. We can go ahead.

CO-CHAIR SCHONDER: We have 18 responses: 4 yes and 14 no. So it did not meet the importance criteria.

CO-CHAIR CROOKS: Okay. And the final metric in this group is 1438, "Periodic Assessment of Post-Dialysis Weight by

Nephrologist." Myra?

1438, PERIODIC ASSESSMENT OF POST-DIALYSIS WEIGHT BY NEPHROLOGIST

DR. KLEINPETER: So this measure basically discussed in the notes by Karen and Lauren, post-dialysis weight assessment varies by practices widely across dialysis facilities and across the published data. And it is just generally accepted that good clinical practice should include periodic assessment, but the quality of measure that requires facilities to document this is likely to encourage better practices across the patient management at these facilities.

In terms of the summary of the evidence, the periodic assessment in challenging a patient's post-dialysis weight is a widely practiced clinical approach and for achieving optimum hydration. However, there are some unintended consequences of this. And in general this approach is designed to slowly achieve euvolemia.

One of the things that is also mentioned, requested measure submission information, was complete. The testing, however, has not been completed according to the information submitted here. And it will be done within the next 12 months.

There was no data regarding the performance gap. And there was also no data to indicate whether or not the numerator was specified specifically. It's assumed that it will be all patients that are at the dialysis unit, but it didn't really say if there were any specific exclusions.

In terms of the information by the reviewers, in terms of importance, five of the six indicated yes; in terms of acceptability, two completely, one partially, two minimally, and one not at all according to this; in terms of usability, two completely, one partially, two minimally, and one not at all; in terms of feasibility, three completely, three partially; in terms of recommendation, four

yes and two nos on this.

And from the information from the CMS information submitted, the panelists thought that this actually should be assessed once every two weeks, but at least a minimum starting would be once a month. And it should be administered as well after changes in the patient status, such as admissions for heart failure or other cardiovascular-related events.

There was a unanimous vote on this assessment, but they also suggested that this measure would be most effectively done as part of a package with blood pressure monitoring, sodium restriction measures, and potentially complemented by some of the new technologies that exist in terms of the in-line hemodynamic monitoring of the bio-impedance analysis or other blood volume-monitoring devices.

But, once again, it's not ready for prime time. It will require more research and demonstration project or some additional

types of funding. But, at the minimum, it should stress the importance that an assessment needs to be done periodically.

We know from clinical practice, those of us that are active in centers, we often get patients that have been at their community nephrology unit and they haven't had a weight change in months. And when you get copies of the flow sheets, you see that they are nowhere near their current dry weight in months. And the reason they came in is because no one is paying attention and just arbitrarily setting these numbers.

So some type of assessment needs to be done, but whether or not this is the proper way and whether or not this is going to be a yes/no selection or whether or not it's going to be an actual data element in terms of how much of a change, plus or minus, remains to be seen.

CO-CHAIR CROOKS: Robert?

DR. PROVENZANO: You know, I think

this measure, despite the fact that there is not a lot of data, hits on everything we have just discussed. What we are trying to do is get clinical nephrologists to pay attention to an issue that many of us feel has not gotten the attention it requires.

What this does is it says "Doctor or nurse practitioner or PA, we expect some indication from you that you have looked at a dry weight," which, of course, then translates into is the time long enough, should this patient have more frequent dialysis, you know, is my prescription correct.

And it actually gets to where we want it to get with all of the other issues, but the -- in my mind, the best thing about this, even though it's not perfect, is it can't do any harm. It cannot. The most harm it causes is to the nephrologist who says, "Geez, now I've got to check another box." But the reality is it creates an environment where that nephrologist is having

conversations about what we all here want to have the conversation about.

So I think, despite the issue that was pointed out, I would endorse this.

DR. PACE: I just want to clarify again this was one where the box was checked. It wasn't tested, but there is actually reliability data. So it would be for regular endorsement.

CO-CHAIR CROOKS: So when we vote, it will not be for time-limited?

DR. PACE: Right.

CO-CHAIR CROOKS: Okay. Jeffrey?

DR. BERNS: I have a question, actually. I don't quite understand the metric here. And I think it's internally inconsistent. So at one point, it says the numerator, the number of patients in the denominator who have documentation of receiving a new post-dialysis weight prescription. And then it later says that it doesn't require a change in the post-dialysis

weight prescription.

So it basically is saying you as the physician, a rounding nephrologist must write a note for a new weight every month, regardless of whether they change that weight. So leaving the weight intact would satisfy the -- it doesn't say that. What it says is just writing in --

DR. PROVENZANO: I think if the word "new" if that were removed would fix it because new suggests you have to change the number, rather than say, "I looked at it. I think it should stay the same."

DR. BERNS: So, again, the --

CO-CHAIR CROOKS: Let's ask the measure developers about that.

DR. MESSANA: So the TEP's intent was to see prescription assessment. And so one of the points that we brought up during the discussion is that if you require a change in dry weight on a monthly basis, there is a potential unintended consequence. People will

change dry weights. Physicians might change dry weights to be in compliance. So a revalidation or verification of the current weight is a --

CO-CHAIR CROOKS: Was a new assessment.

DR. MESSANA: It's a new assessment.

CO-CHAIR CROOKS: Right. So --

DR. BERNS: So this would require that a rounding physician write an order at least once a month specifying the dry weight, whether that has changed or not from the prior month's dry weight?

DR. MESSANA: Well, that the rounding nephrologist would have to validate or verify the dry weight order. Whether that's done by writing prescriptions, Jeff, or not, I don't know.

DR. BERNS: The only that can be captured is to write -- and I'm not even sure it can be captured but write a new -- is

writing a new order capturable by CROWNWeb. I mean, my practice had been to make rounds once or twice or sometimes three times a week and say, "Patient, you know, EDW seems appropriate" or "Change EDW and make an order to that effect."

DR. LATTS: Can't you just check a box off of EMR based on that?

DR. BERNS: I don't know what the logistics of this, but that's what it seems like. I just want to make sure we understand what is being required, which I think is that the physician write an order with a dry weight every month, whether or not that patient needs a change in dry weight.

DR. MESSANA: I think that the CROWNWeb data requirement would be something that is translated by the facility from documentation, be that physician's note or a physician's order.

DR. BERNS: So how does that impact validity/reliability of that data

because now you're saying that it's okay to have a nurse or a dietician or somebody or secretary in a dialysis unit comb through the charts of all their patients for a month looking for evidence that the physician assessed dry weight and make sure that that somehow gets to a forum that's interpretable and understandable by CROWNWeb.

DR. PACE: And can I just say I misspoke. This one does not have reliability and validity testing. I was on the wrong measure. I'm sorry.

DR. BERNS: I think the principle may be the same, but I think we need to understand what we're getting ourselves into if we agree that this becomes a performance measure.

CO-CHAIR CROOKS: This would be eligible only for a time-limited endorsement for testing. So that may be one of the things that gets tested. You know, how does the data --

DR. PACE: Reliability.

CO-CHAIR CROOKS: You know, is it reliable? And is the method appropriate? But I would like to hear from the developers one more time about I am confused, totally confused, about how you plan to get this data into -- you know, you are just going to look on CROWNWeb and if it's there and if it's not really your interest, how it gets entered in the CROWNWeb or what the process is at the dialysis facility.

DR. MESSANA: Peter, I am not sure I understand the question. You asked it a different way.

CO-CHAIR CROOKS: From your perspective, do you have any -- or from the test perspective, how was this information to go from the physician's intent or signature or documentation into CROWNWeb? Is it the physician's responsibility? Is it up to the local dialysis unit to figure out a method?

DR. WOLFE: So this precise

instructions and definition were not part of the specification. And that is it is true that we haven't done that part of the development because this is a relatively new measure.

There was discussion between the DTEP, the data TEP, which was basically asking the question, so is it just a question of getting our computer program to make sure that that box is checked? And, of course, that was a facetious question, but they were asking the question, what level of documentation is needed.

And my understanding of the intent is that in order for that box to be checked, that would be a statement by the physician. And there would be a physician who was in charge of that patient. And that physician would need to be standing behind the fact that yes, they had made an assessment.

So it's to document the physician's willingness to have a statement

made that yes, they did make an assessment. That's the intent. And the actual implementation is still to be worked out.

DR. KLEINPETER: So, Peter, on page 142 of the report that he is referencing, it states that "The CTEP language proposed, the CTEP then proposed language, for the measure that compliance would require, one, a new post-dialysis weight prescription in the reporting month as well as documentation in the patient chart that the post-dialysis weight assessment was, in fact, carried out by a nephrologist."

CO-CHAIR CROOKS: Okay. Joseph?

DR. NALLY: Bob, where the rubber meets the road here, so what we do, you're chair-side. You look at the dry weight. And then in a comprehensive note of the month, we actually have a box, "Dry weight review." Do you check it "Yes"? And if you change it, you make a note. And you have to change the order. So that is doing the right thing.

Then the second question is documentation in the CROWNWeb. So what is the proposal of how an individual gets from what I have just done as the physician to putting that in the CROWNWeb?

DR. WOLFE: I can't speak for exactly how CROWNWeb will be done, but my understanding generally -- and it may be related to the way claims are done, but there are data collected. And it is based upon an assumption that the data are reported accurately. But it is an auditable kind of process.

So that if a step were taken to audit that, they could look at your record and say, "Yes. That's clear evidence that you did do an assessment."

DR. MESSANA: My understanding is that most of the data that is going into CROWNWeb now is being back-submitted, largely by the proceedings in DCI with a small number of batch facilities that were involved in beta

testing, if you will, phase 2 testing, so that the dialysis facility has to have a mechanism for capturing that, those data, about that monthly assessment.

That is true for many other things that are in CROWNWeb that are not lab results. So the facility has to have a mechanism for --

DR. NALLY: So the onus would be upon them to have some clerical person translate physician note into a CROWNWeb?

DR. MESSANA: Yes.

CO-CHAIR CROOKS: I think it is fair to say, though, that the facility will be motivated to get that data, to have a mechanism in place because if this is a CPM and they're going to be monitoring on it, they're going to need to have a method. And as medical director, if you were, you would want to make sure there is a process.

Barbara?

DR. FIVUSH: Just going off this technical issue for one minute and going back

to what Bob said, I actually think, and to what Myra said, we have patients that are dialyzed in outlying units that come in that have not had a reestablishment of an ideal weight in months. And the only reason they're coming in is because they have become hypertensive over a very long period of time and no one has really taken a look at them.

So I do think this is a critical issue that people are not constantly reassessed as they lose weight, as their weight changes, and in children, upward or downward. I mean, you know, there is the other part.

This is an adult measure, but certainly the concept of establishment of an ideal weight or a true target weight is critical. And it's a constant thing changing in patients.

And I don't really think there can be unintended consequences of monitoring patients because we're not suggesting an

intervention other than we're looking at patients. And hopefully they will be an appropriate intervention.

The technical aspects, which I think are trying, -- and I understand having worked with some of the old CPM data that abstracting this data might be challenging, because it's time-limited, I actually think there's a year to sort of figure out if we can do it. But I don't think that lessens my desire that this may be a good, good way to monitor patients in an important topic area.

CO-CHAIR CROOKS: Okay.

DR. MESSANA: No disagreement with that.

CO-CHAIR CROOKS: Let's try to keep it to a couple of more comments. I think we're moving towards a consensus here. Alan?

DR. VASSALOTTI: I want to. I think there are gaps in care in this measure. And I would ask the panel, is there anybody who doesn't think there is a gap in care in

this measure? We have no data. So we just have to go by our judgment --

CO-CHAIR CROOKS: Alan?

DR. VASSALOTTI: -- for anyone who doesn't think there are gaps in care in this measure.

CO-CHAIR CROOKS: Speak now or forever hold your piece. Okay. Alan?

DR. KLIGER: So, Lisa, this is the example in my opinion of a proposed performance measure for which there is not 100 percent data and not all the links put together but one that we should adopt.

DR. PACE: Barbara and then Frederick, regarding your comment, is there any reason this measure should not apply to pediatric patients since it is a monitoring measure?

DR. FIVUSH: I guess my only concern is it is difficult in children that are growing this concept. Nutritionally we have concerns about growth and weight gain.

And they're going to be changing targets. I guess it's less established. Right. I'm thinking --

CO-CHAIR CROOKS: That's all the more reason to do it, then.

DR. FIVUSH: I'm thinking. I'm thinking.

CO-CHAIR CROOKS: That argues for it, not against it.

DR. FIVUSH: Right. I'm thinking about the nutritional part. No, I actually can't think of a reason why we shouldn't be doing the same thing. I don't know if Rick can, but it wasn't proposed in that way. But certainly our younger patients absolutely --

CO-CHAIR CROOKS: Just to think about it a little bit more, let's give you a little more time. I think that's a --

DR. FIVUSH: I think --

CO-CHAIR CROOKS: If you come with that agreement, we could ask the extent of that, I suppose.

DR. FIVUSH: Right. And I think with the fact that there is a -- you know, the CROWNWeb system should pick up again the pediatric patients. It won't come through claims, but that is something they can sort out again because we don't have Medicare populations.

DR. VASSALOTTI: Can I make a proposal to extend this measure to pediatric patients?

CO-CHAIR SCHONDER: Can I just point out that it's actually not written to exclude pediatrics?

DR. FIVUSH: I thought the target population, again, just like every other measure, said over 18, even though -- is that true?

DR. PACE: It does say for target population, adult.

DR. FIVUSH: Right. It's the same thing. It's not in the numerator or denominator.

DR. PACE: Right.

DR. FIVUSH: It's the same thing as the other measures in the --

DR. PACE: I know, but the intent was for adults.

DR. FIVUSH: Right. That's right.

DR. PACE: And so --

DR. FIVUSH: As you pointed out with the --

DR. PACE: Right. So --

CO-CHAIR CROOKS: So if we pass that we can make a comment back to the developers, that we thought it would be appropriate for all age groups.

DR. WOLFE: And can I respond that the committee was, the TEP was, comprised of people who were working with adults? And they I think thought they framed their experience and their knowledge base in terms of their own experience. I don't think there was any intent to exclude pediatrics.

CO-CHAIR CROOKS: Okay.

DR. FIVUSH: I want to be sure Rick feels the same way I feel.

DR. KASKEL: That's fine. I mean, we had the data. It's there. It's recorded. But you want to make sure it's assessed.

CO-CHAIR CROOKS: Okay. So can we move to voting on this?

DR. PACE: So are there any objections to voting on this with the condition that it also include pediatric patients? Any objections to that?

(No response.)

DR. PACE: So when you are voting, keep that in mind that will be part of the conditions.

DR. BERNS: I just want to ask a question of clarification. Does this pertain only to in-center hemodialysis or all hemo and PD patients?

DR. KLIGER: No PD.

DR. PACE: It's not PD.

DR. KLIGER: It is specified as

hemo.

DR. BERNS: Is it?

DR. PACE: And I think that is a good question. It does say --

CO-CHAIR SCHONDER: It says, "Outpatient dialysis facilities." It does not include home on this.

DR. PACE: The denominator detail says denominator includes only in-center hemodialysis patients. So is that appropriate that it only be in centers or no?

DR. BERNS: It does say "in-center." I'm just missing it.

DR. PACE: 2A.8.

DR. BERNS: Only in-center. Okay. Thank you.

DR. KLIGER: I would suggest we leave that "patients who are home, either hemo or peritoneal." The one-month interval may or may not be appropriate. So I would leave it as it stands.

CO-CHAIR CROOKS: Okay. Are we

ready? So this is a time-limited measure.

DR. PACE: Time-limited with the condition of adding pedes and 1438, importance to measure and report.

(Pause.)

DR. PACE: Okay. Everyone thinks that they sent their -- no? Okay. Let's go ahead and see what the --

CO-CHAIR SCHONDER: We have a unanimous 18 yeses.

DR. PACE: So, remember, do not press it until the clock starts. So let me ask you this. Did anyone vote against the importance? Did anyone vote no if they want to say? Right, right, right, right. Okay.

So let's -- well, we can't vote again on something, but we'll go to -- I know what we can do. Go back to one of the questions that we didn't do because -- yes? Okay. So on this one, all right. Everyone? And, again, wait until the timer starts. Okay. Okay. All right. Okay.

(Pause.)

DR. PACE: So okay. So now we'll go on to scientific acceptability of 1438. And wait until the timer starts.

(Pause.)

DR. PACE: Okay. Okay. Everyone voted? Okay. Let's stop.

CO-CHAIR SCHONDER: We have nine completely, eight partially, and two minimally.

DR. PACE: All right. So --

CO-CHAIR CROOKS: How can it be completely if they haven't done any testing at all?

DR. PACE: Right.

CO-CHAIR CROOKS: That's what I have a problem with this.

DR. PACE: And I should have specified. This would be related to the, primarily to the, specifications and if there are exclusions, those aspects, those minimal aspects, that are under that criterion.

CO-CHAIR CROOKS: We should say that, then.

DR. PACE: Right. Okay.

CO-CHAIR CROOKS: Okay.

DR. PACE: Usability?

(Pause.)

CO-CHAIR SCHONDER: Nine completely, nine partially, and two minimally.

DR. PACE: Okay. And then, finally, feasibility?

(Pause.)

CO-CHAIR SCHONDER: Seven completely, eight partially, five minimally.

DR. PACE: Okay. And last, then, recommend for endorsement?

(Pause.)

CO-CHAIR SCHONDER: Twenty yeses, unanimous.

DR. PACE: Okay. Okay. So what should we do? Should we take a --

CO-CHAIR CROOKS: Can we take a quick break at this point?

DR. PACE: Okay. We'll take a quick break. And then when we come back, we're going to pick up what our agenda would have been starting today. So we'll start with brief introduction of measures by the measure developers. And then we'll move into probably the infection measures first.

Right. If you haven't checked out, please do that. And get back here as quickly as possible. Thank you.

(Whereupon, the above-entitled matter went off the record at 10:08 a.m. and resumed at 10:27 a.m.)

CO-CHAIR CROOKS: We are back from checking out. So thank you for that. And we are going to now go to consideration of candidate measures and at this point let the measure developers have a brief introduction of their measures.

We have on the line a group from CDC. And I would like to invite them to go first, followed by the CMS developers. And

then we are going to go right into the infection metrics. We will pass hospitalization metrics and come back to that later. Okay?

So is CDC on the line?

DR. PATEL: Yes, sir. I can hear you.

CO-CHAIR CROOKS: Say that again. That wasn't very clear.

DR. PATEL: Can you hear me okay?

CO-CHAIR CROOKS: Yes. Yes. It's coming across a little mumbly. So speak with great enunciation. Thank you.

DR. PACE: And are you on a speakerphone?

DR. PATEL: I am. Is this any better?

DR. PACE: Yes. And tell us your name.

DR. PATEL: This is Priti Patel.

CO-CHAIR CROOKS: Okay. Please go ahead.

DR. PATEL: Okay. Thank you, sir.

CONSIDERATION OF CANDIDATE MEASURES BRIEF INTRODUCTION OF MEASURES BY DEVELOPER(S)

DR. PATEL: Good morning, everyone. I am a medical epidemiologist in the Division of Healthcare Quality Promotion at the Centers for Disease Control and Prevention, or CDC. And most of you know CDC is a public health agency within the Department of Health and Human Services with responsibility for prevention and surveillance of healthcare-associated infection.

CDC has substantial experience measuring healthcare-associated infections and disseminating the data for use, direct use, and prevention and quality improvement activities.

As all of you know, bloodstream infections cause substantial morbidity and mortality in the hemodialysis patient population. Many of these bloodstream infections are complications of the dialysis

vascular access, including central lines.

We have seen dramatic reductions in central line-associated bloodstream infections in inpatient populations and have reason to believe that expanding uptake of recommended practices in outpatient hemodialysis centers can similarly reduce the burden of infections in this population. As a result, we have submitted measures that reflected these national dialysis infection prevention priorities.

All three of the measures we submitted are currently in use and are collected in the National Healthcare Safety Network, or NHSN, systems. NHSN is an extremely stable system used by more than 3,000 U.S. hospitals for healthcare-associated infection reporting and is tied to public reporting mandates.

An advantage of the NHSN system is the ability of facilities to view and analyze their data and create comparative reports for

rate benchmarking as soon as the data are entered. This feature allows NHSN to function as a quality improvement tool, not solely a mechanism for data collection.

Use of the three candidate infection measures that we submitted through NHSN, the measures have been in use since 1999 and have been collected through NHSN since its inception in 2006 providing a substantial experience with the collection, use, and interpretation of these measures.

The measures have been validated. And studies have demonstrated the quality improvement interventions can impact these outcome measures.

Currently approximately 130 dialysis facilities collect and report these measures to NHSN. And at least one state has mandated that dialysis centers report to NHSN. And several end-stage renal disease networks have initiated quality improvement projects utilizing the infection measures in NHSN.

We anticipate expanding the use of these measures through additional QI projects and other efforts. We believe these measures have an important and established track record demonstrating their feasibility and usability.

On behalf of CDC, we appreciate the opportunity to submit them for your consideration. Thank you very much.

CO-CHAIR CROOKS: Thank you.

All right. How is the CMS group going to -- CMS, proceed.

DR. WOLFE: Thank you very much.

I think that that summarizes much of the information that justifies and motivates the CMS metrics as well, which are very similar to the CDC measures in terms of the definitions and the actual evaluation of infection.

The difference is in the data collection system. And I don't know if that actually constitutes a different measure or not because, as I heard some discussion

before, that once a measure is approved, it can be implemented and reported by a variety of different organizations.

However, I would like to point out that the NHSN is currently limited to voluntary facilities who are participating in it. It is very successful with them. I am aware of the fact that there is a data collection burden on facilities right now in terms of learning to deal with new data collection systems through CMS. So I don't know if that is a consideration for this Committee or not.

I believe that an infection measure is extremely important based upon what our TEP has recommended and what you have heard from the CDC.

Can I ask, Peter, if this is the time when I should also talk about other measures that the Committee will be considering this afternoon or will that be --

CO-CHAIR CROOKS: Yes. We should

do that.

DR. WOLFE: It is somewhat difficult to put it all together.

CO-CHAIR CROOKS: Including going back to the issue from yesterday?

DR. WOLFE: Perhaps. I would prefer to talk about the SHR first.

CO-CHAIR CROOKS: Well, this is your chance. This would be probably the only chance to really discuss measures.

DR. PACE: Actually, you will have time during the public comment period as well, which we will have at the end of the morning and end of the day.

But what we wanted this time for was to provide an introduction to the measures that the Committee is going to be addressing at the end. So if you have any remarks about the hospitalization measure --

CO-CHAIR CROOKS: Thank you.

