NATIONAL QUALITY FORUM

CONFERENCE CALL FOR END STAGE RENAL DISEASE (ESRD) STEERING COMMITTEE

February 11, 2011

Committee Members Participating via Conference Call: Peter Crooks, MD (Co-Chair); Kristine Schonder, PharmD (Co-Chair); Constance Anderson, BSN, MBA; Sue Barnes, RN, BSN, CIC; Jeffrey Berns, MD; Barbara Fivush, MD; Jerry Jackson, MD; Frederick Kaskel, MD, PhD; Myra Kleinpeter, MD, MPH; Alan Kliger, MD; Lisa Latts, MD, MSPH, MBA; Kathe LeBeau; Joseph V. Nally, Jr., MD; Andrew Narva, MD (ex officio); Jessie Pavlinac, MS, RD, CSR, LD; Robert Provenzano, MD; JosephVassalotti, MD; Ruben Velez, MD; Harvey Wells

Committee Members Not Present on Call: Roberta Wager, RN, MSN

NQF Staff Present on Call: Karen Pace, PhD, RN, Senior Program Director; Lauren Richie, MA, Project Manager

Others Present on Call: Claudia Dahlerus, Arbor Research Collaborative for Health; Tom Dudley, Centers for Medicare & Medicaid Services; Sabrina Gomes, Arbor Research Collaborative for Health; Renee Henry, Centers for Medicare & Medicaid Services; Sheri Ling, Arbor Research Collaborative for Health; Lisa McGonigal, Kidney Care Partners; Jose Menoyo, Genzyme; Joe Messana, Arbor Research Collaborative for Health; Robyn Nishimi, MD, Kidney Care Partners; Priti Patel, Centers for Disease Control and Prevention; Robert Wolfe, Arbor Research Collaborative for Health

WELCOME AND INTRODUCTIONS

After roll call of the Steering Committee members and measure stewards and developers, Drs. Crooks and Schonder welcomed the Steering Committee members and thanked them for their continued participation. Dr. Crooks (Co-Chair) then reviewed the agenda before discussions and evaluations of the measures began.

The purpose of this follow-up call was to address outstanding agenda items from the in-person meeting held on January 11-12, 2011, including:

- review measure developer responses to questions and proposed conditions for those measures conditionally recommended for endorsement in preparation for final recommendation;
- evaluate competing infection measures to select the best measure for endorsement recommendation;
- evaluate related measures to determine if recommendations for specification harmonization are needed; and
- review additional questions or issues.

The measure developers and stewards were available on the call to respond to questions from the Committee as needed. An NQF Member and public comment period occurred at the end of the call; no comments were made at that time. The full transcripts and audio recordings from the conference call can be found on the project web page.

The Committee voted after the call using an online survey tool. In addition, the Committee finished its discussion of a few items via e-mail.

MEASURE EVALUATION SUMMARY

The following summary includes the Committee's original evaluation of 32 measures and any follow-up since the in-person meeting including final action on conditional recommendations. There are now eleven measures recommended for endorsement.

This updated summary focused on the following issues and measures.

Measures with Conditional Recommendations

After reviewing and discussing the measure developers' responses to questions and proposed conditions, the Committee recommended the following measures for endorsement:

- 1438 Periodic assessment of post-dialysis weight by nephrologist (time-limited)
- 1463 Standardized hospitalization ratio for admissions
- 1430 Lower limit of hemoglobin for pediatric patients
- 1454 Proportion of patients with hypercalcemia

Competing Infection Measures

After reviewing and discussing the following competing infection-related measures (new and endorsed), the Committee provisionally recommended them for endorsement, pending further comparison.

- 1460 National Healthcare Safety Network (NHSN) bloodstream infection measure
- 1456 Bacteremia (rate)
- 1457 Access-related bacteremia (rate) [stratified by access]

Related Measures with Potential Harmonization Issues

The Committee discussed the following measures presenting harmonization issues (comparison tables are provided at the end of this document). The endorsed measures have less detailed specifications, and harmonization will be addressed in the upcoming renal endorsement maintenance project.

- 1418 Frequency of adequacy measurement for pediatric hemodialysis patients
- 1421 Method of adequacy measurement for pediatric hemodialysis patients
- 1423 Minimum spKt/V for pediatric hemodialysis patients
- 1454 Proportion of patients with hypercalcemia

Measures and Evaluations

Dialysis Adequacy

Legend: Y- Yes; N-No; C-Completely; P-Partially; M-Minimally; N-Not At All

1418 Frequency of adequacy measurement for pediatric hemodialysis patients

Description: Percentage of all pediatric (less than18 years) patients receiving in-center hemodialysis (irrespective of frequency of dialysis) with documented monthly adequacy measurements (spKt/V) or its components in the calendar month.
Numerator Statement: Number of patients in the denominator with monthly adequacy measurements (spKt/V) or its components in the calendar month.
Denominator Statement: Number of pediatric patients (less than18 years) receiving in-center hemodialysis (irrespective of frequency of dialysis)who are in the facility and on hemodialysis for the entire study period.
Exclusions: Patients on home dialysis, patients not in the facility for the entire calendar month.
Adjustment/Stratification: No risk adjustment necessary N/A No stratification is required for this measure.
Level of Analysis: Facility/Agency
Type of Measure: Process
Data Source: Electronic clinical data CROWNWeb
Measure Steward: Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, MD 21244

Steering Committee Recommendation for Endorsement: Y-17; N-3
Rationale: Although not proximal to desired outcome, there is a performance gap and children are a vulnerable population, so error on side of endorsing measures.

If applicable, Conditions/Questions for Developer:
Developer Response:
Steering Committee Follow-up: Related Measure: 0247 Hemodialysis adequacy clinical performance measure I: Hemodialysis adequacy—Monthly measurement of delivered dose (previously endorsed)
Recommendation: In the future, preferably combine into one measure stratified for adult and pediatric (including home HD if possible). For all measures of dialysis adequacy (frequency, method, and results), the Committee recommends switching to measuring standard Kt/V so that all patients canbe combined regardless of frequency and one measure can be stratified by adult and pediatric. What would be required to move to that measurement? Would a standard Kt/V accommodate home patients who may have adequacy measured on a weekly basis? Is there a standard Kt/V threshold that would apply to all patients and all frequencies?
Developer Follow-up: The CTEP did not discuss stdKt/V as an option for measuring dialysis adequacy. In addition, based on our literature review, evidence that evaluates the impact of dialysis adequacy is based on spKt/V. This has implications in identifying a cut-off for stdKt/V in the pediatric population. Based on these points, we propose that the current measure remain as developed by the TEP with the use of spKt/V. In addition, we suggest that the use of stdKt/V be re-evaluated with a future TEP when more evidence regarding its use in the pediatric population becomes available.

1. Importance to Measure and Report: Y-18; N-2
(1a. Impact; 1b. Performance gap; 1c. Outcome or Evidence)
Rationale: Addresses a vulnerable population.
Although frequency of measuring dose is not proximal to the outcome and the evidence is about adequate dose, measuring dose is necessary, and there is a demonstrated performance gap, i.e., 20% do not have dose reported.
On a related measure (#1421), the Committee discussed the lack of basis for excluding home hemodialysis patients, who also need to receive adequate dialysis.

2. Scientific Acceptability of Measure Properties: C-5; P-11; M-4; N-0
(2a. Precise specifications; 2b. Reliability testing; 2c. Validity testing; 2d. Exclusions justified; 2e. Risk adjustment/stratification; 2f. Meaningful differences; 2g. Comparability; 2h. Disparities)
Rationale: Specifications are precise, and reliability of Kt/V data element is demonstrated. Only face validity addressed; systematic assessment not reported.

3. Usability: C-12; P-7; M-1; N-0
(3a. Meaningful/useful for public reporting and quality improvement; 3b. Harmonized; 3c. Distinctive or additive value to existing measures)
Rationale: In order to improve adequacy of dose, need to measure dose.

4. Feasibility: C-15; P-5; M-; N-0
(4a. Clinical data generated during care process; 4b. Electronic sources; 4c. Exclusions – no additional data source; 4d. Susceptibility to inaccuracies/ unintended consequences identified; 4e. Data collection strategy can be implemented)
Rationale: Easily collected by CMS data collection system.

1421 Method of adequacy measurement for pediatric hemodialysis patients

Description: Percentage of pediatric (less than18 years old) in-center HD patients (irrespective of frequency of dialysis) for whom delivered HD dose was measured by spKt/V as calculated using UKM or Daugirdas II during the reporting period.

1421 Method of adequacy measurement for pediatric hemodialysis patients

Numerator Statement: Number of patients in the denominator for whom delivered HD dose was calculated using UKM or Daugirdas II during the reporting period and for whom the frequency of HD per week is specified.
Denominator Statement: Number of pediatric (less than18 years old) in-center HD patients (irrespective of frequency of dialysis) in the sample for analysis.
Exclusions: Patients on home dialysis, patients not in the facility for the entire calendar month.
Adjustment/Stratification: No risk adjustment necessary N/A No stratification is required for this measure.
Level of Analysis: Facility/Agency
Type of Measure: Process
Data Source: Electronic Health/Medical Record CROWNWeb
Measure Steward: Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, MD 21244

Steering Committee Recommendation for Endorsement: Y-11; N-9
Rationale: The appropriate measurement of adequacy in pediatric HD patients will likely improve outcomes in children. The vote was split because of the exclusion of home hemodialysis patients, which Committee members thought was a critical flaw in the measure.

If applicable, Conditions/Questions for Developer: Can you clarify that this measurement is for a single dialysis session (e.g., explicitly state in title, numerator, denominator)?
Developer Response: "We propose revising the numerator statement to the following:
'Number of patients in the denominator for whom delivered HD dose for a single dialysis session was calculated using UKM or Daugirdas II during the reporting period and for whom the frequency of HD per week is specified.' "
Steering Committee Follow-up: Related measure 0248: Hemodialysis adequacy clinical performance measure II: Method of measurement of delivered hemodialysis dose (previously endorsed)
Recommendation: In the future, preferably combine into one measure stratified for adult and pediatric (including home HD if possible).For all measures of dialysis adequacy (frequency, method, and results), the Committee recommends switching to measuring standard Kt/V so that all patients can be combined regardless of frequency and one measure can be stratified by adult and pediatric. What would be required to move to that measurement? Would a standard Kt/V accommodate home patients who may have adequacy measured on a weekly basis? Is there a standard Kt/V threshold that would apply to all patients and all frequencies?
Developer Follow-up: The revised measure specifications were submitted.
The CTEP did not discuss stdKt/V as an option for measuring dialysis adequacy. In addition, based on our literature review, evidence that evaluates the impact of dialysis adequacy is based on spKt/V. This has implications in identifying a cut-off for stdKt/V in the pediatric population. Based on these points, we propose that the current measure remain as developed by the TEP with the use of spKt/V. In addition, we suggest that the use of stdKt/V be re-evaluated with a future TEP when more evidence regarding its use in the pediatric population becomes available.

1. Importance to Measure and Report: Y-19; N-1
(1a. Impact; 1b. Performance gap; 1c. Outcome or Evidence)
Rationale: Although the method for assessing dose is not proximal to the outcome and the evidence is about adequate dose, it is critical to appropriately measure the adequacy of hemodialysis in pediatric patients. The developer provided additional information that 20% of pediatric patients do not have delivered dose measured. The exclusion of home hemodialysis patients was questioned because those patients also need adequate dosing. The developer stated the exclusion was due to lack of data, not based in the clinical evidence. The Committee discussed that standard Kt/V would allow all patients regardless of frequency to be included in the measure of minimum adequacy.

2. Scientific Acceptability of Measure Properties: C-6; P-13; M-1; N-0
(2a. Precise specifications; 2b. Reliability testing; 2c. Validity testing; 2d. Exclusions justified; 2e. Risk adjustment/stratification; 2f. Meaningful differences; 2g. Comparability; 2h. Disparities)
Rationale: Specifications are precise. The method is associated with frequency of dialysis, but this measure is just about the method for a single session, so either method (UKM, Daugirdas) in numerator is acceptable. The Committee suggested explicitly identifying in the title and specifications that the method is for a single session. Reliability of method data element demonstrated. Only face validity addressed; systematic assessment not reported.

3. Usability: C-6; P-11; M-2; N-1
(3a. Meaningful/useful for public reporting and quality improvement; 3b. Harmonized; 3c. Distinctive or additive value to existing measures)
Rationale: In order to improve adequacy of dose, need to accurately measure dose.

4. Feasibility: C-7; P-11; M-2; N-0
(4a. Clinical data generated during care process; 4b. Electronic sources; 4c. Exclusions – no additional data source; 4d. Susceptibility to inaccuracies/ unintended consequences identified; 4e. Data collection strategy can be implemented)
Rationale: The needed data elements are easily collectable and reliable through the proposed Crownweb system.

1423 Minimum spKt/V for pediatric hemodialysis patients

Description: Percentage of all pediatric (less than18 years old) in-center HD patients who have been on hemodialysis for 90 days or more and dialyzing 3 or 4 times weekly whose delivered dose of hemodialysis (calculated from the last measurements of the month using the UKM or Daugirdas II formula) was a spKt/Vgreater than or equal to1.2.
Numerator Statement: Number of patients in the denominator whose delivered dose of hemodialysis (calculated from the last measurements of the month using the UKM or Daugirdas II formula) was a spKt/Vgreater than =1.2.
Denominator Statement: Number of pediatric (less than18 years old) in-center HD patients who have been on hemodialysis for 90 days or more and dialyzing 3 or 4 times weekly.
Exclusions: Patients on home hemodialysis, patients on hemodialysisless than90 days, patients receiving dialysis less than3x/week or greater than 4x/week, patients not in the facility for the entire calendar month.
Adjustment/Stratification: No risk adjustment necessary N/A Stratification of target values by age was considered, with higher targets for younger patients, however there are insufficient data to support any stratified target measures at this time.
Level of Analysis: Facility/Agency
Type of Measure: Outcome
Data Source: Electronic clinical data CROWNWeb
Measure Steward: Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, MD 21244

Steering Committee Recommendation for Endorsement: Y-11; N-9
Rationale: The rationale for endorsement is that a minimal level for HD adequacy is important in pediatric patients.
The rationale against endorsement questions the evidence for setting the minimal dose at 1.2 (perhaps it should be higher for pediatric patients) and the questions the use of spKt/V for different frequencies of dialysis.

If applicable, Conditions/Questions for Developer:
Developer Response:
Steering Committee Follow-up: Related measure 0250: Hemodialysis adequacy clinical performance measure III: Hemodialysis adequacy—HD adequacy CPM III: Minimum delivered hemodialysis dose
Recommendation: Specifications should be completely harmonized except for frequency of dialysis in pediatric measure of 3-4x/wk.
In the future, for all measures of dialysis adequacy (frequency, method, and results), the Committee recommends switching to measuring standard Kt/V so that all patients can be combined regardless of frequency and one measure can be stratified by adult and pediatric. What would be required to move to that measurement? Would a standard Kt/V accommodate home patients who may have adequacy measured on a weekly basis? Is there a standard Kt/V threshold that would apply to all patients and all frequencies?
Developer Follow-up: The CTEP did not discuss stdKt/V as an option for measuring dialysis adequacy. In addition, based on our literature review, evidence that evaluates the impact of dialysis adequacy is based on spKt/V. This has implications in identifying a cut-off for stdKt/V in the pediatric population. Based on these points, we propose that the current measure remain as developed by the TEP with the use of spKt/V. In addition, we suggest that the use of stdKt/V be re-evaluated with a future TEP when more evidence regarding its use in the pediatric population becomes available. Measure has not been revised.

1. Importance to Measure and Report: Y-13; N-7
(1a. Impact; 1b. Performance gap; 1c. Outcome or Evidence)
Rationale: Although it is questionable whether 1.2 is the correct target and whether it's appropriate for all ages up to 18, there is some evidence that < 1.2 is linked to poorer outcomes in pediatric patients. Some Committee members advocated that a minimally acceptable target was needed; and others cautioned that if endorsed in a performance measure, the minimum may become the standard. At present there are opportunities for improvement in this area because a number of pediatric patients are not receiving adequate minimal HD.

2. Scientific Acceptability of Measure Properties: C-4; P-6; M-6; N-4
(2a. Precise specifications; 2b. Reliability testing; 2c. Validity testing; 2d. Exclusions justified; 2e. Risk adjustment/stratification; 2f. Meaningful differences; 2g. Comparability; 2h. Disparities)
Rationale: The specifications are precise. It was noted that if you assess adequacy of dialysis for patients dialyzing at different frequencies (as specified in this measure), then the measure should be standard Kt/V, not single pool Kt/V. One of the pediatric expert Committee members stated that the goal was to include as many patients as possible in the denominator so patients dialyzing 3-4 days week were included in the denominator. Another Committee member commented that that is the reason for using standard Kt/V: the patient getting dialyzed 4x/wk is going to have a lower spKt/V and look worse even though the patient has better urea removal. A pediatric expert on the Steering Committee stated that the younger patients having dialysis 4x/wk and they want them to meet the 1.2 with each treatment because they need it (actually represents different standard in one measure). Reliability of the spKt/V element was demonstrated. Only face validity addressed; systematic assessment not reported.

3. Usability: C-4; P-12; M-4; N-0
(3a. Meaningful/useful for public reporting and quality improvement; 3b. Harmonized; 3c. Distinctive or additive value to existing measures)

1423 Minimum spKt/V for pediatric hemodialysis patients
Rationale: The measure is meaningful and will positively affect patient care. It is useful for public reporting and is easily understood by multiple audiences.
4. Feasibility: C-7; P-10; M-3; N-0 *(4a. Clinical data generated during care process; 4b. Electronic sources; 4c. Exclusions – no additional data source; 4d. Susceptibility to inaccuracies/ unintended consequences identified; 4e. Data collection strategy can be implemented)* Rationale: Reliable data entry for this measure is already in place and iscommonly used to report to CMS. The feasibility of measurement without error is high.

1425 Measurement of nPCR for pediatric hemodialysis patients
Description: Percentage of pediatric (less than18 years old) in-center HD patients (irrespective of frequency of dialysis) with documented monthly nPCR measurements. Numerator Statement: Number of patients in the denominator with monthly nPCR measurements. Denominator Statement: Number of all pediatric (less than18 years old) in-center hemodialysis patients (irrespective of frequency of dialysis) with documented monthly nPCR measurements. Exclusions: Patients on home dialysis, patients not in the facility for the entire one-month study period. Adjustment/Stratification: No risk adjustment necessary N/A No stratification is required for this measure. Level of Analysis: Facility/Agency Type of Measure: Process Data Source: Electronic clinical data CROWNWeb Measure Steward: Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, MD 21244
Steering Committee Recommendation for Endorsement: Time-Limited Y-12; N-8 Rationale: The rationale for endorsement is that this measure of nutrition, nPCR, can be easily calculated and can provide important information about the nutrition of pediatric HD patients. Its use can result in improved improved long-term outcomes in pediatric patients. The rationale against endorsement is that the evidence is not robust enough to qualify this as a performance measure.
If applicable, Conditions/Questions for Developer: As stated, the denominator has the same information as the numerator. It is assumed that the last part of the denominator statement should be removed. Can you please clarify if this is the case? Developer Response: We thank the NQF Steering Committee for the opportunity to correct this. The denominator should read: "Number of all pediatric (<18 years old) in-center hemodialysis patients (irrespective of frequency of dialysis)". Steering Committee Follow-up: Developer Follow-up: The revised measure specifications were submitted.
1. Importance to Measure and Report: Y-14; N-6 *(1a. Impact; 1b. Performance gap; 1c. Outcome or Evidence)* Rationale: Good nutrition and protein intake is critical in the pediatric ESRD patient. The nPCR is a better marker of nutritional status than serum albumin. Measuring lab values is not proximal to desired outcomes. Additionally, there is little to no evidence about specific target values or interventions to change them, so it raises the question of whether they are appropriate for a performance measure. However, the Committee thought that measuring nPCR has the potential for high impact in dialysis prescription when used in combination with Kt/V.
2. Scientific Acceptability of Measure Properties: C-3; P-13; M-4; N-0 *(2a. Precise specifications; 2b. Reliability testing; 2c. Validity testing; 2d. Exclusions justified; 2e. Risk adjustment/stratification; 2f. Meaningful differences; 2g. Comparability; 2h. Disparities)* Rationale: The ratings are primarily based on the specifications (in the future, the Steering Committee will be instructed that the highest rating for untested measures is minimal). The measure is untested, but the specifications are precise.
3. Usability: C-6; P-7; M-6; N-1 *(3a. Meaningful/useful for public reporting and quality improvement; 3b. Harmonized; 3c. Distinctive or additive value to existing measures)* Rationale: Although measuring nutrition alone will not improve nutritional outcomes, it is the first step in addressing an important issue for pediatric patients.
4. Feasibility: C-7; P-11; M-2; N-0 *(4a. Clinical data generated during care process; 4b. Electronic sources; 4c. Exclusions – no additional data source; 4d. Susceptibility to inaccuracies/ unintended consequences identified; 4e. Data collection strategy can be implemented)* Rationale: The data are routinely generated, and the calculation of the measure is similar to that of the measure of frequency of measuring Kt/V. Facilities already report the data electronically.

1426 Assessment of iron stores

Description: Percentage of all adult (greater than or equal to18 years old) dialysis patients for whom serum ferritin and transferrin saturation percentage (TSAT) are measured simultaneously at least once during the three-month study period.
Numerator Statement: Number of patients in the denominator for whom serum ferritin and TSAT are measured simultaneously at least once during the study period. Simultaneous measurements are those reported with the same collection date.
Denominator Statement: All adult (greater than =18 years old) hemodialysis or peritoneal dialysis patients in the facility for the entire three-month study period.
Exclusions: None.
Adjustment/Stratification: No risk adjustment necessary N/A
Level of Analysis: Facility/Agency
Type of Measure: Process
Data Source: Electronic clinical data CROWNWeb
Measure Steward: Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, MD 21244

Steering Committee Recommendation for Endorsement: No
Rationale: Did not pass Importance to Measure and Report

1. Importance to Measure and Report: Y-5; N-13
(1a. Impact; 1b. Performance gap; 1c. Outcome or Evidence)
Rationale: This measure was intended to replace measure 0252 (removing measurement of CHr). Measuring a lab value is not proximal to the desired outcome. A measure of hemoglobin value is a better indicator of management of anemia and quality of care. There is no evidence that serum ferritin and TSAT need to be measured simultaneously.

