

NATIONAL QUALITY FORUM
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END STAGE RENAL DISEASE QUALITY MEASURES
STEERING COMMITTEE

+ + + + +
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,
Eules, 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

Welcome, Recap of Day One5
Dr. Crooks, Dr. Schonder	
Consideration of Candidate Measures	12
Fluid Weight Management	12
1432, Dietary Sodium Reduction.	12
Advice (Myra Kleinpeter)	
1434, Sodium Profiling Practice	25
for Hemodialysis (Connie Anderson)	
1435, Restriction of Dialysate.	30
Sodium (Alan Kliger)	
1437, Utilization of Dialysis	36
Duration of Four Hours or Longer for Patients New to Dialysis (Bobbi Wager)	
1439, Utilization of High	77
Ultrafiltration Rate for Fluid Removal (Alan Kliger)	
1438, Periodic Assessment of.	90
Post-Dialysis Weight by Nephrologist (Myra Kleinpeter)	
Brief Introduction of Measures by118
Developer(s)	
Infection132
1477, National Healthcare Safety.132
Network (NHSN) Intravenous (IV) Antibiotic Start Measure (Peter Crooks)	
1460, National Healthcare Safety.153
Network (NHSN) Bloodstream Infection Measure (Sue Barnes)	
1478, National Healthcare Safety.197
Network (NHSN) Vascular Access- Related Bloodstream Infection Measure (Sue Barnes)	

C-O-N-T-E-N-T-S (Cont'd)
 Consideration of Candidate Measures
 (Continued)

Infection (Continued):

1457, Access-related Bacteremia209
(rate) [stratified by access] (Jerry Jackson)	
1456, Bacteremia (rate) (Andrew251
Narva)	
1455, Access-related Bacteremia236
using Medicare claims (rate) [stratified by access] (Jerry Jackson)	
1449, Unavailable Blood Culture264
Results (percentage) (Andrew Narva)	
1469, Clinically Confirmed.275
Access-related Infection (rate) [stratified by access] (Lisa Latts)	

Hospitalization

1463, Standardized.281
Hospitalization Ratio for Admissions (Lisa Latts)	
1464, Standardized.312

Hospitalization Ratio for Days
 (Kristine Schonder)

NQF Member/Public Comment323
Research Recommendations/Performance.325
Measure Gaps	

Adjournment368
-----------------------	------

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
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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

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

3 Fourteen twenty-one was also
4 recommended. And, Lauren, would you highlight
5 the cell with this measure name and number?

6 Okay. There. We should see it in this
7 formula bar. Okay. Oh, I see. All right.
8 Method of adequacy measurement. And that one
9 was recommended.

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

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

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

21 Fourteen thirty-one was
22 measurement of iron stores for pediatric

1 patients. That one did not pass.

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

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

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

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

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

1 period.

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

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

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

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

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

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

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

16 CO-CHAIR CROOKS: Yes.

17 DR. PACE: -- make some comments.

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

20 DR. PACE: All right.

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

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

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

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

1 DR. DUDLEY: Karen?

2 DR. PACE: Yes?

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

5 DR. PACE: Okay. Great.

6 MS. HENRY: Renee Henry here, too.

7 DR. PACE: Who?

8 MS. HENRY: Renee Henry from CMS.

9 DR. PACE: Okay. Great. Okay.

10 So what we're going to do is we are going to
11 finish up. We are going to do fluid
12 management measures that we didn't get to
13 yesterday. And then we will proceed with our
14 agenda for today, which will begin with
15 introductory remarks or brief introductions by
16 the measure developers and stewards and then
17 the measures that we were scheduled to do
18 today.

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

1 But shall we just get into it?

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

8 DR. KLEINPETER: Yes.

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

11 CONSIDERATION OF CANDIDATE MEASURES

12 FLUID WEIGHT MANAGEMENT

13 1432, DIETARY SODIUM REDUCTION ADVICE

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

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

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

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

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

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

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

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

12 And that is pretty much all.

13 DR. PACE: So what were the
14 issues?

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

1 morbidity/mortality reduction is.

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

10 Any other discussion from other
11 reviewers?

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

22 And so there is a problem with

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

12 CO-CHAIR CROOKS: Jessie?

13 MS. PAVLINAC: I agree with all of
14 that. The other issue I thought was
15 problematic was within 90 days, which says to
16 me that every patient within whatever this
17 90-day period was going to have that specific
18 advice, which made no sense from a practical
19 standpoint.

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

22 MS. WAGER: Yes. I was one of the

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

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

16 We worry about phosphorous. We
17 worry about anemia. But we do not emphasize
18 the fluid management. I talked to -- I visit
19 28 clients in the San Antonio and the valley
20 region. I met with 14 dieticians about this.
21 Hardly any of them talk about or document salt
22 restriction or salt intake. What they do if

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

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

11 Thank you.

12 CO-CHAIR CROOKS: Thank you.

13 Alan?

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

20 CO-CHAIR CROOKS: Myra or Joe?

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

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

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

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

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

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

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

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

1 completed as of yet.

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

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

8 CO-CHAIR CROOKS: From CROWNWeb.

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

12 CO-CHAIR CROOKS: Thank you.

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

17 DR. MESSANA: It is a data
18 element.

19 DR. FIVUSH: That just says --

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

1 DR. FIVUSH: Right.

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

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

14 And, Helen, you want to make a --

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

1 otherwise it does just become a check box.

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

9 So other comments before we get to
10 voting? Bob?

11 DR. WOLFE: Thank you.

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

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

20 Other comments?

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

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

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

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

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

13 (Pause.)

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

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

20 CO-CHAIR SCHONDER: Fourteen
21 thirty-four.

22 CO-CHAIR CROOKS: -- 1434, "Sodium

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

3 1434, SODIUM PROFILING PRACTICE FOR
4 HEMODIALYSIS

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

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

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

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

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

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

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

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

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

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

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

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

14 DR. FIVUSH: Right.

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

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

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

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

3 DR. FIVUSH: Right.

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

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

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

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

1 sodium transfer into patients.

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

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

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

15 CO-CHAIR CROOKS: Okay. Other
16 comments?

17 (No response.)

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

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

22 (Pause.)

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

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

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

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

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

1 concentration is greater than some number --
2 and they have picked in this proposed measure
3 138 -- that there will be excessive sodium
4 transfer into patients and negative
5 consequences of that, again I think a very
6 attractive hypothesis and one that many
7 clinicians are using and thinking about now.
8 But, unfortunately, the data for the utility
9 of that hypothesis is not present.

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

16 The measure is really based on the
17 2006 publication of DOPPS that does show some
18 correlation. I'm sorry. I apologize. That's
19 the next measure.

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

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

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

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

1 there.

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

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

13 (No response.)

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

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

3 (No response.)

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

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

8 (Pause.)

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

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

18 DR. PACE: Okay.

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

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

7 My point is only I would like to
8 get back to them and state if they haven't
9 excluded pediatric, that would be an important
10 --

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

13 DR. FIVUSH: Right.

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

17 DR. FIVUSH: To put that in the --

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

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

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

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

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

10 1437, UTILIZATION OF DIALYSIS
11 DURATION OF FOUR HOURS OR LONGER FOR
12 PATIENTS NEW TO DIALYSIS

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

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

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

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

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

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

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

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

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

19 MS. WAGER: And feasibility?

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

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

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

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

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

1 some outcomes, and longer dialysis may improve
2 some outcomes.

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

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

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

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

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

1 half. I felt better. I did better.

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

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

15 Thank you.

16 CO-CHAIR CROOKS: Thanks.

17 Alan?

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

1 clear evidence that more dialysis is doing
2 more.

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

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

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

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

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

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

22 So that's what's even a bit

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

5 Does anybody disagree with that or
6 --

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

10 CO-CHAIR CROOKS: Okay.

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

13 CO-CHAIR CROOKS: Right.

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

19 DR. KLIGER: Yes.

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

22 DR. KLIGER: No.

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

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

11 DR. LATTIS: So how did four hours
12 become the standard?

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

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

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

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

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

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

22 Now, again, having said that, if

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

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

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

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

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

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

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

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

3 DR. LATTIS: Go ahead.

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

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

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

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

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

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

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

1 measures faster.

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

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

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

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

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

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

9 CO-CHAIR CROOKS: Alan?

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

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

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

1 the evidence that that is the case right now.

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

11 CO-CHAIR CROOKS: I would just
12 point out for Lisa, too, that there is a
13 minimum standard here in Kt/V or urea kinetics
14 from the last batch. Two four seven is that
15 patients have that measurement done. Then
16 248, delivered dose, that is measured. I
17 don't know.

18 DR. LATTIS: Yes.

19 CO-CHAIR CROOKS: Yes. Here's a
20 249, that the minimum single pool Kt/V is
21 greater than or equal to 1.2. So there is an
22 NQF standard for a minimum.

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

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

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

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

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

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

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

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

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

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

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

22 DR. MESSANA: No.

1 DR. VASSALOTTI: What?

2 DR. MESSANA: I just --

3 DR. VASSALOTTI: Okay.

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

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

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

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

12 DR. MESSANA: That is not the
13 case.

14 DR. VASSALOTTI: Thank you. I am
15 sorry.

16 DR. MESSANA: Okay.

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

19 And then I think we should --

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

22 DR. VASSALOTTI: We could come

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

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

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

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

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

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

16 DR. VASSALOTTI: Yes.

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

22 DR. KLIGER: I take exception to

1 that. That's not --

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

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

6 DR. MESSANA: Then I am mistaken,
7 Alan.

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

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

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

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

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

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

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

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

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

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

22 DR. MESSANA: Thank you, Alan. I

1 apologize if I misconstrued your earlier
2 comments.

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

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

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

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

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

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

18 CO-CHAIR CROOKS: Okay. Lisa?

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

20 Thank you.

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

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

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

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

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

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

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

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

22 So the question is, is this the

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

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

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

3 CO-CHAIR CROOKS: We have Jerry
4 next.

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

14 (Laughter.)

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

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

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

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

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

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

4 DR. BERNES: KDOQI should have a
5 clinical practice guideline out on
6 hemodialysis by the end of this calendar year.
7 And KDIQO should have an international
8 guideline on dialysis within another probably
9 18 months after that. So that is coming.
10 It's in the pipeline.

11 DR. PACE: Guidelines on the time?

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

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

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

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

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

22 And, I mean, obviously we all have

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

5 (Laughter.)

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

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

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

1 think we are.

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

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

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

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

18 (Pause.)

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

22 CO-CHAIR CROOKS: Okay, then. All

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

4 Alan?

5 1439, UTILIZATION OF

6 HIGH ULTRAFILTRATION RATE FOR FLUID REMOVAL

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

22 DR. KLIGER: I'm sorry. Just one

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

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

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

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

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

3 CO-CHAIR CROOKS: Okay. Jerry?

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

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

17 DR. JACKSON: Not available for
18 time-limited.

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

21 DR. JACKSON: And then I withdraw
22 my comment.

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

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

9 DR. JACKSON: Yes.

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

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

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

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

5 CO-CHAIR CROOKS: All right.
6 Jeffrey?

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

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

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

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

4 Am I thinking correctly or
5 incorrectly?

6 CO-CHAIR CROOKS: Alan?

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

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

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

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

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

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

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

1 measure and we're probably not going to.

2 Well, we'll see, but it sounds like we don't
3 recommend a measure.

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

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

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

4 CO-CHAIR CROOKS: Okay. Other
5 comments?

6 (No response.)

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

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

13 (Pause.)

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

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

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

1 Nephrologist." Myra?

2 1438, PERIODIC ASSESSMENT OF
3 POST-DIALYSIS WEIGHT BY NEPHROLOGIST

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

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

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

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

14 In terms of the information by the
15 reviewers, in terms of importance, five of the
16 six indicated yes; in terms of acceptability,
17 two completely, one partially, two minimally,
18 and one not at all according to this; in terms
19 of usability, two completely, one partially,
20 two minimally, and one not at all; in terms of
21 feasibility, three completely, three
22 partially; in terms of recommendation, four

1 yes and two nos on this.

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

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

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

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

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

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

21 CO-CHAIR CROOKS: Robert?

22 DR. PROVENZANO: You know, I think

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

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

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

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

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

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

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

12 DR. PACE: Right.

13 CO-CHAIR CROOKS: Okay. Jeffrey?

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

1 weight prescription.

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

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

14 DR. BERNES: So, again, the --

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

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

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

5 CO-CHAIR CROOKS: Was a new
6 assessment.

7 DR. MESSANA: It's a new
8 assessment.

9 CO-CHAIR CROOKS: Right. So --

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

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

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

1 writing a new order capturable by CROWNWeb.

2 I mean, my practice had been to make rounds
3 once or twice or sometimes three times a week
4 and say, "Patient, you know, EDW seems
5 appropriate" or "Change EDW and make an order
6 to that effect."

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

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

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

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

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

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

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

18 CO-CHAIR CROOKS: This would be
19 eligible only for a time-limited endorsement
20 for testing. So that may be one of the things
21 that gets tested. You know, how does the data
22 --

1 DR. PACE: Reliability.

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

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

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

22 DR. WOLFE: So this precise

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

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

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

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

1 made that yes, they did make an assessment.

2 That's the intent. And the actual

3 implementation is still to be worked out.

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

14 CO-CHAIR CROOKS: Okay. Joseph?

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

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

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

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

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

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

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

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

11 DR. MESSANA: Yes.

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

20 Barbara?

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

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

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

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

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

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

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

13 CO-CHAIR CROOKS: Okay.

14 DR. MESSANA: No disagreement with
15 that.

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

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

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

3 CO-CHAIR CROOKS: Alan?

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

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

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

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

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

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

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

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

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

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

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

19 DR. FIVUSH: I think --

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

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

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

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

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

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

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

1 DR. PACE: Right.

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

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

6 DR. FIVUSH: Right. That's right.

7 DR. PACE: And so --

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

10 DR. PACE: Right. So --

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

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

22 CO-CHAIR CROOKS: Okay.

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

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

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

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

12 (No response.)

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

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

20 DR. KLIGER: No PD.

21 DR. PACE: It's not PD.

22 DR. KLIGER: It is specified as

1 hemo.

2 DR. BERNS: Is it?

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

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

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

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

14 DR. PACE: 2A.8.

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

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

22 CO-CHAIR CROOKS: Okay. Are we

1 ready? So this is a time-limited measure.

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

5 (Pause.)

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

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

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

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

1 (Pause.)

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

5 (Pause.)

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

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

11 DR. PACE: All right. So --

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

15 DR. PACE: Right.

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

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

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

3 DR. PACE: Right. Okay.

4 CO-CHAIR CROOKS: Okay.

5 DR. PACE: Usability?

6 (Pause.)

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

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

11 (Pause.)

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

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

16 (Pause.)

17 CO-CHAIR SCHONDER: Twenty yeses,
18 unanimous.

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

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

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

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

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

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

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

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

5 So is CDC on the line?

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

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

10 DR. PATEL: Can you hear me okay?

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

14 DR. PACE: And are you on a
15 speakerphone?

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

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

20 DR. PATEL: This is Priti Patel.

21 CO-CHAIR CROOKS: Okay. Please go
22 ahead.

1 DR. PATEL: Okay. Thank you, sir.

2 CONSIDERATION OF CANDIDATE MEASURES BRIEF

3 INTRODUCTION OF MEASURES BY DEVELOPER(S)

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

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

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

1 vascular access, including central lines.

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

12 All three of the measures we
13 submitted are currently in use and are
14 collected in the National Healthcare Safety
15 Network, or NHSN, systems. NHSN is an
16 extremely stable system used by more than
17 3,000 U.S. hospitals for healthcare-associated
18 infection reporting and is tied to public
19 reporting mandates.

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

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

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

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

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

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

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

9 CO-CHAIR CROOKS: Thank you.

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

12 DR. WOLFE: Thank you very much.

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

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

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

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

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

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

22 CO-CHAIR CROOKS: Yes. We should

1 do that.

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

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

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

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

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

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

20 CO-CHAIR CROOKS: Thank you.

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

1 measures from yesterday. And we'll make note
2 of that. But we won't discuss that right now
3 --

4 DR. WOLFE: Thank you.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

1 average of ten with requiring all less than
2 ten.

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

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

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

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

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

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

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

22 CO-CHAIR CROOKS: I think there

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

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

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

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

1 DR. WOLFE: Thank you.

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

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

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

1 DR. WOLFE: Thank you.

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

5 (No response.)

6 DR. PACE: Okay.

7 CO-CHAIR CROOKS: All right.

8 Let's move on, then, to the consideration of
9 candidate measures for infection. And we'll
10 start with 1477, the "National Healthcare
11 Safety Network Intravenous Antibiotic Start
12 Measure." And I have the pleasure of being
13 the primary reviewer.

14 INFECTION

15 1477, NATIONAL HEALTHCARE SAFETY

16 NETWORK (NHSN) INTRAVENOUS (IV)

17 ANTIBIOTIC START MEASURE

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

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

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

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

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

1 DR. KLIGER: It got infected.

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

5 MS. BARNES: Peter, before you
6 start?

7 CO-CHAIR CROOKS: Yes?

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

15 CO-CHAIR CROOKS: Is Dr. Patel --

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

17 CO-CHAIR CROOKS: Yes?

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

1 an IV antibiotic at the same time.

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

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

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

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

21 MS. BARNES: Yes. Thank you.

22 CO-CHAIR CROOKS: Okay. When it

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

5 And as to that validity testing,
6 they claim that the results show high
7 accuracy, which was 79 percent, 88 percent, 69
8 percent of validity. I'm not sure what is
9 high. To me that doesn't sound that high to
10 validate their -- that the accuracy was 79 or
11 69 percent doesn't to me impress me as high
12 accuracy. That is subjective, I guess.

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

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

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

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

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

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

22 And we do actually perform data

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

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

17 CO-CHAIR CROOKS: Okay. Thank
18 you.

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

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

1 CO-CHAIR CROOKS: Okay. Go ahead.

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

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

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

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

22 Regarding the 2F, which is

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

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

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

1 applied in such studies."

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

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

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

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

22 Let's look at what the others

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

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

11 Who is that? Jerry, did you want
12 to

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

15 CO-CHAIR CROOKS: You would have
16 voted no?

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

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

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

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

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

20 So those are my comments.

21 CO-CHAIR CROOKS: Thank you.

22 Reviewers?

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

3 CO-CHAIR CROOKS: Go ahead.

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

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

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

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

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

9 DR. PATEL: Correct.

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

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

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

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

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

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

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

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

11 CO-CHAIR CROOKS: Okay. Thank
12 you.

13 Joseph?

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

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

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

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

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

21 There are going to be financial
22 disincentives for dialysis facilities to

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

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

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

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

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

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

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

15 CO-CHAIR CROOKS: Okay.

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

22 DR. FIVUSH: Right.

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

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

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

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

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

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

5 DR. PACE: So this is measure
6 1477. And we're starting with importance to
7 measure and report.

8 (Pause.)

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

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

14 (Pause.)

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

17 DR. PACE: All right. Usability?

18 (Pause.)

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

21 DR. PACE: Feasibility?

22 (Pause.)

1 CO-CHAIR SCHONDER: Nine partially
2 and 11 minimally.

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

5 (Pause.)

6 CO-CHAIR SCHONDER: Two yes and 18
7 no.

8 CO-CHAIR CROOKS: Thank you.

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

12 1460, NATIONAL HEALTHCARE SAFETY NETWORK
13 (NHSN) BLOODSTREAM INFECTION MEASURE

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

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

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

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

16 (Laughter.)

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

22 So, with that said, measure 1460,

1 which is the number of hemodialysis
2 outpatients with positive blood cultures per
3 100 hemodialysis patient months, just in
4 summary, preliminary evaluations that I
5 received showed 4 of 6 evaluators recommending
6 this measure, some with suggested
7 modifications.

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

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

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

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

7 Areas of concern on this where
8 there were suggested modifications include
9 that there was questioning regarding the
10 21-day time frame, where if an exclusion of
11 repeat cultures and the question raised why is
12 it 21 days.

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

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

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

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

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

1 That's all I have. Thanks.

2 CO-CHAIR CROOKS: Ruben?

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

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

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

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

22 DR. PATEL: Sure. So, you know,

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

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

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

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

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

4 Jeff?

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

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

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

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

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

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

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

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

22 So we are going to be able to

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

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

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

19 CO-CHAIR CROOKS: Joe?

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

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

4 The unintended consequence is if
5 you want to look better, don't ask your
6 employees to expend the extra effort because
7 all you can do is actually hurt yourself if
8 you think about it. If you work hard to get
9 all the positive blood cultures, my unit will
10 look off than Jeff's unit, who just kind of
11 ignores the situation. And I think that's a
12 --

13 DR. BERNES: Other way around.

14 DR. NALLY: Or whatever.

15 DR. BERNES: My unit was the one
16 that --

17 CO-CHAIR CROOKS: Myra? Myra is
18 next.

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

1 admission.

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

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

13 CO-CHAIR CROOKS: Robert?

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

1 rates, which tend to be linked to catheters.

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

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

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

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

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

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

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

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

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

3 MS. BARNES: Yes.

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

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

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

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

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

22 DR. LATTIS: And I would bet that

1 others will be following very closely behind
2 Colorado.

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

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

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

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

22 It is more to what we are trying

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

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

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

1 adverse event occurs.

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

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

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

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

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

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

1 put towards that.

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

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

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

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

9 CO-CHAIR CROOKS: Alan?

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

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

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

6 DR. LATTIS: You've have got to
7 have --

8 DR. KLIGER: That is what Lisa is
9 arguing.

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

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

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

22 DR. LATTIS: But that is not the

1 other measure.

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

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

19 CO-CHAIR CROOKS: Ruben?

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

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

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

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

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

19 CO-CHAIR CROOKS: Dr. Patel?

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

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

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

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

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

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

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

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

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

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

14 MS. BARNES: Absolutely.

15 CO-CHAIR CROOKS: All right?

16 MS. BARNES: Not for performance
17 improvement.

18 CO-CHAIR CROOKS: Right.

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

1 CO-CHAIR CROOKS: Okay. So --

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

5 MS. BARNES: And for neither does
6 the --

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

10 Helen?

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

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

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

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

1 measure. It can be -- you can easily convert
2 the denominator for this metric to be per
3 1,000 patient days, which is what it is in the
4 hospital. Dr. Patel, would you add to that?

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

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

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

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

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

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

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

21 MS. BARNES: I completely agree.

22 And this is already in the NHSN database being

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

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

10 MS. BARNES: Dr. Patel?

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

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

20 In other words, are you capturing
21 20 percent of the actual bloodstream
22 infections, 80 percent, 90 percent? And do

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

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

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

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

1 some exceptions.

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

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

22 But, then, a secondary part of

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

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

18 Robert?

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

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

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

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

15 CO-CHAIR CROOKS: Right.

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

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

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

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

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

16 DR. PACE: Extra burden.

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

1 has to be done verbally on the phone.

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

8 CO-CHAIR CROOKS: Okay. Myra?

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

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

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

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

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

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

22 MS. BARNES: And just to remind

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

4 CO-CHAIR CROOKS: Okay. Jerry?

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

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

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

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

12 Ruben?

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

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

1 spend more time doing this.

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

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

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

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

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

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

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

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

15 CO-CHAIR CROOKS: Okay. Thanks.

16 So are we ready to vote?

17 (No response.)

18 CO-CHAIR CROOKS: All right. Very
19 good.

20 DR. PACE: Okay. This is measure
21 1460, importance to measure and report. And
22 keep in mind what these criteria are. I know

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

3 (Pause.)

4 DR. PACE: Has everybody voted?

5 Okay.

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

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

12 (Pause.)

13 CO-CHAIR SCHONDER: Four complete,
14 16 partially.

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

17 (Pause.)

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

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

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

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

12 So the next one is feasibility.

13 (Pause.)

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

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

19 (Pause.)

20 CO-CHAIR SCHONDER: Thirteen yes
21 and seven no.

22 CO-CHAIR CROOKS: Okay. We would

1 like to get one or two more done before lunch.

2 What time is lunch?

3 DR. PACE: We will do this last
4 CDC measure. And then we will do -- pardon
5 me? Oh, two more CDC. I'm sorry.

6 CO-CHAIR CROOKS: No. There's no
7 --

8 DR. PACE: I thought we did. All
9 right.

10 CO-CHAIR CROOKS: One more NHSN.

11 DR. PACE: Why don't we do that
12 measure. Then we'll have public comments.
13 And then we'll break for lunch.

14 CO-CHAIR CROOKS: Okay. Very
15 good. So the next measure is 1478, "NHSN
16 Vascular Access-Related Bloodstream Infection
17 Measure." Sue?

18 1478, NATIONAL HEALTHCARE SAFETY NETWORK
19 (NHSN) VASCULAR ACCESS-RELATED
20 BLOODSTREAM INFECTION MEASURE

21 MS. BARNES: So this is the number
22 of hemodialysis outpatients with positive

1 blood cultures and in whom the suspected
2 source was reported as either the vascular
3 access or unknown, same denominator.

4 From the preliminary evaluations,
5 two voted in favor and four against. Just so
6 you know, this is basically the very same
7 measure with that one exception that we have
8 already noted, which is that it attributes the
9 infection to a vascular access.

10 So the arguments in favor are all
11 the same, that, you know, the existing
12 database and data stream and testing and the
13 arguments -- and also that, you know, it gives
14 you more information relative to vascular
15 access-related infections.

16 Arguments against are all of those
17 that we already heard as well. I don't think
18 there are any additional arguments against
19 except that possibly this could be considered
20 a greater data burden.

21 DR. BERNIS: Can I just ask for
22 some clarification?

1 CO-CHAIR CROOKS: Jeff, please?

2 DR. BERNES: Who and how is the
3 determination made about -- yes. And how is
4 this documented? Who makes the decision? How
5 is it transmitted, all those sorts of things?

6 MS. BARNES: So, Dr. Patel?

7 DR. PATEL: There is a question on
8 the data entry form or the event report form
9 that basically asks the suspected source of
10 the positive blood culture if there is a
11 positive blood culture.

12 We don't dictate who makes that
13 determination. So it could be the nurse. It
14 could be the physician, attending physician.
15 But we simply ask that question of whoever is
16 submitting that data. So we don't specify who
17 should make that decision.

18 DR. PACE: And is it specified?
19 It just says in the numerator details
20 "suspected source." So that's up to each
21 individual organization to determine how they
22 make that determination of what is the

1 suspected source? Are there any guidelines
2 for that?

3 DR. PATEL: The only guidance that
4 we provide is we provide the same suggestions
5 that are included in the BSI surveillance
6 that's done on the inpatient side,
7 particularly with respect to contaminants or
8 common skin contaminants.

9 So we provide a list of common
10 skin contaminants. And we say that, you know,
11 "If you have a positive culture for some of
12 these, consider whether it could be a
13 contaminant." But, really, the rest of it is
14 up to the person in the facility.

15 MS. BARNES: So, just in summary,
16 I would say that the reason I voted against
17 this measure is only because I think it is
18 really important to minimize data burden. And
19 so one infection measure to me is sufficient.
20 I voted against all the other measures as well
21 for that reason and in favor of NHSN as the
22 gold standard for healthcare-associated

1 infection reporting.

2 DR. VELEZ: I think in this
3 measure, again, it leaves a lot to people's
4 wish lists. If you have a catheter patient,
5 you always are suspicious that a positive
6 blood culture was the catheter. So you would
7 say, "suspected," although you would pick the
8 unknown.

9 Catheter looks great on the
10 outside. Everything looks fine. This measure
11 does take away the diabetic with the foot
12 ulcer because that is eliminated from this.
13 And that is good. But this is suspicion
14 versus unknown. It depends on the day of the
15 week and who is making rounds on how fast they
16 go.

17 And I have a lot of concerns, even
18 though, again, this is a very important
19 measure.

20 CO-CHAIR CROOKS: Isn't it also
21 kind of a bias to the evaluating physician to
22 judge it not to be a vascular access

1 infection? Is that a problem possibly?

2 DR. NALLY: Just to add to this
3 discussion, it is important to know who that
4 person is and whether or not they could be one
5 of a number of physicians that, as you said,
6 20 different hospitals that weigh in on that
7 judgment and dictate a discharge summary.

8 My specific question for Dr. Patel
9 is, of all these positive blood cultures
10 associated with vascular access, my suspicion
11 would be there would be a high number of
12 hospitalizations associated with this. What
13 percent of the positive blood culture
14 access-related are hospitalized?

15 DR. PATEL: I do have that
16 information. Unfortunately, I don't have it
17 right in front of me. If there's a way for me
18 -- we're still on lock-down because of the ice
19 storm. But if there is a way for me to get
20 that to you later today or later this week, I
21 could do that.

22 DR. NALLY: Thank you.

1 DR. PACE: Yes. You can send that
2 to us.

3 DR. PATEL: Okay. I apologize for
4 that.

5 DR. PACE: Send it to Lauren.

6 DR. VASSALOTTI: I just want to
7 add that --

8 CO-CHAIR CROOKS: Jeff, yes?

9 DR. VASSALOTTI: -- I have been
10 adjudicating admissions for the frequent
11 hemodialysis network trial for the Outcomes
12 Committee. We are blinded to patient-specific
13 information. And we look at hospitalizations
14 and data regarding positive blood culture for
15 this very purpose to determine if they are
16 vascular access-related or not.

17 And, even with the best minds and
18 the best experts in the field, well-meaning,
19 blinded to the individual, it is sometimes
20 very difficult, even with a lot of
21 information, to determine this. Even being
22 blinded to the -- without even having any

1 biases for the outcomes or incentives for the
2 outcomes, it can be difficult. So that is a
3 concern.

4 CO-CHAIR CROOKS: Thank you.

5 Alan?

6 DR. KLIGER: I guess what is
7 interesting to me is that the measure still is
8 not -- either one of these, the one that I
9 think is of interest, which is that group of
10 patients with catheters that have bloodstream
11 infections, not the judgment of the doctor if
12 they were related but simply presence of a
13 catheter and bloodstream infection.

14 CO-CHAIR CROOKS: Well, if there
15 is a catheter present, there will be a
16 bloodstream infection sooner or later, right?

17 DR. PACE: You would get that from
18 the other, you would have that in the other
19 measure because you have it stratified by the
20 type of vascular access. I mean, that --

21 DR. KLIGER: That is right. But I
22 guess I am just focusing our attention as we

1 rate these, that my own sense is that it's
2 that cross-referencing that really is of most
3 importance.

4 DR. VASSALOTTI: That is the
5 patient population for where this is probably
6 most actionable. That is the --

7 MS. BARNES: And that is what this
8 measure gives you without the complicated
9 algorithmic definition that is required for
10 the inpatient side. Would you add anything to
11 that, Dr. Patel?

12 DR. PATEL: No. That is exactly
13 right. So it does give you that. And we
14 understand and realize that there is
15 subjectivity and sort of this determination of
16 whether it's access-related or not. And that
17 is the reason that we like to look at both the
18 all BSI measure stratified by vascular access
19 type as well as the BSIs that are determined
20 to be vascular access-related.

21 CO-CHAIR CROOKS: Other comments?

22 DR. VELEZ: And the question is,

1 the measure we just approved, what does this
2 measure add that the other one doesn't already
3 help there? Judgment. That is about it
4 because the other one tells us if you have a
5 catheter and --

6 MS. BARNES: That is why I voted
7 against it and all the other measures as well.
8 I think in my opinion, we need one infection
9 measure because there is a single source most
10 frequently reported in this patient
11 population.

12 CO-CHAIR CROOKS: So I see nods of
13 "I'm ready to vote" on everybody's face. Am
14 I reading right? Okay.

15 DR. PACE: Okay. This is measure
16 1478. And we'll start with importance to
17 measure and report. And wait until the timer
18 starts.

19 (Pause.)

20 CO-CHAIR SCHONDER: Twelve yeses
21 and one no.

22 CO-CHAIR CROOKS: Eight nos.

1 CO-CHAIR SCHONDER: I am sorry.

2 Eight nos.

3 DR. KLIGER: You must be from

4 Chicago.

5 (Laughter.)

6 DR. PACE: Okay. Next is

7 scientific acceptability of measure

8 properties.

9 (Pause.)

10 CO-CHAIR SCHONDER: Two

11 completely, 11 partially, and 7 minimally.

12 DR. PACE: Next is usability.

13 (Pause.)

14 DR. PACE: Is everyone finished?

15 Okay.

16 CO-CHAIR SCHONDER: Two

17 completely, nine partially, seven minimally,

18 one not at all.

19 DR. PACE: Next is feasibility.

20 (Pause.)

21 CO-CHAIR SCHONDER: Eight

22 partially, ten minimally, two not at all.

1 DR. PACE: Okay. And, finally,
2 would you recommend this measure for
3 endorsement?

4 (Pause.)

5 CO-CHAIR SCHONDER: Four yes and
6 16 no.

7 CO-CHAIR CROOKS: Okay. It is
8 time to allow for public comment and also
9 comments from the measure developers. Who
10 would like to start? Anyone? No? Anyone on
11 the phone?

12 THE OPERATOR: As a reminder, that
13 is *1 for a comment over the telephone.

14 (No response.)

15 THE OPERATOR: We have no one over
16 the telephone at this time, sir.

17 CO-CHAIR CROOKS: Thank you.

18 All right. Then I guess we are
19 good to break for lunch. We are going to try
20 to -- do we want to do a lunch like we did
21 yesterday, where we come back in 15 minutes
22 and get moving again? I would recommend that.

1 If the Committee could do that, I would
2 appreciate it. And so, Kristine, thank you
3 very much.

4 DR. PACE: So we will try to
5 reconvene at 12:15.

6 (Whereupon, the above-entitled
7 matter went off the record at 11:56 p.m. and
8 resumed at 12:17 p.m.)

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

2 (12:17 p.m.)

3 CO-CHAIR SCHONDER: We will start
4 off with measure number 1456, "Bacteremia
5 (Rate)." And Andrew stepped out. So I'll
6 tell you what. In the interest of time, let's
7 move forward, then, put Jerry on the spot, let
8 him finish chewing. We'll move ahead, then,
9 to 1457. And we'll come back to the bac. So
10 1457, "Access-Related Bacteremia (Rate)."

11 1457, ACCESS-RELATED BACTEREMIA (RATE)

12 [STRATIFIED BY ACCESS]

13 DR. JACKSON: Six-month rolling
14 average rate of access-related bacteremia
15 treated with IV antibiotics among adult
16 dialysis patients expresses a rate for 1,000
17 hemodialysis patient days. So the numerator
18 is the number of new antibiotic starts. And,
19 specifically for vascular acts, those vascular
20 acts, as related with a positive blood
21 culture, the denominator is the number of
22 patient days for maintenance in the dialysis.

1 It excludes patients under 18 years of age.

2 The reviewers were very strongly
3 positive on the importance of measure and
4 report. There was one disagreement on that,
5 but overall it was felt very highly important.

6 It was extremely widespread
7 variation on the responses to the scientific
8 acceptability of the measure properties.
9 Likewise, the usability and feasibility was
10 rated fairly low. The main strength was the
11 importance to measure and report. The
12 weakness was that there was full evidence
13 provided about a performance gap. There was
14 no reliability testing as yet.

15 It was unclear. There was one
16 comment that it was unclear in the denominator
17 when stratification is done if a patient who
18 has a catheter, yet has a developing fistula
19 or graft would be included as a catheter
20 patient or how best to find that could be a
21 significant subcategory.

22 The biggest concern among the

1 reviewers was the made for a subjective call
2 on the source of the infection being the
3 access. And one other comment was that for an
4 antibiotic prescribed, that it could be one
5 episode of infection and because it's
6 prescribed on two consecutive calendar months,
7 that it might be counted twice, but that
8 clearly does not occur that often.

9 So in going through the --

10 DR. PACE: Can you use the
11 microphone?

12 DR. JACKSON: Yes. Sorry. Do I
13 need to repeat anything that I've reviewed
14 yet? Overall I'm only seeing three votes:
15 one yes, two nos -- oh, two and two. I'm
16 sorry.

17 DR. PACE: I think three and one.
18 Three and one.

19 DR. JACKSON: No. It's importance
20 to measure. My drive does not have all of the
21 responses. Could you scroll over to the final
22 tally? Two and two. Okay.

1 I would just like to comment that
2 the document that CMS put out on their overall
3 strategy for studying infections was pretty
4 convincing to me. And it would require
5 looking at these as a family of measures.

6 I know we're looking at this as an
7 individual measure, but it looks like what
8 they were trying to accomplish, what the
9 workgroup was trying to accomplish, is looking
10 at quite a few aspects of infection in
11 dialysis units, as described in their
12 overlapping Venn diagrams and their documents.
13 So I hope everybody has seen that and reviewed
14 that.

15 CO-CHAIR SCHONDER: Any comments
16 from the other reviewers?

17 (No response.)

18 CO-CHAIR SCHONDER: From the
19 Committee?

20 MS. BARNES: I would just again
21 mention my philosophy or perspective when
22 looking at performance improvement overall is

1 that measurement is just one aspect of that.
2 And so to not, you know, put all of the eggs
3 in one basket or consider this to be the only
4 way to get improved performance by measurement
5 -- and when CMS is talking about, you know, a
6 myriad of metrics for just one aspect of care,
7 I would be concerned.

8 CO-CHAIR CROOKS: I would like to
9 just kind of step back for a minute. And this
10 is sort of germane to what you are saying.
11 And look at what their approach was. If
12 people had time to read the document the TEP
13 prepared about why they submitted five metrics
14 that are kind of interrelated with Venn
15 diagrams showing how they relate to each
16 other, I think they made a nice case of, you
17 know, if you really want to understand in a
18 global way what is going on, this matrix of
19 metrics -- matrix of metrics, wow, I like that
20 -- would, you know, give you a broad picture,
21 be able to dissect out different things, you
22 know, maybe in theory. I'm not sure if it

1 works in reality.

2 But I was attracted. I found that
3 kind of compelling that this would be the idea
4 world. You would have all of this information
5 and you would be able to drill down and get
6 stuff, you know.

7 Do you have a problem with that or
8 you think that is just too unrealistic?

9 MS. BARNES: No. I am in support
10 of diagrams.

11 (Laughter.)

12 MS. BARNES: But I do think that
13 it would be prudent for CMS and other
14 regulators to look to content experts when
15 metrics are being proposed. And in this case
16 APIC and SHEA would be the predominant for
17 this country professional organizations that
18 represent content experts. And NHSN is the
19 partner of SHEA and APIC. So --

20 CO-CHAIR CROOKS: I'm surprised,
21 you know, they weren't at the table. Wait.
22 We have some --

1 DR. MESSANA: Excuse me. Dr.
2 Priti Patel was a member of the CTEP and
3 contributed significantly. So we did have a
4 content expert.

5 CO-CHAIR CROOKS: That's good to
6 know.

7 MS. BARNES: CDC, not APIC or
8 SHEA, though.

9 CO-CHAIR CROOKS: Okay. Other --

10 CO-CHAIR SCHONDER: Comments?

11 CO-CHAIR CROOKS: I find, you
12 know, it's kind of artistic, you know, the way
13 that all fits together. You know, but I don't
14 know whether practically it works out. It's
15 a lot of -- I would also like to just say
16 that, as opposed to the -- I mean, I think the
17 data collection is less of a burden here,
18 although just saying it's on CROWNWeb doesn't
19 make it necessarily easier because it's got to
20 get into CROWNWeb in some way. There has to
21 be a process. There has to be human
22 interaction to get that done.

1 DR. LATTIS: Can I just ask a
2 question about that? If the data elements are
3 in CROWNWeb and dialysis facilities have to
4 use CROWNWeb, does that mean they have to fill
5 out the data elements? I mean, is there some
6 requirement for a complete data entry into
7 CROWNWeb? So even if we don't approve the
8 measure, the data will be in CROWNWeb? How
9 does it work?

10 DR. MESSANA: Are you asking --

11 DR. LATTIS: The measure developer?
12 Sure. Yes, yes.

13 DR. MESSANA: Because of the time
14 lag in developing the business requirements
15 documents and the data elements for CROWNWeb,
16 all of the data elements for all of the
17 measures that we submitted, including the
18 infection measures, have been requested and
19 are in the next iteration, you know, iteration
20 of CROWNWeb.

21 My understanding -- I'm not a
22 CROWNWeb expert -- is that they can inactivate

1 those. But to make it possible to enter the
2 data, they have the business requirements
3 prior to even submission of these measures to
4 you all.

5 So the data elements are
6 available, but whether they need to be used or
7 not I'm less certain about.

8 CO-CHAIR SCHONDER: Connie?

9 MS. ANDERSON: Right now dialysis
10 facilities as of July 1st of 2010 have to
11 report access-related infections. And it has
12 to be documented by a positive blood culture.
13 And it has to be treated with antibiotics.
14 And those are now currently going to the
15 dialysis, to the facility bills. They're
16 required.

17 CO-CHAIR SCHONDER: Peter?

18 MS. ANDERSON: So there is no
19 burden of providing that information.

20 CO-CHAIR CROOKS: This measure and
21 the whole group of measures, these five
22 measures, these four or five measures, are all

1 for time-limited only because they have not
2 been tested. And that also appears to me in
3 a sense that this is kind of a complex,
4 comprehensive look at it, you know, maybe it's
5 a chance to find out if it works.

6 I don't think in their testing,
7 they're going to mandate every -- would you
8 make everybody participate or you'd say we're
9 going to test in a subset of facilities or,
10 you know, in terms of burden?

11 DR. MESSANA: I think that
12 decision would require input from our CMS
13 officers in CMS.

14 DR. WOLFE: That impact, to my
15 knowledge, there is no way to do a sample
16 within CROWNWeb when it is -- except they are
17 being rolled in. Some facilities do not
18 currently have a requirement to contribute to
19 CROWNWeb.

20 CO-CHAIR CROOKS: Let me ask this
21 question to you, too. These data elements
22 that you need for this metric, you are going

1 to be collecting them anyway, right? I mean,
2 this isn't -- you're not going to add it if
3 you get endorsement or not add it if you don't
4 get endorsement. Is that --

5 DR. MESSANA: The data elements
6 are available. I am less certain about
7 whether they can be inactivated or not
8 relating to Lisa's question. inactivated.

9 DR. WOLFE: But it is important, I
10 think, to distinguish between two sets of data
11 elements. There are data elements in
12 CROWNWeb. And several of the measures are
13 defined in terms of CROWNWeb data.

14 There is another measure, which is
15 based upon the billing data, which you
16 referred to. And I think it's important and
17 valuable for the Committee to consider the
18 differences between these measures and the
19 data burdens that are inherent in them.

20 CO-CHAIR CROOKS: Well, one of the
21 five is --

22 DR. WOLFE: It's not as though

1 there is a package which does it all. There
2 is a measure based upon the claims,
3 recognizing that that is currently in place
4 and those are already being submitted. And
5 the CROWNWeb is submitted, not for the entire
6 universe yet.

7 DR. MESSANA: Right. So, for the
8 Committee, 1455 I believe is the claims-based
9 measure and all of the other or part of that
10 CROWNWeb data collection package.

11 CO-CHAIR CROOKS: I guess what I
12 am getting at is if I believed that endorsing
13 these measures for time-limited endorsement
14 would not increase the burden on dialysis
15 facilities, I would be more likely to vote for
16 it, you know, as opposed to saying by
17 endorsing these, now for tests, we're putting
18 a big burden on dialysis facilities.

19 DR. MESSANA: So the CROWNWeb data
20 to date is almost entirely batch submission --
21 okay? -- as I pointed out in my opening
22 comments yesterday. So 60 percent of

1 facilities are submitting by batch.

2 The three largest dialysis
3 organizations have ongoing work and actually
4 had representation, active representation, on
5 the data TEP when they considered these
6 measures and in the synchronization
7 subsequently. And so they have already been
8 exposed to these data elements and had
9 significant input.

10 So other than taking the clinical
11 information, no matter which of the measures,
12 if you talk about the NHSN measures or our
13 measures, you have to abstract from the
14 clinical record. And then with NHSN, you have
15 to enter at a web portal. With the CROWNWeb
16 measures, that same abstraction should lead to
17 a batch submission as part of the overall
18 CROWNWeb batch submission. So it's unclear to
19 me which is the bigger or less data collection
20 burden.

21 DR. WOLFE: In terms of the
22 abstraction, it's essentially the same

1 information. In terms of submission,
2 currently it's already built into CROWNWeb for
3 many, many facilities that are in the change
4 but not at the independence. And for the
5 claims data, that is already in place.

6 DR. DUDLEY: Joe and Bob? This is
7 Tom Dudley from CMS. Can you hear me?

8 CO-CHAIR CROOKS: Yes.

9 CO-CHAIR SCHONDER: Yes. Go
10 ahead.

11 DR. DUDLEY: Okay. With regards
12 to CROWNWeb and the data submission, the full
13 national rollout for CROWNWeb is currently
14 scheduled for late spring of this year. And
15 as Bob and Joe have mentioned, the data
16 elements to support these measures are
17 included.

18 And under the conditions for
19 coverage that were published in 2007 or 2008,
20 facilities are required to submit 100 percent
21 of the data as required by CMS. So as far as
22 the burden question, there won't be any

1 additional burden outside of what is already
2 required by the facilities.

3 CO-CHAIR SCHONDER: Barb?

4 DR. FIVUSH: I guess I just have a
5 couple of comments based on what I heard. I
6 would just like to point out to start with,
7 though, my understanding is that, although
8 many of our dialysis units are part of LDOs,
9 they're an independent unit. And the burden
10 on them is already greater because they're not
11 part of an LDO.

12 And so if there's 100 percent
13 reporting, I think we have to think about
14 independent dialysis facilities. We can't
15 just erase the burden because they're not part
16 of an LDO.

17 But in listening to what Tom said
18 and in listening back here, I'm confused as to
19 Tom indicated that this was part of the
20 CROWNweb system. And, regardless of whether
21 we approve this measure, that data is going to
22 be collected, irregardless. So it doesn't

1 change the data burden, whether we measure it
2 or not, in a sense.

3 I thought I heard you saying we
4 might not collect it if we weren't going to
5 approve the measure. And I --

6 DR. MESSANA: I expressed
7 ignorance about whether or not --

8 DR. FIVUSH: Okay. We might.

9 DR. MESSANA: -- the data
10 collection would continue.

11 DR. FIVUSH: So I guess I don't
12 know the answer to the question.

13 CO-CHAIR CROOKS: We just heard
14 that as part of the conditions of coverage,
15 this is going to be required. If you have
16 this information, you need to submit it,
17 whether you're a small, independent unit or an
18 LDO.

19 DR. FIVUSH: But, Peter, I thought
20 what Tom said -- and there are other people
21 who may have better knowledge of it. As part
22 of the conditions of coverage, you're going to

1 have to participate in CROWNWeb, which is
2 correct.

3 But the question is, is the
4 CROWNWeb -- maybe Tom can tell us -- is the
5 CROWNWeb going to change depending on what
6 measures -- are the specifications and what
7 you enter on CROWNWeb going to change or
8 expand depending on what NQF ultimately
9 endorses? Are they going to expand the
10 measure set?

11 CO-CHAIR CROOKS: I think that is
12 what I was asking. And I think I got an
13 answer that no, they are going to collect this
14 information anyway.

15 DR. FIVUSH: Regardless --

16 CO-CHAIR CROOKS: Regardless.

17 DR. FIVUSH: -- of what we do.

18 DR. PACE: Tom, do you want to
19 confirm that? This has already been set in
20 terms -- I mean, CROWNWeb is well underway.

21 DR. FIVUSH: Right.

22 DR. PACE: It is going to roll

1 out.

2 DR. DUDLEY: Yes. The data
3 elements -- we were required to submit the
4 data elements to the developers of CROWNWeb
5 last May. So we built in the elements based
6 on our best knowledge at that point in time.
7 We don't have the opportunity to add
8 additional elements at this time to the last
9 rollout of CROWNWeb. The conditions would
10 come back.

11 Can we remove elements or
12 deactivate? Yes. We have that option. And
13 based on the Steering Committee's decision, we
14 will definitely take that under consideration
15 if we deactivate or make some of the data
16 elements optional.

17 But at this point we're expecting
18 facilities, regardless of large facilities,
19 LDOs or SDOs or independents, we expect them
20 to submit the data as required.

21 DR. PACE: Can I make one comment
22 or question to Tom? I mean, just as in your

1 home health or nursing home data collection,
2 not every data element has to be for the
3 purpose of quality measurement. A lot of it
4 relates to clinical care and care planning.
5 And so, you know, it could be valuable
6 information. It may not be -- not every data
7 element has to be justified by being in a
8 quality measure.

9 DR. DUDLEY: That is correct.

10 That is to NDS, which I am very intimately
11 involved with. But NDS itself is kind of
12 unique in that it is used for payment survey
13 and quality measurement. But, to answer your
14 question, yes. They're not solely for the
15 purposes of measuring quality.

16 CO-CHAIR SCHONDER: Connie?

17 MS. ANDERSON: Just a point of
18 clarification. The SDOs do not do that entry
19 into CROWNWeb. We are manually entering. And
20 there is a significant burden to the SDOs and
21 the independents to have to enter this data.

22 We were part of the phase-in of

1 CROWNWeb in one of the trial centers. So I
2 can attest to it personally. It is hours and
3 hours of data entry time.

4 DR. DUDLEY: Yes. And I
5 appreciate that. The developers -- and I'm
6 certainly on the measure development site.
7 I'm not in the condition side. I'm kind of
8 being a messenger here. So I'm trying to
9 separate myself.

10 Having been in the facilities, I
11 respect and understand that, but the
12 conditions do require 100 percent submission.
13 I know the developers are working with NRAA
14 right now on a means to support the smaller
15 facilities or the independents to figure out
16 a way for them to also do the batch
17 submission. Unfortunately, I don't know the
18 status of that at this point.

19 And I know that it's been
20 acknowledged that the burden concern for the
21 smaller facilities with fewer resources is
22 realized. I just don't have an update for you

1 on that as far as how far along they are in
2 building in additions to the batch submission.

3 CO-CHAIR CROOKS: My thought about
4 the whole group is if this data is being
5 collected anyway, you know, it's an
6 opportunity to really see if this kind of
7 approach is useful without adding any
8 additional burden. There is a burden there
9 already, agreed, but it wouldn't add
10 additional burden. It would be useful to take
11 a look at it.

12 Now, they may not need NQF
13 endorsement to do that project. In other
14 words, you know, they should be deciding this
15 is a broad-based approach to infection
16 management, quality improvement in the
17 dialysis setting. And we need to do this.
18 You know, I'm not sure they need NQF
19 endorsement to do that, but I would encourage
20 them to do that.

21 CO-CHAIR SCHONDER: Andrew?

22 DR. NARVA: Since all of these

1 would only have a time-limited approval
2 because none of them have been tested and
3 since they are going to be tested anyway, I'm
4 not really sure. This is a completely
5 academic discussion we are having. And do we
6 need to consider them as a suite, then,
7 instead of individually? Because individually
8 they don't necessarily make that much sense.

9 DR. BURSTIN: Just to point out,
10 again, time-limited measures are endorsed,
11 which means CMS could use them immediately,
12 even while testing them. So you have to feel
13 comfortable that these measures truly meet all
14 of the -- you know, again, meet all of the
15 evaluation criteria. And I guess we need to
16 have some sense of comfort that what's in here
17 will likely be resulting in being reliable and
18 valid.