DR. PACE: -- to introduce those? And you can tell us your question about the

measures from yesterday. And we'll make note of that. But we won't discuss that right now --

DR. WOLFE: Thank you.

DR. PACE: -- if that's okay.

DR. WOLFE: The SHR, the standardized hospitalization ratio, is a measure which is a primary outcome identified as having high impact along with mortality. And the level of importance is extremely high, not only from a patient perspective in terms of impact upon the patients' outcomes but also in terms of national health policy in terms of cost of care. This is something that has direct impact upon our ability to allocate resources for all the essential needs of the ESRD patients.

The hospitalization metric is risk-adjusted. This is important. It does account for patient characteristics, patient conditions, including comorbidities. And with extra data flow, it wouldn't surprise me and

I think there is every expectation that that would be brought to this Committee for continual improvement and development, but right now it is based upon the data that are available from the claims.

It has been reported for many years. So there is a large amount of experience with it. It is very actionable. It has been shown to be related to vascular access practices to dialysis adequacy practices and to anemia management practices, all of which are modifiable behaviors on the part of the providers.

I have heard some concerns, valid concerns, about the timeliness of the hospitalization. The hospitalization metric does require nine months to be completely reported. And it's based upon claims. So it takes time for those claims to be finalized. So there is a nine-month lag.

I've heard people comment about a four-year lag. And that is not a lag in the

data at all. There is only a nine-month lag in the data. The reason four years are used for certain kinds of statistics or has been used is in order to come up with a stable value, just as you wouldn't use a one day's hemoglobin, you would use a rolling average over several values.

The hospitalization metric is recommended for one year. And that is in order to increase the stability to an appropriate level. And that has been developed over time to be a good, stable metric.

That is all that I have about hospitalization. If further questions do arise during the deliberations of the Committee, we would be glad to clarify if we can.

I would like to recount my conversation with Alan Kliger yesterday afternoon, having to do with measure 1430, the pediatric hemoglobin, where there was a

recommendation by this Committee to replace the criterion of an average less than 10 with having all 3 values in a 3-month period less than 10.

The TEP had not considered that. It had considered many, many alternatives. It was a several-day deliberation on the part of the TEP, experts from around this country, who are extremely knowledgeable and very thoughtful about this.

And it wasn't just a two-day process that they looked at. This was a multi-week process with many articles reviewed beforehand, thoughtful deliberations, many ideas put forward during the two-day in-person interaction, some of which would be put up as "Well, that's maybe a good idea" and after some deliberation maybe not.

In talking with Alan, I think this may be an example of such an idea that seems, well, maybe that's a good idea, but after you think about it, maybe not, to replace the

average of ten with requiring all less than ten.

Here is why. One of the problems with the anemia management, low-end threshold, is it somewhat difficult to distinguish the nonresponsive and I'll say untreatable patient? And there are some where, whatever you do, you are not going to be able to get that hemoglobin up from the inadequately treated.

By the way, one of the best predictors of being the nonresponsive patient is a persistent low value of hemoglobin in the face of continued therapy. So the focus upon patients who are consistently low is likely to focus upon those who are actually untreatable, as opposed to those who are under-treated.

So that would be the disadvantage of changing it, is it's more likely to focus upon the very people you don't want to focus upon and you might lose more of the people that you do want to focus upon, those who are

under-treated, where their values may be fluctuating but not brought under control as quickly as possible.

I put that in the context of the deliberations of the TEP because I think that in several of the discussions here, there had been some interesting ideas, which the TEP did consider very thoughtfully. And there are reasons why they were not incorporated into the measures.

And I can only respectfully submit that technical expert panels, which were assembled, which spent weeks reviewing hundreds of articles I think should be weighed very heavily in this Committee's deliberations and particularly as you think about maybe this is a good idea.

I love to have great ideas and toss them out. And I expect 80 percent of them to be shot down because 20 percent is actually pretty good.

CO-CHAIR CROOKS: I think there

would be an opportunity after we are done with our work, but there are several steps before there is actual endorsement by the National Quality Forum, including comment period and so on, to go back and look through notes, "Oh, yes. We did look at that one. The reason it was rejected was" such and such and bring that back, right, Karen?

DR. PACE: Right. So we appreciate that information. And we can see if we have time at the end of this meeting to have further discussion about that.

The process for this kind of thing anyway is for us to ask for a response from the measure developer in terms of whether that is possible, whether they agree, and the rationale. And then that will be formally then taken into consideration for the final recommendation.

So the vote yesterday with that condition is not a final thing anyway, I mean, according to our process, but that --

DR. WOLFE: Thank you.

And regardless of the decision about what to do right now, whether to accept the ten or take time to change it, part of the reason I wanted to say this was because the TEPs did have very careful, thoughtful deliberations. And ideas which come up right here perhaps should go back as not statements that this measure isn't going to work but perhaps as recommendations for the next cycle. I am just concerned about the process.

CO-CHAIR CROOKS: We appreciate the hard work that the workgroup put in and the expertise that was there. And we respect that. So I think that you will have a chance to rebut, so to speak, say, "Well, that is a great idea, it seems like, but here is the problem with it," you know. And I think that we will have a chance for that interaction.

DR. PACE: And that often happens. So it's a back and forth between the Committee and the developer.

DR. WOLFE: Thank you.

DR. PACE: Okay. Is anyone from CMS on the line? Do you have any comments introductory to your measures at this point?

(No response.)

DR. PACE: Okay.

CO-CHAIR CROOKS: All right. Let's move on, then, to the consideration of candidate measures for infection. And we'll start with 1477, the "National Healthcare Safety Network Intravenous Antibiotic Start Measure." And I have the pleasure of being the primary reviewer.

INFECTION

1477, NATIONAL HEALTHCARE SAFETY NETWORK (NHSN) INTRAVENOUS (IV) ANTIBIOTIC START MEASURE

CO-CHAIR CROOKS: This measure, the brief description, "Provide a monthly rate of outpatient intravenous antibiotic starts, initiation of a new antibiotic not in use in previous 21 days. Per 100 patient months

within outpatient dialysis unit, the 21-day rule is used to exclude counting antibiotics that are given for the same infection.

"The numerator and denominator statements are coming up. The numerator quite simply, total number of intravenous antibiotics started not in use in previous 21 days in the outpatient unit. The denominator includes patients receiving hemodialysis at the facility."

They do say "on the first two hemodialysis days of the month," which is a little confusing. I think what they mean is this is a way to try to capture the total population. And that might be reworded a little better, but I think, on further thought, I figured out what they meant.

I made a lot of notes on this, actually right on the form. And when I opened it up this morning, it was gobbledygook. I have no idea why, like a virus attacked it. So let's go to the evaluation by --

DR. KLIGER: It got infected.

CO-CHAIR CROOKS: Yes, it got infected. I needed IV antibiotics for my computer.

MS. BARNES: Peter, before you start?

CO-CHAIR CROOKS: Yes?

MS. BARNES: I should have asked this before, but I wonder if Priti, Dr. Patel from the CDC, could share the reasoning behind why these three measures are offered separately, as opposed to how they are combined in the current NHSN dialysis event module.

CO-CHAIR CROOKS: Is Dr. Patel --

DR. PATEL: Yes, I am on the line.

CO-CHAIR CROOKS: Yes?

DR. PATEL: So the way in which facilities will enter this data can be combined. So, for example, a patient can have more than one event. They can have a positive blood culture. And obviously they can receive

an IV antibiotic at the same time.

The way in which we report out the data is separated. So we calculate separate rates for bloodstream infections for bacteremia access-associated bloodstream infections and for IV antibiotic starts. And clearly there will be some overlap between those, but they are also separate measures.

So overall IV antibiotic use is something that is important not just as a measure of infection but is as a measure of antibiotic pressure resulting in antibiotic resistance potentially and has importance I think for facilities when they look at their own burden of antibiotic use.

So, for that reason, we actually report out the measures separately, even though they are collected together.

CO-CHAIR CROOKS: Does that answer your concern, Sue?

MS. BARNES: Yes. Thank you.

CO-CHAIR CROOKS: Okay. When it

comes to the section, the next section, scientific, I wanted to mention that there is no reliability testing. And the answer really avoided the topic. I took note of that.

And as to that validity testing, they claim that the results show high accuracy, which was 79 percent, 88 percent, 69 percent of validity. I'm not sure what is high. To me that doesn't sound that high to validate their -- that the accuracy was 79 or 69 percent doesn't to me impress me as high accuracy. That is subjective, I guess.

Do others at the table have an opinion about what is high accuracy? Maybe you look at a lot of this validity testing.

DR. PACE: You know, this is a question that came up in the measure testing task force about how do you look at these testing results. And there really isn't a specific threshold that they felt that was appropriate to identify that would apply to all types of measures, all the types of data

sources and conditions. You know, some of that relates to even the number of events that you might be expecting in terms of doing appropriate reliability and validity testing.

So we do ask for, as you see, the submitter to talk about those results in the context of norms for the particular test or the context.

So I don't know if Dr. Patel has anything to say. You know, since CDC does a lot of data collection, you might be able to put it more in perspective for us in relationship to their data. Dr. Patel, do you have any comments about the validity results or the testing results?

DR. PATEL: Yes. I mean, the only thing I can say, I don't have a good sense of what would be considered the norm for these tests. You know, the fact that we actually did do a validation study I think is important.

And we do actually perform data

checks to the extent possible on the data. So there's a lot of this informal data checking that goes on where we look at the data. And if we see something that looks out of line; for example, we have had instances where facilities have reported very few bloodstream infections but they have a very high IV antibiotic usage, that would be a prompt for us to actually call up the facility and say, "What is going on here? Are you actually capturing all of the data?"

So that is a very informal way of doing it. And, unfortunately, I don't have any better way to quantify for you the accuracy of this aside from saying that we do look at the data.

CO-CHAIR CROOKS: Okay. Thank you.

I'm sorry? I'm still doing my thing. Should I be allowed to --

DR. KLEINPETER: I just want one more question of here --

CO-CHAIR CROOKS: Okay. Go ahead.

DR. KLEINPETER: -- because is there a difference in reporting between those with catheters versus grafts versus fistula? It's just a question.

DR. PATEL: The reporting is not different. The report would come in the same way. We collect information on whether the patients who received in this case an IV antibiotic has a fistula, graft, or catheter. We collect the vascular access type. And then during the analysis, we stratify both the numerator and the denominator by vascular access type.

So we would report a rate of IV antibiotic starts stratified by each vascular access type.

CO-CHAIR CROOKS: I should have explained that this measure was intended to be stratified. You can look at the whole thing or you can look at it by vascular access type.

Regarding the 2F, which is

identification of meaningful differences in performance, while this was not answered sufficiently and it says, the answer base says it could be done, but we aren't doing it or reporting it to you. So they haven't shown us that they can show meaningful differences in performance.

You know, with a lot of these measures in infection, the ones I looked at a lot -- and we haven't talked a lot about disparities in care, but I don't know why disparities in care can't be addressed. It is something that is asked on the evaluation. And we know that there are disparities in care, at least in vascular access and probably in vascular access infection.

And I believe there is some data on that. And it just says across the board in all infection measures, nobody really addresses that. And it could take them that much time to look up the data and say, "Oh, there is a difference. And this could be

applied in such studies."

When it comes to the feasibility, well, usability was not formally tested. But I think this should be understandable by the public. And I don't have a big argument that it's probably useable just on its face.

Feasibility, some data will be processed like this. Other data and -- oh, they started the sentence with "Other data." So it's very confusing what they're referring to.

Also under feasibility is that the data collection doesn't start out electronic. And the plan for electronic data capture is quite vague.

So my recommendation was that the importance seems clear, but the measure has not been adequately tested to receive full endorsement in my view. We consider yes, if time-limited, but cannot recommend endorsement at this point in development.

Let's look at what the others

said. Do you have it? So in terms of importance, you had five of six reviewers said it didn't meet the importance criteria; under scientific acceptability, partially four, minimally two; under usability, complete two, partially three, not at all one.

And under feasibility, we have two complete, two partial, one minimally, and one not at all. And under recommendations, we have three nos, two yeses, and one abstention.

Who is that? Jerry, did you want to

DR. JACKSON: It was not entered. I would have voted no.

CO-CHAIR CROOKS: You would have voted no?

DR. JACKSON: There are a couple of technical issues. One is that it collects data on patients who have been treated in the unit on days one and two of the month.

Oftentimes incident patients come in obviously on other days. And they have a

high incidence of catheters and, therefore, higher rate of infection. So those patients are going to be missed at least two to three weeks on average.

I think you are missing a significant high-risk subgroup limiting those two days. And then it also referred to the months under surveillance, implying that not all months are under surveillance. And that can be clarified.

But my third issue is the data collection forum is something that is not commonly used in most dialysis facilities other than the ones that it has been field-tested on. And given all of the expanded data collection through CROWNWeb that we are going to be faced with, this is yet another forum that would be somewhat of a burden.

So those are my comments.

CO-CHAIR CROOKS: Thank you.

Reviewers?

DR. PATEL: Is it possible to clarify that point?

CO-CHAIR CROOKS: Go ahead.

DR. PATEL: So on the first point, the only thing that's collected on the first two days of the month is the denominator. What we found is that the denominator doesn't actually change all of that much during the course of the month. So if you capture it at a snapshot in time, it's fairly representative of what is happening over the course of the month.

The numerator is captured for every patient throughout the month. The denominator is simply simplified to make it easier to capture that information. So, rather than having to actually count patient days every day of the month, they're really just picking a point prevalence on the first few days of the month.

And our experience is what we have seen is that is fairly representative, despite

the fact that there are patients who are coming and going. The overall numbers remain fairly stable over time.

CO-CHAIR CROOKS: Okay. So to rephrase that, all infections are picked up. Even a patient who is not in the denominator would still be picked up if they get an infection during that month?

DR. PATEL: Correct.

CO-CHAIR CROOKS: Correct. Okay. All right. I would just like to remind the developers that unless you are specifically asked a question, you really can't respond to the comments by the Committee. I think you were sort of asked a question. So we'll let you get away with it.

Other reviewers? Sue is one. And you were one of the contra opinions about it. Can you tell us a little bit about that?

MS. BARNES: Yes, absolutely. You know, in favor of this is the existing database and history and data flow from a

number of facilities already as well as the denominator simplification, which is really important in data burden for facilities collecting the data.

The reason that I voted against is because I in principle believe that the focus on measurement exceeds what is productive in our country. And with the continuing exponentially increasing regulatory mandates for data, specifically infection data, what I am seeing in my community is a diversion of very limited expert resources away from preventing infections towards sitting in front of the computer and banging out reports. And that is the extent of the job as well as a mass exodus of experienced people because it's become a job of reporting and data collection.

I think it is even worse in dialysis centers, where there are no dedicated infection preventionists. And these staff have to do so many different things. I think it is really important to consider the burden

when you are -- even though this is not an organization that mandates collection of data, absolutely, that is what happens. When you endorse measures, that is what happens. That is what is happening in every single state.

So I voted against. Sorry. Long way around of saying I voted in favor of one of the three NHSN measures as what I felt was most representative of infection in this population and limiting it to one.

CO-CHAIR CROOKS: Okay. Thank you.

Joseph?

DR. VASSALOTTI: Yes. I wanted to expand on that a little bit. I think it's one thing to have a quality improvement activity in a single dialysis facility, for that facility to look at their antibiotic utilization and to modify their behavior over time to determine if perhaps we are giving antibiotics indiscriminately. Perhaps that is resulting in resistant organisms, resistant

bacterial infections in our patients. And that is detrimental to patient care.

I applaud the work the CDC is doing with the facilities. And I applaud the facilities for volunteering to participate in this activity, which is extremely important.

However, I think it is a completely different thing now to start comparing dialysis facilities based on their antibiotic utilization rate because it is a completely different thing.

Suppose your unit has a lot of catheters. You're going to have a completely different rate. Suppose you have a different patient population. You have a completely different rate. We have to be very, very, very careful about discouraging intravenous antibiotic use in dialysis facilities, which would have unintended consequences that we don't understand.

There are going to be financial disincentives for dialysis facilities to

provide intravenous antibiotics for patients in the bundling error. There are many in health policy who are concerned about that and the implications of what that could mean.

So, for all of those reasons, I am very, very concerned about this measure.

DR. FIVUSH: I have tried to look at this, but it looks to me like the target population is all patients. So this is not an adult measure. And I'm concerned about the high use of capita rates in pediatric patients and, frankly, pretty fragile and vulnerable and children that have complex orders may be related to HIV or other underlying illnesses. And I even try to stratify.

I am concerned about unintended consequences of not appropriately using antibiotics. Although I am also concerned about overuse, I agree with Joseph's point. I am concerned about it.

And I can tell you there are reasons for the high rates of catheters in

pediatric patients. Some are warranted or reasonable. We go to transplant much faster in children than in adults often. So we don't want to use up an access we may need later. We still don't do a good enough job. And there are issues. And we do need to have a much better access.

But we have looked at the use of catheters. It is extraordinarily high in children for some good reasons and some bad reasons. But I am just afraid this measure is going to -- right, right. I'm just saying. So this particular measure is going to in the long run, I think, be problematic.

CO-CHAIR CROOKS: Okay.

DR. BERNS: I guess my concern is unintended consequences also, either not giving antibiotics empirically while they're appropriate or telling the patients "Well, you need to go to the emergency room to get your antibiotics."

DR. FIVUSH: Right.

DR. BERNS: And these patients will start showing up in emergency rooms or oral antibiotics will be used inappropriately. So I think it's missing the mark for that reason.

CO-CHAIR CROOKS: Okay. Any other comments before we vote? Alan?

DR. KLIGER: Just one quick one. I think, as we look at all of these measures, we're compelled to remember that infections have become clearly one of the most important adverse events that cause premature death and other consequences. So that I am very much aware of how we need to look at each of these measures appropriately, but I would urge us -- we are looking at a whole series now.

And Sue made a comment before, a question that I think is particularly critical, which is, can we help to construct an appropriate comprehensive measure that doesn't offer a large burden and, yet, really does capture the need to understand, report,

and make public infection rates, particularly for patients who have longstanding catheters?

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

DR. PACE: So this is measure 1477. And we're starting with importance to measure and report.

(Pause.)

CO-CHAIR SCHONDER: We have 12 yeses and 8 nos.

DR. PACE: All right. So we will move on to scientific acceptability of measure properties.

(Pause.)

CO-CHAIR SCHONDER: Two completely, 12 partially, and 6 minimally.

DR. PACE: All right. Usability?

(Pause.)

CO-CHAIR SCHONDER: One completely, 12 partially, and 7 minimally.

DR. PACE: Feasibility?

(Pause.)

CO-CHAIR SCHONDER: Nine partially and 11 minimally.

DR. PACE: Okay. And, finally, whether you recommend the measure.

(Pause.)

CO-CHAIR SCHONDER: Two yes and 18 no.

CO-CHAIR CROOKS: Thank you.

Moving on to 1460, "NHSN Bloodstream Infection Measure," Sue Barnes primary reviewer.

1460, NATIONAL HEALTHCARE SAFETY NETWORK (NHSN) BLOODSTREAM INFECTION MEASURE

MS. BARNES: I want to say just a couple of words in addition to what was said before about kind of generally about this category of metrics. And I want to reassure the patients in the room that, although a lot of the measures have been voted down, it is my experience within my discipline of infection prevention that measurement is one important but also not the only aspect of one component

of performance improvement projects. As a matter of fact, where there is evidence, it is, arguably, the least important component of performance improvement projects.

So I think that when we are looking to change practice, maybe we are looking. We need to also look really robustly at the existing clinical guidelines, practice guidelines, products, and changing practice through those avenues instead.

I would also just put in a word of concern or maybe a suggested area of focus is if any of the NHSN measures are accepted and approved, which I think this one will be personally --

(Laughter.)

MS. BARNES: -- that there be work done between CROWNWeb and NHSN in order to interface and build a health information exchange process electronically in order to reduce the data burden on ESRD facilities.

So, with that said, measure 1460,

which is the number of hemodialysis outpatients with positive blood cultures per 100 hemodialysis patient months, just in summary, preliminary evaluations that I received showed 4 of 6 evaluators recommending this measure, some with suggested modifications.

The main arguments in favor of accepting this measure are that -- and this is very important, I think -- it is extensively tested. And it is already used in numerous states.

The NHSN database is well-established. And in Colorado, currently there is a legislative mandate for reporting into NHSN by dialysis facilities on bloodstream infection rates. And that is just the beginning. That will be expanding. There is no doubt about that.

The gold standard for infection reporting in every state is NHSN. So with an eye towards not adding additional data burden

to ESRD facilities, I think it is imperative that if an infection measure is selected, that NHSN is the repository or the source for that data. But there again needs to be work to interface, build the interface, between CROWNWeb and NHSN.

Areas of concern on this where there were suggested modifications include that there was questioning regarding the 21-day time frame, where if an exclusion of repeat cultures and the question raised why is it 21 days.

Then someone also had a concern that it's not risk-adjusted except for access type, but I would just comment there that catheters are the single or access, temporary access, is single greatest risk factor for bloodstream infections in this population.

Another concern was that it needs to be continuous versus discontinuous, that including patients on the first two working days of the month is problematic, as we have

already heard, although we also heard the argument in favor of a simplified denominator, which I think is also very important when you are considering data burden.

Blood contaminants are not excluded. The data source form is not standard, where we talked about the need for interface with CROWNWeb and using patient year versus patient months, although within the measure summary NHSN shows how it is very easy to convert the patient months to patient years and also to patient days with a simple mathematic calculation.

I think it is important to mention also that this would permit, NHSN permits, facilities to view and analyze their own data. They have a history that shows that this measure has been helpful in identifying bloodstream infection outbreaks and also stimulating performance improvement efforts, which have resulted in reduced bloodstream infection rates.

That's all I have. Thanks.

CO-CHAIR CROOKS: Ruben?

DR. VELEZ: A question more on the process, maybe somebody. If I remember the numerator, it did say that admission to the hospital first, positive blood cultures. How is that data gathered? I mean, how do we --

MS. BARNES: There are three separate measures in the standard NHSN dialysis event module. This measure includes only one of those three. So it's just the positive, blood positive, cultures as the numerator. There is no hospitalization in the numerator for this measure.

DR. VELEZ: But in the definition, if you have positive blood cultures the first day you get hospitalized, that counts in your numerator. I just want to find out, how do we get that data?

MS. BARNES: Dr. Patel, can you comment?

DR. PATEL: Sure. So, you know,

this is kind of the reverse of how we look at hospital-acquired infections. The patient, for example, acquires the infection, what we would consider as the community or outpatient hemodialysis setting.