1431 Measurement of iron stores for pediatric patients

Description: Percentage of all pediatric (less than18 years old) hemodialysis and peritoneal dialysis patients prescribed an ESA at any time during the study period or who have a Hbless than11.0 g/dL in at least one month of the study period for whom serum ferritin concentration and percent transferrin saturation (TSAT) are measured at least once in a three-month period.
Numerator Statement: Number of dialysis patients in the denominator for whom serum ferritin concentration and percent transferrin saturation (TSAT) are measured at least once in a three-month study period for all hemodialysis and peritoneal dialysis patients.
Denominator Statement: All pediatric (less than18 years old) hemodialysis and peritoneal dialysis patients prescribed an erythropoiesis-stimulating agent (ESA) at any time during the study period or who have a hemoglobin less than11.0 g/dL in at least one month of the study period. The hemoglobin value reported for the end of each study period (end-of-month hemoglobin) is used for this calculation.
Exclusions: Patients who are not in the facility for the entire three-month study period.
Adjustment/Stratification: No risk adjustment necessary N/A No stratification is required for this measure.
Level of Analysis: Facility/Agency
Type of Measure: Process
Data Source: Electronic clinical data CROWNWeb (Consolidated Renal Operations in a Web Enabled Network)
Measure Steward: Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, MD 21244

Steering Committee Recommendation for Endorsement: Y-9; N-11
Rationale: The rationale for endorsement is primarily that pediatric measures are needed. The rationales against endorsement are the same as those for for the adult measure, i.e., obtaining lab values is not proximal to desired outcome, and measure of Hb values is a better measure of anemia management.

1. Importance to Measure and Report: Y-11; N-9
(1a. Impact; 1b. Performance gap; 1c. Outcome or Evidence)
Rationale: Measuring lab values is not proximal to desired outcomes, and the evidence presented was about anemia and treatment of anemia rather than measurement of iron values. There is no evidence that serum ferritin and TSAT need to be measured simultaneously. However, some Committee members thought that this measure focus could be acceptable in a new area of performance measurement for pediatric patients.

2. Scientific Acceptability of Measure Properties: C-3; P-12; M-5; N-0
(2a. Precise specifications; 2b. Reliability testing; 2c. Validity testing; 2d. Exclusions justified; 2e. Risk adjustment/stratification; 2f. Meaningful differences; 2g. Comparability; 2h. Disparities)
Rationale: Measure specifications are precise. Reliability of data elements for ferritin and TSAT demonstrated. Face validity referenced, but no description of systematic assessment.

3. Usability: C-5; P-10; M-5; N-
(3a. Meaningful/useful for public reporting and quality improvement; 3b. Harmonized; 3c. Distinctive or additive value to existing measures)

1431 Measurement of iron stores for pediatric patients

Rationale: The information obtained could be understandable and useful to impact use of iron therapy in pediatric anemic patients.

4. Feasibility: C-7; P-10; M-2; N-1

(4a. Clinical data generated during care process; 4b. Electronic sources; 4c. Exclusions – no additional data source; 4d. Susceptibility to inaccuracies/ unintended consequences identified; 4e. Data collection strategy can be implemented)

Rationale: One member expressed concern about the complexity and number of data elements required; however, others noted that all the data elements are currently collected via CMS data system and can be easily used in the measure.

1428 Use of iron therapy when indicated

Description: Percentage of all adult (greater than or equal to18 years old) dialysis patients with a serum ferritin less than 100 ng/mL and a transferrin saturation percentage (TSAT) less than 50% on at least one simultaneous measurement who received IV iron in the following three months.

Numerator Statement: Number of patients in the denominator who received IV iron within three months following the first occurrence of serum ferritin less than 100 ng/mL and TSAT less than 50% during the study period.

Denominator Statement: All adult (greater than =18 years) hemodialysis (HD) and peritoneal dialysis (PD) patients in the facility for the entire three-month reporting period who had serum ferritin less than100 ng/mL and TSAT less than50% on at least one simultaneous measurement reported during the three-month study period. Simultaneous measurements are those reported with the same collection date.

Exclusions: 1. Patients with mean hemoglobin (Hgb) greater than 12g/dl who did not receive an erythropoietin stimulating agent (ESA) during the 3 month study period. The last recorded Hgb value of each month of the study period will be used in calculating the mean.
2. Patients with documented history of anaphylaxis to IV iron products.

Adjustment/Stratification: No risk adjustment necessary N/A

Level of Analysis: Facility/Agency

Type of Measure: Outcome

Data Source: Electronic clinical data CROWNWeb

Measure Steward: Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, MD 21244

Steering Committee Recommendation for Endorsement: No

Rationale: Did not pass Importance to Measure and Report

If applicable, Conditions/Questions for Developer:

Developer Response:

Steering Committee Follow-up: The Steering Committee recommended the pediatric measure (#1433), which will be for time-limited endorsement, but not the adult measure. The Committee was asked to review its decision and rationale. The Committee agreed that its decisions should stand. Numerous problems with the adult measure were expressed, as noted under the Importance criterion. The pediatric measure was recommended for endorsement because it has a much better definition of when iron therapy is indicated; there is no clear evidence to support the application of pediatric definitions to adults (e.g., Hb <11 for pediatric). Although the pediatric measure raised some issues under the Importance criterion, e.g., no data on performance gap, lack of evidence for the Hb<11 value, the Committee agreed with the pediatric experts' rationale that such a measure was needed to support the proactive management of iron deficiency anemia in pediatric patients in whom iron and ESA requirements often are higher.

The Steering Committee did not suggest changes to the adult measure. The Committee will review any new information received during the upcoming comment period to determine if the recommendation should be revisited.

Developer Follow-up:

1. Importance to Measure and Report: Y-5; N-15

(1a. Impact; 1b. Performance gap; 1c. Outcome or Evidence)

Rationale: Iron therapy is indicated for iron deficiency anemia and might limit doses of ESAs. However, the evidence presented was about patients treated with ESAs to higher target hemoglobin levels, not about effectiveness of iron therapy or the relationship of iron therapy to ESA use. Iron therapy guidelines are opinion based. All facility scores at 75th percentile indicated that ESRD patients are receiving iron therapy. The developer provided additional information that 3,700 out of 10,000 patients who met the denominator specifications were not receiving iron therapy. The values specified in the measure are not well-grounded in the evidence. The specification of TSAT < 50% eliminates virtually no additional patients besides those with ferritin < 100 ng/ml. Iron deficiency anemia is defined as ferritin < 30 ng/ml rather than <100 ng/ml. The exclusion of Hb ≥12 may be too high because 12 is the upper limit; perhaps Hb should be 10. The values used in the measure could lead to inappropriate IV iron, which exposes patients to harm. If Hb is 11.5 and the patient is slightly deficient in other values, then iron might not be clearly indicated. Even if Hb <10 and ferritin = 90, the patient may not be iron deficient. There is no evidence that ferritin and TSAT need simultaneous measurement. The measure includes PD patients but does not allow oral iron therapy. Missing is consideration of evaluation of the cause of iron deficiency, trends over time in TSAT, ferritin, and hemoglobin, as well as intensity of iron administration in response to the test results obtained. Anemia management is

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important, but an intermediate outcome of hemoglobin levels is a better measure.

1433 Use of iron therapy for pediatric patients
Description: Percentage of all pediatric (less than18 years old) hemodialysis and peritoneal dialysis patients with hemoglobin less than11.0 g/dL and in whom simultaneous values of serum ferritin concentration was less than100 ng/ml and TSATless than20% who received IV iron or were prescribed oral iron within the following three months. Numerator Statement: Number of patients in the denominator who received IV iron or were prescribed oral iron within three months following the first occurrence of serum ferritin less than100 ng/mL and transferrin saturation (TSAT) less than 20% during the study period. Denominator Statement: All pediatric (less than18 years old) hemodialysis and peritoneal dialysis patients in the facility for the entire three-month reporting period with hemoglobin less than11 g/dL and in whom simultaneous values of serum ferritin was less than100 ng/mL and TSATless than20% during the three-month study period. Exclusions: Patients who are not in the facility for the entire three-month study period. Adjustment/Stratification: No risk adjustment necessary N/A No stratification is required for this measure. Level of Analysis: Facility/Agency Type of Measure: Process Data Source: Electronic clinical data CROWNWeb (Consolidated Renal Operations in a Web Enabled Network) Measure Steward: Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, MD 21244
Steering Committee Recommendation for Endorsement: Time-limited, because key data elements regarding iron therapy not tested. Y-14; N-6 Rationale: The measure has a better description of iron deficiency than does the adult measure (1428) with TSAT <20%. Iron therapy is indicated for iron deficiency anemia and might limit doses of ESAs.
If applicable, Conditions/Questions for Developer: Why are simultaneous values for ferritin and TSAT required? Developer Response: "Measurement of ferritin levels and tranferrin saturation levels represent different approaches to the assessment of iron stores. Both values are necessary for the proper assessment of iron status, and for practical reasons, especially for pediatric patients on peritoneal dialysis, a single blood draw is commonly used for the measurement of both values. In addition, there is no evidence that iron therapy is beneficial for patients in whom transferrin saturation levels are low but ferritin levels are markedly elevated. Nevertheless, if the ferritin levels and transferrin saturation levels are not obtained simultaneously, then the appropriate clinical action still applies. Thus, in response to the NQF comment, it is not critical to obtain simultaneous values for ferritin and TSAT; however, both measures are necessary prior to the initiation of iron therapy. We suggest revising the measure description to the following: 'Percentage of all pediatric (<18 years old) hemodialysis and peritoneal dialysis patients with hemoglobin <11.0 g/dL and in whom serum ferritin concentration was <100 ng/ml and TSAT<20% who received IV iron or were prescribed oral iron within the following three months' Relatedly, we suggest revising the denominator to the following: 'All pediatric (<18 years old) hemodialysis and peritoneal dialysis patients in the facility for the entire three-month reporting period with hemoglobin <11 g/dL and in whom serum ferritin was <100 ng/mL and TSAT<20% during the three month study period.' The numerator remains as: 'Number of patients in the denominator who received IV iron or were prescribed oral iron within three months following the first occurrence of serum ferritin <100 ng/mL and transferrin saturation (TSAT) <20% during the study period.' " Steering Committee Follow-up: Developer Follow-up: The revised measure specifications were submitted.
1. Importance to Measure and Report: Y-13; N-7 *(1a. Impact; 1b. Performance gap; 1c. Outcome or Evidence)* Rationale: The measure has a better description of iron deficiency than does the adult measure (#1428) with TSAT <20%, but data on sensitivity and specificity of ferritin and TSAT levels in children were not identified. Iron therapy is indicated for iron deficiency anemia and might limit doses of ESAs. Iron therapy guidelines are opinion based. No specific data on a performance gap was provided. No evidence was provided to support Hb level <11; however, the pediatric specialists indicated that 11 was accepted as the threshold for anemia in pediatric patients. New data suggest that cytokines interfere with erythropoiesis, which may make these values more important. Ferritin levels may be age-dependent, which might suggest it is less useful as a marker. However the pediatric experts advocated for this measure because it emphasizes proactive management. There is no evidence that ferritin and TSAT need simultaneous measurement.
2. Scientific Acceptability of Measure Properties: C-4; P-11; M-4; N-0 *(2a. Precise specifications; 2b. Reliability testing; 2c. Validity testing; 2d. Exclusions justified; 2e. Risk adjustment/stratification; 2f.*

1433 Use of iron therapy for pediatric patients

Meaningful differences; 2g. Comparability; 2h. Disparities)

Rationale: The ratings are primarily based on the specifications (in the future, the Steering Committee will be instructed that the highest rating for untested measures is minimal). Measure specifications are precise. Reliability of data elements for lab values were presented, but there was nothing about iron therapy, the central topic of the measure; therefore, this measure will be considered untested. Face validity was mentioned, but a description of systematic assessment was not provided. Facilities could meet measure by prescribing oral iron, even if it is not taken or responsive or is inappropriate for HD patients, whichs call into question the measure's validity as a quality indicator. What happens if ferritin and TSAT values are not simultaneous, i.e., excluded from denominator?

3. Usability: C-3; P-14; M-3; N-0

(3a. Meaningful/useful for public reporting and quality improvement; 3b. Harmonized; 3c. Distinctive or additive value to existing measures)

Rationale: If valid, could provide information about appropriate management of anemia.

4. Feasibility: C-7; P-11; M-2; N-0

(4a. Clinical data generated during care process; 4b. Electronic sources; 4c. Exclusions – no additional data source; 4d. Susceptibility to inaccuracies/ unintended consequences identified; 4e. Data collection strategy can be implemented)

Rationale: Data generated from routine care and reported electronically. Is there an unintended consequence of overuse of iron therapy?

1429 Avoidance of iron therapy in iron overload

Description: Percentage of all adult (greater than or equal to18 years old) dialysis patients with a serum ferritin greater than or equal to1200 ng/mL or a TSAT greater than or equal to50% on at least one simultaneous measurement during the three-month study period who did not receive IV iron in the following three months.

Numerator Statement: Number of patients in the denominator who did not receive IV iron within three months following the first occurrence of serum ferritin greater than or equal to1200 ng/mL or TSAT greater than =50% during the study period.

Denominator Statement: All adult (greater than =18 years) hemodialysis (HD) and peritoneal dialysis (PD) patients in the facility for the entire three-month reporting period who had serum ferritin greater than =1200 ng/mL or TSAT greater than =50% on at least one simultaneous measurement reported during the three-month study period. Simultaneous measurements are those reported with the same collection date.

Exclusions: None

Adjustment/Stratification: No risk adjustment necessary N/A

Level of Analysis: Facility/Agency

Type of Measure: Outcome

Data Source: Electronic clinical data CROWNWeb

Measure Steward: Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, MD 21244

Steering Committee Recommendation for Endorsement: No

Rationale: Did not pass Importance to Measure and Report

1. Importance to Measure and Report: Y-9; N-11

(1a. Impact; 1b. Performance gap; 1c. Outcome or Evidence)

Rationale: The rationale for considering this criterion as met is the consequence of potential harm of IV iron overload.

The rationale for considering this criterion as not met was related to inadequate evidence. Evidence of levels associated with harm were not identified. The definition of iron overload in dialysis patients (this measure is not limited to HD) is not evidence based. Most dialysis patients have adequate bone marrow iron stores with ferritin > 100-300 ng/ml; therefore, on this basis alone continued iron administration may be excessive in some patients. A better indicator of excess iron administration would be an increasing ferritin level. TSAT ≥ 50% is very rare, and is therefore largely irrelevant in this measure (40% may be a better upper limit). Hence the measure is really focused on ferritin > 1,200 ng/ml. The developer provided additional information from CROWNweb sample: 10,000 out of 40,000 patients who met the denominator criteria did not receive IV iron in the following 3 months. However, this raised the question of timing of the lab values in relation to prior IV iron administration.

1424 Monthly hemoglobin measurement for pediatric patients

Description: Percentage of all pediatric (less than18 years) hemodialysis and peritoneal dialysis patients who have monthly measures for hemoglobin.

Numerator Statement: Number of pediatric (less than18 years old) hemodialysis and peritoneal dialysis patients who have monthly measures for hemoglobin. The hemoglobin value reported for the end of each reporting month (end-of-month hemoglobin) is used for the calculation.

1424 Monthly hemoglobin measurement for pediatric patients
Denominator Statement: All pediatric (less than18 years old) hemodialysis and peritoneal dialysis patients. Exclusions: Patients who are not in the facility for the entire calendar month. Adjustment/Stratification: No risk adjustment necessary N/A No stratification is required for this measure. Level of Analysis: Facility/Agency Type of Measure: Process Data Source: Electronic clinical data CROWNWeb (Consolidated Renal Operations in a Web Enabled Network) Measure Steward: Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, MD 21244
Steering Committee Recommendation for Endorsement: Y-20; N-0 Rationale: Although measuring hemoglobin value is not proximal to the desired outcome and the evidence provided was about the relationship between hemoglobin levels and outcomes, the current poor performance data warrant the use of this measure.
1. Importance to Measure and Report: Y-19; N-0 *(1a. Impact; 1b. Performance gap; 1c. Outcome or Evidence)* Rationale: Although measuring hemoglobin value is not proximal to the desired outcome and the evidence provided was about the relationship between hemoglobin levels and outcomes, the current poor performance data warrant the use of this measure. In a 2008 study, hemoglobin was reported in less than three of the six study months in 29% of pediatric ESRD patients and was not reported in any of the six study months for 11% of patients.
2. Scientific Acceptability of Measure Properties: C-15; P-5; M-; N-0 *(2a. Precise specifications; 2b. Reliability testing; 2c. Validity testing; 2d. Exclusions justified; 2e. Risk adjustment/stratification; 2f. Meaningful differences; 2g. Comparability; 2h. Disparities)* Rationale: The measure is precisely specified. Reliability was demonstrated for "Hb ≥ 9", but measure is based on Hb value and collection date. Face validity was mentioned, but there is no description of systematic assessment.
3. Usability: C-18; P-2; M-; N-0 *(3a. Meaningful/useful for public reporting and quality improvement; 3b. Harmonized; 3c. Distinctive or additive value to existing measures)* Rationale: The information provided by this measure is meaningful, understandable, and useful to providers and patients.
4. Feasibility: C-18; P-1; M-; N-0 *(4a. Clinical data generated during care process; 4b. Electronic sources; 4c. Exclusions – no additional data source; 4d. Susceptibility to inaccuracies/ unintended consequences identified; 4e. Data collection strategy can be implemented)* Rationale: Data for the measure are in the process of being collected via the ESRD CPM, and units are familiar with the procedure.

1430 Lower limit of hemoglobin for pediatric patients
Description: Percentage of pediatric (less than18 years old) hemodialysis and peritoneal dialysis patients, with ESRD greater than =3 months, who have a mean hemoglobin less than10 g/dL for a 3 month reporting period, irrespective of ESA use. The hemoglobin value reported at the end of each reporting month (end-of-month hemoglobin) is used for the calculation. Numerator Statement: Number of pediatric (less than18 years old) hemodialysis and peritoneal dialysis patients, with End Stage Renal Disease (ESRD) greater than or equal to3 months, who have a mean hemoglobin less than10.0 g/dL for a 3 month reporting period, irrespective of erythropoiesis-stimulating agent (ESA) use. The hemoglobin value reported for the end of each reporting month (end-of-month hemoglobin) is used for the calculation. Denominator Statement: All pediatric (less than18 years old) hemodialysis and peritoneal dialysis patients with ESRD greater than or equal to3 months Exclusions: Patients on dialysis less than3 months at the start of the reporting period, patients who are not in the facility for the entire one-month study period. Adjustment/Stratification: No risk adjustment necessary N/A No stratification is required for this measure. Level of Analysis: Facility/Agency Type of Measure: Outcome Data Source: Electronic clinical data CROWNWeb (Consolidated Renal Operations in a Web Enabled Network) Measure Steward: Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, MD 21244
Steering Committee Recommendation for Endorsement: Final: Y-12; N-7; A-1; Initial: Y-18; N-2 with Conditions Rationale: Anemia is related to morbidity and mortality and how patients feel and function. The provided data indicated that 14-19% of pediatric patients had hemoglobin levels < 10 g/dl in 2007.
If applicable, Conditions/Questions for Developer: Conditions: 1) exclude patients w/sickle cell anemia, 2) numerator: number of patients with Hb < 10 for each of 3 months (Y-13; N-7) Developer Response: Arbor Research and the Pediatric Clinical Technical Expert Panel (C-TEP) discussed the points recommended by the NQF Steering Committee:

1430 Lower limit of hemoglobin for pediatric patients

"A. In regards the exclusion of patients with sickle cell disease, the Pediatric C-TEP generally agrees with this suggestion since achievement of the minimum hemoglobin target is more difficult in these patients. The C-TEP also recognizes that facilities that dialyze fewer pediatric patients are more likely to be impacted by patients with sickle cell disease Given that published data suggests that only a very small number of pediatric patients have a diagnosis of sickle cell disease (0.3% of dialysis patients, NAPRTCS 2008 Annual Report, https://web.emmes.com/study/ped/annlrept/annlrept.html), the burden of data collection should be balanced with the measure improvement gained with exclusion of these patients. With all these points in mind, the C-TEP proposes to move forward with the measure and that exclusion of sickle cell patients will be submitted as a measure maintenance step as soon as data for this diagnosis are available from CMS data.
B. In regards the definition of the lower limit for Hb, the NQF suggested the use of a persistently low Hb level below 10g/dL for the 3 month reporting period rather than the original measure which uses a 3 month mean below 10g/dL. Although the C-TEP recognizes that patients who start hemodialysis with very low hemoglobin levels may have difficulty in achieving the Hb target, the requirement for inclusion of patients with ESRD of 3 months mitigates this concern. In addition, the C-TEP does not support this proposed revision for the following reasons: a. In facility-level analyses comparing achievement of hemoglobin levels based on persistently low Hb levels as suggested by the NQF vs the original proposed measure, the mean facility-level percent of patients missing this target was 3.3% of facilities compared to 14.9% with the latter target. This suggests a marked reduction in the sensitivity of the measure in capturing pediatric patients with anemia; b. Literature providing evidence for morbidity and mortality associated with low hemoglobin levels are based on mean values rather than on persistently low hemoglobin levels; c. Existing policies, including the use of the Quality Incentive Payment utilizes mean hemoglobin levels; d. Requiring a persistently low hemoglobin level to define this measure may lead to substandard care as clinicians may delay appropriate clinical response; e. Finally, requiring persistently low Hb levels creates a measure that is more likely to identify patients with ESA resistance anemia rather than in identifying patients who would benefit from more aggressive anemia treatment."
Steering Committee Follow-up: The majority of the Steering Committee accepted the developer's response. However, the Committee remained somewhat divided about viewing this as a measure indicating overall management of anemia (percent with Hb <10 using the mean over 3 months) vs. changing it to a measure of patients with persistently low Hb (percent with Hb <10 for each of 3 moths)..
Developer Follow-up:

1. Importance to Measure and Report: Final: Y-17; N-1; Initial: Y-19; N-0
(1a. Impact; 1b. Performance gap; 1c. Outcome or Evidence)
Rationale: Anemia is related to morbidity and mortality and how patients feel and function. The provided data indicated that 14-19% of pediatric patients had hemoglobin levels < 10 g/dl in 2007; more recent data were not provided. Although there is little to no evidence to support a specific value for the pediatric population, there is no evidence that it should be different from the adult measure.

