Clinical and Data Technical Expert Panel Meetings Synthesis Report

Submitted to CMS on July 30, 2010

Prepared by Arbor Research Collaborative for Health and University of Michigan Kidney Epidemiology and Cost Center

Executive Summary

The Centers for Medicare & Medicaid Services (CMS) has contracted with Arbor Research Collaborative For Health (Arbor Research) and University of Michigan Kidney Epidemiology and Cost Center (UM-KECC) to develop Quality Measures (QMs) for ESRD for the following six measure areas:

- Anemia Management/Iron Targets (Target value for Serum Ferritin, Target value for Transferrin Saturation)
- Mineral and Bone Disorder (formerly Mineral Metabolism)
- Hemodialysis Vascular Access Related Infections (formerly Dialysis Access Related Infections)
- Pediatric Hemodialysis Adequacy
- Pediatric Anemia (Anemia Management)
- Fluid Weight Management

The purpose of the project is to develop measurements that can be used to provide quality care to Medicare beneficiaries. As a part of the QM development process, Technical Expert Panels (TEPs) were formed.

TEP Objectives

In March 2010, six Clinical Technical Expert Panels (C-TEPs) were convened in a two-day meeting (on March 10 and 11, 2010) to provide expertise and input to CMS and its contractors, Arbor Research and UM-KECC, on the development and implementation of measures that will be used to assess and improve the quality of care for Americans with ESRD. The C-TEPs provided guidance in the development of new quality measures in specific clinical areas, as well as in defining target values for specific current measures. The C-TEP members considered potential measures using the framework of CMS and the National Quality Forum (NQF) which identifies four criteria: *importance, scientific acceptability, feasibility, and usability*. Follow-up conference calls with C-TEP participants were held on April 20, 2010 (Fluid Weight Management), April 27, 2010 (Fluid Weight Management) June 22, 2010 (Hemodialysis Vascular Access-Related Infections and Fluid Weight Management), June 17, 2010 (Pediatric Hemodialysis Adequacy and Pediatric Anemia), and July 7, 2010 (Fluid Weight Management). Anemia Management and Mineral and Bone Disorder had no follow-up conference calls for the C-TEPs.

On April 26 and 27, 2010, a Data Technical Expert Panel (D-TEP) was convened to review the measures recommended by the C-TEPs with respect to the feasibility of collecting the data necessary for calculating the measures and defining the specifications needed for business requirements and information technology (IT) implementation of measure collection. The D-TEP reviewed data sources, data flows, timeliness of data collection points, accuracy of data and burden of collection, and identified any practical problems of implementation. The D-TEP also reviewed other data elements of interest to CMS, such as hospitalization. Follow-up conference calls with D-TEP participants were held on June 22, 2010 (Hemodialysis Vascular Access Related Infections and Fluid Weight Management). Anemia Management, Mineral and Bone Disorder, Pediatric Hemodialysis Adequacy, and Pediatric Anemia had no follow-up conference calls for the D-TEP.

Subsequent to the D-TEP recommendations, the development process for each measure area continued as follows:

- C-TEP response to D-TEP recommendations
- D-TEP response to C-TEP response
- Final reconciliation of C-TEP and D-TEP comments

This report documents the results of the discussions and deliberations by and among the TEPs during all stages of the development process.

TEP Participants

The TEPs were comprised of individuals with the following areas of expertise and perspectives:

- Topic Knowledge: ESRD
- Performance Measurement
- Quality Improvement
- Purchaser Perspective

The C-TEPs included individuals with these additional areas of expertise and perspectives:

- Consumer Perspective
- Health Care Disparities

A list of C-TEP members can be found in Appendix B, and a list of D-TEP members can be found in Appendix C.

1 Anemia Management/Iron Targets

The current Phase III ESRD CPMs include routine measurement of serum ferritin and percent transferrin saturation (TSAT) laboratory values as indicators of iron stores for dialysis patients prescribed an erythropoiesis-stimulating agent (ESA). The Anemia Management/Iron Targets TEP was tasked with identifying one or more iron markers as potential quality measures for which a consensus target level can be proposed. The TEP conducted a careful review of published clinical evidence and existing clinical guidelines, and concluded that the evidence did not support establishing a measure based solely on target levels of serum ferritin and/or TSAT that was applicable to all dialysis patients. However, the TEP did identify serum ferritin and TSAT levels at which intravenous iron administration is either indicated or not indicated. Therefore, the proposed CPMs recommended by the TEP address adherence to IV iron dosing in response to specific indications, rather than setting target levels that all patients are expected to attain. The proposed measures promote judicious IV iron dosing practices, yet leave individual treatment decisions for most patients to the judgment of the practitioner.

After review of the evidence and the current clinical practice guidelines, the Anemia Management/Iron Targets TEP recommended the following CPMs for assessing the quality of anemia management care provided to US dialysis patients:

Summary of Quality Measures Recommended for Anemia Management/Iron Targets

Description	Numerator	Denominator	Exclusions
Percentage of all adult (>= 18 years old) dialysis patients for whom serum ferritin and TSAT are measured simultaneously at least once during the three-month study period	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	All adult (>=18 years old) hemodialysis or peritoneal dialysis patients in the facility for the entire three-month study period	None

Description	Numerator	Denominator	Exclusions
Percentage of all adult (>= 18 years old) dialysis patients with a serum ferritin < 100ng/mL and a TSAT < 50% on at least one simultaneous measurement who received IV iron in the following three months	Number of patients in the denominator who received IV iron within three months following the first occurrence of serum ferritin <100 ng/mL and TSAT <50% during the study period	All adult (>=18 years) hemodialysis and peritoneal dialysis patients in the facility for the entire three-month reporting period who had serum ferritin <100 ng/mL and TSAT <50% on at least one simultaneous measurement reported during the three-month study period. Simultaneous measurements are those reported with the same collection date	1. Patients with mean hemoglobin > 12 who did not receive an ESA during the 3 month study period. The last recorded hemoglobin 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
Percentage of all adult (>= 18 years old) dialysis patients with a serum ferritin >= 1200 ng/mL or a TSAT >= 50% on at least one simultaneous measurement during the three-month study period who did not receive IV iron in the following three months	Number of patients in the denominator who did not receive IV iron within three months following the first occurrence of serum ferritin >= 1200 ng/mL or TSAT >=50% during the study period	All adult (>=18 years) hemodialysis and peritoneal dialysis patients in the facility for the entire three-month reporting period who had serum ferritin >=1200 ng/mL or TSAT >=50% on at least one simultaneous measurement reported during the three-month study period. Simultaneous measurements are those reported with the same collection date	

Background

The 1972 Amendments to the Social Security Act extended Medicare coverage to persons with ESRD who require dialysis or a kidney transplant to sustain life. In order to improve care for ESRD patients, the National Kidney Foundation–Dialysis Outcomes Quality Initiative (NKF – DOQI) Clinical Practice Guidelines established a set of recommendations for high-quality dialysis care. The guidelines were released in the fall of 1997, addressing practices of HD adequacy, PD adequacy, anemia management, and vascular access. In 1999 the NKF-DOQI process was renamed Kidney Diseases Outcomes Quality Initiative (KDOQI), and in 2001, the first updated clinical practice guidelines were published.