You know, it's possible that they may not present to their dialysis facility if possible. They may present to an emergency room or a hospital. And that's where they have the blood culture done or diagnosed and are potentially admitted to the hospital.

So, although it is sometimes a challenge to get that information, essentially we rely upon the outpatient dialysis facility to find out what happened to that patient when they were admitted to the hospital and if they were admitted for a bloodstream infection, if that would also be reported. So if that was the admitted diagnosis, that would be reported as a positive blood culture event.

CO-CHAIR CROOKS: So there really isn't a good method for getting that. It's

like a hope and a prayer that someone will go back in the database or put it on the form, it sounds like.

Jeff?

DR. BERNS: This sounds like a huge logistical problem to me. And parts of it are unclear. So what does actually a day mean? A day of hospital admission, I don't know if that's 24 hours or just a calendar day, which is going to cause some confusion I think in collecting data.

But to suspect that a dialysis unit, either an inpatient dialysis unit or an outpatient dialysis unit, has the wherewithal or even any reason to collect this data accurately and make sure it gets back to dialysis, you know, we are also mixing a whole bunch of stuff here.

So we're mixing a positive blood culture due to pneumonia, positive blood culture due to a diabetic foot ulcer or a urinary tract infection that has absolutely

nothing to do with anything that the dialysis unit has any responsible for or impact on. It's just people show up for all kinds of different reasons with infections.

If the issue here is catheters, then let's focus on catheters. It's not to say that a microbiologic performance measure might not have some value --

CO-CHAIR CROOKS: Sue, would you like to respond to this? Let Sue give -- tell us what you think.

MS. BARNES: Actually, the next measure is this exact measure except for it specifies that it must be access-related, vascular access-related.

The reason I voted in favor of the blood culture only, although what you state is certainly the case, when we're doing surveillance for healthcare-associated infections, to me it is important to look at the larger picture.

So we are going to be able to

trend over time where there are issues and where interventions are necessary. It's not perfect unless you do 100 percent record review, very detailed record review, which is never going to happen in any place in any facility. You're not going to have a completely accurate report.

But I think what this will give you is a tool to support performance improvement. And I believe that that is the whole point of it. So it's not perfect, but when compared to the other one, which we'll speak to next, there is a lot more work on the part of the ESRD facilities to determine whether it's access-related or not.

There is less data burden in my opinion with this one. And that is why I voted in favor of this one.

CO-CHAIR CROOKS: Joe?

DR. NALLY: Speaking to that issue of data burden, particularly the common admission to the hospital and the one-day

positive blood culture, that will take extra effort on behalf of the dialysis unit to collect that data.

The unintended consequence is if you want to look better, don't ask your employees to expend the extra effort because all you can do is actually hurt yourself if you think about it. If you work hard to get all the positive blood cultures, my unit will look off than Jeff's unit, who just kind of ignores the situation. And I think that's a --

DR. BERNS: Other way around.

DR. NALLY: Or whatever.

DR. BERNS: My unit was the one that --

CO-CHAIR CROOKS: Myra? Myra is next.

DR. KLEINPETER: One of the things that we're going to burden the dialysis units with is determining whether it's an inpatient status admission versus an outpatient status

admission.

We have time and time again where patients come to the hospital for a one-day stay. Somebody sees an access. They can't get peripheral access. And they use our catheter that's now infected. That's not counted as a hospital-associated infection because they maintain an outpatient status.

So we need to look at one of these other I guess counting metrics that we're going to create a burden for, for the dialysis units if we move forward with this measure.

CO-CHAIR CROOKS: Robert?

DR. PROVENZANO: Yes. I absolutely agree with Myra. This can be gamed way too easily. And although I think we are all talking about the same thing -- and, Sue, I commend you for really being concise in how you view this -- infections are high in dialysis units. They're higher in units that have too many catheters. I think what we are talking about here is decreasing infections

rates, which tend to be linked to catheters.

So creating a measure that can be gamed to create problems add a logistical burden to over-stressed staff I think is the wrong approach. So I would have difficulty supporting this as written.

CO-CHAIR CROOKS: Can you identify a better approach to get at it? Alan has one.

DR. KLIGER: Yes. I endorse Jeff's approach.

CO-CHAIR CROOKS: To do vascular access-related, specifically --

MS. BARNES: Okay. So that is the next measure, actually.

CO-CHAIR CROOKS: That is actually more of a burden.

MS. BARNES: That is the next measure. So we can just say we approve the next measure and then go on from there.

DR. LATTS: Can I ask a question? Sue, this is currently part of NHSN. So it's out there. It's being reported. Whether it's

an NQF-approved measure or not, it's out there.

MS. BARNES: Yes.

DR. LATTS: And the states are going to -- Colorado has already mandated it. Other states will soon mandate it. I'm guessing. I mean, I'm assuming that others will be following soon.

MS. BARNES: The dialysis event module, which includes three metrics, one of which is this one and the other two are hospitalization and IV antibiotics.

DR. LATTS: So whether we approve this or not, it's out there. And it's going to be something that the facilities will be reporting.

MS. BARNES: Let me just confirm that with Dr. Patel. That's right, isn't it?

DR. PATEL: Yes. These are all currently part of NHSN and being collected as part of Colorado's state mandate.

DR. LATTS: And I would bet that

others will be following very closely behind Colorado.

MS. BARNES: They absolutely will, yes. That is our experience in the rest of the community relative to healthcare-associated infection reporting.

DR. LATTS: So I would argue to not approve it because of data burden is a not valid argument given that it will be reported anyways.

DR. PROVENZANO: It is currently reported only in one state. So I don't know that we can jump and state that the other states will come in line.

I want to get back maybe -- and I don't want to speak for Jeff -- and focus on the problems that we know: stratification of accesses in facilities, which is already being monitored, and relating that to positive blood cultures or antibiotics or whatever other matrices of infection.

It is more to what we are trying

to prevent than positive blood cultures in a diverse population that has multiple reasons for blood cultures, but I want to be very sensitive again to what Myra pointed out. Many of these patients show up in an emergency room with sepsis, with a catheter, didn't come to the dialysis unit.

If this becomes an issue of who is taking ownership of that infection, I can guarantee you that a nephrologist is going to say, "You're admitted." The hospital is going to say, "No, you're not." We're going to create an environment that really is not where we want to go.

MS. BARNES: And I know this flies in the face of what currently exists in terms of politics between facilities, but I hope that we are moving more towards a continuum of care philosophy, as opposed to this is my facility and this is your facility. And the whole purpose of these performance metrics is to improve care, regardless of where the

adverse event occurs.

DR. PROVENZANO: Obviously we're moving from a bundled dialysis situation to an ACO model theoretically, January 1st, 2012.

Much of what we just explained hopefully will be repaired and go away. The situation that Myra points to is artificial. It's predicated on a lot of silly things, but it is the reality today.

DR. LATTS: I am sorry. Just one quick clarifying question. If they show up in the ER with sepsis, it is going to be a POA. And so the hospital won't be dinged for it. It's going to be an outpatient-acquired infection.

DR. BERNS: Again, just returning to burden and the logistics of this, if people show up in the emergency room, they may not have been to dialysis for days. The blood cultures drawn on an admission day, the results are known two or three or reported out two or three or four days later.

We have patients from our dialysis facilities who may end up in any number of hospitals throughout the greater Philadelphia area in potentially three states. And to expect that a dialysis unit is going to call on each hospital day until they get confirmation, there are no positive blood cultures, after they have figured out where the patient went in the first place, it is just a burden that is just unrealistic without some support for this. It is unrealistic to expect the dialysis can or should be asked to do this.

MS. BARNES: I don't think the measure proposes that level of surveillance anywhere in there. It says "hospital," yes, that you count those, but it doesn't say how you count those. And it's the same kind of thing that applies to post-discharge hospital-acquired infections. You know, there is a wide variation in how comprehensive that is depending on the resources that you had to

put towards that.

I don't see it saying anywhere that you have to call every hospital to find those dates. What I think will happen is that most likely there will be an under-reporting of positive cultures that occur in the hospital setting.

And, again, we're looking at casting a wide net, a large net. We're looking at the bigger picture. We're looking at it's not perfect. It's not going to catch every infection. It's not going to catch every infection perfectly. It doesn't need to. This is for performance improvement.

DR. LATTS: The other thing I would like to sort of put out there is in terms of the catheter-related or the access-related measure that we're going to review in a second, which I think is probably a better measure from a dialysis perspective. I would think we would want both so that you can compare the two and have a very clear idea

of the infections of the population as a whole and then what percentage of them are catheter-related so that we have an understanding of what the opportunity is and having the denominator, which we are only going to get through this measure, is a much better measure I think than just having the catheter-related by itself.

CO-CHAIR CROOKS: Alan?

DR. KLIGER: In a world of infinite resources, I would agree with you. I think that it would be a much more richer way to examine the question.

I am still concerned about focusing our attention on the right places so that we leave resources for volume, for blood pressure, for all the things that we're talking about in the wider sense. And here is where I again say that I think that Jeff's idea is the right one. We should focus on infection, infection rates, antibiotic use in relation to catheters.

CO-CHAIR CROOKS: There is a greater data burden, actually, for that measure, though, because someone has got to make a somewhat subjective decision, you know -- for both?

DR. LATTS: You've have got to have --

DR. KLIGER: That is what Lisa is arguing.

DR. LATTS: I am saying that you need to know the world of septicemia, of positive blood cultures. And then of those, you need to say which ones are access-related.

So I don't even understand how you can have the access-related blood cultures without knowing first the total positive blood cultures. I don't see how you can have the other measure without having this measure first.

DR. KLIGER: By having your denominator be those with catheters.

DR. LATTS: But that is not the

other measure.

DR. PACE: I just want to make a couple of points here. One is that the measure we are talking about, although it is all bloodstream infections, is stratified by type of vascular access. The difference for the next one is that someone then makes a judgment whether they think that that infection was primarily related to the vascular access, but I would just ask and ask our patients here.

It seems that the -- and it seems also from a clinical standpoint, any bloodstream infection is of importance and is an issue for both patients and providers. So why you wouldn't want a more global bloodstream infection measure, that's I guess my question.

CO-CHAIR CROOKS: Ruben?

DR. VELEZ: Again, you know, going back to what has been said -- and I think Jeff summarized it very well -- I have a worry

about data collection on this. And we are going to discuss the same thing on the next measure. It's the same thing. This first hospitalization date comes up again.

And, you know, I think we either ask the owners of the measure, would they consider dropping that or are we going to have the same discussion later on?

MS. BARNES: Maybe could we ask Dr. Patel to address that one issue around hospital day because I don't really perceive that to be a huge showstopper for either measure but would appreciate her expert response on that.

DR. PACE: Right. And also they reported some validity data. So if she has any specifics about validity around that particular issue as well?

CO-CHAIR CROOKS: Dr. Patel?

DR. PATEL: Right. What I would like to bring to people's attention is what some folks have said already, that what we are

trying to do is capture the entire picture of infections that happen in the community setting in this population.

Though what we found in most instances, there are certainly challenges in getting this information at times, we don't expect facilities to call hospitals on a daily basis to try to get this information. But the reality is that the reason patients are admitted to hospitals is important for their clinical care.

So when a patient comes back to the unit from the hospital, I think it's really important, I think most clinicians would agree, it's important to know why they were admitted to the hospital, why they were admitted to the hospital, were they diagnosed with a bloodstream infection, did they have change to their vascular access, and were they started on IV antibiotics that need to be continued in the outpatient setting. So a lot of that information is information that is

routinely pursued for clinical care reasons that are completely separate from this surveillance activity.

So what we envision is that most of this is information that should be captured as part of that process anyway, as part of the facility team taking care of the patient.

To address the issue of gaming the numbers, I think we're concerned about that, but we're also concerned that if you exclude this portion, if you say, "We're only going to count blood cultures that are done in the outpatient unit," you can pretty much be guaranteed that that will be gamed because blood cultures can be done in so many other places. And it's easy for facilities to send their patients elsewhere and have blood cultures done there.

So those are our two concerns. And to address the question about validity testing, I don't recall that we specifically looked at this aspect in terms of how many of

the blood cultures were captured that were done during an admission, for example, because we don't actually make a distinction. When the facility reports that information to us, we don't know whether the blood culture was done in the outpatient unit or elsewhere, but that's something that we can try to look at in the future.

CO-CHAIR CROOKS: Okay. So to summarize this portion of the discussion, I would say data collection will not be perfect and data collection does not have to be perfect.

MS. BARNES: Absolutely.

CO-CHAIR CROOKS: All right?

MS. BARNES: Not for performance improvement.

CO-CHAIR CROOKS: Right.

MS. BARNES: For publication, for research, but this is neither. This is for performance improvement. It does not need to be perfect.

CO-CHAIR CROOKS: Okay. So --

DR. PACE: NQF endorsement is for measures for both public reporting and quality improvement.

MS. BARNES: And for neither does the --

CO-CHAIR CROOKS: For neither does it have to be perfect, is it ever perfect, really.

Helen?

DR. BURSTIN: One very minor point. I just want to confirm with CDC that this measure is, in fact, fully harmonized with our current bloodstream infection measure for hospitals.

DR. PACE: That would be a direct question for you, Dr. Patel.

CO-CHAIR CROOKS: Dr. Patel, did you hear the question?

MS. BARNES: It is not, actually. And Dr. Patel can add onto this, but this is a different setting. It is a different

measure. It can be -- you can easily convert the denominator for this metric to be per 1,000 patient days, which is what it is in the hospital. Dr. Patel, would you add to that?

DR. PATEL: Right. So it is not captured the exact same way. The burden of data capture has been decreased substantially because we realize this is being primarily done in outpatient settings.

So we don't have as vigorous a case definition that needs to be applied. We just simply collect, you know, primarily very objective information and try to build the case definition based on that.

And then, of course, the timing is considered to be sort of inverse. So, you know, within two hospital days or later of a hospital admission is considered hospital-acquired. And then we try to capture the community onset.

DR. BURSTIN: I just want to also point out that, at least currently, -- and I

don't know what it is on the dialysis, but there are 22 states that have already mandated use of NHSN for HAIs, which has been the reason that most of the HAI measures going through our process at least have been based on NHSN.

So even if it's not exactly the same because it can't possibly be given a difference in setting, I think there is an important consistency issue there.

And I would hope that, again, we're looking at these measures one by one, but I hope at the end of this -- you know, it might be helpful at some point just to take a look at the overall set of infection measures here, perhaps prioritize them, figure out how to align what is being done in CROWNWeb with what is happening in NHSN because the idea of doing both doesn't make sense, I think, as Sue pointed out.

MS. BARNES: I completely agree. And this is already in the NHSN database being

collected by more than 100 facilities mandated in at least one state. And it looks like that will be expanded based on our experience with other HAI.

DR. BERNS: Has anybody in those states where this is in place done anything to estimate the reliability or the accuracy of the data that is being collected to know how much it actually accounts for?

MS. BARNES: Dr. Patel?

DR. PATEL: I didn't hear that last part of that question. How much it accounts for?

DR. BERNS: The question I'm asking is, in the states in which this is mandated, what efforts have been made to confirm that all the energy that's expended to collect the data generates useful or at least generates accurate and reliable data?

In other words, are you capturing 20 percent of the actual bloodstream infections, 80 percent, 90 percent? And do

you have an estimate of what is the work effort that is involved in generating that or in collecting the data?

DR. PATEL: I will start with the last question first. The best estimate that we have that has actually been published in terms of the amount of staff time required to do the surveillance -- and this is the entire surveillance, not just this particular measure -- is about two hours per month.

So this facility -- I believe this article was cited in the information that we submitted, but there is an article by George, et al., in the British Medical Journal that describes their experience doing this analysis surveillance. They said after a start-up period, it required two hours of staff time per month to actually fully follow the protocol and do the surveillance.

We informally pulled facilities that are doing the surveillance. And for the most part, they have agreed with that with

some exceptions.

In terms of the states that are -- the state that has mandated this and validation efforts, Colorado just recently started. So they intend to take some time to actually look at their data before they publicly report it. And they do have plans for a validation, but it's tied to a validation study that CDC has begun now as well.

The primary purpose of CDC's validation study is to actually look at electronic data that exists at large dialysis organizations and how well they do at capturing bloodstream infections and that the goal is to look at all bloodstream infections, understanding that there are going to be some that are not captured within that outpatient dialysis setting or within the laboratory data sets that are linked to large dialysis organization laboratories.

But, then, a secondary part of

that, one of the sites for that validity study includes Colorado, where they have the mandate. And so they will also be able to compare these three sources of data, one being NHSN. These same dialysis facilities that are reporting to NHSN also have electronic data in the large dialysis organization databases. And then we will do a separate manual data extraction looking at the actual records in the facilities to validate the data that are in both of those.

CO-CHAIR CROOKS: Let me suggest that if you are asking questions now or discussing that you need this for clarification for your vote, rather than to persuade others because I think we are getting close to being able to vote.

Robert?

DR. PROVENZANO: Let me just mention I practice in Colorado. It is a burden. It is a burden. On Monday morning, the facility administrators with the LDOs

start making the phone calls. And, at least my estimation of observing the amount of time and effort put into this, it's more than two hours a month. I mean, I can tell you from firsthand experience.

CO-CHAIR CROOKS: But as a clinician, you want to know when that patient comes back, this patient has septicemia and was hospitalized and here is what happened in the hospital, right?

DR. PROVENZANO: No, no, no. I'm not saying I don't want to know that. What I'm saying, I'm addressing how much time it takes.

CO-CHAIR CROOKS: Right.

DR. PROVENZANO: It is a burden on the staff.

CO-CHAIR CROOKS: Wouldn't it be okay that when the patient comes back and you get their discharge summary, then you enter it into the computer? Does it have to be real time, that day?

DR. PROVENZANO: I think what happens, Peter, is that when a patient doesn't show up, the process then begins. You know, where is the patient? Why are they there? And so because of the mandate, they start collecting that data so that they can report on it.

DR. PACE: Wouldn't you being doing that anyway? Even if you weren't collecting this data for this measure, if a patient doesn't show up, you're not going to be doing the same thing or what?

DR. PROVENZANO: Again, the question was, what was the burden on the staff? Now we --

DR. PACE: Extra burden.

DR. PROVENZANO: It's an additional burden of patient admitted for congestive heart failure to patient admitted for sepsis. Did you get blood cultures? Do you have that result? So it's the layering because there is no data communication. It

has to be done verbally on the phone.

MS. BARNES: Okay. So, then, just to remind you that the next measure will involve even more data burden. So that's why I was arguing in favor of this one, which would also position facilities to participate in the existing NHSN dialysis event module.

CO-CHAIR CROOKS: Okay. Myra?

DR. KLEINPETER: One other thing in terms of the data burden. For those people that are in places where there is a huge ambulance diversion problem, on my Monday morning, the nurses have to call every hospital in the area, even though I sent them to the one that's two miles away.

You know, it's a 50/50 shot if they end up at that hospital. They could end up anywhere in the metro area depending on the ambulance diversion problem.

DR. LATTS: Aren't you going to have to do that anyways? I mean, don't you want to find them?

DR. KLEINPETER: I want to find them, but the issue is I don't always get the information until some social worker is calling me to say, "I want to send this patient home. This is what happened." And the nurses may have expended a lot of effort trying to find this patient.

DR. LATTS: I mean, I 100 percent agree that is a problem. I just don't see what that has to do with this measure. I mean, it's a huge problem for clinical practice. It's a huge problem.

And, you know, we need interoperable medical records so the hospital is going to send you electronically everything you need to know what happened in that hospitalization. I mean, that's one of the problems of our healthcare system today. I just don't necessarily think that's a reflection and a reason that this measure should not be measured.

MS. BARNES: And just to remind

you, Dr. Patel did confirm that it is not in this measure. There is nowhere in this measure an expectation that you do that.

CO-CHAIR CROOKS: Okay. Jerry?

DR. JACKSON: I am not saying this is the best measure in the whole set to address what we are trying to accomplish here, but generally if somebody is admitted to the hospital, they have a positive blood culture, they're going to come out of the hospital on an antibiotic. That information is going to be communicated to us at the dialysis center. Just to say that's another way that we are going to be able to -- that is going to trigger our knowledge to add that to the data collection.

CO-CHAIR CROOKS: Yes. I would argue that there is no requirement. This is real time. You have to put it in three minutes after the culture report comes back. You can put it in a week later. And that is fine.

So why is the staff calling? They may be calling for other reasons, but they don't need to be calling to get blood culture reports.

I might add you mentioned that if a patient is admitted for congestive heart failure, you wouldn't suspect a bacteremia. That is not correct. You know, a patient can present with CHF due to bacteremia. So we have to be looking for blood cultures for any hospitalization, right? Yes.

Ruben?

DR. VELEZ: I think it is more the reality -- and maybe I live in a place that in my unit, they go to 22 different facilities -- yes, you can put the data in when it comes to you.

Many times a discharge summary will not tell you when that positive blood culture happened. Was it day one or day five of the hospital? So we would have to ask a lot more questions. The staff will have to

spend more time doing this.

I was very supportive and I am still supportive of all the infection because, I mean, that's really high on our radar gun. And we have to do something. It's just a scenario of this first day of hospitalization.

I understand the reason for it. It is just the reality of it.

CO-CHAIR CROOKS: I think we have heard enough about -- you know, this is maybe a sizeable fraction, maybe a small fraction, but, you know, perfect isn't necessary or required to improve quality or to report publicly.

DR. VASSALOTTI: I want to ask Dr. Patel, can you harmonize the data from the hospital and from the dialysis facility in Colorado? You will know for a single patient if they have a positive blood culture, irrespective of location?

CO-CHAIR CROOKS: That is a question for Dr. Patel?

DR. PATEL: You mean would we be able to tell whether the positive blood culture that occurred was in a hospital or in the outpatient dialysis facility?

DR. VASSALOTTI: Yes. Can you put the data together from the two sources?

DR. PATEL: I don't know that we have a way of doing that right now. I mean, the only way that we can look at that is through one of these validation efforts, where we are actually actively going and finding cases that occurred in hospitals and making sure that they were also identified by the outpatient dialysis facility.

CO-CHAIR CROOKS: Okay. Thanks.

So are we ready to vote?

(No response.)

CO-CHAIR CROOKS: All right. Very good.

DR. PACE: Okay. This is measure 1460, importance to measure and report. And keep in mind what these criteria are. I know

we had a lot of discussion about feasibility, but that's on feasibility.

(Pause.)

DR. PACE: Has everybody voted? Okay.

CO-CHAIR SCHONDER: It was 17 yes and 2 no.

DR. PACE: Okay. We will go to scientific acceptability of measure properties. Go ahead. Wait until the timer is started.