2. Scientific Acceptability of Measure Properties: Final: C-7: P-9; M-2; N-0; Initial: Did not vote on rating because of recommended changes.
(2a. Precise specifications; 2b. Reliability testing; 2c. Validity testing; 2d. Exclusions justified; 2e. Risk adjustment/stratification; 2f. Meaningful differences; 2g. Comparability; 2h. Disparities)
Rationale: Patients with sickle cell anemia are harmed with Hb > 9 and should be excluded.
Patients could have increasing trends and still be included in the numerator as specified. Some Committee members advocated for a change from average <10 to <10 in each of the 3 months (Y-13; N-7) in order to identify persistent anemia. There is a need for action when hemoglobin is <10, and a performance measure should identify when action is inadequate.
Other Committee members advocated for the average over 3 months as specified because the measure aggregates data from all patents and is an indicator of how well anemia is managed overall; it is not intended for clinical management individual patients. The 3-month average takes into account biologic variability. The proposed change focuses on outliers versus overall management.
Additionally, a measure using the average would be harmonized with the adult measure.
When asked, the developer indicated that its TEP did not discuss persistently low hemoglobin.

3. Usability: Final: C-8: P-8; M-2; N-0; Initial: Did not vote on rating because of recommended changes
(3a. Meaningful/useful for public reporting and quality improvement; 3b. Harmonized; 3c. Distinctive or additive value to existing measures)
Rationale: A performance measure of mangement of anemia is useful for quality improvement.

4. Feasibility: Final: C-12: P-4; M-2; N-0; Initial: Did not vote on rating because of recommended changes.
(4a. Clinical data generated during care process; 4b. Electronic sources; 4c. Exclusions – no additional data source; 4d. Susceptibility to inaccuracies/ unintended consequences identified 4e. Data collection strategy can be implemented)
Rationale: The data are required in CROWNweb.
The developer indicated that the proposed change was possible with the data available, but ultimately did not agree with the condition..

1432 Dietary sodium reduction advice

1432 Dietary sodium reduction advice
Description: The proportion of patients who have received formal advice on dietary sodium restriction by the renal dietician within the past 90 days. Numerator Statement: Number of patients in the denominator who have received formal advice on dietary sodium restriction by the renal dietician within the past 90 days. Denominator Statement: Number of patients in an outpatient dialysis facility undergoing chronic maintenance dialysis. Exclusions: None. Adjustment/Stratification: No risk adjustment necessary N/A No stratification is required for this measure. Level of Analysis: Facility/Agency Type of Measure: Process Data Source: Electronic clinical data CROWNWeb Measure Steward: Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, MD 21244
Steering Committee Recommendation for Endorsement: No Rationale: Did not pass Importance to Measure and Report
1. Importance to Measure and Report: Y-5; N-15 *(1a. Impact; 1b. Performance gap; 1c. Outcome or Evidence)* Rationale: Although dietary salt restriction is appropriate and evidence-based, the focus of this measure is on dietary advice. There is insufficient evidence linking dietary advice to sodium intake, to impact on volume, and to its consequences. No basis for the 90-day period was provided. The measure reports the provider's perspective and is susceptible to becoming a documentation/checkbox measure, or to being fulfilled by just giving patients an information sheet. There is a critical need for measures that address patient self-management from the patient perspective, e.g., whether the patient reports receiving counseling or what is learned; however, this measure won't do that. Some Committee members noted that patients may not be aware of the link between sodium intake and volume, but despite its flaws, the measure will raise awareness of the need to address dietary sodium.

1434 Sodium profiling practice for hemodialysis
Description: Proportion of patients who were not prescribed sodium profiling in the reporting month. Numerator Statement: Number of patients in denominator who were not prescribed sodium profiling in the reporting month. Denominator Statement: Number of patients in an outpatient dialysis facility undergoing chronic maintenance HD. Exclusions: None. Adjustment/Stratification: No risk adjustment necessary N/A No stratification is required for this measure. Level of Analysis: Facility/Agency Type of Measure: Process Data Source: Electronic clinical data CROWNWeb Measure Steward: Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, MD 21244
Steering Committee Recommendation for Endorsement: No Rationale: Did not pass Importance to Measure and Report
1. Importance to Measure and Report: Y-4: N-16 *(1a. Impact; 1b. Performance gap; 1c. Outcome or Evidence)* Rationale: Data on prevalence of sodium profiling or performance gap were not presented. Evidence regarding the use and consequences of the practice was weak. There was no discussion of when sodium profiling might be appropriate (e.g., for those particularly prone to intradialytic hypotension). The measure is based on a reasonable hypothesis that sodium profiling causes excess sodium transfer, leading to increased volume and its consequences, but it has not been adequately studied to warrant being a performance measure.

1435 Restriction of dialysate sodium
Description: Proportion of patients who were prescribed a dialysate sodium concentration less than or equal to 138 mEq/L for all sessions in the reporting month. Numerator Statement: Number of patients in denominator who were prescribed a dialysate sodium concentration less than or equal to 138 mEq/L in the reporting month. Denominator Statement: Number of patients in an outpatient dialysis facility undergoing chronic maintenance hemodialysis (HD). Exclusions: None. Adjustment/Stratification: No risk adjustment necessary N/A No stratification is required for this measure. Level of Analysis: Facility/Agency Type of Measure: Process

1435 Restriction of dialysate sodium

Data Source: Electronic clinical data CROWNWeb
Measure Steward: Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, MD 21244

Steering Committee Recommendation for Endorsement: No
Rationale: Did not pass Importance to Measure and Report

1. Importance to Measure and Report: Y-2; N-18
(1a. Impact; 1b. Performance gap; 1c. Outcome or Evidence)
Rationale: Data concerning the frequency of dialysate sodium >138 were not available, and no sub-group analysis of dialysate sodium use has been done. The measure is based on a reasonable hypothesis, but not strong evidence. Evidence to support the specific threshold of 138 was not provided.

1437 Utilization of dialysis duration of four hours or longer for patients new to dialysis

Description: The proportion of patients new to dialysis whose prescribed dialysis session length is at least 240 minutes.
Numerator Statement: Number of patients in denominator whose prescribed dialysis session length is at least 240 minutes.
Denominator Statement: Number of patients in an outpatient dialysis facility undergoing chronic maintenance hemodialysis.
Exclusions: Patients not receiving dialysis treatment three times per week.
Adjustment/Stratification: No risk adjustment necessary N/A No stratification is required for this measure.
Level of Analysis: Facility/Agency
Type of Measure: Process
Data Source: Electronic clinical data CROWNWeb
Measure Steward: Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, MD 21244

Steering Committee Recommendation for Endorsement: No
Rationale: Did not pass Importance to Measure and Report

1. Importance to Measure and Report: Y-6; N-14
(1a. Impact; 1b. Performance gap; 1c. Outcome or Evidence)
Rationale: Although it is clear that several outcomes are better when "more" dialysis is compared with "less" treatment, and that there is wide variation in dialysis prescription across dialysis facilities; the specific link to longer dialysis sessions when prescribed for 3x/week has less support. More frequent hemodialysis treatments (> 3x/week) improve solute clearance (e.g., urea measured by Kt/Vurea) and removal of volume; however, there is little convincing evidence that a cut-off of 4 hours of treatment when delivered 3x/week provides better outcomes. There is little evidence regarding subsets of patients (e.g., small patients, very large patients) who may have different metabolic requirements for dialysis. There is some data showing improved outcomes from nocturnal dialysis (in-center 3x/week for 6-8 hours); however, it is not definitive for a specific cut-off. The DOPPS study showed correlation between longer dialysis and survival, e.g., in Australia the average is 4.5 hours. The DOPPS is an observational study, and there were correlations in addition to length of session. The HEMO randomized controlled trial failed to show improved outcomes with higher delivered dose, but it did not study differences in time or frequency (delivered in 2.5-4.5 hours, 3x/week). KDOQI will have released a clinical practice guideline by the end of this year, and KDIGO probably 18 months after then.
Some Committee members thought that even with the limitations on evidence, the 4-hour timeframe was sufficiently established to warrant a performance measure and that 4 hours should be considered a minimum standard. However, a Committee member asked why this measure would be applicable to new but not all patients.

1439 Utilization of high ultrafiltration rate for fluid removal

Description: Proportion of patients who did not receive an ultrafiltration rate greater than or equal to 15 ml/kg/hr in the reporting month.
Numerator Statement: Number of patients in the denominator who did not receive an ultrafiltration (UF) rate greater than or equal to 15 ml/kg/hr for the month's reported dialysis session.
Denominator Statement: Number of patients in an outpatient dialysis facility undergoing chronic maintenance hemodialysis (HD).
Exclusions: None.
Adjustment/Stratification: No risk adjustment necessary N/A No stratification is required for this measure.
Level of Analysis: Facility/Agency
Type of Measure: Process
Data Source: Electronic clinical data CROWNWeb
Measure Steward: Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, MD 21244

Steering Committee Recommendation for Endorsement: No
Rationale: Did not pass Importance to Measure and Report

1. Importance to Measure and Report: Y-4; N-14

1439 Utilization of high ultrafiltration rate for fluid removal

(1a. Impact; 1b. Performance gap; 1c. Outcome or Evidence)

Rationale: Data on prevalence or performance gap were not presented. Although some published data show that high ultrafiltration rates correlate with reduced survival, there is no clear evidence that a "cut-off" of 15 ml/kg/hr is an appropriate standard of care. In the observational studies, high ultrafiltration rate is confounded with short sessions. Potential harm from this approach, i.e., inadequate fluid removal in some high-risk patients, has not been assessed. The quoted guideline focuses on intermediate outcomes of euvolemia and normotensive, not the specific ultrafiltration rate.

1438 Periodic assessment of post-dialysis weight by nephrologists

Description: The proportion of patients who have documentation of receiving a new post-dialysis weight prescription from a nephrologist in the reporting month.
Numerator Statement: Number of patients in denominator who have documentation of receiving a new post-dialysis weight prescription from a nephrologist in the reporting month.
Denominator Statement: Number of patients in an outpatient dialysis facility undergoing chronic maintenance hemodialysis (HD).
Exclusions: None.
Adjustment/Stratification: No risk adjustment necessary N/A No stratification is required for this measure.
Level of Analysis: Facility/Agency
Type of Measure: Process
Data Source: Electronic clinical data CROWNWeb
Measure Steward: Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, Maryland 21244

Steering Committee Recommendation for Endorsement: Time-limited
Final: Y-19; N-0; A-1; Initial: Y-20; N-0 with Condition
Rationale: The Committee thought that some measure to highlight the importance of fluid and weight management was necessary, and this is the best measure at this time because of the issues discussed with the other measures on this topic. Additionally, there are no potential unintended harms from implementing this measure.

If applicable, Conditions/Questions for Developer: Condition: include pediatric
Question: Should "new" be removed from description and simply refer to post-dialysis weight?
Developer Response: "Arbor Research/UM-KECC and the Pediatric C-TEP agree that the pediatric population should be included in this measure for reasons summarized in the measure information form. In addition, fluid assessment and weight monitoring are even more critical in the pediatric population because of linear growth and gain in body mass. The C-TEP notes that although the proposed measure requires reporting of a monthly prescription for post-dialysis weight, this does not denote that actual monthly assessments are performed. Nevertheless, the Pediatric C-TEP believes that this measure encourages good clinical practice and can potentially be used to identify patients who are not experiencing weight gain. Finally, the Pediatric C-TEP recommends that this measure be calculated separately for the pediatric population rather than as a pooled measure with the adult population.
The adult Fluid Weight Management (FWM) Clinical TEP that was organized by Arbor Research/UM-KECC (contractors for the CMS) and charged with the task of evaluating and proposing potential measures in the area of fluid-weight management recently deliberated on the issue of extending measure 1438 to the pediatric population in response to the recent NQF vote supporting the time-limited endorsement of this measure.
There was consensus among the FWM C-TEP members with regards to extending the implementation of this measure to the pediatric population. However, it must be emphasized that this recommendation was based on the collective clinical experience of the FWM C-TEP supporting the notion that monitoring volume on a regular basis in the pediatric population is likely to be a worthwhile endeavor, consistent with good clinical practice. It is therefore an opinion-based recommendation at this time that has not been subjected to the rigor of a formal review of evidence.
Based on the conversation at the Steering Committee meeting, it was our understanding that the suggestion to remove the word 'new' from the description was rescinded. We note that the word 'new' prescription should be retained in view of the TEP's reasoning that it will likely push the requirement for a formal monthly prescription by dialysis facilities.
To address the Steering Committee's concerns, we could add the phrase 'irrespective of whether or not a change in post dialysis weight prescription was made' in the description and other areas to be consistent and remove any ambiguity in this regard."
Steering Committee Follow-up: The Steering Committee accepted the developer's response.
Developer Follow-up: The revised measure specifications were submitted.

1. Importance to Measure and Report: Final: Y-18; N-0; Initial: Y-18; N-0
(1a. Impact; 1b. Performance gap; 1c. Outcome or Evidence)
Rationale: The Committee thought that some measure to highlight the importance of fluid and weight management was necessary. Although no information was provided on a performance gap, there was consensus among the Committee that there was a gap in performance on routinely assessing weight. Assessing weight is not proximal to desired outcomes; however, it is the best measure at

1438 Periodic assessment of post-dialysis weight by nephrologists
this time because of the issues discussed with the other measures on this topic. Additionally, there are no potential unintended harms from implementing this measure. The Committee agreed that there is no reason why the measure should not apply to pediatric patients. When the Steering Committee asked the developer if the measure should also apply to home hemodialysis patients, the comment was made that monthly might not be appropriate.
2. Scientific Acceptability of Measure Properties: Final: C-8: P-7; M-3; Initial: C-9; P-8; M-2; N-0 *(2a. Precise specifications; 2b. Reliability testing; 2c. Validity testing; 2d. Exclusions justified; 2e. Risk adjustment/stratification; 2f. Meaningful differences; 2g. Comparability; 2h. Disparities)* Rationale: The ratings are primarily based on the specifications (in the future, the Steering Committee will be instructed that the highest rating for untested measures is minimal). The specifications for a "new" post-dialysis weight prescription may imply that the prescription must be changed; however, patients should have a post-dialysis weight assessment every month even if the prescription does not change. It was unclear what information will be entered in CROWNweb to identify whether the numerator is met (e.g., just a yes/no or date and prescription). The measure is untested; therefore reliability and validity are no known.
3. Usability: Final: C-9: P-9; M-0; N-0; Initial: C-9; P-9; M-2; N- *(3a. Meaningful/useful for public reporting and quality improvement; 3b. Harmonized; 3c. Distinctive or additive value to existing measures)* Rationale: The measure may provide initial information regarding fluid weight management.
4. Feasibility: Final:C-9: P-9; M-0; N-0; Initial: C-7; P-8; M-5; N-0 *(4a. Clinical data generated during care process; 4b. Electronic sources; 4c. Exclusions – no additional data source; 4d. Susceptibility to inaccuracies/ unintended consequences identified; 4e. Data collection strategy can be implemented)* Rationale: Data would be collected and acted upon as part of process of care and will be included in the CMS data system.

1454 Proportion of patients with hypercalcemia
Description: Proportion of patients with 3-month rolling average of total uncorrected serum calcium greater than 10.2 mg/dL. Numerator Statement: Number of patients in the denominator with 3-month rolling average of total uncorrected serum calcium greater than 10.2 mg/dL. Denominator Statement: Number of adult (greater than or equal to18 years old) hemodialysis or peritoneal dialysis patients treated at the outpatient dialysis facility for at least 30 days who have been on dialysis for greater than 90 days with at least one calcium measurement during the prior 90 days. Exclusions: None Adjustment/Stratification: No risk adjustment necessary N/A Level of Analysis: Facility/Agency Type of Measure: Outcome Data Source: Electronic clinical data CROWNWeb Measure Steward: Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, MD 21244
Steering Committee Recommendation for Endorsement: Final: Y-11; N-8; A-1; Initial: Y-18; N-2 with Conditions Rationale: Although evidence for a specific threshold value is weak, the 10.2 value is the upper limit of normal, and higher values represent toxicity of therapies prescribed for dialysis patients. Unlike the measure of high phosphorous, hypercalcemia represents a marker of toxicity from drug therapies, and the response is to decrease those therapies rather than lead to more drug therapies and potential additional toxicities.
If applicable, Conditions/Questions for Developer: Condition: 1) numerator: number of patients with total uncorrected Ca > 10.2 for each of 3 months (Y-13; N-7) Developer Response: "The Arbor Research investigators appreciate the NQF Steering Committee suggestion and have discussed it with the Mineral and Bone Disorder Clinical Technical Expert Panel (C-TEP) who contributed to the development of the proposed measure. Published studied assessing the association of serum calcium with clinical outcomes were largely based on single calcium levels and not on persistently high calcium levels. However, the C-TEP proposed measure only included patients with a three-month rolling average of total uncorrected serum calcium > 10.2 mg/dl. This conservative approach was chosen to identify patients who may be more likely to experience poor clinical outcomes due to the prolonged exposure to elevated serum calcium levels over time. The proposed revision would identify patients who are consistently exposed to very high calcium levels over the prior three months. However, the C-TEP members had the opinion, supported by the data reported below, that only very few patients would meet this criterion, since it less likely that patients have high calcium for three consecutive months. This was confirmed using Crown web data collected from March 2010 through May 2010: while 6,284 patients (3%) met the requirements for the proposed measure, only 1,584 patients (0.8%) met those for the revised measure. Similarly, the number of facilities that would be flagged based on given % of patients meeting the measure criteria decreased dramatically (see Table 1 below). For example, 780 facilities had 5% or more of patients meeting the proposed criteria, while only 113 had ≥5% of patients meeting the revised

1454 Proportion of patients with hypercalcemia

criteria. Based on these data, the C-TEP felt that the proposed change may negatively impact the quality of care delivered, since only very few patients with persistently high calcium over a three-month period would be included."

Steering Committee Follow-up: The majority of the Steering Committee accepted the developer's response. However, the Committee remained somewhat divided about viewing this as a measure indicating overall management of hypercalcemia (Ca > 10.2) using the mean over 3 months vs. changing it to a measure of patients with persistently high calcium.

Developer Follow-up:

1. Importance to Measure and Report: Final: Y-16; N-2; Initial: Y-16; N-4

(1a. Impact; 1b. Performance gap; 1c. Outcome or Evidence)

Rationale: Although evidence for a specific threshold value is weak, the 10.2 value is the upper limit of normal, and higher values represent toxicity of therapies prescribed for dialysis patients. In 2009-2010, 13,690 patients (4.5%) had values > 10.2, and in 95% (n = 3,318) of the 3,493 facilities, 13% of patients were hypercalcemic. Hypercalcemia is likely the result of therapies, i.e., calcium, Vitamin D, calcium-based binders. Uncorrected calcium is appropriate because of the variability associated with methods to calculate corrected calcium.

Unlike the measure of high phosphorous, hypercalcemia represents a marker of toxicity from drug therapies, and the response is to decrease those therapies rather than lead to more drug therapies and potential additional toxicities.

2. Scientific Acceptability of Measure Properties: Final: C-4: P-11; M-3; N-0; Initial: Did not vote on rating because of recommended changes.

(2a. Precise specifications; 2b. Reliability testing; 2c. Validity testing; 2d. Exclusions justified; 2e. Risk adjustment/stratification; 2f. Meaningful differences; 2g. Comparability; 2h. Disparities)

Rationale: It was suggested that the denominator be limited to patients receiving therapies that lead to hypercalcemia. The developer pointed out that it is difficult to identify when over-the counter drugs are used, and the Committee agreed it would be important to include all patients.

Some Committee members advocated for a change to > 10.2 in each of the 3 months (Y-13; N-7), which is consistent with using trends for patient management. A patient could have a decreasing trend and still be included in the numerator. The developer confirmed that the change would be possible with the data.

Other Committee members advocated for the average over 3 months as specified because the measure aggregates data from all patents and is an indicator of overall management; it is not intended for clinical management individual patients.

3. Usability: Final: C-7: P-9; M-2; N-0; Initial: Did not vote on rating because of recommended changes.

(3a. Meaningful/useful for public reporting and quality improvement; 3b. Harmonized; 3c. Distinctive or additive value to existing measures)

Rationale: Identifying erformance related to managng hypercalcemia is useful for quality improvement.

4. Feasibility: Final: C-9: P-7; M-2; N-0; Initial: Did not vote on rating because of recommended changes.

(4a. Clinical data generated during care process; 4b. Electronic sources; 4c. Exclusions – no additional data source; 4d. Susceptibility to inaccuracies/ unintended consequences identified; 4e. Data collection strategy can be implemented)

Rationale: The data are required in CROWNweb.

The developer indicated that the proposed change was possible with the data available, but ultimately did not agree with the condition..