19 So it's not as if it's -- I mean,
20 unless CMS thinks otherwise, we can't say for
21 sure that these measures won't be put into use
22 while they're being tested and assessed.

1 DR. PACE: One other point. You
2 know, obviously we'll have a competing measure
3 in the NHSN measure, which does have some
4 reliability and validity information. And,
5 even though these data are collected, the data
6 elements are collected, it doesn't mean that
7 they can't construct measures in different
8 configurations using those same data elements.

9 So one of the questions that we'll
10 be addressing when we look at comparison of
11 measures is what is the difference between the
12 CMS measure and the CDC measure. And are
13 there justifications for those differences?
14 Could the data that is going to be available
15 in CROWNWeb be exactly the same measure, which
16 I think came up in the discussion before? Why
17 not have some interconnection between those?

18 But those will be addressed when
19 we get to comparing measures. So the question
20 before you now is --

21 CO-CHAIR CROOKS: There was no CDC
22 system. I'm sorry.

1 DR. PACE: Yes. No. Go ahead.

2 CO-CHAIR CROOKS: I just caught
3 this thought from your head. It was amazing.
4 If there is no CDC proposal, how would we
5 respond to this?

6 DR. DUDLEY: This is Tom again.
7 Can I just chime in about the
8 interconnectivity of the two systems?

9 DR. PACE: Yes.

10 DR. DUDLEY: There are active
11 conversations going on and have been for a
12 while between CDC and CMS, but the connecting
13 of the data between NHSN and CROWNWeb, not
14 that within the government there are any
15 hurdles or anything, but there are obstacles
16 that we are trying to overcome to make that
17 possible. We are sure that will happen, but
18 we want to minimize any duplication of data
19 collection.

20 There are efforts underway to have
21 the two systems communication with each other.
22 We're just not there yet.

1 DR. PACE: And, Tom, let me just
2 ask you to maybe comment on, then -- again,
3 this will be an issue for when we get to
4 comparison, but do you want to make any
5 comment just in terms of overall why CMS
6 decided to develop measures that were similar
7 but slightly different than the CDC measure?
8 Was there some discussion about that in terms
9 of evaluating that measure and deciding it
10 wasn't meeting some particular need?

11 DR. DUDLEY: From CMS'
12 perspective, I think Joe mentioned earlier we
13 had CDC participation in the TEPs that we had
14 last year. And there was -- the discussions
15 we have had with Priti and her team have
16 revolved around the availability of data via
17 the NHSN versus the authority that CMS has for
18 collecting data through CROWNWeb, which is 100
19 percent; whereas, I believe NHSN participation
20 within the ESRD facilities is somewhere around
21 4 or 5 percent right now. Granted, Colorado
22 is requiring 100 percent. And other states

1 will probably be joining in.

2 Up until the measures were
3 released, I wasn't aware of CDC's efforts to
4 submit the measures, which is -- that's my
5 issue. And there is no intent for them to be
6 separate from each other or overlapping.

7 DR. PACE: Okay. Thank you.

8 CO-CHAIR SCHONDER: Are there any
9 other comments from the Committee?

10 (No response.)

11 CO-CHAIR SCHONDER: We will move
12 to voting, then.

13 DR. PACE: So we are on 1457. And
14 we're starting with importance to measure and
15 report. And wait until you see the timer.

16 (Pause.)

17 CO-CHAIR CROOKS: We have 18 yes
18 and 2 no.

19 DR. PACE: Okay. Next, scientific
20 acceptability of measure properties. And,
21 again, we realize that there is no reliability
22 and validity testing. So this really relates

1 to primarily how it is specified.

2 (Pause.)

3 CO-CHAIR CROOKS: Three
4 completely, 11 partially, 5 minimally.

5 DR. PACE: Okay. Next is
6 usability.

7 (Pause.)

8 CO-CHAIR CROOKS: Fifteen
9 partially, three minimally, and two not at
10 all.

11 DR. PACE: Feasibility?

12 (Pause.)

13 CO-CHAIR CROOKS: Fifteen
14 partially, four minimally.

15 DR. PACE: And finally recommend
16 for endorsement? Again, this would be
17 preliminary based, time-limited.

18 (Pause.)

19 CO-CHAIR CROOKS: Eleven yes, nine
20 no. We've got 20.

21 CO-CHAIR SCHONDER: I think we
22 will just continue on with 1455 since

1 essentially it's the same measure except using
2 Medicare claims. So, Jerry?

3 1455, ACCESS-RELATED BACTEREMIA USING
4 MEDICARE CLAIMS (RATE) [STRATIFIED BY ACCESS]

5 DR. JACKSON: This is the overall
6 access-related bacteremia six-month rolling
7 average rate of access-connected bacteremia
8 among adult hemodialysis patients. And it's
9 stratified by type of access.

10 And the numerator is based on the
11 claims forms. And specifically we can ask
12 when this becomes a requirement, but the --
13 whether it's felt related to the access would
14 be indicated placement of a modifier V8 on the
15 claim form by month. And then the specific
16 access will be either V5, V6, or V7 to
17 indicate whether it is a catheter, fistula, or
18 graft.

19 The reviewers agreed that it was
20 highly important to measure and report. There
21 was less agreement on the elements of the
22 scientific acceptability, same for usability

1 and feasibility.

2 There is no reliability or
3 validity testing as yet. As mentioned before,
4 this makes more sense when looking at the
5 totality of the CMS infection-related intent
6 and purposes and the Venn diagram.

7 The overall vote when I had this
8 -- I'm not sure there are some additional ones
9 -- was two votes yes and two votes no.

10 CO-CHAIR SCHONDER: Any other
11 comments from the other reviewers?

12 CO-CHAIR CROOKS: I think this has
13 some value in terms of sort of a cross-check,
14 right, of kind of saying, are we getting all
15 of the data? Is it valid? And in the setting
16 of what could be a really big project, it's a
17 nice addition. Plus, you have something up
18 and running sooner.

19 CO-CHAIR SCHONDER: Alan?

20 DR. KLIGER: Well, could I ask
21 that question, actually, of the developers.
22 Why did you give us two identical measures

1 except for the data source?

2 DR. DUDLEY: This is Tom again.
3 That was because of the uncertainty of the
4 rollout with CROWNWeb and as far as the timing
5 we have the vehicle for the claimants'
6 submission and CROWNWeb. We intend to replace
7 claimants' submission ultimately.

8 DR. PACE: Yes. Because I haven't
9 compared these measures yet. Those who
10 reviewed it, are the numerator and denominator
11 statements pretty much the same so that the
12 only distinction is what codes, for example,
13 off of claims versus information out of the
14 CROWNWeb? Go ahead, developer.

15 DR. MESSANA: So the instructions
16 for using the V8 modifier result in adding
17 that modifier to the claims as of July 2010.
18 And I'm going off the top of my head, off
19 memory but when there is bacteremia and it's
20 felt to be related to vascular access for a
21 hemodialysis patient, peritoneal infection for
22 a pede patient. So we're talking about chemo

1 only at this point.

2 And so the instructions for using
3 the V8 modifier result in a similar numerator
4 to the CROWNWeb-based specification. It's a
5 largely, not entirely but largely, different
6 data source. The difference is that in all of
7 our CROWNWeb-based specifications, in that
8 totalitarian, in total that group, not
9 totalitarian, although --

10 (Laughter.)

11 DR. MESSANA: No. But in that
12 group of five, you have to have antibiotic
13 start. So our CROWNWeb ones are really a
14 small subset of all infections and dialysis
15 patients. That is the fundamental difference
16 other than the data source.

17 CO-CHAIR SCHONDER: Any other
18 comments from the Committee?

19 DR. PACE: Again, this is
20 something we will have to resolve when we get
21 through these measures. We do at NQF have
22 measures sometimes that it's one measure, but

1 there are different ways that you could
2 construct the measure based on which data you
3 are developing. If we have a measure that
4 way, we like to know that we're getting
5 comparable results across data sources if
6 we're saying you can do it one or multiple
7 ways.

8 So I think the question before you
9 now is the way it is specified, did that make
10 sense? Yes.

11 DR. FIVUSH: I have a concern.
12 The claims data is used for Medicare patients.
13 You know, again, I don't know in the adult
14 world what the Medicare/private sector
15 breakdown is, but in pediatrics, we know that
16 more patients are not on Medicare. And that
17 includes we have looked at our 18-year-olds
18 and our 19-year-olds and our 20-year-olds.
19 And I just don't know how valid.

20 I mean, the appeal of the CROWNWeb
21 is that it is going to be when it rolls out
22 100 percent and we are going to have a better

1 idea. And I don't know if you only look at
2 Medicare claims data. And I would look to the
3 people around this room. Does that give us,
4 really, the -- is that going to tell us the
5 whole picture? Is it going to somehow skew
6 the data of patients that are not
7 Medicare-insured? Is that going to change?
8 Is that not going to be a valid look at this
9 measure that we're really look at bacteremia,
10 but we're not looking at it in our total
11 population. And we may be looking at it
12 differently by insurers.

13 DR. LATTIS: And that was going to
14 be my question as well. I mean, why is this
15 labeled a Medicare claims measure? Why
16 couldn't it be -- why isn't it just a claims
17 measure and we use our claims as well?

18 I mean, that is actually quite
19 attractive. Claims-based measures are quite
20 attractive because there is no additional data
21 burden and it is apples to apples. You know,
22 methodology is clear. And it can be an apples

1 to apples comparison.

2 So I'm not clear why this is
3 labeled a Medicare claims measure, as opposed
4 to a claims measure.

5 CO-CHAIR SCHONDER: Robert?

6 DR. WOLFE: It is because it is
7 truth in advertising. It is limited. What we
8 have access to are the Medicare claims. And
9 those claims are submitted for patients with
10 Medicare insurance.

11 I think there was a question of,
12 what kind of coverage is that? And I can't
13 give a complete answer, but for adults over
14 time, Medicare becomes a primary care for
15 almost everybody.

16 One of the distinctive things
17 about kids is a very large fraction of them
18 gets transplants fairly quickly. So there
19 will be a gap, absolutely, of missing a fair
20 number of kids in that interim before they get
21 a transplant. That is one of the limitations
22 of the entire claims process. Is this limited

1 to adults? I'm sorry?

2 DR. FIVUSH: We have looked at our
3 data because, again, we're talking about small
4 numbers of patients. I just know in the --
5 I'm talking about in the young adults, where
6 this is an important question as well.

7 I understand that it's over 18,
8 but, even in that population of 18 to 25, I am
9 putting it up as it doesn't change the
10 validity, but we're not really looking at
11 apples to apples. But I understand.

12 DR. WOLFE: Your question is
13 well-taken, but we aren't trying to limit this
14 to Medicare only. But it's a constraint of
15 the data flow, rather.

16 DR. LATTIS: So I guess the
17 question is, can we remove that Medicare
18 limitation and have it be claims, period,
19 understanding that it has been tested in a
20 Medicare population but that the claims --
21 well, right, right -- understanding that it
22 will be tested in a Medicare population given

1 what you have access to but that the
2 methodology is as applicable to a commercial
3 population as it would be to a Medicare
4 population.

5 CO-CHAIR CROOKS: Do you collect
6 the same V indicators on the --

7 DR. LATTIS: Yes.

8 CO-CHAIR CROOKS: I mean, I don't
9 know.

10 DR. LATTIS: I mean, you know, our
11 systems are -- HCPCS are an evolving
12 technology, but yes, we collect it.

13 CO-CHAIR SCHONDER: Robert?

14 DR. PROVENZANO: Just two
15 questions. One, will this create an
16 additional burden on facilities? And, two,
17 it's a validation tool for the previous
18 measure. And is that what we are supposed to
19 be doing here?

20 CO-CHAIR CROOKS: I have been
21 dissuaded that is a validation tool. I don't
22 think it is. It isn't identical. So let's

1 drop that notion. That was my superimposing
2 something on them. So I apologize. I
3 apologize.

4 Ask your other question.

5 DR. PROVENZANO: Does it create an
6 additional burden --

7 CO-CHAIR CROOKS: Burden, right.

8 DR. PROVENZANO: -- on the
9 facilities?

10 CO-CHAIR SCHONDER: Barbara?

11 DR. FIVUSH: I think it is an
12 important measure. I think when CROWNWeb
13 comes out, we're going to be collecting it.
14 It's going to happen. And I don't know why we
15 would collect it in two ways if we think -- I
16 mean, I believe that CROWNWeb is going to be
17 very reliable. So I don't know when we have
18 a question about more burden or not comparing
19 apples to apples or then changing the measure,
20 why we wouldn't wait for CROWNWeb when we
21 heard that CROWNWeb is going to roll out.

22 And since it's not going to

1 validate CROWNWeb because we've heard it's not
2 a validation, I'm just wondering what
3 additional knowledge will we get if CROWNWeb
4 rolls out and is the system we think it will
5 be and it's not to validate CROWNWeb.

6 DR. LATTIS: I don't think it would
7 be additional burden because you're going to
8 be billing these anyways. I mean, your
9 billing companies are going to be billing the
10 complete information on the situation based on
11 the capabilities of ICD-9 or ICD-10 and with
12 the CPT codes and the HCPCS codes. So the
13 information will be there, but who will
14 collect that --

15 DR. FIVUSH: Well, that will be
16 Medicare or the private payers, then, to do
17 what we will with the claims data.

18 CO-CHAIR SCHONDER: Myra?

19 DR. KLEINPETER: Where would the
20 VA patients fit in this scheme of things?
21 Because some are being dialyzed at our
22 community unions. And their claims process is

1 totally different. And they're doing the
2 contracts differently. And where does the VA
3 I guess participate in the quality aspect of
4 a lot of this? Because we have all heard that
5 there are some quality deficits at some of the
6 VAs related to some of the long-term care of
7 the older veterans.

8 DR. MESSANA: If the question is a
9 question directed to us, my understanding is
10 that, first off, some veterans have Medicare,
11 secondary or Medicare coverage. And so those
12 I think will end up in the Medicare data.

13 CROWNWeb, right, so we're shifting
14 between measures and data sources. The
15 CROWNWeb includes all.

16 DR. BURSTIN: I have a question, I
17 guess, perhaps for Sue. So since this is a
18 claims-based measure of access-related
19 bacteremia and this measure is not tested, is
20 there any known information about the
21 reliability and validity of claims-based
22 bacteremia measures?

1 MS. BARNES: I don't have the
2 exact reference. I can get it for you or
3 them. There is a lot of published data
4 suggesting that claims information alone is
5 very inaccurate in terms of
6 healthcare-associated infection rate
7 generation.

8 DR. LATTIS: Is that because --
9 they're very accurate, I believe, in terms of
10 identifying the infection. No?

11 MS. BARNES: Actually not. And
12 that's due to a number of factors, partially
13 due to -- you know, it's as good as the
14 information put in.

15 DR. LATTIS: Right.

16 MS. BARNES: Encoders don't
17 necessarily do good case finding. And case
18 finding is important. You know, you can't
19 just look at a record and if somebody didn't
20 assign a code, then the coder can't claim it.
21 So, actually, there's quite a bit of published
22 evidence that claims data is not a sufficient

1 method or source for HAI data.

2 DR. MESSANA: Although I have no
3 information to dispute that statement, we're
4 not talking about generally applicable studies
5 of claims-based accuracy here. First off,
6 this is the dialysis world. And it's based
7 off of a type 72 dialysis claim. And it's a
8 specific modifier. So this is somewhat
9 different than searching through ICD-9 codes
10 to find infections.

11 CO-CHAIR SCHONDER: Any other
12 comments? We'll move to vote, then.

13 DR. PACE: This is measure 1455,
14 importance to measure and report.

15 (Pause.)

16 CO-CHAIR CROOKS: Fourteen yes,
17 six no.

18 DR. PACE: Okay. Scientific
19 acceptability of measure properties? And
20 this, again, would be related primarily to the
21 specifications.

22 (Pause.)

1 CO-CHAIR CROOKS: Fifteen
2 partially, four minimally, one not at all.

3 DR. PACE: Okay. Usability?
4 (Pause.)

5 CO-CHAIR CROOKS: Thirteen
6 partially, four minimally, three not at all.

7 DR. PACE: Feasibility?
8 (Pause.)

9 CO-CHAIR CROOKS: Four completely,
10 nine partially, six minimally, one not at all.

11 DR. PACE: And recommend for
12 endorsement?

13 (Pause.)

14 CO-CHAIR CROOKS: Seven yes, 13
15 no.

16 CO-CHAIR SCHONDER: Okay. We will
17 go back to measure 1456, "Bacteremia and
18 Rate." Andy?

19 1456, BACTEREMIA (RATE)

20 DR. NARVA: This is a process
21 measure. And it's part of the suite of
22 measures that is meant to sort of cover the

1 different ways in which infections,
2 particularly access infections, are
3 identified.

4 The purpose was to help focus
5 quality efforts on culture-positive
6 infections, which perhaps would be less
7 subject to interpretation and provide better,
8 more accurate monitoring and a stronger,
9 firmer basis on which to design a quality
10 improvement program.

11 The gap it is addressing is the
12 large variation in access-related infection,
13 although this covers a broader group of
14 patients.

15 It is a six-month rolling average
16 rate of bacteremia with IV antibiotics. And
17 the rate is per 1,000 patient days. The
18 denominator is the number of months that a
19 hemodialysis patient initiated an antibiotic
20 for a new infection. And the numerator is
21 those patients for whom there are blood
22 culture results consistent with infection. It

1 could be stratified for access type.

2 There are a number of comments and
3 a fair amount of I guess ambivalence towards
4 this measure. It has not been tested. There
5 are concerns about the subjectivity in
6 determining the cause of bacteremia.

7 It's not clear how this would
8 improve care and on the other side was thought
9 to be valuable for public reporting and
10 quality improvement. And one of the two
11 supporters thought it would only be for
12 time-limited testing, which is, of course, the
13 only option that is available.

14 Summarizing the reviews, three out
15 of four thought it was important, although
16 there was no data on the opportunity for
17 improvement. The scientific acceptability was
18 one partial and two minimal. Usability was
19 one complete, one partial, one minimal, one
20 abstainer. Feasibility was two complete, one
21 partial, one abstainer. And the
22 recommendation was two yes and two no.

1 CO-CHAIR SCHONDER: Comments?

2 DR. LATTIS: I just have a
3 question. For most of these measures, they're
4 continually listed as process measures. I
5 guess to me, they are outcome measures. So I
6 am confused there.

7 DR. PACE: I think we would
8 consider them outcome, but I don't know why
9 they were --

10 DR. NARVA: Described as output.
11 In your value, in your notes, you also talked
12 about that.

13 DR. WOLFE: The overall infection
14 rate is an outcome measure. The vascular
15 access, specific rates were thought of more as
16 process and quality improvement efforts. So
17 that once you know that your infection rate is
18 high, you can then focus upon which types of
19 patient those infection rates are higher than
20 expected in.

21 If your infection rate is high but
22 the same as expected for each type of vascular

1 access, then it's probably the mix of vascular
2 access that is causing your infection rate to
3 be high. But if you have a high infection
4 rate and it's high amongst, let's say,
5 fistula, then you've got a problem with
6 fistulas and you can focus upon that. So
7 that's why some of them are quality
8 improvement effort tools and some of them are
9 just outcome tools.

10 DR. LATTIS: To me an infection is
11 an outcome, --

12 DR. PACE: Right.

13 DR. LATTIS: -- end of story,
14 whatever kind of infection it is. A process
15 is something that leads to the outcome.

16 DR. PACE: And that is what -- we
17 would classify them in our database as outcome
18 measures. So this is overall bacteremia, this
19 particular --

20 DR. NARVA: The basic number is
21 bacteremia. The dialysis patients that I was
22 most involved with had large numbers of lower

1 extremity infections. And there were also
2 many people with non-access-related infections
3 who could receive IV antibiotics who didn't
4 necessarily have septicemia, but it was a very
5 -- you know, one of the few advantages to them
6 of being on dialysis was they could have a
7 parenteral course of antibiotics without
8 actually being admitted to the hospital. And
9 that happened not infrequently.

10 So I guess I am worried about
11 identifying the actual cause of the indication
12 for starting antibiotics and also even
13 retrieving the blood culture because it could
14 have been obtained in many different places.
15 But that came up previously.

16 DR. MESSANA: Right. That is
17 similar to NHSN's 1460.

18 DR. PACE: Sue, this would be
19 similar to the one we talked about initially
20 that was based on the IV antibiotic starts is
21 basically how you determine this, right? Oh,
22 okay.

1 DR. NARVA: I was wondering if any
2 of the other folks who were primary reviewers
3 had comments.

4 DR. JACKSON: Yes. It seems to me
5 very similar to 1460 except this pairs
6 antibiotic starts with the positive blood
7 culture. And I think 1460, it's just positive
8 blood cultures. And so when we compared them,
9 the data source --

10 DR. PACE: Yes. Ultimately we
11 would need to look at these in comparison.

12 MS. BARNES: Yes. I think it adds
13 burden in terms of trying to connect the two
14 without any value, adding value, the two being
15 antibiotic and positive culture.

16 DR. LATTIS: And then the next set
17 of measures would add the third burden, being
18 the clinically confirmed infection.

19 CO-CHAIR CROOKS: But we already
20 established that this data is going to be
21 collected anyway. So it doesn't add to the
22 burden existing unless I misunderstood what we

1 heard earlier.

2 MS. BARNES: I thought I
3 understood that not everybody was on CROWNWeb.
4 Is that not true?

5 MS. ANDERSON: Well, not yet. And
6 the difference is the LDOs will be able to
7 batch. The SDOs will be manually entering all
8 of the data. That's --

9 CO-CHAIR CROOKS: SDO mean small
10 dialysis organization.

11 MS. ANDERSON: I'm sorry. Yes.

12 CO-CHAIR CROOKS: LDO is a large
13 dialysis.

14 MS. BARNES: So to me there is a
15 huge data burden.

16 MS. ANDERSON: There is a huge
17 data burden to manually enter the data.

18 DR. PACE: I think what we were
19 hearing is that --

20 CO-CHAIR CROOKS: They have to do
21 it.

22 DR. PACE: -- the CMS coverage

1 rules, if you want CMS reimbursement, you
2 provide the data that goes on.

3 MS. BARNES: Oh, I see.

4 CO-CHAIR CROOKS: If you want to
5 get paid, you have to put the data in.

6 DR. PROVENZANO: Well, I mean, I
7 just want to be clear because I know a lot of
8 people in the room have dealt with CROWNWeb.
9 Everything in the world isn't in CROWNWeb to
10 be collected. The conditions of coverage
11 mandate that facilities will participate.

12 I know that there are a lot of
13 data pieces that are there that can be turned
14 on and turned off. I guess my question is, is
15 this body making the decision what gets turned
16 on or what gets turned off or are these things
17 already mandated to be collected, they're
18 going to be collected, and we're deciding
19 whether or not they are going to be endorsed?

20 CO-CHAIR CROOKS: That is exactly
21 what I was trying to establish. And Tom
22 Dudley -- I thought we had a pretty clear

1 answer but maybe, maybe not.

2 DR. PROVENZANO: It wasn't clear
3 to me, I guess. So that's maybe just me.

4 DR. PACE: First of all, let me
5 just explain NQF is not endorsing CROWNWeb or
6 the individual data elements, though to a
7 certain extent if we endorse a measure that
8 requires those data elements, it's kind of in
9 that direction. But independent of
10 measurement, CMS has mandated certain data be
11 collected. And it's part of their coverage
12 rules.

13 So, Tom, if you are still on the
14 line, could you just clarify once again what
15 CMS is mandating regarding data collection,
16 regarding CROWNWeb?

17 DR. DUDLEY: Sure, Karen. What
18 you said was accurate. There are two separate
19 things: the endorsement versus requirements
20 under CROWNWeb. What is in CROWNWeb are the
21 elements that the data fields need to be
22 collected to monitor or assess the care advice

1 to the ESRD population under the Medicare
2 program.

3 At this point the intent is it
4 will be collected. Will all of them be
5 required? I don't have my crystal ball with
6 me. Potentially some of the elements will be
7 optional.

8 But, I mean, my perspective for
9 the Steering Committee would be look at the
10 measure on the merits, not what CMS will or
11 will not require within CROWNWeb.

12 DR. PROVENZANO: So call me
13 simple. If they're not required, the
14 probability that they're going to be required
15 if we endorse them to me would see much
16 higher, which would increase a burden of work
17 on facilities.

18 DR. DUDLEY: They are all ready
19 built into the system. That will be rolled
20 out. Will there be an increase in burden?

21 DR. PROVENZANO: When you say
22 they're built in the system, you know, my

1 iPhone has a lot of stuff built into it that
2 I don't use, most of it. That's what I am
3 trying to determine.

4 When you say built in but not
5 required, that's different than built in and
6 required. And my concern is that if they
7 currently are not required but built in -- and
8 I understand why they are built in -- and we
9 endorse something with the understanding,
10 well, it's no big deal because they're all
11 required, that's just not accurate.

12 DR. DUDLEY: Okay. I appreciate
13 what you are saying. And, unfortunately, I
14 don't have an answer because it falls outside
15 of the quality measure development area. It's
16 not required in CROWNweb. That's another
17 area, is CMS. I don't want to speak on their
18 behalf regarding what will be turned on, what
19 will be turned off.

20 DR. PACE: Okay. Tom, thanks.
21 What we can do is follow up and get the answer
22 to that question of is everything that is in

1 CROWNWeb going to be required --

2 DR. PROVENZANO: Well, regarding
3 this.

4 DR. PACE: Right, exactly,
5 regarding these data elements. So that's
6 something that we can provide the information
7 when we get to the point of these comparisons.
8 I think that would be useful information when
9 you are comparing measures. And we can work
10 with Tom to get that from their colleagues at
11 CMS.

12 CO-CHAIR SCHONDER: Are there any
13 other comments?

14 (No response.)

15 CO-CHAIR SCHONDER: Okay. Then I
16 think we will go ahead and move to vote kind
17 of on the basis of the merits of the measure
18 itself.

19 DR. PACE: Okay. Fourteen
20 fifty-six, we'll start with importance to
21 measure and report.

22 (Pause.)

1 CO-CHAIR SCHONDER: We have 16
2 yeses and 4 nos.

3 DR. PACE: Okay. We'll go on to
4 scientific acceptability and measure
5 properties. And, again, in this instance,
6 it's primarily related to how it is specified.

7 (Pause.)

8 CO-CHAIR CROOKS: One completely,
9 two partially, three minimally.

10 (Laughter.)

11 CO-CHAIR CROOKS: What did I say?
12 Fifteen, 15 partially, and three. One
13 completely, three -- anyway, did we get it?

14 (Laughter.)

15 CO-CHAIR CROOKS: On the record,
16 we got it? Okay.

17 DR. PACE: Usability.

18 (Pause.)

19 CO-CHAIR CROOKS: Trying again,
20 two -- no.

21 (Laughter.)

22 CO-CHAIR CROOKS: Partially 11,

1 minimally seven, not at all one.

2 DR. PACE: Feasibility?

3 (Pause.)

4 CO-CHAIR CROOKS: One completely,
5 11 partially, 8 minimally.

6 DR. PACE: Okay. And recommend
7 for endorsement?

8 (Pause.)

9 CO-CHAIR CROOKS: Nine yes, 11 no.

10 CO-CHAIR SCHONDER: Okay. Andy,
11 we will continue with you with measure number
12 1449, "Unavailable Blood Culture Results.
13 Microphone, please.

14 1449, UNAVAILABLE BLOOD CULTURE RESULTS
15 (PERCENTAGE)

16 DR. NARVA: This measure is one
17 minus the rate from the previous measure. The
18 denominator is the same: The hemodialysis
19 patients who have initiated antibiotic
20 treatment for new infection in the last six
21 months. And the numerator is the number of
22 patients for which there is a group who start

1 antibiotics but for whom there are no blood
2 culture results available.

3 And the purpose of this, described
4 a little bit differently, is the focus is on
5 reducing access infections by improving
6 timeliness and level of reporting of
7 infection-related measures and to prevent
8 gaming of facility-level incomes through
9 non-reporting.

10 I don't know if that is a problem
11 myself, but there are a number of concerns
12 with this. It is also untested. And so it
13 will only be available for a time-limited
14 endorsement.

15 The difficulty in ascertaining
16 missing results from a test that wasn't
17 actually done, there's no data on the
18 opportunity for improvement. And several
19 reviewers did not see how this would improve
20 care.

21 And I think, even form the
22 developers' text, I'll quote, "It is not known

1 the extent to which patient or dialysis
2 facility health records lack results of blood
3 culture results that have warranted IV
4 antibiotics." So I'm not sure how much of a
5 problem this is.

6 And there is also concern about
7 undue burden of documentation and
8 determination of the meaning of the results or
9 the absence of them.

10 It might be a better measure for
11 looking for the appropriate use of
12 antibiotics, rather than surveillance of
13 infection.

14 So the overall assessment by the
15 primary reviewers was the importance of this
16 issue. Again, three out of four thought it
17 was important; in terms of scientific
18 acceptability, three minimal and one
19 abstainer. Usability was one partial, one
20 minimal, one not at all, one abstainer. The
21 feasibility was one complete, two partial.
22 And the recommendation was split 50/50.

1 CO-CHAIR SCHONDER: Joe?

2 DR. VASSALOTTI: How do you
3 exclude a patient being hospitalized and high
4 blood culture? Is that addressed in this
5 measure? We didn't get details.

6 So patient in a hospital has a
7 positive blood culture, comes to the dialysis
8 unit and gets treated appropriately. The
9 physicians decide that they don't need to
10 repeat the blood culture that was done in the
11 hospital because they have that data.

12 Is there any way of excluding
13 those patients from this assessment?

14 DR. MESSANA: So my understanding
15 as the TEP deliberated these kinds of issues,
16 the new antibiotic start was a requirement for
17 the denominator here. So if a patient was
18 hospitalized for a bacteremia and came back to
19 your unit and there was a new antibiotic
20 start, then there's a justification for that.
21 It's the bacteremia.

22 So all of these measures differ in

1 that regard from the earlier ones that you
2 considered because new antibiotic start is the
3 only subset of the dialysis patients that
4 these measures are looking at.

5 DR. LATTIS: So that means a new IV
6 antibiotic start by the dialysis facility, as
7 opposed to if it was started in the hospital,
8 it doesn't count?

9 DR. MESSANA: Well, but once the
10 patient comes back to the dialysis facility,
11 then there has to be an antibiotic start
12 because you transition to outpatient.

13 DR. NARVA: If someone was in the
14 hospital, had a blood culture, was started on
15 a two-week course of antibiotics and got, you
16 know, the first dose of vancomycin last week
17 and the second dose back in the unit, that
18 would be a new start in the unit.

19 DR. MESSANA: That's correct.

20 DR. NARVA: You routinely wouldn't
21 get a blood culture to fill up later.

22 DR. MESSANA: One would presume

1 that you would have access to the blood
2 culture results to justify your starting the
3 vancomycin. I don't think it says anywhere
4 that it has to be a blood culture drawn and
5 send to your facility's laboratory.

6 DR. NARVA: But you have to be
7 able to retrieve it, though, right?

8 DR. MESSANA: Well, one would
9 presume that you have information to justify
10 the antibiotic start. So the implication is
11 that you have that information.

12 CO-CHAIR CROOKS: But for purposes
13 of the metric, that would come out as a
14 positive for this, right? In other words,
15 they didn't get the blood culture for the
16 antibiotic start. So it would be an
17 unavailable blood culture result, right? And
18 so that would count against that facility if
19 that's a negative outcome.

20 DR. MESSANA: I don't believe that
21 that was the intent. Although it's ambiguous,
22 the numerator description is somewhat

1 ambiguous --

2 CO-CHAIR CROOKS: Yes.

3 DR. MESSANA: -- as written, my
4 understanding is that unavailable means that
5 there were not blood cultures associated with
6 that antibiotic start. It does not specify
7 whether that was a blood culture drawn by the
8 dialysis facility or a blood culture that the
9 facility is aware of as part of the clinical
10 information that was transmitted.

11 DR. PROVENZANO: This then gets
12 back to I think what practitioners in the
13 large cities who deal with multiple hospitals
14 deal with. And, granted, it may just be a
15 phone call to the doc, who says, "Oh, yes.
16 This is gram-positive bacteremia. We started
17 vanco" but may be interpreted by the
18 facilities of tracking backwards to try to
19 find out if cultures were done, if they were
20 positive, where the patient went.

21 And then you start talking about
22 the burden factor, rather than, as I read it

1 initially, no cultures are done by
2 antibiotics, are started as a measure of
3 inappropriate antibiotic use. That's kind of
4 how I looked at it, but -- that's my point,
5 yes.

6 DR. MESSANA: If I may comment,
7 this measure and then the subsequent 1450 were
8 developed during a coordination session
9 between the clinical TEP and the data TEP,
10 trying to make sure, sure that there were not
11 perverse or adverse incentives created to
12 start antibiotics without drawing blood
13 cultures. So they wanted to track that as a
14 process measure to prevent a loophole.

15 PARTICIPANT: Any time you start
16 looking for measures of unavailable
17 information depending upon how much
18 subjectivity there is to that information, I'm
19 not -- I understand you are essentially trying
20 to prevent gaming of the system, it sounds
21 like, but how that improves patient care and
22 does that rise to the level of a standard,

1 it's a great deal of confusion.

2 CO-CHAIR CROOKS: And as one of
3 the reviewers, I was confused by the is this
4 only the cultures that were done, but the
5 report isn't available or is it counting
6 cultures that weren't done when they could
7 have been done? And that isn't clearly stated
8 in the numerator statement, I don't think.

9 CO-CHAIR SCHONDER: Ruben?

10 DR. VELEZ: I think, in summary, I
11 mean, the way I see it is it is not the arrow.
12 It is the Indian. You know, it can be
13 unavailable because I'm busy today and I don't
14 have time to check on the culture. So they
15 were unavailable.

16 So it creates a different scenario
17 here that, even though we want to hopefully
18 have appropriate blood cultures done when
19 we're doing antibiotics, where the cultures
20 were done, I know this measure has nothing to
21 do with whether they were positive or
22 negative. That is not the issue. Cultures

1 were done somewhere. And we need to identify
2 where they were done.

3 CO-CHAIR SCHONDER: Any other
4 comments?

5 (No response.)

6 CO-CHAIR SCHONDER: Move to
7 voting.

8 DR. PACE: Okay. This is measure
9 1449. And we're going to start with
10 importance to measure and report.

11 (Pause.)

12 DR. PACE: Has everyone voted?
13 Okay.

14 CO-CHAIR CROOKS: It is our first
15 tie: nine, nine.

16 DR. PACE: We will just continue
17 on. We will just move on. We will go on to
18 scientific acceptability. Go ahead. And, as
19 before, this is mainly about the
20 specifications at this point.

21 (Pause.)

22 CO-CHAIR CROOKS: One completely,

1 six partially, nine minimally, three not at
2 all.

3 DR. PACE: All right. Usability?
4 (Pause.)

5 CO-CHAIR CROOKS: One completely,
6 four partially, ten minimally, four not at
7 all.

8 DR. PACE: Feasibility?
9 (Pause.)

10 CO-CHAIR CROOKS: Two completely,
11 five partially, ten minimally, two not at all.

12 DR. PACE: Okay. And recommend
13 for endorsement?

14 (Pause.)

15 CO-CHAIR CROOKS: One yes, 18 no.

16 CO-CHAIR SCHONDER: Okay. The
17 next measure that is up -- actually, Bob
18 stepped out. So we'll move ahead to measure
19 number 1469, "Clinically Confirmed
20 Access-Related Infection Rate." Lisa?

21 1469, CLINICALLY CONFIRMED ACCESS-RELATED
22 INFECTION (RATE) [STRATIFIED BY ACCESS]

1 DR. LATTIS: Okay. So this is
2 building on a theme here, as you can tell.
3 This is very similar to the previous
4 access-related infection rate, but the
5 addition here, then, as with the previous
6 measure, is clinically confirmed. So in this
7 we add a third data element, which is that
8 somebody has to confirm that there is an
9 infection and that it is related to the
10 access.

11 So, in the interest of time maybe
12 since we have discussed these so much, I won't
13 go through in detail other than just to add
14 that the additional data element, the clinical
15 confirmation is very unclear to me in terms of
16 how that all happens.

17 I'm guessing it's just a data
18 element in CROWNWeb and somebody has to
19 ascertain, either a doctor or a nurse, you
20 know, click a box, "Yes, this was an
21 infection," "Yes, it was access-related" is
22 what I'm assuming. And I don't know if the

1 developers -- if we want them to add to that.

2 In terms of the evaluations that I
3 saw, I had four people, all of whom said that
4 yes, it was important in terms of scientific
5 acceptability. It looks like you've got the
6 same four.

7 So I thought it was not because of
8 some of the ambiguity around the measures.
9 There were two partially, one minimally; in
10 terms of usability, one not at all, one
11 minimally, two partially; and feasibility, two
12 partially, and two minimally; and then two yes
13 and two nos in terms of the recommendations at
14 this point.

15 So, again, I think building on the
16 theme that we have had so far, it is all of
17 the things we have discussed to date plus the
18 additional difficulty of a clinically
19 confirmed infection and clinically
20 access-related.

21 CO-CHAIR SCHONDER: Any comments
22 from the Committee?

1 CO-CHAIR CROOKS: This is another
2 one for time-limited endorsement only.

3 CO-CHAIR SCHONDER: Can I ask
4 about Lisa's question about how will clinical
5 confirmation be tracked for this particular
6 measure?

7 DR. MESSANA: It is not specified
8 in here. In the memo or white paper that went
9 out, the clarification from CMS, I think it's
10 discussed in there. Generally a professional
11 person, a doctor or a nurse, would have to
12 specify that it was a vascular access
13 infection.

14 DR. LATTIS: Which would lead to
15 some major validity. I mean, there is just so
16 much. It's very squishy.

17 CO-CHAIR SCHONDER: Okay. Any
18 other comments?

19 (No response.)

20 CO-CHAIR SCHONDER: Call the vote.

21 DR. PACE: This is measure 1469,
22 importance to measure and report.

1 (Pause.)

2 CO-CHAIR CROOKS: Nine yes and
3 nine no.

4 DR. PACE: Okay. We will have to
5 go on. Scientific acceptability of measure
6 properties? And, again, this would be the
7 specification.

8 (Pause.)

9 CO-CHAIR CROOKS: Nine partially,
10 six minimally, three not at all.

11 DR. PACE: We will go on.
12 Usability?

13 (Pause.)

14 CO-CHAIR CROOKS: Two partially,
15 12 minimally, one not at all -- 4 partially.

16 (Pause.)

17 CO-CHAIR CROOKS: Two partially,
18 13 minimally, 3 not at all.

19 DR. PACE: Okay. And then
20 recommend for endorsement?

21 (Pause.)

22 DR. PACE: Okay.

1 CO-CHAIR CROOKS: I have 2 yes and
2 16 no, 2 yes and 16 no.

3 CO-CHAIR SCHONDER: Okay. We'll
4 go back to measure number 1453, the
5 "Clinically Confirmation Infection (Rate)."
6 Bob, you need to stay put.

7 DR. WOLFE: Could I interject
8 something that these were proposed as a suite.
9 And one of them has been approved, but others
10 that are key to it have not. So some of these
11 others just don't really make as much sense.

12 And we would propose that there
13 are more important things for the Committee to
14 do and that we would withdraw them just to
15 simplify things.

16 No. The remainder that have not
17 just been --

18 DR. PACE: On the clinically
19 confirmed measures is what you are talking
20 about?

21 DR. WOLFE: Yes.

22 DR. PACE: All right.

1 DR. WOLFE: I think that several
2 of these, they were keyed together and then --

3 DR. PROVENZANO: That was easy.
4 That makes sense.

5 DR. NALLY: Hey, Bob, you had me
6 at yes.

7 CO-CHAIR SCHONDER: Just to
8 clarify, 1453 and 1450 are being withdrawn?

9 DR. WOLFE: Yes. We would like to
10 have more time I think for the remaining
11 measure.

12 CO-CHAIR CROOKS: Thank you.

13 CO-CHAIR SCHONDER: Thank you very
14 much.

15 DR. PACE: And I am sure you are
16 acting in concert with CMS.

17 DR. WOLFE: Yes. We have been
18 waiting on --

19 DR. PACE: Okay.

20 DR. WOLFE: We have been going
21 back and forth to get that.

22 DR. PACE: All right.

1 DR. WOLFE: Thank you.

2 DR. PACE: Thank you.

3 CO-CHAIR SCHONDER: So then we
4 will move to the last two measures, which are
5 the hospitalization measures. We will start
6 with measure number 1463, the "Standardized
7 Hospitalization Ratio for Admissions." Lisa
8 again?

9 HOSPITALIZATION

10 1463, STANDARDIZED HOSPITALIZATION RATIO FOR
11 ADMISSIONS

12 DR. LATTI: Okay. So switching
13 gears, standardized hospitalization measure
14 for admissions, so this is a measure, a
15 standardized measure, outcomes measure,
16 looking at hospitalization for admission.

17 And the numerator is the number of
18 inpatient hospital admissions among eligible
19 patients at the facility during the reporting
20 period. And the denominator essentially is
21 all patients on hemodialysis at the facility.

22 There are a couple of things I

1 want to point out. So this is an outcome
2 measure, which is very important and something
3 we need. The numerator is looking at -- hold
4 on. I'm sorry. Let me get the numbers here.

5 The numerator is looking at the --
6 the reporting periods -- the denominator is
7 reporting period, which is currently listed as
8 three years, which is a very long time period,
9 although it does say "designated time period."
10 So if the Committee felt that was too long and
11 wanted to proceed, I think we could probably
12 recommend a shorter period of time.

13 The information is coming from
14 CROWNWeb. This is risk-adjusted. And I
15 wanted to point out that it is currently
16 proposed to be risk-adjusted for age, race,
17 sex, diabetes, ethnicity, duration of ESRD,
18 nursing home status, BMI incidence,
19 comorbidity index incidence, and calendar
20 year.

21 There is then a linear predictor
22 for each patient based on the regression

1 coefficient and the stage 1 model, which is
2 used to compute a risk adjustment. And then
3 it's basically a very complex analysis.

4 And then there's a ratio of the
5 expected versus the predicted admission rate
6 for each patient. And that is reported, then,
7 for each facility is what is their actual
8 hospitalization rate or admission rate for
9 this measure versus the expected. So,
10 actually, it is reported as a ratio.

11 So a couple of problems that I had
12 with this, one of the big ones off the top is
13 race. I have a big problem, actually, using
14 race in the risk adjustment, as opposed to
15 stratifying by race because then, surprise,
16 surprise, when they look at race differences,
17 they didn't find any. Well, you won't find
18 any differences if you use it to risk-adjust.

19 And I think one of the major
20 problems we have with dialysis is -- well, one
21 of the problem we have across the healthcare
22 system is race and ethnic minority health

1 disparities.

2 And I think if you risk-stratify
3 them out, I have a big problem with that. So
4 that is something that I would must rather see
5 in a stratification, as opposed to a risk
6 adjustment.

7 I think another problem that I
8 have that -- I don't know if we want to talk
9 about it here or talk about it a little later
10 -- is harmonizing with other measures in the
11 NQF world for admission rates. I'm sure there
12 are some, at least for nursing home. There is
13 a readmission rate. And there's a home health
14 admission and nursing home admission rate. So
15 we need to talk about harmonizing with those
16 at some point.

17 So in terms of the other
18 reviewers, there were five in the group that
19 I have, five also that you have. So I have
20 the complete five here. In terms of -- let me
21 page over here -- importance, everybody agreed
22 this was important; for scientific

1 acceptability, three minimally, one partially,
2 one completely; usability, four minimally, one
3 completely; feasibility, two completely, two
4 partially, no minimally; and recommendations
5 for approval, two yeses and three nos.

6 And in terms of the comments,
7 there were several comments. Several people
8 commented that the three years was too long,
9 as I mentioned earlier. And I think we could
10 potentially recommend a shorter time frame.

11 I do want to mention that I think
12 that this measure and the days, which we will
13 discuss next, are critically important. And
14 so I don't know if there is a way to fix this
15 in such a way that we can still have a measure
16 because I think it is so important to have a
17 measure or if this is critically flawed. So
18 I think that is the discussion that we need to
19 have.

20 DR. VASSALOTTI: I also voted for
21 this. I thought that if there is a kind of a
22 beauty and it's simple, it's understandable,

1 it's something patients understand, it's
2 something the community understands, I think
3 some of the statistics and risk adjustment are
4 complex, but I will leave to the developer.
5 I would like to hear what the developer says
6 about the reason for the race, how that
7 figured into the TEP's discussion, the DTEP's
8 discussion.

9 But I thought that this is
10 attractive. And I think it is actionable for
11 clinicians, particularly in terms of the data.
12 We could dial down to things like the access
13 infection, things like the CHF admissions.

14 So, I mean, certainly many of the
15 admissions are actionable potentially. So
16 that was my rationale.

17 CO-CHAIR SCHONDER: Bob, back
18 here?

19 DR. PROVENZANO: I agree it is
20 something we would all like to know, but it is
21 more complex I think than we appreciate.
22 There are some segments of our society that,

1 despite our best educational efforts, use the
2 emergency room and the hospital as a site of
3 their primary care. That is going to skew
4 this data.

5 Additionally, practically
6 speaking, nephrologists don't have control
7 over these patients. I do not make a
8 decision, nor do many nephrologists, as to who
9 gets admitted when, where. There are
10 hospitalists. There are primary care
11 physicians. And patients will seek out many
12 other avenues. So our control over this
13 measure is quite limited.

14 And, now, is this changing? It
15 is, maybe with the kind of care organizations
16 and a whole different view of seamless
17 processes, this might be less of a burden, but
18 right now I think it is somewhat flawed.

19 DR. LATTIS: Can I just interject
20 one quick question for the developer? Because
21 based on the way the submission was written,
22 my reading was that ER visits are excluded.

1 It's only if the patient is actually admitted
2 to the hospital, but it was a little fuzzy.

3 DR. PROVENZANO: Right. I think
4 you are right. Oh, I'm sorry.

5 DR. WOLFE: That is correct. We
6 are also considering an alternative measure
7 for ER utilization, recognizing that that may
8 be a more specific kind of different level of
9 issue.

10 But this is a hospitalization.
11 And it stands on the merits of being the
12 hospitalization without trying to encompass
13 the added issue of emergency rooms.

14 DR. PROVENZANO: But let me follow
15 up to Lisa. Emergency rooms now almost
16 universally use criteria that allow payment.
17 If a patient hits a criterion that will allow
18 admission for payment, they admit them. It
19 balances very well their legal risk with the
20 financial risk.

21 Therefore, every single dialysis
22 patient that goes into an emergency room, if

1 they use it as their primary source of care
2 can fit that criteria. And a disproportionate
3 number of them are admitted. So until that
4 separation occurs, I would still be
5 uncomfortable with this.

6 DR. WOLFE: Can I make a
7 clarification, which I may not have said
8 correctly? If they are admitted through an
9 ER, that is an admission, but if they go to an
10 ER with -- yes. Okay. Okay. I'm sorry.

11 DR. BERNES: So I agree with Bob on
12 the points, the initial point he made, which
13 is that we very often have no control over
14 hospital admission. Hospital admission is a
15 moving target. What was an admission or what
16 would have created an admission -- I think
17 this is what Bob is alluding to -- six months
18 ago is now in observation status. And we have
19 absolutely no control over how that decision
20 is made, whether it is one or the other.

21 And then I have a concern about
22 the risk adjustment methodology, which may be

1 a little bit more complex. So the denominator
2 excludes people in the first 90 days of
3 dialysis. And, yet, the risk adjustment is
4 based on several factor at incidents,
5 specifically BMI but, more importantly,
6 comorbidity.

7 And, yet, this is obviously going
8 to be people who are admitted to the hospital
9 three years, five years, ten years after
10 incidence with a risk adjustment that is
11 completely irrelevant based both upon BMI and
12 comorbidities.

13 So I think, in order to be
14 statistically valid, it would seem to me that
15 this ought to be a time variable of risk
16 adjustment or a comorbidity index and BMI
17 somewhat more approximate to the time of
18 admission if it's going to be clinically or
19 statistically meaningful. And that is sort of
20 a different issue than whether this really
21 even makes sense for other reasons.

22 DR. WOLFE: Are you asking the

1 developer that question?

2 DR. BERNES: I don't know whether
3 we need clarification because it is what it
4 is, but I think as we consider the value of
5 this as a measure, we should think about
6 whether or not the statistical underpinning is
7 reasonable and valid.

8 DR. VELEZ: I would like to hear
9 what the CAHPS discussion was if we have
10 access to it.

11 DR. WOLFE: So there have been
12 several questions. Would it be appropriate
13 for me to address the race question as well as
14 this one? Race is in the adjustment right now
15 for the SHR that has been produced and has
16 been made available to facilities.

17 Your comment that it would not
18 show up is true at the national level.
19 Nationally we will see observed equal to
20 expected for all the race groups. But at each
21 facility, if they are treating their certain
22 race groups differentially from the national

1 norm, you would see that.

2 So I am giving you an answer that
3 it is partially still in there. You would
4 still see differences from the norm for each
5 race at a facility. For a facility-specific
6 metric, that may be the most important
7 information. For a national policy, you would
8 do a different analysis.

9 For the purposes of a facility,
10 knowing how it is doing compared to standard
11 practice, there may be some value in the race
12 adjustment. But I do believe that the TEP was
13 not definitive on that and would be welcome to
14 change if appropriate.

15 But I do want you to consider the
16 possibility that when facilities think about
17 how am I doing with my patients and what
18 should they be compared to, it may be that it
19 should be for patients like their patients.

20 The three-year versus one-year, in
21 fact, we are seeking endorsement of the
22 concept. And it has been a three-year in the

1 past. That's what we had experience with.

2 But we also know that it is likely to be used
3 in a one-year measure and would value that
4 endorsement as well.

5 ER use, we have covered that it
6 includes hospitalization after ER. There is
7 the time-dependent variable question. And
8 that is a very important question also.

9 For better or for worse, this has
10 an historical context, which is that it has
11 been based primarily off of the 2728 form,
12 which is available with an active filling out
13 now of each comorbidity.

14 The alternative that we have is to
15 use the Medicare claims serially as a
16 time-dependent measure looking at ICD-9 and
17 diagnosis codes. And we think that that has
18 value. We also think that there are
19 limitations of it. And this is a choice that
20 you have to make between two imperfect
21 measures, the case with adjustment.

22 DR. NALLY: That was specifically

1 my question about this, particularly as you
2 are risk-adjusting and using kind of a
3 reference denominator. Currently you would be
4 using Medicare claims form. My understanding
5 is that is through 2008 would be the reference
6 there and then eventually when CROWNWeb goes
7 national, particularly related to
8 hospitalizations.

9 I spoke with the executive
10 director of the network in Indianapolis and
11 then had some e-mail exchange with the
12 Pittsburgh people that there could be a
13 couple-year lag phase to all the -- until it's
14 well-developed that the CROWNWeb
15 hospitalization is in place.

16 So what is your prediction of the
17 timeline for the transition of the methodology
18 of claims going to CROWNWeb? And how do you
19 adjudicate those ratios in terms of what time
20 population you're using?