(Pause.)

CO-CHAIR SCHONDER: Four complete, 16 partially.

DR. PACE: Okay. Next is usability. Wait until the timer starts.

(Pause.)

CO-CHAIR SCHONDER: Six completely, ten partially, three minimally, and one not at all.

DR. PACE: And before we vote on the measure, -- and I should have said this at

the very beginning or reminded you we have a lot of infection measures. And what we are doing right now is to see if each individually would meet the criteria.

Once we get through that, we are going to definitely have to look at this set to determine if we've got duplicative measures, if there is a way to choose the best way to measure this in this population. So, again, we're evaluating each individually right now.

So the next one is feasibility.

(Pause.)

CO-CHAIR SCHONDER: One completely, nine partially, and nine minimally.

DR. PACE: And then, finally, do you recommend the measure for endorsement?

(Pause.)

CO-CHAIR SCHONDER: Thirteen yes and seven no.

CO-CHAIR CROOKS: Okay. We would

like to get one or two more done before lunch. What time is lunch?

DR. PACE: We will do this last CDC measure. And then we will do -- pardon me? Oh, two more CDC. I'm sorry.

CO-CHAIR CROOKS: No. There's no --

DR. PACE: I thought we did. All right.

CO-CHAIR CROOKS: One more NHSN.

DR. PACE: Why don't we do that measure. Then we'll have public comments. And then we'll break for lunch.

CO-CHAIR CROOKS: Okay. Very good. So the next measure is 1478, "NHSN Vascular Access-Related Bloodstream Infection Measure." Sue?

1478, NATIONAL HEALTHCARE SAFETY NETWORK (NHSN) VASCULAR ACCESS-RELATED BLOODSTREAM INFECTION MEASURE

MS. BARNES: So this is the number of hemodialysis outpatients with positive

blood cultures and in whom the suspected source was reported as either the vascular access or unknown, same denominator.

From the preliminary evaluations, two voted in favor and four against. Just so you know, this is basically the very same measure with that one exception that we have already noted, which is that it attributes the infection to a vascular access.

So the arguments in favor are all the same, that, you know, the existing database and data stream and testing and the arguments -- and also that, you know, it gives you more information relative to vascular access-related infections.

Arguments against are all of those that we already heard as well. I don't think there are any additional arguments against except that possibly this could be considered a greater data burden.

DR. BERNS: Can I just ask for some clarification?

CO-CHAIR CROOKS: Jeff, please?

DR. BERNS: Who and how is the determination made about -- yes. And how is this documented? Who makes the decision? How is it transmitted, all those sorts of things?

MS. BARNES: So, Dr. Patel?

DR. PATEL: There is a question on the data entry form or the event report form that basically asks the suspected source of the positive blood culture if there is a positive blood culture.

We don't dictate who makes that determination. So it could be the nurse. It could be the physician, attending physician. But we simply ask that question of whoever is submitting that data. So we don't specify who should make that decision.

DR. PACE: And is it specified? It just says in the numerator details "suspected source." So that's up to each individual organization to determine how they make that determination of what is the

suspected source? Are there any guidelines for that?

DR. PATEL: The only guidance that we provide is we provide the same suggestions that are included in the BSI surveillance that's done on the inpatient side, particularly with respect to contaminants or common skin contaminants.

So we provide a list of common skin contaminants. And we say that, you know, "If you have a positive culture for some of these, consider whether it could be a contaminant." But, really, the rest of it is up to the person in the facility.

MS. BARNES: So, just in summary, I would say that the reason I voted against this measure is only because I think it is really important to minimize data burden. And so one infection measure to me is sufficient. I voted against all the other measures as well for that reason and in favor of NHSN as the gold standard for healthcare-associated

infection reporting.

DR. VELEZ: I think in this measure, again, it leaves a lot to people's wish lists. If you have a catheter patient, you always are suspicious that a positive blood culture was the catheter. So you would say, "suspected," although you would pick the unknown.

Catheter looks great on the outside. Everything looks fine. This measure does take away the diabetic with the foot ulcer because that is eliminated from this. And that is good. But this is suspicion versus unknown. It depends on the day of the week and who is making rounds on how fast they go.

And I have a lot of concerns, even though, again, this is a very important measure.

CO-CHAIR CROOKS: Isn't it also kind of a bias to the evaluating physician to judge it not to be a vascular access

infection? Is that a problem possibly?

DR. NALLY: Just to add to this discussion, it is important to know who that person is and whether or not they could be one of a number of physicians that, as you said, 20 different hospitals that weigh in on that judgment and dictate a discharge summary.

My specific question for Dr. Patel is, of all these positive blood cultures associated with vascular access, my suspicion would be there would be a high number of hospitalizations associated with this. What percent of the positive blood culture access-related are hospitalized?

DR. PATEL: I do have that information. Unfortunately, I don't have it right in front of me. If there's a way for me -- we're still on lock-down because of the ice storm. But if there is a way for me to get that to you later today or later this week, I could do that.

DR. NALLY: Thank you.

DR. PACE: Yes. You can send that to us.

DR. PATEL: Okay. I apologize for that.

DR. PACE: Send it to Lauren.

DR. VASSALOTTI: I just want to add that --

CO-CHAIR CROOKS: Jeff, yes?

DR. VASSALOTTI: -- I have been adjudicating admissions for the frequent hemodialysis network trial for the Outcomes Committee. We are blinded to patient-specific information. And we look at hospitalizations and data regarding positive blood culture for this very purpose to determine if they are vascular access-related or not.

And, even with the best minds and the best experts in the field, well-meaning, blinded to the individual, it is sometimes very difficult, even with a lot of information, to determine this. Even being blinded to the -- without even having any

biases for the outcomes or incentives for the outcomes, it can be difficult. So that is a concern.

CO-CHAIR CROOKS: Thank you.

Alan?

DR. KLIGER: I guess what is interesting to me is that the measure still is not -- either one of these, the one that I think is of interest, which is that group of patients with catheters that have bloodstream infections, not the judgment of the doctor if they were related but simply presence of a catheter and bloodstream infection.

CO-CHAIR CROOKS: Well, if there is a catheter present, there will be a bloodstream infection sooner or later, right?

DR. PACE: You would get that from the other, you would have that in the other measure because you have it stratified by the type of vascular access. I mean, that --

DR. KLIGER: That is right. But I guess I am just focusing our attention as we

rate these, that my own sense is that it's that cross-referencing that really is of most importance.

DR. VASSALOTTI: That is the patient population for where this is probably most actionable. That is the --

MS. BARNES: And that is what this measure gives you without the complicated algorithmic definition that is required for the inpatient side. Would you add anything to that, Dr. Patel?

DR. PATEL: No. That is exactly right. So it does give you that. And we understand and realize that there is subjectivity and sort of this determination of whether it's access-related or not. And that is the reason that we like to look at both the all BSI measure stratified by vascular access type as well as the BSIs that are determined to be vascular access-related.

CO-CHAIR CROOKS: Other comments?

DR. VELEZ: And the question is,

the measure we just approved, what does this measure add that the other one doesn't already help there? Judgment. That is about it because the other one tells us if you have a catheter and --

MS. BARNES: That is why I voted against it and all the other measures as well. I think in my opinion, we need one infection measure because there is a single source most frequently reported in this patient population.

CO-CHAIR CROOKS: So I see nods of "I'm ready to vote" on everybody's face. Am I reading right? Okay.

DR. PACE: Okay. This is measure 1478. And we'll start with importance to measure and report. And wait until the timer starts.

(Pause.)

CO-CHAIR SCHONDER: Twelve yeses and one no.

CO-CHAIR CROOKS: Eight nos.

CO-CHAIR SCHONDER: I am sorry. Eight nos.

DR. KLIGER: You must be from Chicago.

(Laughter.)

DR. PACE: Okay. Next is scientific acceptability of measure properties.

(Pause.)

CO-CHAIR SCHONDER: Two completely, 11 partially, and 7 minimally.

DR. PACE: Next is usability.

(Pause.)

DR. PACE: Is everyone finished? Okay.

CO-CHAIR SCHONDER: Two completely, nine partially, seven minimally, one not at all.

DR. PACE: Next is feasibility.

(Pause.)

CO-CHAIR SCHONDER: Eight partially, ten minimally, two not at all.

DR. PACE: Okay. And, finally, would you recommend this measure for endorsement?

(Pause.)

CO-CHAIR SCHONDER: Four yes and 16 no.

CO-CHAIR CROOKS: Okay. It is time to allow for public comment and also comments from the measure developers. Who would like to start? Anyone? No? Anyone on the phone?

THE OPERATOR: As a reminder, that is *1 for a comment over the telephone.

(No response.)

THE OPERATOR: We have no one over the telephone at this time, sir.

CO-CHAIR CROOKS: Thank you.

All right. Then I guess we are good to break for lunch. We are going to try to -- do we want to do a lunch like we did yesterday, where we come back in 15 minutes and get moving again? I would recommend that.

If the Committee could do that, I would appreciate it. And so, Kristine, thank you very much.

DR. PACE: So we will try to reconvene at 12:15.

(Whereupon, the above-entitled matter went off the record at 11:56 p.m. and resumed at 12:17 p.m.)

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

(12:17 p.m.)

CO-CHAIR SCHONDER: We will start off with measure number 1456, "Bacteremia (Rate)." And Andrew stepped out. So I'll tell you what. In the interest of time, let's move forward, then, put Jerry on the spot, let him finish chewing. We'll move ahead, then, to 1457. And we'll come back to the bac. So 1457, "Access-Related Bacteremia (Rate)."

1457, ACCESS-RELATED BACTEREMIA (RATE)

[STRATIFIED BY ACCESS]

DR. JACKSON: Six-month rolling average rate of access-related bacteremia treated with IV antibiotics among adult dialysis patients expresses a rate for 1,000 hemodialysis patient days. So the numerator is the number of new antibiotic starts. And, specifically for vascular acts, those vascular acts, as related with a positive blood culture, the denominator is the number of patient days for maintenance in the dialysis.

It excludes patients under 18 years of age.

The reviewers were very strongly positive on the importance of measure and report. There was one disagreement on that, but overall it was felt very highly important.

It was extremely widespread variation on the responses to the scientific acceptability of the measure properties. Likewise, the usability and feasibility was rated fairly low. The main strength was the importance to measure and report. The weakness was that there was full evidence provided about a performance gap. There was no reliability testing as yet.

It was unclear. There was one comment that it was unclear in the denominator when stratification is done if a patient who has a catheter, yet has a developing fistula or graft would be included as a catheter patient or how best to find that could be a significant subcategory.

The biggest concern among the

reviewers was the made for a subjective call on the source of the infection being the access. And one other comment was that for an antibiotic prescribed, that it could be one episode of infection and because it's prescribed on two consecutive calendar months, that it might be counted twice, but that clearly does not occur that often.

So in going through the --

DR. PACE: Can you use the microphone?

DR. JACKSON: Yes. Sorry. Do I need to repeat anything that I've reviewed yet? Overall I'm only seeing three votes: one yes, two nos -- oh, two and two. I'm sorry.

DR. PACE: I think three and one. Three and one.

DR. JACKSON: No. It's importance to measure. My drive does not have all of the responses. Could you scroll over to the final tally? Two and two. Okay.

I would just like to comment that the document that CMS put out on their overall strategy for studying infections was pretty convincing to me. And it would require looking at these as a family of measures.

I know we're looking at this as an individual measure, but it looks like what they were trying to accomplish, what the workgroup was trying to accomplish, is looking at quite a few aspects of infection in dialysis units, as described in their overlapping Venn diagrams and their documents. So I hope everybody has seen that and reviewed that.

CO-CHAIR SCHONDER: Any comments from the other reviewers?

(No response.)

CO-CHAIR SCHONDER: From the Committee?

MS. BARNES: I would just again mention my philosophy or perspective when looking at performance improvement overall is

that measurement is just one aspect of that. And so to not, you know, put all of the eggs in one basket or consider this to be the only way to get improved performance by measurement -- and when CMS is talking about, you know, a myriad of metrics for just one aspect of care, I would be concerned.

CO-CHAIR CROOKS: I would like to just kind of step back for a minute. And this is sort of germane to what you are saying. And look at what their approach was. If people had time to read the document the TEP prepared about why they submitted five metrics that are kind of interrelated with Venn diagrams showing how they relate to each other, I think they made a nice case of, you know, if you really want to understand in a global way what is going on, this matrix of metrics -- matrix of metrics, wow, I like that -- would, you know, give you a broad picture, be able to dissect out different things, you know, maybe in theory. I'm not sure if it

works in reality.

But I was attracted. I found that kind of compelling that this would be the idea world. You would have all of this information and you would be able to drill down and get stuff, you know.

Do you have a problem with that or you think that is just too unrealistic?

MS. BARNES: No. I am in support of diagrams.

(Laughter.)

MS. BARNES: But I do think that it would be prudent for CMS and other regulators to look to content experts when metrics are being proposed. And in this case APIC and SHEA would be the predominant for this country professional organizations that represent content experts. And NHSN is the partner of SHEA and APIC. So --

CO-CHAIR CROOKS: I'm surprised, you know, they weren't at the table. Wait. We have some --

DR. MESSANA: Excuse me. Dr. Priti Patel was a member of the CTEP and contributed significantly. So we did have a content expert.

CO-CHAIR CROOKS: That's good to know.

MS. BARNES: CDC, not APIC or SHEA, though.

CO-CHAIR CROOKS: Okay. Other --

CO-CHAIR SCHONDER: Comments?

CO-CHAIR CROOKS: I find, you know, it's kind of artistic, you know, the way that all fits together. You know, but I don't know whether practically it works out. It's a lot of -- I would also like to just say that, as opposed to the -- I mean, I think the data collection is less of a burden here, although just saying it's on CROWNWeb doesn't make it necessarily easier because it's got to get into CROWNWeb in some way. There has to be a process. There has to be human interaction to get that done.

DR. LATTS: Can I just ask a question about that? If the data elements are in CROWNWeb and dialysis facilities have to use CROWNWeb, does that mean they have to fill out the data elements? I mean, is there some requirement for a complete data entry into CROWNWeb? So even if we don't approve the measure, the data will be in CROWNWeb? How does it work?

DR. MESSANA: Are you asking --

DR. LATTS: The measure developer? Sure. Yes, yes.

DR. MESSANA: Because of the time lag in developing the business requirements documents and the data elements for CROWNWeb, all of the data elements for all of the measures that we submitted, including the infection measures, have been requested and are in the next iteration, you know, iteration of CROWNWeb.

My understanding -- I'm not a CROWNWeb expert -- is that they can inactivate

those. But to make it possible to enter the data, they have the business requirements prior to even submission of these measures to you all.

So the data elements are available, but whether they need to be used or not I'm less certain about.

CO-CHAIR SCHONDER: Connie?

MS. ANDERSON: Right now dialysis facilities as of July 1st of 2010 have to report access-related infections. And it has to be documented by a positive blood culture. And it has to be treated with antibiotics. And those are now currently going to the dialysis, to the facility bills. They're required.

CO-CHAIR SCHONDER: Peter?

MS. ANDERSON: So there is no burden of providing that information.

CO-CHAIR CROOKS: This measure and the whole group of measures, these five measures, these four or five measures, are all

for time-limited only because they have not been tested. And that also appears to me in a sense that this is kind of a complex, comprehensive look at it, you know, maybe it's a chance to find out if it works.

I don't think in their testing, they're going to mandate every -- would you make everybody participate or you'd say we're going to test in a subset of facilities or, you know, in terms of burden?

DR. MESSANA: I think that decision would require input from our CMS officers in CMS.

DR. WOLFE: That impact, to my knowledge, there is no way to do a sample within CROWNWeb when it is -- except they are being rolled in. Some facilities do not currently have a requirement to contribute to CROWNWeb.

CO-CHAIR CROOKS: Let me ask this question to you, too. These data elements that you need for this metric, you are going

to be collecting them anyway, right? I mean, this isn't -- you're not going to add it if you get endorsement or not add it if you don't get endorsement. Is that --

DR. MESSANA: The data elements are available. I am less certain about whether they can be inactivated or not relating to Lisa's question. inactivated.

DR. WOLFE: But it is important, I think, to distinguish between two sets of data elements. There are data elements in CROWNWeb. And several of the measures are defined in terms of CROWNWeb data.

There is another measure, which is based upon the billing data, which you referred to. And I think it's important and valuable for the Committee to consider the differences between these measures and the data burdens that are inherent in them.

CO-CHAIR CROOKS: Well, one of the five is --

DR. WOLFE: It's not as though

there is a package which does it all. There is a measure based upon the claims, recognizing that that is currently in place and those are already being submitted. And the CROWNWeb is submitted, not for the entire universe yet.

DR. MESSANA: Right. So, for the Committee, 1455 I believe is the claims-based measure and all of the other or part of that CROWNWeb data collection package.

CO-CHAIR CROOKS: I guess what I am getting at is if I believed that endorsing these measures for time-limited endorsement would not increase the burden on dialysis facilities, I would be more likely to vote for it, you know, as opposed to saying by endorsing these, now for tests, we're putting a big burden on dialysis facilities.

DR. MESSANA: So the CROWNWeb data to date is almost entirely batch submission -- okay? -- as I pointed out in my opening comments yesterday. So 60 percent of

facilities are submitting by batch.

The three largest dialysis organizations have ongoing work and actually had representation, active representation, on the data TEP when they considered these measures and in the synchronization subsequently. And so they have already been exposed to these data elements and had significant input.

So other than taking the clinical information, no matter which of the measures, if you talk about the NHSN measures or our measures, you have to abstract from the clinical record. And then with NHSN, you have to enter at a web portal. With the CROWNWeb measures, that same abstraction should lead to a batch submission as part of the overall CROWNWeb batch submission. So it's unclear to me which is the bigger or less data collection burden.

DR. WOLFE: In terms of the abstraction, it's essentially the same

information. In terms of submission, currently it's already built into CROWNWeb for many, many facilities that are in the change but not at the independence. And for the claims data, that is already in place.

DR. DUDLEY: Joe and Bob? This is Tom Dudley from CMS. Can you hear me?

CO-CHAIR CROOKS: Yes.

CO-CHAIR SCHONDER: Yes. Go ahead.

DR. DUDLEY: Okay. With regards to CROWNWeb and the data submission, the full national rollout for CROWNWeb is currently scheduled for late spring of this year. And as Bob and Joe have mentioned, the data elements to support these measures are included.

And under the conditions for coverage that were published in 2007 or 2008, facilities are required to submit 100 percent of the data as required by CMS. So as far as the burden question, there won't be any

additional burden outside of what is already required by the facilities.

CO-CHAIR SCHONDER: Barb?

DR. FIVUSH: I guess I just have a couple of comments based on what I heard. I would just like to point out to start with, though, my understanding is that, although many of our dialysis units are part of LDOs, they're an independent unit. And the burden on them is already greater because they're not part of an LDO.

And so if there's 100 percent reporting, I think we have to think about independent dialysis facilities. We can't just erase the burden because they're not part of an LDO.

But in listening to what Tom said and in listening back here, I'm confused as to Tom indicated that this was part of the CROWNWeb system. And, regardless of whether we approve this measure, that data is going to be collected, irregardless. So it doesn't

change the data burden, whether we measure it or not, in a sense.

I thought I heard you saying we might not collect it if we weren't going to approve the measure. And I --

DR. MESSANA: I expressed ignorance about whether or not --

DR. FIVUSH: Okay. We might.

DR. MESSANA: -- the data collection would continue.

DR. FIVUSH: So I guess I don't know the answer to the question.

CO-CHAIR CROOKS: We just heard that as part of the conditions of coverage, this is going to be required. If you have this information, you need to submit it, whether you're a small, independent unit or an LDO.

DR. FIVUSH: But, Peter, I thought what Tom said -- and there are other people who may have better knowledge of it. As part of the conditions of coverage, you're going to

have to participate in CROWNWeb, which is correct.

But the question is, is the CROWNWeb -- maybe Tom can tell us -- is the CROWNWeb going to change depending on what measures -- are the specifications and what you enter on CROWNWeb going to change or expand depending on what NQF ultimately endorses? Are they going to expand the measure set?

CO-CHAIR CROOKS: I think that is what I was asking. And I think I got an answer that no, they are going to collect this information anyway.

DR. FIVUSH: Regardless --

CO-CHAIR CROOKS: Regardless.

DR. FIVUSH: -- of what we do.

DR. PACE: Tom, do you want to confirm that? This has already been set in terms -- I mean, CROWNWeb is well underway.

DR. FIVUSH: Right.

DR. PACE: It is going to roll

out.

DR. DUDLEY: Yes. The data elements -- we were required to submit the data elements to the developers of CROWNWeb last May. So we built in the elements based on our best knowledge at that point in time. We don't have the opportunity to add additional elements at this time to the last rollout of CROWNWeb. The conditions would come back.

Can we remove elements or deactivate? Yes. We have that option. And based on the Steering Committee's decision, we will definitely take that under consideration if we deactivate or make some of the data elements optional.

But at this point we're expecting facilities, regardless of large facilities, LDOs or SDOs or independents, we expect them to submit the data as required.

DR. PACE: Can I make one comment or question to Tom? I mean, just as in your

home health or nursing home data collection, not every data element has to be for the purpose of quality measurement. A lot of it relates to clinical care and care planning. And so, you know, it could be valuable information. It may not be -- not every data element has to be justified by being in a quality measure.

DR. DUDLEY: That is correct. That is to NDS, which I am very intimately involved with. But NDS itself is kind of unique in that it is used for payment survey and quality measurement. But, to answer your question, yes. They're not solely for the purposes of measuring quality.

CO-CHAIR SCHONDER: Connie?

MS. ANDERSON: Just a point of clarification. The SDOs do not do that entry into CROWNWeb. We are manually entering. And there is a significant burden to the SDOs and the independents to have to enter this data.

We were part of the phase-in of

CROWNWeb in one of the trial centers. So I can attest to it personally. It is hours and hours of data entry time.

DR. DUDLEY: Yes. And I appreciate that. The developers -- and I'm certainly on the measure development site. I'm not in the condition side. I'm kind of being a messenger here. So I'm trying to separate myself.

Having been in the facilities, I respect and understand that, but the conditions do require 100 percent submission. I know the developers are working with NRAA right now on a means to support the smaller facilities or the independents to figure out a way for them to also do the batch submission. Unfortunately, I don't know the status of that at this point.

And I know that it's been acknowledged that the burden concern for the smaller facilities with fewer resources is realized. I just don't have an update for you

on that as far as how far along they are in building in additions to the batch submission.