Table 1. Number (%) of facilities that would be flagged, by % of patients meeting the measure criteria (proposed vs. revised)

	Number (%) of facilities where measure is met			
Facility % of patients meeting criteria	≥5%	≥10%	≥15%	≥20%
Proposed criteria (% of patients with 3 month rolling average Ca > 10.2)	780 (23%)	235 (7%)	66 (2%)	14 (< 1%)
Revised criteria (% of patients with Ca > 10.2 in all three months)	113 (3.4%)	15 (< 1%)	4 (< 1%)	3 (< 1%)

1427 Adult dialysis patients—serum phosphorus greater than 6 mg/dl

1427 Adult dialysis patients—serum phosphorus greater than 6 mg/dl

Description: Proportion of patients with 3-month rolling average of serum phosphorus greater than 6 mg/dL.
Numerator Statement: Number of patients with 3-month rolling average of serum phosphorus greater than 6 mg/dL.
Denominator Statement: Number of adult (greater than or equal to18 years old) hemodialysis or peritoneal dialysis patients treated at the outpatient dialysis facility for at least 30 days who have been on dialysis for greater than 90 days with at least one phosphorus measurement during the prior 90 days.
Exclusions: None
Adjustment/Stratification: No risk adjustment necessary
Level of Analysis: Facility/Agency
Type of Measure: Outcome
Data Source: Electronic administrative data/claims; Electronic clinical data; Lab data. When available, the electronic data can be entered into CROWNWeb either through manual web-based entry or batch transmission for larger organizations.
Measure Steward: Genzyme Corporation, 500 Kendall Street, Cambridge, MA 02142

Steering Committee Recommendation for Endorsement: No
Rationale: Did not pass Importance to Measure and Report

If applicable, Conditions/Questions for Developer:
Developer Response:
Steering Committee Follow-up: The Steering Committee recommended the hypercalcemia measure (1454), considering it an indicator of toxicity of drug therapies. The hyperphosphatemia measure was not recommended, which raised the question why it was not also considered an indicator of toxicity.
The Steering Committee noted that the primary rationale for the different decisions was a difference in the causes and treatment responses. Hypercalcemia is related to drug therapies including calcium, Vitamin D, calcium-based binders; and the response to high levels is to decrease or remove therapies. Hyperphosphatemia in contrast reflects the kidney disease state, and there is also the possibility that high serum phosphorus results from metabolic bone disease with high turnover, for instance from high parathyroid hormone activity. Hyperphosphatemia may be treated with dietary restriction, longer or more frequent dialysis, or additional therapy with phosphate binders, which is a controversial aspect of care. Although care for individual patients should address hyperphosphatemia, the current evidence did not warrant a specific threshold performance measure.
Developer Follow-up:

1. Importance to Measure and Report: Y-7; N-13
(1a. Impact; 1b. Performance gap; 1c. Outcome or Evidence)
Rationale: Establishing a specific threshold value has not been definitively identified in the evidence. Although observational studies have shown increased risk of mortality with high levels of phosphorus, different reference ranges and comparison values have been analyzed. Some Committee members commented that no interventional studies have been conducted, so the impact of lowering phosphorus on morbidity and mortality is not known. Use of calcium-based vs. non-calcium-based binders is a very controversial area. Other Committee members noted that increasing dialysis time brings values closer to normal. KDOQI guidelines are opinion-based, and KDIGO experts did not recommend performance measures. Some committee members noted caution in making conclusions based on observational studies. We used to think that getting hemoglobin to normal was a reasonable goal, but efforts to do so caused more mortality.
The developer commented that, at the facility level, those with levels > 6.0 vs. 3.5-5.0 have poorer outcomes.
The rationale for considering this criterion not met is that it is an intermediate outcome without sufficient evidence for setting a threshold value or that interventions to lower phosphorous have an effect on morbidity or mortality. The rationale for considering this criterion met is that it is an intermediate outcome linked to higher mortality and therefore should be measured and reported.

1461 Proportion of patients with hypophosphatemia

Description: Proportion of patients with 3-month rolling average of serum phosphorus less than 2.5 mg/dL.
Numerator Statement: Number of patients in the denominator with 3-month rolling average of serum phosphorus less than 2.5 mg/dL.
Denominator Statement: Number of adult (greater than or equal to18 years old) hemodialysis or peritoneal dialysis patients treated at the outpatient dialysis facility for at least 30 days who have been on dialysis for greater than 90 days with at least one phosphorus measurement during the prior 90 days.
Exclusions: None.
Adjustment/Stratification: No risk adjustment necessary N/A
Level of Analysis: Facility/Agency
Type of Measure: Outcome
Data Source: Electronic clinical data CROWNWeb
Measure Steward: Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, MD 21244

1461 Proportion of patients with hypophosphatemia

Steering Committee Recommendation for Endorsement: No
Rationale: Did not pass Importance to Measure and Report

1. Importance to Measure and Report: Y-2; N-17
(1a. Impact; 1b. Performance gap; 1c. Outcome or Evidence)
Rationale: Hypophasphatemia is a marker for malnutrition. Establishing a specific threshold value has not been definitively identified in the evidence; however, 2.5 is the lower limit of the normal range. 2009 data indicated that 0.6% of the ESRD patients had phosphorus < 2.5, and 29% of facilities had at least one patient that met the criteria. Hypophasphatemia can be affected by intensity of dialysis. These patients are often very sick and malnourished with high mortality, and it's not clear that feeding them will help.

1463 Standardized hospitalization ratio for admissions

Description: Risk-adjusted standardized hospitalization ratio for admissions for dialysis facility patients.
Numerator Statement: Number of inpatient hospital admissions among eligible patients at the facility during the reporting period.
Denominator Statement: Number of hospital admissions that would be expected among eligible patients at the facility during the reporting period, given the patient mix at the facility.
Exclusions: None.
Adjustment/Stratification: Risk-adjustment devised specifically for this measure/condition The denominator of the SHR uses expected hospital admissions calculated from a Cox model (Cox, 1972) as extended to handle repeated events (Lawless and Nadeau, 1995; Lin et al., 2000; Kalbfleisch and Prentice, 2002). For computational purposes, we adopt a model with piecewise constant baseline rates (e.g. Cook and Lawless, 2007) and computational methodology as developed in Liu, Schaubel and Kalbfleisch (2010). A stage 1 model is first fitted to the national data with piecewise-constant baseline rates stratified by facility; hospitalization rates are adjusted for patient age, race, sex, diabetes, ethnicity, duration of ESRD, nursing home status, BMI at incidence, comorbidity index at incidence, and calendar year. This model allows the baseline hospitalization rates to vary between strata (facilities), but assumes that the regression coefficients are the same across all strata; this approach is robust to possible differences between facilities in the patient mix being treated. The linear predictor for each patient based on the regression coefficients in the stage 1 model is used to compute a risk adjustment factor that is then used as an offset in the stage 2 model. N/A
Level of Analysis: Facility/Agency
Type of Measure: Outcome
Data Source: Public health data/vital statistics; Electronic Health/Medical Record Data for the hospitalization measures are derived from an extensive national ESRD patient database, which is largely derived from the Standard Information Management System (SIMS) database maintained by the 18 ESRD Networks, the CMS Annual Facility Survey (Form CMS-2744), Medicare dialysis and hospital payment records, the CMS Medical Evidence Form (Form CMS-2728), transplant data from the Organ Procurement and Transplant Network (OPTN), the Death Notification Form (Form CMS-2746), the Nursing Home Minimum Dataset, and the Social Security Death Master File. The database is comprehensive for Medicare patients. Information on hospitalizations is obtained from Medicare Inpatient Claims Standard Analysis Files (SAFs).
Measure Steward: Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, MD 21244

Steering Committee Recommendation for Endorsement: Final: Y-17; N-2; A-1; Initial: Y-18; N-2 with Conditions
Rationale: The measure addresses a National Priorities Partnership (NPP) goal, and although risk adjustment may be complex, the reporting of hospitalization is important and useful.

If applicable, Conditions/Questions for Developer: Conditions: 1) Need to remove race/ethnicity from risk model or provide justification supported by data and analysis. 2) Change time period to 1 rather than 3 years or provide data and analysis that stable estimates require more data.
Question: What is data source? Submission says public health/vital statistics and EHR. Shouldn't it be claims data?
Developer Response: "After consulting with and considering recommendations from Arbor Research/UM-KECC, CMS has decided to remove race and ethnicity from the SHR risk model. If needed, analyses for the SHR model without race and ethnicity can be provided at a later date.
It was our intent to have SHR (Admissions) approved as a measure that can be calculated over any given time period within the range of 6 months to 3 years. The period of time depends on the purpose of the statistic and would have a minimum period of 6 months. For example, the SHR has been reported both for 1-year and 3-year periods in the Dialysis Facility Reports in order to help facilities identify persistent patterns. The 1-year values allow for an assessment of changes over time, while the 3-year value gives a summary value and provides more stability for very small facilities. The 1-year SHR is a stable measure as indicated by its high correlation with the 3-year SHR (?=0.85, 2006-2008 data). Similarly, the 6-month SHR is relatively stable as indicated by its high correlation with the 1-year SHR (?=0.88, 2008 data).
The source is the CMS Medicare Claims data."
Steering Committee Follow-up: The Steering Committee accepted the developer's response.

1463 Standardized hospitalization ratio for admissions

Developer Follow-up: The revised measure specifications were submitted.

1. Importance to Measure and Report: Final: Y-17; N-1; Initial:Y-20; N-0
(1a. Impact; 1b. Performance gap; 1c. Outcome or Evidence)
Rationale: Hospitalizations are a proxy outcome for deteriorating health status. The measure relates to an NPP goal and is important to measure in the ESRD population.
Several Committee members suggested that hospitalization was not under the control of ESRD facilities or clinicians. Other Committee members stated that when patients are managed well the number of hospitalizations is decreased. No one suggests that all hospitalizations can be avoided.

2. Scientific Acceptability of Measure Properties: Final: C-5: P-10; M-3; N-0; Initial: C-7; P-12; M-1; N-0
(2a. Precise specifications; 2b. Reliability testing; 2c. Validity testing; 2d. Exclusions justified; 2e. Risk adjustment/stratification; 2f. Meaningful differences; 2g. Comparability; 2h. Disparities)
Rationale: The Committee questioned the need for a 3-year time period, and the developer indicated that 1 year was acceptable. NQF criteria indicate that race and ethnicity (often associated with disparities in care) should not be used as factors in risk models.

3. Usability: Final: C-6: P-11; M-1; N-0; Initial: C-8; P-9; M-3; N-0
(3a. Meaningful/useful for public reporting and quality improvement; 3b. Harmonized; 3c. Distinctive or additive value to existing measures)
Rationale: Usability was not demonstrated. Several Committee members questioned actionability by providers of ESRD care. Other Committee members noted that dialysis care and management of anemia, vascular access, and fluid can directly influence hospitalizations. Therefore, hospitalization rates can be used to identify when care processes should be examined for improvement.

4. Feasibility: Final: C-12: P-6; M-0; N-0; Initial: C-12; P-6; M-2; N-0
(4a. Clinical data generated during care process; 4b. Electronic sources; 4c. Exclusions – no additional data source; 4d. Susceptibility to inaccuracies/ unintended consequences identified; 4e. Data collection strategy can be implemented)
Rationale: The measure is based on claims data and requires no additional data collection.

1464 Standardized hospitalization ratio for days

Description: Risk-adjusted standardized hospitalization ratio for days for dialysis facility patients.
Numerator Statement: Number of days hospitalized among eligible patients at the facility during the reporting period.
Denominator Statement: Number of days hospitalized that would be expected among eligible patients at the facility during the reporting period, given the patient mix at the facility.
Exclusions: None.
Adjustment/Stratification: Risk-adjustment devised specifically for this measure/condition The denominator of the SHR uses expected hospital days calculated from a Cox model (Cox, 1972) as extended to handle repeated events (Lawless and Nadeau,1995; Lin et al., 2000; Kalbfleisch and Prentice, 2002). For computational purposes, we adopt a model with piecewise constant baseline rates (e.g. Cook and Lawless, 2007) and computational methodology as developed in Liu, Schaubel and Kalbfleisch (2010). A stage 1 model is first fitted to the national data with piecewise-constant baseline rates stratified by facility; hospitalization rates are adjusted for patient age, race, sex, diabetes, ethnicity, duration of ESRD, nursing home status, BMI at incidence, comorbidity index at incidence, and calendar year. This model allows the baseline hospitalization rates to vary between strata (facilities), but assumes that the regression coefficients are the same across all strata; this approach is robust to possible differences between facilities in the patient mix being treated. The linear predictor for each patient based on the regression coefficients in the stage 1 model is then used to compute a risk adjustment factor that is used as an offset in the stage 2 model. N/A
Level of Analysis: Facility/Agency
Type of Measure: Outcome
Data Source: Electronic administrative data/claims; Public health data/vital statistics Data for the hospitalization measures are derived from an extensive national ESRD patient database, which is largely derived from the Standard Information Management System (SIMS) database maintained by the 18 ESRD Networks, the CMS Annual Facility Survey (Form CMS-2744), Medicare dialysis and hospital payment records, the CMS Medical Evidence Form (Form CMS-2728), transplant data from the Organ Procurement and Transplant Network (OPTN), the Death Notification Form (Form CMS-2746), the Nursing Home Minimum Dataset, and the Social Security Death Master File. The database is comprehensive for Medicare patients. Information on hospitalizations is obtained from Medicare Inpatient Claims Standard Analysis Files (SAFs).
Measure Steward: Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, MD 21244

Steering Committee Recommendation for Endorsement: No
Rationale: Did not pass Importance to Measure and Report

1. Importance to Measure and Report: Y-4; N-16
(1a. Impact; 1b. Performance gap; 1c. Outcome or Evidence)

1464 Standardized hospitalization ratio for days

Rationale: When asked why this measure was needed, the developer indicated it was a measure of complexity. The Committee believed that how long a patient stays in the hospital is not only an indicator of patient condition when admitted, but also of hospital practices and quality. Therefore, this measure should not be a performance measure.

1477 National Healthcare Safety Network (NHSN) intravenous (IV) antibiotic start measure

Description: Monthly rate of outpatient intravenous antibiotic starts (initiation of a new antibiotic not in use in previous 21 days) per 100 patient months within outpatient dialysis unit. The 21 day rule is used to exclude counting antibiotics that are given for the same infection.
Numerator Statement: Total number of intravenous antibiotics started (not in use in previous 21 days) in the outpatient unit.
Denominator Statement: The denominator is the number of patients receiving hemodialysis at the facility on the first two hemodialysis days of the month (i.e., patient-months).
Exclusions: Patients receiving outpatient hemodialysis during the month during which surveillance is being conducted but not present in the facility during the first two calendar days of the month are not included in the denominator
Adjustment/Stratification: Analysis by subgroup. Rates are stratified by single greatest risk factor for infection—type of vascular access. The vascular access variables that are included in this analysis are arteriovenous (AV) fistula, AV graft, permanent central line, temporary central line. If more than one access type is present the antibiotic start is attributed to the access with the greatest risk (i.e., arteriovenous (AV) fistulaless than AV graftless thanpermanent central lineless thantemporary central line). Both the numerator and denominator are stratified by patient vascular access type, where permanent central lines are defined as tunneled central lines (or tunneled central venous catheters) and temporary central lines are defined as nontunneled central lines (or nontunneled central venous catheters)
Details of stratified measures:
1. IV antibiotic start rate in CVC (central venous catheter) patients = the numerator below divided by denominator below times 100
1a. NUMERATOR. Events are included in the numerator if the "In-unit IV antimicrobial start" field on Form 57.109 is checked AND any of the following fields on Form 57.109 under 'Vascular accesses' are checked as being present: "Permanent central line", "Temporary central line", or "Port access device".
1b. DENOMINATOR. The denominator equals the sum of the numeric values entered for the following fields on Form 57.119: "Permanent central line", "Temporary central line", and "Port access device".
2. IV antibiotic start rate in AVG (arteriovenous graft) patients = the numerator below divided by denominator below times 100
2a. NUMERATOR. Events are included in the numerator if the "In-unit IV antimicrobial start" field on Form 57.109 is checked AND if the field labeled "Graft" on Form 57.109 under 'Vascular accesses' is checked as being present AND none of the following fields on the same form are checked as being present: "Permanent central line", "Temporary central line", or "Port access device".
2b. DENOMINATOR. The denominator equals the numeric value entered for the field labeled, "Graft" on Form 57.119.
3. IV antibiotic start rate in AVF (arteriovenous fistula) patients = the numerator below divided by denominator below times 100
3a. NUMERATOR. Events are included in the numerator if the "In-unit IV antimicrobial start" field on Form 57.109 is checked AND if the field labeled "Fistula" on Form 57.109 under 'Vascular accesses' is checked as being present AND none of the following fields on the same form are checked as being present: "Graft", "Permanent central line", "Temporary central line", or "Port access device".
3b. DENOMINATOR. The denominator equals the numeric value entered for the field labeled, "Fistula" on Form 57.119.
Level of Analysis: Facility/Agency; Population: national
Type of Measure: Other. This measure is both process and outcome
Data Source: Paper medical record/flow-sheet; Pharmacy data; Electronic clinical data; Electronic Health/Medical Record National Healthcare Safety Network (NHSN) Dialysis Event form (numerator)—collected with each event
NHSN ouptaient dialysis denominator form (denominator) —collected monthly
Measure Steward: Centers for Disease Control and Prevention, 1600 Clifton Road NE, Mailstop A-31, Atlanta, GA 30333

Steering Committee Recommendation for Endorsement: Y-2; N-18
Rationale: Although an important topic for measurement, the validity, usability, and feasibility were concerns.

1. Importance to Measure and Report: Y-12; N-8
(1a. Impact; 1b. Performance gap; 1c. Outcome or Evidence)
Rationale: Reducing healthcare-associated infection is an NPP goal, and outcome measures do not require evidence—they should be outcomes that are relevant to the target population. Some Committee members questioned using antibiotic starts as a proxy for infection given some of the issues with inappropriate antibiotic use.

2. Scientific Acceptability of Measure Properties: C-2; P-12; M-6; N-0
(2a. Precise specifications; 2b. Reliability testing; 2c. Validity testing; 2d. Exclusions justified; 2e. Risk adjustment/stratification; 2f. Meaningful differences; 2g. Comparability; 2h. Disparities)
Rationale: It was not clear if antibiotic starts for patients admitted after the first 2 days (who often have catheters and higher risk of

1477 National Healthcare Safety Network (NHSN) intravenous (IV) antibiotic start measure
infection) are included. In response to questions about the specifications, the developer clarified that the denominator statement of patients on first 2 days of the month is just to minimize the burden of data collection, but all antibiotic starts in the month are counted in the numerator. No specific reliability testing was reported, but data element validity was conducted. Data element validity testing was conducted on a small sample. A Committee member questioned the adequacy of the results (e.g., of 85 recent IV antibiotic starts that were identified by the facilities in the study, 59 (69.4%) had an appropriate surveillance form completed for the event.
3. Usability: C-1; P-12; M-7; N-0 *(3a. Meaningful/useful for public reporting and quality improvement; 3b. Harmonized; 3c. Distinctive or additive value to existing measures)* Rationale: There was some confusion that the measure was intended to identify inappropriate antibiotic starts rather than to serve as a proxy for infection.
4. Feasibility: C-0; P-9; M-11; N-0 *(4a. Clinical data generated during care process; 4b. Electronic sources; 4c. Exclusions – no additional data source; 4d. Susceptibility to inaccuracies/ unintended consequences identified 4e. Data collection strategy can be implemented)* Rationale: Requires data collection and reporting. No clear plan for electronic data capture. The CDC NHSN reporting system has been in place for a considerable time. The data collection form is not commonly used in dialysis facilities

1460 National Healthcare Safety Network (NHSN) bloodstream infection measure
Description: Number of hemodialysis outpatients with positive blood cultures per 100 hemodialysis patient-months. Numerator Statement: The number of new positive blood culture events based on blood cultures drawn as an outpatient or within 1 calendar day after a hospital admission. A positive blood culture is considered a new event and counted only if it occurred 21 days or more after a previous positive blood culture in the same patient. Denominator Statement: Number of maintenance hemodialysis patients treated in the outpatient hemodialysis unit on the first 2 working days of the month. Exclusions: Patients receiving inpatient hemodialysis are excluded. Adjustment/Stratification: other Simple Stratification Both the numerator and denominator are stratified by vascular access type since vascular access type is the single greatest risk factor for bloodstream infection in this population. The vascular access variables that are collected and included in this analysis are: arteriovenous (AV) fistula, AV graft, permanent central line, and temporary central line. If more than one access type is present in a patient, the bloodstream infection event is attributed to the access type with the greatest risk (i.e., AV fistula less than AV graft less than permanent central line less than temporary central line). During denominator collection (see URL below), the user is asked to count each patient as having only 1 vascular access type, following the algorithm described. During numerator collection, all vascular access types present at the time of the bloodstream infection event are reported and the algorithm is applied during analysis of the data. Both the numerator and denominator are stratified by patient vascular access type, where permanent central lines are defined as tunneled central lines (or tunneled central venous catheters) and temporary central lines are defined as nontunneled central lines (or nontunneled central venous catheters). Details of stratified measures: 1. BSI rate in CVC (central venous catheter) patients = the numerator and denominator below times 100 1a. NUMERATOR. Events are included in the numerator if the "patient with positive blood culture" field on Form 57.109 is checked AND any of the following fields on Form 57.109 under 'Vascular accesses' are checked as being present: "Permanent central line", "Temporary central line", or "Port access device". 1b. DENOMINATOR. The denominator equals the sum of the numeric values entered for the following fields on Form 57.119: "Permanent central line", "Temporary central line", and ""Port access device". 2. BSI rate in AVG (arteriovenous graft) patients = the numerator and denominator below times 100 2a. NUMERATOR. Events are included in the numerator if the "patient with positive blood culture" field on Form 57.109 is checked AND if the field labeled "Graft" on Form 57.109 under 'Vascular accesses' is checked as being present AND none of the following fields on the same form are checked as being present: "Permanent central line", "Temporary central line", or "Port access device". 2b. DENOMINATOR. The denominator equals the numeric value entered for the field labeled, "Graft" on Form 57.119. 3. BSI rate in AVF (arteriovenous fistula) patients = the numerator and denominator below times 100 3a. NUMERATOR. Events are included in the numerator if the "patient with positive blood culture" field on Form 57.109 is checked AND if the field labeled "Fistula" on Form 57.109 under 'Vascular accesses' is checked as being present AND none of the following fields on the same form are checked as being present: "Graft", "Permanent central line", "Temporary central line", or "Port access device". 3b. DENOMINATOR. The denominator equals the numeric value entered for the field labeled, "Fistula" on Form 57.119.