In order to improve the quality of ESRD care in the US, the Center for Medicare & Medicaid Services (CMS) initiated the ESRD Core Indicators Project in 1994, and began collecting clinical data on ESRD patients. In 1999, CMS merged the ESRD Core Indicators Project into the ESRD Clinical Performance Measures (CPMs) initiative in response to section 4558(b) of the Balanced Budget Act of 1997, and used the NKF DOQI clinical practice guidelines as a guide for development of new CPMs. This effort resulted in the creation of sixteen ESRD CPMs, including measures for HD adequacy, PD adequacy, anemia management, and vascular access management. Attainment of these CPMs for patients on dialysis has been measured each year since 1999 based upon data collected from a nationally representative random sample of US dialysis patients, stratified by ESRD network region.

The KDOQI anemia guidelines were updated in 2006 and revised further in 2007. In September 2006, multiple TEPs were convened to support Arbor Research/UM-KECC's work, with the goal of reviewing and updating existing CPMs. The Anemia Management TEP was tasked with reviewing the performance of the existing CPMs and relationship of these CPMs to the revised KDOQI guidelines. Based on the TEP recommendations, the four anemia management CPMs were revised to reflect the published evidence. Three of these CPMs address iron targets and iron therapy. Of these three, one CPM (Anemia Management CPM IIa: Assessment of Iron Stores) was a process measure that was endorsed by NQF, and is in use as one of the current Phase III ESRD CPMs. The current KDOQI Guidelines, as well as the current CPMs are described below.

Clinical Practice Guidelines

Relevant recommendations related to iron measures and iron dosing from the KDOQI Anemia Guidelines (2006) [1] are as follows:

#	Topic	Recommendation (Work Group opinion):
3.2.1	Frequency of iron status tests	Iron status tests should be performed: • Every month during initial ESA treatment • At least every 3 months during stable ESA treatment or in patients with HD-CKD not treated with an ESA
3.2.2	Interpretation of iron status tests	Results of iron status tests, Hb, and ESA dose should be interpreted together to guide iron therapy

3.2.3	Targets of iron therapy	Sufficient iron should be administered to generally maintain the following indices of iron status during ESA treatment:
		• HD-CKD patients:
		  • Serum ferritin>200 ng/mL AND
		  • TSAT >20%, or CHr >29 pg/cell

#	Topic	Recommendation (Work Group opinion):

		• ND-CKD and PD-CKD patients:
		  • Serum ferritin>100 ng/mL AND
		  • TSAT >20%

3.2.4	Upper level of ferritin	There is insufficient evidence to recommend routine administration of IV iron if serum ferritin is greater than 500 ng/mL. When ferritin level is greater than 500 ng/mL, decisions regarding IV iron administration should weigh ESA responsiveness, Hb and TSAT level, and the patient's clinical status.

3.2.5	Route of administration	• HD-CKD patients:
		  • The preferred route of administration is IV (STRONG RECOMMENDATION).
		• ND-CKD and PD-CKD patients:
		  • The route of iron administration can be either IV or oral.

3.2.6	Hypersensitivity reactions	Resuscitative medication and personnel trained to evaluate and resuscitate anaphylaxis should be available whenever a dose of iron dextran is administered.

Current CMS Quality Measures

- *CPM IIa: Assessment of iron stores (endorsed by NQF, Phase III ESRD CPM)*

  Percentage of all adult (>=18 years old) hemodialysis or peritoneal dialysis patients prescribed an ESA at any time during the reporting period or who have a Hemoglobin <11.0 g/dL in at least one month of the reporting period for whom serum ferritin concentration AND either TSAT or reticulocyte Hemoglobin content (CHr) are measured at least once in a three-month period for in-center hemodialysis patients, and at least twice during a six-month period for peritoneal dialysis patients and home hemodialysis patients.

- *CPM IIb: Maintenance of iron stores (not endorsed by NQF, in use as CROWNWeb CPM)*

  Percentage of all adult HD and PD patients prescribed an ESA at any time during the study period or who have a recorded hemoglobin < 11.0 g/dL in at least one month of the study period for whom at least one serum ferritin concentration >= 200 ng/mL for HD patients or >=100 ng/mL for PD patients and either one transferrin saturation >= 20% or one reticulocyte hemoglobin content (CHr) >= 29pg,

during a three-month study period for in-center HD patients and a six-month study period for home HD and PD patients.

- *CPM III: Administration of supplemental iron (not endorsed by NQF, in use as CROWNWeb CPM)*

  Percentage of all adult HD and PD patients prescribed an ESA at any time during the study period or who have a recorded hemoglobin < 11.0 g/dL in at least one month of the study period with at least one of the following during any month of the study period: TSAT < 20%, reticulocyte hemoglobin content (CHr) < 29pg, or serum ferritin concentration < 200 ng/mL for HD patients or <100 ng/mL for PD patients, who are prescribed IV iron at any time during a three-month study period for in-center HD patients or a six-month study period for home-HD or PD patients. Excluded from the denominator are those who have not been prescribed intravenous iron for any month and with iron saturation percentage >50% or serum ferritin > 500 ng/mL.

NQF Comments

The following comments are from the NQF Revised Voting draft of National Voluntary Consensus Standards for ESRD Care, 2007 [2]:

> Three measures related to iron management were submitted–a process measure for testing, an outcome measure for maintenance of iron stores, and a process measure for prescribing intravenous iron therapy. Only the process measure for testing was recommended for inclusion in the set of consensus standards on the condition that home hemodialysis patients also are included. The other two measures were not recommended by the workgroup because of the lack of consensus on the specified achieved values and safety concerns and lack of exclusions related to IV iron therapy. The workgroup members discussed that the guideline targets were opinion based with acknowledged "serious limitations to the evidence" and did not feel the evidence was sufficient to put the guideline targets into performance measures. A workgroup member noted that the primary goal/outcome of iron therapy is to lower the ESA dose and has not been tied to specific patient outcomes.

Recent Clinical Studies

Recent clinical trials provide evidence that targeting higher hemoglobin (Hgb) levels when treating anemia in patients with CKD may increase the risk of adverse outcomes. The Trial to Reduce Cardiovascular Endpoints with Aranesp Therapy (TREAT) study found higher rates of stroke, thromboembolism, and cancer-related deaths in patients with CKD and diabetes who were treated to the higher Hgb target. The Correction of Hemoglobin and Outcomes in Renal Insufficiency (CHOIR) study [4] (CKD patients) and the Normal Hematocrit study [5] (dialysis patients at high cardiovascular risk) both found higher rates of death and cardiovascular complications among patients treated to higher Hgb targets. Two meta-analyses, which included both dialysis and non-dialysis CKD studies, also supported these findings [6,1].