CO-CHAIR CROOKS: My thought about the whole group is if this data is being collected anyway, you know, it's an opportunity to really see if this kind of approach is useful without adding any additional burden. There is a burden there already, agreed, but it wouldn't add additional burden. It would be useful to take a look at it.

Now, they may not need NQF endorsement to do that project. In other words, you know, they should be deciding this is a broad-based approach to infection management, quality improvement in the dialysis setting. And we need to do this. You know, I'm not sure they need NQF endorsement to do that, but I would encourage them to do that.

CO-CHAIR SCHONDER: Andrew?

DR. NARVA: Since all of these

would only have a time-limited approval because none of them have been tested and since they are going to be tested anyway, I'm not really sure. This is a completely academic discussion we are having. And do we need to consider them as a suite, then, instead of individually? Because individually they don't necessarily make that much sense.

DR. BURSTIN: Just to point out, again, time-limited measures are endorsed, which means CMS could use them immediately, even while testing them. So you have to feel comfortable that these measures truly meet all of the -- you know, again, meet all of the evaluation criteria. And I guess we need to have some sense of comfort that what's in here will likely be resulting in being reliable and valid.

So it's not as if it's -- I mean, unless CMS thinks otherwise, we can't say for sure that these measures won't be put into use while they're being tested and assessed.

DR. PACE: One other point. You know, obviously we'll have a competing measure in the NHSN measure, which does have some reliability and validity information. And, even though these data are collected, the data elements are collected, it doesn't mean that they can't construct measures in different configurations using those same data elements.

So one of the questions that we'll be addressing when we look at comparison of measures is what is the difference between the CMS measure and the CDC measure. And are there justifications for those differences? Could the data that is going to be available in CROWNWeb be exactly the same measure, which I think came up in the discussion before? Why not have some interconnection between those?

But those will be addressed when we get to comparing measures. So the question before you now is --

CO-CHAIR CROOKS: There was no CDC system. I'm sorry.

DR. PACE: Yes. No. Go ahead.

CO-CHAIR CROOKS: I just caught this thought from your head. It was amazing. If there is no CDC proposal, how would we respond to this?

DR. DUDLEY: This is Tom again. Can I just chime in about the interconnectivity of the two systems?

DR. PACE: Yes.

DR. DUDLEY: There are active conversations going on and have been for a while between CDC and CMS, but the connecting of the data between NHSN and CROWNWeb, not that within the government there are any hurdles or anything, but there are obstacles that we are trying to overcome to make that possible. We are sure that will happen, but we want to minimize any duplication of data collection.

There are efforts underway to have the two systems communication with each other. We're just not there yet.

DR. PACE: And, Tom, let me just ask you to maybe comment on, then -- again, this will be an issue for when we get to comparison, but do you want to make any comment just in terms of overall why CMS decided to develop measures that were similar but slightly different than the CDC measure? Was there some discussion about that in terms of evaluating that measure and deciding it wasn't meeting some particular need?

DR. DUDLEY: From CMS' perspective, I think Joe mentioned earlier we had CDC participation in the TEPs that we had last year. And there was -- the discussions we have had with Priti and her team have revolved around the availability of data via the NHSN versus the authority that CMS has for collecting data through CROWNWeb, which is 100 percent; whereas, I believe NHSN participation within the ESRD facilities is somewhere around 4 or 5 percent right now. Granted, Colorado is requiring 100 percent. And other states

will probably be joining in.

Up until the measures were released, I wasn't aware of CDC's efforts to submit the measures, which is -- that's my issue. And there is no intent for them to be separate from each other or overlapping.

DR. PACE: Okay. Thank you.

CO-CHAIR SCHONDER: Are there any other comments from the Committee?

(No response.)

CO-CHAIR SCHONDER: We will move to voting, then.

DR. PACE: So we are on 1457. And we're starting with importance to measure and report. And wait until you see the timer.

(Pause.)

CO-CHAIR CROOKS: We have 18 yes and 2 no.

DR. PACE: Okay. Next, scientific acceptability of measure properties. And, again, we realize that there is no reliability and validity testing. So this really relates

to primarily how it is specified.

(Pause.)

CO-CHAIR CROOKS: Three completely, 11 partially, 5 minimally.

DR. PACE: Okay. Next is usability.

(Pause.)

CO-CHAIR CROOKS: Fifteen partially, three minimally, and two not at all.

DR. PACE: Feasibility?

(Pause.)

CO-CHAIR CROOKS: Fifteen partially, four minimally.

DR. PACE: And finally recommend for endorsement? Again, this would be preliminary based, time-limited.

(Pause.)

CO-CHAIR CROOKS: Eleven yes, nine no. We've got 20.

CO-CHAIR SCHONDER: I think we will just continue on with 1455 since

essentially it's the same measure except using Medicare claims. So, Jerry?

1455, ACCESS-RELATED BACTEREMIA USING MEDICARE CLAIMS (RATE) [STRATIFIED BY ACCESS]

DR. JACKSON: This is the overall access-related bacteremia six-month rolling average rate of access-connected bacteremia among adult hemodialysis patients. And it's stratified by type of access.

And the numerator is based on the claims forms. And specifically we can ask when this becomes a requirement, but the -- whether it's felt related to the access would be indicated placement of a modifier V8 on the claim form by month. And then the specific access will be either V5, V6, or V7 to indicate whether it is a catheter, fistula, or graft.

The reviewers agreed that it was highly important to measure and report. There was less agreement on the elements of the scientific acceptability, same for usability

and feasibility.

There is no reliability or validity testing as yet. As mentioned before, this makes more sense when looking at the totality of the CMS infection-related intent and purposes and the Venn diagram.

The overall vote when I had this -- I'm not sure there are some additional ones -- was two votes yes and two votes no.

CO-CHAIR SCHONDER: Any other comments from the other reviewers?

CO-CHAIR CROOKS: I think this has some value in terms of sort of a cross-check, right, of kind of saying, are we getting all of the data? Is it valid? And in the setting of what could be a really big project, it's a nice addition. Plus, you have something up and running sooner.

CO-CHAIR SCHONDER: Alan?

DR. KLIGER: Well, could I ask that question, actually, of the developers. Why did you give us two identical measures

except for the data source?

DR. DUDLEY: This is Tom again. That was because of the uncertainty of the rollout with CROWNWeb and as far as the timing we have the vehicle for the claimants' submission and CROWNWeb. We intend to replace claimants' submission ultimately.

DR. PACE: Yes. Because I haven't compared these measures yet. Those who reviewed it, are the numerator and denominator statements pretty much the same so that the only distinction is what codes, for example, off of claims versus information out of the CROWNWeb? Go ahead, developer.

DR. MESSANA: So the instructions for using the V8 modifier result in adding that modifier to the claims as of July 2010. And I'm going off the top of my head, off memory but when there is bacteremia and it's felt to be related to vascular access for a hemodialysis patient, peritoneal infection for a pede patient. So we're talking about chemo

only at this point.

And so the instructions for using the V8 modifier result in a similar numerator to the CROWNWeb-based specification. It's a largely, not entirely but largely, different data source. The difference is that in all of our CROWNWeb-based specifications, in that totalitarian, in total that group, not totalitarian, although --

(Laughter.)

DR. MESSANA: No. But in that group of five, you have to have antibiotic start. So our CROWNWeb ones are really a small subset of all infections and dialysis patients. That is the fundamental difference other than the data source.

CO-CHAIR SCHONDER: Any other comments from the Committee?

DR. PACE: Again, this is something we will have to resolve when we get through these measures. We do at NQF have measures sometimes that it's one measure, but

there are different ways that you could construct the measure based on which data you are developing. If we have a measure that way, we like to know that we're getting comparable results across data sources if we're saying you can do it one or multiple ways.

So I think the question before you now is the way it is specified, did that make sense? Yes.

DR. FIVUSH: I have a concern. The claims data is used for Medicare patients. You know, again, I don't know in the adult world what the Medicare/private sector breakdown is, but in pediatrics, we know that more patients are not on Medicare. And that includes we have looked at our 18-year-olds and our 19-year-olds and our 20-year-olds. And I just don't know how valid.

I mean, the appeal of the CROWNWeb is that it is going to be when it rolls out 100 percent and we are going to have a better

idea. And I don't know if you only look at Medicare claims data. And I would look to the people around this room. Does that give us, really, the -- is that going to tell us the whole picture? Is it going to somehow skew the data of patients that are not Medicare-insured? Is that going to change? Is that not going to be a valid look at this measure that we're really look at bacteremia, but we're not looking at it in our total population. And we may be looking at it differently by insurers.

DR. LATTS: And that was going to be my question as well. I mean, why is this labeled a Medicare claims measure? Why couldn't it be -- why isn't it just a claims measure and we use our claims as well?

I mean, that is actually quite attractive. Claims-based measures are quite attractive because there is no additional data burden and it is apples to apples. You know, methodology is clear. And it can be an apples

to apples comparison.

So I'm not clear why this is labeled a Medicare claims measure, as opposed to a claims measure.

CO-CHAIR SCHONDER: Robert?

DR. WOLFE: It is because it is truth in advertising. It is limited. What we have access to are the Medicare claims. And those claims are submitted for patients with Medicare insurance.

I think there was a question of, what kind of coverage is that? And I can't give a complete answer, but for adults over time, Medicare becomes a primary care for almost everybody.

One of the distinctive things about kids is a very large fraction of them gets transplants fairly quickly. So there will be a gap, absolutely, of missing a fair number of kids in that interim before they get a transplant. That is one of the limitations of the entire claims process. Is this limited

to adults? I'm sorry?

DR. FIVUSH: We have looked at our data because, again, we're talking about small numbers of patients. I just know in the -- I'm talking about in the young adults, where this is an important question as well.

I understand that it's over 18, but, even in that population of 18 to 25, I am putting it up as it doesn't change the validity, but we're not really looking at apples to apples. But I understand.

DR. WOLFE: Your question is well-taken, but we aren't trying to limit this to Medicare only. But it's a constraint of the data flow, rather.

DR. LATTS: So I guess the question is, can we remove that Medicare limitation and have it be claims, period, understanding that it has been tested in a Medicare population but that the claims -- well, right, right -- understanding that it will be tested in a Medicare population given

what you have access to but that the methodology is as applicable to a commercial population as it would be to a Medicare population.

CO-CHAIR CROOKS: Do you collect the same V indicators on the --

DR. LATTS: Yes.

CO-CHAIR CROOKS: I mean, I don't know.

DR. LATTS: I mean, you know, our systems are -- HCPCS are an evolving technology, but yes, we collect it.

CO-CHAIR SCHONDER: Robert?

DR. PROVENZANO: Just two questions. One, will this create an additional burden on facilities? And, two, it's a validation tool for the previous measure. And is that what we are supposed to be doing here?

CO-CHAIR CROOKS: I have been dissuaded that is a validation tool. I don't think it is. It isn't identical. So let's

drop that notion. That was my superimposing something on them. So I apologize. I apologize.

Ask your other question.

DR. PROVENZANO: Does it create an additional burden --

CO-CHAIR CROOKS: Burden, right.

DR. PROVENZANO: -- on the facilities?

CO-CHAIR SCHONDER: Barbara?

DR. FIVUSH: I think it is an important measure. I think when CROWNWeb comes out, we're going to be collecting it. It's going to happen. And I don't know why we would collect it in two ways if we think -- I mean, I believe that CROWNWeb is going to be very reliable. So I don't know when we have a question about more burden or not comparing apples to apples or then changing the measure, why we wouldn't wait for CROWNWeb when we heard that CROWNWeb is going to roll out.

And since it's not going to

validate CROWNWeb because we've heard it's not a validation, I'm just wondering what additional knowledge will we get if CROWNWeb rolls out and is the system we think it will be and it's not to validate CROWNWeb.

DR. LATTS: I don't think it would be additional burden because you're going to be billing these anyways. I mean, your billing companies are going to be billing the complete information on the situation based on the capabilities of ICD-9 or ICD-10 and with the CPT codes and the HCPCS codes. So the information will be there, but who will collect that --

DR. FIVUSH: Well, that will be Medicare or the private payers, then, to do what we will with the claims data.

CO-CHAIR SCHONDER: Myra?

DR. KLEINPETER: Where would the VA patients fit in this scheme of things? Because some are being dialyzed at our community unions. And their claims process is

totally different. And they're doing the contracts differently. And where does the VA I guess participate in the quality aspect of a lot of this? Because we have all heard that there are some quality deficits at some of the VAs related to some of the long-term care of the older veterans.

DR. MESSANA: If the question is a question directed to us, my understanding is that, first off, some veterans have Medicare, secondary or Medicare coverage. And so those I think will end up in the Medicare data.

CROWNWeb, right, so we're shifting between measures and data sources. The CROWNWeb includes all.

DR. BURSTIN: I have a question, I guess, perhaps for Sue. So since this is a claims-based measure of access-related bacteremia and this measure is not tested, is there any known information about the reliability and validity of claims-based bacteremia measures?

MS. BARNES: I don't have the exact reference. I can get it for you or them. There is a lot of published data suggesting that claims information alone is very inaccurate in terms of healthcare-associated infection rate generation.

DR. LATTS: Is that because -- they're very accurate, I believe, in terms of identifying the infection. No?

MS. BARNES: Actually not. And that's due to a number of factors, partially due to -- you know, it's as good as the information put in.

DR. LATTS: Right.

MS. BARNES: Encoders don't necessarily do good case finding. And case finding is important. You know, you can't just look at a record and if somebody didn't assign a code, then the coder can't claim it. So, actually, there's quite a bit of published evidence that claims data is not a sufficient

method or source for HAI data.

DR. MESSANA: Although I have no information to dispute that statement, we're not talking about generally applicable studies of claims-based accuracy here. First off, this is the dialysis world. And it's based off of a type 72 dialysis claim. And it's a specific modifier. So this is somewhat different than searching through ICD-9 codes to find infections.

CO-CHAIR SCHONDER: Any other comments? We'll move to vote, then.

DR. PACE: This is measure 1455, importance to measure and report.

(Pause.)

CO-CHAIR CROOKS: Fourteen yes, six no.

DR. PACE: Okay. Scientific acceptability of measure properties? And this, again, would be related primarily to the specifications.

(Pause.)

CO-CHAIR CROOKS: Fifteen partially, four minimally, one not at all.

DR. PACE: Okay. Usability?

(Pause.)

CO-CHAIR CROOKS: Thirteen partially, four minimally, three not at all.

DR. PACE: Feasibility?

(Pause.)

CO-CHAIR CROOKS: Four completely, nine partially, six minimally, one not at all.

DR. PACE: And recommend for endorsement?

(Pause.)

CO-CHAIR CROOKS: Seven yes, 13 no.

CO-CHAIR SCHONDER: Okay. We will go back to measure 1456, "Bacteremia and Rate." Andy?

1456, BACTEREMIA (RATE)

DR. NARVA: This is a process measure. And it's part of the suite of measures that is meant to sort of cover the

different ways in which infections, particularly access infections, are identified.

The purpose was to help focus quality efforts on culture-positive infections, which perhaps would be less subject to interpretation and provide better, more accurate monitoring and a stronger, firmer basis on which to design a quality improvement program.

The gap it is addressing is the large variation in access-related infection, although this covers a broader group of patients.

It is a six-month rolling average rate of bacteremia with IV antibiotics. And the rate is per 1,000 patient days. The denominator is the number of months that a hemodialysis patient initiated an antibiotic for a new infection. And the numerator is those patients for whom there are blood culture results consistent with infection. It

could be stratified for access type.

There are a number of comments and a fair amount of I guess ambivalence towards this measure. It has not been tested. There are concerns about the subjectivity in determining the cause of bacteremia.

It's not clear how this would improve care and on the other side was thought to be valuable for public reporting and quality improvement. And one of the two supporters thought it would only be for time-limited testing, which is, of course, the only option that is available.

Summarizing the reviews, three out of four thought it was important, although there was no data on the opportunity for improvement. The scientific acceptability was one partial and two minimal. Usability was one complete, one partial, one minimal, one abstainer. Feasibility was two complete, one partial, one abstainer. And the recommendation was two yes and two no.

CO-CHAIR SCHONDER: Comments?

DR. LATTS: I just have a question. For most of these measures, they're continually listed as process measures. I guess to me, they are outcome measures. So I am confused there.

DR. PACE: I think we would consider them outcome, but I don't know why they were --

DR. NARVA: Described as output. In your value, in your notes, you also talked about that.

DR. WOLFE: The overall infection rate is an outcome measure. The vascular access, specific rates were thought of more as process and quality improvement efforts. So that once you know that your infection rate is high, you can then focus upon which types of patient those infection rates are higher than expected in.

If your infection rate is high but the same as expected for each type of vascular

access, then it's probably the mix of vascular access that is causing your infection rate to be high. But if you have a high infection rate and it's high amongst, let's say, fistula, then you've got a problem with fistulas and you can focus upon that. So that's why some of them are quality improvement effort tools and some of them are just outcome tools.

DR. LATTS: To me an infection is an outcome, --

DR. PACE: Right.

DR. LATTS: -- end of story, whatever kind of infection it is. A process is something that leads to the outcome.

DR. PACE: And that is what -- we would classify them in our database as outcome measures. So this is overall bacteremia, this particular --

DR. NARVA: The basic number is bacteremia. The dialysis patients that I was most involved with had large numbers of lower

extremity infections. And there were also many people with non-access-related infections who could receive IV antibiotics who didn't necessarily have septicemia, but it was a very -- you know, one of the few advantages to them of being on dialysis was they could have a parenteral course of antibiotics without actually being admitted to the hospital. And that happened not infrequently.

So I guess I am worried about identifying the actual cause of the indication for starting antibiotics and also even retrieving the blood culture because it could have been obtained in many different places. But that came up previously.

DR. MESSANA: Right. That is similar to NHSN's 1460.

DR. PACE: Sue, this would be similar to the one we talked about initially that was based on the IV antibiotic starts is basically how you determine this, right? Oh, okay.

DR. NARVA: I was wondering if any of the other folks who were primary reviewers had comments.

DR. JACKSON: Yes. It seems to me very similar to 1460 except this pairs antibiotic starts with the positive blood culture. And I think 1460, it's just positive blood cultures. And so when we compared them, the data source --

DR. PACE: Yes. Ultimately we would need to look at these in comparison.

MS. BARNES: Yes. I think it adds burden in terms of trying to connect the two without any value, adding value, the two being antibiotic and positive culture.

DR. LATTS: And then the next set of measures would add the third burden, being the clinically confirmed infection.

CO-CHAIR CROOKS: But we already established that this data is going to be collected anyway. So it doesn't add to the burden existing unless I misunderstood what we

heard earlier.

MS. BARNES: I thought I understood that not everybody was on CROWNWeb. Is that not true?

MS. ANDERSON: Well, not yet. And the difference is the LDOs will be able to batch. The SDOs will be manually entering all of the data. That's --

CO-CHAIR CROOKS: SDO mean small dialysis organization.

MS. ANDERSON: I'm sorry. Yes.

CO-CHAIR CROOKS: LDO is a large dialysis.

MS. BARNES: So to me there is a huge data burden.

MS. ANDERSON: There is a huge data burden to manually enter the data.

DR. PACE: I think what we were hearing is that --

CO-CHAIR CROOKS: They have to do it.

DR. PACE: -- the CMS coverage

rules, if you want CMS reimbursement, you provide the data that goes on.

MS. BARNES: Oh, I see.

CO-CHAIR CROOKS: If you want to get paid, you have to put the data in.

DR. PROVENZANO: Well, I mean, I just want to be clear because I know a lot of people in the room have dealt with CROWNWeb. Everything in the world isn't in CROWNWeb to be collected. The conditions of coverage mandate that facilities will participate.

I know that there are a lot of data pieces that are there that can be turned on and turned off. I guess my question is, is this body making the decision what gets turned on or what gets turned off or are these things already mandated to be collected, they're going to be collected, and we're deciding whether or not they are going to be endorsed?

CO-CHAIR CROOKS: That is exactly what I was trying to establish. And Tom Dudley -- I thought we had a pretty clear

answer but maybe, maybe not.

DR. PROVENZANO: It wasn't clear to me, I guess. So that's maybe just me.

DR. PACE: First of all, let me just explain NQF is not endorsing CROWNWeb or the individual data elements, though to a certain extent if we endorse a measure that requires those data elements, it's kind of in that direction. But independent of measurement, CMS has mandated certain data be collected. And it's part of their coverage rules.

So, Tom, if you are still on the line, could you just clarify once again what CMS is mandating regarding data collection, regarding CROWNWeb?

DR. DUDLEY: Sure, Karen. What you said was accurate. There are two separate things: the endorsement versus requirements under CROWNWeb. What is in CROWNWeb are the elements that the data fields need to be collected to monitor or assess the care advice

to the ESRD population under the Medicare program.

At this point the intent is it will be collected. Will all of them be required? I don't have my crystal ball with me. Potentially some of the elements will be optional.

But, I mean, my perspective for the Steering Committee would be look at the measure on the merits, not what CMS will or will not require within CROWNWeb.

DR. PROVENZANO: So call me simple. If they're not required, the probability that they're going to be required if we endorse them to me would see much higher, which would increase a burden of work on facilities.

DR. DUDLEY: They are all ready built into the system. That will be rolled out. Will there be an increase in burden?

DR. PROVENZANO: When you say they're built in the system, you know, my

iPhone has a lot of stuff built into it that I don't use, most of it. That's what I am trying to determine.

When you say built in but not required, that's different than built in and required. And my concern is that if they currently are not required but built in -- and I understand why they are built in -- and we endorse something with the understanding, well, it's no big deal because they're all required, that's just not accurate.

DR. DUDLEY: Okay. I appreciate what you are saying. And, unfortunately, I don't have an answer because it falls outside of the quality measure development area. It's not required in CROWNWeb. That's another area, is CMS. I don't want to speak on their behalf regarding what will be turned on, what will be turned off.

DR. PACE: Okay. Tom, thanks. What we can do is follow up and get the answer to that question of is everything that is in

CROWNWeb going to be required --

DR. PROVENZANO: Well, regarding this.

DR. PACE: Right, exactly, regarding these data elements. So that's something that we can provide the information when we get to the point of these comparisons. I think that would be useful information when you are comparing measures. And we can work with Tom to get that from their colleagues at CMS.

CO-CHAIR SCHONDER: Are there any other comments?

(No response.)

CO-CHAIR SCHONDER: Okay. Then I think we will go ahead and move to vote kind of on the basis of the merits of the measure itself.

DR. PACE: Okay. Fourteen fifty-six, we'll start with importance to measure and report.

(Pause.)

CO-CHAIR SCHONDER: We have 16 yeses and 4 nos.