21 DR. WOLFE: So for right now, the
22 measure that we are proposing is the one based

1 upon the adjustment for the comorbidity at the
2 time the most recent 2728 is submitted.

3 Now, for example, for patients who
4 get a transplant and return to dialysis, it
5 will not be the initial 2728. It will be the
6 one upon return.

7 Ideally what we would like to have
8 is each time there is a transfer from one
9 facility to a new facility, we would like to
10 have an evaluation of comorbidity at that
11 time. That isn't currently available. So we
12 use the most recent 2728 form.

13 I don't know what will happen in
14 the future, but that would be a new measure
15 submission at the time CROWNWeb data becomes
16 available. And we will have experience with
17 CROWNWeb data at that time. Right now we do
18 have the experience with the claims-based
19 data.

20 We do know that the
21 hospitalization is actionable in that it is
22 very strongly related to catheter utilization.

1 And it is very strongly related to the percent
2 of patients who are on target for media
3 management. And it is very strongly related
4 to the percent of patients.

5 This is more historical because
6 now the percent of patients who are on target
7 for URR is so high. But, as that was changing
8 over time, that was having a substantial
9 impact upon hospitalizations.

10 So, whatever imperfections there
11 are in the hospitalization measure, it has a
12 lot of validity in terms of being related to
13 the factors that are under the providers'
14 control.

15 DR. NALLY: So to address a
16 straightforward question, if in first quarter
17 2011, right now if I am running a CQI meeting
18 at my facility and this information has been
19 available and this ratio of admissions, the
20 data that I am looking at for my CQI now will
21 represent what period of time when those
22 admissions and the adjustments actually took

1 place?

2 DR. WOLFE: It will be the
3 calendar year prior to the time that you're
4 looking at it if you're looking at it after
5 September. Each calendar year becomes
6 available nine months later. So each calendar
7 year, you can start looking at September and
8 subsequent to that.

9 And the annual values are
10 available to you in your facility reports
11 right now. And those have a lag of nine
12 months. And then, in addition to that last
13 year, you had the year before that and the
14 year before that. So there are three
15 sequential years you can look at trends. And
16 they are available up until the last year,
17 calendar year, before --

18 DR. NALLY: So today I would be
19 looking at years seven, eight, and nine?

20 DR. WOLFE: Today you would be
21 looking at 2010 as the last year --

22 DR. NALLY: Okay. It would

1 include data --

2 DR. WOLFE: -- because --

3 DR. NALLY: No.

4 DR. WOLFE: -- 2009 -- yes. I'm
5 sorry. Two thousand nine was reported in
6 September of last year.

7 DR. NALLY: Right.

8 DR. WOLFE: Thank you. That's
9 right.

10 CO-CHAIR CROOKS: Two comments.

11 One is that the standardized ratio for
12 hospitalizations is very similar to the
13 mortality, standardized mortality, which is
14 also reported on ESRD comparing, I think. In
15 that sense, it's something that the community
16 is used to looking at. Intuitively it makes
17 sense, despite the complexity of
18 standardizing.

19 But I also want to take an
20 opposite point of view from Bob and Jeff on
21 that this isn't the nephrologist's
22 responsibility that the patient gets

1 hospitalized. I mean, if you're not taking
2 responsibility for hospitalizations, you will
3 be very soon if you're going to start working
4 with ACOs.

5 Vascular access is still one of
6 the most common causes of hospitalization. If
7 you're proactively managing vascular access,
8 you decrease hospitalizations. CHF is by the
9 second or one of the top causes of
10 hospitalization. If you're managing your
11 patients right in dialysis, they're not going
12 to go to the emergency room for CHF.

13 So you are, as a matter of fact,
14 the metric is to say, is a nephrologist
15 actually doing what they can do to decrease
16 hospitalization and the dialysis facility
17 together? Are the providers keeping patients
18 out of the hospital or not? That's the whole
19 point of it.

20 So to say I have no control, it's
21 not my problem, I reject that. And I think it
22 is your problem. It is. And it is going to

1 become increasingly your problem as we start
2 to move into models of care where you have to
3 take responsibility for that.

4 DR. BERNES: If I can just retort?
5 I mean, if I ever ever -- well, if I almost
6 never, but if I got a call from the emergency
7 room doctor and said, "Would you like your
8 patient admitted?" or "Do you think your
9 patient needs to be admitted?" I can sort of
10 go along with that notion. But that
11 absolutely rarely happens.

12 So that somebody in the emergency
13 room who has little or no experience taking
14 care of a patient with dialysis, doesn't know,
15 you know, at 6:00 o'clock in the morning if
16 they could go to dialysis at 7:00 and not be
17 admitted to the hospital because they're a
18 tiny bit short of breath or the potassium is
19 5.2, I have no control over that.

20 And that's where I'm sort of
21 bothered by this.

22 CO-CHAIR CROOKS: Maybe you

1 should. Maybe you would be working
2 proactively to work with this hospital and
3 say, "This is the system of care."

4 DR. BERNES: No.

5 CO-CHAIR CROOKS: Also, if you're
6 caring for them extremely well, maybe they
7 wouldn't be going to the emergency room in the
8 first place. So I think there are several
9 levels at which you could be interacting, but
10 you have to take some responsibility for the
11 system of care that your patient is in and not
12 just say, "They're out of the dialysis unit.
13 They're out of my hands," you know.

14 DR. PROVENZANO: Peter, you have
15 been a nephrologist for a long time in a
16 system where you don't face many of the issues
17 we face in a fragmented care world.

18 It is not that nephrologists do
19 not want to care for this patient. Many
20 people, myself included, many people at this
21 table, the RPA have worked for 20 years to
22 make nephrologists primarily responsible and

1 manage the care.

2 All the data suggests exactly what
3 you know, that we are best suited to care for
4 them, but the systems won't allow for that in
5 many instances. And this is why I am a big
6 proponent of ACOs.

7 I don't want to send the message
8 that any of us say it's not our problem. What
9 we are saying is we continue to have problems
10 accessing these patients. So my patient may
11 go to the ER with heart failure. They will
12 call a cardiologist. Often the problem is
13 they don't even bother to call us when it's a
14 dialysis patient on the floor in heart
15 failure.

16 So the system is fragmented. And
17 I'm just saying that this will be interpreted
18 as how can we impact this. It's going to be
19 problematic.

20 CO-CHAIR SCHONDER: Helen?

21 DR. BURSTIN: I just want to put
22 out that we are definitely, I think, in this

1 place where every single committee encounters
2 this exact thing. It's not unique to
3 dialysis. It's the identical conversation we
4 had where we had admission measures, the
5 identical conversation we had about admissions
6 from home care. This is the state of the
7 world, as we already know.

8 It is not fully advanced to the
9 ACO level, but certainly I think what we are
10 trying to do is endorse a set of measures we
11 think will drive improvement and drive
12 improvement really in care overall at a system
13 level, even if our system isn't quite there
14 yet.

15 And so we have increasingly talked
16 about the concept of the right set of measures
17 for shared accountability that really helps
18 drive what the patients need, so just a
19 context setting.

20 CO-CHAIR SCHONDER: Alan?

21 DR. KLIGER: I want to just add
22 some perspective, if I can. Clinicians years

1 ago looked at mortality and hospitalization in
2 raw numbers that were very hard to understand.
3 We then, thanks to Bob and his group, got
4 tools to understand standardizing both and
5 examining both with a lag time that started
6 off in many years that's now down to nine
7 months, I think a very formidable
8 accomplishment for tools for us.

9 I would argue that, while it is
10 clear there are limitations to the
11 actionability of some of these measures and I
12 surely share the concerns of my colleagues
13 here about those limitations, that,
14 nonetheless, these tools are giving, I
15 believe, very important information about
16 patient care and about facility-specific care
17 as well.

18 And I would argue that placing
19 these tools that have been developed over
20 years or the one we're considering now is the
21 standardized hospitalization ratio. Endorsing
22 this here with information sources as they

1 become more available and easier to use is the
2 right thing for us to do.

3 CO-CHAIR SCHONDER: Barbara?

4 DR. FIVUSH: I see this is for all
5 patients and there are no exclusions for age.
6 So I think this is -- I listened to Alan's
7 comments -- extremely important because I
8 listened to the comments about how difficult
9 it is.

10 I would just urge that every
11 patient does have a 2728. So you are going to
12 pick up comorbidities on pediatric patients,
13 but you are not going to get Medicare claims
14 to follow up on comorbidities that develop.
15 And I know this hasn't been seen by the
16 pediatric TEP.

17 So I would just say that if this
18 measure does go forward, I would really ask
19 for some consideration of thought into how are
20 you going to pick up comorbidities in the
21 pediatric world, not saying this isn't an
22 important measure?

1 And comorbidities are totally
2 different in the age groups. You know, we
3 know that. And we have had that conversation,
4 even in the bundling, how different the
5 comorbidities are in different ages that --
6 and I know that is going to be part of the
7 analysis but that you consider that if this
8 measure goes forward. I think that requires
9 some consideration.

10 CO-CHAIR SCHONDER: Myra?

11 DR. KLEINPETER: One other thing I
12 think is in looking at economically
13 disadvantaged populations of patients, be it
14 rural or urban. Sometimes they just don't
15 have the other resources available. So a
16 hospitalization is done to make sure they get
17 the care because they don't have benefits for
18 home health or they don't have home health
19 agencies that will go into the projects or
20 there are other issues related to distances
21 that they have to travel from those rural
22 areas. So that is one of the things that is

1 going to impact that we don't have a way of
2 measuring or capturing with the measure the
3 way it reads right now.

4 DR. FIVUSH: I understand exactly
5 what Myra is saying as well. So I didn't want
6 to sound negative about the measure. I just
7 think that -- I mean, a lot of times we do end
8 up admitting children because that is really
9 the only way we can facilitate what needs to
10 be done because their parents can't, for
11 example.

12 So I think there is some validity
13 to a lot of these comments. I think the
14 measure, I think the importance of the
15 measure, can't be underscored but that we need
16 to think kind of to look at some of those
17 things.

18 DR. VASSALOTTI: I guess I would
19 just ask everybody to consider I recognize
20 that there are definite limitations to this
21 measure. They're certainly going to
22 disadvantage certain dialysis facilities. I

1 understand and am sensitive to that, how
2 difficult it must be for certain dialysis
3 units.

4 I also understand if you are in a
5 place where certain emergency room behaviors
6 may be different than others, you know. So
7 there are all of these aspects of this that
8 potentially could disadvantage certain
9 dialysis units.

10 However, I think we have to -- for
11 me at least, dialysis patients have a very
12 high rate of admissions. And, at least for
13 me, quite a large proportion of those are
14 related to things I think that the
15 nephrologist has control over, like congestive
16 heart failure, like vascular access-related
17 infection.

18 And so the question is, does this
19 measure capture those things with some issues
20 that are problematic? Is that better than
21 just voting it down?

22 DR. NALLY: Well, I would agree

1 with that concept and then have a specific
2 question because it seems to me that when we
3 talk about burden being put upon a facility,
4 I think most of the burden to capture this
5 information doesn't rest with the facility.
6 Is that true or --

7 DR. WOLFE: That is correct.
8 There is no data burden at all on the facility
9 because these are --

10 DR. NALLY: So, again, to echo, it
11 is a very important parameter that tracks over
12 years, quarters and years. And now we have
13 the delta move down to nine months. Maybe
14 that will improve with CROWNWeb.

15 Things are clearly moving in the
16 right direction. And, at least in this case,
17 we're not asking to impose an additional
18 burden on our dialysis facility staff to keep
19 up with the information required.

20 DR. LATTIS: So I would propose we
21 move ahead. Did you have another comment?

22 DR. WOLFE: I would just like to

1 give a point of clarification about the
2 timing. The discrepancy between your memory
3 and mine is because we are both right.

4 (Laughter.)

5 DR. WOLFE: The current DFRs are a
6 year lag. The next cycle will be one year
7 later based upon the March quarterly staff,
8 instead of the June quarterly staff. And
9 that's technical. Don't worry about it. But
10 the next cycle will be a year advanced.

11 DR. LATTIS: So I would propose we
12 move forward to the question. And I would
13 propose feedback that we give to the
14 developers based on the discussions we have
15 had, including decreasing the time period to
16 one year and also investigating using race as
17 a stratification, rather than as a risk
18 adjustment.

19 DR. PACE: Right. That is
20 actually in our criteria that NQF recommends
21 that factors associated with disparities be
22 stratified versus included in risk models

1 unless there is strong justification that it
2 is really a proxy for some biological issue
3 going on.

4 So we will get back to them about
5 that and what that means in terms of their
6 modeling and testing in terms of -- but I
7 think we will keep that caveat that we will
8 have discussions about that.

9 CO-CHAIR SCHONDER: Any other
10 comments? Are we ready to vote?

11 (No response.)

12 CO-CHAIR SCHONDER: all right.

13 DR. PACE: So this is 1463. And
14 we'll start with importance to measure and
15 report.

16 (Pause.)

17 CO-CHAIR CROOKS: Everybody
18 agrees. Twenty yes.

19 DR. PACE: All right. Scientific
20 acceptability of measure properties?

21 (Pause.)

22 CO-CHAIR CROOKS: Seven

1 completely, 12 partially, one minimally.

2 DR. PACE: Usability?

3 (Pause.)

4 CO-CHAIR CROOKS: Eight

5 completely, nine partially, three minimally.

6 DR. PACE: Okay. And feasibility?

7 (Pause.)

8 CO-CHAIR CROOKS: Twelve

9 completely, six partially, two minimally.

10 DR. PACE: Okay. Then recommend
11 for endorsement?

12 (Pause.)

13 DR. PACE: Right. We will clarify
14 the time period, and also we will get an
15 answer about the ethnicity and race factors.

16 CO-CHAIR CROOKS: Eighteen yes and
17 two no.

18 1464, STANDARDIZED HOSPITALIZATION RATIO FOR
19 DAYS

20 CO-CHAIR SCHONDER: Okay. Last
21 measure, "Standardized Hospitalization Ratio
22 for Days." And that is finally my measure

1 This is very, very similar to the last measure
2 that we talked about. The description is a
3 risk-adjusted standardized hospitalization
4 ratio for days for dialysis facility patients.

5 The numerator statement is the
6 number of days hospitalized among eligible
7 patients at the facility during the reporting
8 period. The denominator is the number of days
9 hospitalized that would be expected among
10 eligible patients at the facility during the
11 reporting period given the patient mix at the
12 facility.

13 With regards to the risk
14 adjustments, the same risk adjustments were
15 applied to this measure as to the previous
16 measure, including age, race, sex, diabetes,
17 et cetera, et cetera, as are really,
18 essentially, all of the other data elements
19 throughout the measure, so not to belabor that
20 point anymore.

21 As far as the reviewers, we had
22 five reviewers of the measure. Four voted yes

1 for importance. One voted no. As far as
2 scientific evidence, it was a bit across the
3 board. There was one complete, two partials,
4 and three minimal; usability, one complete,
5 one partial, three minimally; feasibility, two
6 complete, one partial, two minimally. And as
7 far as recommend for endorsement, two yeses
8 and three nos.

9 So I will open it up to the
10 Committee for discussion, again very similar
11 to what we just discussed.

12 DR. PROVENZANO: My only comment,
13 similar to the previous measure, is a
14 hospitalized patient, we exert even less
15 control. And I guess I am trying to better
16 understand the purpose of this measure
17 considering the other.

18 Can you ask the developer that
19 question?

20 CO-CHAIR SCHONDER: Can you
21 comment?

22 DR. WOLFE: Yes. The intent here

1 is to get a measure which reflects the total
2 burden of disease for the patient, which does
3 incorporate the length, the duration of the
4 hospitalization, as well as the number of
5 hospitalizations.

6 It also is somewhat of a surrogate
7 for the complexity of the hospitalization. We
8 considered using DRG weights to weight the
9 hospitalization, but we thought that the
10 empirical evidence about how many days in
11 hospital were spent was a more direct measure
12 than whatever DRG complexities are brought in
13 to measure the burden of each hospitalization.

14 I think that we were also swayed
15 by the fact that DRG encoding is based upon
16 the discretion of the way people code the
17 diagnoses as well.

18 The intent of this is primarily
19 for patient information so that they can just
20 understand what is in store for them at
21 different facilities, but it would also be
22 useful, we suspect, for the providers and for

1 other purposes.

2 The real distinction is to get at
3 the total burden of disease, rather than just
4 the number of admissions interpreted on the
5 basis of hospitalization by capturing the
6 duration as well as the number.

7 DR. BERNES: This just strikes me
8 on the surface as being very, very, very far
9 away from being a performance measure and
10 either a research tool or some other
11 educational maybe parameter, but I think adds
12 -- it's really nothing. It's not actionable.
13 It's one of the furthest things away I think
14 from a real performance measure that we've
15 seen in the last two days.

16 DR. FIVUSH: I would say that with
17 the last one, letting go of the comorbidities
18 in pediatrics, I have a hard time looking at
19 our younger patients, some of whom have to
20 remain in the hospital for dialysis because
21 they can't get dialyzed elsewhere.

22 And I don't know what this is

1 going to tell us except make fun of our
2 patients hesitant to go to certain centers
3 where they really could only go to certain
4 centers.

5 And I can tell you we talked a
6 little bit about the patient population under
7 the age of two. And they can only be dialyzed
8 in centers. And so they actually live in
9 hospitals, which is terrible. I am not going
10 to debate how we deliver healthcare.

11 So with this one, I would really
12 want to see some exclusion of pediatric
13 patients. But we really don't understand
14 comorbidities if we're going to really report
15 on hospital days. So I just wanted to know
16 that.

17 CO-CHAIR SCHONDER: Alan?

18 DR. KLIGER: Thanks.

19 Bob, it sounds like a very
20 interesting idea. I wonder if you have done
21 any preliminary testing of this measure.

22 DR. WOLFE: Much less testing. We

1 had much less experience with this. And we
2 have not evaluated its relationship to
3 outcomes. It is different from just the
4 admissions. So there are some facilities that
5 tend to have many short admissions and other
6 facilities that tend to have a few long ones.

7 And to the extent that that is
8 interesting and useful information, it is
9 useful to separate them because they are two
10 different components of the healthcare
11 process.

12 DR. KLIGER: I guess I would, for
13 one, propose that we see some evidence of
14 utility of such a measure before we make it an
15 NQF-endorsed performance measure.

16 DR. NALLY: As a reviewer, let me
17 kind of amplify that. I can understand giving
18 a performance measure and feedback to a
19 dialysis facility about the types, numbers of
20 admissions you have to think about strategies
21 that you might want to devise to attack that
22 problem.

1 Once the patient enters the
2 hospital, particularly if it is not your
3 facility and you're dealing with many, how
4 long they are there may be a function not only
5 of their caregivers but also of availability
6 of nursing home beds and other things in the
7 area. And there are so many variables there
8 that I don't think that would be of help or
9 actionable at the level of the facility in any
10 type of CQI measure.

11 DR. VASSALOTTI: I just want to
12 say that I did vote for this, but I think
13 there are more problems with this. And I
14 think I could change my vote easily based on
15 this discussion.

16 But I just want to say to the
17 physicians in the room it is possible that
18 some of these things are actionable, right?
19 It is possible that duration, it is possible
20 that there is a strong correlation with the
21 catheter and the duration of hospitalization.
22 I mean, it is possible, right? I mean, do we

1 want to at least admit that we should -- you
2 know, I am not saying we should necessarily
3 endorse it, but, I mean, at least we should
4 ask CMS to evaluate this further, go get more
5 data, and perhaps resubmit it.

6 DR. KLIGER: Joe, that is just
7 what I asked for. I think that is right.

8 CO-CHAIR SCHONDER: Lisa?

9 DR. LATTS: Yes. I would agree
10 with all that has been said. I mean, days per
11 1,000 is something that we follow closely from
12 a payer, insurance company payer. But I don't
13 see the value of doing it at the facility
14 level, at least so far.

15 And I think that the admissions
16 measure is a far more valuable measure in
17 terms of what we have been talking about and
18 would use it for. And I would agree that this
19 is not ready for prime time.

20 CO-CHAIR CROOKS: Bob, you mean to
21 tell me that you can't control admissions to
22 a nursing home?

1 DR. WOLFE: Only if we own it.

2 (Laughter.)

3 CO-CHAIR CROOKS: My second
4 comment is even Kaiser Permanente can't
5 guarantee the availability of a nursing home
6 bed when we want it and when we need it. So
7 I would go along with your reasoning here.

8 CO-CHAIR SCHONDER: Any other
9 comments?

10 (No response.)

11 CO-CHAIR SCHONDER: Okay. We will
12 move this one to vote as well.

13 DR. PACE: Okay. Fourteen
14 sixty-four, importance to measure and report?

15 (Pause.)

16 DR. PACE: Are people voting? You
17 can try again if you think you may have jumped
18 the gun. We can't restart it, unfortunately.
19 So vote again if you are unsure. Okay. We'll
20 do a hand vote on this.

21 (Show of hands.)

22 DR. PACE: Oh, okay. Yes.

1 CO-CHAIR SCHONDER: So we had four
2 yeses. Go ahead.

3 CO-CHAIR CROOKS: Four yes and 16
4 no.

5 DR. PACE: Okay. So the
6 technology worked most of the time, right?
7 Right.

8 Let's take a break. And then
9 maybe we'll do public comment. And then we'll
10 have our discussion about performance gaps.
11 And we will talk about related and -- we will
12 discuss the plan for dealing with related and
13 competing measures.

14 (Whereupon, the above-entitled
15 matter went off the record at 2:23 p.m. and
16 resumed at 2:38 p.m.)

17 CO-CHAIR SCHONDER: We'll go ahead
18 and reconvene here. We are going to take the
19 opportunity now for any public comments that
20 we may have, either in person or on the phone
21 and from the measure developers as well. Are
22 there any comments?

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NQF DR./PUBLIC COMMENT

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

1 the same page with what actions were taken.

2 We have to look at related and competing
3 measures.

4 There are some things we need to
5 get back to the measure developers about with
6 responses and the one issue about one oft he
7 conditions and maybe we don't need that
8 condition. But we'll get a formal response.
9 And then you'll be able to act on that again.

10 I think a couple of times there
11 has been some discussion about perhaps some of
12 the recommendations were inconsistent. But
13 once we look at all of those together, we can
14 identify if there are any issues of
15 inconsistency and have you take a look at
16 those and at least justify or give a rationale
17 why, you know, seemingly similar measures, one
18 was recommended and one not, those kinds of
19 things, if those exist.

20 So we'll I think, you know, as was
21 mentioned earlier, say we need to look at the
22 set now that's there and then see if there's

1 anything that we need to get more
2 clarification about and certainly still deal
3 with the related and competing measures.

4 So before we get into this next
5 thing about quality, are there any questions
6 about that or anything that you want to bring
7 to our attention that we need to do or --

8 (No response.)

9 RESEARCH RECOMMENDATIONS/PERFORMANCE

10 MEASURE GAPS

11 DR. PACE: So what we'll do is
12 we're going to have a discussion, then, about
13 gaps in performance measures, research
14 recommendations.

15 What we handed out today was just
16 kind of an addition to the discussion that we
17 started on the conference call. So this is
18 just draft, but, again, it's to have something
19 to start with to see if there are things that
20 you want to strike or add. And it's laid out
21 in -- Lauren, do you want to put it up on the
22 screen? It's laid out in structure, process,

1 outcome, intermediate outcome in terms of, you
2 know, what are the concepts that are related
3 to quality of care or that would signify
4 quality of care and would be reasonable to
5 think about having performance measures.

6 So what we did here is tried to
7 lay these things out that were mentioned on
8 the conference call in this format. We have
9 identified with an asterisk where we have
10 NQF-endorsed measures. The little plus sign
11 is proposed measures that were being looked at
12 in this project.

13 Underneath the table are some of
14 the things that are often discussed and, as we
15 have talked about, that are a little more
16 distal from the desired health outcomes, the
17 assessment things and that nature.

18 So this is just trying to capture
19 the things that were discussed on the phone
20 and then open it up for you to change or
21 certainly to add to in terms of what you think
22 are the concepts and areas that would really

1 be good quality performance measures.

2 CO-CHAIR CROOKS: This says ESRD,
3 but I thought -- are we going to talk more
4 generally about chronic kidney disease, too,
5 in this discussion?

6 DR. PACE: We can because that
7 will certainly lead into our next project. So
8 that's certainly open for discussion as well.

9 CO-CHAIR CROOKS: Good.

10 CO-CHAIR SCHONDER: Alan?

11 DR. KLIGER: Well, there are two
12 major areas that are holes in this portfolio.
13 The first has to do with education, the
14 education of patients, into the nature of
15 disease, the choices available for therapy.

16 And the second major area is
17 patient perception of care. We mentioned that
18 briefly on the telephone, but it's a key area
19 that the rest of the world is indeed looking
20 at, that hospitals are looking at and other
21 care organizations are looking at, that we
22 don't have any measures in this portfolio that

1 I would suggest we need to consider.

2 MS. LeBEAU: Yes. If I could
3 follow up on that? I think, obviously
4 starting with the second first from my
5 perspective, I think about it in terms of the
6 patients' experience of treatment because I
7 think it gets at a compliance issue very well.
8 If you're crashing, cramping, nauseous,
9 throwing up virtually every time you are on
10 treatment, it's really hard to keep going back
11 to treatment. I think if we could look at
12 that and get at it and understand how we
13 impact that, it would be very valuable.

14 The other thing that I think,
15 education absolutely, this concept I'm not
16 sure how we address, but I am pretty sure that
17 when the original benefit was put in place, it
18 was not to create a population of debilitated
19 and disabled patients. So my words for this
20 are "functional wellness."

21 I don't think the KDQOL gets at
22 this. I really don't. I think it's some

1 combination of that and work status. And,
2 again, I think it's a complicated measure.

3 I also just, in reflecting on the
4 last two days, thought a lot about what was
5 talked about at the Boston conference and the
6 conversations and report that I read about Tom
7 Parker and Barry Straube talking about how
8 composite measures are really where we need to
9 go so we can really get a good representation
10 of the things that we're trying to improve.

11 So thank you.

12 CO-CHAIR SCHONDER: Myra?

13 DR. KLEINPETER: So in terms of
14 framing some of the other discussions, I
15 guess, in terms of where we have gaps and what
16 we need to do additional research on and where
17 there may be areas that the developer
18 community needs to work on, looking at
19 transition of care from CKD to ESRD, we have
20 no real I guess coordination of care for the
21 accountable care organizations. And we have
22 no coordination as evidence between the

1 primary care referring physicians to the
2 nephrologists, who are then responsible for
3 all of the care that has gone on in that
4 preceding nine-month period if we're looking
5 at some of the hospitalizations related to
6 these ESRD patients.

7 And in looking at vulnerable
8 populations, prisoners, the rural patients,
9 minorities, including Indian Health Service,
10 blacks and Hispanics, where there are
11 historically high rates of ESRD among these
12 populations of patients, and what health
13 disparities when they do exist, what are we
14 doing to combat them and how are we reducing
15 those disparities when they are identified.

16 CO-CHAIR SCHONDER: Lisa?

17 DR. LATTIS: And to follow up on
18 Myra's comments, I think also transition of
19 care, period, transition of care between
20 settings. You know, we talked today about
21 some of the difficulties in getting
22 information from hospital to dialysis unit and

1 vice versa.

2 And I think in the new world
3 order, we have got to start measuring and
4 improving those processes and making sure that
5 they are appropriate methods and strategies so
6 that coordination between inpatient,
7 outpatient, specialty primary care, et cetera,
8 happen. So there have got to be metrics
9 around those.

10 DR. PACE: I just want to mention
11 in the last project, we did endorse the CAHPS
12 in-center hemodialysis survey. So that is an
13 NQF-endorsed measure, the CAHPS results.

14 CO-CHAIR CROOKS: Alan, does that
15 serve the need, as I know you helped develop
16 that?

17 DR. KLIGER: I did. I was
18 involved in helping develop those measures.
19 And, surely, that is part of it, but my
20 perception is that patients and
21 patient-measured outcomes are what I am
22 talking about. So, you know CAHPS really taps

1 into a limited set of perceptions. CAHPS was
2 not developed by patients. CAHPS was
3 developed by professionals. I think
4 patient-derived measures and patient measures
5 are something we haven't had enough experience
6 with.

7 DR. BERNES: Can I just ask a
8 question about the practicalities at getting
9 at what you suggested, Alan? Having patients
10 provide us with information about "Have you
11 received meaningful education about home
12 dialysis and transplant?" because we can
13 provide that information, but if the patients
14 don't perceive themselves as having -- and I
15 know your group has published on this
16 knowledge gap.

17 Obviously there is an issue of
18 translating that into some kind of a metric
19 that can be used. And it gets to the
20 nutrition. We talked about the dietary salt
21 intake. You know, if there is a way to query
22 the patients, I don't know how that would be

1 done practically, but that is probably an
2 important part of measuring what we do, the
3 process of care that we provide as a dialysis
4 provider.

5 DR. NALLY: I would have a
6 specific question along that line that we
7 might be able to directly impact. A year ago
8 last week, the CMS benefit was put in place
9 for the pre-ESRD education. My question
10 specifically relates to how many people on the
11 patient and provider side have taken advantage
12 of that benefit, completed education? And is
13 there any information of pre and post-testing
14 to reassess a tool that was purposely put in
15 to educate and empower patients in their
16 decision-making process about modalities and
17 all of the important things that were seemed
18 appropriate for that education process?

19 And I think it would be a very
20 helpful learning step to know where we stand
21 a year later into that, what impact, if any,
22 that has had, what are the barriers to

1 implementation. Does CMS need any help with
2 bringing that to the patient front? What are
3 the successes and limitations of that
4 educational effort?

5 And that should be information
6 that should be becoming available.

7 MS. WAGER: If you don't mind if I
8 comment on that, I do education for truth in
9 options for Fresenius Medical Care. And it
10 has made an impact.

11 The barriers we see, nothing
12 against the physicians here, but it's
13 physician referral. Okay? The comment I
14 would like to make is I want to thank the NQF
15 for having this but allowing four patients to
16 be on this Committee.

17 This is the first time that I have
18 been involved with AAKP or the NKF or been a
19 patient for 53 years that I have been on a
20 committee with 4 patients because, as you all
21 know, what you all decide, it affects us.

22 So I thank you so much for

1 everything that -- I mean, for allowing us
2 here but also listening to us and our input.
3 So thank you.

4 MS. PAVLINAC: Along the same
5 lines of the patient education that has been
6 there for a year, there has been a
7 Medicare-approved benefit for nutrition
8 counseling with the GFR of less than 50. And,
9 again, we don't have good data to know how it
10 is utilized, but it is a referral and
11 oftentimes under-utilized.

12 Yes, there is the caveat. And the
13 barrier is that you have to qualify for
14 Medicare Part B. And you can't do that with
15 CKD now. But, still, that is under-utilized
16 from a nutrition perspective, too. And we do
17 know that coming into dialysis, whether you're
18 an adult or a kiddo, nutrition status will
19 make a difference to the outcomes that the
20 units are being held responsible for.

21 DR. VASSALOTTI: I wanted to make
22 a comment to follow up on what Joe said about

1 the KDE, the kidney disease education. I want
2 to thank RPA for working with the National
3 Kidney Foundation to help promote that. And
4 I would like to see data not only on the
5 utilization and the feasibility of it.

6 We get the sense that it is being
7 used mostly in large practices that have a lot
8 of patients, maybe practices that have
9 physician extenders. What does it do? You
10 know, do patients have more -- is there more
11 home dialysis associated with KDE? Do
12 patients start hemodialysis with a fistula
13 more likely when they receive KDE than not and
14 those kinds of things? And it would be
15 interesting to explore possibilities of maybe
16 expanding it.

17 And I think, to follow up on what
18 Roberta said, maybe perhaps there are other
19 ways that highly educated physicians aren't
20 always the best educators. Maybe there are
21 other ways to educate patients.

22 DR. KLIGER: Can I just follow up

1 on that? We actually published and studied,
2 looked at that and looked at objective
3 evidence of understanding or of understanding
4 choices among patients.

5 And our findings were that a
6 remarkably high number of patients who did get
7 education from their physicians did not have
8 a clear understanding of what their choices
9 were or where they were going and that when
10 they went through a more formal education
11 process, that a substantial number increased.
12 That's what Jeff was referring to before.

13 And I do think it's important to
14 examine not only the utilization of the
15 funding for education but some actually
16 outcome measures. That's a process measure
17 but perhaps some real outcome measures that
18 have to do with patient education and choices
19 in the ESRD.

20 CO-CHAIR SCHONDER: Andrew?

21 DR. NARVA: I think we need system
22 change to improve outcomes in CKD. And I

1 really hope that NQF goes ahead and looks at
2 performance measures in CKD but keeps them
3 really simple.

4 Right now the only thing that is
5 out there is basically doing the "microalbumin
6 test" on diabetics. That's it. And just in
7 terms of very simple measures for identifying
8 people with CKD would be a start because when
9 you talk and try to promote systems change,
10 you talk to large groups of community health
11 centers or other organizations which provide
12 primary care to high-risk populations, when
13 there is no market, there is no HEDIS measure.
14 There is no NQF measure. It can be hard.

15 And if there is a measure, people
16 pay attention to that. And a lot of the
17 people who pay attention to that are the
18 non-physicians, who actually drive what
19 happens in the primary care setting.

20 So I think it's very important.
21 But I also hope that you resist what often
22 happens in the renal community, which is to

1 include everything in there all at once and
2 make it so overwhelming that it becomes
3 intimidating and very difficult for your
4 target audience to accept. That's for kidney.

5 CO-CHAIR CROOKS: I am going to
6 give three specific metric names, hoping that
7 this will get into the record and stimulate
8 some thought. One of them I have already
9 created or have been involved in. This is the
10 issue of patients, the outcome of patients,
11 actually getting an optimal start of the ESRD,
12 kind of the end process of getting educated
13 and empowered.

14 An optimal start of the ESRD is a
15 patient who starts either with a preemptive
16 transplant, a home dialysis modality, or if
17 they have to go in center, they have a
18 fistula.

19 A non-optimal start is a patient
20 starts with a catheter. It's a metric that we
21 have developed in Southern California Kaiser
22 Permanente. And we have published on it. And

1 I am going to try to bring it in next round.

2 I am going to look, see if it is feasible to
3 bring it in.

4 Another CKD metric that we should
5 be able to get at is nephrologist referral of
6 appropriate CKD patients. So that can be
7 defined. What is an appropriate CKD patient?
8 Stage 3 diabetic maybe or, you know, we could
9 talk all day but some definition of
10 appropriate patient. Certainly CKD stage 4
11 patients and beyond should all be referred.

12 And this is something that could
13 be applied at the health plan level. We're so
14 used to thinking of sort of dialysis
15 facility-level metrics.

16 And then a third metric related to
17 dialysis, which is where I think the field
18 needs to move to, would be called the percent
19 of or more intensive dialysis for appropriate
20 patients. The denominator would be the number
21 of patients who started on dialysis who want
22 a more intensive therapy. So this way I am

1 saying "more intensive," instead of more
2 frequent or longer. It could be that or any
3 combination thereof.

4 So the denominator is the number
5 of patients who want more intensive dialysis.
6 And the numerator is the number of patients
7 who get more intensive dialysis as a starting
8 metric to push things in the direction that
9 they should probably go.

10 DR. VASSALOTTI: I think those are
11 great. And I read I think Witkowski's paper
12 in the AJKD that looked at the optimal start.
13 I think the catheter start is not included,
14 but a graft is considered an optimal start,
15 right? I just wanted to clarify.

16 CO-CHAIR CROOKS: Yes. In our
17 system, up to five percent of new hemo starts
18 is going to have grafts. More than that is
19 considered excessive and not optimal.

20 DR. VASSALOTTI: And then I want
21 to follow up. I was going to also talk about
22 even though a nephrologist may not always be

1 the best educator, may not be the best to do
2 everything, the nephrologist is key to
3 everything that happens in the transition.

4 So I think that the measure could
5 be -- and this is a KDIQO opinion-based
6 guideline. You know, nephrology referral for
7 a GFR less than 30 might be a place to start.
8 I think that's open to discussion.

9 I think the evidence for that is
10 pretty strong in terms of observation data,
11 showing that patients who start dialysis
12 without seeing a nephrologist or late
13 referral, if you will, a crashing -- I think
14 that's something that could be considered. I
15 am willing to hear what others think about
16 that.

17 CO-CHAIR SCHONDER: Connie?

18 MS. ANDERSON: Actually, one of
19 the things we measure is the metrics of how
20 long the patient has been under the care of a
21 nephrologist and referred from a primary care
22 doc. And we found it correlates very well

1 with well-educated patients. They get
2 referred to the CKD programs. They get their
3 access in early versus those patients that are
4 referred under less than a month or whatever.
5 So I think that's a very important metric.

6 DR. VASSALOTTI: And the reason
7 that the less than 30 is somewhat arbitrary,
8 admittedly, one of the very difficult things
9 about individual patients is you can't always
10 predict the trajectory of their kidney
11 disease. And you can't always predict how
12 quickly they will -- when will they need
13 dialysis. And acute kidney injury can change
14 that.

15 So I think that's why having a
16 specific recommendation might be worth
17 considering.

18 DR. BERNS: Maybe just a word of
19 caution -- and I agree with the principle, but
20 there is increasing recognition that albumin
21 urea alone, even in the absence of reduced
22 GFR, portends the same poor prognosis as a

1 reduced GFR.

2 And I think we also -- we have
3 nephrologists in the audience. I think they
4 have all seen people with CKD, stage 3 with a
5 creatinine of 1.4 or so, 1.6. It's been like
6 that for 15 years. And so there is an adverse
7 effect that we would just need to be cognizant
8 of or the 82-year-old who has a creatinine of
9 1.3. And it's always going to be 1.3.

10 So we just need to be careful as
11 we think about crafting performance measures
12 that it does what we want it to do and that it
13 doesn't do things that we think shouldn't
14 occur as a result.

15 DR. VASSALOTTI: Yes. I think
16 that is a really good point. Obviously I am
17 not implying that that is the only reason to
18 refer. There are all kinds of other reasons.
19 You know, you may have normal GFR with heavy
20 proteinuria. And that might be a perfect
21 reason to see a nephrologist.

22 DR. BERNS: There was a very

1 interesting study that was done at one of the
2 VAs -- I don't remember in which city -- where
3 they actually really modeled. It wasn't an
4 actual experiment, but they modeled what would
5 have happened in their patients had they put
6 in a dialysis access based upon then existing
7 KDOQI recommendations.

8 And, as you can imagine, in people
9 who were in their 20s and 30s, about half of
10 them ended up getting used or something like
11 that. But as you got further and further up
12 in age, there was a tiny fraction of dialysis
13 accesses that would have ever been used. So
14 now you have the potential of subjecting
15 patients to unnecessary surgery if we're not
16 careful.

17 DR. VASSALOTTI: The only thing
18 that I am struck by -- and I will cease and
19 desist after this -- is that if you read the
20 USRDS 2010, over 40 percent of patients had no
21 nephrologic care before they started and
22 before they had a diagnosis of end-stage renal

1 disease. That is an incredible statistic.

2 And that is really a lot of lost opportunity.

3 DR. BERNIS: Ample opportunity for
4 improvement.

5 DR. NARVA: I have enjoyed this
6 interchange, but I think it really represents
7 why we need to get so far beyond early
8 referral. I mean, the kidney community's
9 response to improving outcomes is early
10 referral.

11 Meanwhile, all the nephrologists
12 are overwhelmed. We don't have all that much
13 evidence for a lot of what we do. And the
14 greatest opportunities are earlier, whenever
15 you decide to refer the patients.

16 And I hope that the NQF can
17 stimulate looking at this in a much broader
18 way because congestive heart failure is as
19 lethal as kidney disease, as chronic kidney
20 disease. And the issue in congestive heart
21 failure isn't when you refer the patient to
22 the cardiologist. It's, you know, there are

1 a whole bunch of early interventions and
2 education that occur. And so we need to sort
3 of move it in that direction, I hope.

4 And also this whole issue of
5 self-management, which, you know, is a
6 relatively new concept, needs to be fleshed
7 out and supported by organizations that have
8 the kind of credibility that the NQF has to
9 really make it a legitimate measure of the
10 quality of care.

11 DR. JACKSON: One measure that I
12 would like to see is the percentage of
13 patients who have been seen by a nephrologist
14 for six months who choose hemodialysis and who
15 start their first outpatient dialysis with a
16 fistula.

17 Currently that's a pretty low
18 number. And so I think, even when the
19 referral occurs in a timely manner, in a lot
20 of cases, we, the nephrologists, are not
21 getting them prepared adequately.

22 CO-CHAIR CROOKS: That is the

1 greatest, just to get a little feedback to
2 that, that is the greatest portion of this
3 optimal starts metric of patients who start
4 hemodialysis successfully with a fistula.

5 And nationally you can look at
6 USRDS data. And optimal starts, as I defined
7 it, is about 25-27 percent. In other words,
8 75, 70-75, percent of patients start ETSRD,
9 their first modality is hemodialysis with a
10 catheter.

11 How well have we been able to do
12 in Kaiser Permanente, where we have a lot of
13 control, where no CKD patients, very few CKD
14 patients, go undetected and then referred? We
15 have put a lot of effort into modality
16 education at the right time. We have been
17 able to push it as high as 55 to 60 percent.
18 I am not saying we have reached the upper
19 limit yet. I think we might be able to get as
20 high -- certain areas, subgroups working
21 within our system have reached close to 80
22 percent optimal starts. You're not going to

1 get much above that. But there's going to be
2 20 or 30 percent that you can't -- even if you
3 have identified them, you're not going to be
4 able to get optimal starts for a number of
5 reasons.

6 But that is just to sort of give
7 you -- there is a gap. And a gap can be
8 closed. So it's worthwhile focusing on that.

9 DR. JACKSON: Do you know the
10 ratio of grafts versus fistulas in that
11 population that you're identifying as optimal
12 starts?

13 CO-CHAIR CROOKS: Yes. We have
14 defined up to five percent grafts as
15 acceptable, of new hemo starts. More than
16 that count as non-optimal.

17 DR. FIVUSH: I am going to switch
18 gears for one minute and just say that Rick
19 and I both have very much -- and I didn't say
20 this before because I didn't have a chance,
21 but we both very much appreciated the
22 opportunity to be here and represent the -- I

1 don't know if there have been two
2 pediatricians on any of the ESRD NQF panels
3 because there haven't been pediatric measures.
4 So it's --

5 DR. KASKEL: We represent about a
6 quarter of all pediatric nephrologists.

7 (Laughter.)

8 CO-CHAIR CROOKS: On the East
9 Coast anyway.

10 DR. FIVUSH: It has been a great
11 process that we actually -- I mean, we're
12 years behind, but I think we have really made
13 some progress in getting some pediatric
14 measures, which may get endorsed and
15 ultimately may make pediatricians accountable
16 for the things that we think are important.

17 I would say one area and
18 opportunity that we haven't talked about --
19 and RPA has talked about this, and ASPN has
20 talked about this -- is the transition period,
21 the 18 to -- I mean, just how we -- I'm
22 talking about pediatric to adult transitions

1 that you had mentioned that transition. And
2 Rick has done some work in this as well.

3 And we just expect our kids to
4 become adults automatically sometimes. And
5 they're chronically ill. And I think we may
6 need to look at how we transition those
7 patients because our goal would obviously be
8 to have them totally rehabilitated adults.
9 And I think we have a lot of work to do, but
10 maybe that's an area for measure development.
11 There's been a lot of work that has started in
12 that area.

13 Many of the patients that end up
14 in the internists' hands, as Andy would talk
15 about from his work, really, the roots of
16 their disease is in childhood. So I think we
17 really have to think about that whole
18 progression and spectrum.

19 MS. LeBEAU: Please don't laugh.
20 I am all about patient-reported measures and
21 education. And I am about to ask a question,
22 which is, are there clinical lab values that

1 we are not yet looking at that may have some
2 predictive value?

3 This is obviously an area that I
4 don't know a lot about. I don't know albumin,
5 PTH. Are there things we are missing? Is
6 there something that we haven't put our finger
7 on yet that has a great correlation, just a
8 question? Thank you. Yes.

9 DR. KLIGER: I am listening to all
10 of our discussion. And I am impressed that it
11 is very nephrocentric. I mean, it's centered
12 on what the nephrologists can do on end-stage
13 kidney disease.

14 And one of the things that would
15 be useful for us to remember, I guess, is that
16 the majority of people with kidney disease are
17 not transplanted or have dialysis.

18 And we have learned a lot in the
19 last few years about that. We have learned
20 that those patients have a high incidence of
21 heart disease. And heart disease predisposes
22 to kidney disease and vice versa. And,

1 indeed, we have learned other systems likewise
2 that have feedback loops.

3 I guess I would make a plea for
4 stopping thinking about what we do with so
5 much of our time and taking a step back and
6 again looking at it from the patients'
7 perspective of having multi-system disease, of
8 having some chronic kidney disease and heart
9 failure and diabetes and talk about optimal
10 management, optimal management measurements
11 for people with multi-system disease.

12 DR. NALLY: We have a CKD registry
13 of about 60,000 people right now in our health
14 care system. And, as you start looking at the
15 numbers, you recognize breaking things down
16 into silos is really a day of the past.

17 And I think, as the primary care
18 groups are looking at these ideas of medical
19 homes, of accountable care organizations, it's
20 going to be how different subspecialists, be
21 it cardiologists, nephrologists, interact with
22 that medical home concept or, in essence,

1 educating, empowering, and caring for the
2 whole patient and the appropriate specialists
3 coming up to the trough, whenever appropriate,
4 to help out in that care and that at some
5 point in our case, if the disease progresses
6 and dialysis and transplant are clearly on the
7 horizon assuming more and more of that care.

8 And it's this interaction now -- I
9 think the Annals this month had a whole series
10 of articles on medical homes and perspective,
11 primary care perspective, of the specialist,
12 et cetera.

13 And my prediction is we're going
14 to evolve in that direction. And so how we in
15 our given subspecialty can provide tools to
16 help empower that patient and they are a
17 primary care giver to make this a more
18 efficient and accountable system is going to
19 be the future.

20 So we need to broaden our net, I
21 think, and be, as you say, a lot less
22 nephrocentric.

1 DR. PROVENZANO: My only comment I
2 think goes to what the RPA has worked on for
3 a long time. And now you're hearing more in
4 the media. And that is end-of-life
5 discussions.

6 This is a huge opportunity for us
7 to see to it that patients get the right
8 education. I think many of us know that
9 conservative therapy for CKD stage 3 -- I'm
10 sorry -- late-stage 4 and 5 for an elderly
11 person is absolutely appropriate. It will
12 help with expectations. And I think it checks
13 a lot of the boxes that I think we're
14 obligated to pay more attention to.

15 So I would look for measures
16 focusing on end-of-life education.

17 CO-CHAIR SCHONDER: Are there any
18 other comments related to performance gaps?

19 MS. LeBEAU: A side issue. We
20 were talking about physician education and
21 formal education and the difference it has in
22 what the patient absorbs. And so this is a

1 measure suggestion. It is sort of a how-to
2 suggestion and address the rehabilitation
3 status of a lot of patients.

4 Patient educators are a great
5 opportunity. We, with all due respect to
6 everybody's clinical expertise, get the extra
7 added benefit of we have been there. And so
8 offer an empowerment and a hope and a lot of
9 things that patients coming down the pipeline
10 need to hear to be encouraged and to take that
11 investment and really wrap their hands around
12 taking control of what they can, so just a
13 thought.

14 DR. LATTIS: You know, my only
15 comment is sort of a question, I mean, similar
16 to sort of our initial question on our initial
17 call. Now that we have put out all of these
18 great ideas to NQF, what do you do with them?
19 And how do you make them happen?

20 DR. PACE: Well, as you know, NQF
21 is not a measure developer. What we will do
22 is include these in our report and our, you

1 know, hope is that those that are involved in
2 measure development will look at these
3 suggestions and think of ways that they can
4 move them into measure development and
5 ultimately come back to NQF.

6 But, Helen, I don't know if you
7 want to say anything else about that with some
8 of our other projects?

9 DR. BURSTIN: The other thing that
10 we are able to do is when we do the call for
11 measures for this next round, we will make
12 sure we highlight these specific areas that
13 you have indicated.

14 Again, somebody can't go from that
15 point to submission in just a couple of
16 months, but it may at least stimulate them to
17 think that these are the kinds of measures
18 they want and not just a lot of the same
19 measures.

20 Our fear is we tend to get a lot
21 of look-alike measures that are slightly
22 different. Just change the condition that's

1 still smoking, still blood pressure, et
2 cetera. We really need to, what you're really
3 saying here is, get to a deeper, richer set of
4 measures that can really drive improvement.
5 So hopefully that will help, too.

6 MS. SINGER: I am Dale Singer with
7 the Renal Physicians Association. And, just
8 as a way of foreshadowing based on the
9 conversation, we are working right now with
10 the AMA Physician Consortium for Performance
11 Improvement in preparation for your next call.
12 And many of the topics you have just discussed
13 will be included in some of our proposed
14 measures.

15 DR. PACE: Just a couple of
16 reminders. We will be in touch with you, as
17 you know. We know your e-mail.

18 (Laughter.)

19 DR. PACE: If you would -- yes?

20 DR. VELEZ: Please be sure that we
21 receive them because we are all playing with
22 firewalls and things when there are fires.

1 DR. PACE: Right, right. That's a
2 good point.

3 So, I mean, I'm going to just ask
4 you to, first of all, be sure not to walk off
5 with your voting thing or have those already
6 been collected?

7 If you would leave your thumb
8 drive? We will be glad to send you any of the
9 updated files. And I would like to just take
10 a few minutes to see if you want to give us
11 any suggestions, as Ruben was just saying,
12 that would help our communication, help
13 organize things. We know there are lots and
14 lots of materials. And we really do try to
15 organize things, but if you have some
16 suggestions, we would love to hear them. And
17 Ruben's is to make sure we know that you are
18 getting the stuff because of things getting
19 filtered out by firewalls.

20 DR. BERNES: Increasingly,
21 organizations are using either SharePoint or
22 similar technology, where you won't have to be

1 sending files back.

2 DR. PACE: Exactly. NQF is
3 actually moving to SharePoint. We're going to
4 be doing some pilots next month. And then
5 we'll be rolling it out to the projects
6 because we have identified that, too. It
7 would be much nicer to have a place where
8 everything is, we can update it and avoid the
9 e-mail stuff.

10 Any other comments about prep for
11 the meeting, evaluations, the meeting itself?
12 We're certainly --

13 DR. FIVUSH: I am curious. How
14 long have you been using this device?

15 DR. PACE: This is the second
16 time.

17 DR. FIVUSH: You know, my question
18 is -- yes. The audience response is -- I said
19 to Jerry I wonder what the impact of that is
20 on the way people vote. I don't know how to
21 know the answer to that, but it just occurred
22 to me that, I guess, to be honest, it's a good

1 thing. It's a great thing. I just was
2 curious.