Although the cause of higher event rates among patients randomized to higher Hgb targets remains incompletely understood, higher ESA doses have been implicated as a possible explanation, and recent opinion in the nephrology community has coalesced around strategies to limit ESA dose when possible. To this end, alternate methods to facilitate ESA-mediated erythropoesis, and support Hgb levels with lower ESA doses, are increasingly recommended, and the judicious use of IV iron therapy remains central to this strategy [7,8,9].

At the same time, the TEP recognizes evidence limitations with respect to long-term safety of IV iron therapy, and for this reason the proposed CPMs leave most treatment decisions about IV iron dosing to the judgment of the practitioner. For example, no judgment is made about IV iron dosing to patients with ferritin in the 100 to 1200 ng/mL range or TSAT <50%.

1.1 Assessment of Iron Stores

Description	Numerator	Denominator	Exclusions
Percentage of all adult (>= 18 years old) dialysis patients for whom serum ferritin and TSAT are measured simultaneously at least once during the three-month study period	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	All adult (>=18 years old) hemodialysis or peritoneal dialysis patients in the facility for the entire three-month study period	None

Rationale

This proposed process measure is designed to assure that all patients undergo testing for iron status at least once in a three-month period and that testing for serum ferritin and TSAT are done on the same day. The measure assesses whether iron testing is obtained in a manner that is consistent with the 2006 KDOQI recommendations, specifically that testing should occur at least every three-months, that testing should occur in most (or all) patients, and that iron status tests should be interpreted together.

Revisions to current CPM:

- The specification that serum ferritin and TSAT be measured on the same day. This requirement is based on the rationale that the clinical utility of serum ferritin and TSAT is highest when measured and interpreted together. Based on CROWNWeb test data, 99% of patients with ferritin and TSAT measured within one month had the measurements on the same day (Table A1).
- The specification to measure serum ferritin and TSAT for all patients, not just those receiving ESAs or with Hgb <11 g/dL:
    - This approach is consistent with the 2006 KDOQI recommendations. It is also consistent with the current trend in practice to limit ESA therapy when possible, as judicious use of

intravenous iron decreases ESA requirements and in some patients can support Hgb levels without the need for ESA therapy for several months or more.
    - Occasionally, patients have Hgb levels in the normal or near-normal range without requiring any long-term pharmacologic (ESA or iron) therapy. While some practitioners may not measure iron stores routinely in these patients, the prevalence of this condition is very low, estimated at 2% or less of dialysis patients [10,11].
    - Preliminary CROWNWeb data indicate that ferritin and TSAT levels are measured in ~95% of patients, and that this practice does not vary by Hgb level.
- Dropping the use of reticulocyte hemoglobin content (CHr) as an alternative to TSAT levels for assessment or iron stores:
    - Although the use of CHr was added to the 2006 CPM to harmonize with the KDOQI guidelines, the utility of measuring CHr instead of TSAT for the assessment of iron stores is uncertain [12,13].
    - Additionally, the practice of CHr measurement remains uncommon in US dialysis facilities. Based on preliminary CROWNWeb data reported for 226,210 patients in December 2009, 204,905 (91%) had TSAT values; 10,363 (4.6%) had CHr values; and only 545 (0.2%) had CHr but not TSAT values. The addition of CHr to the CPM can be considered should future data support its utility, and its measurement becomes more common.

Importance

The measure focus is important because prudent use of IV iron in dialysis patients improves management of anemia; lowers the dose of ESA needed to maintain the Hgb in the target range; avoids potential harm of excess iron administration; and encourages optimum utilization of pharmacologic and laboratory resources.

Scientific Acceptability

The proposed process measure acknowledges that the clinical utility of serum ferritin and TSAT is highest when the two tests are drawn together and interpreted together.

Usability

The proposed measures are straightforward¸ are easily interpreted by the intended audiences (e.g., consumers, purchasers, providers, policy makers). Physicians and dialysis care teams can understand the results of the measure and are likely to find them useful for decision making.

Feasibility

The required data elements, including the dates and results of the iron status analytes, are readily available in the CROWNWeb database.

Data TEP Recommendation

Study period needs to be a rolling period and not a fixed quarterly study period.

- ***Final Reconciliation of C-TEP and D-TEP Comments***

The D-TEP comments confirm the approach recommended by the C-TEP and no reconciliation is needed.

1.2 Use of Iron Therapy When Indicated

Description	Numerator	Denominator	Exclusions
Percentage of all adult (>= 18 years old) dialysis patients with a serum ferritin < 100ng/mL and a TSAT < 50% on at least one simultaneous measurement who received IV iron in the following three months	Number of patients in the denominator who received IV iron within three months following the first occurrence of serum ferritin <100 ng/mL and TSAT <50% during the study period	All adult (>=18 years) hemodialysis and peritoneal dialysis patients in the facility for the entire three-month reporting period who had serum ferritin <100 ng/mL and TSAT <50% on at least one simultaneous measurement reported during the three-month study period. Simultaneous measurements are those reported with the same collection date	1. Patients with mean hemoglobin > 12 who did not receive an ESA during the 3 month study period. The last recorded hemoglobin value of each month of the study period will be used in calculating the mean.

Rationale

The proposed measure is designed to assure that IV iron is administered to patients who are iron-depleted.

Revisions to current CPM:

- The serum ferritin level at which patients should be receiving IV iron was set at 100 ng/mL for HD and PD patients, rather than 100 ng/mL for PD patients and 200 ng/mL for HD patients (as per the KDOQI recommendations and the prior CPM). Though many providers give replacement doses of IV iron to HD patients with ferritin <200 ng/mL, the cut-point of 100 ng/mL was chosen because this is a level below which there is clear consensus about iron deficiency for all dialysis patients receiving an ESA, i.e. the need for IV iron therapy to optimize Hgb response to ESA dosing. Further, the TEP acknowledges that the long-term safety of IV iron remains incompletely known, due to limitations in the literature. To this end, IV iron dosing in the 100 to 200 ng/mL ferritin range is left to the discretion of the practitioner.
- The TSAT cut-point was increased from 20 to 50%. The TEP felt that TSAT (e.g. <20%) should not be used independently to determine if a patient is iron deficient, due to high within-subject and between-assay variability, and the influence of inflammation on lowering TSAT levels. Rather, the cut-point of 50% was chosen because iron is typically withheld above this value due to concerns

about iron overload. The TEP recognized that very few patients have both ferritin <100 ng/mL and TSAT >50%.

- The revised measure evaluates IV iron use subsequent to a laboratory determination of iron deficency, rather than at any time during the study period, to measure more accurately whether clinicians are responding to appropriately to laboratory evidence of iron deficiency.
- CHr was dropped from the measure, per the rationale given above for the first proposed measure.

Importance

The measure focus, therapeutic response to iron status tests, is important because prudent use of IV iron in dialysis patients improves management of anemia; lowers the dose of ESA needed to maintain the hemoglobin in the target range; avoids potential harm of excess iron administration; and encourages optimum utilization of pharmacologic and laboratory resources.