DR. PACE: Okay. We'll go on to scientific acceptability and measure properties. And, again, in this instance, it's primarily related to how it is specified.

(Pause.)

CO-CHAIR CROOKS: One completely, two partially, three minimally.

(Laughter.)

CO-CHAIR CROOKS: What did I say? Fifteen, 15 partially, and three. One completely, three -- anyway, did we get it?

(Laughter.)

CO-CHAIR CROOKS: On the record, we got it? Okay.

DR. PACE: Usability.

(Pause.)

CO-CHAIR CROOKS: Trying again, two -- no.

(Laughter.)

CO-CHAIR CROOKS: Partially 11,

minimally seven, not at all one.

DR. PACE: Feasibility?

(Pause.)

CO-CHAIR CROOKS: One completely, 11 partially, 8 minimally.

DR. PACE: Okay. And recommend for endorsement?

(Pause.)

CO-CHAIR CROOKS: Nine yes, 11 no.

CO-CHAIR SCHONDER: Okay. Andy, we will continue with you with measure number 1449, "Unavailable Blood Culture Results. Microphone, please.

1449, UNAVAILABLE BLOOD CULTURE RESULTS (PERCENTAGE)

DR. NARVA: This measure is one minus the rate from the previous measure. The denominator is the same: The hemodialysis patients who have initiated antibiotic treatment for new infection in the last six months. And the numerator is the number of patients for which there is a group who start

antibiotics but for whom there are no blood culture results available.

And the purpose of this, described a little bit differently, is the focus is on reducing access infections by improving timeliness and level of reporting of infection-related measures and to prevent gaming of facility-level incomes through non-reporting.

I don't know if that is a problem myself, but there are a number of concerns with this. It is also untested. And so it will only be available for a time-limited endorsement.

The difficulty in ascertaining missing results from a test that wasn't actually done, there's no data on the opportunity for improvement. And several reviewers did not see how this would improve care.

And I think, even form the developers' text, I'll quote, "It is not known

the extent to which patient or dialysis facility health records lack results of blood culture results that have warranted IV antibiotics." So I'm not sure how much of a problem this is.

And there is also concern about undue burden of documentation and determination of the meaning of the results or the absence of them.

It might be a better measure for looking for the appropriate use of antibiotics, rather than surveillance of infection.

So the overall assessment by the primary reviewers was the importance of this issue. Again, three out of four thought it was important; in terms of scientific acceptability, three minimal and one abstainer. Usability was one partial, one minimal, one not at all, one abstainer. The feasibility was one complete, two partial. And the recommendation was split 50/50.

CO-CHAIR SCHONDER: Joe?

DR. VASSALOTTI: How do you exclude a patient being hospitalized and high blood culture? Is that addressed in this measure? We didn't get details.

So patient in a hospital has a positive blood culture, comes to the dialysis unit and gets treated appropriately. The physicians decide that they don't need to repeat the blood culture that was done in the hospital because they have that data.

Is there any way of excluding those patients from this assessment?

DR. MESSANA: So my understanding as the TEP deliberated these kinds of issues, the new antibiotic start was a requirement for the denominator here. So if a patient was hospitalized for a bacteremia and came back to your unit and there was a new antibiotic start, then there's a justification for that. It's the bacteremia.

So all of these measures differ in

that regard from the earlier ones that you considered because new antibiotic start is the only subset of the dialysis patients that these measures are looking at.

DR. LATTS: So that means a new IV antibiotic start by the dialysis facility, as opposed to if it was started in the hospital, it doesn't count?

DR. MESSANA: Well, but once the patient comes back to the dialysis facility, then there has to be an antibiotic start because you transition to outpatient.

DR. NARVA: If someone was in the hospital, had a blood culture, was started on a two-week course of antibiotics and got, you know, the first dose of vancomycin last week and the second dose back in the unit, that would be a new start in the unit.

DR. MESSANA: That's correct.

DR. NARVA: You routinely wouldn't get a blood culture to fill up later.

DR. MESSANA: One would presume

that you would have access to the blood culture results to justify your starting the vancomycin. I don't think it says anywhere that it has to be a blood culture drawn and send to your facility's laboratory.

DR. NARVA: But you have to be able to retrieve it, though, right?

DR. MESSANA: Well, one would presume that you have information to justify the antibiotic start. So the implication is that you have that information.

CO-CHAIR CROOKS: But for purposes of the metric, that would come out as a positive for this, right? In other words, they didn't get the blood culture for the antibiotic start. So it would be an unavailable blood culture result, right? And so that would count against that facility if that's a negative outcome.

DR. MESSANA: I don't believe that that was the intent. Although it's ambiguous, the numerator description is somewhat

ambiguous --

CO-CHAIR CROOKS: Yes.

DR. MESSANA: -- as written, my understanding is that unavailable means that there were not blood cultures associated with that antibiotic start. It does not specify whether that was a blood culture drawn by the dialysis facility or a blood culture that the facility is aware of as part of the clinical information that was transmitted.

DR. PROVENZANO: This then gets back to I think what practitioners in the large cities who deal with multiple hospitals deal with. And, granted, it may just be a phone call to the doc, who says, "Oh, yes. This is gram-positive bacteremia. We started vanco" but may be interpreted by the facilities of tracking backwards to try to find out if cultures were done, if they were positive, where the patient went.

And then you start talking about the burden factor, rather than, as I read it

initially, no cultures are done by antibiotics, are started as a measure of inappropriate antibiotic use. That's kind of how I looked at it, but -- that's my point, yes.

DR. MESSANA: If I may comment, this measure and then the subsequent 1450 were developed during a coordination session between the clinical TEP and the data TEP, trying to make sure, sure that there were not perverse or adverse incentives created to start antibiotics without drawing blood cultures. So they wanted to track that as a process measure to prevent a loophole.

PARTICIPANT: Any time you start looking for measures of unavailable information depending upon how much subjectivity there is to that information, I'm not -- I understand you are essentially trying to prevent gaming of the system, it sounds like, but how that improves patient care and does that rise to the level of a standard,

it's a great deal of confusion.

CO-CHAIR CROOKS: And as one of the reviewers, I was confused by the is this only the cultures that were done, but the report isn't available or is it counting cultures that weren't done when they could have been done? And that isn't clearly stated in the numerator statement, I don't think.

CO-CHAIR SCHONDER: Ruben?

DR. VELEZ: I think, in summary, I mean, the way I see it is it is not the arrow. It is the Indian. You know, it can be unavailable because I'm busy today and I don't have time to check on the culture. So they were unavailable.

So it creates a different scenario here that, even though we want to hopefully have appropriate blood cultures done when we're doing antibiotics, where the cultures were done, I know this measure has nothing to do with whether they were positive or negative. That is not the issue. Cultures

were done somewhere. And we need to identify where they were done.

CO-CHAIR SCHONDER: Any other comments?

(No response.)

CO-CHAIR SCHONDER: Move to voting.

DR. PACE: Okay. This is measure 1449. And we're going to start with importance to measure and report.

(Pause.)

DR. PACE: Has everyone voted? Okay.

CO-CHAIR CROOKS: It is our first tie: nine, nine.

DR. PACE: We will just continue on. We will just move on. We will go on to scientific acceptability. Go ahead. And, as before, this is mainly about the specifications at this point.

(Pause.)

CO-CHAIR CROOKS: One completely,

six partially, nine minimally, three not at all.

DR. PACE: All right. Usability?

(Pause.)

CO-CHAIR CROOKS: One completely, four partially, ten minimally, four not at all.

DR. PACE: Feasibility?

(Pause.)

CO-CHAIR CROOKS: Two completely, five partially, ten minimally, two not at all.

DR. PACE: Okay. And recommend for endorsement?

(Pause.)

CO-CHAIR CROOKS: One yes, 18 no.

CO-CHAIR SCHONDER: Okay. The next measure that is up -- actually, Bob stepped out. So we'll move ahead to measure number 1469, "Clinically Confirmed Access-Related Infection Rate." Lisa?

1469, CLINICALLY CONFIRMED ACCESS-RELATED INFECTION (RATE) [STRATIFIED BY ACCESS]

DR. LATTS: Okay. So this is building on a theme here, as you can tell. This is very similar to the previous access-related infection rate, but the addition here, then, as with the previous measure, is clinically confirmed. So in this we add a third data element, which is that somebody has to confirm that there is an infection and that it is related to the access.

So, in the interest of time maybe since we have discussed these so much, I won't go through in detail other than just to add that the additional data element, the clinical confirmation is very unclear to me in terms of how that all happens.

I'm guessing it's just a data element in CROWNWeb and somebody has to ascertain, either a doctor or a nurse, you know, click a box, "Yes, this was an infection," "Yes, it was access-related" is what I'm assuming. And I don't know if the

developers -- if we want them to add to that.

In terms of the evaluations that I saw, I had four people, all of whom said that yes, it was important in terms of scientific acceptability. It looks like you've got the same four.

So I thought it was not because of some of the ambiguity around the measures. There were two partially, one minimally; in terms of usability, one not at all, one minimally, two partially; and feasibility, two partially, and two minimally; and then two yes and two nos in terms of the recommendations at this point.

So, again, I think building on the theme that we have had so far, it is all of the things we have discussed to date plus the additional difficulty of a clinically confirmed infection and clinically access-related.

CO-CHAIR SCHONDER: Any comments from the Committee?

CO-CHAIR CROOKS: This is another one for time-limited endorsement only.

CO-CHAIR SCHONDER: Can I ask about Lisa's question about how will clinical confirmation be tracked for this particular measure?

DR. MESSANA: It is not specified in here. In the memo or white paper that went out, the clarification from CMS, I think it's discussed in there. Generally a professional person, a doctor or a nurse, would have to specify that it was a vascular access infection.

DR. LATTS: Which would lead to some major validity. I mean, there is just so much. It's very squishy.

CO-CHAIR SCHONDER: Okay. Any other comments?

(No response.)

CO-CHAIR SCHONDER: Call the vote.

DR. PACE: This is measure 1469, importance to measure and report.

(Pause.)

CO-CHAIR CROOKS: Nine yes and nine no.

DR. PACE: Okay. We will have to go on. Scientific acceptability of measure properties? And, again, this would be the specification.

(Pause.)

CO-CHAIR CROOKS: Nine partially, six minimally, three not at all.

DR. PACE: We will go on. Usability?

(Pause.)

CO-CHAIR CROOKS: Two partially, 12 minimally, one not at all -- 4 partially.

(Pause.)

CO-CHAIR CROOKS: Two partially, 13 minimally, 3 not at all.

DR. PACE: Okay. And then recommend for endorsement?

(Pause.)

DR. PACE: Okay.

CO-CHAIR CROOKS: I have 2 yes and 16 no, 2 yes and 16 no.

CO-CHAIR SCHONDER: Okay. We'll go back to measure number 1453, the "Clinically Confirmation Infection (Rate)." Bob, you need to stay put.

DR. WOLFE: Could I interject something that these were proposed as a suite. And one of them has been approved, but others that are key to it have not. So some of these others just don't really make as much sense.

And we would propose that there are more important things for the Committee to do and that we would withdraw them just to simplify things.

No. The remainder that have not just been --

DR. PACE: On the clinically confirmed measures is what you are talking about?

DR. WOLFE: Yes.

DR. PACE: All right.

DR. WOLFE: I think that several of these, they were keyed together and then --

DR. PROVENZANO: That was easy. That makes sense.

DR. NALLY: Hey, Bob, you had me at yes.

CO-CHAIR SCHONDER: Just to clarify, 1453 and 1450 are being withdrawn?

DR. WOLFE: Yes. We would like to have more time I think for the remaining measure.

CO-CHAIR CROOKS: Thank you.

CO-CHAIR SCHONDER: Thank you very much.

DR. PACE: And I am sure you are acting in concert with CMS.

DR. WOLFE: Yes. We have been waiting on --

DR. PACE: Okay.

DR. WOLFE: We have been going back and forth to get that.

DR. PACE: All right.

DR. WOLFE: Thank you.

DR. PACE: Thank you.

CO-CHAIR SCHONDER: So then we will move to the last two measures, which are the hospitalization measures. We will start with measure number 1463, the "Standardized Hospitalization Ratio for Admissions." Lisa again?

HOSPITALIZATION

1463, STANDARDIZED HOSPITALIZATION RATIO FOR ADMISSIONS

DR. LATTS: Okay. So switching gears, standardized hospitalization measure for admissions, so this is a measure, a standardized measure, outcomes measure, looking at hospitalization for admission.

And the numerator is the number of inpatient hospital admissions among eligible patients at the facility during the reporting period. And the denominator essentially is all patients on hemodialysis at the facility.

There are a couple of things I

want to point out. So this is an outcome measure, which is very important and something we need. The numerator is looking at -- hold on. I'm sorry. Let me get the numbers here.

The numerator is looking at the -- the reporting periods -- the denominator is reporting period, which is currently listed as three years, which is a very long time period, although it does say "designated time period." So if the Committee felt that was too long and wanted to proceed, I think we could probably recommend a shorter period of time.

The information is coming from CROWNWeb. This is risk-adjusted. And I wanted to point out that it is currently proposed to be risk-adjusted for age, race, sex, diabetes, ethnicity, duration of ESRD, nursing home status, BMI incidence, comorbidity index incidence, and calendar year.

There is then a linear predictor for each patient based on the regression

coefficient and the stage 1 model, which is used to compute a risk adjustment. And then it's basically a very complex analysis.

And then there's a ratio of the expected versus the predicted admission rate for each patient. And that is reported, then, for each facility is what is their actual hospitalization rate or admission rate for this measure versus the expected. So, actually, it is reported as a ratio.

So a couple of problems that I had with this, one of the big ones off the top is race. I have a big problem, actually, using race in the risk adjustment, as opposed to stratifying by race because then, surprise, surprise, when they look at race differences, they didn't find any. Well, you won't find any differences if you use it to risk-adjust.

And I think one of the major problems we have with dialysis is -- well, one of the problem we have across the healthcare system is race and ethnic minority health

disparities.

And I think if you risk-stratify them out, I have a big problem with that. So that is something that I would must rather see in a stratification, as opposed to a risk adjustment.

I think another problem that I have that -- I don't know if we want to talk about it here or talk about it a little later -- is harmonizing with other measures in the NQF world for admission rates. I'm sure there are some, at least for nursing home. There is a readmission rate. And there's a home health admission and nursing home admission rate. So we need to talk about harmonizing with those at some point.

So in terms of the other reviewers, there were five in the group that I have, five also that you have. So I have the complete five here. In terms of -- let me page over here -- importance, everybody agreed this was important; for scientific

acceptability, three minimally, one partially, one completely; usability, four minimally, one completely; feasibility, two completely, two partially, no minimally; and recommendations for approval, two yeses and three nos.

And in terms of the comments, there were several comments. Several people commented that the three years was too long, as I mentioned earlier. And I think we could potentially recommend a shorter time frame.

I do want to mention that I think that this measure and the days, which we will discuss next, are critically important. And so I don't know if there is a way to fix this in such a way that we can still have a measure because I think it is so important to have a measure or if this is critically flawed. So I think that is the discussion that we need to have.

DR. VASSALOTTI: I also voted for this. I thought that if there is a kind of a beauty and it's simple, it's understandable,

it's something patients understand, it's something the community understands, I think some of the statistics and risk adjustment are complex, but I will leave to the developer. I would like to hear what the developer says about the reason for the race, how that figured into the TEP's discussion, the DTEP's discussion.

But I thought that this is attractive. And I think it is actionable for clinicians, particularly in terms of the data. We could dial down to things like the access infection, things like the CHF admissions.

So, I mean, certainly many of the admissions are actionable potentially. So that was my rationale.

CO-CHAIR SCHONDER: Bob, back here?

DR. PROVENZANO: I agree it is something we would all like to know, but it is more complex I think than we appreciate. There are some segments of our society that,

despite our best educational efforts, use the emergency room and the hospital as a site of their primary care. That is going to skew this data.

Additionally, practically speaking, nephrologists don't have control over these patients. I do not make a decision, nor do many nephrologists, as to who gets admitted when, where. There are hospitalists. There are primary care physicians. And patients will seek out many other avenues. So our control over this measure is quite limited.

And, now, is this changing? It is, maybe with the kind of care organizations and a whole different view of seamless processes, this might be less of a burden, but right now I think it is somewhat flawed.

DR. LATTS: Can I just interject one quick question for the developer? Because based on the way the submission was written, my reading was that ER visits are excluded.

It's only if the patient is actually admitted to the hospital, but it was a little fuzzy.

DR. PROVENZANO: Right. I think you are right. Oh, I'm sorry.

DR. WOLFE: That is correct. We are also considering an alternative measure for ER utilization, recognizing that that may be a more specific kind of different level of issue.

But this is a hospitalization. And it stands on the merits of being the hospitalization without trying to encompass the added issue of emergency rooms.

DR. PROVENZANO: But let me follow up to Lisa. Emergency rooms now almost universally use criteria that allow payment. If a patient hits a criterion that will allow admission for payment, they admit them. It balances very well their legal risk with the financial risk.

Therefore, every single dialysis patient that goes into an emergency room, if

they use it as their primary source of care can fit that criteria. And a disproportionate number of them are admitted. So until that separation occurs, I would still be uncomfortable with this.

DR. WOLFE: Can I make a clarification, which I may not have said correctly? If they are admitted through an ER, that is an admission, but if they go to an ER with -- yes. Okay. Okay. I'm sorry.

DR. BERNS: So I agree with Bob on the points, the initial point he made, which is that we very often have no control over hospital admission. Hospital admission is a moving target. What was an admission or what would have created an admission -- I think this is what Bob is alluding to -- six months ago is now in observation status. And we have absolutely no control over how that decision is made, whether it is one or the other.

And then I have a concern about the risk adjustment methodology, which may be

a little bit more complex. So the denominator excludes people in the first 90 days of dialysis. And, yet, the risk adjustment is based on several factor at incidents, specifically BMI but, more importantly, comorbidity.

And, yet, this is obviously going to be people who are admitted to the hospital three years, five years, ten years after incidence with a risk adjustment that is completely irrelevant based both upon BMI and comorbidities.

So I think, in order to be statistically valid, it would seem to me that this ought to be a time variable of risk adjustment or a comorbidity index and BMI somewhat more approximate to the time of admission if it's going to be clinically or statistically meaningful. And that is sort of a different issue than whether this really even makes sense for other reasons.

DR. WOLFE: Are you asking the

developer that question?

DR. BERNS: I don't know whether we need clarification because it is what it is, but I think as we consider the value of this as a measure, we should think about whether or not he statistical underpinning is reasonable and valid.

DR. VELEZ: I would like to hear what the CAHPS discussion was if we have access to it.

DR. WOLFE: So there have been several questions. Would it be appropriate for me to address the race question as well as this one? Race is in the adjustment right now for the SHR that has been produced and has been made available to facilities.

Your comment that it would not show up is true at the national level. Nationally we will see observed equal to expected for all the race groups. But at each facility, if they are treating their certain race groups differentially from the national

norm, you would see that.

So I am giving you an answer that it is partially still in there. You would still see differences from the norm for each race at a facility. For a facility-specific metric, that may be the most important information. For a national policy, you would do a different analysis.

For the purposes of a facility, knowing how it is doing compared to standard practice, there may be some value in the race adjustment. But I do believe that the TEP was not definitive on that and would be welcome to change if appropriate.

But I do want you to consider the possibility that when facilities think about how am I doing with my patients and what should they be compared to, it may be that it should be for patients like their patients.

The three-year versus one-year, in fact, we are seeking endorsement of the concept. And it has been a three-year in the

past. That's what we had experience with. But we also know that it is likely to be used in a one-year measure and would value that endorsement as well.

ER use, we have covered that it includes hospitalization after ER. There is the time-dependent variable question. And that is a very important question also.

For better or for worse, this has an historical context, which is that it has been based primarily off of the 2728 form, which is available with an active filling out now of each comorbidity.

The alternative that we have is to use the Medicare claims serially as a time-dependent measure looking at ICD-9 and diagnosis codes. And we think that that has value. We also think that there are limitations of it. And this is a choice that you have to make between two imperfect measures, the case with adjustment.

DR. NALLY: That was specifically

my question about this, particularly as you are risk-adjusting and using kind of a reference denominator. Currently you would be using Medicare claims form. My understanding is that is through 2008 would be the reference there and then eventually when CROWNWeb goes national, particularly related to hospitalizations.

I spoke with the executive director of the network in Indianapolis and then had some e-mail exchange with the Pittsburgh people that there could be a couple-year lag phase to all the -- until it's well-developed that the CROWNWeb hospitalization is in place.

So what is your prediction of the timeline for the transition of the methodology of claims going to CROWNWeb? And how do you adjudicate those ratios in terms of what time population you're using?

DR. WOLFE: So for right now, the measure that we are proposing is the one based

upon the adjustment for the comorbidity at the time the most recent 2728 is submitted.

Now, for example, for patients who get a transplant and return to dialysis, it will not be the initial 2728. It will be the one upon return.

Ideally what we would like to have is each time there is a transfer from one facility to a new facility, we would like to have an evaluation of comorbidity at that time. That isn't currently available. So we use the most recent 2728 form.

I don't know what will happen in the future, but that would be a new measure submission at the time CROWNWeb data becomes available. And we will have experience with CROWNWeb data at that time. Right now we do have the experience with the claims-based data.

We do know that the hospitalization is actionable in that it is very strongly related to catheter utilization.

And it is very strongly related to the percent of patients who are on target for media management. And it is very strongly related to the percent of patients.

This is more historical because now the percent of patients who are on target for URR is so high. But, as that was changing over time, that was having a substantial impact upon hospitalizations.

So, whatever imperfections there are in the hospitalization measure, it has a lot of validity in terms of being related to the factors that are under the providers' control.

DR. NALLY: So to address a straightforward question, if in first quarter 2011, right now if I am running a CQI meeting at my facility and this information has been available and this ratio of admissions, the data that I am looking at for my CQI now will represent what period of time when those admissions and the adjustments actually took

place?

DR. WOLFE: It will be the calendar year prior to the time that you're looking at it if you're looking at it after September. Each calendar year becomes available nine months later. So each calendar year, you can start looking at September and subsequent to that.

And the annual values are available to you in your facility reports right now. And those have a lag of nine months. And then, in addition to that last year, you had the year before that and the year before that. So there are three sequential years you can look at trends. And they are available up until the last year, calendar year, before --

DR. NALLY: So today I would be looking at years seven, eight, and nine?

DR. WOLFE: Today you would be looking at 2010 as the last year --

DR. NALLY: Okay. It would

include data --

DR. WOLFE: -- because --

DR. NALLY: No.