3 DR. PROVENZANO: I think it is a
4 better method of people being comfortable.

5 DR. FIVUSH: I was wondering if
6 you had looked at that. But I agree. I think
7 it's a much better, more honest way.

8 DR. KLIGER: I have another
9 general question. I was impressed in part of
10 our deliberations that the developers of the
11 measures, who had spent a huge amount of time
12 in different kinds of TEPs, had a limited
13 ability to share with us their thinking that
14 underlay their recommendations.

15 I mean, there are some times where
16 it was pretty clear, but there were others
17 where, I mean, for example, Bob was just
18 jumping up and down out of his seat and
19 grabbed me and others after our deliberations
20 to say, "I don't think you understood the
21 depth to which we discussed this or understood
22 this."

1 And we using our best judgment sat
2 here and sort of said, "Well, why don't we try
3 this?" or "Why don't we try that?" You know,
4 and that's what we do.

5 But I just raised the question
6 about thinking about a way to more effectively
7 allow the developers to have an integrated
8 role in discussing the rationale for each of
9 the measures.

10 DR. PACE: We will think about it.
11 We have tried various scenarios, and we go
12 back and forth. But I think it is worthwhile
13 that we need to take a look at that again.

14 DR. BURSTIN: And part of all of
15 this sometimes is that the clinical folks
16 aren't here so that you are asking questions
17 that they may clearly be able to help on the
18 measure development side, but what you really
19 want to do is have somebody from the TEP that
20 you could have asked that to. And that has
21 been a struggle for us on several of these
22 projects, yes.

1 DR. FIVUSH: I agree with Alan. I
2 felt that with many of the measures, the CMS
3 measures, we certainly had part of the
4 measure-developing team. But we often heard
5 "I am just a statistical person." And I
6 really would like to have been able to have a
7 clinical physician or a physician member of
8 the TEP to clarify why, I think, or available
9 by phone. That might have been really helpful
10 with some of the complicated --

11 DR. PACE: Right. And I think,
12 you know, we have certainly time limitations.
13 And so we can't go back from the beginning and
14 have a presentation of each measure. And so
15 we try to balance these things, but I think we
16 always need to be reminded and be sure that
17 when there's a question, that we do consult
18 the measure developers who are here. So I
19 think we will continue to figure out effective
20 ways to do that.

21 CO-CHAIR CROOKS: Here is a simple
22 one. You know, and it may sound silly, but

1 maybe on the application form, you should have
2 a box that says, "Up means good" or "Up means
3 bad." You know what I'm saying? Which
4 direction is a good direction for the metric
5 to move?

6 Sometimes, especially if you're
7 looking at one and you haven't had a lot of
8 time to digest it all, you know, you're still
9 wondering, what are they trying to do here?
10 And which way is the desired movement? Does
11 that sound silly or --

12 DR. PACE: It is actually one of
13 the things on the submission, but it's one of
14 those things that it's not prominent. So we
15 are looking at --

16 CO-CHAIR CROOKS: It should come
17 right after the description of the measure.

18 DR. PACE: Right. We are looking
19 for --

20 CO-CHAIR CROOKS: "Up is good."

21 DR. PACE: -- changing what comes
22 up --

1 CO-CHAIR CROOKS: "Down is good."

2 DR. PACE: -- front first. So,
3 you know, we will add that in as we are moving
4 some things so that that would be at least
5 like the numerator and denominator statement
6 up front after the description and then the
7 details when you get into specifications. But
8 I think we have gotten feedback that that
9 would be easier for people to see that kind of
10 full picture up front before you get into the
11 details.

12 DR. BERNES: Related to that is
13 very explicitly stating the goal of the
14 measure, quantitatively if possible. In other
15 words, what is it that we expect to achieve as
16 a society with this measure?

17 It's a change from where we are
18 now to some specific number. Is it just
19 getting better than we are? Is it 90 percent
20 compliance, 99 percent compliance? And it
21 gets to some of the -- sometimes it was
22 unclear and the gap was unclear.

1 CO-CHAIR CROOKS: Another thing
2 that, Karen, we talked about last night,
3 actually, is the confusion of the term
4 "scientific acceptability." The clinicians
5 and scientists immediately think this is more
6 of why this is a good outcome or the
7 justification of it. This is good science to
8 study this, and that is not what it means.

9 I was suggesting to Karen maybe we
10 rename it or separate it out: measure
11 specification. And maybe that goes up
12 earlier.

13 And then just call it validity and
14 reliability, you know. I think that would
15 really help because some of our people, even
16 late into the first day, are still -- you can
17 tell when they're discussing, thinking of
18 rating science as the medical science and not
19 the statistical science.

20 So that might really help the
21 steering committees, at least, to rename those
22 sections or you could put the second sections

1 called specifications validity and
2 reliability.

3 DR. PACE: Right. Okay. Well,
4 certainly if you have any suggestions, feel
5 free to send them to me and Lauren. So we
6 welcome your suggestions and really have
7 enjoyed working with you and look forward to
8 our continued work on the project.

9 We'll need to set up a conference
10 call. So we will be getting back to you to
11 schedule it very shortly.

12 DR. PROVENZANO: I just want to
13 again comment. I have done a lot of these in
14 different venues. I think, Karen, you and
15 your team should be congratulated. This was
16 very well-orchestrated, planned, communicated.
17 So I want to personally just thank you and
18 your team. It's really great, very enjoyable
19 meeting.

20 (Applause.)

21 DR. NARVA: Peter and Kristine did
22 a good job of moderating.

1 CO-CHAIR SCHONDER: On behalf of
2 Peter, myself, and the NQF staff, we would
3 like to thank all of you for your work on the
4 reviews.

5 Even though we didn't get through
6 all of the agenda items, I think it goes
7 without question we accomplished a lot in
8 these past two days. So we look forward to
9 being in touch with all of you.

10 DR. PACE: And you guys are the
11 group to beat now in terms of preparation, of
12 doing evaluations in advance of the meeting.
13 So we are really appreciative. So thank you.

14 (Whereupon, the above-entitled
15 matter went off the record at 3:23 p.m.)
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A				
AAKP 334:18	263:4 266:18	251:12 274:20,21	293:12	175:10 177:8,20
ability 18:16	273:18 276:5	275:4,21 276:20	actively 89:1	190:7 291:13
119:21 124:15	278:5 285:1	308:16	193:11	296:15 328:16
361:13	311:20 366:4	accommodate 54:6	activities 118:17	356:2
able 10:4 20:3 76:6	acceptable 48:22	accomplish 72:11	activity 147:16	addressed 63:4
82:4 128:8 137:11	349:15	81:16,16 190:7	148:6 177:3	84:18 88:5 140:12
161:22 185:3,17	acceptance 19:18	212:8,9	acts 209:19,20	231:18 267:4
190:14 193:2	72:7	accomplished	actual 15:19 93:18	addresses 140:20
213:21 214:5	accepted 90:9	368:7	102:2 121:17	addressing 84:21
257:6 269:7 324:9	154:13	accomplishment	130:3 182:21	88:5 123:17
333:7 340:5	accepting 155:9	304:8	185:9 255:11	186:13 231:10
348:11,17,19	access 3:22 4:5,8	account 124:20	283:7 345:4	251:11
349:4 357:10	4:12 68:10 119:1	accountability	acute 343:13	adds 256:12 316:11
362:17 363:6	125:10 139:11,14	303:17	acutely 64:5	adequacy 6:8 45:19
above-entitled	139:17,21 140:15	accountable 329:21	add 15:13 33:11	47:9 51:16 54:17
116:11 208:6	140:16 150:4,7	350:15 353:19	55:2 165:3 179:21	58:18,19 60:22,22
322:14 368:14	156:14,16,17	354:18	180:4 190:15	61:6 70:6,7 73:16
absence 266:9	164:4,5 174:6,10	accounts 182:9,13	191:5 201:2 202:7	73:19,21,22 75:9
343:21	176:19 197:3,9	accuracy 136:7,10	204:10 205:2	125:10
absolute 69:6	200:22 201:10	136:12,14 138:15	219:2,3 226:7	adequate 15:16
absolutely 51:12	203:20 204:18	182:7 249:5	229:9 256:17,21	46:3,3 54:12 55:8
66:1 108:15	209:12 211:3	accurate 162:7	275:7,13 276:1	55:12 59:10,20
145:20 147:3	236:4,9,13,16	182:19 248:9	303:21 325:20	74:3,6 75:10
160:22 164:15	238:20 242:8	251:8 259:18	326:21 365:3	88:13
167:3 178:14	244:1 251:2 252:1	261:11	added 288:13	adequately 141:18
242:19 289:19	253:15 254:1,2	accurately 103:12	356:7	347:21
300:11 328:15	265:5 269:1	160:16	adding 44:7 85:1	adhered 51:4
355:11	274:22 275:10	achieve 87:16,17	113:3 155:22	Adjournment 4:22
absorbs 355:22	277:12 286:12	90:22 365:15	229:7 238:16	adjudicate 294:19
abstainer 252:20	291:10 299:5,7	achieving 90:19	256:14	adjudicating
252:21 266:19,20	343:3 345:6	acknowledge 32:2	addition 153:15	202:10
abstention 142:10	accesses 167:18	acknowledged	237:17 275:5	adjustment 283:2
abstract 221:13	345:13	228:20	297:12 325:16	283:14 284:6
abstracting 106:7	accessing 302:10	ACO 169:4 303:9	additional 72:15	286:3 289:22
abstraction 221:16	access-associated	ACOs 299:4 302:6	92:22 121:2	290:3,10,16
221:22	135:5	acquires 159:3	155:22 187:18	291:14 292:12
academic 230:5	access-connected	act 324:9	197:18 223:1	293:21 295:1
accept 75:14 131:3	236:7	acting 280:16	226:8 229:8,10	310:18
339:4	access-related 4:4	actionability	237:8 241:20	adjustments
acceptability 14:1	4:7,11 161:14,15	304:11	244:16 245:6	296:22 313:14,14
26:5 33:4 37:11	162:15 165:12	actionable 71:1	246:3,7 275:14	administered 92:7
81:1 91:16 114:3	171:18 173:13,15	125:8 204:6	276:18 309:17	administrators
142:4 152:12	196:16,19 197:15	286:10,15 295:21	329:16	185:22
194:9 206:7 210:8	201:14 202:16	316:12 319:9,18	Additionally 287:5	admission 158:5
234:20 236:22	204:16,20 209:10	actions 324:1	additions 229:2	160:8 162:22
249:19 252:17	209:11,14 217:11	active 51:16 93:5	address 9:13 43:16	163:22 164:1
	236:3,6 247:18	221:4 232:10	57:3 74:20 77:9	169:20 178:2

180:18 281:16 283:5,8 284:11,14 284:14 288:18 289:9,14,14,15,16 290:18 303:4 admissions 4:15 92:8 202:10 281:7 281:11,14,18 286:13,15 296:19 296:22 303:5 308:12 316:4 318:4,5,20 320:15 320:21 admit 288:18 320:1 admitted 20:16 159:11,16,17,19 168:11 176:10,16 176:17 187:18,19 190:8 191:6 255:8 287:9 288:1 289:3 289:8 290:8 300:8 300:9,17 admittedly 343:8 admitting 307:8 adopt 107:13 adult 8:9 30:19 105:15 109:19 149:10 209:15 236:8 240:13 335:18 350:22 adults 27:8 35:1 36:2 110:5,17 150:3 242:13 243:1,5 351:4,8 advance 368:12 advanced 303:8 310:10 advantage 119:20 333:11 advantages 255:5 adverse 151:12 169:1 271:11 344:6 advertising 242:7 advice 3:6 12:5,13 12:15 15:18 16:5 16:9,18 18:18	19:18 22:8 23:15 49:7 259:22 Advocate 2:7 afraid 41:14 150:11 afternoon 122:21 126:21 age 27:21 34:14 110:14 210:1 282:16 305:5 306:2 313:16 317:7 345:12 agencies 306:19 agency 118:9 agenda 5:10 11:14 116:3 368:6 ages 306:5 ago 39:20 46:11 50:5 67:10 75:11 76:12 289:18 304:1 333:7 agree 16:13 19:21 70:5 99:16 130:16 149:19 164:15 172:11 176:15 181:21 189:9 286:19 289:11 308:22 320:9,18 343:19 361:6 363:1 agreed 183:22 229:9 236:19 284:21 agreement 108:21 236:21 agrees 311:18 ahead 39:16 48:3 89:16 113:8 117:22 139:1 144:3 194:10 209:8 222:10 232:1 238:14 262:16 273:18 274:18 309:21 322:2,17 338:1 ain't 86:19 AJKD 341:12	al 183:14 Alan 1:22 3:8,12 18:13 30:6 40:17 45:5 51:9 53:4 59:7 61:22 62:6 77:4 81:21 86:6 106:18 107:3,8 126:20 127:19 151:7 165:8 172:9 203:5 237:19 303:20 317:17 327:10 331:14 332:9 363:1 Alan's 305:6 albumin 343:20 352:4 algorithm 20:14 algorithmic 204:9 align 181:17 allocate 124:15 allow 207:8 288:16 288:17 302:4 362:7 allowed 138:20 allowing 334:15 335:1 allows 120:2 alluding 289:17 altar 42:12 alternative 288:6 293:14 alternatives 127:6 AMA 358:10 amazing 232:3 ambiguity 276:8 ambiguous 269:21 270:1 ambivalence 252:3 ambulance 188:12 188:19 American 2:6 amount 15:5 39:21 125:7 183:7 186:2 252:3 361:11 Ample 346:3 amplify 318:17 analysis 25:18	92:18 139:12 183:15 283:3 292:8 306:7 analyze 119:21 157:16 Anderson 1:14 3:7 19:20 25:2,5 26:12 81:17 217:9 217:18 227:17 257:5,11,16 342:18 Andrew 2:8 4:6,10 87:19 209:5 229:21 337:20 Andy 250:18 264:10 351:14 anecdotally 68:12 anemia 7:19 9:11 9:12 17:17 74:1 125:11 128:4 ANN 2:13 Annals 354:9 annual 297:9 answer 53:6 135:19 136:3 140:3 224:12 225:13 227:13 242:13 259:1 261:14,21 292:2 312:15 360:21 answered 140:2 antibiotic 3:18 132:11,17,20,21 135:1,6,9,12,12 135:15 138:8 139:10,16 147:18 148:10,18 172:21 190:11 209:18 211:4 239:12 251:19 255:20 256:6,15 264:19 267:16,19 268:2,6 268:11 269:10,16 270:6 271:3 antibiotics 133:2,7 134:3 147:21 149:1,18 150:18	150:21 151:3 166:12 167:20 176:20 209:15 217:13 251:16 255:3,7,12 265:1 266:4,12 268:15 271:2,12 272:19 anticipate 121:1 Antonio 17:19 anybody 8:21 43:5 45:8 57:12 58:13 106:21 182:5 anymore 313:20 anyway 130:14,21 177:6 187:9 219:1 225:14 229:5 230:3 256:21 263:13 350:9 anyways 167:10 188:21 246:8 APIC 214:16,19 215:7 apologies 79:19 apologize 31:18 56:18 60:1 62:1 78:6 202:3 245:2 245:3 appeal 240:20 appears 218:2 applaud 148:3,4 Applause 367:20 apples 241:21,21 241:22 242:1 243:11,11 245:19 245:19 applicable 244:2 249:4 application 364:1 applied 141:1 180:11 313:15 340:13 applies 170:19 apply 107:16 136:21 appreciate 121:6 130:10 131:12 175:13 208:2
--	---	--	---	--

228:5 261:12 286:21 appreciated 349:21 appreciative 368:13 approach 22:21 90:18,21 165:5,8 165:10 213:11 229:7,15 appropriate 22:20 33:18 47:7,19 59:15,16,22 98:5 100:3 106:3 110:14 112:10,20 126:11 136:21 137:4 150:19 151:20 266:11 272:18 291:12 292:14 331:5 333:18 340:6,7,10 340:19 354:2,3 355:11 appropriately 149:17 151:15 267:8 appropriateness 61:9 approval 54:10 230:1 285:5 approve 165:18 166:13 167:8 216:7 223:21 224:5 approved 9:6 122:1 154:14 205:1 279:9 approving 53:17 approximate 290:17 approximately 120:16 arbitrarily 93:13 arbitrary 343:7 Arbor 2:19,23 area 19:6 57:11 82:22 83:8 106:12 154:12 170:4	188:14,18 261:15 261:17 319:7 327:16,18 350:17 351:10,12 352:3 areas 63:3 156:7 306:22 326:22 327:12 329:17 348:20 357:12 arena 84:18 arguably 154:3 argue 53:11 167:7 190:18 304:9,18 argues 108:8 arguing 51:13,14 173:9 188:5 argument 141:5 157:2 167:9 arguments 60:4 155:8 197:10,13 197:16,18 arrow 272:11 article 183:12,13 articles 127:13 129:14 354:10 artificial 169:7 artistic 215:12 ascertain 275:19 ascertaining 265:15 aside 138:15 asked 25:2 82:21 100:13 134:8 140:13 145:13,15 170:12 320:7 362:20 asking 23:5 45:11 56:4,7 101:7,11 182:15 185:13 216:10 225:12 290:22 309:17 362:16 asks 198:9 aspect 153:22 177:22 213:1,6 247:3 aspects 54:14 66:8 106:4 114:21,22	212:10 308:7 ASPN 350:19 assembled 129:13 assess 9:6 259:22 assessed 16:5,6 92:4 99:6 111:5 230:22 assessing 88:15 assessment 3:13 6:17 18:18 64:3 89:22 90:2,6,10 90:16 92:12 93:3 93:14 96:18 97:6 97:8 101:20 102:1 102:12 103:17 104:4 266:14 267:13 326:17 assign 248:20 assigned 82:11 associated 32:13 37:2 38:3,5 79:1 201:10,12 270:5 310:21 336:11 Associates 1:19 2:5 Association 2:6,23 358:7 assumed 13:5 91:10 assuming 166:7 275:22 354:7 assumption 28:12 103:11 assure 59:20 asterisk 326:9 attack 318:21 attacked 133:21 attending 198:14 attention 31:22 61:13 83:8 93:12 94:4,6 172:15 175:21 203:22 325:7 338:16,17 355:14 attest 228:2 attracted 214:2 attractive 31:6 33:16 82:3 241:19	241:20 286:10 attributes 197:8 audience 339:4 344:3 360:18 audit 103:15 auditable 103:12 Australia 46:13 authority 233:17 automatically 351:4 availability 11:21 74:13 233:16 319:5 321:5 available 58:11 79:17 83:17 125:5 217:6 219:6 231:14 252:13 265:2,13 272:5 291:16 293:12 295:11,16 296:19 297:6,10,16 305:1 306:15 327:15 334:6 363:8 avenues 154:10 287:12 average 8:6 19:6 65:3 67:2 126:6 127:2 128:1 143:4 209:14 236:7 251:15 avoid 88:22 360:8 avoidance 7:9 avoided 136:4 aware 64:6 122:8 151:14 234:3 270:9 A-F-T-E-R-N-O-... 209:1 a.m 1:10 5:2 116:12,13	89:10 104:22 110:12 113:18 116:2,9,14 117:3 123:5 130:5,8 131:8,21 160:2,16 167:15 174:21 176:12 186:8,19 190:20 207:21 209:9 213:9 223:18 226:10 250:17 267:18 268:10,17 270:12 279:4 280:21 286:17 311:4 324:5 328:10 353:5 357:5 360:1 362:12 363:13 367:10 backwards 270:18 back-submitted 103:20 bacteremia 4:4,6,7 135:5 191:7,9 209:4,10,11,14 236:3,6,7 238:19 241:9 247:19,22 250:17,19 251:16 252:6 254:18,21 267:18,21 270:16 bacterial 148:1 bad 29:13 45:10 64:22 75:6 80:2 150:10 364:3 balance 363:15 balances 288:19 ball 260:5 banging 146:14 bar 6:7 Barb 223:3 Barbara 1:18 104:20 107:14 245:10 305:3 barely 88:16 Barnes 1:15 3:21 3:23 134:5,8 135:21 145:20 153:10,14 154:17
---	--	---	---	---

158:8,20 161:12 165:13,17 166:3,9 166:17 167:3 168:15 170:14 175:9 178:14,16 178:19 179:5,20 181:21 182:10 188:2 189:22 196:21 198:6 199:15 204:7 205:6 212:20 214:9,12 215:7 248:1,11,16 256:12 257:2,14 258:3	220:20 221:1,17 221:18 228:16 229:2 257:7 bath 35:1 beat 368:11 beauty 285:22 becoming 334:6 bed 321:6 beds 319:6 beginning 59:21 155:18 195:1 363:13 begins 187:3 begun 184:9 behalf 121:6 163:2 261:18 368:1 behavior 23:6 147:19 behaviors 125:12 308:5 belabor 313:19 believe 46:2 63:9 71:15 119:5 121:3 122:14 140:17 146:6 162:10 183:11 220:8 233:19 245:16 248:9 269:20 292:12 304:15 believed 220:12 benchmarking 120:1 benefit 45:3 328:17 333:8,12 335:7 356:7 benefits 13:8 306:17 BERNS 1:17 73:4 73:12 85:7 95:14 96:14 97:10,20 98:9,21 99:13 111:16 112:2,12 112:15 150:16 151:1 160:5 163:13,15 169:16 182:5,14 197:21 198:2 289:11	291:2 300:4 301:4 316:7 332:7 343:18 344:22 346:3 359:20 365:12 best 9:12 16:5,6 57:3 59:19 60:10 60:15 69:6 76:8 94:16 128:11 183:5 190:6 195:8 202:17,18 210:20 226:6 287:1 302:3 336:20 342:1,1 362:1 bet 166:22 beta 103:22 better 9:2,5 19:12 20:1,7 38:14 39:5 40:1,1,10,10 41:17 42:4 44:2,7 45:6,7 46:21 47:13 54:1 63:2 68:12,21 69:17 90:12 117:17 133:16 138:14 150:7 163:5 165:8 171:20 172:7 224:21 240:22 251:7 266:10 293:9 308:20 314:15 361:4,7 365:19 beyond 340:11 346:7 bias 200:21 biases 203:1 big 13:16 14:15 15:7 40:6 51:6 141:5 220:18 237:16 261:10 283:12,13 284:3 302:5 bigger 171:10 221:19 biggest 210:22 billing 219:15 246:8,9,9	bills 217:15 biological 311:2 bio-impedance 92:18 bit 5:14 19:16 42:1 42:22 67:22 88:6 108:17 145:19 147:15 248:21 265:4 290:1 300:18 314:2 317:6 blacks 330:10 blinded 202:12,19 202:22 blood 4:9 35:2 73:22 92:14,19 134:22 155:2 157:5 158:6,12,16 159:10,20 160:19 160:20 161:17 163:1,9 167:19 168:1,3 169:19 170:7 172:16 173:12,15,16 177:12,15,17 178:1,5 187:20 190:9 191:3,10,19 192:19 193:2 197:1 198:10,11 200:6 201:9,13 202:14 209:20 217:12 251:21 255:13 256:6,8 264:12,14 265:1 266:2 267:4,7,10 268:14,21 269:1,4 269:15,17 270:5,7 270:8 271:12 272:18 358:1 bloodstream 3:20 3:22 118:18,21 119:3 135:4,5 138:6 153:10,13 155:17 156:18 157:19,21 159:17 174:5,14,17 176:18 179:14	182:21 184:15,16 196:16,20 203:10 203:13,16 BMI 282:18 290:5 290:11,16 board 5:7 140:18 314:3 Bob 9:9 23:10 102:15 105:1 222:6,15 274:17 279:6 280:5 286:17 289:11,17 298:20 304:3 317:19 320:20 361:17 Bobbi 3:10 18:14 36:9 40:18 Bob's 62:8 body 58:8 68:5 85:11,14,15 258:15 boots 85:18 Boston 57:21 329:5 bother 302:13 bothered 300:21 box 20:10 21:16 23:1 62:15 70:15 94:20 95:6 98:8 101:10,15 102:19 275:20 364:2 boxes 355:13 brainstorming 62:22 branded 17:15 break 115:22 116:2 196:13 207:19 322:8 breakdown 240:15 breaking 353:15 breath 300:18 brief 3:15 11:15 116:5,18 118:2 132:19 briefly 327:18 bright 5:5 bring 130:7 175:21 325:6 340:1,3
---	--	--	---	---

bringing 334:2	227:20 228:20	118:2 120:5 132:9	301:17,19 302:1,3	172:22 173:21
British 183:14	229:8,8,10 241:21	capabilities 246:11	303:6,12 304:16	203:10
broad 213:20	244:16 245:6,7,18	capita 149:11	304:16 306:17	catheter-related
broaden 354:20	246:7 256:13,17	capturable 98:1	326:3,4 327:17,21	171:17 172:3,8
broader 66:1 74:20	256:22 257:15,17	capture 19:13	329:19,20,21	caught 232:2
75:16 251:13	260:16,20 266:7	133:14 141:14	330:1,3,19,19	cause 118:19
346:17	270:22 287:17	144:9,16 151:22	331:7 333:3 334:9	151:12 160:10
broadly 75:7	309:3,4,8,18	176:1 180:7,19	338:12,19 342:20	252:6 255:11
broad-based	315:2,13 316:3	308:19 309:4	342:21 345:21	causes 94:19 299:6
229:15	burdens 219:19	326:18	347:10 353:14,17	299:9
broad-stroke 50:3	BURSTIN 2:12	captured 97:21,22	353:19 354:4,7,11	causing 29:12
50:15	22:15 179:11	144:13 177:5	354:17	254:2
brought 71:17	180:21 230:9	178:1 180:6	careers 76:10	caution 343:19
96:19 125:2 129:2	247:16 302:21	184:18	careful 43:8 65:16	caveat 311:7
315:12	357:9 362:14	captures 40:22	131:6 148:17	335:12
BSI 199:5 204:18	business 216:14	capturing 104:3	344:10 345:16	CDC 10:21 116:21
BSIs 204:19	217:2	138:11 182:20	carefully 33:21	117:5 118:8,8,13
BSN 1:14,15	busy 272:13	184:15 307:2	58:11	121:6,16 122:17
build 154:19 156:5		316:5	caregivers 319:5	134:10 137:10
180:13	C	cardiologist 302:12	caring 301:6 354:1	148:3 179:12
building 229:2	CAHPS 291:9	346:22	carried 102:12	184:9 196:4,5
275:2 276:15	331:11,13,22	cardiologists	case 43:4 52:1 56:9	215:7 231:12,21
built 222:2 226:5	332:1,2	353:21	56:13 139:9	232:4,12 233:7,13
260:19,22 261:1,4	calculate 135:3	cardiomyopathies	161:18 180:11,14	CDC's 11:20
261:5,7,8	calculation 157:13	69:20	213:16 214:15	184:11 234:3
bunch 75:2 160:18	calculator 20:14	cardiomyopathy	248:17,17 293:21	cease 345:18
347:1	calendar 73:6	58:1	309:16 354:5	cell 6:5 7:19
bundled 169:3	160:9 211:6	cardiovascular	cases 193:12	center 1:9 42:18
bundling 54:14	282:19 297:3,5,6	13:4 48:14 57:16	347:20	44:21 74:14
149:2 306:4	297:17	cardiovascular-r...	casting 55:20 171:9	190:12 339:17
burden 119:8	California 339:21	92:9	catch 49:6 171:11	centered 352:11
122:9 135:15	call 9:4 138:9 170:5	care 2:19,21 49:9	171:12	centers 1:15 2:17
143:19 146:3,22	171:3 176:7	53:9 55:13 59:11	category 153:17	2:21 93:5 112:11
151:21 154:21	188:13 211:1	59:16,18 63:3	catheter 71:11	118:7 119:7
155:22 157:4	260:12 270:15	64:4 74:9,18	139:10 164:6	120:19 146:19
162:16,21 163:20	277:20 300:6	81:13,14,18	168:6 200:4,6,9	228:1 317:2,4,8
164:11 165:4,16	302:12,13 325:17	106:20,22 107:5	203:13,15 205:5	338:11
167:8 169:17	326:8 356:17	124:14 140:11,12	210:18,19 236:17	central 119:1,3
170:10 173:2	357:10 358:11	140:15 148:2	295:22 319:21	certain 126:3 217:7
180:6 185:21,21	366:13 367:10	168:19,22 176:11	339:20 341:13	219:6 259:7,10
186:16 187:14,16	called 48:5 340:18	177:1,7 213:6	348:10	291:21 307:22
187:18 188:4,10	367:1	227:4,4 242:14	catheters 71:13	308:2,5,8 317:2,3
197:20 199:18	calling 75:3 189:4	247:6 252:8	139:4 143:1	348:20
215:17 217:19	191:1,2,3	259:22 265:20	148:13 149:22	certainly 35:15
218:10 220:14,18	calls 186:1	271:21 287:3,10	150:9 152:2	55:6,9 60:7 64:13
221:20 222:22	candidate 3:4 4:2	287:15 289:1	156:16 161:5,6	69:13 105:16
223:1,9,15 224:1	12:11 116:17	300:2,14 301:3,11	164:21 165:1	108:15 161:18

176:5 228:6 286:14 303:9 307:21 325:2 326:21 327:7,8 340:10 360:12 363:3,12 367:4 certainty 51:12 cetera 66:8 313:17 313:17 331:7 354:12 358:2 CF 85:13 chair 68:22 76:7 chair-side 51:6 102:17 challenge 159:13 challenges 176:5 challenging 90:17 106:7 chance 123:9,10 131:15,19 218:5 349:20 change 8:6 9:11 93:8,19 95:22 96:5,11,20 97:1,1 98:5,15 102:20,21 131:4 144:8 154:6 176:19 222:3 224:1 225:5,7 241:7 243:9 292:14 319:14 326:20 337:22 338:9 343:13 357:22 365:17 changed 97:13 changes 92:7 105:12 changing 105:18 108:1 128:19 154:9 245:19 287:14 296:7 364:21 characteristics 124:20 characterize 59:5 characterized 60:18 charge 101:18	charged 57:9 62:10 84:13 chart 102:11 charts 99:4 check 10:5 20:10 21:4,4,16 23:1 94:20 98:7 102:20 272:14 checked 80:14,17 95:6 101:10,15 116:8 checking 116:15 138:2 checks 138:1 355:12 chemo 238:22 chewing 209:8 CHF 191:9 286:13 299:8,12 Chicago 206:4 chief 57:17 childhood 351:16 children 34:22 35:4 105:12 107:20 149:13 150:3,10 307:8 Children's 1:20 chime 232:7 choice 293:19 choices 327:15 337:4,8,18 choose 67:6 195:8 347:14 chronic 25:15 37:5 88:8,14 327:4 346:19 353:8 chronically 351:5 chute 50:12 CIC 1:15 cite 15:2 cited 183:12 cities 270:13 city 345:2 CKD 329:19 335:15 337:22 338:2,8 340:4,6,7 340:10 343:2	344:4 348:13,13 353:12 355:9 claim 136:6 236:15 248:20 249:7 claimants 238:5,7 claims 4:8 103:9 109:5 125:5,18,19 220:2 222:5 236:2 236:4,11 238:13 238:17 240:12 241:2,15,16,17 242:3,4,8,9,22 243:18,20 246:17 246:22 248:4,22 293:15 294:4,18 305:13 claims-based 220:8 241:19 247:18,21 249:5 295:18 clarification 111:17 185:15 197:22 227:18 277:9 289:7 291:3 310:1 325:2 clarifications 10:8 clarified 143:10 clarify 82:13 95:5 126:17 144:2 259:14 280:8 312:13 341:15 363:8 clarifying 169:11 classify 254:17 clear 27:9 28:7,14 38:13 41:1,10,14 51:18 60:21 78:8 80:5 103:16 117:9 141:17 171:22 241:22 242:2 252:7 258:7,22 259:2 304:10 337:8 361:16 clearance 41:7 58:19,20 clearly 28:9 44:6 50:7 69:4 70:17 70:21 71:18 135:7	151:11 211:8 272:7 309:15 354:6 362:17 clerical 104:9 Cleveland 2:1 click 275:20 clients 17:19 Clinic 2:1 clinical 50:15 57:9 73:5 82:7 90:9,18 93:4 94:4 154:8 174:13 176:11 177:1 189:11 221:10,14 227:4 270:9 271:9 275:14 277:4 351:22 356:6 362:15 363:7 clinically 4:10 55:8 256:18 274:19,21 275:6 276:18,19 279:5,18 290:18 clinician 186:7 clinicians 31:7 46:1 176:14 286:11 303:22 366:4 clinics 71:8 clock 113:12 close 55:12 76:6 185:17 348:21 closed 349:8 closely 167:1 320:11 closer 75:22 CMS 2:18 10:1,2 11:8 92:3 116:22 121:10,11,15 122:11 132:3 212:2 213:5 214:13 218:12,13 222:7,21 230:11 230:20 231:12 232:12 233:5,11 233:17 237:5 257:22 258:1 259:10,15 260:10 261:17 262:11	277:9 280:16 320:4 333:8 334:1 363:2 Coast 350:9 code 248:20 315:16 coder 248:20 codes 238:12 246:12,12 249:9 293:17 coefficient 283:1 cognizant 344:7 coincidence 68:9 Collaborative 2:19 2:23 colleagues 262:10 304:12 collect 120:17 139:8,11 160:15 163:3 180:12 182:18 224:4 225:13 244:5,12 245:15 246:14 collected 20:10 21:14 63:11,17 103:10 119:14 120:8 135:18 144:5 166:20 182:1,8 223:22 229:5 231:5,6 256:21 258:10,17 258:18 259:11,22 260:4 359:6 collecting 146:4 160:11 183:3 187:6,10 219:1 233:18 245:13 collection 120:4,10 121:20 122:9,11 137:11 141:13 143:12,16 146:17 147:2 175:1 178:11,12 190:16 215:17 220:10 221:19 224:10 227:1 232:19 259:15 collects 142:18
--	--	--	--	--

Colorado 155:14 166:5 167:2 184:4 185:2,20 192:18 233:21	110:12 123:12 125:21 130:4 151:17 156:15 158:21 207:8,13 210:16 211:3 212:1 226:21 233:2,5 271:6 291:17 309:21 314:12,21 321:4 322:9 323:1,11 334:8,13 335:22 355:1 356:15 367:13	212:19 219:17 220:8 234:9 239:18 260:9 276:22 279:13 282:10 303:1 314:10 323:3 334:16,20	comparison 231:10 233:4 242:1 256:11	complicate 44:18 complicated 204:8 329:2 363:10
Colorado's 166:21	commented 285:8	committees 366:21	comparisons 262:7	complications 118:22
column 6:1	comments 5:8 8:18 8:22 9:17,22 16:21 23:9,20 26:13 27:4 29:16 34:2 38:2 61:7 62:2 72:9 81:9,20 82:9,13 89:5 106:17 132:3 137:14 143:20 145:14 151:7 196:12 204:21 207:9 212:15 215:10 220:22 223:5 234:9 237:11 239:18 249:12 252:2 253:1 256:3 262:13 273:4 276:21 277:18 285:6,7 298:10 305:7,8 307:13 311:10 321:9 322:19,22 323:7,8 330:18 355:18 360:10	Committee's 129:15 226:13	compelled 151:10	component 153:22 154:3
comb 99:3	common 162:21 199:8,9 299:6	commonly 143:13	compelling 214:3	components 318:10
combat 330:14	communication 187:22 232:21 359:12	communicated 190:12 367:16	competing 231:2 322:13 323:20 324:2 325:3	composite 329:8
combination 329:1 341:3	community 55:3 93:7 146:11 159:4 167:5 176:2 180:20 246:22 286:2 298:15 329:18 338:10,22	community's 346:8	complemented 92:16	comprehensive 102:18 151:20 170:21 218:4
combined 134:13 134:20	community's 346:8	comorbidities 124:21 290:12 305:12,14,20 306:1,5 316:17 317:14	complete 12:19 37:12 91:3 142:5 142:8 194:13 216:6 242:13 246:10 252:19,20 266:21 284:20 314:3,4,6	comprised 110:16
come 17:14 56:22 78:5 105:3 108:20 109:4 116:2 117:3 126:4 131:7 139:7 142:21 164:3 167:14 168:6 190:10 207:21 209:9 226:10 269:13 357:5 364:16	comorbidity 282:19 290:6,16 293:13 295:1,10	comorbidity 282:19 290:6,16 293:13 295:1,10	completed 12:20 14:10 21:1 36:20 91:4 333:12	compute 283:2
comes 45:3 53:2 78:2 87:5 136:1 141:2 175:4 176:12 186:8,19 190:20 191:16 245:13 267:7 268:10 364:21	companies 246:9	comorbidities 124:21 290:12 305:12,14,20 306:1,5 316:17 317:14	completely 14:2,4,6 26:5,7,9 33:7 37:13,17,20 81:2 81:3,5 91:17,19 91:21 114:9,13 115:8,13 125:17 148:8,11,13,15 152:16,20 162:7 177:2 181:21 194:19 195:15 206:11,17 230:4 235:4 250:9 263:8 263:13 264:4 273:22 274:5,10 285:2,3,3 290:11 312:1,5,9	computer 101:9 134:4 146:14 186:21
comfort 230:16	comorbidity 282:19 290:6,16 293:13 295:1,10	comorbidity 282:19 290:6,16 293:13 295:1,10	concentrated 12:20 14:10 21:1 36:20 91:4 333:12	concentrates 41:12
comfortable 230:13 361:4	comorbidities 124:21 290:12 305:12,14,20 306:1,5 316:17 317:14	comorbidities 124:21 290:12 305:12,14,20 306:1,5 316:17 317:14	concentrated 12:20 14:10 21:1 36:20 91:4 333:12	concentration 30:11 31:1
coming 19:8 44:20 72:2 73:9 105:6 117:12 133:5 145:2 282:13 335:17 354:3 356:9	commercial 244:2	comorbidity 282:19 290:6,16 293:13 295:1,10	concentrated 12:20 14:10 21:1 36:20 91:4 333:12	concentrations 31:12
commend 164:18	committee 1:4,9 13:2,2 37:9 62:9 110:16 122:13,20 123:17 125:2 126:17 127:1 131:21 145:14 202:12 208:1	comorbidity 282:19 290:6,16 293:13 295:1,10	concentrated 12:20 14:10 21:1 36:20 91:4 333:12	concept 72:10 105:16 107:21 292:22 303:16 309:1 328:15 347:6 353:22
commensurate 85:10	comment 4:18 22:7 22:16 23:3 39:10 39:15,18 47:6 53:2 63:8 65:21 66:14 80:11 81:11 83:22 86:8 107:15	comorbidity 282:19 290:6,16 293:13 295:1,10	concentrated 12:20 14:10 21:1 36:20 91:4 333:12	conception 40:2
comment 4:18 22:7 22:16 23:3 39:10 39:15,18 47:6 53:2 63:8 65:21 66:14 80:11 81:11 83:22 86:8 107:15	comment 4:18 22:7 22:16 23:3 39:10 39:15,18 47:6 53:2 63:8 65:21 66:14 80:11 81:11 83:22 86:8 107:15	comorbidity 282:19 290:6,16 293:13 295:1,10	concentrated 12:20 14:10 21:1 36:20 91:4 333:12	concepts 50:4 71:16 326:2,22
		comorbidity 282:19 290:6,16 293:13 295:1,10	concentrated 12:20 14:10 21:1 36:20 91:4 333:12	conceptually 40:5
		comorbidity 282:19 290:6,16 293:13 295:1,10	concentrated 12:20 14:10 21:1 36:20 91:4 333:12	concern 8:19 40:20 50:2 69:15 72:9 81:13,17 107:20 135:20 150:16 154:12 156:7,13 156:19 203:3 210:22 228:20 240:11 261:6 266:6 289:21
		comorbidity 282:19 290:6,16 293:13 295:1,10	concentrated 12:20 14:10 21:1 36:20 91:4 333:12	concerned 70:3 131:11 149:3,6,10 149:16,18,20 172:14 177:9,10 213:7
		comorbidity 282:19 290:6,16 293:13 295:1,10	concentrated 12:20 14:10 21:1 36:20 91:4 333:12	concerns 8:18 32:7 107:22 125:14,15

177:19 200:17 252:5 265:11 304:12 concert 280:16 concise 164:18 condition 8:4,5 111:10 113:3 130:21 228:7 324:8 357:22 conditions 7:18,19 10:14 111:15 124:21 137:1 222:18 224:14,22 226:9 228:12 258:10 324:7 conducted 32:19 conference 57:21 325:17 326:8 329:5 367:9 configurations 231:8 confirm 166:17 179:12 182:17 190:1 225:19 275:8 confirmation 170:7 275:15 277:5 279:5 confirmed 4:10 256:18 274:19,21 275:6 276:19 279:19 conflicted 71:6 confounded 79:15 86:18 confounding 86:13 confused 100:5,6 223:18 253:6 272:3 confusing 133:13 141:10 confusion 160:10 272:1 366:3 congestive 57:13 58:1 87:10 187:19 191:6 308:15 346:18,20	congratulated 367:15 conjecture 28:17 connect 256:13 connecting 232:12 Connie 3:7 25:1 217:8 227:16 342:17 consecutive 211:6 consensus 23:19 45:15 106:18 consequence 70:11 96:22 163:4 consequences 15:20,20 26:22 28:22 29:14 31:5 57:15 75:14 78:19 87:4,12 90:20 105:21 148:19 149:17 150:17 151:13 conservative 355:9 consider 16:4 18:9 26:20 51:2 63:15 66:10 129:8 141:19 146:22 159:4 175:7 199:12 213:3 219:17 230:6 253:8 291:4 292:15 306:7 307:19 328:1 consideration 3:4 4:2 12:11 82:14 116:16 118:2 121:8 122:12 130:18 132:8 226:14 305:19 306:9 323:4 considered 127:5,6 137:18 180:16,18 197:19 221:5 268:2 315:8 341:14,19 342:14 considering 122:21 157:4 288:6 304:20 314:17	343:17 consistency 181:10 consistent 251:22 consistently 128:15 Consortium 358:10 CONSTANCE 1:14 constant 105:18 constantly 105:10 constitutes 121:21 constraint 243:14 construct 151:19 231:7 240:2 constructed 18:22 consult 363:17 contaminant 199:13 contaminants 157:5 199:7,8,10 content 214:14,18 215:4 context 9:5 75:16 129:4 137:7,8 293:10 303:19 continual 125:3 continually 253:4 continue 61:12 224:10 235:22 264:11 273:16 302:9 363:19 continued 4:2,4 128:14 176:21 367:8 continuing 146:8 continuous 68:5 156:20 continuum 168:18 contra 145:18 contracts 247:2 contrarian 83:4 contribute 218:18 contributed 215:3 control 2:22 58:14 59:10 61:2 73:21 118:7 129:2 287:6 287:12 289:13,19 296:14 299:20	300:19 308:15 314:15 320:21 348:13 356:12 controlled 44:5 controversial 49:10 49:12 Cont'd 4:1 conversation 34:17 41:21 69:11 95:2 126:20 303:3,5 306:3 358:9 conversations 95:1 232:11 329:6 convert 157:11 180:1 convinced 65:3 convincing 39:3 61:11 212:4 coordination 271:8 329:20,22 331:6 copies 93:9 corner 69:7 70:16 correct 52:2 94:13 145:9,10 191:8 225:2 227:9 268:19 288:5 309:7 correctly 86:4 289:8 correlates 342:22 correlation 31:18 46:12 78:8 319:20 352:7 correlations 46:20 46:21 corresponds 13:5 cost 124:14 Counsel 2:13 counseling 14:17 22:9,22 335:8 count 144:17 170:17,18 177:12 268:8 269:18 349:16 counted 164:7 211:7 counteract 65:13	counting 133:2 164:10 272:5 countries 46:12 country 127:8 146:8 214:17 counts 158:17 couple 41:19 46:11 106:17 142:17 153:15 174:3 223:5 281:22 283:11 324:10 357:15 358:15 couple-year 294:13 course 17:3 22:18 77:13 85:16 94:10 101:10 144:9,11 180:15 252:12 255:7 268:15 cover 250:22 coverage 222:19 224:14,22 242:12 247:11 257:22 258:10 259:11 covered 293:5 covers 251:13 Co-Chair 1:13,14 8:16 9:8,16,18,21 12:2,9 16:12,20 18:12,20 20:8 21:2,8,12 23:2,16 24:3,14,17,20,22 27:4,17 28:11 29:9,15,18 30:1,4 34:1,4,9 36:4 39:13 40:16 42:15 43:10,13 48:4 51:9 52:11,19 62:16 63:18 71:3 76:5,19,22 81:20 82:9 83:3 84:4,10 85:5 86:6 87:14 89:4,7,17,20 93:21 95:10,13 96:15 97:5,9 99:18 100:2,15 102:14 104:12 106:13,16 107:3,7
--	--	---	--	---

108:4,8,16,20	235:8,13,19,21	crashing 328:8	97:5,9 99:18	258:20 263:8,11
109:11 110:11,22	237:10,12,19	342:13	100:2,15 102:14	263:15,19,22
111:6 112:5,22	239:17 242:5	create 119:22	104:12 106:13,16	264:4,9 269:12
113:9 114:8,12,16	244:5,8,13,20	164:11 165:3	107:3,7 108:4,8	270:2 272:2
115:1,4,7,12,17	245:7,10 246:18	168:13 244:15	108:16,20 110:11	273:14,22 274:5
115:21 116:14	249:11,16 250:1,5	245:5 328:18	110:22 111:6	274:10,15 277:1
117:8,11,21 121:9	250:9,14,16 253:1	created 271:11	112:22 114:12,16	278:2,9,14,17
122:22 123:4,8,20	256:19 257:9,12	289:16 339:9	115:1,4,21 116:14	279:1 280:12
129:22 131:12	257:20 258:4,20	creates 94:21	117:8,11,21 121:9	298:10 300:22
132:7,18 134:2,7	262:12,15 263:1,8	272:16	122:22 123:4,8,20	301:5 311:17,22
134:15,17 135:19	263:11,15,19,22	creating 53:20	129:22 131:12	312:4,8,16 320:20
135:22 138:17	264:4,9,10 267:1	165:2	132:7,18 134:2,7	321:3 322:3 327:2
139:1,18 142:15	269:12 270:2	creatinine 344:5,8	134:15,17 135:19	327:9 331:14
143:21 144:3	272:2,9 273:3,6	credibility 347:8	135:22 138:17	339:5 341:16
145:4,10 147:11	273:14,22 274:5	criteria 6:19 7:5	139:1,18 142:15	347:22 349:13
150:15 151:6	274:10,15,16	24:16 30:3 34:11	143:21 144:3	350:8 363:21
152:3,9,15,19	276:21 277:1,3,17	50:13 51:3 76:21	145:4,10 147:11	364:16,20 365:1
153:1,6,8 158:2	277:20 278:2,9,14	89:19 142:3	150:15 151:6	366:1
159:21 161:9	278:17 279:1,3	193:22 195:4	152:3 153:8 158:2	cross-check 237:13
162:19 163:17	280:7,12,13 281:3	230:15 288:16	159:21 161:9	cross-referencing
164:13 165:7,11	286:17 298:10	289:2 310:20	162:19 163:17	204:2
165:15 172:9	300:22 301:5	criterion 7:12 8:12	164:13 165:7,11	CROWNWeb
173:1 174:19	302:20 303:20	114:22 127:2	165:15 172:9	20:11 21:6,8,13
175:19 178:9,15	305:3 306:10	288:17	173:1 174:19	21:14 63:12 98:1
178:18 179:1,7,18	311:9,12,17,22	critical 13:17 20:4	175:19 178:9,15	98:17 99:8 100:8
185:12 186:6,15	312:4,8,16,20	105:9,18 151:19	178:18 179:1,7,18	100:10,19 103:2,5
186:18 188:8	314:20 317:17	critically 47:5	185:12 186:6,15	103:7,20 104:6,10
190:4,17 192:9,21	320:8,20 321:3,8	63:22 65:12	186:18 188:8	109:3 143:16
193:15,18 194:6	321:11 322:1,3,17	285:13,17	190:4,17 192:9,21	154:18 156:6
194:13,18 195:14	323:6,16 327:2,9	Crooks 1:10,13 3:2	193:15,18 195:22	157:8 181:17
195:20,22 196:6	327:10 329:12	3:19 8:16 9:8,16	196:6,10,14 198:1	215:18,20 216:3,4
196:10,14 198:1	330:16 331:14	9:18,21 12:2,9	200:20 202:8	216:7,8,15,20,22
200:20 202:8	337:20 339:5	16:12,20 18:12,20	203:4,14 204:21	218:16,19 219:12
203:4,14 204:21	341:16 342:17	20:8 21:2,8,12	205:12,22 207:7	219:13 220:5,10
205:12,20,22	347:22 349:13	23:2,16 24:3,17	207:17 213:8	220:19 221:15,18
206:1,10,16,21	350:8 355:17	24:22 27:4,17	214:20 215:5,9,11	222:2,12,13
207:5,7,17 209:3	363:21 364:16,20	28:11 29:9,15,18	217:20 218:20	223:20 225:1,4,5
212:15,18 213:8	365:1 366:1 368:1	30:4 34:1,4 36:4	219:20 220:11	225:7,20 226:4,9
214:20 215:5,9,10	Co-Chairs 1:10	39:13 40:16 42:15	222:8 224:13	227:19 228:1
215:11 217:8,17	CPM 50:16 104:15	43:10,13 48:4	225:11,16 229:3	231:15 232:13
217:20 218:20	106:6	51:9 52:11,19	231:21 232:2	233:18 238:4,6,14
219:20 220:11	CPT 246:12	62:16 63:18 71:3	234:17 235:3,8,13	239:13 240:20
222:8,9 223:3	CQI 296:17,20	76:5,22 81:20	235:19 237:12	245:12,16,20,21
224:13 225:11,16	319:10	82:9 83:3 84:4,10	244:5,8,20 245:7	246:1,3,5 247:13
227:16 229:3,21	crafting 344:11	85:5 86:6 87:14	249:16 250:1,5,9	247:15 257:3
231:21 232:2	cramping 74:2	89:4,7,20 93:21	250:14 256:19	258:8,9 259:5,16
234:8,11,17 235:3	75:4 328:8	95:10,13 96:15	257:9,12,20 258:4	259:20,20 260:11