Scientific Acceptability

The proposed measure is supported by ample evidence that IV iron administration to patients with low serum ferritin is associated in a rise in hemoglobin, a decrease in ESA utilization, or both [14-20]. Although a ferritin < 100 ng/mL coupled with a high TSAT is unexpected, most practitioners would not administer IV iron to a patient with a TSAT >= 50%.

Usability

The proposed measure is straightforward¸ and easily interpreted by the intended audiences (e.g., consumers, purchasers, providers, policy makers). Physicians and dialysis care teams can understand the results of the measure and are likely to find them useful for decision making.

Feasibility

The required data elements, including the dates and results of the iron status analytes and whether IV iron is administered, are readily available in the CROWNWeb database.

Data TEP Recommendations

Include exclusions in denominator criteria and not as separate exclusions.

Change the new proposed data element ‘history of anaphylaxis’ to ‘is it unsafe to give the patient IV iron?’

Using the yes/no variable IV Iron Prescribed is not be a consistent way to find all patients who actually were prescribed IV iron in a month, since a patient may start and complete a repletion course of IV iron within a month, and only the last record of each month is submitted in CROWNWeb.

Resolve inconsistencies between 'received'/'administered' and 'prescribed' for Erythropoiesis Stimulating Agents (ESA) and IV iron. The D-TEP recommended the use of 'prescribed' to measure intent to treat.

The data element of total IV iron dose per month will be added in the next release of CROWNWeb. The D-TEP members agreed that using this new data element would be a more reliable indicator of whether the patient was administered IV iron in a month, but were concerned about the potential data collection burden of entering that data for non-LDO facilities without an electronic billing system (if such facilities exist). All electronic billing systems would have this information.

Three months seems to be an excessive follow-up period for evaluation of whether a provider has taken action after receiving a low iron determination. One month may be sufficient. Patient needs to be in facility for the follow-up period as well as the initial three months, and the shorter follow-up time will lose fewer patients from the denominator (four month total period vs. six month total period).

If patient has a subsequent iron determination that takes them out of the low iron range, then that patient should be counted in the numerator, even if not administered IV iron. The D-TEP also raised the possibility of a patient being administered IV iron outside of the dialysis facility (i.e. in the hospital). While the facility may not have access to that information, increased TSAT levels may be an indicator of treatment.

Suggest adding date of earliest IV iron administered in month and date of last IV iron administered in month OR adding a subject assessment (i.e. data element of 'was IV iron administered when appropriate?'). Any of these variables could be designed to only be required if a patient falls into one of the high/low iron categories to reduce data collection burden.

If a patient had a low iron determination that was not the last measurement of the month, it would not be reported since CROWNWeb only includes last record.

Study period needs to be a rolling three month period and not a fixed quarterly study period.

- ***C-TEP Response to D-TEP Recommendations***

The C-TEP did not have objections to renaming the proposed data element 'history of anaphylaxis' to 'is it unsafe to give the patient IV iron?'

The C-TEP did not object to the D-TEP recommendation to use the new data element of 'total IV iron dose per month' instead of the data element 'IV Iron Prescribed' to determine if a patient was administered IV iron in the month.

Regarding the D-TEP comment that three months seems to be an excessive follow-up period for evaluation of whether a provider has taken action after receiving a low iron determination, the C-TEP did not agree. The C-TEP felt that three months follow-up time was appropriate because iron levels move slowly. The C-TEP also did not want to create any incentives for facilities to perform iron status testing more frequently than quarterly.

Regarding the D-TEP comment about whether patients who have a subsequent iron determination that takes them out of the low iron range even if not administered IV iron should be counted in the measure numerator, the C-TEP did not agree with the D-TEP. Again, the C-TEP did not want to create incentives for increasing the frequency of lab tests. If facilities could test patients repeatedly with the hope of getting a result above the threshold, that would encourage over-utilization of lab tests.

Regarding the rolling study period, the D-TEP comments confirm the approach recommended by the C-TEP.

- ***Final Reconciliation of C-TEP and D-TEP Comments***

The C-TEP performed a careful review of the comments and recommendations made by the D-TEP. For several of the issues, the C-TEP agreed with the D-TEP and accepted those revisions to the proposed measures. However, regarding the length of the follow-up period and the selection of patients into the measure numerator, the C-TEP presented reasonable justifications for not accepting the D-TEP's recommendations. Those suggestions from the D-TEP will not be incorporated in the proposed measures.

1.3 Avoidance of Iron Therapy in Iron Overload

Description	Numerator	Denominator	Exclusions
Percentage of all adult (>= 18 years old) dialysis patients with a serum ferritin >= 1200 ng/mL or a TSAT >= 50% on at least one simultaneous measurement during the three-month study period who did not receive IV iron in the following three months	Number of patients in the denominator who did not receive IV iron within three months following the first occurrence of serum ferritin >= 1200 ng/mL or TSAT >=50% during the study period	All adult (>=18 years) hemodialysis and peritoneal dialysis patients in the facility for the entire three-month reporting period who had serum ferritin >=1200 ng/mL or TSAT >=50% on at least one simultaneous measurement reported during the three-month study period. Simultaneous measurements are those reported with the same collection date	None

Rationale

The proposed measure is designed to assure that IV iron is not administered to patients with evidence of iron overload. There was no comparable prior CPM.

Importance

The measure focus, the therapeutic response to iron status tests, is important because prudent use of IV iron in dialysis patients improves management of anemia; lowers the dose of ESA needed to maintain

the hemoglobin in the target range; avoids potential harm of excess iron administration; and encourages optimum utilization of pharmacologic and laboratory resources.

Scientific Acceptability

The proposed measure marks the limit for either ferritin or TSAT above which no IV iron should be given. The ferritin limit of 1200 ng/mL is supported by a series of observational studies which demonstrate no safety signal for patients with serum ferritin values up to that level [21-23]. The safety of ferritin >1200 ng/mL has not been evaluated.

At the same time, TEP members recognized that some practitioners may chose to not dose IV iron to patients with ferritin of 500 to 1200 ng/mL, and the measure does not evaluate IV iron dosing in this ferritin range.

Usability

The proposed measure is straightforward¸ and easily interpreted by the intended audiences (e.g., consumers, purchasers, providers, policy makers). Physicians and dialysis care teams can understand the results of the measure and are likely to find them useful for decision making.

Feasibility

The required data elements, including the dates and results of the iron status analytes and whether IV iron is administered, are readily available in the CROWNWeb database.

Data TEP Recommendations

Using the yes/no variable IV Iron Prescribed is not be a consistent way to find all patients who actually were prescribed IV iron in a month, since a patient may start and complete a repletion course of IV iron within a month, and only the last record of each month is submitted in CROWNWeb.

Resolve inconsistencies between ‘received’/’administered’ and ‘prescribed’ for ESA and IV iron. The D-TEP recommended the use of ‘prescribed’ to measure intent to treat.