1460 National Healthcare Safety Network (NHSN) bloodstream infection measure

Level of Analysis: Facility/Agency; Population: national; Population: regional/network; Can be measured at all levels
Type of Measure: Outcome
Data Source: Paper medical record/flow-sheet; Electronic Health/Medical Record; Lab data 57.119 Denominators for Outpatient Dialysis 57.109 Dialysis Event
Measure Steward: Centers for Disease Control and Prevention, Division of Healthcare Quality Promotion, 1600 Clifton Rd., MS A-31, Atlanta, GA 30333

Steering Committee Recommendation for Endorsement: Y-13; N-7; Initial: pending compariosn of competing measures
Rationale: Patients receiving hemodialysis are at risk for bacteremia, particularly related to vascular access so it is an improtant and useful measure.

If applicable, Conditions/Questions for Developer: Clarify "during a month that the outpatient unit is performing surveillance"—does that mean the data are not collected continuously?
Will denominator specifications for first 2 days of the month miss incident dialysis patients who have the highest risk of catheters for access, infections, and readmission to the hospital?
Developer Response: "1. This statement was included under the 'Numerator Time Window' measure specification. The intent of specifying 'during the month that the outpatient unit is performing surveillance' was to indicate how numerator and denominator data correlate with one another in time, not that data collection is not continuous. Numerator data are collected and reported continuously; denominator data are collected and reported monthly. NHSN requires facilities to report data for a minimum of 6 months per year. Facilities are encouraged to exceed that minimum duration of reporting and in some cases are legislatively mandated to do so.
2. A patient who is new to a particular dialysis facility would be excluded from a denominator if they entered the facility sometime after the first week of the month. However, assuming they remain in the facility, they would be captured in the following month's denominator. It is important to remember that all patient events are reported regardless of when a patient enters the facility. Thus, a high-risk or incident patient who enters a facility mid-month and develops a bloodstream infection during that month will be reported in the numerator data. Although that specific patient may not have been present at the beginning of the month, the bloodstream infection rate calculated for that month will still reflect the patient's event. So these infections would not be 'missed' or undercounted. The denominator used is a snapshot in time and stratified by vascular access type. In any given week (represented by the 2-day snapshot), the proportion of patients with each vascular access type does not markedly differ. It is possible that rates based on patient-month denominator data do not perfectly correlate with rates calculated on the basis of patient-days. For example, rates in the highest risk vascular access strata could be slightly over-estimated: (a) if incident patients come in with a catheter and routinely have the catheter removed and switch to another vascular access type in 0-3 weeks (i.e., by the time they are counted in the next month's denominator), (b) if those patients have a uniquely high frequency of infection or other events during those initial 0-3 weeks, and (c) if the facility has a high frequency of new admissions every month that represent this type of incident patient. This series of events seems unlikely to occur on a regular basis, in part because catheter patients who develop a bloodstream infection or other access complication are unlikely to quickly transition to a permanent access (i.e., combination of (a) and (b) happening in the same patient is rare). This hypothetical effect should also be mitigated by the fact that catheter patients have the highest likelihood of death, hospitalization or other events that would reduce their overall exposure time within the outpatient dialysis facility. I.e., a catheter patient who is present on the first 2 days of the month and counted in the denominator is least likely to contribute a full patient-month of observation-time.
When NHSN infection rates based on 100 patient-month denominators are roughly translated (by dividing by 3) to rates per 1000 catheter-days, they are comparable to figures reported in the literature based on measured catheter-day denominators, suggesting that use of patient-month denominators does not introduce a substantial bias into rates for the catheter group. The alternative would be to count all patients who receive dialysis on each day by vascular access type, adding substantially to the burden of data collection without clear benefit.
Colorado just released preliminary data submitted to NHSN from dialysis facilities under their reporting mandate. I believe someone from the committee had asked about this, so I am sharing. A link to the full report is below; only certain sections pertain to dialysis reporting. Of note, Colorado has decided to publicly report the NHSN access-related BSI (what they call 'AAB') measure. I know there are concerns about additional reporting burden for that measure in comparison to the NHSN BSI measure. However, I did want to highlight several qualities of the NHSN access-related BSI measure for the committee to consider: 1. Access-related BSI (ARB) is a measure that has meaning to clinicians because it is viewed as a potentially preventable subset of BSI. 2.This measure is often the focus of prevention studies—i.e., interventions such as improvements in central line or other vascular access care are often evaluated using the ARB measure. This is where we would expect to see the greatest impact. 3. As noted above, Colorado has chosen to publicly report this measure. 4. As a subcategory of BSI, ARB is not independently reported. It is based upon a single variable response, thus the incremental burden of reporting ARB is small.
We believe there is great value in collecting and evaluating both the ARB and BSI measure for quality improvement. These measures are collected together and complement one another. While the BSI measure is more objective and simple, it has been our experience that the minimal added burden involved in collecting the variable to make the ARB determination is outweighed by this measure's

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relevance to clinicians / users and to quality improvement efforts.
http://www.cdphe.state.co.us/hf/PatientSafety/HFAcquiredInfectionsReport11.pdf"
Steering Committee Follow-up: NQF and the ESRD Steering Committee requested that CMS and CDC collaborate on submitting one measure of bacteremia in ESRD patients, stratified by type of vascular access, that will meet both government agencies' needs and for which data could eventually be exchanged electronically between the two agencies. For now, at a minimum, facilities should be able to submit the same data to both agencies.

Related Measure: PSM-001-10 National Healthcare Safety Network (NHSN) central line-associated bloodstream infection (CLABSI) outcome measure
Why is this measure for ESRD bloodstream infection different than CDC's recently updated measure?

Developer Follow-up: CMS and CDC agreed to work together on one measure; however, they were not able to accomplish identifying crosswalked specifications for use with CROWNweb in the time allowed for this project. CMS agreed that it could use the CDC definitions as long as the NHSN form or data system is not required, because ESRD facilities are required to submit data through CROWNweb, which also has the option for batch submission. NQF clarified that although detailed measure specifications often identify specific data collection tools (e.g., CMS MDS for nursing homes), endorsed measures can be implemented with different data collection tools and systems as long as the data definitions in the endorsed measure and measure construction logic are followed. CDC also agreed that the measure does not require use of the NHSN data tools and systems and agreed to clarify definitions if needed. If measure 1460 is endorsed, then CMS will incorporate the measure specifications into its CROWNweb system. CMS and CDC agreed to pursue data sharing arrangements so that ESRD facilities could submit data to either agency.

Positive blood culture was defined as a blood culture that results in growth of 1 or more organisms.

This measure has always been distinct from the inpatient CLABSI measure for several reasons.
1) Surveillance not primarily performed by Infection Preventionists or physicians
Measures in the dialysis event module were developed for use by dialysis care personnel in outpatient hemodialysis facilities. In inpatient settings, infection control professionals typically conduct case-finding and apply CLABSI case definitions, sometimes in conjunction with physicians and microbiologists. These professionals are not routinely available in outpatient dialysis settings to apply complex case definitions or assess clinical infection data. Measures were selected in a way to maximize ease and consistency of reporting in this setting using simple, objective event descriptions that would not require infectious disease or other expertise to make determinations. For example, the first highlighted section (2. Definitions of CLABSI) describes the definition of a primary BSI, "not secondary to an infection meeting CDC/NHSN criteria at another body site". This initial step requires the user to be familiar with a range of CDC / NHSN healthcare-associated infection (HAI) definitions just to be able to distinguish a primary from secondary BSI. In our opinion, this level of complexity would be unacceptable for users in dialysis settings, particularly since they would not be routinely performing surveillance for these other HAI types and thus, would not be familiar with the definitions used as exclusion criteria. Diagnoses made in outpatient settings may also lack the evidence (or documentation of evidence) necessary to meet rigorous definitions for CLABSI or CLABSI exclusion criteria, impacting the feasibility of use of these definitions beyond inpatient settings.

2) Hemodialysis access types other than central lines
The CLABSI measure only records central line-associated BSI. In hemodialysis settings, BSI rates among patients with fistulas or grafts are also of interest. Thus, a measure that is not restricted to one vascular access type is needed.

3) Burden of denominator collection
Denominator collection for the CLABSI measure requires measurement of central line days, which is overly burdensome for this setting, which has a more stable patient population compared to inpatient ward or ICU settings.

1. Importance to Measure and Report: Y-17; N-2
(1a. Impact; 1b. Performance gap; 1c. Outcome or Evidence)
Rationale: Reducing healthcare-associated infections is an NPP goal, and outcome measures do not require evidence. There is variation in performance.

2. Scientific Acceptability of Measure Properties: C-4; P-16; M-; N-0
(2a. Precise specifications; 2b. Reliability testing; 2c. Validity testing; 2d. Exclusions justified; 2e. Risk adjustment/stratification; 2f. Meaningful differences; 2g. Comparability; 2h. Disparities)
Rationale: It was not clear if the specifications will miss incident dialysis patients who have the highest risk of catheters for access, infections, and readmission to the hospital. In response to questions about the specifications, the developer clarified that the

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denominator statement of patients on first 2 days of month is just to minimize the burden of data collection, but all bloodstream infections in the month are counted in the numerator. "During a month that the outpatient unit is performing surveillance" implies that the data are not collected continuously—is that appropriate? Data element validity testing was conducted on a small sample and results were satisfactory (88%, 89%, 78%). Type of vascular access is a primary risk factor for bloodstream infection, and the measure is stratified by type of access. It was questioned whether including all infections even if not related to dialysis (e.g., diabetic foot ulcer) was a valid quality indicator. However, all infections are important.

3. Usability: C-6; P-10; M-3; N-1

(3a. Meaningful/useful for public reporting and quality improvement; 3b. Harmonized; 3c. Distinctive or additive value to existing measures)

Rationale: Measure of bloodstream infection would be usable for both public reporting and quality improvement.

4. Feasibility: C-1; P-9; M-9; N-0

(4a. Clinical data generated during care process; 4b. Electronic sources; 4c. Exclusions – no additional data source; 4d. Susceptibility to inaccuracies/ unintended consequences identified; 4e. Data collection strategy can be implemented)

Rationale: The CDC NHSN reporting system has been in place for a considerable time although the data collection form may not be commonly used in dialysis facilities. A feasibility issue was raised about getting blood culture results for patients who had been admitted to the hospital. However, dialysis facilities need to obtain information on hospitalized patients when they return to dialysis, and bloodstream infection would be important information. Dialysis facilities would not need to obtain other than their usualinformation on hospitalized patients. Colorado has mandated use of these NHSN measures, and other states are expected to follow. Twenty-two states have mandated NHSN for HAIs. It would be best if NHSN and CROWNweb could transfer data so that facilities could use either system for reporting. Some concern was expressed about the incentive to not identify those positive blood cultures on hospital admission.

1478 National Healthcare Safety Network (NHSN) vascular access-related bloodstream infection measure

Description: Number of hemodialysis outpatients with positive blood cultures and in whom the suspected source was reported as either the vascular access or unknown, per 100 hemodialysis patient-months.

Numerator Statement: The number of bloodstream infections that are suspected to be related to the vascular access—i.e., not including positive blood cultures that likely reflect contamination nor that represent secondary bloodstream infections with a nonvascular primary site of origin.

Denominator Statement: Number of maintenance hemodialysis patients treated in the outpatient hemodialysis unit on the first 2 working days of the month.

Exclusions: Patients receiving inpatient hemodialysis are excluded

Adjustment/Stratification: other Simple stratification Both the numerator and denominator are stratified by vascular access type since vascular access type is the single greatest risk factor for access-related bloodstream infection in this population. The vascular access variables that are collected and included in this analysis are: arteriovenous (AV) fistula, AV graft, permanent central line, and temporary central line. If more than one access type is present in a patient, the bloodstream infection event is attributed to the access type with the greatest risk (i.e., AV fistula less than AV graft less than permanent central line less than temporary central line). During denominator collection (see URL below), the user is asked to count each patient as having only 1 vascular access type, following the algorithm described. During numerator collection, all vascular access types present at the time of the bloodstream infection event are reported and the algorithm is applied during analysis of the data. Both the numerator and denominator are stratified by patient vascular access type, where permanent central lines are defined as tunneled central lines (or tunneled central venous catheters) and temporary central lines are defined as nontunneled central lines (or nontunneled central venous catheters).

Details of stratified measures:

1. Access-related BSI rate in CVC (central venous catheter) patients = the numerator below divided by denominator below times 100

1a. NUMERATOR. Events are included in the numerator if the "patient with positive blood culture" field on Form 57.109 is checked, along with either "Vascular access" or "Uncertain" (under 'Suspected source of positive blood culture'), AND any of the following fields on Form 57.109 under 'Vascular accesses' are checked as being present: "Permanent central line", "Temporary central line", or "Port access device".

1b. DENOMINATOR. The denominator equals the sum of the numeric values entered for the following fields on Form 57.119: "Permanent central line", "Temporary central line", and ""Port access device".

2. Access-related BSI rate in AVG (arteriovenous graft) patients = the numerator below divided by denominator below times 100

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2a. NUMERATOR. Events are included in the numerator if the "patient with positive blood culture" field on Form 57.109 is checked, along with either "Vascular access" or "Uncertain" (under 'Suspected source of positive blood culture'), AND if the field labeled "Graft" on Form 57.109 under 'Vascular accesses' is checked as being present AND none of the following fields on the same form are checked as being present: "Permanent central line", "Temporary central line", or "Port access device". 2b. DENOMINATOR. The denominator equals the numeric value entered for the field labeled, "Graft" on Form 57.119. 3. Access-related BSI rate in AVF (arteriovenous fistula) patients = the numerator below divided by denominator below times 100 3a. NUMERATOR. Events are included in the numerator if the "patient with positive blood culture" field on Form 57.109 is checked, along with either "Vascular access" or "Uncertain" (under 'Suspected source of positive blood culture'), AND if the field labeled "Fistula" on Form 57.109 under 'Vascular accesses' is checked as being present AND none of the following fields on the same form are checked as being present: "Graft", "Permanent central line", "Temporary central line", or "Port access device". 3b. DENOMINATOR. The denominator equals the numeric value entered for the field labeled, "Fistula" on Form 57.119. Level of Analysis: Facility/Agency; Population: national; Population: regional/network; Can be measured at all levels Type of Measure: Outcome Data Source: Paper medical record/flow-sheet; Electronic Health/Medical Record; Lab data 57.119 Denominators for Outpatient Dialysis 57.109 Dialysis Event Measure Steward: Centers for Disease Control and Prevention, 1600 Clifton Rd., MS A-31, Atlanta, GA 30333
Steering Committee Recommendation for Endorsement: Y-4; N-16 Rationale: While the topic is important, the subjectivity of attributing infection to vascular access and the impact on validity makes it questionable as a performance measure.
1. Importance to Measure and Report: Y-12; N-8 *(1a. Impact; 1b. Performance gap; 1c. Outcome or Evidence)* Rationale: Reducing healthcare-associated infections is an NPP goal, and outcome measures do not require evidence. There is variation in performance. The rationale for considering this criterion as not met was the lack of evidence for identifying the cause of a bloodstream infection, especially given that measure 1460 stratifies bloodstream infection by access type and that all bloodstream infections are important. However, other Committee members noted that vascular access infections were most appropriate to measure for ESRD care.
2. Scientific Acceptability of Measure Properties: C-2; P-11; M-7; N-0 *(2a. Precise specifications; 2b. Reliability testing; 2c. Validity testing; 2d. Exclusions justified; 2e. Risk adjustment/stratification; 2f. Meaningful differences; 2g. Comparability; 2h. Disparities)* Rationale: A primary issue was lack of specificity for determining that the infection was related to vascular access. Each facility can decide how and who makes that determination. CDC only provides list of common skin contaminants for consideration. A question was raised as to whether this measure will miss incident dialysis patients coming from the hospital who have the highest risk of catheters for access, infections, and readmission to the hospital. Patients who are transiting at another clinic and those who are no-shows or who are hospitalized on one of those 2 days of the month would be excluded and their infections missed. The developer clarified that the denominator statement of patients on first 2 days of month is just to minimize burden of data collection, but all infections in the month are counted in the numerator. Data element validity testing was conducted on a small sample, and results were not strong for identifying source of infection. Of 53 positive blood cultures for which the suspected source was reported to the surveillance system and reviewed, 63.9% were determined to have been correctly characterized and reported. Type of vascular access is a primary risk factor, and the measure is stratified by type of access.
3. Usability: C-2; P-9; M-7; N-1 *(3a. Meaningful/useful for public reporting and quality improvement; 3b. Harmonized; 3c. Distinctive or additive value to existing measures)* Rationale: This measure is usable only if it can be accurately determined that the infection is attributable to vascular access; therefore, it does not provide any advantage over the simpler measure of bloodstream infections (1460).
4. Feasibility: C-0; P-8; M-10; N-2 *(4a. Clinical data generated during care process; 4b. Electronic sources; 4c. Exclusions – no additional data source; 4d. Susceptibility to inaccuracies/ unintended consequences identified 4e. Data collection strategy can be implemented)* Rationale: The CDC reporting system has been in place for a considerable time although the data collection form may not be commonly used in dialysis facilities. The feasibility of getting blood culture results for patients who had been admitted to the hospitalwas questioned. However, dialysis facilities need to obtain information on hospitalized patients when they return to dialysis, and bloodstream infection would be an important piece of information.

1456 Bacteremia (rate)
Description: Six-month rolling average rate of bacteremia with IV antibiotic therapy, among adult chronic HD patients (Express as: rate

1456 Bacteremia (rate)

per 1000 HD patient days).
Numerator Statement: Number of months that hemodialysis (HD) patients initiated a new IV antibiotic therapy for a newly suspected infection during the six-month period ending with the current reporting month, and for which blood cultures were consistent with bacteremia.
Denominator Statement: All adult (18+) chronic maintenance HD patient days during the six-month period ending with the current reporting month.
Exclusions: Patients less than 18 years old.
Adjustment/Stratification: No risk adjustment necessary N/A This measure can be stratified by vascular access type (fistula/graft/catheter).
Level of Analysis: Facility/Agency
Type of Measure: Process
Data Source: Electronic clinical data CROWNWeb (Consolidated Renal Operations in a Web Enabled Network)
Measure Steward: Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, MD 21244

Steering Committee Recommendation for Endorsement: Final: No; Initial: Y-9; N-11
Rationale: This measure more directly competes with the CDC measure 1460; therefore, both this measure and measure 1457 were reviewed as competing measures. Because this measure was untested it could not be demonstrated to be superior to a tested measure with adequate reliability and validity; therefore, it was not recommended for endorsement.

If applicable, Conditions/Questions for Developer: Do you have any testing data on reliability and validity? Can you clarify why you indicated the measure as a process measure if it's being used as a marker for infection? Did you intend to develop process measures about diagnosing and treating infections? Can you clarify or provide reference to regulatory requirements for ESRD facilities to provide data to CROWNweb?
Developer Response: "1. Do you have any testing data on reliability and validity?
The validity and reliability of collecting the data elements used in both the CMS and CDC proposed infection measures from clinical data at US dialysis facilities has been demonstrated during the last several years through the voluntary CDC National Health Safety Network (NHSN) surveillance program for access-related infections. In addition, there have been numerous studies of vascular access-related infection rates among dialysis patients which have reported similarly defined infection outcomes as indicated in the forms submitted to NQF regarding these measures. The reviews of the scientific literature made by practice guideline committees (KDOQI, CDC, UK Renal Assoc, Australian Council on Healthcare Standards) provide ample evidence that the data elements used in calculation of the proposed infection measures are reliable and valid data elements.
CMS is delighted that the NQF Steering Committee has identified infection rates as an important outcome for dialysis patients and CMS expects to implement data collection and measurement for the final definitions approved by the NQF. Multiple definitions for both the numerator and denominator of an infection measure have been proposed by both the CDC and CMS, with different goals and practical issues motivating each definition.
The CMS measures 1456 and 1457 differ from the CDC measure 1460 in a few ways.
1) The CMS measures count only those infections in which IV antibiotics were administered and in which the blood culture results were consistent with bacteremia as indicated by the caregiver. The CDC measure appears to count all positive blood cultures, as noted in their measure description.
2) The CMS definition that limits infection ascertainment to those patients with IV antibiotic use was intended to reduce data collection burden by limiting the review of laboratory blood test results to the small number (2-5%) of patients with IV antibiotics. Clinical technical expert panel members felt that this restriction would focus the measure upon patients with serious infections while at the same time greatly reducing data collection burden. The CMS proposal to limit the infection definition to only those positive blood cultures consistent with a diagnosis of bacteremia was intended to reduce the false positive rate of the measure. Furthermore, this determination of access-related bacteremia is already required of dialysis units as part of claims reporting for the V8 modifier.
3) The CDC definition is less subjective, but does not spell out how to deal with multiple blood cultures, one of which was positive, but with multiple negative results, for example.
4) While CMS believes that the conditions of positive blood culture and IV antibiotic use are both important, for the reasons given above, CMS is prepared to measure and test infection rates according to any or all of the specifications for the numerator provided in these three proposed measures.
5) Both CMS and the CDC have recommended that, in addition to data needed to calculate an overall infection rate, data also be collected concerning attribution to vascular access. This would allow calculation of access type-specific infection rates, which would be valuable to a facility in their attempts to identify the causes for elevated infection rates.
6) The CMS and CDC measures differ with regard to the denominator specification of time at risk. CMS believes that both the CDC and the CMS proposals are valid and implementable. The CMS definition, which accounts for partial months at risk by removing patient-months at the time of death or transplant or transfer is more precise, but would have relatively modest impact upon the calculated rate.