261:16 262:1 275:18 282:14 294:6,14,18 295:15,17 309:14 CROWNWeb-ba... 239:4,7 crucial 59:16 crystal 260:5 CSR 2:2 CTEP 35:21 102:6 102:7 215:2 culture 4:9 134:22 159:10,20 160:20 160:21 161:17 163:1 178:5 190:9 190:20 191:3,20 192:19 193:3 198:10,11 199:11 200:6 201:13 202:14 209:21 217:12 251:22 255:13 256:7,15 264:12,14 265:2 266:3 267:4,7,10 268:14,21 269:2,4 269:15,17 270:7,8 272:14 cultures 155:2 156:11 158:6,12 158:16 163:9 167:20 168:1,3 169:20 170:8 171:6 173:12,15 173:17 177:12,15 177:18 178:1 187:20 191:10 197:1 201:9 256:8 270:5,19 271:1,13 272:4,6,18,19,22 culture-positive 251:5 curious 360:13 361:2 current 63:4 73:14 93:10 97:3 134:13 179:14 310:5 currently 16:10	63:11 65:5 119:13 120:16 122:5 155:14 165:21 166:20 167:11 168:16 180:22 217:14 218:18 220:3 222:2,13 261:7 282:7,15 294:3 295:11 347:17 cutoff 32:18 39:4 79:9 80:4 cycle 131:10 310:6 310:10 C-O-N-T-E-N-T-S 3:1 4:1 <hr/> D <hr/> daily 176:7 Dale 2:23 358:6 Dallas 2:5 danger 53:16 data 12:21 14:22 15:7,16,18 19:13 21:7,15,17,21 22:4,11,12 26:18 29:7 31:8 32:10 36:20 38:7 44:5 44:20 45:4,6,19 46:10,17 47:18 58:2,5 61:17 63:10,16 64:12,13 65:1,2 79:8,11,17 86:8,10 90:8 91:7 91:8 93:18 94:2 95:8 98:17,22 99:21 100:6 101:7 103:10,11,19 104:3,14 106:6,7 107:1,12 111:4 118:15 119:22 120:1,4 121:19 122:8,10 124:22 125:4 126:1,2 134:19 135:3 136:22 137:11,13 137:22 138:1,2,3	138:11,16 140:17 140:21 141:7,8,9 141:13,14 142:19 143:11,16 145:22 146:3,4,10,10,17 147:2 154:21 155:22 156:4 157:4,6,16 158:7 158:19 160:11,15 162:16,21 163:3 167:8 173:2 175:1 175:16 178:11,12 180:7 182:8,18,19 183:3 184:6,13,19 185:4,6,8,10 187:6,10,22 188:4 188:10 190:15 191:16 192:16 193:6 197:12,20 198:8,16 199:18 202:14 215:17 216:2,5,6,8,15,16 217:2,5 218:21 219:5,10,11,13,15 219:19 220:10,19 221:5,8,19 222:5 222:12,15,21 223:21 224:1,9 226:2,4,15,20 227:1,2,6,21 228:3 229:4 231:5 231:5,8,14 232:13 232:18 233:16,18 237:15 238:1 239:6,16 240:2,5 240:12 241:2,6,20 243:3,15 246:17 247:12,14 248:3 248:22 249:1 252:16 256:9,20 257:8,15,17,17 258:2,5,13 259:6 259:8,10,15,21 262:5 265:17 267:11 271:9 275:7,14,17 286:11 287:4	295:15,17,19 296:20 298:1 302:2 309:8 313:18 320:5 335:9 336:4 342:10 348:6 database 145:22 155:13 160:2 181:22 197:12 254:17 databases 185:7 date 21:2 22:4,13 175:4 220:20 276:17 dates 171:4 DAVENPORT 2:13 DaVita 2:3 day 3:2 5:3 19:7 123:14 144:18 158:17 160:7,8,10 169:20 170:6 175:11 186:22 191:20,20 192:6 200:14 340:9 353:16 366:16 days 4:16 16:15 132:22 133:8,12 142:20,22 143:7 144:6,18,20 156:12,22 157:12 169:19,22 180:3 180:17 209:17,22 251:17 285:12 290:2 312:19,22 313:4,6,8 315:10 316:15 317:15 320:10 329:4 368:8 day's 126:5 DCI 103:21 deactivate 226:12 226:15 deal 62:17 122:10 261:10 270:13,14 272:1 325:2 dealing 319:3	322:12 dealt 258:8 death 50:8 151:12 debacle 50:18 debate 57:13 317:10 debates 54:18 58:13 debilitated 328:18 decade 50:5 decide 5:9 267:9 334:21 346:15 decided 233:6 deciding 229:14 233:9 258:18 decision 131:2 173:4 198:4,17 218:12 226:13 258:15 287:8 289:19 decision-making 333:16 decrease 15:5 299:8,15 decreased 180:7 decreasing 164:22 310:15 dedicated 146:19 deeper 358:3 deficits 247:5 define 44:4 68:11 defined 27:18,20 219:13 340:7 348:6 349:14 defining 61:6 definite 307:20 definitely 35:20 195:6 226:14 302:22 definition 30:14 101:1 158:15 180:11,14 204:9 340:9 definitions 121:17 definitive 292:13 delay 75:17 deliberated 58:11
--	---	--	--	--

267:15	depth 361:21	329:17 356:21	30:11,16 31:12	254:21 255:6
deliberation 127:7	describe 88:16	developers 9:15	dialysis 2:7 3:9,10	257:10,13 266:1
127:18	described 30:9	10:15 11:16 20:6	8:10 13:12,18,19	267:7 268:3,6,10
deliberations 36:1	38:10,10 212:11	31:10 32:11 34:20	17:3,9 20:18	270:8 283:20
126:16 127:14	253:10 265:3	64:2 78:21 79:2	25:14 35:1 36:7,8	288:21 290:3
129:5,15 131:7	describes 183:15	96:16 100:4	36:10,12,15,16	295:4 299:11,16
361:10,19	description 36:14	110:13 116:6,18	37:4 38:3,4,6,11	300:14,16 301:12
deliver 317:10	132:19 269:22	116:22 145:12	38:12,14,16,17,18	302:14 303:3
delivered 52:16	313:2 364:17	207:9 226:4 228:5	39:1,9 40:8,11,12	307:22 308:2,9,11
delivery 28:20	365:6	228:13 237:21	41:1,14 44:20	309:18 313:4
delta 309:13	design 251:9	265:22 276:1	46:13 47:10 49:4	316:20 318:19
demand 48:18	designated 282:9	310:14 322:21	51:17 53:3,4,22	330:22 332:12
demanding 48:19	designed 16:7	324:5 361:10	54:5,13,17 55:3	333:3 335:17
48:19,20	90:22	362:7 363:18	57:18 58:15 59:20	336:11 339:16
demonstrated	desire 106:11	Developer(s) 3:15	63:11 64:4,11,16	340:14,17,19,21
81:18 120:13	desired 326:16	118:3	65:19,19 66:7	341:5,7 342:11
demonstrating	364:10	developing 59:16	67:2,11 68:12	343:13 345:6,12
121:5	desist 345:19	210:18 216:14	69:12 70:13,14	347:15 352:17
demonstration	despite 87:6 94:1	240:3	73:8,16,16,19	354:6
92:22	95:3 144:22 287:1	development 63:1	74:2,3,14,15 75:3	dialyze 65:4 69:14
denominator 25:11	298:17	101:4 125:3	75:10 77:10 79:13	dialyzed 17:7 39:20
25:13 27:11 28:10	detail 112:8 275:13	141:21 228:6	79:14 85:17 87:6	39:21 49:7 65:5
30:17 35:19 37:4	detailed 162:4	261:15 351:10	88:8,13 90:7	105:3 246:21
38:9,10 77:19	details 198:19	357:2,4 362:18	91:11 94:12 99:3	316:21 317:7
95:19 109:22	267:5 365:7,11	device 360:14	100:11,21 104:2	dictate 198:12
112:8,9 133:4,8	determination	devices 92:19	112:6 118:22	201:7
139:13 144:6,7,15	198:3,13,22	devise 318:21	119:10 120:17,19	dictated 17:6
145:6 146:2 157:2	204:15 266:8	devoted 60:10	125:10 133:1	Diet 21:16
172:5 173:21	determine 147:20	76:10	134:13 143:13	dietary 3:5 12:5,13
180:2 197:3	162:14 195:7	DFRs 310:5	146:19 147:17	12:15 13:7,14
209:21 210:16	198:21 202:15,21	diabetes 2:9 67:2	148:9,18,22	15:4,18 16:5
238:10 251:18	255:21 261:3	282:17 313:16	155:16 158:10	21:22 22:8 332:20
264:18 267:17	determined 204:19	353:9	159:7,14 160:12	dietician 15:19
281:20 282:6	determining	diabetic 67:9	160:13,14,17	22:10 99:2
290:1 294:3 313:8	163:21 252:6	160:21 200:11	161:1 163:2,20	dieticians 17:20
340:20 341:4	detrimental 148:2	340:8	164:11,20 166:9	18:17 19:19
365:5	develop 19:15	diabetics 338:6	168:7 169:3,19	differ 267:22
Department	57:10 63:2 233:6	diagnosed 159:10	170:1,5,12 171:20	difference 17:13
118:10	305:14 331:15,18	176:17	181:1 184:13,19	40:6 42:20 45:1
dependence 38:5	developed 126:12	diagnoses 315:17	184:20 185:5,7	46:8 73:1 121:19
dependent 13:12	271:8 304:19	diagnosis 159:19	188:7 190:12	139:3 140:22
depending 11:20	332:2,3 339:21	293:17 345:22	192:17 193:4,14	174:6 181:9
85:20 170:22	developer 19:2	diagram 237:6	209:16,22 212:11	231:11 239:6,15
188:18 225:5,8	130:15 131:22	diagrams 212:12	216:3 217:9,15	257:6 335:19
271:17	216:11 238:14	213:15 214:10	220:14,18 221:2	355:21
depends 44:3	286:4,5 287:20	dial 286:12	223:8,14 229:17	differences 140:1,6
200:14	291:1 314:18	dialysate 3:8 30:5,6	239:14 249:6,7	219:18 231:13

283:16,18 292:4	104:18 294:10	311:8 329:14	212:2 213:12	34:12,18,19 35:11
different 34:22	disabled 328:19	355:5	documentation	35:13,14,17,18,20
35:1,3 39:8 50:14	disadvantage	disease 1:3 2:21	20:12 22:8 95:19	37:13,17,20 40:18
51:7 88:20 100:14	128:18 307:22	13:4 64:7 88:9,14	98:19 100:19	43:7,11,14,19,20
121:21 122:3	308:8	118:7 120:20	101:12 102:10	43:22 44:1,3,11
139:7 146:21	disadvantaged	315:2 316:3 327:4	103:2 266:7	44:13,17 45:9,18
148:8,11,14,14,16	306:13	327:15 336:1	documented 198:4	46:9,18 48:1,3,6
161:4 179:22,22	disagree 43:5	343:11 346:1,19	217:12	50:2 51:10 52:18
191:15 201:6	disagreement	346:20 351:16	documents 212:12	54:11 55:1,22
213:21 231:7	106:14 210:4	352:13,16,21,21	216:15	56:1,2,3,4,6,8,10
233:7 239:5 240:1	disagreements 62:6	352:22 353:7,8,11	doing 41:1 55:21	56:12,14,16,17,20
247:1 249:9 251:1	disappointing	354:5	60:10 67:19 76:10	56:22 57:8 58:16
255:14 261:5	87:21	Diseases 2:9	102:22 108:13	58:17,22 59:2,4,6
272:16 287:16	discharge 186:20	disincentives	137:3 138:13,19	59:8 60:8,16
288:8 290:20	191:18 201:7	148:22	140:4 148:4	61:22 62:3 63:7
292:8 306:2,4,5	discipline 153:20	dismissing 83:1	161:18 181:19	63:19 65:15 69:3
308:6 315:21	discontinuous	disparities 31:13	183:15,21 187:9	71:5,15 73:4,11
318:3,10 353:20	156:20	140:11,12,14	187:12 192:1	73:12 74:7 75:6
357:22 361:12	discouraging	284:1 310:21	193:8 195:3	75:17 76:16 77:7
367:14	148:17	330:13,15	244:19 247:1	80:10 81:7,12,22
differentially	discrepancy 310:2	disproportionate	272:19 292:10,17	82:12 83:4,11,17
291:22	discretion 315:16	289:2	299:15 320:13	83:19,21 84:1,9
differently 241:12	discuss 123:10	dispute 249:3	330:14 338:5	84:12 85:7 86:7
247:2 265:4	124:2 175:2	dissect 213:21	360:4 368:12	87:20 89:9,14
difficult 5:14	285:13 322:12	disseminating	dollars 76:12	90:4 93:22 95:5
107:20 123:3	discussed 90:5 94:3	118:15	DOPPS 31:17	95:12,14 96:9,14
128:5 202:20	275:12 276:17	dissuaded 244:21	46:10,18 47:17	96:17 97:7,10,15
203:2 305:8 308:2	277:10 314:11	distal 326:16	78:5,7 86:8,10	97:20 98:7,9,16
339:3 343:8	326:14,19 358:12	distances 306:20	dose 38:6 52:16	98:21 99:9,13
difficulties 330:21	361:21	distinction 71:17	268:16,17	100:1,12,22 102:4
difficulty 165:5	discussing 185:14	178:3 238:12	doubt 66:1,4	102:15 103:6,18
265:15 276:18	362:8 366:17	316:2	155:19	104:8,11,21
digest 364:8	discussion 15:10	distinctive 242:16	downward 105:13	106:14,19 107:4,9
Digestive 2:9	63:20 73:18 84:3	distinctly 34:22	Dr 3:2,2 5:4 9:1,14	107:14,19 108:6
diligent 15:4	96:20 101:6	distinguish 128:5	9:17,20 10:1 11:1	108:10,19 109:1,8
dinged 169:13	121:22 130:12	219:10	11:2,3,5,7,9 12:8	109:14,18,20
direct 118:15	175:8 178:10	diverse 168:2	12:14 14:13,15	110:1,2,4,6,7,8,10
124:15 179:16	194:1 201:3 230:5	diversion 146:11	15:12 17:10 18:14	110:15 111:1,3,8
315:11	231:16 233:8	188:12,19	18:21 19:1,4	111:13,16,20,21
directed 247:9	285:18 286:7,8	Division 118:6	20:13 21:5,9,13	111:22 112:2,3,8
direction 53:15	291:9 314:10	doc 270:15 342:22	21:17,19,20 22:1	112:12,14,15,17
259:9 309:16	319:15 322:10	doctor 51:5 94:7	22:2,15 23:11	113:2,6,11 114:2
341:8 347:3	324:11 325:12,16	203:11 275:19	24:10 26:2 27:6	114:6,11,15,18
354:14 364:4,4	327:5,8 342:8	277:11 300:7	27:12,14,15,19	115:3,5,9,14,19
directions 84:22	352:10	doctors 66:9	28:1,3,4,6,16	116:1 117:6,10,14
directly 333:7	discussions 129:6	document 17:21	29:11,20 30:8	117:16,18,20
director 2:14	233:14 310:14	90:12 101:21	33:2,10,14 34:6	118:1,4 121:12

123:2,6,11,21	218:11,14 219:5,9	291:2,8,11 293:22	359:8	306:12
124:4,5,6 130:9	219:22 220:7,19	294:21 296:15	drop 245:1	edema 87:11
131:1,20 132:1,2	221:21 222:6,11	297:2,18,20,22	dropping 175:7	educate 67:5
132:6 134:1,9,15	223:4 224:6,8,9	298:2,3,4,7,8	dry 87:16,17 93:10	333:15 336:21
134:16,18 136:16	224:11,19 225:15	300:4 301:4,14	94:10 96:21 97:1	educated 67:15
137:9,13,16	225:17,18,21,22	302:21 303:21	97:2,12,14,17	336:19 339:12
138:21 139:2,6	226:2,21 227:9	305:4 306:11	98:13,15 99:6	educating 354:1
142:13,17 144:1,4	228:4 229:22	307:4,18 308:22	102:17,19	education 21:6,22
145:9 147:14	230:9 231:1 232:1	309:7,10,20,22	DTEP 101:7	22:5 327:13,14
149:7 150:16,22	232:6,9,10 233:1	310:5,11,19	DTEP's 286:7	328:15 332:11
151:1,8 152:5,11	233:11 234:7,13	311:13,19 312:2,6	Dudley 2:17 11:1,3	333:9,12,18 334:8
152:17,21 153:3	234:19 235:5,11	312:10,13 314:12	11:3 222:6,7,11	335:5 336:1 337:7
158:3,15,20,22	235:15 236:5	314:22 316:7,16	226:2 227:9 228:4	337:10,15,18
160:5 162:20	237:20 238:2,8,15	317:18,22 318:12	232:6,10 233:11	347:2 348:16
163:13,14,15,19	239:11,19 240:11	318:16 319:11	238:2 258:22	351:21 355:8,16
164:14 165:9,20	241:13 242:6	320:6,9 321:1,13	259:17 260:18	355:20,21
166:4,13,18,19,22	243:2,12,16 244:7	321:16,22 322:5	261:12	educational 66:7
167:7,11 169:2,10	244:10,14 245:5,8	323:1,2,18 325:11	due 160:20,21	75:19 287:1
169:16 171:15	245:11 246:6,15	327:6,11 329:13	191:9 248:12,13	316:11 334:4
172:10 173:6,8,10	246:19 247:8,16	330:17 331:10,17	356:5	educator 342:1
173:20,22 174:2	248:8,15 249:2,13	332:7 333:5	duplication 232:18	educators 336:20
174:20 175:10,15	249:18 250:3,7,11	335:21 336:22	duplicative 195:7	356:4
175:19,20 179:2	250:20 253:2,7,10	337:21 341:10,20	duration 3:9 36:7	EDW 98:4,5
179:11,16,17,18	253:13 254:10,12	343:6,18 344:15	36:11 63:11	effect 47:16 78:16
179:21 180:4,5,21	254:13,16,20	344:22 345:17	282:17 315:3	78:17 98:6 344:7
182:5,10,11,14	255:16,18 256:1,4	346:3,5 347:11	316:6 319:19,21	effective 44:10
183:4 185:19	256:10,16 257:18	349:9,17 350:5,10	dying 67:18	51:21 363:19
186:11,16 187:1,8	257:22 258:6	352:9 353:12	D.C 1:10	effectively 92:13
187:13,16,17	259:2,4,17 260:12	355:1 356:14,20		362:6
188:9,20 189:1,8	260:18,21 261:12	357:9 358:15,19	E	effector 58:8
190:1,5 191:13	261:20 262:2,4,19	358:20 359:1,20	earlier 62:1 233:12	efficient 354:18
192:15,15,22	263:3,17 264:2,6	360:2,13,15,17	257:1 268:1 285:9	effort 163:2,6
193:1,5,7,20	264:16 267:2,14	361:3,5,8 362:10	324:21 346:14	183:2 186:3 189:6
194:4,8,15,21	268:5,9,13,19,20	362:14 363:1,11	366:12	254:8 334:4
195:17 196:3,8,11	268:22 269:6,8,20	364:12,18,21	early 5:5 17:4 49:5	348:15
197:21 198:2,6,7	270:3,11 271:6	365:2,12 367:3,12	343:3 346:7,9	efforts 121:3
198:18 199:3	272:10 273:8,12	367:21 368:10	347:1	157:20 182:16
200:2 201:2,8,15	273:16 274:3,8,12	draft 325:18	easier 72:5 144:16	184:4 193:10
201:22 202:1,3,5	275:1 277:7,14,21	dramatic 119:2	215:19 305:1	232:20 234:3
202:6,9 203:6,17	278:4,11,19,22	drawing 271:12	365:9	251:5 253:16
203:21 204:4,11	279:7,18,21,22	drawn 169:20	easily 164:16 180:1	287:1
204:12,22 205:15	280:1,3,5,9,15,17	269:4 270:7	319:14	eggs 213:2
206:3,6,12,14,19	280:19,20,22	DRG 315:8,12,15	East 350:8	eight 19:9 44:22
207:1 208:4	281:1,2,12 285:20	drill 214:5	easy 157:10 177:16	45:2,6 84:20
209:13 211:10,12	286:19 287:19	drive 211:20	280:3	114:9 115:13
211:17,19 215:1,1	288:3,5,14 289:6	303:11,11,18	echo 309:10	205:22 206:2,21
216:1,10,11,13	289:11 290:22	338:18 358:4	economically	297:19 312:4

eighteen 5:20 312:16	empower 333:15 354:16	enjoyable 367:18	essentially 159:13 221:22 236:1 271:19 281:20 313:18	284:21 307:19 311:17
either 27:10,20 84:22 112:18 150:17 160:13 175:5,12 197:2 203:8 236:16 275:19 316:10 322:20 339:15 359:21	empowered 339:13	enjoyed 346:5 367:7	establish 258:21	everybody's 205:13 356:6
elderly 355:10	empowering 354:1	enlarge 5:16	established 108:2 121:4 256:20	evidence 14:17,18 29:5 32:12,14,15 36:22 39:4,6 41:1 41:11,15 43:12,20 44:1 48:11 52:1,5 54:21 58:11 61:11 63:1 68:2 78:17 79:22 81:14,19 82:7,15,17,22 90:16 99:5 103:16 154:2 210:12 248:22 314:2 315:10 318:13 329:22 337:3 342:9 346:13
electronic 141:13 141:14 184:13 185:6	empowerment 356:8	enlisting 89:1	establishment 105:16	evidence-based 66:15 72:16
electronically 154:20 189:15	EMR 98:8	enter 134:19 186:20 217:1 221:15 225:7 227:21 257:17	esteemed 57:19	evolutionary 42:2
element 21:15,18 21:21 22:4,11,12 93:18 227:2,7 275:7,14,18	Encoders 248:16	entered 100:9 120:2 142:13	estimate 182:7 183:1,5	evolve 354:14
elements 216:2,5 216:15,16 217:5 218:21 219:5,11 219:11 221:8 222:16 226:3,4,5 226:8,11,16 231:6 231:8 236:21 259:6,8,21 260:6 262:5 313:18	encoding 315:15	entering 227:19 257:7	estimation 186:2	evolving 244:11
elephant 65:9	encompass 288:12	enters 319:1	et 66:8 183:14 313:17,17 331:7 354:12 358:1	ex 2:8
Eleven 235:19	encounters 303:1	entire 176:1 183:8 220:5 242:22	ethnic 283:22	exact 44:19 161:13 180:6 248:2 303:2
eligible 23:22 24:5 99:19 281:18 313:6,10	encourage 90:12 229:19	entirely 13:12 220:20 239:5	ethnicity 282:17 312:15	exactly 18:15 19:22 40:19 103:7 181:7 204:12 231:15 258:20 262:4 302:2 307:4 360:2
eliminated 200:12	encouraged 356:10	entrenched 68:16	ETSRD 348:8	examine 172:13 337:14
emergency 150:20 151:2 159:8 168:5 169:18 287:2 288:13,15,22 299:12 300:6,12 301:7 308:5	endorse 95:4 147:4 165:9 259:7 260:15 261:9 303:10 320:3 331:11	entry 198:8 216:6 227:18 228:3	Euless 2:8	examining 29:5 78:22 304:5
emphasize 17:17	endorsement 24:6 51:7 83:20 95:9 99:19 115:15 130:3 141:19,20 179:2 195:18 207:3 219:3,4 220:13 229:13,19 235:16 250:12 259:19 264:7 265:14 274:13 277:2 278:20 292:21 293:4 312:11 314:7	enunciation 117:13	euvoemia 90:22	example 26:22 45:12 69:19 82:15 107:10 127:20 134:20 138:5 159:3 178:2 238:12 295:3 307:11 361:17
empirical 315:10	endorsed 83:5 84:16 230:10 258:19 350:14	environment 94:21 168:13	evaluate 320:4	excellent 39:14
empirically 150:18	endorsing 220:12 220:17 259:5 304:21	envision 177:4	evaluated 63:12 318:2	exception 58:22 67:17 197:7
employees 163:6	ends 29:12 33:19	epidemiologist 118:5	evaluating 195:10 200:21 233:9	
employers 48:17 49:21	end-of-life 355:4 355:16	episode 211:5	evaluation 63:13 121:17 133:22 140:13 230:15 295:10	
	end-stage 64:7 120:20 345:22 352:12	equal 30:17 52:21 77:18 291:19	evaluations 155:4 197:4 276:2 360:11 368:12	
	energy 182:17	ER 169:12 287:22 288:7 289:9,10 293:5,6 302:11	evaluators 155:5	
		erase 223:15	event 134:13,21 158:10 159:20 166:9 169:1 188:7 198:8	
		error 149:2	events 92:10 137:2 151:12	
		especially 364:6	eventually 294:6	
		ESRD 12:22 13:6 14:18 57:14 124:17 154:21 156:1 162:14 233:20 260:1 282:17 298:14 327:2 329:19 330:6,11 337:19 339:11,14 350:2	everybody 24:8 28:14 69:5 73:17 76:8 89:14 194:4 212:13 218:8 242:15 257:3	

exceptions 184:1	355:12	163:6 187:16	270:18 291:16	353:9
excess 13:11 28:22	expected 253:20,22	356:6	292:16 307:22	fair 104:13 242:19
excessive 13:9	283:5,9 291:20	extraction 185:9	315:21 318:4,6	252:3
29:12 31:3 341:19	313:9	extraordinarily	facility 20:17 22:10	fairly 65:1,3 144:10
exchange 154:20	expecting 137:3	150:9	25:14 98:18	144:22 145:3
294:11	226:17	extremely 119:16	100:11 104:2,7,13	210:10 242:18
exclude 7:19	expend 163:6	122:15 124:10	133:10 138:9	falls 261:14
109:13 110:21	expended 182:17	127:9 148:6 210:6	147:17,18 159:7	family 75:3 212:5
133:2 177:10	189:6	301:6 305:7	159:14 162:6	far 70:19 72:6
267:3	experience 59:10	extremity 255:1	168:20,20 177:7	87:10 222:21
excluded 35:9	75:19 110:18,20	extricate 62:14	178:4 183:11	229:1,1 238:4
157:6 287:22	118:13 120:10	eye 155:22	185:22 192:17	276:16 313:21
excludes 210:1	125:8 144:21	eyes 32:22	193:4,14 199:14	314:1,7 316:8
290:2	153:20 167:4	e-mail 294:11	217:15 266:2	320:14,16 346:7
excluding 58:19	182:3 183:15	358:17 360:9	268:6,10 269:18	FASN 2:4
267:12	186:5 293:1		270:8,9 281:19,21	fast 200:15
exclusion 27:16,18	295:16,18 300:13	F	283:7 291:21	faster 50:1 150:2
156:10 317:12	318:1 328:6 332:5	face 83:14 128:14	292:5,9 295:9,9	fatigued 55:7
exclusions 20:19	experienced 146:16	141:6 168:16	296:18 297:10	favor 145:21 147:7
25:17 91:13	experiment 345:4	205:13 301:16,17	299:16 309:3,5,8	155:8 157:2
114:21 305:5	expert 129:12	faced 143:17	309:18 313:4,7,10	161:16 162:18
Excuse 215:1	146:12 175:13	facetious 101:11	313:12 318:19	188:5 197:5,10
executive 294:9	215:4 216:22	facilitate 307:9	319:3,9 320:13	199:21
exert 314:14	expertise 131:14	facilities 26:21	facility's 269:5	fear 357:20
exist 92:17 324:19	356:6	31:12 38:17 90:7	facility-level 265:8	feasibility 14:5
330:13	experts 82:22	90:11,14 103:22	340:15	26:9 33:7 37:19
existing 54:22	127:8 202:18	112:6 119:21	facility-specific	63:16 81:4 91:21
145:21 154:8	214:14,18	120:17 122:6,9	292:5 304:16	115:10 121:5
188:7 197:11	explain 18:4 259:5	134:19 135:14	facing 54:13	141:2,7,12 142:7
256:22 345:6	explained 139:19	138:6 143:13	FACP 2:3	152:21 194:1,2
exists 168:16	169:5	146:1,3 148:4,5,9	fact 23:3 24:1 94:1	195:12 206:19
184:13	explains 86:12	148:18,22 154:21	101:19 102:12	210:9 235:11
exodus 146:16	explicitly 365:13	155:16 156:1	109:2 122:8	237:1 250:7
expand 54:11	explore 336:15	157:16 162:14	137:19 145:1	252:20 264:2
147:15 225:8,9	exponentially	166:15 167:18	154:2 179:13	266:21 274:8
expanded 143:16	146:9	168:17 170:2	292:21 299:13	276:11 285:3
182:3	exposed 221:8	176:7 177:16	315:15	312:6 314:5 336:5
expanding 119:5	expressed 224:6	182:1 183:20	factor 156:17	feasible 340:2
121:1 155:18	expresses 209:16	185:5,10 188:6	270:22 290:4	feature 120:2
336:16	extend 109:9	191:15 216:3	factors 248:12	feedback 72:22
expect 94:8 129:19	extenders 336:9	217:10 218:9,17	296:13 310:21	310:13 318:18
170:5,12 176:7	extending 53:6	220:15,18 221:1	312:15	348:1 353:2 365:8
226:19 351:3	extensively 155:10	222:3,20 223:2,14	failed 47:15	feel 40:5,6 94:5
365:15	extent 23:6 108:21	226:18,18 228:10	failure 57:13 58:1	111:2 230:12
expectation 125:1	138:1 146:15	228:15,21 233:20	87:11 92:9 187:19	367:4
190:3	259:7 266:1 318:7	244:16 245:9	191:7 302:11,15	feeling 46:16 80:9
expectations	extra 124:22 163:1	258:11 260:17	308:16 346:18,21	feels 111:2

felt 40:1 58:2,9 136:20 147:8 210:5 236:13 238:20 282:10 363:2	64:20 111:3 190:22 200:10 fine-tune 72:4 finger 352:6 finish 11:11 84:2 209:8	341:17 349:14 FIVUSH 1:18 21:13,19 22:1 27:6,14,19 28:3,6 34:12,19 35:13,17 69:3 104:21 107:19 108:6,10 108:19 109:1,14 109:20 110:2,6,8 111:1 149:7 150:22 223:4 224:8,11,19 225:15,17,21 240:11 243:2 245:11 246:15 305:4 307:4 316:16 349:17 350:10 360:13,17 361:5 363:1	focusing 58:21 172:15 203:22 349:8 355:16 folks 175:22 256:2 362:15 follow 183:18 261:21 288:14 305:14 320:11 328:3 330:17 335:22 336:17,22 341:21 followed 116:22 following 166:8 167:1 follow-up 36:1 food 18:5 foods 18:2 foot 160:21 200:11 forbid 49:4 force 136:18 foreshadowing 358:8 forever 107:8 form 21:21 63:13 82:19,21 83:2 133:19 157:6 160:2 198:8,8 236:15 265:21 293:11 294:4 295:12 364:1 formal 22:8 31:11 324:8 337:10 355:21 formally 130:17 141:3 format 326:8 formidable 304:7 forms 236:11 formula 6:7 forth 131:21 280:21 362:12 Fortunately 42:15 forum 1:1 99:7 130:4 143:12,18 forward 28:7 62:4 62:9 63:20 127:15 164:12 209:7	305:18 306:8 310:12 323:5 367:7 368:8 found 144:7 176:4 214:2 342:22 Foundation 2:1,4 336:3 four 3:9 13:22 33:3 36:7,11 37:20,22 39:4 40:12 43:8 43:15,17,21 44:7 44:11 45:1,5 46:4 46:6,14 49:8,10 52:14 53:7,18 54:8,8 55:7,11 71:9,10 74:4,11 81:2,6 88:17 91:22 126:2 142:4 169:22 194:13 197:5 207:5 217:22 235:14 250:2,6,9 252:15 266:16 274:6,6 276:3,6 285:2 313:22 322:1,3 334:15 Fourteen 5:20 6:3 6:10,14,17,21 7:6 7:9,16 8:2,9 24:20 29:20 34:6 89:11 249:16 262:19 321:13 four-year 125:22 fraction 73:20 192:11,11 242:17 345:12 fragile 149:12 fragmented 301:17 302:16 frame 156:10 285:10 framed 110:18 framing 329:14 France 15:4 frankly 48:18 149:12 Frederick 1:20
fewer 228:21 FHM 41:3 47:20 field 62:9 82:17 202:18 340:17 fields 259:21 field-tested 143:15 Fifteen 235:8,13 250:1 263:12 fifty-four 8:2 fifty-six 262:20 figure 19:12 100:21 106:9 181:16 228:15 363:19 figured 133:17 170:8 286:7 figuring 53:13 files 359:9 360:1 fill 216:4 268:21 filling 293:12 filtered 359:19 final 6:2 10:18 89:21 130:18,21 211:21 finalized 125:19 finally 115:10 153:3 195:17 207:1 235:15 312:22 financial 65:7,11 65:14 66:10,20 148:21 288:20 find 22:21 59:21 72:3 158:18 159:15 171:3 188:22 189:1,7 210:20 215:11 218:5 249:10 270:19 283:17,17 finding 193:11 248:17,18 findings 337:5 fine 9:8 10:10	finished 10:12 206:14 fires 358:22 firewalls 358:22 359:19 firmer 251:9 first 15:14 41:5 42:10 62:17 69:1 71:21 116:7,22 123:7 133:11 144:4,5,19 156:21 158:6,16 170:9 173:16,19 175:3 183:5 192:6 247:10 249:5 259:4 268:16 273:14 290:2 296:16 301:8 327:13 328:4 334:17 347:15 348:9 359:4 365:2 366:16 firsthand 186:5 fistula 71:10 139:4 139:10 210:18 236:17 254:5 336:12 339:18 347:16 348:4 fistulas 254:6 349:10 fit 246:20 289:2 fits 54:2,2,3 215:13 five 14:8,11 26:11 33:9 40:8,12 46:7 67:3,9 81:4 91:15 115:13 142:2 191:20 213:13 217:21,22 219:21 239:12 274:11 284:18,19,20 290:9 313:22	fix 96:10 285:14 flawed 285:17 287:18 flaws 23:8 fleshed 347:6 flexibility 11:22 flies 168:15 floor 302:14 flow 93:9 124:22 145:22 243:15 fluctuating 129:2 fluid 3:5,12 11:11 12:3,12 13:11 15:5 17:3,5,18 19:9 24:1 36:3 55:2 57:5 59:22 60:12 77:3,6,12 78:10,12 85:10 fluid-overloaded 17:15 focus 74:8 128:14 128:16,19,20,22 146:6 154:12 161:6 167:16 172:20 251:4 253:18 254:6 265:4 focused 61:8		

107:15	gap 15:17 25:18	242:13 310:1,13	348:14 357:14	225:7,9,13,22
free 367:5	32:10 36:21 91:8	324:16 339:6	362:11 363:13	230:3 231:14
frequency 38:7	106:22 210:13	349:6 359:10	goal 184:16 351:7	232:11 238:18
53:8	242:19 251:11	given 15:18 19:18	365:13	240:21,22 241:4,5
frequent 38:20	332:16 349:7,7	23:15 62:7 76:11	gobbledygook	241:7,8,13 245:13
40:12 41:6 44:6	365:22	133:3 143:15	133:20	245:14,16,21,22
54:1 68:11 70:13	gaps 4:19 81:13,18	167:9 181:8	God 49:4	246:7,9 256:20
74:14 94:12	106:20 107:5	243:22 313:11	goes 138:3 258:2	258:18,19 260:14
202:10 341:2	322:10 325:10,13	354:15	288:22 294:6	262:1 273:9
frequently 205:10	329:15 355:18	giver 354:17	306:8 338:1 355:2	280:20 287:3
Fresenius 334:9	gathered 158:7	gives 49:15 197:13	366:11 368:6	290:7,18 294:18
Friday 68:17	gears 281:13	204:8	going 5:6,9 10:3	299:3,11,22 301:7
friends 67:18	349:18	giving 50:22 54:12	11:10,10,11 16:17	302:18 305:11,13
front 146:13	Geez 94:20	147:20 150:18	19:22 22:4,12	305:20 306:6
201:17 334:2	general 2:13 13:1,4	292:2 304:14	23:5,6 46:7 48:12	307:1,21 311:3
365:2,6,10	50:3 90:21 361:9	318:17	48:18,22 50:10,16	317:1,9,14 322:18
frustrated 66:16	generally 44:21	glad 126:17 359:8	53:17 58:20 60:13	323:5,18,19
68:13	90:9 103:8 153:16	global 64:3 174:16	60:14 62:14 73:14	325:12 327:3
frustration 70:19	190:8 249:4	213:18	73:15 76:2 81:15	328:10 337:9
full 141:18 210:12	277:10 327:4	go 5:12 7:13 19:2	82:4 86:19 87:9	339:5 340:1,2
222:12 365:10	generate 47:19	20:6 22:21 28:7	88:1,12,19 93:16	341:18,21 344:9
fully 68:3 179:13	generates 182:18	34:16 39:16 48:3	93:18 100:7	348:22 349:1,3,17
183:18 303:8	182:19	50:4 53:19 63:1	103:19 104:16,17	353:20 354:13,18
fun 317:1	generating 183:2	65:16 72:5,6 78:1	104:21,22 108:1	359:3 360:3
function 13:13 68:6	generation 248:7	80:20 85:10 89:10	116:3,16 117:1	gold 155:20 199:22
120:2 319:4	George 183:13	89:16 100:18	121:11 123:4,17	good 14:20 23:17
functional 328:20	germane 213:10	107:2 113:7,17,18	128:8 131:9	24:18 28:13,18
fundamental	getting 5:5 43:15	114:3 116:16,21	138:10 143:3,17	29:10 34:4 42:11
239:15	43:17,21 45:6	117:1,21 130:5	145:2 148:13,21	43:11 45:5 50:6
funding 93:1	59:10 65:5 76:6	131:8 133:22	150:12,13 160:10	64:10,13,22 82:6
337:15	79:13 84:17,20	139:1 144:3 150:2	161:22 162:5,6	86:15 88:15 90:9
further 126:15	99:15 101:9	150:20 160:1	163:20 164:11	106:11,11 112:4
130:12 133:16	159:22 176:6	165:19 168:14	166:5,14 168:10	118:4 126:12
320:4 345:11,11	185:16 220:12	169:6 191:15	168:11,12 169:12	127:17,21 129:17
furthest 316:13	237:14 240:4	194:8,10 200:16	169:14 170:5	129:21 137:17
future 88:21 178:8	330:21 332:8	222:9 232:1	171:11,12,18	150:5,10 159:22
295:14 354:19	339:11,12 345:10	238:14 250:17	172:6 174:20	193:19 196:15
fuzzy 288:2	347:21 350:13	262:16 263:3	175:2,7 177:11	200:13 207:19
	359:18,18 365:19	273:17,18 275:13	181:4 184:17	215:5 248:13,17
	367:10	278:5,11 279:4	187:11 188:20	327:1,9 329:9
G	GFR 335:8 342:7	289:9 299:12	189:15 190:10,11	335:9 344:16
gain 87:6 107:22	343:22 344:1,19	300:10,16 302:11	190:14,14 193:11	359:2 360:22
gained 15:6	give 18:1 39:17	305:18 306:19	195:6 207:19	364:2,4,20 365:1
gains 88:22	56:20 85:3 108:17	316:17 317:2,3	211:9 213:18	366:6,7 367:22
gamed 164:15	161:10 162:8	320:4 321:7 322:2	217:14 218:7,9,22	gotten 76:12 87:21
165:3 177:14	204:13 213:20	322:17 329:9	219:2 223:21	94:5 365:8
gaming 177:8	237:22 241:3	339:17 341:9	224:4,15,22 225:5	government 232:14
265:8 271:20				

grabbed 361:19	108:2 136:12	345:5	359:16	112:10 118:20
gradual 78:12	150:16 164:10	happening 144:11	heard 10:21 61:8	119:7 133:9,12
graft 71:10 139:10	174:17 203:6,22	147:5 181:18	121:22 122:17	155:1,3 159:5
210:19 236:18	207:18 220:11	happens 61:2	125:14,21 157:1,1	196:22 202:11
341:14	223:4 224:11	131:20 147:3,4	192:10 197:17	209:17 236:8
grafts 139:4 341:18	230:15 243:16	187:2 275:16	223:5 224:3,13	238:21 251:19
349:10,14	247:3,17 252:3	300:11 338:19,22	245:21 246:1	264:18 281:21
grams 19:7	253:5 255:10	342:3	247:4 257:1 363:4	331:12 336:12
gram-positive	258:14 259:3	hard 14:22 68:21	hearing 16:8 49:21	347:14 348:4,9
270:16	307:18 314:15	85:7 131:13 163:8	70:17 257:19	hemodynamic
granted 233:21	318:12 329:15,20	304:2 316:18	355:3	92:17
270:14	352:15 353:3	323:3 328:10	heart 57:13 58:1	hemoglobin 7:14
great 11:5,9 53:16	360:22	338:14	78:17 86:16 87:10	7:17 45:12 49:15
57:11 72:13	guessing 166:7	harm 50:8 94:18,18	92:8 187:19 191:6	50:6,18 126:6,22
117:13 129:18	275:17	harmful 74:13 79:5	302:11,14 308:16	128:9,13
131:17 200:9	guidance 199:3	harmonize 192:16	346:18,20 352:21	Henry 2:18 11:6,6
272:1 341:11	guideline 50:15	harmonized 179:13	352:21 353:8	11:8,8
350:10 352:7	72:12,15 73:2,5,8	harmonizing	hearts 62:4,5 86:16	hesitant 317:2
356:4,18 361:1	342:6	284:10,15	heavily 129:15	Hey 280:5
367:18	guidelines 73:11	HARVEY 2:7	heavy 344:19	hibernating 58:6
greater 8:10 31:1	154:8,9 199:1	HCPCS 244:11	HEDIS 338:13	high 3:11 32:14,16
52:21 77:17 170:3	gun 192:4 321:18	246:12	held 335:20	50:18 66:22 77:2
173:2 197:20	guys 368:10	head 232:3 238:18	Helen 2:12 22:14	77:6 79:1,11,14
223:10		health 2:2,20,24	48:21 179:10	80:2 124:9,10
greatest 156:17	H	13:16 88:6 118:9	302:20 357:6	136:6,9,9,11,14
346:14 348:1,2	HAI 181:4 182:4	118:10 124:13	help 45:8 50:7 63:2	138:7 143:1
group 9:10 31:14	249:1	149:3 154:19	73:2 86:20 151:19	149:11,22 150:9
35:15 36:3 46:10	HAIs 181:3	227:1 266:2	205:3 251:4 319:8	164:19 192:4
70:21 89:21	half 40:1 46:14	283:22 284:13	334:1 336:3 354:4	201:11 253:18,21
116:20 121:10	49:11,11 71:10	306:18,18 326:16	354:16 355:12	254:3,3,4 267:3
203:9 217:21	75:11 345:9	330:9,12 338:10	358:5 359:12,12	296:7 308:12
229:4 239:8,12	HAMMERSMIT...	340:13 353:13	362:17 366:15,20	330:11 337:6
251:13 264:22	2:13	healthcare 3:17,19	helped 331:15	348:17,20 352:20
284:18 304:3	hand 321:20	3:21 118:6 119:14	helpful 157:18	higher 80:1 143:2
332:15 368:11	handed 325:15	132:10,15 153:12	181:14 333:20	164:20 253:19
groups 110:14	handled 34:21	189:18 196:18	363:9	260:16
291:20,22 306:2	hands 301:13	283:21 317:10	helping 32:2	highlight 6:4
338:10 353:18	321:21 351:14	318:10	331:18	357:12
growing 35:4	356:11	healthcare-associ...	helps 303:17	highlighted 57:22
107:21	happen 162:5	118:12,14 119:17	hemo 42:16,17	85:4
growth 107:22	171:4 176:2	161:19 167:6	47:11 61:19	highly 210:5
guarantee 168:10	232:17 245:14	199:22 248:6	111:18 112:1,18	236:20 336:19
321:5	295:13 331:8	hear 51:13 56:21	341:17 349:15	high-risk 143:6
guaranteed 177:14	356:19	100:4 117:6,10	hemodialysis 3:7	338:12
guess 10:5 14:9	happened 159:15	179:19 182:11	25:1,4,15 37:6	Hispanics 330:10
33:14 57:6 83:14	186:9 189:5,16	222:7 286:5 291:8	38:20 67:6 73:6	historical 293:10
86:7 89:7 107:19	191:20 255:9	342:15 356:10	77:14 111:18	296:5

historically 330:11	290:8 299:18	43:18,21 44:8,11	129:17 131:17	implemented 122:2
history 145:22	300:17 301:2	44:22 45:1,2,5,6	133:21 171:22	implication 269:10
157:17	315:11 316:20	45:16 46:3,4,14	172:20 181:18	implications 50:21
hits 94:2 288:17	317:15 319:2	49:8,10,11,11,13	214:3 241:1	50:21,22 149:4
HIV 149:14	330:22	53:7,18 54:9 55:7	317:20	implying 60:11
hold 107:8 282:3	hospitalists 287:10	55:11 64:21 68:7	ideal 105:4,17	143:8 344:17
holes 327:12	hospitalization	68:16 69:19 71:9	Ideally 295:7	importance 6:19
home 68:10 74:15	4:13,14,16 11:20	71:10 74:4,11	ideas 127:15 129:7	7:4,11 8:12,15
112:7,18 189:5	57:15 66:3 117:3	75:11 160:9	129:18 131:7	24:16 25:21 26:3
227:1,1 282:18	123:19 124:7,18	183:10,17 186:4	353:18 356:18	29:21 30:3 33:2
284:12,13,14	125:16,16 126:8	228:2,3	identical 237:22	34:7,11 37:8
303:6 306:18,18	126:15 158:13	how-to 356:1	244:22 303:3,5	57:11 64:14 76:17
319:6 320:22	166:12 175:4	huge 88:22 160:6	identification	76:20 80:22 89:12
321:5 332:11	189:17 191:11	175:12 188:11	140:1	89:19 91:15 93:2
336:11 339:16	192:6 281:5,7,9	189:11,12 257:15	identified 124:8	113:3,14 124:10
353:22	281:10,13,16	257:16 355:6	193:13 251:3	135:13 141:17
homes 353:19	283:8 288:10,12	361:11	326:9 330:15	142:2,3 152:6
354:10	293:6 294:15	human 118:10	349:3 360:6	174:14 193:21
honest 360:22	295:21 296:11	215:21	identify 32:12	204:3 205:16
361:7	299:6,10,16 304:1	hundreds 129:14	70:22 136:21	210:3,11 211:19
honestly 85:9	304:21 306:16	hurdles 232:15	165:7 273:1	234:14 249:14
hope 63:21 70:14	312:18,21 313:3	hurt 163:7	324:14	262:20 266:15
160:1 168:17	315:4,7,9,13	hydration 90:19	identifying 59:14	273:10 277:22
181:11,13 212:13	316:5 319:21	hypercalcemia 8:3	157:18 248:10	284:21 307:14
338:1,21 346:16	hospitalizations	hypertension 13:18	255:11 338:7	311:14 314:1
347:3 356:8 357:1	201:12 202:13	14:21	349:11	321:14
hopefully 106:2	294:8 296:9	hypertensive 105:7	ignorance 224:7	important 13:13
169:6 272:17	298:12 299:2,8	hypertonic 26:20	ignores 163:11	24:11 26:17 33:19
358:5	315:5 330:5	hypophosphatem...	ill 351:5	35:9 38:7 41:21
hoping 339:6	hospitalized 158:17	8:14	illnesses 149:14	42:7,13 47:2,3,18
Hopkins 1:18	186:9 201:14	hypotension 27:1	imagine 345:8	47:22 54:13,19
horizon 354:7	267:3,18 299:1	hypotheses 47:19	immediately	55:4 60:7,9,13
hospital 1:21,22	313:6,9 314:14	82:3	230:11 366:5	61:20 63:22 65:13
158:6 159:9,11,16	hospitals 119:17	hypothesis 28:18	impact 63:5 81:14	79:10 106:12
160:8 162:22	170:3 176:7,10	29:3,5,8,9,11	98:22 120:14	121:4 122:15
164:3 168:11	179:15 193:12	30:22 31:6,9	124:9,12,15 161:2	124:19 135:10
169:13 170:6,16	201:6 270:13	33:17 43:2	218:14 296:9	137:21 146:3,22
171:3,7 175:11	317:9 327:20	hypothesis-gener...	302:18 307:1	148:6 151:11
176:13,16,17	hospital-acquired	47:3	328:13 333:7,21	153:21 154:3
180:4,17,18	159:2 170:20	<hr/>	334:10 360:19	155:10 157:3,14
186:10 188:14,17	180:19	I	impactful 60:14	161:20 176:10,14
189:14 190:9,10	hospital-associated	ICD-10 246:11	imperative 156:1	176:15 181:10
191:21 192:17	164:7	ICD-9 246:11	imperfect 293:20	199:18 200:18
193:3 255:8 267:6	hour 46:2 77:19	249:9 293:16	imperfections	201:3 210:5 219:9
267:11 268:7,14	79:5 80:3	ice 201:18	296:10	219:16 236:20
281:18 287:2	hours 3:9 36:8,11	idea 10:10 17:9	implementation	243:6 245:12
288:2 289:14,14	39:4,22 43:8,15	88:9 127:17,20,21	102:3 334:1	248:18 252:15