The data element of total IV iron dose per month will be added in the next release of CROWNWeb. The D-TEP members agreed that using this new data element would be a more reliable indicator of whether the patient was administered IV iron in a month, but were concerned about the potential data collection burden of entering that data for non-LDO facilities without an electronic billing system (if such facilities exist). All electronic billing systems would have this information.

Three months seems to be an excessive follow-up period for evaluation of whether a provider has taken action after receiving a high ferritin or TSAT, especially if a subsequent interim lab shows improvement of these parameters. One month may be sufficient. Patient needs to be in facility for the follow-up period as well as the initial three months, and the shorter follow-up time will lose fewer patients from the denominator (four month total period vs. six month total period).

If patient has a subsequent iron determination that takes them out of the high iron range, then that patient should be counted in the numerator, as long as wasn't administered IV iron prior to the subsequent normal determination.

Suggest adding date of earliest IV iron administered in month and date of last IV iron administered in month OR adding a subject assessment (i.e. data element of 'was IV iron administered when appropriate?'). Any of these variables could be designed to only be required if a patient falls into one of the high/low iron categories to reduce data collection burden.

If a patient had a high iron determination that was not the last measurement of the month, it would not be reported since CROWNWeb only includes last record.

Study period needs to be a rolling three month period and not a fixed quarterly study period.

- ***C-TEP Response to D-TEP Recommendations***

The C-TEP did not object to the D-TEP recommendation to use the new data element of 'total IV iron dose per month' instead of the data element 'IV Iron Prescribed' to determine if a patient was administered IV iron in the month.

Regarding the D-TEP comment that three months seems to be an excessive follow-up period for evaluation of whether a provider has taken action after receiving a high iron determination, the C-TEP did not agree. The C-TEP felt that three months follow-up time was appropriate because iron levels move slowly. The C-TEP also did not want to create any incentives for facilities to perform iron status testing more frequently than quarterly.

Regarding the D-TEP comment regarding whether patients who have a subsequent iron determination that takes them out of the high iron range should be counted in the measure numerator, the C-TEP did not agree with the D-TEP. Again, the C-TEP did not want to create incentives for increasing the frequency of lab tests. If facilities could test patients repeatedly with the hope of getting a result below the threshold, that would encourage over-utilization of lab tests.

Regarding the rolling study period, the D-TEP comments confirm the approach recommended by the C-TEP.

- ***Final Reconciliation of C-TEP and D-TEP Comments***

The C-TEP performed a careful review of the comments and recommendations made by the D-TEP. For several of the issues, the C-TEP agreed with the D-TEP and accepted those revisions to the proposed measures. However, regarding the length of the follow-up period and the selection of patients into the measure numerator, the C-TEP presented reasonable justifications for not accepting the D-TEP's recommendations. Those suggestions from the D-TEP will not be incorporated in the proposed measures.

1.4 TEP General Discussion/Recommendations

The D-TEP discussed the proposed CPMs individually. However, during those discussions several issues were raised that were more widely applicable, and are described below:

- Definitions for what constitutes an in center patient needs to be standardized across all measures. When modality is an issue (in-center HD, PD, HHD) make sure that definitions and calculations clearly identify modalities included and excluded.
- Where measures are process measures (i.e., was a test done) then requiring the actual dose of drug administered or biochemical value is not required.
- The D-TEP recommends that all clinical values be accepted in CROWNWeb by removing limitations on the ranges of values accepted in the system. They felt that it would be preferable to allow all data to be submitted, and any necessary cleaning of the data could be performed in the system.
- The D-TEP also felt it would be preferable to have all data accepted into CROWNWeb, not just the last values of the month.
- For all measures with a laboratory value, the D-TEP recommends including a data element indicating the laboratory that performed the analysis, with a drop-down list of the largest 9-10 labs + other, with a facility default auto-populated. This was the recommendation to address concerns over variability of laboratory measurements, which was discussed with respect to hemoglobin, ferritin and transferrin saturation (TSAT). For certain measurements, accuracy of measurements is not well defined, and the total analytical error that is allowed is quite large. D-TEP members agreed that better standards need to be developed for these analytes, and while this is not the responsibility of the dialysis facilities, there is concern that facilities are treating patients based on these data.
- The D-TEP suggested that facilities should be able to access a list of qualifying and non-qualifying patients for each measure for use in quality improvement activities.
- The D-TEP recommended including significant digits to the hundredths for lab values (currently only to tenths) to allow for future improvements in lab precision. If that level of detail is not needed for the measures, the rounding off could occur in the system, rather than at entry.
- The D-TEP recommended excluding transient patients from all measures.
- Clarify that data element 5.3.3 is Kt/V HD ‘result’ or ‘value’.
- Rename data element 4.8.7 to remove ‘(delivered)’.
- The D-TEP recommended that pediatric measures should be made consistent with existing or proposed adult measures. Some exceptions are justified, but should be kept to a minimum.

- D-TEP members would like to see revisions to measures language prior to finalization.

1.5 References

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1.6 Appendix: CROWNWeb Test Calculations

Current CPMs

All three of the current iron targets CPMs (above) are currently being calculated in CROWNWeb. Preliminary CPM data are presented below, including data from CROWNWeb Phase II facilities, and test data from CROWNWeb batch submitting facilities.

Table A1: Anemia Management CPMs–Phase II CROWNWeb Test Data, 2009

	July	Aug.	Sept.	Oct.	Nov.	Dec.
AM CPM IIa	86.50%	91.70%	96.80%	97.20%	97.30%	97.20%
AM CPM IIb	69.90%	76.30%	81.70%	82.50%	82.40%	82.20%
AM CPM III	86.60%	88.20%	92.90%	92.60%	92.60%	92.80%

Proposed Iron Targets CPMs–Test Calculations

Using data from CROWNWeb Phase II, test calculations of the proposed CPM were performed. The study period was July–September 2009, with follow-up data through December 2009. The CROWNWeb data include approximately 3400 facilities, heavily weighted to facilities affiliated with large dialysis organizations; therefore the test calculations do not reflect a representative sample of dialysis patients.