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CMS plans to implement collection of the relevant data elements in calendar year 2011 and, upon approval by the NQF, will test the validity and reliability of the resulting data flow as described in detail below. In addition to evaluation of the approved measure, CMS will evaluate measures based on the alternative definitions suggested above and will provide data demonstrating the reliability and validity of using those alternative definitions in the calculation of infection rate measures.

Our proposed testing plan embodies 3 important features as described below: (a) assessment of reliability in collecting these particular data from US dialysis units, (b) validity assessment, and (c) proposed data collection that minimizes data collection burden.

(a) Reliability assessment of access-related bacteremia data to be collected for proposed measure

(i) It is important to note that, previously, the CDC's National Health Safety Network (NHSN) project has demonstrated that access-related bacteremia data can be reliably collected from nearly 150 volunteer hemodialysis (HD) units. However, it is our understanding to be confirmed with the CDC that the geographic distribution of these voluntary sites is not nationally representative. Nonetheless, the results from this NHSN project can serve as an important set of statistics that can be used for comparative purposes regarding distribution of rates of access-related bacteremia among HD patients. However, since the CDC program is based on volunteer participation, is limited in its geographic representation (< 3% of dialysis facilities currently participate, with geographic distribution not representative of US), and substantial training with follow-up/feedback is a key feature of study participation, it is not known to what extent the NHSN findings will be representative of access-related bacteremia rates across the US.

(ii) In July, 2010, CMS required all US dialysis facilities to report, each month, all cases of dialysis access-related bacteremia in hemodialysis patients (HCPCS Modifier V8):

Figure 1: Definition of Medicare Claims HCPCS Modifier V8

'Dialysis access-related infection present (documented and treated) during the billing month. Reportable dialysis access-related infection is limited to peritonitis for peritoneal dialysis patients or bacteremia for hemodialysis patients. Facilities must report any peritonitis related to a peritoneal dialysis catheter, and any bacteremia related to hemodialysis access (including arteriovenous fistula, arteriovenous graft, or vascular catheter) if identified during the billing month. For individuals that receive different modalities of dialysis during the billing month and an infection is identified, the V8 code should only be indicated on the claim for the patient's primary dialysis modality at the time the infection was first suspected. Non-access related infections should not be coded as V8. If no dialysis-access related infection is present by this definition, providers should instead report modifier V9.'

The HCPCS Modifier V8 claims data and related modifiers have now been collected since July, 2010 with the first of these data expected to be available for analysis by March, 2011. These claims data will serve as another important set of statistics to be used for comparative purposes regarding distribution of rates of access-related bacteremia among HD patients, nationally and at a facility-level. These data will be nationally representative since they are provided by all dialysis units in the US. Furthermore, based on claims data reporting, rates of overall bacteremia will be determined to assess the percentage of reported cases of bacteremia in HD patients which are access-related, and to describe this on an overall national-level as well as the distribution of this percentage across US HD facilities (i.e., facility-level distribution).

(iii) When a facility does not report a HCPCS Modifier V8 for a particular patient during a month, it is not known the extent to which this is due to a patient not having a bacteremia versus the information not being available in a patient's medical records. The data collection we have proposed using CROWNWeb will allow quantification of unavailable information in having dialysis units provide the following information for patients who have been given a new IV antibiotic prescription during the month, and specifically asking whether the information was unavailable for whether blood cultures were consistent with bacteremia:

Proposed Data Collection Elements for Access-related Bacteremia Measure

(1) Did this patient initiate a new intravenous (IV) antibiotic therapy this month? (either newly prescribed in the unit this month, or patient discharged from the hospital/other health care facility with a new antibiotic prescription this month)

Yes No

(2) Were the blood cultures consistent with bacteremia?

Yes No Unavailable Blood cultures not collected

If YES, please answer remaining question:

(3) Was this bacteremia related to the dialysis access?

No, this was a non-access related infection
Yes HD- Catheter
Yes HD-Arteriovenous FISTULA
Yes HD-Arteriovenous GRAFT
Yes PD- Catheter (Use of this choice to be evaluated later by PD C-TEP)
Unavailable

Statistical analyses will be performed to assess inter-rater agreement between variables collected via claims data V8 and V9 modifier data and those collected via CROWNWEB for our proposed time-limited access-related bacteremia measure. Measures of inter-rater agreement will include the percent of identical values between the two raters, the unweighted kappa coefficient for nominal variables or

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weighted kappa for ordinal variables, and the intraclass correlation coefficient for continuous variables. For dichotomous variables, we will use McNemar's test to test whether the claims data and CROWNWEB data are likely to report a given response. These analyses will be performed separately for each variable used to calculate the measure. We will also calculate a summary variable, such as the percent discrepant among variables checked, for each patient and each facility.

We will consider discrepancies in two ways: First, we will calculate summaries of discrepancies for each variable across all facilities. This calculation will alert us to any variables that appear to be difficult with regards to reliable data collection. Second, we will calculate summaries of discrepancies over all variables for each facility. The distribution of these discrepancy summaries will be assessed for its variability and possible outliers. This analysis will alert us to any facility-specific issues related to data reliability. An effort will be made to contact some of these facilities with highly discrepant results to understand the reasons for this. In addition, we plan to also contact some of the facilities with a high % of unavailable information (regarding blood cultures results) in order to understand the reasons for the high % of unavailable information.

Although the major focus of reliability testing will be the assessment of concordance/discordance between the data collected via CROWNWeb versus Claims data, the distribution of access-related bacteremia rates across facilities represented in CROWNWeb, Claims data, and the CDC NHSN program will also be described.

(b) Validity assessment of access-related bacteremia data to be collected for proposed measure

As indicated previously, prior guidelines (KDOQI, CDC, UK Renal Association, Australian Council on Healthcare Standards) have indicated the importance of limiting rates of access-related bacteremia in hemodialysis patients based on: (1) evidence from numerous randomized clinical trials and other studies demonstrating the ability to reduce catheter-related bacteremia by various approaches, and (2) higher rates of bacteremia are strongly associated with higher rates of serious infection (e.g. septicemia) which are known and have shown to be closely related to higher rates of death and hospitalization, and higher costs. These prior studies provide ample evidence of the face validity of the proposed measure.

Prior results based on 32 facilities participating in the CDC NHSN program have provided preliminary evidence indicating wide variability in access-related bacteremia rates across these 32 facilities (Klevens et al., Seminars in Dialysis, 2006). Furthermore, we recently have published preliminary findings demonstrating high variability in access-related infection rates across all US dialysis units based on CMS Claims data (Lueth et al., JASN, volume 21, 2010, page 468A). However, as part of our time-limited testing of the proposed measure, we will describe the variation in access-related bacteremia rates across all US dialysis units as part of the assessment of construct validity. Correlation between facility access-related bacteremia rates and facility SMR and facility SHR will also be performed. Furthermore, access-related bacteremia rates will be described separately for each access type to determine the consistency with numerous prior studies which have shown much higher rates of infection and/or bacteremia to be associated with catheters versus arteriovenous fistulae or grafts. The above proposed analyses will form the basis of determining the construct validity of the proposed measure.

(c) The required data collection is not overly burdensome to dialysis units

Limiting data collection burden is an important consideration in developing a new measure as indicated by NQF members, as well as by CMS Data-TEP and CMS Clinical TEP members. To greatly decrease data collection burden, reporting of access-related bacteremia for the CMS proposed measure is limited to patients having been given a new IV antibiotic prescription during the reporting month. The CMS Clinical Technical Expert Panel felt that this restriction would provide a focus upon serious infections while limiting data collection burden. This was embraced by the Data Technical Expert Panel which consisted of representatives from all types of US dialysis organizations (e.g., LDOs, MDOs, SDOs, not-for-profit dialysis organizations, etc). Since only 2-5% of HD patients on average receive a new IV antibiotic prescription during a month, the CMS measure is expected to require data collection for ~5 patients per month on average in a facility treating 100 HD patients. Thus, no data collection will be required for 95% of patients in a typical facility for access-related bacteremia. Dialysis organization representatives indicated that whether a patient received a new IV antibiotic prescription is typically available in the patient's medical records.

2. Can you clarify why you indicated the measure as a process measure if it's being used as a marker for infection? Did you intend to develop process measures about diagnosing and treating infections?

To fit with the NQF's definition of a process measure, please view our access-related bacteremia measure as an outcome measure and we can make this change on the measures form for the future. We had proposed two measures which would have served as process measures regarding diagnosis and follow-up of infections (e.g. percentage of patients with an IV antibiotic prescription for whom blood culture results were unavailable or cultures not collected, and (2) percentage of patients with an IV antibiotic prescription for whom whether clinical confirmation of the suspected infection was unavailable (i.e. suggesting that follow-up may not be well-documented). However these were not approved by the NQF.

3. Can you clarify or provide reference to regulatory requirements for ESRD facilities to provide data to CROWNweb?

The CMS Conditions for Coverage contain the regulatory requirements that facilities have to submit data to CW beginning last year Feb 1, 2009. This is stated in sec 494.180(h) of the final rule for the updated CfCs passed in 2008 and published in the Federal Register. Facilities are being phased in for reporting, however the regulations as written make submission mandatory, which will be for all facilities

1456 Bacteremia (rate)
upon national roll-out. Additionally, the required data elements for the measures are already included in the current CW business requirements. See June 2008 Conditions for Coverage at http://projectcrownweb.org/assets/massmailings/june2008.pdf." Steering Committee Follow-up: An untested measure without reliability and validity data could not be demonstrated to be superior to a tested measure with adequate reliability and validity data. NQF and the ESRD Steering Committee requested that CMS and CDC collaborate on submitting one measure of bacteremia in ESRD patients, stratified by type of vascular access, that will meet both government agencies' needs and for which data could eventually be exchanged electronically between the two agencies. For now, at a minimum, facilities should be able to submit the same data to both agencies. Developer Follow-up: CMS and CDC agreed to work together on one measure; however, they were not able to accomplish identifying crosswalked specifications for use with CROWNweb in the time allowed for this project. CMS agreed that it could use the CDC definitions as long as the NHSN form or data system is not required, because ESRD facilities are required to submit data through CROWNweb, which also has the option for batch submission. NQF clarified that although detailed measure specifications often identify specific data collection tools (e.g., CMS MDS for nursing home measures), endorsed measures may be implemented with different data collection tools and systems as long as the data definitions in the endorsed measure and measure construction logic are followed. CDC also agreed that the measure does not require use of the NHSN data tools and systems and agreed to clarify definitions if needed. If measure 1460 is endorsed, then CMS will incorporate the measure specifications into its CROWNweb system by a date yet to be determined. CMS and CDC agreed to pursue data sharing arrangements so that ESRD facilities could submit data to either agency.
1. Importance to Measure and Report: Y-16; N-4 *(1a. Impact; 1b. Performance gap; 1c. Outcome or Evidence)* Rationale: Reducing healthcare-associated infections is an NPP goal, and outcome measures do not require evidence. The developer categorized the measure as a process measure, but it appears to be an outcome measure. Although a large variation across dialysis facilities was asserted on the submission form, no data were presented. The Committee agreed that reducing all bacteremias is an important goal.
2. Scientific Acceptability of Measure Properties: C-1; P-15; M-4; N-0 *(2a. Precise specifications; 2b. Reliability testing; 2c. Validity testing; 2d. Exclusions justified; 2e. Risk adjustment/stratification; 2f. Meaningful differences; 2g. Comparability; 2h. Disparities)* Rationale: This is an untested measure The numerator requires both IV antibiotic start and positive blood cultures, but the denominator is all ESRD patients. Therefore, it is a measure of bacteremia not of a process. Although the developer states there are too few pediatric patients for a meaningful measure, is there any reason to exclude pediatric patients from a measure that would cover all ESRD patients? Type of vascular access is primary risk factor, and the developer states that the measure could be stratified by type of access.
3. Usability: C-0; P-11; M-7; N-1 *(3a. Meaningful/useful for public reporting and quality improvement; 3b. Harmonized; 3c. Distinctive or additive value to existing measures)* Rationale: A reliable and valid measure of infection would be useful.
4. Feasibility: C-1; P-11; M-8; N-0 *(4a. Clinical data generated during care process; 4b. Electronic sources; 4c. Exclusions – no additional data source; 4d. Susceptibility to inaccuracies/ unintended consequences identified 4e. Data collection strategy can be implemented)* Rationale: Required data are mandated in CROWNweb. The numerator requirement for including both antibiotic starts and positive blood culture was seen as potentially more burdensome than focusing on just positive blood culture. However, the understanding is that the data are required in CROWNweb regardless of what quality measures are endorsed.

1457 Access-related bacteremia (rate)
Description: Overall access-related bacteremia: Six-month rolling average rate of access-related bacteremia with IV antibiotic therapy, among adult chronic hemodialysis (HD) patients (Express as: rate per 1000 HD patient days) Specific access types: Six-month rolling average rate of fistula/graft/catheter-related bacteremia with IV antibiotic therapy, among adult chronic hemodialysis (HD) patients using a fistula/graft/catheter for HD access (Express as: rate per 1000 fistula/graft/catheter patient days). Numerator Statement: Overall access-related bacteremia: Number of months that hemodialysis (HD) patients initiated a new IV antibiotic therapy for a newly suspected infection during the six-month period ending with the current reporting month, and for which the infection was related to the HD access, and blood cultures were consistent with bacteremia. Specific access types: Number of months that HD patients initiated a new IV antibiotic therapy for a newly suspected infection during the six-month period ending with the current reporting month, and for which the infection was related to the fistula/graft/catheter used as HD access, and blood cultures were consistent with bacteremia. Denominator Statement: Overall access-related bacteremia: All adult (18+) chronic maintenance HD patient days during the six-month

1457 Access-related bacteremia (rate)
period ending with the current reporting month. Specific access types: All adult (18+) chronic maintenance HD fistula/graft/catheter days during the six-month period ending with the current reporting month. Exclusions: HD patients less than 18 yrs old. Adjustment/Stratification: No risk adjustment necessary N/A This measure can be stratified by vascular access type as noted in the numerator and denominator statements. Level of Analysis: Facility/Agency Type of Measure: Process Data Source: Electronic clinical data CROWNWeb Measure Steward: Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, MD 21244
Steering Committee Recommendation for Endorsement: Final: No; Initial: Y-11; N-9 pending comparison of competing measures Rationale: This measure and measure 1456, which more directly competes with the CDC measure 1460, were reviewed as competing measures. Because this measure is untested it could not be demonstrated to be superior to a tested measure with adequate reliability and validity; therefore, it was not recommended for endorsement.
If applicable, Conditions/Questions for Developer: Do you have any testing data on reliability and validity? Can you clarify why you indicated this measure as a process measure if it's being used as a marker for infection? Did you intend to develop process measures about diagnosing and treating infections? Can you clarify or provide reference to regulatory requirements for ESRD facilities to provide data to CROWNweb? Developer Response: See developer response to measure 1456. Steering Committee Follow-up: An untested measure without reliability and validity data could not be demonstrated to be superior to a tested measure with adequate reliability and validity data. NQF and the ESRD Steering Committee requested that CMS and CDC collaborate on submitting one measure of bacteremia in ESRD patients, stratified by type of vascular access, that will meet both government agencies' needs and for which data could eventually be exchanged electronically between the two agencies. For now, at a minimum, facilities should be able to submit the same data to both agencies. Developer Follow-up: CMS and CDC agreed to work together on one measure; however, they were not able to accomplish identifying crosswalked specifications for use with CROWNweb in the time allowed for this project. CMS agreed that it could use the CDC definitions as long as the NHSN form or data system is not required, because ESRD facilities are required to submit data through CROWNweb, which also has the option for batch submission. NQF clarified that although detailed measure specifications often identify specific data collection tools (e.g., CMS MDS for nursing home measures), endorsed measures may be implemented with different data collection tools and systems as long as the data definitions in the endorsed measure and measure construction logic are followed. CDC also agreed that the measure does not require use of the NHSN data tools and systems and agreed to clarify definitions if needed. If measure #1460 is endorsed, the CMS will incorporate the measure specifications into its CROWNweb system by a date yet to be determined. CMS and CDC agreed to pursue data sharing arrangements so that ESRD facilities could submit data to either agency.
1. Importance to Measure and Report: Y-18; N-2 *(1a. Impact; 1b. Performance gap; 1c. Outcome or Evidence)* Rationale: Reducing healthcare-associated infections is an NPP goal, and outcome measures do not require evidence. The developer categorized this measure as a process measure, but it appears to be an outcome measure. Although a large variation across dialysis facilities was asserted in the submission, no data were presented. Nonetheless, the Committee agreed that reducing all bacteremias is an important goal, and access-related infections are most directly related to dialysis care.
2. Scientific Acceptability of Measure Properties: C-3; P-11; M-5; N- *(2a. Precise specifications; 2b. Reliability testing; 2c. Validity testing; 2d. Exclusions justified; 2e. Risk adjustment/stratification; 2f. Meaningful differences; 2g. Comparability; 2h. Disparities)* Rationale: This is an untested measure The numerator requires three elements: IV antibiotic start, positive blood cultures, and determination that infection is related to vascular access. However, the denominator is all ESRD patients, so it is a measure of bacteremia not of a process. The measure requires a determination that the infection was related to vascular access, but it provides no definitions or guidance. Although the developer states there are too few pediatric patients for a meaningful measure, is there any reason to exclude pediatric patients from a measure that would cover all ESRD patients? Type of vascular access is the primary risk factor for infection, and the measure is stratified by type of access.
3. Usability: C-0; P-15; M-3; N-2 *(3a. Meaningful/useful for public reporting and quality improvement; 3b. Harmonized; 3c. Distinctive or additive value to existing measures)* Rationale: If reliable and valid, the information would be meaningful and useful.
4. Feasibility: C-0; P-15; M-4; N-0 *(4a. Clinical data generated during care process; 4b. Electronic sources; 4c. Exclusions – no additional data source; 4d. Susceptibility to*

1457 Access-related bacteremia (rate)

inaccuracies/ unintended consequences identified 4e. Data collection strategy can be implemented)
Rationale: Required data are mandated in CROWNweb. The CMS representative said that the conditions of coverage published in 2007 require facilities to submit 100% of data required by CMS. The developer said it was essentially the same information as needed for the CDC measure.

1455 Access-related bacteremia—using Medicare claims (rate)

Description: Overall access-related bacteremia: Six-month rolling average rate of access-related bacteremia among adult chronic hemodialysis (HD) patients
(Express as: rate per 1000 HD patient days)
Specific access types: Six-month rolling average rate of fistula/graft/catheter-related bacteremia among adult chronic hemodialysis (HD) patients using a fistula/graft/catheter for HD access
(Express as: rate per 1000 days of fistula/graft/catheter use)
Numerator Statement: Overall access-related bacteremia: For the months in the denominator, number of months in which a monthly hemodialysis claim reported an access-related bacteremia using HCPCS modifier V8.
Specific access types: For the months in the denominator, number of months in which a monthly hemodialysis claim reported an access-related bacteremia using HCPCS modifier V8 with the particular type of access (fistula/graft/catheter) as indicated by HCPCS modifiers V5, V6, or V7 for vascular access in use at the end of the preceding month.
Denominator Statement: Overall access-related bacteremia: All adult (18+) chronic maintenance HD patient days during the six-month period ending with the current reporting month.
Specific access types: All adult (18+) chronic maintenance HD patient days during the six-month period ending with the current reporting month with the particular type of access (fistula/graft/catheter) as indicated by HCPCS modifiers V5, V6, or V7 for vascular access in use at the end of the preceding month.
Exclusions: HD patients less than 18 yrs old.
Adjustment/Stratification: No risk adjustment necessary N/A As stated in numerator and denominator statements, this measure can be stratified by type of access (fistula/graft/catheter) as indicated by HCPCS modifiers V5, V6, or V7 for vascular access in use at the end of the preceding month.
Level of Analysis: Facility/Agency
Type of Measure: Process
Data Source: Electronic administrative data/claims Medicare claims
Measure Steward: Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, MD 21244

Steering Committee Recommendation for Endorsement: Y-7; N-13
Rationale: The measure is not tested, and claims data is thought to be an inferior source of data compared to record abstraction.

1. Importance to Measure and Report: Y-14; N-6
(1a. Impact; 1b. Performance gap; 1c. Outcome or Evidence)
Rationale: Reducing healthcare-associated infections is an NPP goal, and outcome measures do not require evidence. Developer categorized this measure as a process measure, but it appears to be an outcome measure. Although a large variation across dialysis facilities was asserted on the submission form, no data were presented. The Committee agreed that reducing all bacteremias is an important goal.

2. Scientific Acceptability of Measure Properties: C-0; P-15; M-4; N-1
(2a. Precise specifications; 2b. Reliability testing; 2c. Validity testing; 2d. Exclusions justified; 2e. Risk adjustment/stratification; 2f. Meaningful differences; 2g. Comparability; 2h. Disparities)
Rationale: This is an untested measure that will be based on claims data rather than the clinical data reported in CROWNweb. In response to a question of why an identical measure with a different data source was submitted, the CMS representative said it was because of uncertainty regarding the timing of CROWNweb. Another question was raised about the reliability and validity of claims in identifying bacteremia using HCPCS modifiers. Although the developer states there are too few pediatric patients for a meaningful measure, is there any reason to exclude pediatric patients from a measure that would cover all ESRD patients? There is no definition or guidance on how to determine that a bacteremia is access-related. There may be the potential for counting a single episode of infection twice if the episode bridges 2 calendar months and the modifier is used in each of those months. The developer explained that the measure uses only Medicare claims because it had access to only Medicare claims.