266:17 276:4 279:13 282:2 284:22 285:13,16 292:6 293:8 304:15 305:7,22 309:11 323:5 333:2,17 337:13 338:20 343:5 350:16 importantly 290:5 impose 309:17 impossible 86:14 impress 136:11 impressed 352:10 361:9 imprimatur 51:1 improve 38:21,22 39:1 52:9 53:4 64:3 88:13 168:22 192:13 252:8 265:19 309:14 329:10 337:22 improved 37:2 38:5 44:22 213:4 improvement 13:9 41:11 54:15 118:16 120:3,14 120:21 125:3 147:16 154:1,4 157:20 162:10 171:14 178:17,21 179:4 212:22 229:16 251:10 252:10,17 253:16 254:8 265:18 303:11,12 346:4 358:4,11 improves 53:11 271:21 improving 42:14 53:3 265:5 331:4 346:9 inaccurate 248:5 inactivate 216:22 inactivated 219:7,8 inadequacies 68:1 inadequate 58:14	inadequately 128:9 inappropriate 271:3 inappropriately 151:3 incentive 66:21 incentives 65:7,11 65:14 203:1 271:11 incentivize 71:12 inception 120:9 incidence 143:1 282:18,19 290:10 352:20 incident 39:11 71:19 142:21 incidents 290:4 include 37:5 41:6 90:10 111:10 112:7 156:8 298:1 339:1 356:22 included 28:8 57:17 199:5 210:19 222:17 301:20 310:22 341:13 358:13 includes 112:9 133:9 158:10 166:10 185:2 240:17 247:15 293:6 including 119:1 123:4 124:21 130:4 156:21 216:17 310:15 313:16 330:9 incomes 265:8 inconsistencies 8:19 inconsistency 324:15 inconsistent 80:12 95:17 324:12 incorporate 315:3 incorporated 129:9 incorrect 65:22 incorrectly 86:5	increase 41:9 42:17 87:15 126:10 220:14 260:16,20 increased 27:1 28:19,20 38:4 52:9 337:11 increases 70:9 increasing 41:7,7 41:15 87:6 146:9 343:20 increasingly 300:1 303:15 359:20 incredible 346:1 independence 222:4 independent 223:9 223:14 224:17 259:9 independents 226:19 227:21 228:15 index 282:19 290:16 Indian 272:12 330:9 Indianapolis 294:10 indicate 91:9 236:17 indicated 7:3 77:21 91:16 223:19 236:14 357:13 indicates 12:17 37:3 indication 94:9 255:11 indicators 244:6 indiscriminately 147:21 individual 103:3 198:21 202:19 212:7 259:6 343:9 individualized 53:21 55:13 59:12 59:18 74:9,17 individually 84:14 195:3,10 230:7,7	industry 53:14,17 54:5 65:17 inexorably 79:15 infected 134:1,3 164:6 infection 3:17,21 3:22 4:4,11 11:19 116:7 117:2 118:12 119:10,18 120:6,22 121:18 122:14 132:9,14 133:3 135:11 140:9,16,19 143:2 145:8 146:10,20 147:9 152:1 153:10,13,20 155:17,20 156:2 157:19,22 159:3 159:17 160:22 164:7 167:6,21 168:9 169:15 171:12,13 172:21 172:21 174:9,14 174:17 176:18 179:14 181:15 192:3 195:2 196:16,20 197:9 199:19 200:1 201:1 203:13,16 205:8 211:2,5 212:10 216:18 229:15 238:21 248:6,10 251:12 251:20,22 253:13 253:17,19,21 254:2,3,10,14 256:18 264:20 266:13 274:20,22 275:4,9,21 276:19 277:13 279:5 286:13 308:17 infections 118:14 118:19,22 119:4,8 135:4,6 138:7 145:5 146:13 148:1 151:10 156:18 159:2	161:4,20 164:19 164:22 170:20 172:1 174:5 176:2 182:22 184:15,16 197:15 203:11 212:3 217:11 239:14 249:10 251:1,2,6 255:1,2 265:5 infection-related 237:5 265:7 inference 14:20 43:9 infinite 172:11 influence 23:6 informal 138:2,12 informally 183:20 information 12:16 12:18 13:6,21 14:20 23:13 26:15 26:15 53:2,3 80:13,16,18 83:13 83:15 91:3,5,14 92:2,3 100:17 121:14 130:10 139:8 144:16 154:19 159:13 176:6,8,22,22 177:5 178:4 180:13 183:12 189:3 190:11 197:14 201:16 202:13,21 214:4 217:19 221:11 222:1 224:16 225:14 227:6 231:4 238:13 246:10,13 247:20 248:4,14 249:3 262:6,8 269:9,11 270:10 271:17,18 282:13 292:7 296:18 304:15,22 309:5,19 315:19 318:8 330:22 332:10,13 333:13 334:5
---	--	--	---	--

infrequently 255:9	234:5 237:5 260:3	347:1	62:7 74:21 75:8	198:1 202:8
inherent 219:19	269:21 314:22	intimately 227:10	88:4,7 94:5 95:3	298:20 337:12
initial 37:22 59:14	315:18	intimidating 339:3	104:22 105:10	Jeffrey 1:17 85:6
63:8 80:21 289:12	intention 59:8	intradialytic 27:1	123:5 143:11	95:13
295:5 356:16,16	interact 353:21	intravenous 3:18	161:5 162:20	Jeff's 163:10
initially 255:19	interacting 301:9	132:11,16,20	168:8 174:15	165:10 172:19
271:1	interaction 127:16	133:6 148:17	175:10,18 177:8	Jerry 1:19 4:5,9
initiate 73:15	131:19 215:22	149:1	181:10 189:2	27:6 71:3 83:3
initiated 120:21	354:8	introduce 123:21	233:3 234:5	86:21 142:11
251:19 264:19	interchange 346:6	introduction 3:15	266:16 272:22	190:4 209:7 236:2
initiation 132:21	interconnection	116:5,18 118:3	288:9,13 290:20	360:19
injury 343:13	231:17	123:16	311:2 324:6 328:7	Jessie 2:2 16:12
inpatient 119:4	interconnectivity	introductions	332:17 339:10	job 31:22 62:16
160:13 163:21	232:8	11:15	346:20 347:4	146:15,17 150:5
199:6 204:10	interest 9:1 100:9	introductory 11:15	355:19	367:22
281:18 331:6	203:9 209:6	132:4	issued 71:7	Joe 2:19 18:20 77:8
input 218:12 221:9	275:11	intuitively 68:4	issues 8:20 14:14	162:19 222:6,15
335:2	interested 60:19	298:16	14:16 32:4 35:2	233:12 267:1
instance 263:5	interesting 129:7	inverse 180:16	64:6 66:2,10	320:6 335:22
instances 138:5	203:7 317:20	invested 69:5	78:20 79:20 94:15	Joe's 62:8
176:5 302:5	318:8 336:15	investigating	142:18 150:6	Johns 1:18
Institute 2:9 13:1	345:1	310:16	162:1 267:15	join 10:4
instruction 21:3	interface 154:19	investment 356:11	301:16 306:20	joining 234:1
instructions 13:7	156:5,5 157:8	invite 81:7 116:21	308:19 324:14	joke 75:1
101:1 238:15	interim 242:20	involve 188:4	items 368:6	Joseph 2:1,4
239:2	interject 279:7	involved 103:22	iteration 216:19,19	102:14 147:13
insufficient 15:17	287:19	183:2 227:11	IV 3:18 132:16	Joseph's 149:19
insurance 242:10	intermediate 326:1	254:22 331:18	134:3 135:1,6,9	Journal 183:14
320:12	intermittent 68:6	334:18 339:9	138:7 139:9,15	JR 2:1
insurers 241:12	internal 71:20	357:1	166:12 176:20	judge 200:22
intact 96:6	internally 95:16	involves 54:15	209:15 251:16	judgment 107:2
intake 13:10 15:19	international 73:7	in-center 111:18	255:3,20 266:3	174:8 201:7
17:5,6,22 19:7	internists 351:14	112:9,13,15	268:5	203:11 205:3
332:21	interoperable	331:12		362:1
integrated 362:7	189:14	in-depth 65:2	J	July 217:10 238:17
intend 184:5 238:6	interpretable 99:7	in-line 92:17	jacket 85:18	jump 12:10 167:13
intended 23:12	interpretation	in-person 127:15	Jackson 1:19 4:5,9	jumped 321:17
27:8 30:9 71:18	120:11 251:7	iPhone 261:1	27:12,15 46:9	jumping 361:18
72:1 139:19	interpreted 270:17	iron 6:18,22 7:2,7	71:5,15 83:4,17	June 310:8
intends 77:9	302:17 316:4	7:10,10	83:21 84:9,12	justification 267:20
intensive 340:19,22	interrelated 213:14	irregardless 223:22	142:13,17 190:5	311:1 366:7
341:1,5,7	interval 77:20	irrelevant 290:11	209:13 211:12,19	justifications
intent 28:15,16	112:19	irrespective 192:20	236:5 256:4	231:13
30:21 34:14 59:2	intervention 106:1	issue 16:14 26:20	347:11 349:9	justified 227:7
70:17 96:17	106:3	34:21 43:14 54:12	January 1:6 169:4	justifies 121:14
100:18 101:14	interventions 88:11	54:18 57:22 58:7	Jeff 97:18 160:4	justify 269:2,9
102:2 110:4,21	120:14 162:2	58:14 60:9,13	167:16 174:21	324:16

K				
kabooney 5:20	214:3 215:12	10:10 11:4 21:20	241:21 243:4	52:13,20 58:18
Kaiser 1:15 321:4	218:3 227:11	23:4,8,17 33:16	244:9,10 245:14	60:19 61:14
339:21 348:12	228:7 229:6	40:2,3 41:3 45:10	245:17 248:13,18	
Karen 2:14 11:1	237:14 242:12	45:13 48:15 49:4	253:8,17 255:5	L
16:2 31:20,21	254:14 259:8	49:9 52:17 55:6	258:7,12 260:22	lab 104:6 351:22
32:5,8,9,21 36:5	262:16 271:3	55:11,20 60:3	265:10 268:16	labeled 241:15
48:22 72:22 79:18	285:21 287:15	61:18 62:6,12	272:12,20 275:20	242:3
80:8 82:11 90:5	288:8 294:2	63:19 64:11,11,12	275:22 284:8	laboratories
130:8 259:17	307:16 318:17	64:18 66:6 68:14	285:14 286:20	184:21
366:2,9 367:14	323:21 325:16	70:8 74:4,19	291:2 293:2	laboratory 184:19
KASKEL 1:20	332:18 339:12	82:19 83:1 85:2	295:13,20 300:14	269:5
111:3 350:5	347:8 365:9	86:14 88:7,16	300:15 301:13	lack 266:2
KATHE 1:25	kinds 88:14 126:3	93:4,22 94:12	302:3 303:7	lag 125:20,22,22
KDE 336:1,11,13	161:3 267:15	97:19 98:4,9	305:15 306:2,3,6	126:1 216:14
KDIQO 73:7 342:5	324:18 336:14	99:21 100:2,7	308:6 316:22	294:13 297:11
KDOQI 72:14 73:4	344:18 357:17	105:13 108:13	317:15 320:2	304:5 310:6
73:14,18 345:7	361:12	109:2 110:4	324:17,20 326:2	laid 325:20,22
KDQOL 328:21	kinetics 52:13	113:17 118:8,18	330:20 331:15,22	language 20:5,7
keep 5:12 106:17	73:19	121:20 122:12	332:15,21,22	102:6,7
111:14 193:22	Kleinpeter 1:21 3:6	131:18 136:16	333:20 334:21	large 39:7 57:18
309:18 311:7	3:14 12:6,8,14	137:1,9,10,19	335:9,17 336:10	61:4 125:7 151:21
328:10	14:15 19:4 20:13	140:8,11,14	340:8 342:6	171:9 184:13,20
keeping 299:17	21:5,9 90:4 102:4	145:21 158:22	344:19 346:22	185:7 226:18
keeps 338:2	138:21 139:2	159:6 160:9,17	347:5 349:9 350:1	242:17 251:12
key 279:10 327:18	163:19 188:9	167:12,17 168:15	352:4,4 355:8	254:22 257:12
342:2	189:1 246:19	170:20 173:4,11	356:14,20 357:1,6	270:13 308:13
keyed 280:2	306:11 329:13	174:20 175:5	358:17,17 359:13	336:7 338:10
kid 335:18	Kliger 1:22 3:8,12	176:15 178:5	359:17 360:17,20	largely 68:18
kidney 1:15 2:4,6,9	15:12 17:10 18:14	180:12,17 181:1	360:21 362:3	103:20 239:5,5
2:19,21 327:4	19:1 28:16 29:11	181:13 182:8	363:12,22 364:3,8	larger 161:21
336:1,3 339:4	30:8 33:10,14	186:7,12 187:3	365:3 366:14	largest 221:2
343:10,13 346:8	40:18 43:7,11,19	188:16 189:13,16	knowing 82:17	lasting 40:8
346:19,19 352:13	43:22 44:3,13	191:8 192:10,12	84:15 173:16	late 47:9 222:14
352:16,22 353:8	45:18 46:18 51:10	192:18 193:7,22	292:10	342:12 366:16
kids 242:17,20	58:22 59:4 60:16	197:6,11,13	knowledge 110:19	late-stage 355:10
351:3	77:7 81:7,22 86:7	199:10 201:3	190:15 218:15	Latts 1:24 4:12,15
kilogram 77:18	107:9 111:20,22	212:6 213:2,5,17	224:21 226:6	44:11 48:3,6
79:4 80:3	112:17 126:20	213:20,22 214:6	246:3 332:16	52:18 63:19 98:7
kilos 19:9 55:10	134:1 151:8 165:9	214:21 215:6,12	knowledgeable	165:20 166:4,13
84:21	172:10 173:8,20	215:12,13,14	127:9	166:22 167:7
kind 5:6 12:10	203:6,21 206:3	216:19 218:4,10	known 169:21	169:10 171:15
55:20 70:15	237:20 303:21	220:16 224:12	247:20 265:22	173:6,10,22
103:12 130:13	317:18 318:12	227:5 228:13,17	knows 45:2	188:20 189:8
153:16 159:1	320:6 327:11	228:19 229:5,14	Kristine 1:10,14	216:1,11 241:13
163:10 170:18	331:17 336:22	229:18 230:14	4:17 5:8 208:2	243:16 244:7,10
200:21 213:9,14	352:9 361:8	231:2 240:4,13,13	367:21	246:6 248:8,15
	know 5:14,17 10:3	240:15,19 241:1	Kt/V 38:6,22 47:13	253:2 254:10,13

256:16 268:5	legitimate 347:9	line 10:1 11:4 24:19	lived 75:2	214:14 218:4
275:1 277:14	length 36:16 70:9	79:21 116:20	living 40:10	229:11 231:10
281:12 287:19	315:3	117:5 132:3	local 100:21	241:1,2,8,9
309:20 310:11	lessens 106:10	134:16 138:4	location 192:20	248:19 256:11
320:9 330:17	lesson 61:20	167:14 259:14	lock-down 201:18	260:9 283:16
356:14	lethal 346:19	333:6	logistical 160:6	297:15 307:16
laugh 351:19	letting 316:17	linear 282:21	165:3	323:20 324:2,13
laughed 60:2	let's 9:18 12:2	lines 119:1 335:5	logistics 98:10	324:15,21 328:11
Laughter 71:14	29:19 30:4 34:4	line-associated	169:17	340:2 348:5 351:6
75:5 154:16 206:5	49:10,12,13 55:14	119:3	long 51:20 67:6,11	355:15 357:2
214:11 239:10	55:16 77:1 87:1,2	link 15:21 17:5,10	67:12 87:17 94:11	362:13 367:7
263:10,14,21	96:15 106:16	38:17	105:7 147:6	368:8
310:4 321:2 350:7	108:17 113:7,16	linked 41:16 165:1	150:14 282:8,10	looked 9:3 41:4
358:18	114:7 132:8	184:20	285:8 301:15	70:21 78:15 94:9
Lauren 2:15 6:4	133:22 141:22	linking 15:18	318:6 319:4	96:12 127:12
22:2 90:6 202:5	161:6 209:6	links 15:16 107:12	342:20 355:3	140:9 150:8
325:21 367:5	244:22 254:4	Lisa 1:24 2:19 4:12	360:14	177:22 240:17
lay 42:8 323:18	322:8	4:15 51:10 52:12	longer 3:10 36:8,11	243:2 271:4 304:1
326:7	level 7:21 54:21	54:12 63:18 65:15	37:1 38:18 39:1	326:11 337:2,2
layering 187:21	58:12 59:22 80:3	107:9 173:8	40:9,10,11 42:19	341:12 361:6
LD 2:2	81:15 101:12	274:20 281:7	46:13 68:11,22	looking 9:5 13:3
LDO 223:11,16	124:10 126:11	288:15 320:8	70:14 83:9 341:2	25:21 36:2 40:22
224:18 257:12	170:15 265:6	330:16	longstanding 152:2	41:17 44:5 45:19
LDOs 185:22 223:8	271:22 288:8	Lisa's 219:8 277:4	long-term 15:7	52:3,6 53:13
226:19 257:6	291:18 303:9,13	list 63:3 199:9	79:1 247:6	60:18 68:2 74:8
lead 221:16 277:14	319:9 320:14	listed 253:4 282:7	look 5:16 10:10	74:17,18 84:13
327:7	340:13	listened 305:6,8	15:14,15 16:1	99:5 106:1 151:16
leading 57:16 65:8	levels 301:9	listening 69:10	20:4 33:21 34:13	154:6,7 171:8,10
leads 13:10 74:4	life 40:10 67:2	223:17,18 335:2	43:7 47:4,22 58:4	171:10 181:12
254:15	72:17	352:9	63:19 68:14 69:17	185:9 191:10
lean 85:14	lifestyle 54:2	lists 200:4	73:15 75:7,15	212:5,6,9,22
learned 17:4 22:20	likewise 210:9	liter 30:12	76:4 83:15 86:9	237:4 241:10,11
67:13 352:18,19	353:1	literature 31:15	88:10 100:7	243:10 266:11
353:1	limit 7:16 45:14	32:16 44:15 79:7	102:17 103:15	268:4 271:16
learning 122:10	87:18 243:13	80:6	105:8 130:5,6	281:16 282:3,5
333:20	348:19	little 5:14 6:20	135:14 136:15,18	293:16 296:20
leave 49:5 112:18	limitation 243:18	11:22 19:16 39:3	138:3,16 139:20	297:4,4,7,19,21
112:20 172:16	limitations 242:21	39:6 42:1 44:18	139:21 140:21	298:16 306:12
286:4 359:7	293:19 304:10,13	46:6 67:22 88:6	141:22 147:18	316:18 327:19,20
leaves 200:3	307:20 334:3	108:17,18 117:12	149:7 151:9,14	327:21 329:18
leaving 96:6	363:12	133:13,16 145:19	154:7 159:1	330:4,7 346:17
LeBEAU 1:25	limited 26:18 41:16	147:15 265:4	161:20 163:5,10	352:1 353:6,14,18
41:18 67:21 328:2	122:5 146:12	284:9 288:2 290:1	164:9 178:7	364:7,15,18
351:19 355:19	242:7,22 287:13	300:13 317:6	181:15 184:6,12	looks 77:11 138:4
left 61:3	332:1 361:12	326:10,15 348:1	184:16 193:9	149:8 182:2 200:9
legal 288:19	limiting 143:6	live 40:9 67:7,11,12	195:6 202:13	200:10 212:7
legislative 155:15	147:10	191:14 317:8	204:17 213:11	276:5 338:1

look-alike 357:21	37:6 209:22	matter 22:16,18	4:19 5:21 6:5	157:10,18 158:10
loophole 271:14	major 43:3 58:8	116:12 154:2	9:15 10:14 11:16	158:14 161:7,13
loops 353:2	277:15 283:19	208:7 221:11	12:14,17,18 14:8	161:13 164:12
lose 35:5 105:11	327:12,16	299:13 322:15	16:4,7,10 18:7,15	165:2,14,18,19
128:21	majority 352:16	368:15	18:16,18 19:2,3	166:1 170:15
lost 66:18,19 346:2	making 15:9 43:9	MBA 1:14,24	19:12,17 20:1,4	171:18,20 172:6,7
lot 5:5 10:20 17:8	186:1 193:12	McGONIGAL	23:12,13,14,14	173:3,18,18 174:1
61:5 65:10 67:16	200:15 258:15	2:19	24:11,11 25:5,8,8	174:4,17 175:3,6
67:17 75:18,22	331:4	MD 1:13,17,18,19	25:18,19,20 27:10	175:13 179:13,14
94:2 133:18	manage 302:1	1:20,21,22,24 2:1	28:22 29:6,21	180:1 183:9
136:15 137:11	management 3:5	2:3,4,5,8,12,21,21	30:9,10 31:2,16	187:10 188:3
138:2 140:8,10,10	11:12 12:4,12	mean 19:2 28:5	31:19 33:3 34:7	189:10,20 190:2,3
148:12 153:18	13:17 14:21 17:18	32:8 43:16 45:10	34:20 36:14,18	190:6 193:20,21
162:13 169:8	55:3 57:5 59:22	62:11 74:22 81:12	37:8 39:11,19	194:9,22 195:9,18
176:21 189:6	60:12 66:3 88:6	86:7 87:1 88:16	40:21 41:12 42:5	196:4,12,15,17,20
191:22 194:1	90:13 125:11	98:2 105:13 111:3	43:16 44:14 47:13	197:7 199:17,19
195:2 200:3,17	128:4 229:16	130:21 133:13	50:13 51:1,4,15	200:3,10,19 203:7
202:20 215:15	296:3 353:10,10	137:16 149:4	51:18 55:5,15,16	203:19 204:8,18
227:3 247:4 248:3	Manager 2:15	158:7 160:8 166:7	57:2 59:3,9 60:14	205:1,2,9,15,17
258:7,12 261:1	managing 299:7,10	186:4 188:21	61:9 64:1,15,22	206:7 207:2,9
296:12 307:7,13	mandate 75:14	189:8,11,17 192:4	66:17 70:1,8,15	209:4 210:3,8,11
329:4 336:7	155:15 166:6,21	193:1,8 203:20	70:21 71:6,18	211:20 212:7
338:16 346:2,13	185:3 187:5 218:7	215:16 216:4,5	72:10,12,17,21	216:8,11 217:20
347:19 348:12,15	258:11	219:1 225:20	73:1 76:3,17 77:7	219:14 220:2,9
351:9,11 352:4,18	mandated 120:19	226:22 230:19	77:15,22 78:7	223:21 224:1,5
354:21 355:13	166:5 181:2 182:1	231:6 240:20	79:21 81:15 82:8	225:10 227:8
356:3,8 357:18,20	182:16 184:3	241:14,18 244:8	84:17 85:3,9,16	228:6 231:2,3,12
364:7 367:13	258:17 259:10	244:10 245:16	86:3,19 88:1,3	231:12,15 233:7,9
368:7	mandates 119:19	246:8 257:9 258:6	89:9,12 90:4,11	234:14,20 236:1
lots 50:22 359:13	146:9 147:2	260:8 272:11	91:2 92:13 94:1	236:20 239:22
359:14	mandating 74:4	277:15 286:14	96:16 99:12,17	240:2,3 241:9,15
love 18:19 29:4	259:15	299:1 300:5 307:7	101:5 102:8	241:17 242:3,4
129:18 359:16	manner 347:19	319:22,22 320:3	105:15 106:20	244:18 245:12,19
low 32:17 87:8	manual 185:8	320:10,20 335:1	107:1,6,11,16,18	247:18,19 249:13
128:13,15 210:10	manually 227:19	346:8 350:11,21	109:9,16 113:1,4	249:14,19 250:17
347:17	257:7,17	352:11 356:15	116:5,18 121:21	250:21 252:4
lower 7:16 32:15	man's 51:8	359:3 361:15,17	122:1,15 123:19	253:14 259:7
254:22	March 310:7	meaning 266:8	124:8 126:21	260:10 261:15
low-end 128:4	mark 151:4	meaningful 140:1,6	130:15 131:9	262:17,21 263:4
lunch 196:1,2,13	marker 54:16	290:19 332:11	132:12,17,18	264:11,16,17
207:19,20	market 338:13	means 21:11 61:18	135:11,11 136:17	266:10 267:5
	Marriott 1:9	228:14 230:11	139:19 141:17	271:2,7,14 272:20
M	mass 85:14 146:16	268:5 270:4 311:5	149:6,10 150:11	273:8,10 274:17
MA 2:15	materials 359:14	364:2,2 366:8	150:13 151:20	274:18 275:6
main 155:8 210:10	mathematic 157:13	meant 133:17	152:5,7,12 153:4	277:6,21,22 278:5
maintain 164:8	matrices 167:21	250:22	153:10,13 154:22	279:4 280:11
maintenance 25:15	matrix 213:18,19	measure 3:18,21,23	155:6,9 156:2	281:6,13,14,15,15

282:2 283:9	70:22 80:11 83:6	measure-develop...	memo 277:8	36:6 62:22 77:2
285:12,15,17	87:22 88:10,21	363:4	memory 238:19	84:7 89:21 95:15
287:13 288:6	89:2 92:15 110:3	measuring 64:16	310:2	124:18 125:16
291:5 293:3,16	116:5,7,17,19	118:14 227:15	mention 83:11	126:8,13 180:2
294:22 295:14	118:2,3 119:9,12	307:2 331:3 333:2	136:2 157:14	218:22 269:13
296:11 305:18,22	120:6,7,11,12,15	mechanism 104:2,7	185:20 212:21	292:6 299:14
306:8 307:2,6,14	120:18,22 121:2,3	104:15 120:4	285:11 331:10	332:18 339:6,20
307:15,21 308:19	121:16 122:20	media 296:2 355:4	mentioned 77:8	340:4,16 341:8
311:14,20 312:21	123:10,16 124:1	Medicaid 2:17	78:6,6 91:2 191:5	343:5 348:3 364:4
312:22 313:1,15	129:10 132:4,9	medical 49:7 57:18	222:15 233:12	metrics 8:20 53:13
313:16,19,22	134:11 135:8,17	104:18 118:5	237:3 285:9	53:14 117:2,3
314:13,16 315:1	136:22 140:9,19	183:14 189:14	324:21 326:7	121:15 153:17
315:11,13 316:9	147:4,8 151:9,15	334:9 353:18,22	327:17 351:1	164:10 166:10
316:14 317:21	153:19 154:13	354:10 366:18	merits 260:10	168:21 213:6,13
318:14,15,18	158:9 179:3 181:4	Medicare 2:17 4:8	262:17 288:11	213:19,19 214:15
319:10 320:16,16	181:12,15 195:2,8	109:6 236:2,4	message 302:7	331:8 340:15
321:14 322:21	199:20 205:7	240:12,16 241:2	MESSANA 2:19	342:19
324:5 325:10	212:5 216:17,18	241:15 242:3,8,10	21:17,20 35:20	metro 1:9 188:18
329:2 331:13	217:3,21,22,22	242:14 243:14,17	55:22 56:2,4,8,12	microalbumin
337:16 338:13,14	219:12,18 220:13	243:20,22 244:3	56:16,20 57:8	338:5
338:15 342:4,19	221:6,11,12,13,16	246:16 247:10,11	58:17 59:6 61:22	microbiologic
347:9,11 351:10	222:16 225:6	247:12 260:1	63:7 96:17 97:7	161:7
356:1,21 357:2,4	230:10,13,21	293:15 294:4	97:15 98:16	microphone 211:11
362:18 363:14,18	231:7,11,19 233:6	305:13 335:14	100:12 103:18	264:13
364:17 365:14,16	234:2,4 237:22	Medicare-appro...	104:11 106:14	miles 188:15
366:10	238:9 239:21,22	335:7	215:1 216:10,13	milliequivalents
measured 20:3	241:19 247:14,22	Medicare-insured	218:11 219:5	30:12
38:6,22 52:16	250:22 253:3,4,5	241:7	220:7,19 224:6,9	milliliters 77:18
189:21	254:18 256:17	Medicare/private	238:15 239:11	79:4 80:3
measurement 2:12	262:9 265:7	240:14	247:8 249:2	millions 76:11
6:8,14,22 7:14	267:22 268:4	medicine 1:17,18	255:16 267:14	mind 82:2 94:16
52:15 146:7	271:16 276:8	1:22,23 13:2	268:9,19,22 269:8	111:14 193:22
153:21 213:1,4	279:19 281:4,5	48:13,14 64:13	269:20 270:3	334:7
227:3,13 259:10	284:10 293:21	65:10	271:6 277:7	minds 75:9 202:17
measurements	303:4,10,16	meet 30:3 34:10	messenger 228:8	mine 310:3
353:10	304:11 322:13	76:20 89:19 142:3	met 1:9 17:20	minimal 14:18
measures 1:3 3:4	323:21 324:3,17	195:4 230:13,14	54:20	114:21 252:18,19
3:15 4:2 5:12 9:6	325:3,13 326:5,10	meeting 130:11	metabolic 39:8	266:18,20
10:9 11:12,17	326:11 327:1,22	233:10 296:17	method 6:8 100:3	minimally 14:3,4,6
12:3,11 22:18	329:8 331:18	360:11,11 367:19	100:21 104:17	26:6,8,10 33:5,6,8
24:1 27:20 32:4	332:4,4 337:16,17	368:12	159:22 249:1	37:14,18 81:4
36:3 45:19 48:9	338:2,7 344:11	meets 102:16	361:4	91:17,20 114:10
48:13 49:1 50:1	350:3,14 351:20	member 215:2	methodology	115:8,13 142:5,8
55:16 57:10,10	355:15 357:11,17	363:7	241:22 244:2	152:16,20 153:2
58:3 61:14,16	357:19,21 358:4	members 57:17	289:22 294:17	194:19 195:16
62:17,19 63:13	358:14 361:11	Member/Public	methods 331:5	206:11,17,22
64:14 65:12,19	362:9 363:2,3	4:18	metric 9:12 23:7	235:4,9,14 250:2

250:6,10 263:9 264:1,5 274:1,6 274:11 276:9,11 276:12 278:10,15 278:18 285:1,2,4 312:1,5,9 314:5,6 minimals 314:4 minimize 199:18 232:18 minimum 6:11 51:19 52:13,20,22 70:6 74:19 92:5 93:1 minimums 45:20 minor 28:4 179:11 minorities 330:9 minority 283:22 minus 93:19 264:17 minute 12:10 104:22 213:9 349:18 minutes 36:17 49:5 190:20 207:21 359:10 misconstrued 62:1 missed 143:3 missing 15:21 112:13 143:5 151:4 242:19 265:16 352:5 misspoke 99:10 mistaken 59:6 misunderstood 256:22 mix 254:1 313:11 mixing 160:17,19 modal 6:12 modalities 333:16 modality 339:16 348:9,15 model 60:5 169:4 283:1 modeled 345:3,4 modeling 26:19 28:19 29:12 51:17 51:22 311:6	models 53:9 300:2 310:22 moderating 367:22 modifiable 125:12 modifications 155:7 156:8 modifier 236:14 238:16,17 239:3 249:8 modify 147:19 module 134:14 158:10 166:10 188:7 molecule 61:4 Monday 68:17 185:21 188:12 monitor 106:12 259:22 monitored 167:19 monitoring 92:14 92:18 104:16 105:21 107:17 251:8 Montefiore 1:21 month 20:15 25:7 25:13 30:13,20 92:6 96:4 97:12 98:14 99:4 102:10 102:18 133:12 142:20 144:6,9,12 144:14,18,20 145:8 156:22 183:10,18 186:4 236:15 343:4 354:9 360:4 monthly 7:13 65:18 96:21 104:4 132:19 months 7:22 8:7,8 36:20 46:11 73:9 91:6 93:8,11 105:5 125:17 132:22 143:8,9 155:3 157:9,11 211:6 251:18 264:21 289:17 297:6,12 304:7	309:13 347:14 357:16 month's 97:14 morbidity 64:7 66:22 118:19 morbidity/morta... 15:1 50:20 morning 118:4 123:13 133:20 185:21 188:13 300:15 mortalities 57:16 mortality 42:14,21 64:6 66:22 71:22 78:9 118:20 124:9 298:13,13 304:1 motivated 104:14 motivates 121:15 move 5:9 8:21 12:3 24:18 30:5 36:5 42:14 54:8 62:3,9 76:14 77:1 111:7 116:6 132:8 152:12 164:12 209:7,8 234:11 249:12 262:16 273:6,17 274:18 281:4 300:2 309:13,21 310:12 321:12 340:18 347:3 357:4 364:5 movement 61:4,5 364:10 moving 5:13 46:7 106:18 153:9 168:18 169:3 207:22 289:15 309:15 360:3 365:3 MPH 1:21 2:12,21 MSN 2:6 MSPH 1:24 multiple 46:11 47:8 84:22 168:2 240:6 270:13 multi-system 353:7 353:11	multi-week 127:13 mumbly 117:12 myocardium 58:6 Myra 1:21 3:6,14 12:5 15:12 18:20 19:22 84:19 90:1 105:2 163:17,17 164:15 168:4 169:7 188:8 246:18 306:10 307:5 329:12 Myra's 330:18 myriad 213:6 <hr/> N <hr/> nailed 32:5 NALLY 2:1 48:1 50:2 54:11 62:3 102:15 104:8 162:20 163:14 201:2,22 280:5 293:22 296:15 297:18,22 298:3,7 308:22 309:10 318:16 333:5 353:12 name 6:5 117:19 names 339:6 Narva 2:8 4:6,10 87:20 229:22 250:20 253:10 254:20 256:1 264:16 268:13,20 269:6 337:21 346:5 367:21 national 1:1,16 2:4 2:8 3:17,19,21 23:18 119:10,14 124:13 130:3 132:10,15 153:12 196:18 222:13 291:18,22 292:7 294:7 336:2 nationally 291:19 348:5 nations 64:9 nature 326:17	327:14 nauseous 328:8 NDS 227:10,11 near 93:10 necessarily 189:19 215:19 230:8 248:17 255:4 320:2 necessary 162:2 192:12 need 10:7,18 12:9 19:12 20:1 42:13 47:4 51:4 52:4 54:7 60:16 61:12 65:3,16 70:12 72:3 75:7 76:4 83:15 89:10 99:14 101:19 104:17 150:4,6,20 151:14 151:22 154:7 157:7 164:9 171:13 173:11,13 176:20 178:21 185:14 189:13,16 191:3 205:8 211:13 217:6 218:22 224:16 229:12,17,18 230:6,15 233:10 256:11 259:21 267:9 273:1 279:6 282:3 284:15 285:18 291:3 303:18 307:15 321:6 324:4,7,21 325:1,7 328:1 329:8,16 331:15 334:1 337:21 343:12 344:7,10 346:7 347:2 351:6 354:20 356:10 358:2 362:13 363:16 367:9 needed 38:7 58:10 101:13 134:3 needing 44:19 needs 20:6 23:18
--	--	--	--	--

47:18 63:1 70:7 93:3,14 98:14 124:16 156:4,19 180:11 300:9 307:9 329:18 340:18 347:6 negative 31:4 78:19 269:19 272:22 307:6 neither 85:9 178:20 179:5,7 nephrocentric 352:11 354:22 nephrologic 345:21 nephrologist 3:14 69:12 90:1,3 94:19,22 96:3 97:16 102:13 168:10 299:14 301:15 308:15 340:5 341:22 342:2,12,21 344:21 347:13 nephrologists 57:20 74:11 94:4 287:6,8 301:18,22 330:2 344:3 346:11 347:20 350:6 352:12 353:21 nephrologist's 298:21 nephrology 1:19 2:5 93:7 342:6 net 171:9,9 354:20 network 1:25 3:18 3:20,22 119:15 132:11,16 153:12 196:18 202:11 294:10 networks 120:20 never 162:5 300:6 new 3:10 8:21 19:6 36:8,12,15 37:3 38:11 42:6 53:20 53:21 69:18 70:9 71:8 72:1 92:16	95:20 96:4,10,11 97:5,7,22 98:1 101:4 102:9 122:10 132:21 209:18 251:20 264:20 267:16,19 268:2,5,18 295:9 295:14 331:2 341:17 347:6 349:15 NHSN 3:18,20,22 119:15,15,20 120:2,7,8,18,19 120:22 122:5 132:16 134:13 147:8 153:9,13 154:13,18 155:13 155:16,21 156:3,6 157:10,15 158:9 165:21 166:20 181:3,6,18,22 185:5,6 188:7 196:10,15,19 199:21 214:18 221:12,14 231:3 232:13 233:17,19 NHSN's 255:17 nice 213:16 237:17 nicely 41:5 nicer 360:7 night 42:1,11 366:2 NIH 2:9 62:12 63:6 76:11 NIH-funded 43:4 nine 114:8 115:7,8 125:17 153:1 195:15,15 206:17 235:19 250:10 264:9 273:15,15 274:1 278:2,3,9 297:6,11,19 298:5 304:6 309:13 312:5 nine-month 125:20 126:1 330:4 NISHIMI 2:21 NKF 334:18	nocturnal 44:20 74:15 nods 205:12 noncontroversial 49:15 nonresponsive 128:6,12 non-access-related 255:2 non-compliant 17:15 non-optimal 339:19 349:16 non-physicians 338:18 non-reporting 265:9 non-reviewers 82:10 norm 137:18 292:1 292:4 normal 50:6 344:19 norms 137:7 Northwest 1:14 nos 13:22 14:8,10 24:15 25:22 30:2 34:10 37:9 92:1 142:10 152:10 205:22 206:2 211:15 263:2 276:13 285:5 314:8 note 79:11 96:4 98:19 102:18,21 104:10 124:1 136:4 noted 197:8 notes 16:3 90:5 130:5 133:18 253:11 notified 9:9 notion 245:1 300:10 nPCR 6:15 NQF 4:18 48:21 49:22 51:7 52:22	53:12,18 54:9 62:9 63:4 179:2 225:8 229:12,18 239:21 259:5 284:11 310:20 323:1 334:14 338:1,14 346:16 347:8 350:2 356:18,20 357:5 360:2 368:2 NQF-approved 166:1 NQF-endorsed 51:1 318:15 326:10 331:13 NRAA 228:13 number 6:5 7:20 25:10,13 27:21 30:15 31:1 44:19 45:7,9 49:12,13 57:19 64:19 71:20 76:17 77:2,16 95:18 96:12 103:21 133:6 137:2 146:1 155:1 170:2 196:21 201:5,11 209:4,18 209:21 242:20 248:12 251:18 252:2 254:20 264:11,21 265:11 274:19 279:4 281:6,17 289:3 313:6,8 315:4 316:4,6 337:6,11 340:20 341:4,6 347:18 349:4 365:18 numbers 93:13 145:2 177:9 243:4 254:22 282:4 304:2 318:19 353:15 numerator 7:20 20:9,21 25:10 27:10,20 28:9 30:14 39:10 77:16	91:9 95:18 109:21 133:4,5 139:13 144:13 158:5,13 158:14,18 198:19 209:17 236:10 238:10 239:3 251:20 264:21 269:22 272:8 281:17 282:3,5 313:5 341:6 365:5 numerous 155:11 nurse 66:14 67:14 94:8 99:2 198:13 275:19 277:11 nurses 188:13 189:6 nursing 227:1 282:18 284:12,14 319:6 320:22 321:5 nutrition 73:21 332:20 335:7,16 335:18 nutritional 108:11 Nutritionally 107:21 N.W 1:10 <hr/> O obese 85:11 objections 111:9,11 objective 88:11 180:13 337:2 objectively 20:2 obligated 355:14 observation 47:2,4 289:18 342:10 observational 47:8 47:18 78:15 observed 291:19 observing 186:2 obstacles 232:15 obtained 255:14 obviate 84:5 obviously 60:9 74:22 134:22 142:22 169:2
--	--	--	---	--

231:2 290:7 328:3 332:17 344:16 351:7 352:3 occur 171:6 211:8 344:14 347:2 occurred 82:16 193:3,12 360:21 occurs 169:1 289:4 347:19 odds 80:1 offensive 66:12 offer 41:19 151:21 356:8 offered 134:11 offering 50:14 Office 1:16 officers 57:18 218:13 officio 2:8 offline 9:4 oft 324:6 oftentimes 142:21 335:11 oh 5:17 6:7 26:9 48:2 89:10,15 130:5 140:21 141:8 196:5 211:15 255:21 258:3 270:15 288:4 321:22 okay 5:21 6:6,7 8:2 8:15,16 9:21,22 10:21 11:5,9,9 12:2 14:11 16:20 23:19 24:5,6,17 26:2 27:4 29:15 29:19 30:4,8 34:1 34:18 36:4,5,13 37:21 38:1 43:10 56:3,16 57:8,11 58:9 63:18 67:13 76:5,15,16,22 80:21 81:1,20 82:9 83:3 89:4,7 89:11,15,20 95:13 99:1 102:14 106:13 107:8	110:22 111:6 112:15,22 113:6,7 113:15,20,22,22 113:22 114:2,6,6 114:7 115:3,4,9 115:14,19,19 116:1 117:4,10,21 118:1 124:5 132:2 132:6 135:22 138:17 139:1 145:4,10 147:11 150:15 151:6 152:3,4 153:3 165:13 178:9 179:1 186:19 188:2,8 190:4 193:15,20 194:5,8 194:15 195:22 196:14 202:3 205:14,15 206:6 206:15 207:1,7 211:22 215:9 220:21 222:11 224:8 234:7,19 235:5 249:18 250:3,16 255:22 261:12,20 262:15 262:19 263:3,16 264:6,10 273:8,13 274:12,16 275:1 277:17 278:4,19 278:22 279:3 280:19 281:12 289:10,10 297:22 312:6,10,20 321:11,13,19,22 322:5 323:16 334:13 367:3 old 32:22 106:6 older 35:14 247:7 once 61:15 92:5,6 92:20 97:12 98:3 122:1 195:5 253:17 259:14 268:9 319:1 324:13 339:1 ones 19:5 140:9	143:14 173:13 237:8 239:13 268:1 283:12 318:6 one-day 162:22 164:3 one-month 112:19 one-year 292:20 293:3 ongoing 221:3 onset 180:20 onus 104:8 open 314:9 326:20 327:8 342:8 opened 133:19 opening 220:21 OPERATOR 207:12,15 323:9 323:14 opinion 51:8 107:10 136:14 162:17 205:8 opinions 145:18 opinion-based 342:5 opportunities 346:14 opportunity 8:17 10:15 62:20 64:2 121:7 130:1 172:4 226:7 229:6 252:16 265:18 322:19 346:2,3 349:22 350:18 355:6 356:5 opposed 72:12 128:17 134:12 168:19 215:16 220:16 242:3 268:7 283:14 284:5 opposite 28:17 60:20 298:20 optimal 70:7 339:11,14 341:12 341:14,19 348:3,6 348:22 349:4,11	353:9,10 optimum 90:19 option 226:12 252:13 optional 226:16 260:7 options 334:9 oral 151:3 order 97:11,17 98:1,5,13,20 101:15 102:22 126:4,10 154:18 154:20 290:13 331:3 orders 71:8 149:13 Oregon 2:2 organisms 147:22 organization 147:2 184:21 185:7 198:21 257:10 organizations 57:19 122:3 184:14 214:17 221:3 287:15 327:21 329:21 338:11 347:7 353:19 359:21 organize 359:13,15 organized 323:22 oriented 59:17 original 73:18 328:17 originally 81:10 Orleanian 19:6 ought 290:15 outbreaks 157:19 outcome 14:19 15:7 70:1,2 120:15 124:8 253:5,8,14 254:9 254:11,15,17 269:19 282:1 326:1,1 337:16,17 339:10 366:6 outcomes 32:13 37:2 38:4,5,14,21 39:1,2,5 40:11	41:17 44:22 46:22 52:10 53:11 69:6 69:17 76:8 78:11 79:1 80:2 88:13 124:12 202:11 203:1,2 281:15 318:3 326:16 331:21 335:19 337:22 346:9 outlying 105:3 outpatient 25:14 112:6 119:6 132:20 133:1,8 159:4,14 160:14 163:22 164:8 176:21 177:13 178:6 180:9 184:18 193:4,14 268:12 331:7 347:15 outpatients 155:2 196:22 outpatient-acqui... 169:14 output 253:10 outside 41:22 200:10 223:1 261:14 overall 13:3,18 15:9 30:21 32:20 135:9 145:2 181:15 210:5 211:14 212:2,22 221:17 233:5 236:5 237:7 253:13 254:18 266:14 303:12 overcome 232:16 overlap 135:7 overlapping 212:12 234:6 overload 7:10 overloaded 18:1 overuse 149:19 overwhelmed 346:12 overwhelming
---	---	--	--	--

339:2 over-committing 83:9 over-stressed 165:4 owners 175:6 ownership 168:9 o'clock 300:15	233:1 234:7,13,19 235:5,11,15 238:8 239:19 249:13,18 250:3,7,11 253:7 254:12,16 255:18 256:10 257:18,22 259:4 261:20 262:4,19 263:3,17 264:2,6 273:8,12 273:16 274:3,8,12 277:21 278:4,11 278:19,22 279:18 279:22 280:15,19 280:22 281:2 310:19 311:13,19 312:2,6,10,13 321:13,16,22 322:5 323:18 325:11 327:6 331:10 356:20 358:15,19 359:1 360:2,15 362:10 363:11 364:12,18 364:21 365:2 367:3 368:10	108:11 111:14 125:13 127:7 131:4 162:14 165:21 166:20,21 177:6,6 182:12 183:22 184:22 220:9 221:17 223:8,11,15,19 224:14,21 227:22 250:21 259:11 270:9 306:6 331:19 333:2 335:14 361:9 362:14 363:3 partial 142:8 252:18,19,21 266:19,21 314:5,6 partially 14:2,4 26:6,10 33:5,8 37:14,21 81:2,3,5 91:17,19,22 114:9 115:8,13 142:4,6 152:16,20 153:1 194:14,19 195:15 206:11,17,22 235:4,9,14 248:12 250:2,6,10 263:9 263:12,22 264:5 274:1,6,11 276:9 276:11,12 278:9 278:14,15,17 285:1,4 292:3 312:1,5,9 partials 314:3 PARTICIPANT 271:15 participants 57:21 participate 148:5 188:6 218:8 225:1 247:3 258:11 participating 122:6 participation 89:2 233:13,19 particular 32:17 40:21 61:9,10 77:20 83:12 137:7 150:13 175:18	183:9 233:10 254:19 277:5 particularly 39:6 64:19 129:16 151:18 152:1 162:21 199:7 251:2 286:11 294:1,7 319:2 partner 2:19 214:19 Partners 2:21 parts 160:6 pass 6:18 7:1,4,11 8:11,15 23:8 24:15 110:11 117:2 Patel 2:21 117:6,10 117:16,20,20 118:1,4 134:9,15 134:16,18 137:9 137:13,16 139:6 144:1,4 145:9 158:20,22 166:18 166:19 175:10,19 175:20 179:17,18 179:21 180:4,5 182:10,11 183:4 190:1 192:16,22 193:1,7 198:6,7 199:3 201:8,15 202:3 204:11,12 215:2 path 65:17 patient 2:7 6:12 16:16 17:1,12 18:10 21:3,5,22 22:5,20,21 23:13 42:14 53:22 55:7 59:11,15,17 60:11 66:16 67:1,4,11 67:12 69:18 71:9 71:19 72:2,6 85:4 87:4,5,7,16 90:13 92:8 94:12 98:4 98:14 101:18 102:11 118:20 124:11,20,20	128:7,12 132:22 134:20 144:14,17 145:6 148:2,15 155:3 157:8,9,11 157:11,12 159:2 159:15 170:9 176:12 177:7 180:3 186:7,8,19 187:2,4,11,18,19 189:5,7 191:6,8 192:18 200:4 204:5 205:10 209:17,22 210:17 210:20 238:21,22 251:17,19 253:19 266:1 267:3,6,17 268:10 270:20 271:21 282:22 283:6 288:1,17,22 298:22 300:8,9,14 301:11,19 302:10 302:14 304:16 305:11 313:11 314:14 315:2,19 317:6 319:1 327:17 332:4 333:11 334:2,19 335:5 337:18 339:15,19 340:7 340:10 342:20 346:21 354:2,16 355:22 356:4 patients 2:6 3:10 6:15 7:1,7,14,17 7:20,21 8:3,7,10 8:14 12:22 13:7 13:11,18 16:6,8 17:2,8,14 18:17 18:17 20:16 25:6 25:11,14 27:2,9 27:21 29:1,13 30:10,15,18,19 31:4 35:5 36:8,12 36:15 37:3,5 38:11,12 39:7,7,7 39:11,12 40:6,7,9 40:14,20 42:6,6
P				
PA 94:8 Pace 2:14 5:4 9:14 9:17,20 10:1 11:2 11:5,7,9 14:13 22:2 24:10 26:2 28:1,4 29:20 31:21 33:2 34:6 34:18 35:11,14,18 37:13,17,20 43:14 43:20 44:1 45:9 73:11 76:16 80:10 82:12 83:11,19 84:1 89:9,14 95:5 95:12 99:9 100:1 107:14 109:18 110:1,4,7,10 111:8,13,21 112:3 112:8,14 113:2,6 113:11 114:2,6,11 114:15,18 115:3,5 115:9,14,19 116:1 117:14,18 123:11 123:21 124:5 130:9 131:20 132:2,6 136:16 152:5,11,17,21 153:3 174:2 175:15 179:2,16 187:8,16 193:20 194:4,8,15,21 195:17 196:3,8,11 198:18 202:1,5 203:17 205:15 206:6,12,14,19 207:1 208:4 211:10,17 225:18 225:22 226:21 231:1 232:1,9	package 92:14 220:1,10 page 15:2 102:5 284:21 324:1 paid 31:21 258:5 pairs 256:5 panel 106:21 panelists 92:3 panels 129:12 350:2 paper 277:8 341:11 paradigm 88:20 parameter 309:11 316:11 pardon 196:4 parenteral 255:7 parents 307:10 Parker 329:7 part 13:7,17 14:16 20:20 22:17 59:16 71:11 92:13 101:1 101:3 105:14			