CROWNWeb Data—Iron Targets

Table A2: Number of patients with iron targets data in each month

	July	Aug.	Sept.	July-Sept. Total	Oct.	Nov.	Dec.	Oct.-Dec. Total
Total patients	267,515	263,743	264,412	283,879	280,914	285,978	290,713	208,975
Patients with clinical data	221,261	222,634	219,337	241,733	227,774	225,204	226,210	251,991
Proposed Measure 1								
Patients with ferritin measured	159,841	130,613	129,355	226,638	169,193	131,105	133,621	235,087
Patients with TSAT measured	200,557	202,425	199,181	235,515	212,391	203,422	204,905	243,070

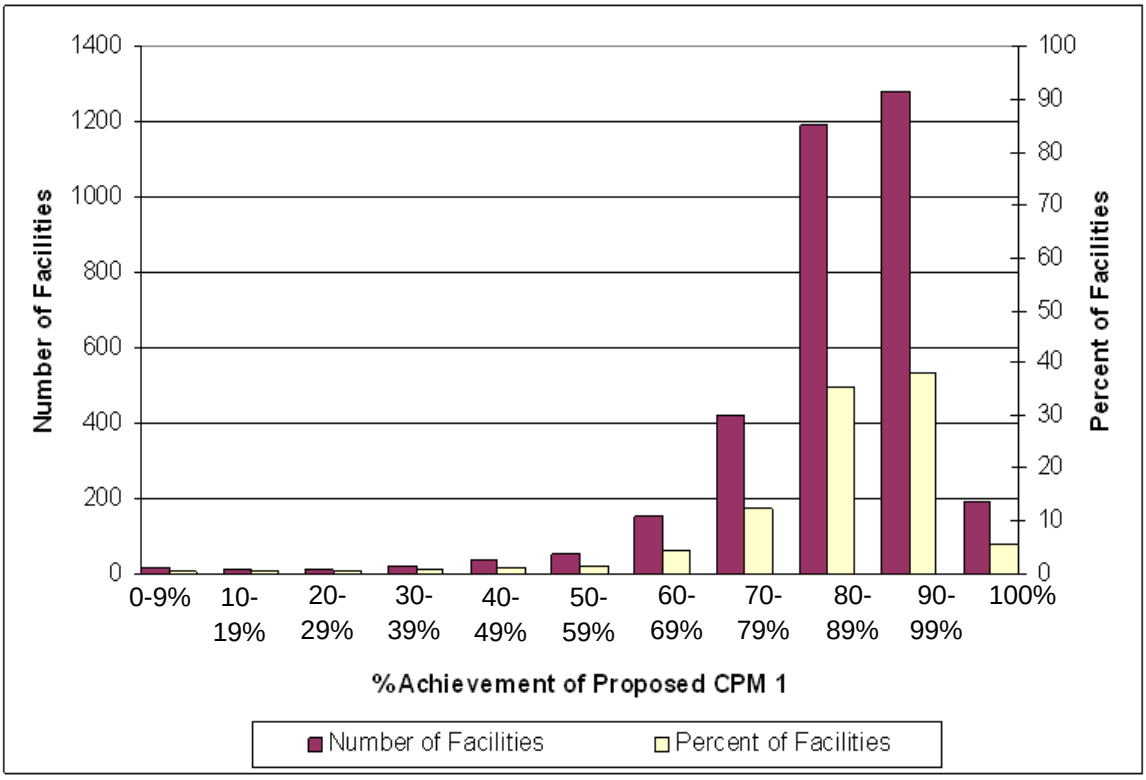
	July	**Aug.**	**Sept.**	**July-Sept. Total**	**Oct.**	**Nov.**	**Dec.**	**Oct.-Dec. Total**
Patients with Chr measured	9,616	10,578	10,592	14,289	11,304	10,019	10,363	14,537
Patients with Chr and not TSAT measured	451	799	637	1,102	568	628	545	1,026
Patients with ferritin and TSAT measured on the same day	155,502	126,104	125,081	222,115	165,012	126,568	129,084	229,876
Patients with ferritin and TSAT measured within 1 week	157,089	127,988	126,597	223,705	166,477	128,480	130,666	231,678
Patients with ferritin and TSAT measured in the month	158,446	129,549	127,923	225,256	167,910	129,883	132,334	233,450
Patients with ferritin and TSAT measured in the quarter	--	--	--	225,884	--	--	--	234,169
Proposed Measure 2								
Patients with ferritin < 100 and TSAT < 50	5633	3768	3397	10,030	4436	2763	2926	7,764
Proposed Measure 3 (*Among patients receiving an ESA with Hgb < 12)*								
Patients with ferritin >= 1200 or TSAT >= 50	12,674	10,079	9,943	34,539	13,256	9,497	10,059	34,305

Test Calculation of Proposed CPM 1

Table A3: Proposed CPM 1 – CROWNWeb Test Data, Jul-Sep 2009

Test Measure	Denominator	Numerator	CPM
Proposed CPM 1: Assessment of iron stores	213,197	200,381	94%

Figure A1: Facility Distribution of CPM 1



Test Calculation of Proposed CPM 2

Table A4: CROWNWeb Test Calculation of CPM 2, Jul-Sep 2009

Test Measure	Denominator	Numerator	CPM
Proposed CPM 2: Use of iron therapy when indicated	10,030	6,338	63%