3. Usability: C-0; P-14; M-4; N-3
(3a. Meaningful/useful for public reporting and quality improvement; 3b. Harmonized; 3c. Distinctive or additive value to existing measures)
Rationale: If reliable and valid, the information would be meaningful and useful.

4. Feasibility: C-4; P-9; M-6; N-1

1455 Access-related bacteremia—using Medicare claims (rate)

(4a. Clinical data generated during care process; 4b. Electronic sources; 4c. Exclusions – no additional data source; 4d. Susceptibility to inaccuracies/ unintended consequences identified; 4e. Data collection strategy can be implemented)

Rationale: The requirement for reporting this on the claim form already exists, so this measure does not add another layer of reporting.

1449 Unavailable blood culture results (percentage)

Description: Six-month rolling average prevalence of "unavailable" blood culture results for adult chronic hemodialysis (HD) patients prescribed IV antibiotics (Express as: percentage).

Numerator Statement: Number of months that HD patients initiated a new IV antibiotic therapy for a newly suspected infection during the six-month period ending with the current reporting month and for which blood culture results were indicated to be "unavailable".

Denominator Statement: Number of months that adult (18+) HD patients initiated a new IV antibiotic therapy for a newly suspected infection during the six-month period ending with the current reporting month.

Exclusions: HD patients less than 18 yrs old, or not prescribed an IV antibiotic.

Adjustment/Stratification: No risk adjustment necessary.This measure can be stratified by vascular access type (fistula/graft/catheter).

Level of Analysis: Facility/Agency

Type of Measure: Structure/management

Data Source: Electronic clinical data CROWNWeb

Measure Steward: Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, MD 21244

Steering Committee Recommendation for Endorsement: Y-1; N-18

Rationale: The Committee did not think the measure was necessary or appropriate for public reporting.

1. Importance to Measure and Report: Y-9; N-9

(1a. Impact; 1b. Performance gap; 1c. Outcome or Evidence)

Rationale: Data on performance gaps were not provided. The measure would be considered to meet the criterion if it is viewed as a process measure of performing blood cultures. The rationale for considering this criterion as not met is that it is primarily a measure of missing data used in conjunction with other measures.

2. Scientific Acceptability of Measure Properties: C-1; P-6; M-9; N-3

(2a. Precise specifications; 2b. Reliability testing; 2c. Validity testing; 2d. Exclusions justified; 2e. Risk adjustment/stratification; 2f. Meaningful differences; 2g. Comparability; 2h. Disparities)

Rationale: This is an untested measure. The term "Unavailable" was not defined: Does unavailable include not ordered and not done? Why are pediatric patients excluded?

3. Usability: C-1; P-4; M-10; N-4

(3a. Meaningful/useful for public reporting and quality improvement; 3b. Harmonized; 3c. Distinctive or additive value to existing measures)

Rationale: As a measure to detect "gaming of the system" or report on a process, this measure might have some usefulness. However, a measure of missing data is not particularly useful for pubic reporting or quality improvement.

4. Feasibility: C-2; P-5; M-10; N-2

(4a. Clinical data generated during care process; 4b. Electronic sources; 4c. Exclusions – no additional data source; 4d. Susceptibility to inaccuracies/ unintended consequences identified; 4e. Data collection strategy can be implemented)

Rationale: The measure is based on absence of data in the field in CROWNweb.

1453 Clinically confirmed infection (rate)

Description: Six-month rolling average rate of clinically confirmed infection with IV antibiotic therapy among adult chronic HD patients (Express as: rate per 1000 HD patient days).

Numerator Statement: Number of months that hemodialysis (HD) patients initiated a new IV antibiotic therapy for a newly suspected infection during the six-month period ending with the current reporting month, and for which the infection was clinically confirmed.

Denominator Statement: All adult (18+) chronic maintenance HD patient days during the six-month period ending with the current reporting month.

Exclusions: Patients less than 18 years old.

Adjustment/Stratification: No risk adjustment necessary N/A This measure can be stratified by vascular access type (fistula/graft/catheter).

Level of Analysis: Facility/Agency

Type of Measure: Process

Data Source: Electronic clinical data CROWNWeb (Consolidated Renal Operations in a Web Enabled Network)

Measure Steward: Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, MD 21244

1453 Clinically confirmed infection (rate)
Steering Committee Recommendation for Endorsement: Withdrawn Rationale: The developer withdrew the measure when measure 1469 was not recommended because all three clinical confirmation measures would be needed.

1469 Clinically confirmed access-related infection (rate)
Description: Clinically confirmed infection: Six-month rolling average rate of clinically confirmed infection with IV antibiotic therapy among adult chronic HD patients (Express as: rate per 1000 HD patient days) Specific access types: Six-month rolling average rate for access-related infection with IV antibiotic therapy, among adult chronic hemodialysis (HD) patients using an arteriovenous fistula for HD access (Express as: rate per 1000 HD fistula days) Six-month rolling average rate for access-related infection with IV antibiotic therapy, among adult chronic hemodialysis (HD) patients using an arteriovenous graft for HD access (Express as: rate per 1000 HD graft days) Six-month rolling average rate for access-related infection with IV antibiotic therapy, among adult chronic hemodialysis (HD) patients using an catheter for HD access (Express as: rate per 1000 HD catheter days) Numerator Statement: Clinically confirmed infection: Number of months that hemodialysis (HD) patients initiated a new IV antibiotic therapy for a newly suspected infection during the six-month period ending with the current reporting month, and for which the infection was clinically confirmed and related to the dialysis access. Specific access types: Number of months that HD patients initiated a new IV antibiotic therapy for a newly suspected infection that was clinically confirmed during the six-month period ending with the current reporting month and for which the infection was related to the fistula/graft/catheter used as HD access. Denominator Statement: Clinically confirmed infection: All adult (18+) chronic maintenance HD patient days during the six-month period ending with the current reporting month. Specific access types: All adult (18+) chronic maintenance HD fistula/graft/catheter days during the six-month period ending with the current reporting month. Exclusions: HD patients less than 18 yrs old (for all access types) Adjustment/Stratification: No risk adjustment necessary N/A This measure can be stratified by vascular access type as noted in the numerator and denominator statements. Level of Analysis: Facility/Agency Type of Measure: Process Data Source: Electronic clinical data CROWNWeb Measure Steward: Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, MD 21244
Steering Committee Recommendation for Endorsement: Y-2; N-16 Rationale: The evidence and measure specifications did not address how to clinically confirm an infection or how to determine if it was related to vascular access.
1. Importance to Measure and Report: Y-9; N-9 *(1a. Impact; 1b. Performance gap; 1c. Outcome or Evidence)* Rationale: The measure is listed as a process measure, but it is really an outcome measure. It was not constructed to reflect the process of clinically confirming an infection. The evidence did not address how to clinically confirm an infection or how to determine if it was related to vascular access. However, the outcome of infection is extremely important.
2. Scientific Acceptability of Measure Properties: C-0; P-9; M-6; N-3 *(2a. Precise specifications; 2b. Reliability testing; 2c. Validity testing; 2d. Exclusions justified; 2e. Risk adjustment/stratification; 2f. Meaningful differences; 2g. Comparability; 2h. Disparities)* Rationale: The measure is untested, and because the specifications do not define clinically confirmed or vascular access-related, the results may be inconsistent. There could be some problem with a shift to oral antibiotics.
3. Usability: C-0; P-4; M-12; N-1 *(3a. Meaningful/useful for public reporting and quality improvement; 3b. Harmonized; 3c. Distinctive or additive value to existing measures)* Rationale: If data are not consistent, the information will not be usable.
4. Feasibility: C-0; P-2; M-13; N-3 *(4a. Clinical data generated during care process; 4b. Electronic sources; 4c. Exclusions – no additional data source; 4d. Susceptibility to inaccuracies/ unintended consequences identified 4e. Data collection strategy can be implemented)*

1469 Clinically confirmed access-related infection (rate)
Rationale: The data elements are to be collected in CROWNweb.

1450 Unavailable clinical confirmation (percentage)
Description: Six-month rolling average prevalence of "unavailable" information regarding clinical confirmation of infection among adult chronic hemodialysis (HD) patients with new IV antibiotic prescription (Express as: percentage). Numerator Statement: Number of months that HD patients initiated a new IV antibiotic therapy for a newly suspected infection during the six-month period ending with the current reporting month, and for which an indication of "unavailable" was provided regarding whether the infection was clinically confirmed or related to dialysis access. Denominator Statement: Number of months that adult (18+) HD patients initiated a new IV antibiotic therapy for a newly suspected infection during the six-month period ending with the current reporting month. Exclusions: HD patients less than 18 yrs old, or not prescribed an IV antibiotic. Adjustment/Stratification: No risk adjustment necessary N/A This measure can be stratified by vascular access type (fistula/graft/catheter). Level of Analysis: Facility/Agency Type of Measure: Structure/management Data Source: Electronic clinical data CROWNWeb Measure Steward: Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, MD 21244
Steering Committee Recommendation for Endorsement: Withdrawn Rationale: The developer withdrew the measure when measure 1469 was not recommended because all three clinical confirmation measures would be needed.

COMPARISON TABLES FOR RELATED MEASURES

	1418 Frequency of adequacy measurement for pediatric hemodialysis patients	0247 Hemodialysis adequacy clinical performance measure I: Hemodialysis adequacy – monthly measurement of delivered dose
Steward	Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, MD 21244	Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Mail Stop S3-01-02, Baltimore, MD 21244-1850

	1418 Frequency of adequacy measurement for pediatric hemodialysis patients	0247 Hemodialysis adequacy clinical performance measure I: Hemodialysis adequacy—monthly measurement of delivered dose
Description	Percentage of all pediatric (less than18 years) patients receiving in-center hemodialysis (irrespective of frequency of dialysis) with documented monthly adequacy measurements (spKt/V) or its components in the calendar month	Percentage of all adult (≥18 years old) HD patients in the sample for analyses with documented monthly adequacy measurements (spKt/V) or its components in the calendar month
Type	Process	Process
Data Source	Electronic clinical data CROWNWeb http://www.projectcrownweb.org/crown/index.php	Paper medical record/flow-sheet; Electronic administrative data/claims; Electronic Health/Medical Record
Level	Facility/Agency	Facility/Agency
Setting	Dialysis Facility	Dialysis Facility
Numerator Statement	Number of patients in the denominator with monthly adequacy measurements (spKt/V) or its components in the calendar month	Number of patients in the denominator with documented monthly adequacy measurements (spKt/V) or its components in the calendar month
Numerator Details	Time Window: The entire calendar month The numerator will be determined by counting the patients in the denominator who meet one of the following criteria in the one month study period: "Kt/V Hemodialysis Collection Date" is populated, AND "Kt/V Hemodialysis" is populated, OR "Kt/V Hemodialysis Collection Date" is populated, AND "BUN Pre-Dialysis" is populated, AND "BUN Post-Dialysis" is populated, AND "Pre-Dialysis Weight" is populated, AND "Pre-Dialysis Weight Unit of Measure" is populated, AND "Post-Dialysis Weight" is populated, AND "Post-Dialysis Weight Unit of Measure" is populated, AND "Delivered Minutes of BUN Hemodialysis Session" is populated.	Time Window:
Denominator Statement	Number of pediatric patients (less than18 years) receiving in-center hemodialysis (irrespective of frequency of dialysis)who are in the facility and on hemodialysis for the entire study period	All adult (≥18 years old) HD patients in the sample for analyses
Denom Categories	Female; Male Pediatric patients less than 18 years old	
Denominator Details	Time Window: The entire calendar month The patient's age will be determined by subtracting the patient's date of birth from the first day of the reporting month. In-center hemodialysis patients are defined as follows: "Admit Date" to the specified facility is prior or equal to the first day of the study period, AND the patient has not been discharged ("Discharge Date" is null or blank), OR "Discharge Date" from the facility is greater than or equal to the last day of the study period AND "Treatment Dialysis Broad Start Date" is prior or equal to the first day of the study period, AND "Dialysis Broad Type of Treatment" = 'HD', AND "Primary Dialysis Setting" ='Dialysis Facility/Center' on the last day of the study period, AND "Date Regular Chronic Dialysis Began" is prior to the first day of the study	Time Window:

	1418 Frequency of adequacy measurement for pediatric hemodialysis patients	0247 Hemodialysis adequacy clinical performance measure I: Hemodialysis adequacy—monthly measurement of delivered dose
	period. The denominator will include all patients less than18 years old who are determined to be in-center hemodialysis patients.	
Exclusions	Patients on home dialysis, patients not in the facility for the entire calendar month	
Exclusion Details	See denominator details.	
Risk Adjustment	No risk adjustment necessary N/A	
Stratification	No stratification is required for this measure.	
Type Score	Rate/proportion better quality = higher score	
Algorithm	The patient's age will be determined by subtracting the patient's date of birth from the first day of the reporting month. In-center hemodialysis patients are defined as follows: "Admit Date" to the specified facility is prior or equal to the first day of the study period, AND the patient has not been discharged ("Discharge Date" is null or blank), OR "Discharge Date" from the facility is greater than or equal to the last day of the study period AND "Treatment Dialysis Broad Start Date" is prior or equal to the first day of the study period, AND "Dialysis Broad Type of Treatment" = 'HD', AND "Primary Dialysis Setting" ='Dialysis Facility/Center' on the last day of the study period, AND "Date Regular Chronic Dialysis Began" is prior to the first day of the study period. The denominator will include all patients less than18 years old who are determined to be in-center hemodialysis patients. The numerator will be determined by counting the patients in the denominator who meet one of the following criteria in the one month study period: "Kt/V Hemodialysis Collection Date" is populated, AND "Kt/V Hemodialysis" is populated, OR "Kt/V Hemodialysis Collection Date" is populated, AND "BUN Pre-Dialysis" is populated, AND "BUN Post-Dialysis" is populated, AND "Pre-Dialysis Weight" is populated, AND "Pre-Dialysis Weight Unit of Measure" is populated, AND "Post-Dialysis Weight" is populated, AND "Post-Dialysis Weight Unit of Measure" is populated, AND "Delivered Minutes of BUN Hemodialysis Session" is populated.	

	1421 Method of adequacy measurement for pediatric hemodialysis patients	0248 Hemodialysis adequacy clinical performance measure II: Method of measurement of delivered hemodialysis dose
Steward	Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, MD 21244	Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Mail Stop S3-01-02, Baltimore, MD 21244-1850
Description	Percentage of pediatric (less than18 years old) in-center HD patients (irrespective of frequency of dialysis) for	Percentage of all adult (≥18 years old) in-center HD patients in the sample for analyses for whom delivered HD dose was

	1421 Method of adequacy measurement for pediatric hemodialysis patients	0248 Hemodialysis adequacy clinical performance measure II: Method of measurement of delivered hemodialysis dose
	whom delivered HD dose was measured by spKt/V as calculated using UKM or Daugirdas II during the reporting period	calculated using UKM or Daugirdas II during the study period and for whom the frequency of HD per week is specified.
Type	Process	Process
Data Source	Electronic Health/Medical Record CROWNWeb http://www.projectcrownweb.org/crown/index.php http://www.projectcrownweb.org/crown/index.php?page=Public_Documents&subPage=Release_Documents	Paper medical record/flow-sheet; Electronic administrative data/claims; Electronic Health/Medical Record
Level	Facility/Agency	Facility/Agency
Setting	Dialysis Facility	Dialysis Facility
Numerator Statement	Number of patients in the denominator for whom delivered HD dose was calculated using UKM or Daugirdas II during the reporting period and for whom the frequency of HD per week is specified	Number of patients in the denominator for whom delivered HD dose was calculated using UKM or Daugirdas II during the study period and for whom the frequency of HD per week is specified
Numerator Details	Time Window: The entire calendar month. The numerator will be determined by counting the patients in the denominator for whom Kt/V "Hemodialysis Method" is 'Daugirdas II' OR 'UKM'.	Time Window:
Denominator Statement	Number of pediatric (less than18 years old) in-center HD patients (irrespective of frequency of dialysis) in the sample for analysis	All adult (≥18 years old) in-center HD patients in the sample for analyses
Denom Categories	Female; Male Pediatric patients less than 18 years old	
Denominator Details	Time Window: The entire calendar month The patient's age will be determined by subtracting the patient's date of birth from the first day of the reporting month. In-center hemodialysis patients are defined as follows: "Admit Date" to the specified facility is prior or equal to the first day of the study period, AND the patient has not been discharged ("Discharge Date" is null or blank), OR "Discharge Date" from the facility is greater than or equal to the last day of the study period AND "Treatment Dialysis Broad Start Date" is prior or equal to the first day of the study period, AND "Dialysis Broad Type of Treatment" = 'HD', AND "Primary Dialysis Setting" = 'Dialysis Facility/Center' on the last day of the study period, AND "Date Regular Chronic Dialysis Began" is prior to the first day of the study period. The denominator will include all patients less than18 years old who are determined to be in-center hemodialysis patients.	Time Window:
Exclusions	Patients on home dialysis, patients not in the facility for the entire calendar month	
Exclusion Details	See denominator exclusions	
Risk	No risk adjustment necessary	

	1421 Method of adequacy measurement for pediatric hemodialysis patients	0248 Hemodialysis adequacy clinical performance measure II: Method of measurement of delivered hemodialysis dose
Adjustment	N/A	
Stratification	No stratification is required for this measure.	
Type Score	Rate/proportion better quality = higher score	
Algorithm	The patient's age will be determined by subtracting the patient's date of birth from the first day of the reporting month. In-center hemodialysis patients are defined as follows: "Admit Date" to the specified facility is prior or equal to the first day of the study period, AND the patient has not been discharged ("Discharge Date" is null or blank), OR "Discharge Date" from the facility is greater than or equal to the last day of the study period AND "Treatment Dialysis Broad Start Date" is prior or equal to the first day of the study period, AND "Dialysis Broad Type of Treatment" = 'HD', AND "Primary Dialysis Setting" = 'Dialysis Facility/Center' on the last day of the study period, AND "Date Regular Chronic Dialysis Began" is prior to the first day of the study period. The denominator will include all patients less than18 years old who are determined to be in-center hemodialysis patients. The numerator will be determined by counting the patients in the denominator for whom Kt/V "Hemodialysis Method" is 'Daugirdas II' OR 'UKM'.	

	1423 Minimum spKt/V for pediatric hemodialysis patients	0250 Hemodialysis adequacy clinical performance measure III: Hemodialysis adequacy—HD adequacy CPM III: Minimum delivered hemodialysis dose
Steward	Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, MD 21244	Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Mail Stop S3-01-02, Baltimore, MD 21244-1850
Description	Percentage of all pediatric (less than18 years old) in-center HD patients who have been on hemodialysis for 90 days or more and dialyzing 3 or 4 times weekly whose delivered dose of hemodialysis (calculated from the last measurements of the month using the UKM or Daugirdas II formula) was a spKt/Vgreater than or equal to1.2	Percentage of all adult (≥18 years old) patients in the sample for analysis who have been on hemodialysis for 6 months or more and dialyzing thrice weekly whose average delivered dose of hemodialysis (calculated from the last measurements of the month using the UKM or Daugirdas II formula) was a spKt/V ≥ 1.2 during the study period
Type	Outcome	Process
Data Source	Electronic clinical data CROWNWeb http://www.projectcrownweb.org/crown/index.php http://www.projectcrownweb.org/crown/index.php?page=Public_Documents&subPage=Release_Documents	Electronic administrative data/claims
Level	Facility/Agency	Facility/Agency
Setting	Dialysis Facility	Dialysis Facility
Numerator Statement	Number of patients in the denominator whose delivered dose of hemodialysis (calculated from the last	Number of patients in denominator whose delivered dose of hemodialysis (calculated from the last measurements of the

	1423 Minimum spKt/V for pediatric hemodialysis patients	0250 Hemodialysis adequacy clinical performance measure III: Hemodialysis adequacy—HD adequacy CPM III: Minimum delivered hemodialysis dose
	measurements of the month using the UKM or Daugirdas II formula) was a spKt/Vgreater than =1.2	month using the UKM or Daugirdas II formula) was a spKt/V ≥ 1.2
Numerator Details	Time Window: Number of patients in the denominator whose delivered dose of hemodialysis (calculated from the last measurements of the month using the UKM or Daugirdas II formula) was a spKt/Vgreater than =1.2 The numerator will be determined by counting the patients in the denominator for whom "Kt/V Hemodialysis Method" is 'Daugirdas II' OR 'UKM' AND "Kt/V" is greater than or equal to 1.2	Time Window:
Denominator Statement	Number of pediatric (less than18 years old) in-center HD patients who have been on hemodialysis for 90 days or more and dialyzing 3 or 4 times weekly	All adult (≥18 years old) patients in the sample for analysis who have been on hemodialysis for 90 days or more and dialyzing thrice weekly and whose RRF is unmeasured or whose RRF<2 ml/min/1.73m2 (if measured in the last three months)
Denom Categories	Female; Male Pediatric patients less than 18 years old	
Denominator Details	Time Window: The entire calendar month. The duration of hemodialysis treatment will be calculated as the difference between the first "Kt/V Collection Date" and "Date Regular Chronic Dialysis Began". The denominator will include all in-center hemodialysis patients less than18 years old who have been on dialysis for 90 days or longer and "Sessions per Week" is equal to 3 or 4. The patient's age will be determined by subtracting the patient's date of birth from the first day of the reporting month. In-center hemodialysis patients are defined as follows: "Admit Date" to the specified facility is prior or equal to the first day of the study period, AND the patient has not been discharged ("Discharge Date" is null or blank), OR "Discharge Date" from the facility is greater than or equal to the last day of the study period AND "Treatment Dialysis Broad Start Date" is prior or equal to the first day of the study period, AND "Dialysis Broad Type of Treatment" = 'HD', AND "Primary Dialysis Setting" = 'Dialysis Facility/Center' on the last day of the study period, AND "Date Regular Chronic Dialysis Began" is prior to the first day of the study period.	Time Window:
Exclusions	Patients on home hemodialysis, patients on hemodialysisless than90 days, patients receiving dialysis less than3x/week or greater than 4x/week, patients not in the facility for the entire calendar month	Patients on HD less than 90 days. Patients with RRF >2 ml/min/1.73m2 (measured in the last three months)
Exclusion Details	Exclusions to this measure include patients receiving dialysis 5 times or more per week, as in those with diseases such as oxalosis in whom frequent dialysis may result in minimal changes in urea clearance with the resulting low spKt/V for a single session. Patients	

	1423 Minimum spKt/V for pediatric hemodialysis patients	0250 Hemodialysis adequacy clinical performance measure III: Hemodialysis adequacy—HD adequacy CPM III: Minimum delivered hemodialysis dose
	receiving dialysis two times a week were also excluded as these patients likely have residual renal function, which is a component of clearance not currently captured.	
Risk Adjustment	No risk adjustment necessary N/A	
Stratification	Stratification of target values by age was considered, with higher targets for younger patients, however there are insufficient data to support any stratified target measures at this time.	
Type Score	Rate/proportion better quality = higher score	
Algorithm	The duration of hemodialysis treatment will be calculated as the difference between the first "Kt/V Collection Date" and "Date Regular Chronic Dialysis Began". The denominator will include all in-center hemodialysis patients less than18 years old who have been on dialysis for 90 days or longer and "Sessions per Week" is equal to 3 or 4. The patient's age will be determined by subtracting the patient's date of birth from the first day of the reporting month. In-center hemodialysis patients are defined as follows: "Admit Date" to the specified facility is prior or equal to the first day of the study period, AND the patient has not been discharged ("Discharge Date" is null or blank), OR "Discharge Date" from the facility is greater than or equal to the last day of the study period AND "Treatment Dialysis Broad Start Date" is prior or equal to the first day of the study period, AND "Dialysis Broad Type of Treatment" = 'HD', AND "Primary Dialysis Setting" = 'Dialysis Facility/Center' on the last day of the study period, AND "Date Regular Chronic Dialysis Began" is prior to the first day of the study period. The numerator will be determined by counting the patients in the denominator for whom "Kt/V Hemodialysis Method" is 'Daugirdas II' OR 'UKM' AND "Kt/V" is greater than or equal to 1.2.	