DR. WOLFE: -- 2009 -- yes. I'm sorry. Two thousand nine was reported in September of last year.

DR. NALLY: Right.

DR. WOLFE: Thank you. That's right.

CO-CHAIR CROOKS: Two comments. One is that the standardized ratio for hospitalizations is very similar to the mortality, standardized mortality, which is also reported on ESRD comparing, I think. In that sense, it's something that the community is used to looking at. Intuitively it makes sense, despite the complexity of standardizing.

But I also want to take an opposite point of view from Bob and Jeff on that this isn't the nephrologist's responsibility that the patient gets

hospitalized. I mean, if you're not taking responsibility for hospitalizations, you will be very soon if you're going to start working with ACOs.

Vascular access is still one of the most common causes of hospitalization. If you're proactively managing vascular access, you decrease hospitalizations. CHF is by the second or one of the top causes of hospitalization. If you're managing your patients right in dialysis, they're not going to go to the emergency room for CHF.

So you are, as a matter of fact, the metric is to say, is a nephrologist actually doing what they can do to decrease hospitalization and the dialysis facility together? Are the providers keeping patients out of the hospital or not? That's the whole point of it.

So to say I have no control, it's not my problem, I reject that. And I think it is your problem. It is. And it is going to

become increasingly your problem as we start to move into models of care where you have to take responsibility for that.

DR. BERNS: If I can just retort? I mean, if I ever ever -- well, if I almost never, but if I got a call from the emergency room doctor and said, "Would you like your patient admitted?" or "Do you think your patient needs to be admitted?" I can sort of go along with that notion. But that absolutely rarely happens.

So that somebody in the emergency room who has little or no experience taking care of a patient with dialysis, doesn't know, you know, at 6:00 o'clock in the morning if they could go to dialysis at 7:00 and not be admitted to the hospital because they're a tiny bit short of breath or the potassium is 5.2, I have no control over that.

And that's where I'm sort of bothered by this.

CO-CHAIR CROOKS: Maybe you

should. Maybe you would be working proactively to work with this hospital and say, "This is the system of care."

DR. BERNS: No.

CO-CHAIR CROOKS: Also, if you're caring for them extremely well, maybe they wouldn't be going to the emergency room in the first place. So I think there are several levels at which you could be interacting, but you have to take some responsibility for the system of care that your patient is in and not just say, "They're out of the dialysis unit. They're out of my hands," you know.

DR. PROVENZANO: Peter, you have been a nephrologist for a long time in a system where you don't face many of the issues we face in a fragmented care world.

It is not that nephrologists do not want to care for this patient. Many people, myself included, many people at this table, the RPA have worked for 20 years to make nephrologists primarily responsible and

manage the care.

All the data suggests exactly what you know, that we are best suited to care for them, but the systems won't allow for that in many instances. And this is why I am a big proponent of ACOs.

I don't want to send the message that any of us say it's not our problem. What we are saying is we continue to have problems accessing these patients. So my patient may go to the ER with heart failure. They will call a cardiologist. Often the problem is they don't even bother to call us when it's a dialysis patient on the floor in heart failure.

So the system is fragmented. And I'm just saying that this will be interpreted as how can we impact this. It's going to be problematic.

CO-CHAIR SCHONDER: Helen?

DR. BURSTIN: I just want to put out that we are definitely, I think, in this

place where every single committee encounters this exact thing. It's not unique to dialysis. It's the identical conversation we had where we had admission measures, the identical conversation we had about admissions from home care. This is the state of the world, as we already know.

It is not fully advanced to the ACO level, but certainly I think what we are trying to do is endorse a set of measures we think will drive improvement and drive improvement really in care overall at a system level, even if our system isn't quite there yet.

And so we have increasingly talked about the concept of the right set of measures for shared accountability that really helps drive what the patients need, so just a context setting.

CO-CHAIR SCHONDER: Alan?

DR. KLIGER: I want to just add some perspective, if I can. Clinicians years

ago looked at mortality and hospitalization in raw numbers that were very hard to understand. We then, thanks to Bob and his group, got tools to understand standardizing both and examining both with a lag time that started off in many years that's now down to nine months, I think a very formidable accomplishment for tools for us.

I would argue that, while it is clear there are limitations to the actionability of some of these measures and I surely share the concerns of my colleagues here about those limitations, that, nonetheless, these tools are giving, I believe, very important information about patient care and about facility-specific care as well.

And I would argue that placing these tools that have been developed over years or the one we're considering now is the standardized hospitalization ratio. Endorsing this here with information sources as they

become more available and easier to use is the right thing for us to do.

CO-CHAIR SCHONDER: Barbara?

DR. FIVUSH: I see this is for all patients and there are no exclusions for age. So I think this is -- I listened to Alan's comments -- extremely important because I listened to the comments about how difficult it is.

I would just urge that every patient does have a 2728. So you are going to pick up comorbidities on pediatric patients, but you are not going to get Medicare claims to follow up on comorbidities that develop. And I know this hasn't been seen by the pediatric TEP.

So I would just say that if this measure does go forward, I would really ask for some consideration of thought into how are you going to pick up comorbidities in the pediatric world, not saying this isn't an important measure?

And comorbidities are totally different in the age groups. You know, we know that. And we have had that conversation, even in the bundling, how different the comorbidities are in different ages that -- and I know that is going to be part of the analysis but that you consider that if this measure goes forward. I think that requires some consideration.

CO-CHAIR SCHONDER: Myra?

DR. KLEINPETER: One other thing I think is in looking at economically disadvantaged populations of patients, be it rural or urban. Sometimes they just don't have the other resources available. So a hospitalization is done to make sure they get the care because they don't have benefits for home health or they don't have home health agencies that will go into the projects or there are other issues related to distances that they have to travel from those rural areas. So that is one of the things that is

going to impact that we don't have a way of measuring or capturing with the measure the way it reads right now.

DR. FIVUSH: I understand exactly what Myra is saying as well. So I didn't want to sound negative about the measure. I just think that -- I mean, a lot of times we do end up admitting children because that is really the only way we can facilitate what needs to be done because their parents can't, for example.

So I think there is some validity to a lot of these comments. I think the measure, I think the importance of the measure, can't be underscored but that we need to think kind of to look at some of those things.

DR. VASSALOTTI: I guess I would just ask everybody to consider I recognize that there are definite limitations to this measure. They're certainly going to disadvantage certain dialysis facilities. I

understand and am sensitive to that, how difficult it must be for certain dialysis units.

I also understand if you are in a place where certain emergency room behaviors may be different than others, you know. So there are all of these aspects of this that potentially could disadvantage certain dialysis units.

However, I think we have to -- for me at least, dialysis patients have a very high rate of admissions. And, at least for me, quite a large proportion of those are related to things I think that the nephrologist has control over, like congestive heart failure, like vascular access-related infection.

And so the question is, does this measure capture those things with some issues that are problematic? Is that better than just voting it down?

DR. NALLY: Well, I would agree

with that concept and then have a specific question because it seems to me that when we talk about burden being put upon a facility, I think most of the burden to capture this information doesn't rest with the facility. Is that true or --

DR. WOLFE: That is correct. There is no data burden at all on the facility because these are --

DR. NALLY: So, again, to echo, it is a very important parameter that tracks over years, quarters and years. And now we have the delta move down to nine months. Maybe that will improve with CROWNWeb.

Things are clearly moving in the right direction. And, at least in this case, we're not asking to impose an additional burden on our dialysis facility staff to keep up with the information required.

DR. LATTS: So I would propose we move ahead. Did you have another comment?

DR. WOLFE: I would just like to

give a point of clarification about the timing. The discrepancy between your memory and mine is because we are both right.

(Laughter.)

DR. WOLFE: The current DFRs are a year lag. The next cycle will be one year later based upon the March quarterly staff, instead of the June quarterly staff. And that's technical. Don't worry about it. But the next cycle will be a year advanced.

DR. LATTS: So I would propose we move forward to the question. And I would propose feedback that we give to the developers based on the discussions we have had, including decreasing the time period to one year and also investigating using race as a stratification, rather than as a risk adjustment.

DR. PACE: Right. That is actually in our criteria that NQF recommends that factors associated with disparities be stratified versus included in risk models

unless there is strong justification that it is really a proxy for some biological issue going on.

So we will get back to them about that and what that means in terms of their modeling and testing in terms of -- but I think we will keep that caveat that we will have discussions about that.

CO-CHAIR SCHONDER: Any other comments? Are we ready to vote?

(No response.)

CO-CHAIR SCHONDER: all right.

DR. PACE: So this is 1463. And we'll start with importance to measure and report.

(Pause.)

CO-CHAIR CROOKS: Everybody agrees. Twenty yes.

DR. PACE: All right. Scientific acceptability of measure properties?

(Pause.)

CO-CHAIR CROOKS: Seven

completely, 12 partially, one minimally.

DR. PACE: Usability?

(Pause.)

CO-CHAIR CROOKS: Eight completely, nine partially, three minimally.

DR. PACE: Okay. And feasibility?

(Pause.)

CO-CHAIR CROOKS: Twelve completely, six partially, two minimally.

DR. PACE: Okay. Then recommend for endorsement?

(Pause.)

DR. PACE: Right. We will clarify the time period, and also we will get an answer about the ethnicity and race factors.

CO-CHAIR CROOKS: Eighteen yes and two no.

1464, STANDARDIZED HOSPITALIZATION RATIO FOR DAYS

CO-CHAIR SCHONDER: Okay. Last measure, "Standardized Hospitalization Ratio for Days." And that is finally my measure

This is very, very similar to the last measure that we talked about. The description is a risk-adjusted standardized hospitalization ratio for days for dialysis facility patients.

The numerator statement is the number of days hospitalized among eligible patients at the facility during the reporting period. The denominator is the number of days hospitalized that would be expected among eligible patients at the facility during the reporting period given the patient mix at the facility.

With regards to the risk adjustments, the same risk adjustments were applied to this measure as to the previous measure, including age, race, sex, diabetes, et cetera, et cetera, as are really, essentially, all of the other data elements throughout the measure, so not to belabor that point anymore.

As far as the reviewers, we had five reviewers of the measure. Four voted yes

for importance. One voted no. As far as scientific evidence, it was a bit across the board. There was one complete, two partials, and three minimals; usability, one complete, one partial, three minimally; feasibility, two complete, one partial, two minimally. And as far as recommend for endorsement, two yeses and three nos.

So I will open it up to the Committee for discussion, again very similar to what we just discussed.

DR. PROVENZANO: My only comment, similar to the previous measure, is a hospitalized patient, we exert even less control. And I guess I am trying to better understand the purpose of this measure considering the other.

Can you ask the developer that question?

CO-CHAIR SCHONDER: Can you comment?

DR. WOLFE: Yes. The intent here

is to get a measure which reflects the total burden of disease for the patient, which does incorporate the length, the duration of the hospitalization, as well as the number of hospitalizations.

It also is somewhat of a surrogate for the complexity of the hospitalization. We considered using DRG weights to weight the hospitalization, but we thought that the empirical evidence about how many days in hospital were spent was a more direct measure than whatever DRG complexities are brought in to measure the burden of each hospitalization.

I think that we were also swayed by the fact that DRG encoding is based upon the discretion of the way people code the diagnoses as well.

The intent of this is primarily for patient information so that they can just understand what is in store for them at different facilities, but it would also be useful, we suspect, for the providers and for

other purposes.

The real distinction is to get at the total burden of disease, rather than just the number of admissions interpreted on the basis of hospitalization by capturing the duration as well as the number.

DR. BERNS: This just strikes me on the surface as being very, very, very far away from being a performance measure and either a research tool or some other educational maybe parameter, but I think adds -- it's really nothing. It's not actionable. It's one of the furthest things away I think from a real performance measure that we've seen in the last two days.

DR. FIVUSH: I would say that with the last one, letting go of the comorbidities in pediatrics, I have a hard time looking at our younger patients, some of whom have to remain in the hospital for dialysis because they can't get dialyzed elsewhere.

And I don't know what this is

going to tell us except make fun of our patients hesitant to go to certain centers where they really could only go to certain centers.

And I can tell you we talked a little bit about the patient population under the age of two. And they can only be dialyzed in centers. And so they actually live in hospitals, which is terrible. I am not going to debate how we deliver healthcare.

So with this one, I would really want to see some exclusion of pediatric patients. But we really don't understand comorbidities if we're going to really report on hospital days. So I just wanted to know that.

CO-CHAIR SCHONDER: Alan?

DR. KLIGER: Thanks.

Bob, it sounds like a very interesting idea. I wonder if you have done any preliminary testing of this measure.

DR. WOLFE: Much less testing. We

had much less experience with this. And we have not evaluated its relationship to outcomes. It is different from just the admissions. So there are some facilities that tend to have many short admissions and other facilities that tend to have a few long ones.

And to the extent that that is interesting and useful information, it is useful to separate them because they are two different components of the healthcare process.

DR. KLIGER: I guess I would, for one, propose that we see some evidence of utility of such a measure before we make it an NQF-endorsed performance measure.

DR. NALLY: As a reviewer, let me kind of amplify that. I can understand giving a performance measure and feedback to a dialysis facility about the types, numbers of admissions you have to think about strategies that you might want to devise to attack that problem.

Once the patient enters the hospital, particularly if it is not your facility and you're dealing with many, how long they are there may be a function not only of their caregivers but also of availability of nursing home beds and other things in the area. And there are so many variables there that I don't think that would be of help or actionable at the level of the facility in any type of CQI measure.

DR. VASSALOTTI: I just want to say that I did vote for this, but I think there are more problems with this. And I think I could change my vote easily based on this discussion.

But I just want to say to the physicians in the room it is possible that some of these things are actionable, right? It is possible that duration, it is possible that there is a strong correlation with the catheter and the duration of hospitalization. I mean, it is possible, right? I mean, do we

want to at least admit that we should -- you know, I am not saying we should necessarily endorse it, but, I mean, at least we should ask CMS to evaluate this further, go get more data, and perhaps resubmit it.

DR. KLIGER: Joe, that is just what I asked for. I think that is right.

CO-CHAIR SCHONDER: Lisa?

DR. LATTS: Yes. I would agree with all that has been said. I mean, days per 1,000 is something that we follow closely from a payer, insurance company payer. But I don't see the value of doing it at the facility level, at least so far.

And I think that the admissions measure is a far more valuable measure in terms of what we have been talking about and would use it for. And I would agree that this is not ready for prime time.

CO-CHAIR CROOKS: Bob, you mean to tell me that you can't control admissions to a nursing home?

DR. WOLFE: Only if we own it.

(Laughter.)

CO-CHAIR CROOKS: My second comment is even Kaiser Permanente can't guarantee the availability of a nursing home bed when we want it and when we need it. So I would go along with your reasoning here.

CO-CHAIR SCHONDER: Any other comments?

(No response.)

CO-CHAIR SCHONDER: Okay. We will move this one to vote as well.

DR. PACE: Okay. Fourteen sixty-four, importance to measure and report?

(Pause.)

DR. PACE: Are people voting? You can try again if you think you may have jumped the gun. We can't restart it, unfortunately. So vote again if you are unsure. Okay. We'll do a hand vote on this.

(Show of hands.)

DR. PACE: Oh, okay. Yes.

CO-CHAIR SCHONDER: So we had four yeses. Go ahead.

CO-CHAIR CROOKS: Four yes and 16 no.

DR. PACE: Okay. So the technology worked most of the time, right? Right.

Let's take a break. And then maybe we'll do public comment. And then we'll have our discussion about performance gaps. And we will talk about related and -- we will discuss the plan for dealing with related and competing measures.

(Whereupon, the above-entitled matter went off the record at 2:23 p.m. and resumed at 2:38 p.m.)

CO-CHAIR SCHONDER: We'll go ahead and reconvene here. We are going to take the opportunity now for any public comments that we may have, either in person or on the phone and from the measure developers as well. Are there any comments?

DR. WOLFE: We would like to thank the Committee for the very hard work and thought and consideration. I think it is very important going forward. Thank you.

CO-CHAIR SCHONDER: Thank you. Any other comments from those in person? Any comments from anyone on the phone?

THE OPERATOR: None at this time, but as a reminder, if you do have a public comment over the telephone, please press *1 at this time.

(No response.)

THE OPERATOR: We have no one in queue at this time.

CO-CHAIR SCHONDER: Okay. Thank you very much.

DR. PACE: I am just going to lay out what we're going to do in terms of we still have to look at related and competing measures, but what we'll do is just kind of get everything organized, make sure we're on

the same page with what actions were taken. We have to look at related and competing measures.

There are some things we need to get back to the measure developers about with responses and the one issue about one oft he conditions and maybe we don't need that condition. But we'll get a formal response. And then you'll be able to act on that again.

I think a couple of times there has been some discussion about perhaps some of the recommendations were inconsistent. But once we look at all of those together, we can identify if there are any issues of inconsistency and have you take a look at those and at least justify or give a rationale why, you know, seemingly similar measures, one was recommended and one not, those kinds of things, if those exist.

So we'll I think, you know, as was mentioned earlier, say we need to look at the set now that's there and then see if there's

anything that we need to get more clarification about and certainly still deal with the related and competing measures.

So before we get into this next thing about quality, are there any questions about that or anything that you want to bring to our attention that we need to do or --

(No response.)

RESEARCH RECOMMENDATIONS/PERFORMANCE MEASURE GAPS

DR. PACE: So what we'll do is we're going to have a discussion, then, about gaps in performance measures, research recommendations.

What we handed out today was just kind of an addition to the discussion that we started on the conference call. So this is just draft, but, again, it's to have something to start with to see if there are things that you want to strike or add. And it's laid out in -- Lauren, do you want to put it up on the screen? It's laid out in structure, process,

outcome, intermediate outcome in terms of, you know, what are the concepts that are related to quality of care or that would signify quality of care and would be reasonable to think about having performance measures.

So what we did here is tried to lay these things out that were mentioned on the conference call in this format. We have identified with an asterisk where we have NQF-endorsed measures. The little plus sign is proposed measures that were being looked at in this project.

Underneath the table are some of the things that are often discussed and, as we have talked about, that are a little more distal from the desired health outcomes, the assessment things and that nature.

So this is just trying to capture the things that were discussed on the phone and then open it up for you to change or certainly to add to in terms of what you think are the concepts and areas that would really

be good quality performance measures.

CO-CHAIR CROOKS: This says ESRD, but I thought -- are we going to talk more generally about chronic kidney disease, too, in this discussion?

DR. PACE: We can because that will certainly lead into our next project. So that's certainly open for discussion as well.

CO-CHAIR CROOKS: Good.

CO-CHAIR SCHONDER: Alan?

DR. KLIGER: Well, there are two major areas that are holes in this portfolio. The first has to do with education, the education of patients, into the nature of disease, the choices available for therapy.

And the second major area is patient perception of care. We mentioned that briefly on the telephone, but it's a key area that the rest of the world is indeed looking at, that hospitals are looking at and other care organizations are looking at, that we don't have any measures in this portfolio that

I would suggest we need to consider.

MS. LeBEAU: Yes. If I could follow up on that? I think, obviously starting with the second first from my perspective, I think about it in terms of the patients' experience of treatment because I think it gets at a compliance issue very well. If you're crashing, cramping, nauseous, throwing up virtually every time you are on treatment, it's really hard to keep going back to treatment. I think if we could look at that and get at it and understand how we impact that, it would be very valuable.

The other thing that I think, education absolutely, this concept I'm not sure how we address, but I am pretty sure that when the original benefit was put in place, it was not to create a population of debilitated and disabled patients. So my words for this are "functional wellness."

I don't think the KDQOL gets at this. I really don't. I think it's some

combination of that and work status. And, again, I think it's a complicated measure.

I also just, in reflecting on the last two days, thought a lot about what was talked about at the Boston conference and the conversations and report that I read about Tom Parker and Barry Straube talking about how composite measures are really where we need to go so we can really get a good representation of the things that we're trying to improve.

So thank you.

CO-CHAIR SCHONDER: Myra?

DR. KLEINPETER: So in terms of framing some of the other discussions, I guess, in terms of where we have gaps and what we need to do additional research on and where there may be areas that the developer community needs to work on, looking at transition of care from CKD to ESRD, we have no real I guess coordination of care for the accountable care organizations. And we have no coordination as evidence between the

primary care referring physicians to the nephrologists, who are then responsible for all of the care that has gone on in that preceding nine-month period if we're looking at some of the hospitalizations related to these ESRD patients.

And in looking at vulnerable populations, prisoners, the rural patients, minorities, including Indian Health Service, blacks and Hispanics, where there are historically high rates of ESRD among these populations of patients, and what health disparities when they do exist, what are we doing to combat them and how are we reducing those disparities when they are identified.

CO-CHAIR SCHONDER: Lisa?

DR. LATTS: And to follow up on Myra's comments, I think also transition of care, period, transition of care between settings. You know, we talked today about some of the difficulties in getting information from hospital to dialysis unit and

vice versa.

And I think in the new world order, we have got to start measuring and improving those processes and making sure that they are appropriate methods and strategies so that coordination between inpatient, outpatient, specialty primary care, et cetera, happen. So there have got to be metrics around those.

DR. PACE: I just want to mention in the last project, we did endorse the CAHPS in-center hemodialysis survey. So that is an NQF-endorsed measure, the CAHPS results.

CO-CHAIR CROOKS: Alan, does that serve the need, as I know you helped develop that?

DR. KLIGER: I did. I was involved in helping develop those measures. And, surely, that is part of it, but my perception is that patients and patient-measured outcomes are what I am talking about. So, you know CAHPS really taps

into a limited set of perceptions. CAHPS was not developed by patients. CAHPS was developed by professionals. I think patient-derived measures and patient measures are something we haven't had enough experience with.

DR. BERNS: Can I just ask a question about the practicalities at getting at what you suggested, Alan? Having patients provide us with information about "Have you received meaningful education about home dialysis and transplant?" because we can provide that information, but if the patients don't perceive themselves as having -- and I know your group has published on this knowledge gap.

Obviously there is an issue of translating that into some kind of a metric that can be used. And it gets to the nutrition. We talked about the dietary salt intake. You know, if there is a way to query the patients, I don't know how that would be

done practically, but that is probably an important part of measuring what we do, the process of care that we provide as a dialysis provider.

DR. NALLY: I would have a specific question along that line that we might be able to directly impact. A year ago last week, the CMS benefit was put in place for the pre-ESRD education. My question specifically relates to how many people on the patient and provider side have taken advantage of that benefit, completed education? And is there any information of pre and post-testing to reassess a tool that was purposely put in to educate and empower patients in their decision-making process about modalities and all of the important things that were seemed appropriate for that education process?