Figure A2: Facility Distribution of Number of Patients in CPM 2 Denominator

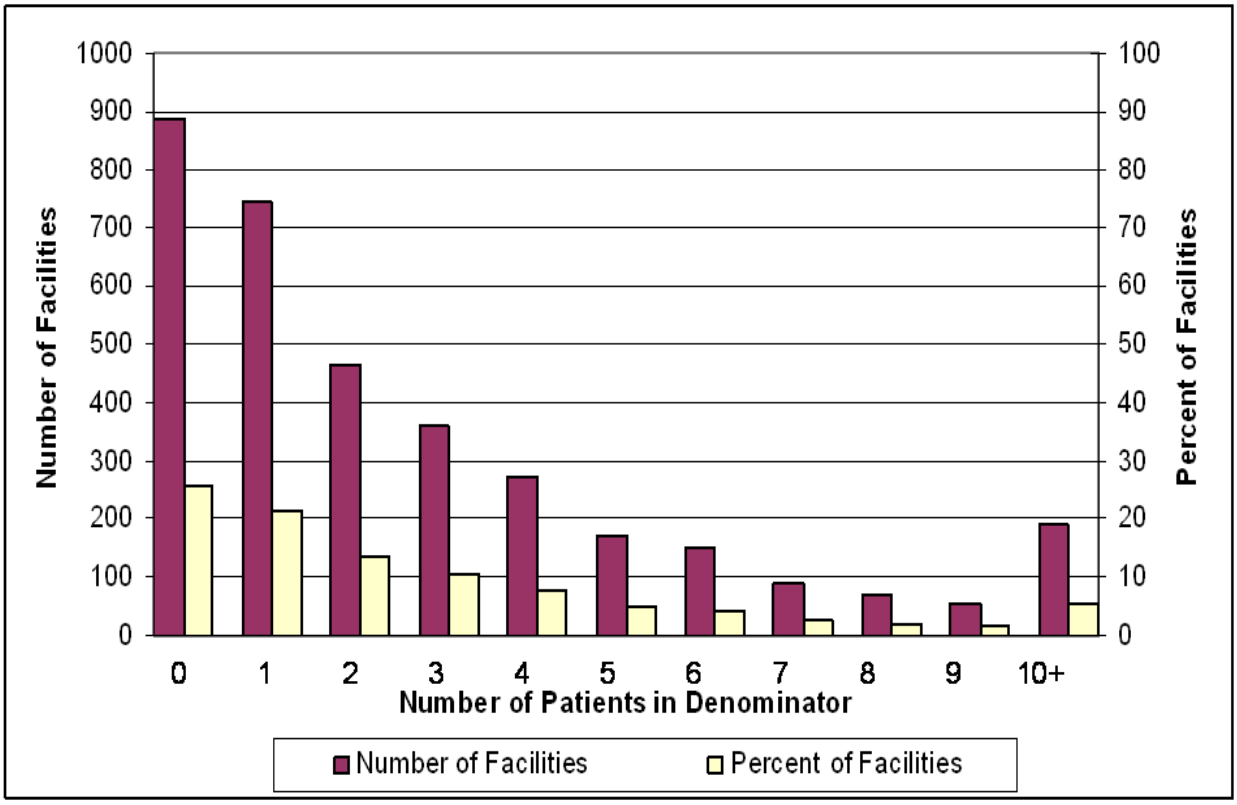
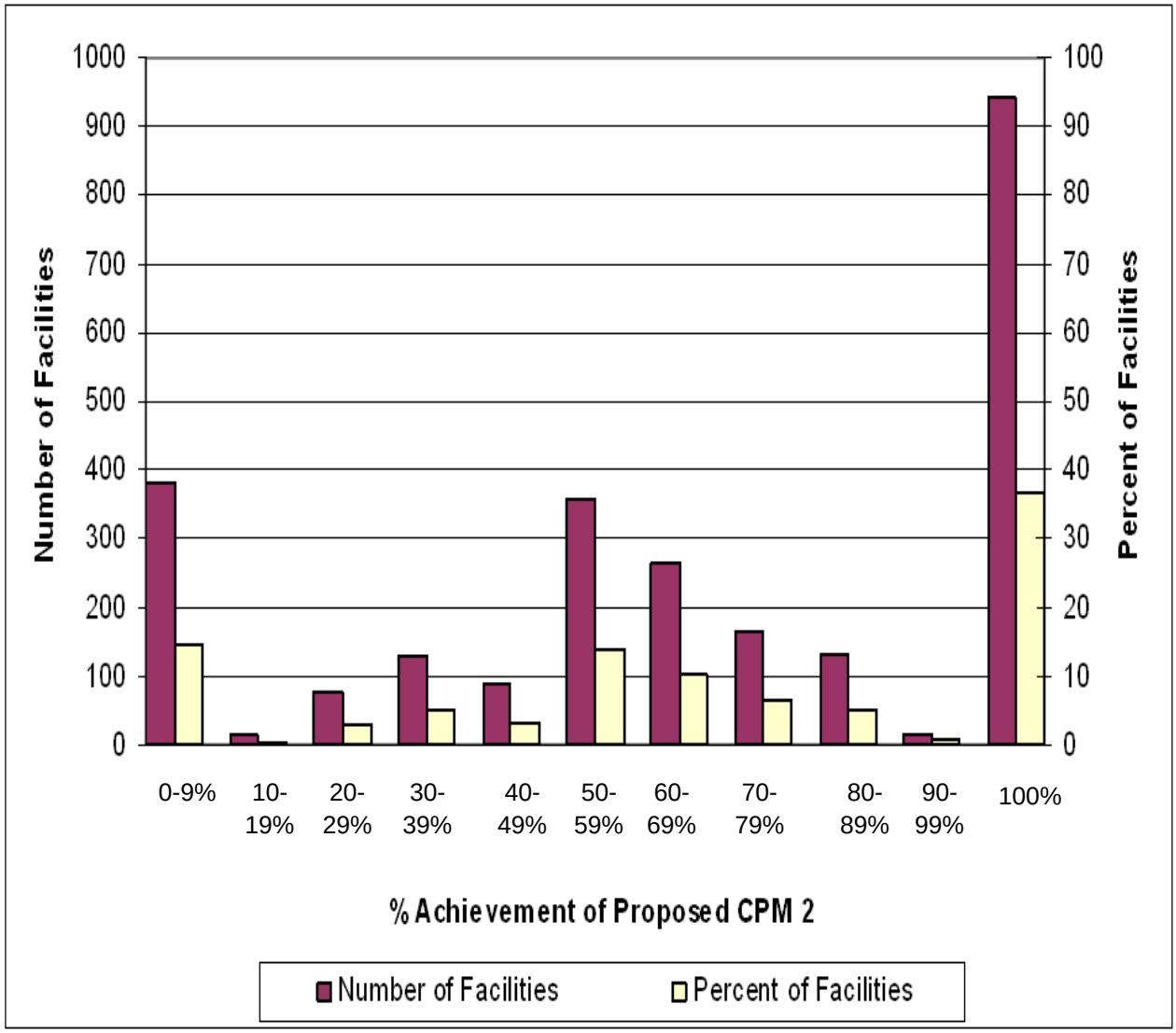


Figure A3: Facility Distribution of CPM 2



Test Calculation of Proposed CPM 3

Table A5: CROWNWeb Test Calculation of CPM, Jul-Sep 2009

Test Measure	Denominator	Numerator	CPM
Proposed CPM 3: Avoidance of iron therapy in iron overload	39,808	10,629	27%