	1454 Proportion of patients with hypercalcemia	0261 Measurement of serum calcium concentration
Steward	Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, MD 21244	Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Mail Stop S3-01-02, Baltimore, MD 21244-1850
Description	Proportion of patients with 3-month rolling average of total uncorrected serum calcium greater than 10.2 mg/dL	Percentage of all adult peritoneal dialysis and hemodialysis patients included in the sample for analysis with serum calcium measured at least once within month
Type	Outcome	Process
Data Source	Electronic clinical data CROWNWeb http://www.projectcrownweb.org/crown/index.php http://www.projectcrownweb.org/crown/index.php?page=	Paper medical record/flow-sheet; Electronic administrative data/claims

	1454 Proportion of patients with hypercalcemia	0261 Measurement of serum calcium concentration
	Public_Documents&subPage=Release_Documents	
Level	Facility/Agency	Facility/Agency
Setting	Dialysis Facility	Dialysis Facility
Numerator Statement	Number of patients in the denominator with 3-month rolling average of total uncorrected serum calcium greater than 10.2 mg/dL	Number of adult (≥18 years of age) dialysis patients included in denominator with serum calcium measured at least once within month
Numerator Details	Time Window: Prior 3 months. If there are multiple serum calcium measurements during the month, the last value will be used for the calculation	Time Window:
Denominator Statement	Number of adult (greater than or equal to18 years old) hemodialysis or peritoneal dialysis patients treated at the outpatient dialysis facility for at least 30 days who have been on dialysis for greater than 90 days with at least one calcium measurement during the prior 90 days	All adult peritoneal dialysis and hemodialysis patients included in the sample for analysis
Denom Categories	Female; Male Adults 18 years or older	
Denominator Details	Time Window: Prior 3 months. See above Denominator Statement	Time Window:
Exclusions	None	Transient dialysis patients (in unit <30 days), pediatric patients and kidney transplant recipients with a functioning graft.
Exclusion Details	N/A	
Risk Adjustment	No risk adjustment necessary N/A	
Stratification	N/A	
Type Score	Rate/proportion better quality = lower score	
Algorithm	Patients are included in the denominator if they are greater than or equal to18 years old as of the first day of the most recent month of the study period, are on dialysis for more than 90 days as of the first day of the most recent month of the study period, are in the facility for at least 30 days as of the last day of the most recent month of the study period, and have at least one serum calcium measurement within the study period. The patient's age will be determined by subtracting the patient's date of birth from the first day of the most recent month of the study period. The patient's time on dialysis will be determined by subtracting the patient's date regular Chronic Dialysis Began from the first day of the most recent month of the study period. Patients on dialysis are determined as follows: Primary Type of Dialysis is Hemodialysis, CAPD or CCPD in the most recent month of the study period. Patients in a facility for at least 30 days are determined as follows: if the discharge date from the specified facility is missing/null or is after the last day of the most recent month of the study period, then the patient's time in the facility is	

	1454 Proportion of patients with hypercalcemia	0261 Measurement of serum calcium concentration
	calculated from the admit date to the last day of the most recent month of the study period; if the discharge date is prior to the last day of the most recent month of the study period, the patient is excluded from the calculation. In addition, the patient must have at least one valid measurement of total serum calcium within the study period. The numerator will be determined by counting the patients in the denominator who meet the following criteria: the average total serum calcium over the 3-month study period is greater than 10.2 mg/dL. If there is more than one serum calcium measurement within each month of the study period, the last value for the month shall be used for the calculation of the average.	

	1460 National Healthcare Safety Network (NHSN) bloodstream infection measure	PSM-001-10 National Healthcare Safety Network (NHSN) central line-associated bloodstream infection (CLABSI) outcome measure
Steward	Centers for Disease Control and Prevention, Division of Healthcare Quality Promotion, 1600 Clifton Rd., MS A-31, Atlanta, GA 30333	Centers for Disease Control and Prevention, 1600 Clifton Rd, NE, Mailstop A-24, Atlanta, GA 30333
Description	Number of hemodialysis outpatients with positive blood cultures per 100 hemodialysis patient-months	Standardized Infection Ratio (SIR) of healthcare-associated, central line-associated bloodstream infections (CLABSI) among patients in intensive care units (ICUs) and Neonatal Intensive Care Units (NICUs)
Type	Outcome	Outcome
Data Source	Paper medical record/flow-sheet; Electronic Health/Medical Record; Lab data 57.119 Denominators for Outpatient Dialysis 57.109 Dialysis Event http://www.cdc.gov/nhsn/psc_da_de.html#3 http://www.cdc.gov/nhsn/PDFs/pscManual/14_Tables_of_Instructions.pdf	Electronic clinical data; Electronic Health/Medical Record; Lab data; Paper medical record/flow-sheet; Special or unique data NHSN Primary BSI collection form NHSN Denominator for ICU form NHSN Denominator for NICU form http://www.cdc.gov/nhsn/forms/57.108_PrimaryBSI_BLANK.pdf, http://www.cdc.gov/nhsn/forms/57.118_DenominatorICU_BLANK.pdf, http://www.cdc.gov/nhsn/forms/57.116_DenominatorNICU_BLANK.pdf Attachment Data Dictionary-634076366986069304.docx
Level	Facility/Agency; Population: national; Population: regional/network; Can be measured at all levels	Population: states; Facility/Agency; Population: national
Setting	Dialysis Facility	Hospital; Long term acute care hospital; Rehabilitation Facility
Numerator Statement	The number of new positive blood culture events based on blood cultures drawn as an outpatient or within 1 calendar day after a hospital admission. A positive blood culture is considered a new event and counted only if it occurred 21 days or more after a previous positive blood culture in the same patient.	Total number of observed healthcare-associated CLABSI among patients in ICUs and NICUs
Numerator Details	Time Window: Cases are included if the positive blood culture occurs during a month that the outpatient unit is performing surveillance Information required: Number of positive blood culture	Time Window: 1. Definition of healthcare-associated Infection (HAI): Any infection reported to NHSN must meet the definition of an NHSN healthcare-associated infection, that is, a localized or systemic

	1460 National Healthcare Safety Network (NHSN) bloodstream infection measure	PSM-001-10 National Healthcare Safety Network (NHSN) central line-associated bloodstream infection (CLABSI) outcome measure
	events and event date Definition: A new positive blood culture (not less than 21 days after a previous positive blood culture in the same patient) in a hemodialysis patient identified from blood cultures taken as an outpatient or within 1 calendar day after a hospital admission. Data specifications: Events are counted if the following field: "patient with a positive blood culture" (on Form 57.109 under Event Details) is checked as being present.	condition resulting from an adverse reaction to the presence of an infectious agent(s) or its toxin(s). There must be no evidence that the infection was present or incubating at the time of admission to the care setting. Clinical evidence may be derived from direct observation of the infection site or review of information in the patient chart or other clinical records. For certain, but not all, infection sites, a physician's or surgeon's diagnosis of infection derived from direct observation during a surgical operation, endoscopic examination, or other diagnostic studies or from clinical judgment may be an acceptable criterion for an NHSN infection, unless there is compelling evidence to the contrary. 2. Definition of CLABSI: Primary bloodstream infections (BSI) are laboratory-confirmed bloodstream infections (LCBI) that are not secondary to an infection meeting CDC/NHSN criteria at another body site (see criteria in Chapter 17 CDC/NHSN Surveillance Definition. Report BSIs that are central line-associated (i.e., a central line or umbilical catheter was in place at the time of, or within 48 hours before, onset of the event). 3. Definition of Central line: An intravascular catheter that terminates at or close to the heart or in one of the great vessels which is used for infusion, withdrawal of blood, or hemodynamic monitoring. The following are considered great vessels for the purpose of reporting central-line BSI and counting central-line days in the NHSN system: Aorta, pulmonary artery, superior vena cava, inferior vena cava, brachiocephalic veins, internal jugular veins, subclavian veins, external iliac veins, common femoral veins, and in neonates, the umbilical artery/vein. NOTE: Neither the insertion site nor the type of device may be used to determine if a line qualifies as a central line. The device must terminate in one of these vessels or in or near the heart to qualify as a central line. 4. Infusion: The introduction of a solution through a blood vessel via a catheter lumen. This may include continuous infusions such as nutritional fluids or medications, or it may include intermittent infusions such as flushes or IV antimicrobial administration, or blood, in the case of transfusion or hemodialysis. 5. Umbilical catheter: A central vascular device inserted through the umbilical artery or vein in a neonate. 6. Temporary central line: A non-tunneled catheter. 7. Permanent central line: Includes o Tunneled catheters, including certain dialysis catheters o Implanted catheters (including ports) 8. CLABSI Criteria: • Laboratory-confirmed bloodstream infection (LCBI): Must meet one for the following criteria: Criterion 1: Patient has a recognized pathogen cultured from one or more blood cultures and organism cultured from blood is not related to an infection at another site. Criterion 2: Patient has at least one of the following signs or symptoms: fever (greater than 38oC), chills, or hypotension and

	1460 National Healthcare Safety Network (NHSN) bloodstream infection measure	PSM-001-10 National Healthcare Safety Network (NHSN) central line-associated bloodstream infection (CLABSI) outcome measure
		signs and symptoms and positive laboratory results are not related to an infection at another site and common skin contaminant (i.e., diphtheroids [Corynebacterium spp.], Bacillus [not B. anthracis] spp., Propionibacterium spp., coagulase-negative staphylococci [including S. epidermidis], viridans group streptococci, Aerococcus spp., Micrococcus spp.) is cultured from two or more blood cultures drawn on separate occasions. Criterion 3: Patient less than 1 year of age has at least one of the following signs or symptoms: fever (greater than 38oC core) hypothermia (less than36oC core), apnea, or bradycardia and signs and symptoms and positive laboratory results are not related to an infection at another site and common skin contaminant (i.e., diphtheroids [Corynebacterium spp.], Bacillus [not B. anthracis] spp., Propionibacterium spp., coagulase-negative staphylococci [including S. epidermidis], viridans group streptococci, Aerococcus spp., Micrococcus spp.) is cultured from two or more blood cultures drawn on separate occasions. 9. CDC Location: A CDC-defined designation given to a patient care area housing patients who have similar disease conditions or who are receiving care for similar medical or surgical specialties. Each facility location that is monitored is "mapped" to one CDC Location. The specific CDC Location code is determined by the type of patients cared for in that area according to the 80% Rule. That is, if 80% of patients are of a certain type (e.g., pediatric patients with orthopedic problems) then that area is designated as that type of location (in this case, an Inpatient Pediatric Orthopedic Ward). 10. Location: The patient care area to which a patient is assigned while receiving care in the healthcare facility. 11. Location of attribution: The location to which the event is being attributed. 12. Date of event: In the case of an infection event, the date when the first signs or symptoms of infection (clinical evidence) appeared, or the date the specimen used to meet the infection criterion was collected, whichever came first. 13. Facility-specific data for individual patient locations (i.e., bedsize of location, affiliation and level of affiliation with a medical school [Teaching statuses: major, graduate, limited, not affiliated - • Major: A hospital that is an important part of the teaching program of a medical school and the majority of medical students rotate through multiple clinical services. • Graduate: Hospital is used by the medical school for graduate trainings only (residency and/or fellowships). • Limited: Hospital is used in the medical school's teaching program to only a limited extent.
Denominator Statement	Number of maintenance hemodialysis patients treated in the outpatient hemodialysis unit on the first 2 working days of the month	Total number of expected CLABSIs, calculated by multiplying the number of central line device days for each location under surveillance for CLABSI during the period by the CLABSI rate for the same types of locations obtained from the standard population. Central line device- day denominator data that are

	1460 National Healthcare Safety Network (NHSN) bloodstream infection measure	PSM-001-10 National Healthcare Safety Network (NHSN) central line-associated bloodstream infection (CLABSI) outcome measure
		collected differ according to the location of the patients being monitored. See 2a.8.
Denom Categories	Female; Male All ages	Female; Male Patients of all ages are included, from premature infant to adult.
Denominator Details	Time Window: First 2 working days of each month Target population is all maintenance hemodialysis patients treated on the first 2 working days of a particular month in an outpatient hemodialysis center. Data specification: The numeric value entered into the field labeled "Total patients" (on Form 57.119) is used as the denominator.	Time Window: The number of central line device days for the location under surveillance for CLABSI during the period is collected. This number is multiplied by the 2006 through 2008 standard population's CLABSI rate for the same type of location to obtain the number of expected CLABSIs. The expected number of CLABSIs is the sum across all location types during the period. The expected number of CLABSIs will be influenced by the number of central line device days in the facility and the CLABSI rate in the standard population; with low numbers of expected infections, it will be necessary to have a data sample of sufficient size to generate meaningful SIRs. Data required to calculate the denominator: 1. Number of appropriate device days for locations under CLABSI surveillance during the period 2. CLABSI rate per 1000 device days for the same location types from the identified population (2006 through 2008; see NHSN Report at http://www.cdc.gov/nhsn/PDFs/dataStat/2009NHSNReport.PDF) . 3. Definition of device days: Device days are used for denominators. Device day denominator data that are collected differ according to the location of the patients being monitored. a. For ICUs, the number of patients with one or more central lines of any type is collected daily, at the same time each day during the month. The totals for the month are entered. b. In NICUs, because of differing infection risks, the number of patients with central lines and those with umbilical catheters is collected daily, at the same time each day, during the month. If a patient had both an umbilical catheter and a central line, count the day only as an umbilical catheter day. For the NICU infants, patients are further stratified by birth weight in five categories since risk of BSI also varies by birthweight. 4. See 2a.3 for definitions of CDC location, location, and location of attribution. 5. Facility-specific data for individual patient locations (i.e., bedsize of location, affiliation and level of affiliation with a medical school [Teaching statuses: major, graduate, limited, not affiliated - a. Major: A hospital that is an important part of the teaching program of a medical school and the majority of medical students rotate through multiple clinical services. b. Graduate: Hospital is used by the medical school for graduate trainings only (residency and/or fellowships). c. Limited: Hospital is used in the medical school's teaching program to only a limited extent.

	1460 National Healthcare Safety Network (NHSN) bloodstream infection measure	PSM-001-10 National Healthcare Safety Network (NHSN) central line-associated bloodstream infection (CLABSI) outcome measure
Exclusions	Patients receiving inpatient hemodialysis are excluded	1. Pacemaker wires and other nonlumened devices inserted into central blood vessels or the heart are excluded as central lines 2. Peripheral intravenous lines are excluded from this measure
Exclusion Details	The exclusion is only relevant for facilities that provide both outpatient (maintenance) and inpatient (acute or maintenance) hemodialysis. Patients who receive inpatient hemodialysis in the same facility are excluded.	See 2a.9
Risk Adjustment	Other Simple Stratification Both the numerator and denominator are stratified by vascular access type since vascular access type is the single greatest risk factor for bloodstream infection in this population. The vascular access variables that are collected and included in this analysis are: arteriovenous (AV) fistula, AV graft, permanent central line, and temporary central line. If more than one access type is present in a patient, the bloodstream infection event is attributed to the access type with the greatest risk (i.e., AV fistula less than AV graft less than permanent central line less than temporary central line). During denominator collection (see URL below), the user is asked to count each patient as having only 1 vascular access type, following the algorithm described. During numerator collection, all vascular access types present at the time of the bloodstream infection event are reported and the algorithm is applied during analysis of the data. http://www.cdc.gov/nhsn/forms/57.119_DenomOutpatDialysis_BLANK.pdf	CLABSI rates per 1000 central line device days are used to calculate the expected number of CLABSI for the denominator of the SIR. They are indirectly standardized rates accounting for the influence of length of stay and length of central line use, and are stratified by patient care location, adjusting for differences in patient morbidity and disease-specific variables which may influence CLABSI risk. See also 2a.4 and 2a.20. URL No such URL. Please see 2a.21.
Stratification	Both the numerator and denominator are stratified by patient vascular access type, where permanent central lines are defined as tunneled central lines (or tunneled central venous catheters) and temporary central lines are defined as nontunneled central lines (or nontunneled central venous catheters). Details of stratified measures: 1. BSI rate in CVC (central venous catheter) patients = the numerator and denominator below times 100 1a. NUMERATOR. Events are included in the numerator if the "patient with positive blood culture" field on Form 57.109 is checked AND any of the following fields on Form 57.109 under 'Vascular accesses' are checked as being present: "Permanent central line", "Temporary central line", or "Port access device". 1b. DENOMINATOR. The denominator equals the sum of the numeric values entered for the following fields on Form 57.119: "Permanent central line", "Temporary central line", and ""Port access device". 2. BSI rate in AVG (arteriovenous graft) patients = the	1. Facility-specific data for individual patient locations (i.e., bedsize of location, affiliation and level of affiliation with a medical school [Teaching statuses: major, graduate, limited, not affiliated - • Major: A hospital that is an important part of the teaching program of a medical school and the majority of medical students rotate through multiple clinical services. • Graduate: Hospital is used by the medical school for graduate trainings only (residency and/or fellowships). • Limited: Hospital is used in the medical school's teaching program to only a limited extent. 2. NICU location catheters are stratified by two types, central and umbilical lines. Numerator and denominator information is further stratified by five birthweight categories.

	1460 National Healthcare Safety Network (NHSN) bloodstream infection measure	PSM-001-10 National Healthcare Safety Network (NHSN) central line-associated bloodstream infection (CLABSI) outcome measure
	numerator and denominator below times 100 2a. NUMERATOR. Events are included in the numerator if the "patient with positive blood culture" field on Form 57.109 is checked AND if the field labeled "Graft" on Form 57.109 under 'Vascular accesses' is checked as being present AND none of the following fields on the same form are checked as being present: "Permanent central line", "Temporary central line", or "Port access device". 2b. DENOMINATOR. The denominator equals the numeric value entered for the field labeled, "Graft" on Form 57.119. 3. BSI rate in AVF (arteriovenous fistula) patients = the numerator and denominator below times 100 3a. NUMERATOR. Events are included in the numerator if the "patient with positive blood culture" field on Form 57.109 is checked AND if the field labeled "Fistula" on Form 57.109 under 'Vascular accesses' is checked as being present AND none of the following fields on the same form are checked as being present: "Graft", "Permanent central line", "Temporary central line", or "Port access device". 3b. DENOMINATOR. The denominator equals the numeric value entered for the field labeled, "Fistula" on Form 57.119.	
Type Score	Rate/proportion better quality = lower score	Ratio
Algorithm	1. Determine the number of bloodstream infection events in the unit for the month under surveillance (X) 2. Determine the outpatient hemodialysis facility patient census (i.e., denominator) for the month under surveillance (Y) 3. Divide X by Y and multiply this by 100 to determine the rate of bloodstream infections per 100 patient-months. Pooled mean rates are calculated by pooling the numerator over time (e.g., for an entire year or over multiple hemodialysis units) and dividing by the corresponding pooled denominator.	The SIR is calculated as follows: 1. Identify the number of CLABSI in each location type 2. Total these numbers for an observed number of CLABSIs 3. Obtain the number of expected number of CLABSIs in the same location types for a standard population using the NHSN data report (http://www.cdc.gov/nhsn/PDFs/dataStat/2009NHSNReport.PDF) 4. Identify the number of expected CLABSIs for the facility based on its location types and numbers of central line device days: a. For each location type, multiply the number of central line device days experienced, by the expected CLABSI rate for that location b. Sum the number of expected CLABSIs from all locations 5. Divide the total number of observed CLABSI events ("2" above) by the "expected" number of CLABSI rates ("4.c." above). 6. Result = SIR (The NHSN analysis tool will perform the calculations once the patient infection data and denominator information are entered into the system.)

NEXT STEPS

The Committee's final evaluations, votes, and recommendations will be presented for NQF Member and public comment. The Steering Committee will review all comments received to determine if any modifications to its recommendations are called for.