And I think it would be a very helpful learning step to know where we stand a year later into that, what impact, if any, that has had, what are the barriers to

implementation. Does CMS need any help with bringing that to the patient front? What are the successes and limitations of that educational effort?

And that should be information that should be becoming available.

MS. WAGER: If you don't mind if I comment on that, I do education for truth in options for Fresenius Medical Care. And it has made an impact.

The barriers we see, nothing against the physicians here, but it's physician referral. Okay? The comment I would like to make is I want to thank the NQF for having this but allowing four patients to be on this Committee.

This is the first time that I have been involved with AAKP or the NKF or been a patient for 53 years that I have been on a committee with 4 patients because, as you all know, what you all decide, it affects us.

So I thank you so much for

everything that -- I mean, for allowing us here but also listening to us and our input. So thank you.

MS. PAVLINAC: Along the same lines of the patient education that has been there for a year, there has been a Medicare-approved benefit for nutrition counseling with the GFR of less than 50. And, again, we don't have good data to know how it is utilized, but it is a referral and oftentimes under-utilized.

Yes, there is the caveat. And the barrier is that you have to qualify for Medicare Part B. And you can't do that with CKD now. But, still, that is under-utilized from a nutrition perspective, too. And we do know that coming into dialysis, whether you're an adult or a kiddo, nutrition status will make a difference to the outcomes that the units are being held responsible for.

DR. VASSALOTTI: I wanted to make a comment to follow up on what Joe said about

the KDE, the kidney disease education. I want to thank RPA for working with the National Kidney Foundation to help promote that. And I would like to see data not only on the utilization and the feasibility of it.

We get the sense that it is being used mostly in large practices that have a lot of patients, maybe practices that have physician extenders. What does it do? You know, do patients have more -- is there more home dialysis associated with KDE? Do patients start hemodialysis with a fistula more likely when they receive KDE than not and those kinds of things? And it would be interesting to explore possibilities of maybe expanding it.

And I think, to follow up on what Roberta said, maybe perhaps there are other ways that highly educated physicians aren't always the best educators. Maybe there are other ways to educate patients.

DR. KLIGER: Can I just follow up

on that? We actually published and studied, looked at that and looked at objective evidence of understanding or of understanding choices among patients.

And our findings were that a remarkably high number of patients who did get education from their physicians did not have a clear understanding of what their choices were or where they were going and that when they went through a more formal education process, that a substantial number increased. That's what Jeff was referring to before.

And I do think it's important to examine not only the utilization of the funding for education but some actually outcome measures. That's a process measure but perhaps some real outcome measures that have to do with patient education and choices in the ESRD.

CO-CHAIR SCHONDER: Andrew?

DR. NARVA: I think we need system change to improve outcomes in CKD. And I

really hope that NQF goes ahead and looks at performance measures in CKD but keeps them really simple.

Right now the only thing that is out there is basically doing the "microalbumin test" on diabetics. That's it. And just in terms of very simple measures for identifying people with CKD would be a start because when you talk and try to promote systems change, you talk to large groups of community health centers or other organizations which provide primary care to high-risk populations, when there is no market, there is no HEDIS measure. There is no NQF measure. It can be hard.

And if there is a measure, people pay attention to that. And a lot of the people who pay attention to that are the non-physicians, who actually drive what happens in the primary care setting.

So I think it's very important. But I also hope that you resist what often happens in the renal community, which is to

include everything in there all at once and make it so overwhelming that it becomes intimidating and very difficult for your target audience to accept. That's for kidney.

CO-CHAIR CROOKS: I am going to give three specific metric names, hoping that this will get into the record and stimulate some thought. One of them I have already created or have been involved in. This is the issue of patients, the outcome of patients, actually getting an optimal start of the ESRD, kind of the end process of getting educated and empowered.

An optimal start of the ESRD is a patient who starts either with a preemptive transplant, a home dialysis modality, or if they have to go in center, they have a fistula.

A non-optimal start is a patient starts with a catheter. It's a metric that we have developed in Southern California Kaiser Permanente. And we have published on it. And

I am going to try to bring it in next round. I am going to look, see if it is feasible to bring it in.

Another CKD metric that we should be able to get at is nephrologist referral of appropriate CKD patients. So that can be defined. What is an appropriate CKD patient? Stage 3 diabetic maybe or, you know, we could talk all day but some definition of appropriate patient. Certainly CKD stage 4 patients and beyond should all be referred.

And this is something that could be applied at the health plan level. We're so used to thinking of sort of dialysis facility-level metrics.

And then a third metric related to dialysis, which is where I think the field needs to move to, would be called the percent of or more intensive dialysis for appropriate patients. The denominator would be the number of patients who started on dialysis who want a more intensive therapy. So this way I am

saying "more intensive," instead of more frequent or longer. It could be that or any combination thereof.

So the denominator is the number of patients who want more intensive dialysis. And the numerator is the number of patients who get more intensive dialysis as a starting metric to push things in the direction that they should probably go.

DR. VASSALOTTI: I think those are great. And I read I think Witkowski's paper in the AJKD that looked at the optimal start. I think the catheter start is not included, but a graft is considered an optimal start, right? I just wanted to clarify.

CO-CHAIR CROOKS: Yes. In our system, up to five percent of new hemo starts is going to have grafts. More than that is considered excessive and not optimal.

DR. VASSALOTTI: And then I want to follow up. I was going to also talk about even though a nephrologist may not always be

the best educator, may not be the best to do everything, the nephrologist is key to everything that happens in the transition.

So I think that the measure could be -- and this is a KDIQO opinion-based guideline. You know, nephrology referral for a GFR less than 30 might be a place to start. I think that's open to discussion.

I think the evidence for that is pretty strong in terms of observation data, showing that patients who start dialysis without seeing a nephrologist or late referral, if you will, a crashing -- I think that's something that could be considered. I am willing to hear what others think about that.

CO-CHAIR SCHONDER: Connie?

MS. ANDERSON: Actually, one of the things we measure is the metrics of how long the patient has been under the care of a nephrologist and referred from a primary care doc. And we found it correlates very well

with well-educated patients. They get referred to the CKD programs. They get their access in early versus those patients that are referred under less than a month or whatever. So I think that's a very important metric.

DR. VASSALOTTI: And the reason that the less than 30 is somewhat arbitrary, admittedly, one of the very difficult things about individual patients is you can't always predict the trajectory of their kidney disease. And you can't always predict how quickly they will -- when will they need dialysis. And acute kidney injury can change that.

So I think that's why having a specific recommendation might be worth considering.

DR. BERNS: Maybe just a word of caution -- and I agree with the principle, but there is increasing recognition that albumin urea alone, even in the absence of reduced GFR, portends the same poor prognosis as a

reduced GFR.

And I think we also -- we have nephrologists in the audience. I think they have all seen people with CKD, stage 3 with a creatinine of 1.4 or so, 1.6. It's been like that for 15 years. And so there is an adverse effect that we would just need to be cognizant of or the 82-year-old who has a creatinine of 1.3. And it's always going to be 1.3.

So we just need to be careful as we think about crafting performance measures that it does what we want it to do and that it doesn't do things that we think shouldn't occur as a result.

DR. VASSALOTTI: Yes. I think that is a really good point. Obviously I am not implying that that is the only reason to refer. There are all kinds of other reasons. You know, you may have normal GFR with heavy proteinuria. And that might be a perfect reason to see a nephrologist.

DR. BERNS: There was a very

interesting study that was done at one of the VAs -- I don't remember in which city -- where they actually really modeled. It wasn't an actual experiment, but they modeled what would have happened in their patients had they put in a dialysis access based upon then existing KDOQI recommendations.

And, as you can imagine, in people who were in their 20s and 30s, about half of them ended up getting used or something like that. But as you got further and further up in age, there was a tiny fraction of dialysis accesses that would have ever been used. So now you have the potential of subjecting patients to unnecessary surgery if we're not careful.

DR. VASSALOTTI: The only thing that I am struck by -- and I will cease and desist after this -- is that if you read the USRDS 2010, over 40 percent of patients had no nephrologic care before they started and before they had a diagnosis of end-stage renal

disease. That is an incredible statistic. And that is really a lot of lost opportunity.

DR. BERNS: Ample opportunity for improvement.

DR. NARVA: I have enjoyed this interchange, but I think it really represents why we need to get so far beyond early referral. I mean, the kidney community's response to improving outcomes is early referral.

Meanwhile, all the nephrologists are overwhelmed. We don't have all that much evidence for a lot of what we do. And the greatest opportunities are earlier, whenever you decide to refer the patients.

And I hope that the NQF can stimulate looking at this in a much broader way because congestive heart failure is as lethal as kidney disease, as chronic kidney disease. And the issue in congestive heart failure isn't when you refer the patient to the cardiologist. It's, you know, there are

a whole bunch of early interventions and education that occur. And so we need to sort of move it in that direction, I hope.

And also this whole issue of self-management, which, you know, is a relatively new concept, needs to be fleshed out and supported by organizations that have the kind of credibility that the NQF has to really make it a legitimate measure of the quality of care.

DR. JACKSON: One measure that I would like to see is the percentage of patients who have been seen by a nephrologist for six months who choose hemodialysis and who start their first outpatient dialysis with a fistula.

Currently that's a pretty low number. And so I think, even when the referral occurs in a timely manner, in a lot of cases, we, the nephrologists, are not getting them prepared adequately.

CO-CHAIR CROOKS: That is the

greatest, just to get a little feedback to that, that is the greatest portion of this optimal starts metric of patients who start hemodialysis successfully with a fistula.

And nationally you can look at USRDS data. And optimal starts, as I defined it, is about 25-27 percent. In other words, 75, 70-75, percent of patients start ETSRD, their first modality is hemodialysis with a catheter.

How well have we been able to do in Kaiser Permanente, where we have a lot of control, where no CKD patients, very few CKD patients, go undetected and then referred? We have put a lot of effort into modality education at the right time. We have been able to push it as high as 55 to 60 percent. I am not saying we have reached the upper limit yet. I think we might be able to get as high -- certain areas, subgroups working within our system have reached close to 80 percent optimal starts. You're not going to

get much above that. But there's going to be 20 or 30 percent that you can't -- even if you have identified them, you're not going to be able to get optimal starts for a number of reasons.

But that is just to sort of give you -- there is a gap. And a gap can be closed. So it's worthwhile focusing on that.

DR. JACKSON: Do you know the ratio of grafts versus fistulas in that population that you're identifying as optimal starts?

CO-CHAIR CROOKS: Yes. We have defined up to five percent grafts as acceptable, of new hemo starts. More than that count as non-optimal.

DR. FIVUSH: I am going to switch gears for one minute and just say that Rick and I both have very much -- and I didn't say this before because I didn't have a chance, but we both very much appreciated the opportunity to be here and represent the -- I

don't know if there have been two pediatricians on any of the ESRD NQF panels because there haven't been pediatric measures. So it's --

DR. KASKEL: We represent about a quarter of all pediatric nephrologists.

(Laughter.)

CO-CHAIR CROOKS: On the East Coast anyway.

DR. FIVUSH: It has been a great process that we actually -- I mean, we're years behind, but I think we have really made some progress in getting some pediatric measures, which may get endorsed and ultimately may make pediatricians accountable for the things that we think are important.

I would say one area and opportunity that we haven't talked about -- and RPA has talked about this, and ASPN has talked about this -- is the transition period, the 18 to -- I mean, just how we -- I'm talking about pediatric to adult transitions

that you had mentioned that transition. And Rick has done some work in this as well.

And we just expect our kids to become adults automatically sometimes. And they're chronically ill. And I think we may need to look at how we transition those patients because our goal would obviously be to have them totally rehabilitated adults. And I think we have a lot of work to do, but maybe that's an area for measure development. There's been a lot of work that has started in that area.

Many of the patients that end up in the internists' hands, as Andy would talk about from his work, really, the roots of their disease is in childhood. So I think we really have to think about that whole progression and spectrum.

MS. LeBEAU: Please don't laugh. I am all about patient-reported measures and education. And I am about to ask a question, which is, are there clinical lab values that

we are not yet looking at that may have some predictive value?

This is obviously an area that I don't know a lot about. I don't know albumin, PTH. Are there things we are missing? Is there something that we haven't put our finger on yet that has a great correlation, just a question? Thank you. Yes.

DR. KLIGER: I am listening to all of our discussion. And I am impressed that it is very nephrocentric. I mean, it's centered on what the nephrologists can do on end-stage kidney disease.

And one of the things that would be useful for us to remember, I guess, is that the majority of people with kidney disease are not transplanted or have dialysis.

And we have learned a lot in the last few years about that. We have learned that those patients have a high incidence of heart disease. And heart disease predisposes to kidney disease and vice versa. And,

indeed, we have learned other systems likewise that have feedback loops.

I guess I would make a plea for stopping thinking about what we do with so much of our time and taking a step back and again looking at it from the patients' perspective of having multi-system disease, of having some chronic kidney disease and heart failure and diabetes and talk about optimal management, optimal management measurements for people with multi-system disease.

DR. NALLY: We have a CKD registry of about 60,000 people right now in our health care system. And, as you start looking at the numbers, you recognize breaking things down into silos is really a day of the past.

And I think, as the primary care groups are looking at these ideas of medical homes, of accountable care organizations, it's going to be how different subspecialists, be it cardiologists, nephrologists, interact with that medical home concept or, in essence,

educating, empowering, and caring for the whole patient and the appropriate specialists coming up to the trough, whenever appropriate, to help out in that care and that at some point in our case, if the disease progresses and dialysis and transplant are clearly on the horizon assuming more and more of that care.

And it's this interaction now -- I think the Annals this month had a whole series of articles on medical homes and perspective, primary care perspective, of the specialist, et cetera.

And my prediction is we're going to evolve in that direction. And so how we in our given subspecialty can provide tools to help empower that patient and they are a primary care giver to make this a more efficient and accountable system is going to be the future.

So we need to broaden our net, I think, and be, as you say, a lot less nephrocentric.

DR. PROVENZANO: My only comment I think goes to what the RPA has worked on for a long time. And now you're hearing more in the media. And that is end-of-life discussions.

This is a huge opportunity for us to see to it that patients get the right education. I think many of us know that conservative therapy for CKD stage 3 -- I'm sorry -- late-stage 4 and 5 for an elderly person is absolutely appropriate. It will help with expectations. And I think it checks a lot of the boxes that I think we're obligated to pay more attention to.

So I would look for measures focusing on end-of-life education.

CO-CHAIR SCHONDER: Are there any other comments related to performance gaps?

MS. LeBEAU: A side issue. We were talking about physician education and formal education and the difference it has in what the patient absorbs. And so this is a

measure suggestion. It is sort of a how-to suggestion and address the rehabilitation status of a lot of patients.

Patient educators are a great opportunity. We, with all due respect to everybody's clinical expertise, get the extra added benefit of we have been there. And so offer an empowerment and a hope and a lot of things that patients coming down the pipeline need to hear to be encouraged and to take that investment and really wrap their hands around taking control of what they can, so just a thought.

DR. LATTS: You know, my only comment is sort of a question, I mean, similar to sort of our initial question on our initial call. Now that we have put out all of these great ideas to NQF, what do you do with them? And how do you make them happen?

DR. PACE: Well, as you know, NQF is not a measure developer. What we will do is include these in our report and our, you

know, hope is that those that are involved in measure development will look at these suggestions and think of ways that they can move them into measure development and ultimately come back to NQF.

But, Helen, I don't know if you want to say anything else about that with some of our other projects?

DR. BURSTIN: The other thing that we are able to do is when we do the call for measures for this next round, we will make sure we highlight these specific areas that you have indicated.

Again, somebody can't go from that point to submission in just a couple of months, but it may at least stimulate them to think that these are the kinds of measures they want and not just a lot of the same measures.

Our fear is we tend to get a lot of look-alike measures that are slightly different. Just change the condition that's

still smoking, still blood pressure, et cetera. We really need to, what you're really saying here is, get to a deeper, richer set of measures that can really drive improvement. So hopefully that will help, too.

MS. SINGER: I am Dale Singer with the Renal Physicians Association. And, just as a way of foreshadowing based on the conversation, we are working right now with the AMA Physician Consortium for Performance Improvement in preparation for your next call. And many of the topics you have just discussed will be included in some of our proposed measures.

DR. PACE: Just a couple of reminders. We will be in touch with you, as you know. We know your e-mail.

(Laughter.)

DR. PACE: If you would -- yes?

DR. VELEZ: Please be sure that we receive them because we are all playing with firewalls and things when there are fires.

DR. PACE: Right, right. That's a good point.

So, I mean, I'm going to just ask you to, first of all, be sure not to walk off with your voting thing or have those already been collected?

If you would leave your thumb drive? We will be glad to send you any of the updated files. And I would like to just take a few minutes to see if you want to give us any suggestions, as Ruben was just saying, that would help our communication, help organize things. We know there are lots and lots of materials. And we really do try to organize things, but if you have some suggestions, we would love to hear them. And Ruben's is to make sure we know that you are getting the stuff because of things getting filtered out by firewalls.

DR. BERNS: Increasingly, organizations are using either SharePoint or similar technology, where you won't have to be

sending files back.

DR. PACE: Exactly. NQF is actually moving to SharePoint. We're going to be doing some pilots next month. And then we'll be rolling it out to the projects because we have identified that, too. It would be much nicer to have a place where everything is, we can update it and avoid the e-mail stuff.

Any other comments about prep for the meeting, evaluations, the meeting itself? We're certainly --

DR. FIVUSH: I am curious. How long have you been using this device?

DR. PACE: This is the second time.

DR. FIVUSH: You know, my question is -- yes. The audience response is -- I said to Jerry I wonder what the impact of that is on the way people vote. I don't know how to know the answer to that, but it just occurred to me that, I guess, to be honest, it's a good

thing. It's a great thing. I just was curious.

DR. PROVENZANO: I think it is a better method of people being comfortable.

DR. FIVUSH: I was wondering if you had looked at that. But I agree. I think it's a much better, more honest way.

DR. KLIGER: I have another general question. I was impressed in part of our deliberations that the developers of the measures, who had spent a huge amount of time in different kinds of TEPs, had a limited ability to share with us their thinking that underlay their recommendations.

I mean, there are some times where it was pretty clear, but there were others where, I mean, for example, Bob was just jumping up and down out of his seat and grabbed me and others after our deliberations to say, "I don't think you understood the depth to which we discussed this or understood this."

And we using our best judgment sat here and sort of said, "Well, why don't we try this?" or "Why don't we try that?" You know, and that's what we do.

But I just raised the question about thinking about a way to more effectively allow the developers to have an integrated role in discussing the rationale for each of the measures.

DR. PACE: We will think about it. We have tried various scenarios, and we go back and forth. But I think it is worthwhile that we need to take a look at that again.

DR. BURSTIN: And part of all of this sometimes is that the clinical folks aren't here so that you are asking questions that they may clearly be able to help on the measure development side, but what you really want to do is have somebody from the TEP that you could have asked that to. And that has been a struggle for us on several of these projects, yes.

DR. FIVUSH: I agree with Alan. I felt that with many of the measures, the CMS measures, we certainly had part of the measure-developing team. But we often heard "I am just a statistical person." And I really would like to have been able to have a clinical physician or a physician member of the TEP to clarify why, I think, or available by phone. That might have been really helpful with some of the complicated --

DR. PACE: Right. And I think, you know, we have certainly time limitations. And so we can't go back from the beginning and have a presentation of each measure. And so we try to balance these things, but I think we always need to be reminded and be sure that when there's a question, that we do consult the measure developers who are here. So I think we will continue to figure out effective ways to do that.

CO-CHAIR CROOKS: Here is a simple one. You know, and it may sound silly, but

maybe on the application form, you should have a box that says, "Up means good" or "Up means bad." You know what I'm saying? Which direction is a good direction for the metric to move?

Sometimes, especially if you're looking at one and you haven't had a lot of time to digest it all, you know, you're still wondering, what are they trying to do here? And which way is the desired movement? Does that sound silly or --

DR. PACE: It is actually one of the things on the submission, but it's one of those things that it's not prominent. So we are looking at --

CO-CHAIR CROOKS: It should come right after the description of the measure.

DR. PACE: Right. We are looking for --

CO-CHAIR CROOKS: "Up is good."

DR. PACE: -- changing what comes up --

CO-CHAIR CROOKS: "Down is good."

DR. PACE: -- front first. So, you know, we will add that in as we are moving some things so that that would be at least like the numerator and denominator statement up front after the description and then the details when you get into specifications. But I think we have gotten feedback that that would be easier for people to see that kind of full picture up front before you get into the details.

DR. BERNS: Related to that is very explicitly stating the goal of the measure, quantitatively if possible. In other words, what is it that we expect to achieve as a society with this measure?

It's a change from where we are now to some specific number. Is it just getting better than we are? Is it 90 percent compliance, 99 percent compliance? And it gets to some of the -- sometimes it was unclear and the gap was unclear.

CO-CHAIR CROOKS: Another thing that, Karen, we talked about last night, actually, is the confusion of the term "scientific acceptability." The clinicians and scientists immediately think this is more of why this is a good outcome or the justification of it. This is good science to study this, and that is not what it means.

I was suggesting to Karen maybe we rename it or separate it out: measure specification. And maybe that goes up earlier.

And then just call it validity and reliability, you know. I think that would really help because some of our people, even late into the first day, are still -- you can tell when they're discussing, thinking of rating science as the medical science and not the statistical science.

So that might really help the steering committees, at least, to rename those sections or you could put the second sections

called specifications validity and reliability.

DR. PACE: Right. Okay. Well, certainly if you have any suggestions, feel free to send them to me and Lauren. So we welcome your suggestions and really have enjoyed working with you and look forward to our continued work on the project.

We'll need to set up a conference call. So we will be getting back to you to schedule it very shortly.

DR. PROVENZANO: I just want to again comment. I have done a lot of these in different venues. I think, Karen, you and your team should be congratulated. This was very well-orchestrated, planned, communicated. So I want to personally just thank you and your team. It's really great, very enjoyable meeting.

(Applause.)

DR. NARVA: Peter and Kristine did a good job of moderating.

CO-CHAIR SCHONDER: On behalf of Peter, myself, and the NQF staff, we would like to thank all of you for your work on the reviews.

Even though we didn't get through all of the agenda items, I think it goes without question we accomplished a lot in these past two days. So we look forward to being in touch with all of you.

DR. PACE: And you guys are the group to beat now in terms of preparation, of doing evaluations in advance of the meeting. So we are really appreciative. So thank you.

(Whereupon, the above-entitled matter went off the record at 3:23 p.m.)

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
Quality Measures

Before: National Quality Forum

Date: 01-12-11

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