52:15 60:15,15	340:6,11,20,21	pede 238:22	189:8 201:13	282:12 296:21
64:8 65:4,8 66:11	341:5,6 342:11	pedes 113:3	220:22 222:20	310:15 312:14
67:1,5 68:10,21	343:1,3,9 345:5	pediatric 6:12,15	223:12 228:12	313:8,11 330:4,19
69:7,13,14,20	345:15,20 346:15	6:22 7:7,14,17	233:19,21,22	350:20
70:4,9,11 71:12	347:13 348:3,8,13	9:11 35:9 69:11	240:22 296:1,4,6	periodic 3:13 89:21
76:9 77:10,13,16	348:14 351:7,13	107:17 109:4,9	340:18 341:17	90:2,10,16
77:20 79:5,12	352:20 353:6	111:10 126:22	345:20 348:7,8,17	periodically 93:3
84:20,21 85:17	355:7 356:3,9	149:11 150:1	348:22 349:2,14	periods 282:6
87:10 88:5 91:11	patient's 90:17	305:12,16,21	365:19,20	peripheral 164:5
93:6 95:18 99:4	patient-derived	317:12 350:3,6,13	percentage 4:10	peritoneal 112:19
105:2,19,22 106:2	332:4	350:22	8:6 172:2 264:15	238:21
106:12 107:17	patient-measured	pediatricians 350:2	347:12	Permanente 1:16
108:15 109:4,10	331:21	350:15	perception 327:17	321:4 339:22
111:11,19 112:10	patient-reported	pediatrics 109:13	331:20	348:12
112:18 124:12,17	351:20	110:21 240:15	perceptions 332:1	permit 157:15
128:15 133:9	patient-specific	316:18	perfect 42:12 94:17	permits 157:15
139:9 142:19,21	202:12	Pennsylvania 1:17	162:3,11 171:11	persistent 128:13
143:2 145:1 148:1	paucity 78:22	people 19:8 43:15	178:11,13,22	person 42:8,10
149:1,9,11 150:1	Pause 24:13 29:22	43:17,21 60:2	179:8,8 192:12	55:9 68:18 104:9
150:19 151:1	34:8 76:18 89:13	65:21 69:2 70:15	344:20	199:14 201:4
152:2 153:18	113:5 114:1,5	74:10,12 75:1,10	perfectly 171:13	277:11 322:20
156:21 164:3	115:6,11,16 152:8	78:10,11 88:17,22	perform 137:22	323:7 355:11
168:5 170:1	152:14,18,22	96:22 105:10	performance 2:12	363:5
174:11,15 176:9	153:5 194:3,12,17	110:17 125:21	12:22 15:17 25:19	personalized 75:1
177:17 203:10	195:13,19 205:19	128:20,21 146:16	32:10 36:21 48:9	personally 154:15
209:16 210:1	206:9,13,20 207:4	161:3 169:17	48:13 49:1 50:13	228:2 367:17
236:8 239:15	234:16 235:2,7,12	188:10 213:12	72:11,17 73:1	perspective 49:20
240:12,16 241:6	235:18 249:15,22	224:20 241:3	82:7 86:3 88:10	100:16,17 124:11
242:9 243:4	250:4,8,13 262:22	255:2 258:8 276:3	91:8 99:16 107:11	137:12 171:20
246:20 251:14,21	263:7,18 264:3,8	285:7 290:2,8	140:2,7 154:1,4	212:21 233:12
254:21 264:19,22	273:11,21 274:4,9	294:12 301:20,20	157:20 161:7	260:8 303:22
267:13 268:3	274:14 278:1,8,13	315:16 321:16	162:9 168:21	328:5 335:16
281:19,21 286:1	278:16,21 311:16	333:10 338:8,15	171:14 178:16,21	353:7 354:10,11
287:7,11 292:17	311:21 312:3,7,12	338:17 344:4	210:13 212:22	persuade 185:16
292:19,19 295:3	321:15	345:8 352:16	213:4 316:9,14	pertain 69:13
296:2,4,6 299:11	PAVLINAC 2:2	353:11,13 360:20	318:15,18 322:10	111:17
299:17 302:10	16:13 335:4	361:4 365:9	325:13 326:5	perverse 271:11
303:18 305:5,12	pay 94:4 338:16,17	366:15	327:1 338:2	Peter 1:10,13 3:19
306:13 308:11	355:14	people's 175:21	344:11 355:18	5:7 52:8 100:12
313:4,7,10 316:19	payer 50:21 320:12	200:3	358:10	102:4 122:18
317:2,13 327:14	320:12	perceive 175:11	period 8:1 9:14	134:5 187:2
328:6,19 330:6,8	payers 48:16,20	332:14	16:17 20:15,17,18	217:17 224:19
330:12 331:20	246:16	percent 48:11 49:2	20:20 59:14 83:9	301:14 367:21
332:2,9,13,22	paying 61:12 93:12	51:11 52:3 107:12	105:7 123:12	368:2
333:15 334:15,20	payment 227:12	129:19,20 136:7,7	127:3 130:4	Peter's 47:6
336:8,10,12,21	288:16,18	136:8,11 162:3	183:17 243:18	PharmD 1:14
337:4,6 339:10,10	PD 111:19,20,21	182:21,22,22	281:20 282:7,8,9	phase 104:1 294:13

phase-in 227:22	pilots 360:4	180:22 181:14	position 83:5 188:6	287:5 333:1
PhD 1:20 2:14	pipeline 73:10	223:6 226:6,17	positive 134:21	practice 3:6 25:1,3
Philadelphia 170:3	356:9	227:17 228:18	155:2 158:6,12,12	66:15 73:5 83:8
philosophy 168:19	Pittsburgh 294:12	230:9 231:1 239:1	158:16 159:20	90:9 93:4 98:2
212:21	place 14:1 37:16	260:3 262:7 271:4	160:19,20 163:1,9	154:6,8,9 185:20
phone 9:4 11:21	49:16 69:17	273:20 276:14	167:19 168:1	189:12 292:11
186:1 188:1	104:15 162:5	282:1,15 284:16	170:7 171:6	practiced 90:18
207:11 270:15	170:9 182:6	289:12 298:20	173:12,16 190:9	practices 90:7,13
322:20 323:8	191:14 220:3	299:19 310:1	191:19 192:19	119:6 125:10,11
326:19 363:9	222:5 294:15	313:20 344:16	193:2 196:22	125:11 336:7,8
phosphorous 8:10	297:1 301:8 303:1	354:5 357:15	198:10,11 199:11	practitioner 94:8
17:16 73:22	308:5 328:17	359:2	200:5 201:9,13	practitioners
physician 67:13	333:8 342:7 360:7	pointed 10:20 27:6	202:14 209:20	270:12
88:11 96:3 97:11	placement 236:14	45:5 95:4 110:8	210:3 217:12	prayer 160:1
98:13 99:5 101:16	places 172:15	168:4 181:20	256:6,7,15 267:7	pre 333:13
101:17,18 103:4	177:16 188:11	220:21	269:14 270:20	preceding 330:4
104:10 198:14,14	255:14	points 32:9 96:19	272:21	precise 19:16
200:21 334:13	placing 304:18	169:7 174:3	possibilities 336:15	100:22
336:9 355:20	plan 59:17 100:6	289:12	possibility 33:16	predicated 169:8
358:10 363:7,7	141:14 322:12	policy 22:16 124:13	292:16	predict 343:10,11
physicians 2:23	340:13	149:3 292:7	possible 79:16	predicted 283:5
17:11 75:9 97:1	plane 49:6	politics 168:17	116:10 129:3	prediction 294:16
201:5 267:9	planned 367:16	pool 52:20	130:16 138:1	354:13
287:11 319:17	planning 227:4	poor 38:3 343:22	144:1 159:6,8	predictive 352:2
330:1 334:12	plans 184:7	population 13:5,6	217:1 232:17	predictor 282:21
336:19 337:7	plasma 85:9,13	14:18 27:13 31:14	319:17,19,19,22	predictors 128:12
358:7	playing 358:21	34:15 35:12 58:15	365:14	predisposes 352:21
physician's 98:19	plea 353:3	109:15,19 118:21	possibly 55:8 181:8	predominant
98:20 100:18,20	pleading 85:2	119:8 133:15	197:19 201:1	214:16
101:22	please 39:16 59:5	147:10 148:15	post-dialysis 3:13	preemptive 339:15
physiologically	116:9 117:21	149:9 156:18	89:22 90:3,6,17	prefer 123:7
86:1	198:1 264:13	168:2 172:1 176:3	95:20,22 102:9,11	prejudice 40:19
physiology 85:8	323:11 351:19	195:9 204:5	post-discharge	preliminary 155:4
PI 53:4	358:20	205:11 241:11	170:19	197:4 235:17
pick 45:7 49:12,13	pleasure 132:12	243:8,20,22 244:3	post-testing 333:13	317:21
55:15 87:1 109:3	plus 93:19 237:17	244:4 260:1	potassium 300:18	premature 33:22
116:3 200:7	276:17 326:10	294:20 317:6	potential 32:3 58:8	151:12
305:12,20	pneumonia 160:20	328:18 349:11	96:22 345:14	prep 360:10
picked 31:2 145:5,7	POA 169:12	populations 57:14	potentially 78:19	preparation 358:11
picking 144:19	point 32:3 35:7	109:7 119:4	79:5 92:15 135:13	368:11
picture 161:21	48:1 52:12 58:10	306:13 330:8,12	159:11 170:4	prepared 213:13
171:10 176:1	63:16 86:16 95:17	338:12	260:6 285:10	347:21
213:20 241:5	109:12 115:22	portal 221:15	286:15 308:8	prescribed 25:6,12
365:10	116:17 122:4	portends 343:22	power 46:17	30:11,16 36:15
piece 42:7 107:8	132:4 141:21	portfolio 327:12,22	practical 16:18	38:18 74:18 211:4
pieces 258:13	144:2,4,19 149:19	portion 177:11	practicalities 332:8	211:6
piggyback 67:22	162:11 179:12	178:10 348:2	practically 215:14	prescription 38:16

53:22 72:4 94:13 95:21 96:1,18 102:9 prescriptions 97:18 presence 203:12 present 1:12 2:10 2:16 31:9 159:7,8 191:9 203:15 presentation 63:8 363:14 presented 16:11 46:10,15 62:18 80:16 President 2:12 presiding 1:11 press 113:12 323:11 pressure 35:2 73:22 92:14 135:12 172:17 358:1 pressuring 49:22 presume 268:22 269:9 pretty 14:12 129:21 149:12 177:13 212:3 238:11 258:22 328:16 342:10 347:17 361:16 prevalence 144:19 prevalent 39:12 prevent 168:1 265:7 271:14,20 preventing 146:13 prevention 2:22 118:8,11,16 119:11 153:21 preventionists 146:20 previous 132:22 133:7 244:17 264:17 275:3,5 313:15 314:13 previously 255:15 pre-ESRD 333:9 primarily 114:20	174:9 180:8,12 235:1 249:20 263:6 293:11 301:22 315:18 primary 12:6 33:11 41:20 81:8 124:8 132:13 153:11 184:11 242:14 256:2 266:15 287:3,10 289:1 330:1 331:7 338:12,19 342:21 353:17 354:11,17 prime 29:6 61:16 92:21 320:19 principle 99:13 146:6 343:19 prior 97:13 217:3 297:3 priorities 119:11 prioritize 181:16 priority 13:16 prisoners 330:8 Priti 2:21 117:20 134:9 215:2 233:15 private 246:16 proactively 299:7 301:2 probability 260:14 probably 23:7 46:4 51:5 65:7 70:6 73:8 82:5 88:1 116:6 123:9 140:15 141:6 171:19 204:5 234:1 254:1 282:11 333:1 341:9 problem 15:8,22 17:4 32:15 55:4 75:11 86:19 114:17 131:18 160:6 188:12,19 189:9,11,12 201:1 214:7 254:5 265:10 266:5	283:13,21 284:3,7 299:21,22 300:1 302:8,12 318:22 problematic 16:15 70:16 150:14 156:22 302:19 308:20 problems 62:11 128:3 165:3 167:17 189:18 283:11,20 302:9 319:13 proceed 11:13 121:11 282:11 proceedings 103:21 process 12:17 23:14 25:8 36:18 42:2 50:11,18 100:10 103:13 104:19 127:12,13 130:13,22 131:11 154:20 158:4 177:6 181:5 187:3 215:21 242:22 246:22 250:20 253:4,16 254:14 271:14 318:11 325:22 333:3,16 333:18 337:11,16 339:12 350:11 processed 141:8 processes 287:17 331:4 produced 291:15 productive 146:7 products 154:9 professional 214:17 277:10 professionals 16:7 332:3 profiling 3:6 25:1,3 25:7,12 28:13 35:4 prognosis 343:22 program 2:14 101:9 251:10 260:2	programs 343:2 progress 350:13 progresses 354:5 progression 351:18 project 2:15 54:15 71:21 92:22 229:13 237:16 326:12 327:7 331:11 367:8 projects 120:21 121:2 154:1,4 306:19 357:8 360:5 362:22 prominent 364:14 promote 336:3 338:9 promoting 83:7 Promotion 118:6 prompt 138:8 proper 93:16 properties 152:13 194:10 206:8 210:8 234:20 249:19 263:5 278:6 311:20 proponent 302:6 proportion 8:3,13 25:6 30:10 36:14 308:13 proposal 103:3 109:9 232:4 propose 18:22 279:12 309:20 310:11,13 318:13 proposed 31:2 102:6,7 107:10 108:14 214:15 279:8 282:16 326:11 358:13 proposers 44:14 proposes 170:15 proposing 44:14 294:22 prospective 47:10 47:14 48:9 52:5 proteinuria 344:20 protocol 183:19	prove 43:2 51:21 proven 40:4 PROVENZANO 2:3 44:17 65:15 74:7 75:6 93:22 96:9 164:14 167:11 169:2 185:19 186:11,16 187:1,13,17 244:14 245:5,8 258:6 259:2 260:12,21 262:2 270:11 280:3 286:19 288:3,14 301:14 314:12 355:1 361:3 367:12 provide 8:17 10:17 36:22 57:7 80:1 123:16 132:19 149:1 199:4,4,9 251:7 258:2 262:6 332:10,13 333:3 338:11 354:15 provided 36:21 80:19 210:13 provider 22:19 88:12 333:4,11 providers 54:5 125:13 174:15 296:13 299:17 315:22 provides 39:5 providing 13:13 69:6 120:9 217:19 proxy 311:2 prudent 214:13 PTH 352:5 public 13:16 26:14 118:9 119:18 123:12 141:5 152:1 179:3 196:12 207:8 252:9 322:9,19 323:1,10 publication 31:17 178:19
---	--	--	---	---

<p>publicly 32:1 184:7 192:14</p> <p>published 44:4 90:8 183:6 222:19 248:3,21 332:15 337:1 339:22</p> <p>pulled 183:20</p> <p>pulmonary 87:11</p> <p>purchaser 49:20</p> <p>purpose 69:9 168:21 184:11 202:15 227:3 251:4 265:3 314:16</p> <p>purposely 333:14</p> <p>purposes 227:15 237:6 269:12 292:9 316:1</p> <p>pursued 177:1</p> <p>push 53:14 341:8 348:17</p> <p>put 5:13 22:2 32:8 35:16,17 71:1 73:12 82:13,18 107:12 123:3 127:15,16 129:4 131:13 137:12 154:11 160:2 171:1,16 186:3 190:19,21 191:16 193:5 209:7 212:2 213:2 230:21 248:14 258:5 279:6 302:21 309:3 325:21 328:17 333:8,14 345:5 348:15 352:6 356:17 366:22</p> <p>putting 103:4 220:17 243:9</p> <p>puzzles 49:8</p> <p>P-R-O-C-E-E-D-... 5:1</p> <p>P.C 1:19</p> <p>p.m 208:7,8 209:2 322:15,16 368:15</p>	<p style="text-align: center;">Q</p> <p>QF 71:20</p> <p>QI 121:2</p> <p>qualify 335:13</p> <p>quality 1:1,3 13:9 40:10 54:14 88:20 90:11 118:6,16 120:3,13,21 130:4 147:16 179:3 192:13 227:3,8,13 227:15 229:16 247:3,5 251:5,9 252:10 253:16 254:7 261:15 325:5 326:3,4 327:1 347:10</p> <p>quantify 138:14</p> <p>quantitatively 365:14</p> <p>quarter 296:16 350:6</p> <p>quarterly 310:7,8</p> <p>quarters 309:12</p> <p>query 332:21</p> <p>question 23:17 34:13 51:7 56:5,7 62:15 69:22 86:11 95:14 100:13 101:8,8,11,12 103:1 111:17 112:4 123:22 136:17 138:22 139:5 145:13,15 151:18 156:11 158:3 165:20 169:11 172:13 174:18 177:20 179:17,19 182:12 182:14 183:5 187:14 192:22 198:7,15 201:8 204:22 216:2 218:21 219:8 222:22 224:12 225:3 226:22 227:14 231:19 237:21 240:8</p>	<p>241:14 242:11 243:6,12,17 245:4 245:18 247:8,9,16 253:3 258:14 261:22 277:4 287:20 291:1,13 293:7,8 294:1 296:16 308:18 309:2 310:12 314:19 332:8 333:6,9 351:21 352:8 356:15,16 360:17 361:9 362:5 363:17 368:7</p> <p>questioning 156:9</p> <p>questions 10:7 50:12 82:15,16 113:19 126:15 185:13 191:22 231:9 244:15 291:12 325:5 362:16</p> <p>queue 323:15</p> <p>quick 115:22 116:2 151:8 169:11 287:20</p> <p>quickly 34:16 78:11 86:21 116:10 129:3 242:18 343:12</p> <p>quite 18:8 60:20 64:5 74:13 85:9 95:15 133:5 141:15 212:10 241:18,19 248:21 287:13 303:13 308:13</p> <p>quote 31:20 32:6 79:19 265:22</p>	<p>312:15 313:16</p> <p>radar 192:4</p> <p>raise 86:15</p> <p>raised 79:20 156:11 362:5</p> <p>ran 62:12</p> <p>randomized 44:5 47:11,14 48:10 52:6</p> <p>range 45:13</p> <p>Raphael/Yale 1:23</p> <p>rapid 58:6 78:16,18 82:5 86:17</p> <p>rarely 300:11</p> <p>rate 3:12 4:5,6,8,11 66:22 71:22 77:3 77:6,11,12,17 79:4 85:12,22 86:14,17 87:8 120:1 132:19 139:15 143:2 148:10,14,16 204:1 209:5,10,11 209:14,16 236:4,7 248:6 250:18,19 251:16,17 253:14 253:17,21 254:2,4 264:17 274:20,22 275:4 279:5 283:5 283:8,8 284:13,14 308:12</p> <p>rated 210:10</p> <p>rates 57:13,14 58:7 78:9,18 79:2,11 79:15 82:5 87:8 87:18 135:4 149:11,22 152:1 155:17 157:22 165:1 172:21 253:15,19 284:11 330:11</p> <p>rate-based 86:2</p> <p>rating 366:18</p> <p>ratio 4:14,16 124:7 281:7,10 283:4,10 296:19 298:11 304:21 312:18,21</p>	<p>313:4 349:10</p> <p>rationale 10:17 56:21 57:7 78:2 130:17 286:16 324:16 362:8</p> <p>ratios 294:19</p> <p>raw 304:2</p> <p>RD 2:2</p> <p>reached 72:16 348:18,21</p> <p>read 6:11 26:1 36:13 213:12 270:22 329:6 341:11 345:19</p> <p>reading 33:15 65:2 205:14 287:22</p> <p>readmission 284:13</p> <p>reads 307:3</p> <p>ready 12:6 24:7 29:6,18 89:8 92:20 113:1 152:4 193:16 205:13 260:18 311:10 320:19</p> <p>real 186:21 190:19 316:2,14 329:20 337:17</p> <p>reality 94:21 169:9 176:9 191:14 192:8 214:1</p> <p>realize 72:18 75:19 84:12 180:8 204:14 234:21</p> <p>realized 228:22</p> <p>really 17:11 18:9 27:18 31:16 32:5 33:16 41:4,12 42:7 49:8 55:4,13 55:20 57:4 66:12 68:22 70:9 71:5 72:3 73:13 74:5 74:16 75:6,22 78:2 81:15 85:13 87:20 88:4 91:12 100:9 105:8,20 123:10 136:3,19</p>
		<p style="text-align: center;">R</p> <p>race 282:16 283:13 283:14,15,16,22 286:6 291:13,14 291:20,22 292:5 292:11 310:16</p>		

140:19 144:18	168:2 177:1 191:2	324:12 325:14	referral 334:13	174:9 203:12
145:13 146:2,22	290:21 344:18	345:7 361:14	335:10 340:5	209:20 236:13
151:21 154:7	349:5	Recommendatio...	342:6,13 346:8,10	238:20 247:6
159:21 164:18	reassess 333:14	4:19 325:9	347:19	249:20 263:6
168:13 175:11	reassessed 105:11	recommended 5:22	referred 143:7	275:9 294:7
176:14 179:9	reassure 153:17	6:4,9,13,16 7:4,8	219:16 340:11	295:22 296:1,3,12
192:4 199:13,18	rebut 131:16	7:11,15,18 8:4,12	342:21 343:2,4	306:20 308:14
204:2 213:17	recall 177:21	9:11 119:6 122:16	348:14	322:11,12 323:20
229:6 230:4	recap 3:2 5:3,6	126:9 324:18	referring 141:10	324:2 325:3 326:2
234:22 237:16	receive 20:17 77:17	recommending	330:1 337:12	330:5 340:16
239:13 241:4,9	134:22 141:18	155:5	reflect 22:19	355:18 365:12
243:10 279:11	255:3 336:13	recommends	reflected 119:10	relates 22:11 137:2
290:20 303:12,17	358:21	310:20	reflecting 329:3	227:4 234:22
305:18 307:8	received 21:3,22	reconfirm 35:21	reflection 189:20	333:10
311:2 313:17	23:14 139:9 155:5	reconsider 9:10	reflects 315:1	relating 167:19
316:12 317:3,11	332:11	reconvene 208:5	regard 86:9 268:1	219:8
317:13,14 326:22	receiving 95:20	322:18	regarding 91:7	relation 172:22
328:10,22 329:8,9	133:9	record 103:15	107:15 139:22	relationship 18:5
331:22 338:1,3	recognition 343:20	116:12 121:4	156:9 202:14	137:13 318:2
344:16 345:3	recognize 307:19	162:3,4 208:7	259:15,16 261:18	relative 167:5
346:2,6 347:9	353:15	221:14 248:19	262:2,5	197:14
350:12 351:15,17	recognized 13:15	263:15 322:15	regardless 96:5	relatively 101:4
353:16 356:11	recognizing 220:3	339:7 368:15	131:2 168:22	347:6
358:2,2,4 359:14	288:7	recorded 111:4	223:20 225:15,16	released 234:3
362:18 363:6,9	recollection 35:22	recording 22:4	226:18	reliability 20:22
366:15,20 367:6	recommend 19:13	records 185:9	regards 40:3 66:17	25:16 77:22 80:15
367:18 368:13	50:16 57:10 59:19	189:14 266:2	222:11 313:13	80:18 83:13 95:8
reason 17:2 50:11	88:3 115:15	recount 126:19	region 17:20	99:10 100:1 136:3
93:11 105:5	141:20 153:4	reduce 71:21 73:2	registered 22:9	137:4 182:7
107:16 108:5,12	195:18 207:2,22	119:7 154:21	registry 353:12	210:14 231:4
119:5 126:2 130:6	235:15 250:11	reduced 157:21	regression 282:22	234:21 237:2
131:5 135:16	264:6 274:12	343:21 344:1	regular 14:16 95:8	247:21 366:14
146:5 151:5	278:20 282:12	reducing 265:5	regulators 214:14	367:2
160:15 161:16	285:10 312:10	330:14	regulatory 146:9	reliable 26:16
176:9 181:4	314:7	reduction 3:5 12:5	rehabilitated 351:8	100:3 182:19
189:20 192:7	recommendation	12:13,15 13:3	rehabilitation	230:17 245:17
199:16,21 204:17	6:2 14:7 15:9	15:1	356:2	rely 159:14
286:6 343:6	19:11 26:11 33:9	reductions 119:2	rehash 10:6	remain 145:2
344:17,21	37:21 59:13 81:6	reestablishment	reimbursement	316:20
reasonable 150:2	91:22 127:1	105:4	258:1	remainder 279:16
291:7 326:4	130:19 141:16	refer 344:18	reject 299:21	remaining 280:10
reasonably 28:18	252:22 266:22	346:15,21	rejected 22:18	remains 13:17
reasoning 134:10	343:16	reference 248:2	84:16 130:7	93:19
321:7	recommendations	294:3,5	relate 213:15	remarkably 337:6
reasons 68:15	10:11,14 13:1	referenced 52:8	related 3:22 84:7	remarks 11:15
129:9 149:5,22	64:1 131:10 142:9	references 58:5	103:9 114:19	123:18
150:10,11 161:4	276:13 285:4	referencing 102:5	125:9 149:14	remember 30:18

39:20 113:11 151:10 158:4 345:2 352:15 remind 73:17 145:11 188:3 189:22 reminded 61:19 195:1 363:16 reminder 23:21 207:12 323:10 reminders 358:16 removal 3:12 38:22 41:8 77:3,6 78:12 remove 226:11 243:17 removed 77:13 78:10 96:10 renal 1:3,25 2:23 64:7 120:20 338:22 345:22 358:7 rename 366:10,21 Renee 2:18 11:6,8 repaired 169:6 repeat 156:11 211:13 267:10 rephrase 145:5 replace 127:1,22 238:6 replacing 68:6 report 24:12 29:21 33:3 34:7 65:20 76:17 89:12 102:5 113:4 120:17,19 135:2,17 139:7,15 151:22 152:7 162:7 184:7 187:6 190:20 192:13 193:21 198:8 205:17 210:4,11 217:11 234:15 236:20 249:14 262:21 272:5 273:10 277:22 311:15 317:14 321:14 329:6 356:22	reported 30:20 31:15 65:18 83:14 103:11 122:2 125:6,18 138:6 159:18,19 165:22 167:9,12 169:21 175:16 197:2 205:10 283:6,10 298:5,14 reporting 20:15 25:7,12 30:13 102:10 119:18,19 139:3,6 140:5 146:17 155:15,21 166:16 167:6 179:3 185:6 200:1 223:13 252:9 265:6 281:19 282:6,7 313:7,11 reports 33:15 119:22 146:14 178:4 191:4 297:10 repository 156:3 represent 214:18 296:21 349:22 350:5 representation 221:4,4 329:9 representative 144:10,22 147:9 represented 58:3 represents 346:6 requested 12:18 91:2 216:18 require 92:21 95:22 96:20 97:10 102:8 125:17 212:4 218:12 228:12 260:11 required 98:12 183:7,17 192:13 204:9 217:16 222:20,21 223:2 224:15 226:3,20 260:5,13,14 261:5 261:6,7,11,16	262:1 309:19 requirement 20:12 61:10 98:17 190:18 216:6 218:18 236:12 267:16 requirements 39:8 216:14 217:2 259:19 requires 90:11 94:6 259:8 306:8 requiring 128:1 233:22 research 2:19,23 4:19 92:21 178:20 316:10 325:9,13 329:16 resist 338:21 resistance 135:13 resistant 147:22,22 resolve 239:20 resources 124:16 146:12 170:22 172:11,16 228:21 306:15 respect 131:14 199:7 228:11 356:5 respectfully 129:11 respond 110:15 145:13 161:10 232:5 response 10:16,19 29:17 33:13 34:3 87:15 89:6 111:12 130:14 132:5 175:14 193:17 207:14 212:17 234:10 262:14 273:5 277:19 311:11 321:10 323:13 324:8 325:8 346:9 360:18 responses 89:18 210:7 211:21 324:6	responsibility 100:20 118:11 298:22 299:2 300:3 301:10 responsible 161:2 301:22 330:2 335:20 rest 10:8 167:4 199:13 309:5 327:19 restart 321:18 restriction 3:8 13:14 15:5 17:22 21:6 22:6 26:17 30:5,6 66:6 92:15 resubmit 320:5 result 119:9 187:21 238:16 239:3 269:17 344:14 resulted 41:10 50:8 157:21 resulting 135:12 147:22 230:17 results 4:10 28:19 37:1 80:1 104:6 136:6,19 137:6,14 137:15 169:21 240:5 251:22 264:12,14 265:2 265:16 266:2,3,8 269:2 331:13 resumed 116:13 208:8 322:16 retort 300:4 retrieve 269:7 retrieving 255:13 retrospective 46:19 return 295:4,6 returning 169:16 revalidation 97:3 reverse 159:1 review 10:8 25:2 32:7 46:19 82:11 102:19 162:4,4 171:19 reviewed 5:11 16:21 127:13	211:13 212:13 238:10 reviewer 12:6 82:1 132:13 153:11 318:16 reviewers 13:21 15:8,11 17:1 19:21 27:5 29:2 32:2 33:11 37:22 38:2 39:15 41:20 80:9,21 81:8 82:14 91:15 142:2 143:22 145:17 210:2 211:1 212:16 236:19 237:11 256:2 265:19 266:15 272:3 284:18 313:21,22 reviewing 129:13 reviews 252:14 368:4 revised 72:14 revisited 50:19 revolution 42:2 revolved 233:16 reworded 133:15 RFA 62:13 richer 172:12 358:3 RICHIE 2:15 23:21 Rick 108:13 111:2 349:18 351:2 right 6:7 9:20 18:8 18:15 20:5 22:1 27:14 28:3 29:20 35:13 40:19 43:13 43:15 45:8,13 48:11 50:12 51:11 51:12 52:1 53:14 54:9 64:18,21 67:19 70:1,12 74:7 76:13 77:1 79:17,21 82:8 85:5 86:3 89:15 95:12 97:9 102:22
--	--	---	--	---

108:2,10 109:1,20 110:1,6,6,10 113:15,15,15,15 113:20,22 114:11 114:15 115:3 116:8 117:1 121:10 122:9 124:2 125:4 130:8 130:9 131:3,7 132:7 133:19 145:11 150:12,12 150:22 152:11,17 166:18 172:15,20 175:15,20 178:15 178:18 180:5 186:10,15 191:11 193:8,18 195:3,11 196:9 201:17 203:16,21 204:13 205:14 207:18 217:9 219:1 220:7 225:21 228:14 233:21 237:14 243:21,21 245:7 247:13 248:15 254:12 255:16,21 262:4 269:7,14,17 274:3 279:22 280:22 287:18 288:3,4 291:14 294:21 295:17 296:17 297:11 298:7,9 299:11 303:16 305:2 307:3 309:16 310:3,19 311:12 311:19 312:13 319:18,22 320:7 322:6,7 338:4 341:15 348:16 353:13 355:7 358:9 359:1,1 363:11 364:17,18 367:3 right-hand 6:1 rise 271:22 risk 156:17 283:2	283:14 284:5 286:3 288:19,20 289:22 290:3,10 290:15 310:17,22 313:13,14 risk-adjust 283:18 risk-adjusted 124:19 156:14 282:14,16 313:3 risk-adjusting 294:2 risk-stratify 284:2 RN 1:15 2:6,14 road 102:16 Robert 2:3,23 93:21 164:13 185:18 242:5 244:13 Roberta 2:6 336:18 robust 86:9,10 robustly 154:7 ROBYN 2:21 role 362:8 roll 225:22 245:21 rolled 218:17 260:19 rolling 126:6 209:13 236:6 251:15 360:5 rollout 222:13 226:9 238:4 rolls 240:21 246:4 room 41:22 46:1 48:17 65:9 69:4,5 69:8 73:3 150:20 153:18 159:9 168:6 169:18 241:3 258:8 287:2 288:22 299:12 300:7,13 301:7 308:5 319:17 rooms 151:2 288:13,15 roots 351:15 round 33:20 340:1 357:11 rounding 96:3	97:11,16 rounds 98:2 200:15 routinely 177:1 268:20 RPA 301:21 336:2 350:19 355:2 rubber 102:15 Ruben 2:5 158:2 174:19 191:12 272:9 359:11 Ruben's 359:17 rule 133:2 rules 258:1 259:12 run 32:21 80:8 150:14 running 237:18 296:17 rural 306:14,21 330:8	302:9,17 305:21 307:5 320:2 341:1 348:18 358:3 359:11 364:3 says 16:15 21:16,19 21:21 22:3,19 23:22 27:12,16 30:19 35:11 43:1 51:19 94:7,19 95:17,21 96:7 112:5,9 140:3,3 140:18 170:16 198:19 269:3 270:15 286:5 327:2 364:2 scenario 192:6 272:16 scenarios 362:11 schedule 367:11 scheduled 11:17 222:14 scheduling 68:20 scheme 246:20 Schonder 1:10,14 3:2 4:17 24:14,20 30:1 34:9 76:19 89:17 109:11 112:5 113:9 114:8 115:7,12,17 152:9 152:15,19 153:1,6 194:6,13,18 195:14,20 205:20 206:1,10,16,21 207:5 209:3 212:15,18 215:10 217:8,17 222:9 223:3 227:16 229:21 234:8,11 235:21 237:10,19 239:17 242:5 244:13 245:10 246:18 249:11 250:16 253:1 262:12,15 263:1 264:10 267:1 272:9 273:3,6 274:16 276:21	277:3,17,20 279:3 280:7,13 281:3 286:17 302:20 303:20 305:3 306:10 311:9,12 312:20 314:20 317:17 320:8 321:8,11 322:1,17 323:6,16 327:10 329:12 330:16 337:20 342:17 355:17 368:1 School 1:17,18,22 1:23 science 2:2 15:15 15:15 49:2 50:4 50:17 53:12 62:7 366:7,18,18,19 scientific 17:11 26:4 33:4 37:11 40:3 68:1 81:1 114:3 136:2 142:4 152:12 194:9 206:7 210:7 234:19 236:22 249:18 252:17 263:4 266:17 273:18 276:4 278:5 284:22 311:19 314:2 366:4 scientists 366:5 screen 20:11 325:22 scroll 211:21 SDO 257:9 SDOs 226:19 227:18,20 257:7 seamless 287:16 searching 249:9 season 85:20 seat 361:18 second 13:22 80:21 103:1 171:19 268:17 299:9 321:3 327:16 328:4 360:15
--	---	---	---	---

S

366:22	send 177:16 189:4	271:8	140:6 161:3 168:5	simplification
secondary 184:22	189:15 202:1,5	sessions 15:6 30:13	169:11,18 187:3	146:2
247:11	269:5 302:7 359:8	38:18 47:12	187:11 291:18	simplified 144:15
secretary 99:3	367:5	set 88:20 181:15	321:21	157:2
section 27:16 84:15	sending 360:1	190:6 195:6	showed 43:4 44:6	simplify 279:15
136:1,1	senior 2:14 57:20	225:10,19 256:16	46:12 155:5	simply 69:21 70:11
sections 366:22,22	sense 16:9,18 32:20	303:10,16 324:22	showing 15:4 44:22	88:10 133:6
sector 240:14	85:22 137:17	332:1 358:3 367:9	79:9 151:2 213:15	144:15 180:12
see 5:15,17,22 6:6,7	172:18 181:19	sets 184:20 219:10	342:11	198:15 203:12
10:19 18:19 19:8	204:1 218:3 224:2	setting 93:13 159:5	shown 44:9 53:5	Singer 2:23 358:6,6
20:21 23:8 29:4	230:8,16 237:4	171:7 176:3,21	125:9 140:5	single 52:20 147:5
37:7,12 62:10	240:10 279:11	179:22 181:9	shows 53:10 80:6	147:17 156:16,17
70:3 72:20 88:2,4	280:4 290:21	184:19 229:17	157:10,17	192:18 205:9
88:17,17 93:9	298:15,17 336:6	237:15 303:19	showstopper	288:21 303:1
96:18 113:8	sensitive 168:4	338:19	175:12	sir 117:6 118:1
130:10 137:5	308:1	settings 180:9	SHR 123:7 124:6	207:16
138:4 171:2	sent 113:7 188:14	330:20	291:15	sit 18:3 68:22 87:17
173:17 189:9	sentence 141:9	seven 13:21 52:14	Sicilians 75:3	site 228:6 287:2
195:3 205:12	separate 135:3,8	84:20 115:12	sickle 7:19	sites 185:1
229:6 234:15	158:9 177:2 185:8	195:21 206:17	side 72:9 199:6	sitting 146:13
258:3 260:15	228:9 234:6	250:14 264:1	204:10 228:7	situation 54:3
265:19 272:11	259:18 318:9	297:19 311:22	252:8 333:11	163:11 169:3,7
284:4 291:19	366:10	several-day 127:7	355:19 362:18	246:10
292:1,4 305:4	separated 75:9	sex 282:17 313:16	sides 72:20	six 8:11 13:21
317:12 318:13	135:3	share 134:10	sign 49:6 326:10	14:10 40:13 44:21
320:13 324:22	separately 74:20	304:12 361:13	signature 100:18	91:16 142:2
325:19 334:11	134:12 135:17	shared 303:17	signed 22:9	194:18 249:17
336:4 340:2	separating 79:16	SharePoint 359:21	significant 143:6	250:10 264:20
344:21 347:12	separation 289:4	360:3	210:21 221:9	274:1 278:10
355:7 359:10	sepsis 168:6 169:12	SHEA 214:16,19	227:20	289:17 312:9
365:9	187:20	215:8	significantly 215:3	347:14
seeing 40:7 146:11	September 297:5,7	sheet 18:2	signify 326:3	sixty-four 321:14
211:14 342:12	298:6	sheets 93:9	silly 169:8 363:22	six-month 209:13
seek 287:11	septicemia 173:11	shifting 247:13	364:11	236:6 251:15
seeking 292:21	186:8 255:4	short 79:13,14	silos 353:16	sizeable 192:11
seemingly 324:17	sequential 297:15	300:18 318:5	similar 121:16	skew 241:5 287:3
seen 93:20 119:2	serially 293:15	shorter 38:2 41:10	233:6 239:3	skin 199:8,10
144:22 212:13	series 77:9 151:16	42:19 282:12	255:17,19 256:5	skyrocketed 74:16
305:15 316:15	354:9	285:10	275:3 298:12	slightly 233:7
344:4 347:13	serum 8:10	shorthand 6:20	313:1 314:10,13	357:21
sees 164:4	serve 60:15 70:4	shortly 367:11	324:17 356:15	slowly 90:22
segments 286:22	331:15	shorts 85:19	359:22	small 34:21 39:7
selected 80:5 156:2	Service 330:9	short-sighted 75:15	similarly 47:7	58:18 103:21
selecting 86:22	Services 2:18	shot 129:20 188:16	119:7	192:11 224:17
selection 93:17	118:10	show 5:15 14:22	simple 157:12	239:14 243:3
self-management	session 19:10 30:20	31:17 41:5 47:15	260:13 285:22	257:9
88:15 347:5	36:16 41:10 43:3	78:8 82:4 136:6	338:3,7 363:21	smaller 69:13

228:14,21	288:4 289:10	365:18	186:17 187:15	331:3 336:12
smoking 358:1	298:5 355:10	specifically 36:2	191:1,22 309:18	338:8 339:11,14
snapshot 144:10	sort 80:4 83:4 89:3	77:11 91:10	310:7,8 368:2	339:19 341:12,13
social 54:3 189:3	106:9 109:5	145:12 146:10	stage 1:3 283:1	341:14 342:7,11
society 286:22	145:15 171:16	165:12 177:21	340:8,10 344:4	347:15 348:3,8
365:16	180:16 204:15	209:19 236:11	355:9	353:14
sodium 3:5,6,8	213:10 237:13	290:5 293:22	stamp 54:10	started 17:2 133:7
12:5,13,15 13:15	250:22 290:19	333:10	stand 61:17 333:20	141:9 176:20
15:19 18:2 21:6	300:9,20 340:14	specification 101:2	standard 23:19	184:5 194:11
21:22 22:5 24:22	347:2 349:6 356:1	239:4 278:7	41:13 44:8,12	268:7,14 270:16
25:3,7,12 26:17	356:15,16 362:2	366:11	46:14 52:7,13,22	271:2 304:5
26:18 28:13,19,19	sorts 198:5	specifications 22:3	54:20,22 155:20	325:17 340:21
29:1,12,13 30:6,7	sound 136:9 307:6	27:8 34:14 114:20	157:7 158:9	345:21 351:11
30:11,16,22 31:3	363:22 364:11	225:6 239:7	199:22 271:22	starting 17:9 49:16
31:12,14 35:3	sounded 60:7	249:21 273:20	292:10	58:10 64:20 92:6
58:19 66:6 85:1	sounds 55:19 88:2	365:7 367:1	standardized 4:14	116:4 152:6
92:15	160:3,5 271:20	specifics 76:2	4:15 124:7 281:6	234:14 255:12
sodiums 32:14	317:19	175:17	281:10,13,15	269:2 328:4 341:7
solely 120:3 227:14	source 156:3 157:6	specified 91:10	298:11,13 304:21	starts 113:12,21
solute 38:22 58:19	197:2 198:9,20	111:22 114:19	312:18,21 313:3	114:4 132:20
solutions 53:20,21	199:1 205:9 211:2	198:18 235:1	standardizing	135:6 139:16
solve 62:11	238:1 239:6,16	240:9 263:6 277:7	298:18 304:4	194:16 205:18
somebody 85:11	249:1 256:9 289:1	specifies 161:14	standards 20:2	209:18 255:20
99:2 158:4 164:4	sources 137:1	specify 198:16	63:2,4	256:6 339:15,20
190:8 248:19	185:4 193:6 240:5	270:6 277:12	standing 71:7	341:17 348:3,6,22
275:8,18 300:12	247:14 304:22	specifying 97:12	101:19	349:4,12,15
357:14 362:19	Southern 339:21	spectacular 31:22	standpoint 16:19	start-up 183:16
somewhat 123:2	spawned 47:10,20	spectrum 351:18	174:13	state 35:8 120:18
128:5 143:18	speak 48:21 103:6	spend 192:1	stands 112:21	147:5 155:21
173:4 249:8	107:7 117:12	spent 129:13	288:11	161:17 166:21
269:22 287:18	131:16 162:13	315:11 361:11	start 3:18 12:4	167:12,13 182:2
290:17 315:6	167:16 261:17	spirit 77:8	19:14 24:10 49:16	184:3 303:6
343:7	speakerphone	spKv/T 6:11	71:9 74:11 116:4	stated 28:9 63:9
soon 120:1 166:6,8	117:15	split 37:10 266:22	132:10,11,17	272:7
299:3	speaking 68:13	spoke 57:6 294:9	134:6 141:13	statement 35:19
sooner 71:13	162:20 287:6	spot 32:9 209:7	148:8 151:2 183:4	79:6 101:16,22
203:16 237:18	specialist 354:11	spread 26:5	186:1 187:5	249:3 272:8 313:5
sophisticated 65:17	specialists 354:2	spring 222:14	205:16 207:10	365:5
sorry 5:18 31:18	specialty 331:7	squishy 277:16	209:3 223:6	statements 131:8
41:18 48:2 56:10	specific 16:17 20:2	St 1:22	239:13 262:20	133:5 238:11
56:15,17 78:1	21:10 32:12 38:17	stability 126:10	264:22 267:16,20	states 31:13 102:6
81:22 99:12	78:20 91:13	stabilized 72:3	268:2,6,11,18	155:12 166:4,6
138:19 147:6	136:20 201:8	stable 119:16 126:4	269:10,16 270:6	167:14 170:4
169:10 196:5	236:15 249:8	126:12 145:3	270:21 271:12,15	181:2 182:6,15
206:1 211:12,16	253:15 288:8	staff 2:10 12:16	273:9 281:5 297:7	184:2 233:22
231:22 243:1	309:1 333:6 339:6	82:13 146:20	299:3 300:1	stating 365:13
257:11 282:4	343:16 357:12	165:4 183:7,17	311:14 325:19	statistic 346:1

statistical 291:6 363:5 366:19	45:2 139:16,20 174:5 203:19	subgroups 348:20	Sue 1:15 3:21,23 135:20 145:17	214:9 222:16 228:14
statistically 290:14 290:19	204:18 209:12 236:4,9 252:1	subject 251:7	151:17 153:10	supported 45:17 347:7
statistician 60:3	274:22 310:22	subjecting 345:14	161:9,10 164:17	supporters 252:11
statistics 126:3 286:3	stratify 139:12 149:15	subjective 136:12 173:4 211:1	165:21 181:19	supporting 43:3 165:6
status 92:8 163:22 163:22 164:8	stratifying 283:15	subjectivity 204:15 252:5 271:18	196:17 247:17	supportive 192:2,3
228:18 282:18	Straube 329:7	submission 12:18 80:13 82:18,21	255:18	suppose 108:22 148:12,14
289:18 329:1	stream 197:12	91:2 217:3 220:20	sufficient 29:7 52:4 82:6 199:19	supposed 244:18
335:18 356:3	Street 1:9	221:17,18 222:1	248:22	sure 34:15 55:4 62:13 79:7 85:21
stay 96:13 164:4 279:6	strength 210:10	222:12 228:12,17	sufficiently 140:3	88:18 97:21 98:11
steady 36:22	stress 93:2	229:2 238:6,7	suggest 37:1 45:20 57:2 112:17	99:6 100:12 101:9
steering 1:4,9 226:13 260:9	strict 87:7	287:21 295:15	185:12 328:1	104:19 111:1,5
366:21	strictly 51:4	357:15 364:13	suggested 16:2 92:12 154:12	136:8 158:22
step 103:14 213:9 333:20 353:5	strike 325:20	submit 121:7 129:11 222:20	155:6 156:8 332:9	160:16 193:13
stepped 209:5 274:18	strikes 316:7	224:16 226:3,20	suggesting 28:18 47:11 105:22	213:22 216:12
steps 42:3,13 130:2	strokes 50:8	234:4	248:4 366:9	229:18 230:4,21
steward 77:21	strong 29:3 311:1 319:20 342:10	submitted 91:5 92:3 119:9,13	suggestion 356:1,2	232:17 237:8
stewards 11:16	stronger 251:8	120:6 183:13	suggestions 199:4 357:3 359:11,16	259:17 266:4
sticking 54:21	strongly 58:2 210:2 295:22 296:1,3	213:13 216:17	367:4,6	271:10,10 280:15
stimulate 339:7 346:17 357:16	struck 345:18	220:4,5 242:9	suggests 96:11 302:2	284:11 306:16
stimulates 13:10	structure 325:22	295:2	suite 230:6 250:21 279:8	323:22 328:16,16
stimulating 157:20	struggle 362:21	submitter 137:6	suited 302:3	331:4 357:12
stipulate 76:7	struggled 48:7	submitting 28:12 198:16 221:1	summarize 178:10	358:20 359:4,17
stop 114:7	struggling 48:7	submitting 28:12 198:16 221:1	summarized 12:16 174:22	363:16
stopping 353:4	studied 20:9 337:1	subpopulation 27:2	summarizes 121:13	surely 304:12 331:19
store 315:20	studies 15:3 31:11 42:16 46:17 47:8	subsequent 9:4 271:7 297:8	Summarizing 252:14	surface 316:8
stores 6:18,22	78:4,14,15,22	subsequently 78:13 221:7	summary 13:20 15:2 32:11 36:21	surgery 345:15
stories 75:1	120:13 141:1	subset 218:9 239:14 268:3	79:22 90:15 155:4	surprise 33:18 124:22 283:15,16
storm 201:19	249:4	subsets 39:6	157:10 186:20	surprised 214:20
story 254:13	study 7:22 33:18 41:3 42:17 43:4	subspecialists 353:20	191:18 199:15	surprising 43:1
straightforward 296:16	47:20 53:5,10	subspecially 354:15	201:7 272:10	surrogate 315:6
strategies 318:20 331:5	61:20 78:7 80:1	substantial 87:13 118:13,19 120:9	superimposing 245:1	surveillance 118:11 143:8,9 161:19
strategy 212:3	137:20 184:9,12	296:8 337:11	support 1:25 12:21 29:8 38:19 44:15	170:15 177:3
stratification 167:17 210:17	185:1 345:1 366:8	substantially 180:7	46:6 79:6 81:19	183:8,9,16,19,21
284:5 310:17	studying 212:3	successes 334:3	162:9 170:11	199:5 266:12
stratified 4:5,8,12	stuff 160:18 214:6 261:1 359:18	successful 122:7		survey 227:12 331:12
	360:9	successfully 348:4		survival 46:13
	subcategory 210:21			susceptible 26:21 27:2
	subgroup 143:6			

suspect 160:12 191:7 315:22	324:15 356:10 359:9 362:13	363:4 367:15,18	TEPs 131:6 233:13 361:12	36:19,19 63:10 80:12 83:12,15
suspected 197:1 198:9,20 199:1 200:7	taken 103:14 105:8 130:18 324:1 333:11	technical 63:7 104:22 106:4 129:12 142:18 310:9	TEP's 59:2,8,13 96:17 286:7	84:11 91:3 99:11 99:20 104:1,1 114:13 136:3,5,15
suspicion 200:13 201:10	takes 53:20 72:17 125:19 186:14	technically 83:16	term 51:21 366:3	136:17,19 137:4 137:15 177:21 197:12 210:14
suspicious 200:5	take-away 33:14	technologies 92:16	terms 10:13 13:3 13:20,22 14:3,7 14:19 15:8 19:17 20:13 25:22 26:2 51:16 78:16 85:12 90:15 91:14,15,16 91:18,20,22 92:17 93:18 110:19 121:16 122:10 124:11,13,13 130:15 137:3 142:1 168:16 171:17 177:22 183:7 184:2 188:10 218:10 219:13 221:21 222:1 225:20 233:5,8 237:13 248:5,9 256:13 266:17 275:15 276:2,4,10,13 284:17,20 285:6 286:11 294:19 296:12 311:5,6 320:17 323:19 326:1,21 328:5 329:13,15 338:7 342:10 368:11	197:12 210:14 218:6 230:12 234:22 237:3 252:12 311:6 317:21,22
swayed 72:8 315:14	talk 17:21 18:3 28:21 122:19 123:7 137:6 221:12 284:8,9,15 309:3 322:11 327:3 338:9,10 340:9 341:21 351:14 353:9	technology 244:12 322:6 359:22	teleconference 2:18 2:18,22	Testing/no 36:19
sweater 85:19	talked 17:18 41:22 42:1 87:3 140:10 157:7 253:11 255:19 303:15 313:2 317:5 326:15 329:5 330:20 332:20 350:18,19,20 366:2	telephone 207:13 207:16 323:11 327:18	2:18,22	tests 137:19 220:17
switch 349:17	talking 47:9 58:18 59:4 60:6 66:19 68:5 70:10 74:10 75:20 85:1 127:19 164:17,22 172:18 174:4 213:5 238:22 243:3,5 249:4 270:21 279:19 320:17 329:7 331:22 350:22 355:20	tell 5:21 17:12 40:4 49:3 67:8,10 68:21 69:2,19 117:18 123:22 145:19 149:21 161:10 186:4 191:19 193:2 209:6 225:4 241:4 275:2 317:1,5 320:21 366:17	2:18,22	Texas 2:8
switching 281:12	targets 108:1	telegraph 207:13 207:16 323:11 327:18	2:18,22	text 265:22
synchronization 221:6	task 136:18	telemeter 207:13 207:16 323:11 327:18	2:18,22	thank 5:4 18:11,12 21:12 23:11 39:13 40:15 56:14 61:22 67:20 112:16 116:10,15 117:13 118:1 121:8,9,12 123:20 124:4 131:1 132:1 135:21 138:17 143:21 147:11 153:8 201:22 203:4 207:17 208:2 234:7 280:12,13 281:1,2 298:8 323:2,5,6 323:16 329:11 334:14,22 335:3 336:2 352:8 367:17 368:3,13
system 109:3 119:16,20 121:20 189:18 223:20 231:22 246:4 260:19,22 271:20 283:22 301:3,11 301:16 302:16 303:12,13 337:21 341:17 348:21 353:14 354:18	Tassin 15:3	telling 49:19 150:19	2:18,22	thereof 341:3
systems 119:15 122:11 232:8,21 244:11 302:4 338:9 353:1	team 177:7 233:15	tells 18:2 205:4	2:18,22	
S-E-S-S-I-O-N 209:1		temporary 156:16	2:18,22	
		ten 19:9 45:15 74:15 84:20 128:1 128:2 131:4 194:19 206:22 274:6,11 290:9	2:18,22	
T		telling 49:19 150:19	2:18,22	
table 57:12 61:8 69:8 80:20 136:13 214:21 301:21 326:13		tells 18:2 205:4	2:18,22	
tablet 24:9		temporary 156:16	2:18,22	
tad 33:19		ten 19:9 45:15 74:15 84:20 128:1 128:2 131:4 194:19 206:22 274:6,11 290:9	2:18,22	
take 10:18 12:7 58:22 72:14 115:20,21 116:1 131:4 140:20 163:1 181:14 184:5 200:11 226:14 229:10 298:19 300:3 301:10 322:8,18		tend 62:5 68:10,12 165:1 318:5,6 357:20	2:18,22	
		TENEE 2:13	2:18,22	
		tension 69:4 73:3	2:18,22	
		ten-kilo 87:5	2:18,22	
		TEP 55:19 57:1,2,9 57:17 58:20 101:7 110:16 122:16 127:5,8 129:5,7 213:12 221:5 267:15 271:9,9 292:12 305:16 362:19 363:8	2:18,22	
		TEPs 131:6 233:13 361:12	2:18,22	
		TEP's 59:2,8,13 96:17 286:7	2:18,22	
		term 51:21 366:3	2:18,22	
		terms 10:13 13:3 13:20,22 14:3,7 14:19 15:8 19:17 20:13 25:22 26:2 51:16 78:16 85:12 90:15 91:14,15,16 91:18,20,22 92:17 93:18 110:19 121:16 122:10 124:11,13,13 130:15 137:3 142:1 168:16 171:17 177:22 183:7 184:2 188:10 218:10 219:13 221:21 222:1 225:20 233:5,8 237:13 248:5,9 256:13 266:17 275:15 276:2,4,10,13 284:17,20 285:6 286:11 294:19 296:12 311:5,6 320:17 323:19 326:1,21 328:5 329:13,15 338:7 342:10 368:11	2:18,22	
		terrible 317:9	2:18,22	
		test 100:17 137:7 218:9 265:16 338:6	2:18,22	
		tested 24:5 25:9 27:3 77:22 79:22 80:14,17 95:7 99:21 141:3,18 155:11 218:2 230:2,3,22 243:19 243:22 247:19 252:4	2:18,22	
		testing 12:20 20:22 25:17,20 32:19	2:18,22	

thesis 42:17	359:18 363:15	156:1 157:3,14	323:4 324:10,20	232:3 252:8,11,15
thing 5:19 8:14	364:13,14 365:4	160:11 161:11	326:5,21 328:3,5	253:15 257:2
14:20 28:4,13	think 9:7,12 10:9	162:8 163:8,11	328:7,11,14,21,22	258:22 266:16
48:12 50:7,19	10:19,22 15:13	164:16,21 165:4	329:2 330:18	276:7 285:21
54:9,19 62:5 68:8	16:3 18:8,14,15	170:14 171:4,19	331:2 332:3	286:9 305:19
68:22 70:12,18	19:1 20:1,3,6 24:7	171:21 172:7,12	333:19 336:17	315:9 323:4 327:3
72:14 75:20,21	26:12 28:5,8 31:5	172:19 174:8,21	337:13,21 338:20	329:4 339:8
76:13 82:1,6 86:3	32:1 33:15,21	175:5 176:13,14	340:17 341:10,11	356:13
86:22 94:16	34:20 35:4 39:16	177:9 181:9,19	341:13 342:4,8,9	thoughtful 127:10
102:22 105:18	40:9,13,18,21	185:16 187:1	342:13,15 343:5	127:14 131:6
108:13 109:21	42:4,7,12,13 45:8	189:19 191:13	343:15 344:2,3,11	thoughtfully 129:8
110:2 130:13,21	47:1,2,7,17,21	192:9 197:17	344:13,15 346:6	thousand 298:5
137:17 138:20	51:10,20 52:2	199:17 200:2	347:18 348:19	three 7:22 8:7,8
139:20 144:5	53:16 54:7 55:2,6	203:9 205:8	350:12,16 351:5,9	14:5,5 25:22 26:4
147:16 148:8,11	55:9,16 56:19	211:17 213:16	351:16,17 353:17	26:7,10 33:5,6,6,7
164:17 170:19	57:3,12 58:13	214:8,12 215:16	354:9,21 355:2,8	37:9,9 38:18
171:15 175:2,3	60:17,21 61:12,20	218:6,11 219:10	355:12,13 357:3	39:22 40:8 41:13
187:12 188:9	62:4,5 63:13,14	219:16 223:13,13	357:17 361:3,6,20	41:16 42:18 43:12
303:2 305:2	63:22 64:5,10	225:11,12 231:16	362:10,12 363:8	44:8,21 46:6,7
306:11 325:5	65:6,11,15,22	233:12 235:21	363:11,15,19	49:10,11,13 52:7
328:14 338:4	66:11,19 67:16	237:12 240:8	365:8 366:5,14	53:18 54:15 64:21
345:17 357:9	68:9 69:3,4,7,8,15	242:11 244:22	367:14 368:6	67:3,9 80:22,22
359:5 361:1,1	70:5 71:1,16 72:1	245:11,12,15	thinking 31:7 74:5	81:3 91:21,21
366:1	72:13 74:4 75:7	246:4,6 247:12	86:4 108:3,6,7,10	98:3 119:12 120:5
things 10:6 40:3	75:13,22 76:1,6	253:7 256:7,12	340:14 353:4	134:11 142:6,10
41:8,19,21 43:2	79:10,20 80:13	257:18 262:8,16	361:13 362:6	143:3 147:8 158:8
54:7,16 66:5 74:1	82:3 86:2,12,15	265:21 269:3	366:17	158:11 166:10
85:3 91:1 99:20	86:17 87:12 89:14	270:12 272:8,10	thinks 113:6	169:21,22 170:4
104:5 146:21	93:22 95:3,16	276:15 277:9	230:20	185:4 190:19
163:19 169:8	96:9,13 98:12,16	280:1,10 282:11	third 143:11	194:19 211:14,17
172:17 198:5	99:13,14 104:12	283:19 284:2,7	256:17 275:7	211:18 221:2
213:21 242:16	105:1,9,20 106:5	285:9,11,16,18	340:16	235:3,9 250:6
246:20 258:16	106:8,10,17,20,22	286:2,10,21	thirst 13:10	252:14 263:9,12
259:19 276:17	107:5 108:12,16	287:18 288:3	Thirteen 195:20	263:13 266:16,18
279:13,15 281:22	108:18,19 109:1	289:16 290:13	250:5	274:1 278:10
286:12,13 306:22	110:18,20 112:3	291:4,5 292:16	thirty 7:16	282:8 285:1,5,8
307:17 308:14,19	121:13 125:1	293:17,18 298:14	thirty-five 34:6	290:9 297:14
309:15 316:13	127:19,22 129:5	299:21 300:8	thirty-four 24:21	312:5 314:4,5,8
319:6,18 324:4,19	129:14,16,22	301:8 302:22	29:21	339:6
325:19 326:7,14	131:15,18 133:13	303:9,11 304:7	thirty-nine 89:11	three-hour 47:12
326:17,19 329:10	133:16 135:14	305:6 306:8,12	thirty-one 6:21	52:7
333:17 336:14	137:20 141:4	307:7,12,13,14,16	thirty-three 7:6	three-month 7:22
341:8 342:19	143:5 145:14	308:10,14 309:4	thought 16:14 50:5	three-times-a-we...
343:8 344:13	146:18,21 147:15	311:7 315:14	66:18 71:2 92:4	53:7
350:16 352:5,14	148:7 150:14	316:11,13 318:20	109:14 110:13,18	three-year 292:20
353:15 356:9	151:4,9,18 154:5	319:8,12,14 320:7	133:17 196:8	292:22
358:22 359:13,15	154:14 155:10	320:15 321:17	224:3,19 229:3	threshold 128:4

136:20	355:3 360:16	226:22 232:6	transmitted 198:5	trying 19:17 34:13
throwing 328:9	361:11 363:12	233:1 238:2	270:10	43:16 57:9 70:22
thumb 359:7	364:8	258:21 259:13	transplant 67:12	72:2,11 94:3
Thursday 68:17	timeline 294:17	261:20 262:10	150:2 242:21	106:5 167:22
tie 273:15	timeliness 125:15	329:6	295:4 332:12	176:1 189:7 190:7
tied 119:18 184:8	265:6	tool 120:3 162:9	339:16 354:6	212:8,9 228:8
time 9:2 10:2 19:15	timely 347:19	244:17,21 316:10	transplanted	232:16 243:13
29:6 37:2 38:6,8,9	timer 113:21 114:4	333:14	352:17	256:13 258:21
39:21,22 41:5,9	194:10,16 205:17	tools 88:15 254:8,9	transplants 242:18	261:3 263:19
41:13,15 42:18	234:15	304:4,8,14,19	travel 306:21	271:10,19 288:12
43:3 45:18,21	times 13:16 38:3,4	354:15	treated 128:10	303:10 314:15
46:14,20 47:14	38:19 40:13,13	top 37:7 238:18	142:19 209:15	326:18 329:10
51:18,20 52:6,9	41:13,16 42:18,20	283:12 299:9	217:13 267:8	364:9
53:6,8 54:20 58:7	43:12 44:8,21	topic 106:12 136:4	treating 291:21	Tuesday 68:17
61:1,10,13,16	52:7 53:18 54:4,8	topics 358:12	treatment 37:1	Tulane 1:21
66:6,17 67:2 72:5	68:16 70:4 98:3	toss 129:19	38:15 39:5 44:9	turned 52:9 258:13
73:11 74:19 77:20	176:6 191:18	total 55:17 58:8	46:2 47:12 54:9	258:14,15,16
83:10 85:1,8	307:7 324:10	85:15 133:6,14	68:7 74:3 264:20	261:18,19
86:18 87:6,16	361:15	173:16 239:8	328:6,10,11	turns 33:20
92:21 94:11 100:5	time-dependent	241:10 315:1	treatments 38:21	Twelve 205:20
105:7 108:18	293:7,16	316:3	41:6 52:8	312:8
122:19 123:12,15	time-limited 23:22	totalitarian 239:8,9	trend 162:1	Twenty 115:17
125:19 126:12	24:2,4,6 55:18	totality 237:5	trends 297:15	311:18
130:11 131:4	72:19 83:7,18,20	totally 100:5 247:1	trial 44:5 47:11,14	twenty-five 6:14
135:1 140:21	87:2 95:11 99:19	306:1 351:8	52:6 202:11 228:1	twenty-nine 7:9
144:10 145:3	106:8 113:1,2	toto 58:4	trials 48:10 49:18	twenty-one 6:3
147:20 156:10	141:20 218:1	touch 358:16 368:9	tried 149:7 326:6	twenty-seven 8:9
162:1 164:2,2	220:13 230:1,10	touching 66:5	362:11	twenty-six 6:17
183:7,17 184:5	235:17 252:12	tough 69:2	trigger 190:15	twenty-three 6:10
186:2,13,22	265:13 277:2	track 121:4 271:13	trough 354:3	twice 98:3 211:7
190:19 192:1	timing 180:15	tracked 277:5	true 66:12 69:2	two 14:2,2,2,4,4,6
196:2 207:8,16	238:4 310:2	tracking 270:18	88:7,8,8 101:2	14:11 15:13 25:22
209:6 213:12	tiny 73:20 300:18	tracks 309:11	104:5 105:17	26:3,5,6,8,10 33:3
216:13 226:6,8	345:12	tract 160:22	109:17 257:4	33:5,8 37:12,13
228:3 242:14	tired 40:7	train 66:18	291:18 309:6	37:13,14,17,17,18
271:15 272:14	title 37:3	trajectory 343:10	truly 66:14 230:13	37:20,22 46:3
275:11 280:10	today 11:14,18	transfer 29:1,13	truth 242:7 334:8	52:14 53:9 57:18
282:8,9,12 285:10	17:8 48:17 62:20	31:4 295:8	try 5:15 18:4 57:3	75:10 79:13 81:2
290:15,17 294:19	62:21 63:20 75:19	transition 268:12	71:12,21 72:4	81:6 91:17,17,19
295:2,8,11,15,17	116:4 169:9	294:17 329:19	77:9 106:16	91:20 92:1,5
296:8,21 297:3	189:18 201:20	330:18,19 342:3	133:14 149:15	114:9 115:8
301:15 304:5	272:13 297:18,20	350:20 351:1,6	176:8 178:7	133:11 142:5,5,7
310:15 312:14	325:15 330:20	transitions 350:22	180:13,19 207:19	142:8,10,20 143:3
316:18 320:19	tolerate 69:21	translate 104:10	208:4 270:18	143:7 144:6
322:6 323:9,12,15	Tom 2:17 11:3	translated 98:18	321:17 338:9	152:15 153:6
328:9 334:17	222:7 223:17,19	translates 94:10	340:1 359:14	156:21 166:11
348:16 353:5	224:20 225:4,18	translating 332:18	362:2,3 363:15	169:21,22 171:22

177:19 180:17 183:10,17 186:3 188:15 193:6 196:1,5 197:5 206:10,16,22 211:6,15,15,15,22 211:22 219:10 232:8,21 235:9 237:9,9,22 244:14 244:16 245:15 252:10,18,20,22 252:22 256:13,14 259:18 263:9,20 266:21 274:10,11 276:9,11,11,12,12 276:13 278:14,17 281:4 285:3,3,5 293:20 298:5,10 312:9,17 314:3,5 314:6,7 316:15 317:7 318:9 327:11 329:4 350:1 368:8	77:12,17 78:9,16 78:18 79:2,3,12 79:14 82:5 85:12 85:22 86:13,17 87:8,18 unanimous 92:11 113:10 115:18 unavailable 4:9 264:12,14 269:17 270:4 271:16 272:13,15 uncalled 67:4 uncertain 26:13,14 uncertainty 238:3 unclear 22:10 39:11 160:7 210:15,16 221:18 275:15 365:22,22 uncomfortable 289:5 uncontroversial 79:3,8 undergoing 25:15 37:5 underlay 361:14 underlying 149:14 underneath 61:17 326:13 underpinning 291:6 underscored 307:15 understand 60:6 60:22 66:14 68:1 68:3 95:15 98:11 99:15 100:13 106:5 148:20 151:22 173:14 192:7 204:14 213:17 228:11 243:7,11 261:8 271:19 286:1 304:2,4 307:4 308:1,4 314:16 315:20 317:13 318:17 328:12 understandable	99:8 141:4 285:22 understanding 16:8 60:5 61:5 69:16 70:20 85:8 101:14 103:8,18 172:4 184:17 216:21 223:7 243:19,21 247:9 261:9 267:14 270:4 294:4 337:3 337:3,8 understandings 66:2 understands 286:2 understood 257:3 361:20,21 underway 225:20 232:20 under-dialyze 65:8 under-dialyzed 65:22 under-dialyzing 40:14,20 66:11 under-reporting 171:5 under-treated 128:17 129:1 under-used 64:14 64:15,17 65:12 under-utilized 335:11,15 undetected 348:14 undue 266:7 unequivocal 48:10 49:2 unfortunately 31:8 138:13 201:16 228:17 261:13 321:18 unheard 19:8 unintended 26:22 70:10 75:14 87:3 87:12 90:20 96:22 105:21 148:19 149:16 150:17 163:4 unions 246:22	unique 227:12 303:2 unit 65:19 91:12 93:7 99:3 100:21 133:1,8 142:20 148:12 160:13,13 160:14 161:2 163:2,9,10,15 168:7 170:5 176:13 177:13 178:6 191:15 223:9 224:17 267:8,19 268:17 268:18 301:12 330:22 United 31:13 units 105:3 163:20 164:12,20,20 212:11 223:8 308:3,9 335:20 universally 288:16 universe 220:6 University 1:17,18 1:22,23 2:2 unknown 197:3 200:8,14 unnecessary 345:15 unrealistic 170:10 170:11 214:8 unsure 321:19 untested 265:12 untreatable 128:6 128:16 update 73:14 228:22 360:8 updated 359:9 upper 45:14 348:18 uptake 119:5 upward 105:12 urban 306:14 urea 41:7 51:17,22 52:13 60:19 61:3 73:19 343:21 urge 87:9 151:15 305:10 urinary 160:22	urine 35:6 URR 296:7 usability 14:3 26:7 26:8 33:6 37:16 81:2 91:19 115:5 121:5 141:3 142:5 152:17 194:16 206:12 210:9 235:6 236:22 250:3 252:18 263:17 266:19 274:3 276:10 278:12 285:2 312:2 314:4 usage 138:8 use 7:2,6 15:4 26:14,15,18 35:1 35:2,3 50:3 53:10 87:7 118:15,15 119:13 120:5,7,10 121:1 126:5,6 132:21 133:7 135:9,15 148:18 149:11 150:4,8 164:5 172:21 181:3 211:10 216:4 230:11,21 241:17 261:2 266:11 271:3 283:18 287:1 288:16 289:1 293:5,15 295:12 305:1 320:18 useable 141:6 useful 63:2 182:18 229:7,10 262:8 315:22 318:8,9 352:15 USRDS 345:20 348:6 usually 27:19 utility 31:8 318:14 utilization 3:9,11 36:7,10 77:2,5 147:19 148:10 288:7 295:22 336:5 337:14
U				
ulcer 160:21 200:12 ultimately 225:8 238:7 256:10 350:15 357:5 ultrafiltration 3:12 58:7 66:7 77:3,6				

utilized 335:10	vanco 270:17	ventricle 61:3	130:20 151:7	22:14,15 32:1
utilizing 120:22	vancomycin 268:16	venues 367:14	152:4 185:15,17	33:11 39:15 40:9
U.S 119:17	269:3	verbally 188:1	193:16 194:21	46:9 48:1 54:4
V	variable 290:15	verification 97:3	205:13 220:15	55:15 60:8 62:20
V 2:1 244:6	293:7	verify 97:17	237:7 249:12	69:16 70:1,2,18
VA 246:20 247:2	variables 319:7	versa 331:1 352:22	262:16 277:20	71:11 75:20 79:18
vague 20:5 141:15	variation 38:16	versus 38:8 42:19	311:10 319:12,14	81:16 82:12 94:15
valid 125:14 167:9	170:21 210:7	139:4,4 156:20	321:12,19,20	95:1,5 98:11
230:18 237:15	251:12	157:9 163:22	360:20	104:19 106:19
240:19 241:8	varies 90:6	200:14 233:17	voted 19:5 39:18	111:1,5,16 113:14
290:14 291:7	variety 41:8 122:2	238:13 259:19	81:10 89:15 114:7	128:20,22 138:21
validate 97:16	various 362:11	283:5,9 292:20	142:14,16 146:5	142:11 150:4
136:10 185:10	VAs 247:6 345:2	310:22 343:3	147:6,7 153:19	153:14,17 158:18
246:1,5	vascular 3:22	349:10	161:16 162:18	163:5 167:15,16
validated 120:12	119:1 125:9	veterans 247:7,10	194:4 197:5	168:3,14 171:21
validation 137:20	139:11,13,16,21	vice 2:12 331:1	199:16,20 205:6	174:2,16 179:12
184:4,8,9,12	140:15,16 161:15	352:22	273:12 285:20	180:21 186:7,12
193:10 244:17,21	165:11 174:6,10	view 74:20 119:21	313:22 314:1	188:22 189:1,4
246:2	176:19 196:16,19	141:19 157:16	votes 211:14 237:9	192:15 202:6
validity 20:22	197:2,9,14 200:22	164:19 287:16	237:9	207:20 213:17
25:17 46:16 80:16	201:10 202:16	298:20	voting 23:10 24:8	225:18 232:18
80:18 83:14 99:11	203:20 204:18,20	vigorous 180:10	32:22 76:14 81:11	233:4 258:1,4,7
136:5,8,15 137:4	209:19,19 238:20	virtually 328:9	111:7,9,13 234:12	261:17 272:17
137:14 175:16,17	253:14,22 254:1	virus 133:21	273:7 308:21	276:1 282:1 284:8
177:20 185:1	277:12 299:5,7	visit 17:18	321:16 359:5	285:11 292:15
231:4 234:22	308:16	visits 287:22	vulnerable 149:12	298:19 301:19
237:3 243:10	VASSALOTTI 2:4	volume 15:20	330:7	302:7,21 303:21
247:21 277:15	9:1 18:21 55:1	28:20 41:7 58:14	V5 236:16	307:5 317:12
296:12 307:12	56:1,3,6,10,14,17	59:9,15 60:20	V6 236:16	318:21 319:11,16
366:13 367:1	56:22 58:16 59:2	61:1,13 66:3	V7 236:16	320:1 321:6 325:6
validity/reliability	60:8 81:12 106:19	73:21 74:21 75:8	V8 236:14 238:16	325:20,21 331:10
98:22	107:4 109:8	77:9 83:8 84:8	239:3	334:14 336:1
valley 17:19	147:14 192:15	85:10,10,13,13	W	340:21 341:5,20
valuable 219:17	193:5 202:6,9	87:22 88:22	Wager 2:6 3:10	344:12 357:7,18
227:5 252:9	204:4 267:2	172:16	16:22 36:13 37:15	359:10 362:19
320:16 328:13	285:20 307:18	volume-monitori...	37:19 38:1 39:17	367:12,17
value 8:7 32:12	319:11 335:21	92:19	66:13 81:10 334:7	wanted 10:5 11:4
126:5 128:13	341:10,20 343:6	volume-related	wait 49:18,21 51:11	53:1 55:2 57:4
161:8 237:13	344:15 345:17	83:6	113:21 114:4	123:15 131:5
253:11 256:14,14	vehicle 238:5	voluntary 23:18	194:10,16 205:17	136:2 147:14
291:4 292:11	VELEZ 2:5 75:17	122:6	214:21 234:15	271:13 282:11,15
293:3,18 320:13	158:3,15 174:20	volunteering 148:5	245:20	317:15 335:21
352:2	191:13 200:2	vomiting 74:2	waiting 280:18	341:15
values 126:7 127:3	204:22 272:10	vote 6:2,2 24:7	waiver 49:7	wants 76:8
129:1 297:9	291:8 358:20	29:19 34:2 76:6	walk 359:4	warranted 150:1
351:22	Venn 212:12	89:8 92:11 95:10	want 9:10 18:21	266:3
	213:14 237:6	113:13,14,16		Washington 1:10

wasn't 42:9,10 82:18 95:7 108:14 117:9 127:11 233:10 234:3 259:2 265:16 345:3	week 38:19 40:13 41:13,16 42:18 43:12 44:9,21 52:7 53:18 54:4,8 68:7,16,16 98:3 190:21 200:15 201:20 268:16 333:8	270:20 277:8 322:15 337:10 368:15	325:12 329:10 330:4 340:13 345:15 350:11 354:13 355:13 360:3,12	317:20 360:19
watch 18:3	201:20 268:16	weren't 187:9 214:21 224:4 272:6	we've 9:3 49:16 87:1 195:7 235:20 246:1 316:14	wonderful 46:19 75:18
water 58:9	333:8	we'll 5:12 10:4,18 10:22 88:2 113:17 114:2 116:1,4,6 124:1 132:9 145:15 162:12 196:12,13 205:16 209:8,9 231:2,9 249:12 262:20 263:3 274:18 279:3 311:14 321:19 322:9,9,17 323:21 324:8,20 325:11 360:5 367:9	wherewithal 160:14	wondering 246:2 256:1 361:5 364:9
way 10:16 16:1 20:21 32:9 34:21 40:5 42:4 53:5,10 53:19 55:5 57:4 59:19 63:5 68:11 74:9,18 76:9 83:7 84:17 86:18 88:21 93:16 100:14 103:9 106:11 108:14 111:2 128:11 133:14 134:18 135:2 138:12,14 139:8 147:7 163:13 164:16 172:13 180:6 190:13 193:8,9 195:8,9 201:17,19 213:4 213:18 215:12,20 218:15 228:16 240:4,9 267:12 272:11 285:14,15 287:21 307:1,3,9 315:16 332:21 340:22 346:18 358:8 360:20 361:7 362:6 364:10	weekly 74:19	we're 5:9 11:10 40:13,19 48:12 49:20,22 55:17 60:10,19 61:5 62:10,14,18 63:5 66:10 70:19 74:9 74:17 75:22 88:1 89:8 99:15 105:22 106:1,18 116:3 151:10 152:6 160:19 161:18 163:20 164:10 168:12 169:2 171:8,9,10,18 172:17 177:9,10 177:11 181:12 195:10 201:18 212:6 218:8 220:17 226:17 232:22 234:14 238:22 240:4,6 241:9,10 243:3,10 245:13 247:13 249:3 258:18 272:19 273:9 304:20 309:17 317:14 323:19,22	white 277:8	we've 96:10 154:11 343:18
ways 15:14 240:1,7 245:15 251:1 336:19,21 357:3 363:20	weeks 92:5 129:13 143:4	we're 5:9 11:10 40:13,19 48:12 49:20,22 55:17 60:10,19 61:5 62:10,14,18 63:5 66:10 70:19 74:9 74:17 75:22 88:1 89:8 99:15 105:22 106:1,18 116:3 151:10 152:6 160:19 161:18 163:20 164:10 168:12 169:2 171:8,9,10,18 172:17 177:9,10 177:11 181:12 195:10 201:18 212:6 218:8 220:17 226:17 232:22 234:14 238:22 240:4,6 241:9,10 243:3,10 245:13 247:13 249:3 258:18 272:19 273:9 304:20 309:17 317:14 323:19,22	wide 38:16 170:21 171:9	word 96:10 154:11 343:18
weak 45:4	weigh 201:6	we're 5:9 11:10 40:13,19 48:12 49:20,22 55:17 60:10,19 61:5 62:10,14,18 63:5 66:10 70:19 74:9 74:17 75:22 88:1 89:8 99:15 105:22 106:1,18 116:3 151:10 152:6 160:19 161:18 163:20 164:10 168:12 169:2 171:8,9,10,18 172:17 177:9,10 177:11 181:12 195:10 201:18 212:6 218:8 220:17 226:17 232:22 234:14 238:22 240:4,6 241:9,10 243:3,10 245:13 247:13 249:3 258:18 272:19 273:9 304:20 309:17 317:14 323:19,22	widely 13:15 90:7 90:18	words 32:13 153:15 182:20 229:14 269:14 328:19 348:7 365:15
weakness 210:12	weighed 129:14	we're 5:9 11:10 40:13,19 48:12 49:20,22 55:17 60:10,19 61:5 62:10,14,18 63:5 66:10 70:19 74:9 74:17 75:22 88:1 89:8 99:15 105:22 106:1,18 116:3 151:10 152:6 160:19 161:18 163:20 164:10 168:12 169:2 171:8,9,10,18 172:17 177:9,10 177:11 181:12 195:10 201:18 212:6 218:8 220:17 226:17 232:22 234:14 238:22 240:4,6 241:9,10 243:3,10 245:13 247:13 249:3 258:18 272:19 273:9 304:20 309:17 317:14 323:19,22	wider 81:21 172:18	work 8:21 54:2 130:2 131:9,13 148:3 154:17 156:4 162:13 163:8 183:1 216:9 221:3 260:16 262:9 301:2 323:3 329:1,18 351:2,9 351:11,15 367:8 368:3
weaknesses 32:4	weight 3:5,13 12:3 12:12 24:1 55:2 57:5 60:12 85:11 87:5,16,18 89:22 90:3,6,17 93:8,10 94:10 95:20 96:1 96:4,5,6,21 97:4 97:12,14,17 98:13 98:15 99:6 102:9 102:12,17,19 105:5,11,12,17,17 107:22 315:8	we're 5:9 11:10 40:13,19 48:12 49:20,22 55:17 60:10,19 61:5 62:10,14,18 63:5 66:10 70:19 74:9 74:17 75:22 88:1 89:8 99:15 105:22 106:1,18 116:3 151:10 152:6 160:19 161:18 163:20 164:10 168:12 169:2 171:8,9,10,18 172:17 177:9,10 177:11 181:12 195:10 201:18 212:6 218:8 220:17 226:17 232:22 234:14 238:22 240:4,6 241:9,10 243:3,10 245:13 247:13 249:3 258:18 272:19 273:9 304:20 309:17 317:14 323:19,22	willingness 101:22	worked 67:13 102:3 106:6 301:21 322:6 355:2
wearing 85:17	weight-based 85:14 85:15,15,22	we're 5:9 11:10 40:13,19 48:12 49:20,22 55:17 60:10,19 61:5 62:10,14,18 63:5 66:10 70:19 74:9 74:17 75:22 88:1 89:8 99:15 105:22 106:1,18 116:3 151:10 152:6 160:19 161:18 163:20 164:10 168:12 169:2 171:8,9,10,18 172:17 177:9,10 177:11 181:12 195:10 201:18 212:6 218:8 220:17 226:17 232:22 234:14 238:22 240:4,6 241:9,10 243:3,10 245:13 247:13 249:3 258:18 272:19 273:9 304:20 309:17 317:14 323:19,22	winter 85:18	worker 189:3
web 221:15	welcome 3:2 5:3 292:13 367:6	we're 5:9 11:10 40:13,19 48:12 49:20,22 55:17 60:10,19 61:5 62:10,14,18 63:5 66:10 70:19 74:9 74:17 75:22 88:1 89:8 99:15 105:22 106:1,18 116:3 151:10 152:6 160:19 161:18 163:20 164:10 168:12 169:2 171:8,9,10,18 172:17 177:9,10 177:11 181:12 195:10 201:18 212:6 218:8 220:17 226:17 232:22 234:14 238:22 240:4,6 241:9,10 243:3,10 245:13 247:13 249:3 258:18 272:19 273:9 304:20 309:17 317:14 323:19,22	wisely 13:15 90:7 90:18	workgroup 73:13 131:13 212:9
Wednesday 1:6 68:17	WellPoint 1:24	we're 5:9 11:10 40:13,19 48:12 49:20,22 55:17 60:10,19 61:5 62:10,14,18 63:5 66:10 70:19 74:9 74:17 75:22 88:1 89:8 99:15 105:22 106:1,18 116:3 151:10 152:6 160:19 161:18 163:20 164:10 168:12 169:2 171:8,9,10,18 172:17 177:9,10 177:11 181:12 195:10 201:18 212:6 218:8 220:17 226:17 232:22 234:14 238:22 240:4,6 241:9,10 243:3,10 245:13 247:13 249:3 258:18 272:19 273:9 304:20 309:17 317:14 323:19,22	wisely 13:15 90:7 90:18	working 71:20 110:17 156:21 228:13 299:3 301:1 336:2 348:20 358:9 367:7
	WELLS 2:7	we're 5:9 11:10 40:13,19 48:12 49:20,22 55:17 60:10,19 61:5 62:10,14,18 63:5 66:10 70:19 74:9 74:17 75:22 88:1 89:8 99:15 105:22 106:1,18 116:3 151:10 152:6 160:19 161:18 163:20 164:10 168:12 169:2 171:8,9,10,18 172:17 177:9,10 177:11 181:12 195:10 201:18 212:6 218:8 220:17 226:17 232:22 234:14 238:22 240:4,6 241:9,10 243:3,10 245:13 247:13 249:3 258:18 272:19 273:9 304:20 309:17 317:14 323:19,22	wisely 13:15 90:7 90:18	works 68:20 214:1 215:14 218:5
	well-developed 294:14	we're 5:9 11:10 40:13,19 48:12 49:20,22 55:17 60:10,19 61:5 62:10,14,18 63:5 66:10 70:19 74:9 74:17 75:22 88:1 89:8 99:15 105:22 106:1,18 116:3 151:10 152:6 160:19 161:18 163:20 164:10 168:12 169:2 171:8,9,10,18 172:17 177:9,10 177:11 181:12 195:10 201:18 212:6 218:8 220:17 226:17 232:22 234:14 238:22 240:4,6 241:9,10 243:3,10 245:13 247:13 249:3 258:18 272:19 273:9 304:20 309:17 317:14 323:19,22	wisely 13:15 90:7 90:18	world 64:9 172:10 173:11 214:4 240:14 249:6 258:9 284:11 301:17 303:7 305:21 327:19 331:2
	well-educated 343:1	we're 5:9 11:10 40:13,19 48:12 49:20,22 55:17 60:10,19 61:5 62:10,14,18 63:5 66:10 70:19 74:9 74:17 75:22 88:1 89:8 99:15 105:22 106:1,18 116:3 151:10 152:6 160:19 161:18 163:20 164:10 168:12 169:2 171:8,9,10,18 172:17 177:9,10 177:11 181:12 195:10 201:18 212:6 218:8 220:17 226:17 232:22 234:14 238:22 240:4,6 241:9,10 243:3,10 245:13 247:13 249:3 258:18 272:19 273:9 304:20 309:17 317:14 323:19,22	wisely 13:15 90:7 90:18	world's 62:11
	well-established 155:14	we're 5:9 11:10 40:13,19 48:12 49:20,22 55:17 60:10,19 61:5 62:10,14,18 63:5 66:10 70:19 74:9 74:17 75:22 88:1 89:8 99:15 105:22 106:1,18 116:3 151:10 152:6 160:19 161:18 163:20 164:10 168:12 169:2 171:8,9,10,18 172:17 177:9,10 177:11 181:12 195:10 201:18 212:6 218:8 220:17 226:17 232:22 234:14 238:22 240:4,6 241:9,10 243:3,10 245:13 247:13 249:3 258:18 272:19 273:9 304:20 309:17 317:14 323:19,22	wisely 13:15 90:7 90:18	worried 255:10
	well-meaning 202:18	we're 5:9 11:10 40:13,19 48:12 49:20,22 55:17 60:10,19 61:5 62:10,14,18 63:5 66:10 70:19 74:9 74:17 75:22 88:1 89:8 99:15 105:22 106:1,18 116:3 151:10 152:6 160:19 161:18 163:20 164:10 168:12 169:2 171:8,9,10,18 172:17 177:9,10 177:11 181:12 195:10 201:18 212:6 218:8 220:17 226:17 232:22 234:14 238:22 240:4,6 241:9,10 243:3,10 245:13 247:13 249:3 258:18 272:19 273:9 304:20 309:17 317:14 323:19,22	wisely 13:15 90:7 90:18	worry 17:16,17 174:22 310:9
	well-orchestrated 367:16	we're 5:9 11:10 40:13,19 48:12 49:20,22 55:17 60:10,19 61:5 62:10,14,18 63:5 66:10 70:19 74:9 74:17 75:22 88:1 89:8 99:15 105:22 106:1,18 116:3 151:10 152:6 160:19 161:18 163:20 164:10 168:12 169:2 171:8,9,10,18 172:17 177:9,10 177:11 181:12 195:10 201:18 212:6 218:8 220:17 226:17 232:22 234:14 238:22 240:4,6 241:9,10 243:3,10 245:13 247:13 249:3 258:18 272:19 273:9 304:20 309:17 317:14 323:19,22	wisely 13:15 90:7 90:18	
	well-taken 243:13	we're 5:9 11:10 40:13,19 48:12 49:20,22 55:17 60:10,19 61:5 62:10,14,18 63:5 66:10 70:19 74:9 74:17 75:22 88:1 89:8 99:15 105:22 106:1,18 116:3 151:10 152:6 160:19 161:18 163:20 164:10 168:12 169:2 171:8,9,10,18 172:17 177:9,10 177:11 181:12 195:10 201:18 212:6 218:8 220:17 226:17 232:22 234:14 238:22 240:4,6 241:9,10 243:3,10 245:13 247:13 249:3 258:18 272:19 273:9 304:20 309:17 317:14 323:19,22	wisely 13:15 90:7 90:18	
	went 5:20 116:12 170:9 208:7	we're 5:9 11:10 40:13,19 48:12 49:20,22 55:17 60:10,19 61:5 62:10,14,18 63:5 66:10 70:19 74:9 74:17 75:22 88:1 89:8 99:15 105:22 106:1,18 116:3 151:10 152:6 160:19 161:18 163:20 164:10 168:12 169:2 171:8,9,10,18 172:17 177:9,10 177:11 181:12 195:10 201:18 212:6 218:8 220:17 226:17 232:22 234:14 238:22 240:4,6 241:9,10 243:3,10 245:13 247:13 249:3 258:18 272:19 273:9 304:20 309:17 317:14 323:19,22	wisely 13:15 90:7 90:18	
		we're 5:9 11:10 40:13,19 48:12 49:20,22 55:17 60:10,19 61:5 62:10,14,18 63:5 66:10 70:19 74:9 74:17 75:22 88:1 89:8 99:15 105:22 106:1,18 116:3 151:10 152:6 160:19 161:18 163:20 164:10 168:12 169:2 171:8,9,10,18 172:17 177:9,10 177:11 181:12 195:10 201:18 212:6 218:8 220:17 226:17 232:22 234:14 238:22 240:4,6 241:9,10 243:3,10 245:13 247:13 249:3 258:18 272:19 273:9 304:20 309:17 317:14 323:19,22	wisely 13:15 90:7 90:18	
		we're 5:9 11:10 40:13,19 48:12 49:20,22 55:17 60:10,19 61:5 62:10,14,18 63:5 66:10 70:19 74:9 74:17 75:22 88:1 89:8 99:15 105:22 106:1,18 116:3 151:10 152:6 160:19 161:18 163:20 164:10 168:12 169:2 171:8,9,10,18 172:17 177:9,10 177:11 181:12 195:10 201:18 212:6 218:8 220:17 226:17 232:22 234:14 238:22 240:4,6 241:9,10 243:3,10 245:13 247:13 249:3 258:18 272:19 273:9 304:20 309:17 317:14 323:19,22	wisely 13:15 90:7 90:18	
		we're 5:9 11:10 40:13,19 48:12 49:20,22 55:17 60:10,19 61:5 62:10,14,18 63:5 66:10 70:19 74:9 74:17 75:22 88:1 89:8 99:15 105:22 106:1,18 116:3 151:10 152:6 160:19 161:18 163:20 164:10 168:12 169:2 171:8,9,10,18 172:17 177:9,10 177:11 181:12 195:10 201:18 212:6 218:8 220:17 226:17 232:22 234:14 238:22 240:4,6 241:9,10 243:3,10 245:13 247:13 249:3 258:18 272:19 273:9 304:20 309:17 317:14 323:19,22	wisely 13:15 90:7 90:18	
		we're 5:9 11:10 40:13,19 48:12 49:20,22 55:17 60:10,19 61:5 62:10,14,18 63:5 66:10 70:19 74:9 74:17 75:22 88:1 89:8 99:15 105:22 106:1,18 116:3 151:10 152:6 160:19 161:18 163:20 164:10 168:12 169:2 171:8,9,10,18 172:17 177:9,10 177:11 181:12 195:10 201:18 212:6 218:8 220:17 226:17 232:22 234:14 238:22 240:4,6 241:9,10 243:3,10 245:13 247:13 249:3 258:18 272:19 273:9 304:20 309:17 317:14 323:19,22	wisely 13:15 90:7 90:18	
		we're 5:9 11:10 40:13,19 48:12 49:20,22 55:17 60:10,19 61:5		

worse 78:11 146:18 293:9	344:6 350:12 352:19	278:15 312:1	1478 3:21 196:15 196:18 205:16	2009 298:4
worth 343:16	yellow 6:1	12th 1:9	15 19:7 24:15 77:18 79:4 80:3 207:21 263:12 344:6	2010 217:10 238:17 297:21 345:20
worthwhile 349:8 362:12	yeses 24:15 25:22 30:2 34:10 113:10 115:17 142:10 152:10 205:20 263:2 285:5 314:7 322:2	12:15 208:5 12:17 208:8 209:2 13 250:14 278:18 130 120:16 132 3:17,17 138 30:12,17 31:3 32:14 14 5:11 17:20 76:20 89:18	153 3:19 16 30:2 194:14 207:6 263:1 279:2 279:2 322:3	2011 1:6 67:4 296:17 2012 169:4 209 4:4 21 132:22 133:7 156:12
worthy 33:17	yesterday 5:11 8:20 11:13 48:8 60:3 123:5 124:1 126:20 130:20 207:21 220:22	1418 5:19 142 102:5 1424 7:13 1428 7:2 1430 126:21 1432 3:5 12:4,13 1434 3:6 24:22 25:3 1435 3:8 30:5,6 1437 3:9 36:6,10 76:17 1438 3:13 89:21 90:2 113:3 114:3 1439 3:11 77:2,5 89:9 1449 4:9 264:12,14 273:9	17 194:6 18 5:12 27:9,13,21 34:10 35:14 36:2 69:14,20 73:9 89:17 109:16 113:10 153:6 210:1 234:17 243:7,8 274:15 350:21	21 132:22 133:7 156:12 21-day 133:1 156:10 22 181:2 191:15 236 4:7 24 160:9 24/7 68:7 240 36:16 248 52:16 249 52:20 25 3:6 243:8 25-27 348:7
wouldn't 33:18 55:11 83:19 124:22 126:5 174:16 186:18 187:8 191:7 229:9 245:20 268:20 301:7	yes/no 93:17 young 243:5 younger 108:15 316:19	1418 5:19 142 102:5 1424 7:13 1428 7:2 1430 126:21 1432 3:5 12:4,13 1434 3:6 24:22 25:3 1435 3:8 30:5,6 1437 3:9 36:6,10 76:17 1438 3:13 89:21 90:2 113:3 114:3 1439 3:11 77:2,5 89:9 1449 4:9 264:12,14 273:9	18-year-olds 240:17 19-year-olds 240:18 197 3:21 1990s 47:9 1999 120:7	253 3:6 243:8 25-27 348:7 251 4:6 264 4:9 2728 293:11 295:2 295:5,12 305:11 275 4:10 28 17:19 39:20 67:10,16 281 4:14 29 67:16
wow 213:19	1	1450 271:7 280:8 1453 279:4 280:8 1455 4:7 220:8 235:22 236:3 249:13 1456 4:6 209:4 250:17,19 1457 4:4 209:9,10 209:11 234:13 1460 3:19 153:9,12 154:22 193:21 255:17 256:5,7 1461 8:13 1463 4:14 281:6,10 311:13 1464 4:15 312:18 1469 4:10 274:19 274:21 277:21 1477 3:17 132:10 132:15 152:6	18-year-olds 240:17 19-year-olds 240:18 197 3:21 1990s 47:9 1999 120:7	253 3:6 243:8 25-27 348:7 251 4:6 264 4:9 2728 293:11 295:2 295:5,12 305:11 275 4:10 28 17:19 39:20 67:10,16 281 4:14 29 67:16
wrap 356:11	1	1450 271:7 280:8 1453 279:4 280:8 1455 4:7 220:8 235:22 236:3 249:13 1456 4:6 209:4 250:17,19 1457 4:4 209:9,10 209:11 234:13 1460 3:19 153:9,12 154:22 193:21 255:17 256:5,7 1461 8:13 1463 4:14 281:6,10 311:13 1464 4:15 312:18 1469 4:10 274:19 274:21 277:21 1477 3:17 132:10 132:15 152:6	18-year-olds 240:17 19-year-olds 240:18 197 3:21 1990s 47:9 1999 120:7	253 3:6 243:8 25-27 348:7 251 4:6 264 4:9 2728 293:11 295:2 295:5,12 305:11 275 4:10 28 17:19 39:20 67:10,16 281 4:14 29 67:16
write 96:4 97:11,21 97:22 98:13	1	1450 271:7 280:8 1453 279:4 280:8 1455 4:7 220:8 235:22 236:3 249:13 1456 4:6 209:4 250:17,19 1457 4:4 209:9,10 209:11 234:13 1460 3:19 153:9,12 154:22 193:21 255:17 256:5,7 1461 8:13 1463 4:14 281:6,10 311:13 1464 4:15 312:18 1469 4:10 274:19 274:21 277:21 1477 3:17 132:10 132:15 152:6	18-year-olds 240:17 19-year-olds 240:18 197 3:21 1990s 47:9 1999 120:7	253 3:6 243:8 25-27 348:7 251 4:6 264 4:9 2728 293:11 295:2 295:5,12 305:11 275 4:10 28 17:19 39:20 67:10,16 281 4:14 29 67:16
writing 62:19 96:8 97:18 98:1	1	1450 271:7 280:8 1453 279:4 280:8 1455 4:7 220:8 235:22 236:3 249:13 1456 4:6 209:4 250:17,19 1457 4:4 209:9,10 209:11 234:13 1460 3:19 153:9,12 154:22 193:21 255:17 256:5,7 1461 8:13 1463 4:14 281:6,10 311:13 1464 4:15 312:18 1469 4:10 274:19 274:21 277:21 1477 3:17 132:10 132:15 152:6	18-year-olds 240:17 19-year-olds 240:18 197 3:21 1990s 47:9 1999 120:7	253 3:6 243:8 25-27 348:7 251 4:6 264 4:9 2728 293:11 295:2 295:5,12 305:11 275 4:10 28 17:19 39:20 67:10,16 281 4:14 29 67:16
written 18:8 39:19 39:19 42:5 109:12 165:6 270:3 287:21	1	1450 271:7 280:8 1453 279:4 280:8 1455 4:7 220:8 235:22 236:3 249:13 1456 4:6 209:4 250:17,19 1457 4:4 209:9,10 209:11 234:13 1460 3:19 153:9,12 154:22 193:21 255:17 256:5,7 1461 8:13 1463 4:14 281:6,10 311:13 1464 4:15 312:18 1469 4:10 274:19 274:21 277:21 1477 3:17 132:10 132:15 152:6	18-year-olds 240:17 19-year-olds 240:18 197 3:21 1990s 47:9 1999 120:7	253 3:6 243:8 25-27 348:7 251 4:6 264 4:9 2728 293:11 295:2 295:5,12 305:11 275 4:10 28 17:19 39:20 67:10,16 281 4:14 29 67:16
wrong 38:10 66:21 74:9 78:7 89:11 99:11 165:5	1	1450 271:7 280:8 1453 279:4 280:8 1455 4:7 220:8 235:22 236:3 249:13 1456 4:6 209:4 250:17,19 1457 4:4 209:9,10 209:11 234:13 1460 3:19 153:9,12 154:22 193:21 255:17 256:5,7 1461 8:13 1463 4:14 281:6,10 311:13 1464 4:15 312:18 1469 4:10 274:19 274:21 277:21 1477 3:17 132:10 132:15 152:6	18-year-olds 240:17 19-year-olds 240:18 197 3:21 1990s 47:9 1999 120:7	253 3:6 243:8 25-27 348:7 251 4:6 264 4:9 2728 293:11 295:2 295:5,12 305:11 275 4:10 28 17:19 39:20 67:10,16 281 4:14 29 67:16
Y	1	1450 271:7 280:8 1453 279:4 280:8 1455 4:7 220:8 235:22 236:3 249:13 1456 4:6 209:4 250:17,19 1457 4:4 209:9,10 209:11 234:13 1460 3:19 153:9,12 154:22 193:21 255:17 256:5,7 1461 8:13 1463 4:14 281:6,10 311:13 1464 4:15 312:18 1469 4:10 274:19 274:21 277:21 1477 3:17 132:10 132:15 152:6	18-year-olds 240:17 19-year-olds 240:18 197 3:21 1990s 47:9 1999 120:7	253 3:6 243:8 25-27 348:7 251 4:6 264 4:9 2728 293:11 295:2 295:5,12 305:11 275 4:10 28 17:19 39:20 67:10,16 281 4:14 29 67:16
year 22:17 57:22 73:6 85:20 106:9 126:9 157:8 222:14 233:14 282:20 297:3,5,7 297:13,13,14,16 297:17,21 298:6 310:6,6,10,16 333:7,21 335:6	1	1450 271:7 280:8 1453 279:4 280:8 1455 4:7 220:8 235:22 236:3 249:13 1456 4:6 209:4 250:17,19 1457 4:4 209:9,10 209:11 234:13 1460 3:19 153:9,12 154:22 193:21 255:17 256:5,7 1461 8:13 1463 4:14 281:6,10 311:13 1464 4:15 312:18 1469 4:10 274:19 274:21 277:21 1477 3:17 132:10 132:15 152:6	18-year-olds 240:17 19-year-olds 240:18 197 3:21 1990s 47:9 1999 120:7	253 3:6 243:8 25-27 348:7 251 4:6 264 4:9 2728 293:11 295:2 295:5,12 305:11 275 4:10 28 17:19 39:20 67:10,16 281 4:14 29 67:16
years 39:20 40:8 67:3,9,10,16 71:20 74:15 75:11 76:12 125:7 126:2 157:11 210:1 282:8 285:8 290:9 290:9,9 297:15,19 301:21 303:22 304:6,20 309:12 309:12 334:19	1	1450 271:7 280:8 1453 279:4 280:8 1455 4:7 220:8 235:22 236:3 249:13 1456 4:6 209:4 250:17,19 1457 4:4 209:9,10 209:11 234:13 1460 3:19 153:9,12 154:22 193:21 255:17 256:5,7 1461 8:13 1463 4:14 281:6,10 311:13 1464 4:15 312:18 1469 4:10 274:19 274:21 277:21 1477 3:17 132:10 132:15 152:6	18-year-olds 240:17 19-year-olds 240:18 197 3:21 1990s 47:9 1999 120:7	253 3:6 243:8 25-27 348:7 251 4:6 264 4:9 2728 293:11 295:2 295:5,12 305:11 275 4:10 28 17:19 39:20 67:10,16 281 4:14 29 67:16
	1	1450 271:7 280:8 1453 279:4 280:8 1455 4:7 220:8 235:22 236:3 249:13 1456 4:6 209:4 250:17,19 1457 4:4 209:9,10 209:11 234:13 1460 3:19 153:9,12 154:22 193:21 255:17 256:5,7 1461 8:13 1463 4:14 281:6,10 311:13 1464 4:15 312:18 1469 4:10 274:19 274:21 277:21 1477 3:17 132:10 132:15 152:6	18-year-olds 240:17 19-year-olds 240:18 197 3:21 1990s 47:9 1999 120:7	253 3:6 243:8 25-27 348:7 251 4:6 264 4:9 2728 293:11 295:2 295:5,12 305:11 275 4:10 28 17:19 39:20 67:10,16 281 4:14 29 67:16
	1	1450 271:7 280:8 1453 279:4 280:8 1455 4:7 220:8 235:22 236:3 249:13 1456 4:6 209:4 250:17,19 1457 4:4 209:9,10 209:11 234:13 1460 3:19 153:9,12 154:22 193:21 255:17 256:5,7 1461 8:13 1463 4:14 281:6,10 311:13 1464 4:15 312:18 1469 4:10 274:19 274:21 277:21 1477 3:17 132:10 132:15 152:6	18-year-olds 240:17 19-year-olds 240:18 197 3:21 1990s 47:9 1999 120:7	253 3:6 243:8 25-27 348:7 251 4:6 264 4:9 2728 293:11 295:2 295:5,12 305:11 275 4:10 28 17:19 39:20 67:10,16 281 4:14 29 67:16
	1	1450 271:7 280:8 1453 279:4 280:8 1455 4:7 220:8 235:22 236:3 249:13 1456 4:6 209:4 250:17,19 1457 4:4 209:9,10 209:11 234:13 1460 3:19 153:9,12 154:22 193:21 255:17 256:5,7 1461 8:13 1463 4:14 281:6,10 311:13 1464 4:15 312:18 1469 4:10 274:19 274:21 277:21 1477 3:17 132:10 132:15 152:6	18-year-olds 240:17 19-year-olds 240:18 197 3:21 1990s 47:9 1999 120:7	253 3:6 243:8 25-27 348:7 251 4:6 264 4:9 2728 293:11 295:2 295:5,12 305:11 275 4:10 28 17:19 39:20 67:10,16 281 4:14 29 67:16
	1	1450 271:7 280:8 1453 279:4 280:8 1455 4:7 220:8 235:22 236:3 249:13 1456 4:6 209:4 250:17,19 1457 4:4 209:9,10 209:11 234:13 1460 3:19 153:9,12 154:22 193:21 255:17 256:5,7 1461 8:13 1463 4:14 281:6,10 311:13 1464 4:15 312:18 1469 4:10 274:19 274:21 277:21 1477 3:17 132:10 132:15 152:6	18-year-olds 240:17 19-year-olds 240:18 197 3:21 1990s 47:9 1999 120:7	253 3:6 243:8 25-27 348:7 251 4:6 264 4:9 2728 293:11 295:2 295:5,12 305:11 275 4:10 28 17:19 39:20 67:10,16 281 4:14 29 67:16
	1	1450 271:7 280:8 1453 279:4 280:8 1455 4:7 220:8 235:22 236:3 249:13 1456 4:6 209:4 250:17,19 1457 4:4 209:9,10 209:11 234:13 1460 3:19 153:9,12 154:22 193:21 255:17 256:5,7 1461 8:13 1463 4:14 281:6,10 311:13 1464 4:15 312:18 1469 4:10 274:19 274:21 277:21 1477 3:17 132:10 132:15 152:6	18-year-olds 240:17 19-year-olds 240:18 197 3:21 1990s 47:9 1999 120:7	253 3:6 243:8 25-27 348:7 251 4:6 264 4:9 2728 293:11 295:2 295:5,12 305:11 275 4:10 28 17:19 39:20 67:10,16 281 4:14 29 67:16
	1	1450 271:7 280:8 1453 279:4 280:8 1455 4:7 220:8 235:22 236:3 249:13 1456 4:6 209:4 250:17,19 1457 4:4 209:9,10 209:11 234:13		

69:19 89:18 155:5
 233:21 263:2
 278:15 334:20
 340:10 355:10
40 48:12 345:20

5

5 3:2 24:14 39:21
 233:21 235:4
 355:10
5.2 300:19
50 335:8
50/50 188:16
 266:22
53 334:19
55 348:17

6

6 76:19 152:16
 155:5
6:00 300:15
60 220:22 348:17
60,000 353:13
69 136:7,11

7

7 152:20 206:11
7:00 300:16
70-75 348:8
72 249:7
75 348:8
77 3:11
775 1:9
79 136:7,10

8

8 152:10 264:5
8:00 1:10
8:11 5:2
80 129:19 182:22
 348:21
82-year-old 344:8
88 136:7

9

90 3:13 16:15
 182:22 290:2
 365:19

90-day 16:17 20:15
 20:17,18,20 71:21
99 365:20

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In the matter of: End Stage Renal Disease
Quality Measures

Before: National Quality Forum

Date: 01-12-11

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