Figure A4: Facility Distribution of Number of Patients in CPM 3 Denominator

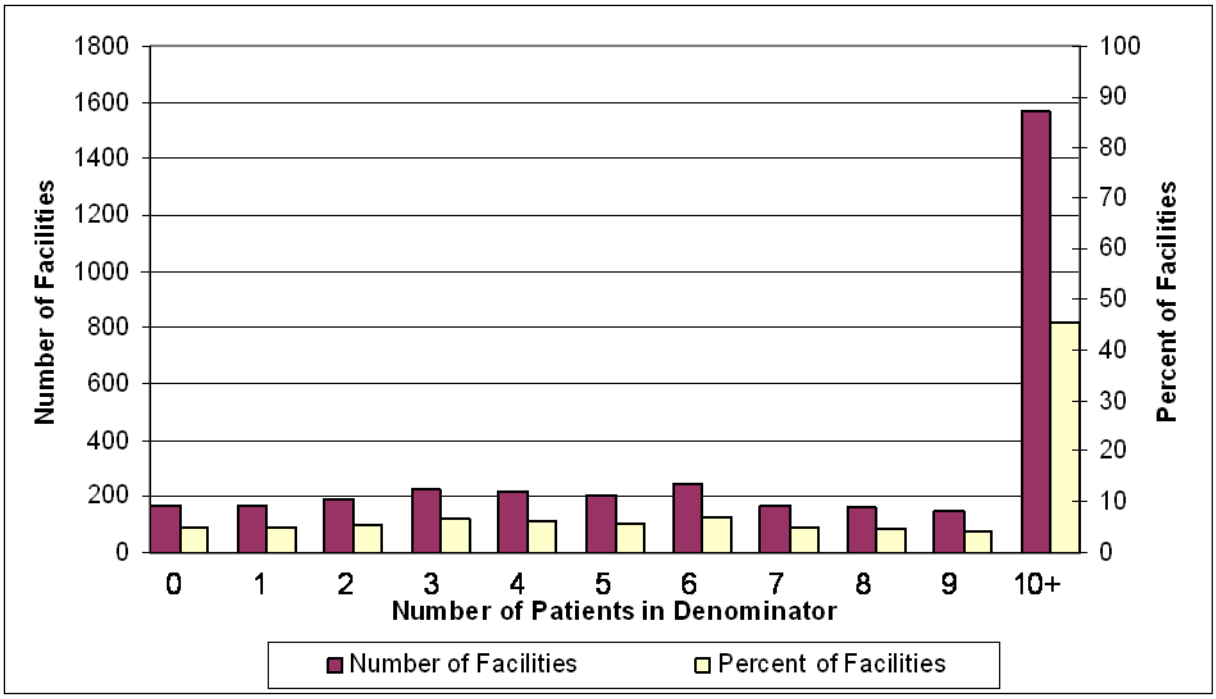
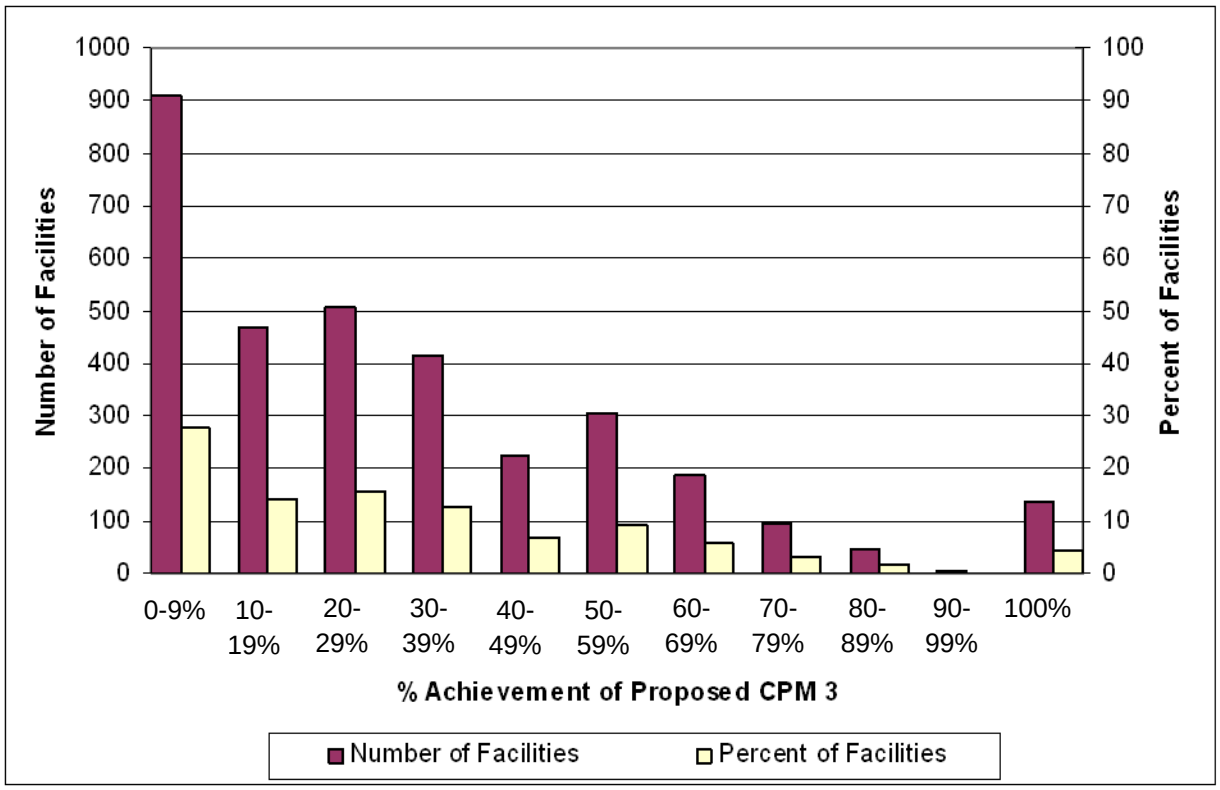


Figure A5: Facility Distribution of CPM 3



2 Mineral and Bone Disorder

The TEP was tasked to identify one or more mineral metabolism markers as potential quality measures for which a consensus target level can be proposed based on the evidence available in the published literature. In addition, the TEP was to establish whether a process measure for PTH should be adopted and, if so, propose a time interval for measurement.

The TEP deliberations yielded two Quality Measure recommendations for Mineral and Bone Disorder as summarized in the following table:

Summary of Quality Measures Recommended for Mineral and Bone Disorder

Description	Numerator	Denominator	Exclusions
Proportion of patients with 3-month rolling average of total uncorrected serum calcium greater than 10.2 mg/dL	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 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	None
Proportion of patients with 3-month rolling average of serum phosphorus less than 2.5 mg/dL	Number of patients with 3-month rolling average of serum phosphorus less than 2.5 mg/dL	Number of adult (>= 18 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	None

The TEP agreed that there is insufficient evidence at this time to support a specific lower limit for serum calcium as a quality measure. While it is clear that moderate to severe acute hypocalcemia may be associated with adverse clinical events (including cardiovascular events), observational data evaluating serum calcium levels in dialysis populations are mixed with regards to the relationship between hypocalcemia and adverse clinical outcomes. None of the observational reports to date have included large numbers of subjects receiving Cinacalcet, which may be a proximate cause of hypocalcemia.

Furthermore, there is no evidence available to determine if treatment to correct hypocalcemia is beneficial or harmful. Further details regarding these deliberations are contained in the Other Recommendations section below.

The TEP members also agreed unanimously that there is insufficient evidence at this time to support a specific upper limit for serum phosphorus as a measure of quality of care. The TEP agrees that serum phosphorus is an important biomarker strongly associated with adverse cardiovascular outcomes and that patients with hyperphosphatemia should be treated to lower their serum phosphorus. However, there is general agreement among all TEP members that the specific method employed to lower phosphorus might itself represent a risk to the patient. The TEP strongly recommends that CMS consider support of a demonstration project addressing the treatment of hyperphosphatemia.

Finally, based on the opinions of both C-TEP and D-TEP members, it was concluded that at this time, there is insufficient evidence to recommend a process quality measure for parathyroid hormone (PTH) measurement. Further details regarding these deliberations are contained in the PTH discussion section below.

Background

In 2003, the National Kidney Foundation (NKF) Kidney Disease Outcomes Quality Initiative (KDOQI) published clinical practice guidelines (CPGs) for Bone Metabolism and Disease in Patients with Chronic Kidney Disease (CKD) [1]. These guidelines for CKD Stage 5D are summarized in the following table:

Summary of KDOQI Mineral and Bone Disorder Guidelines for CKD Stage 5D

	Frequency of Measurement	Target Levels
Calcium	Every month	Normal range, preferably between 8.4 and 9.5 mg/dL
Phosphorus	Every month	Between 3.5 and 5.5 mg/dL
PTH	Every 3 months	Between 150 and 300 pg/mL

To further expand understanding of this important aspect of care, the Centers for Medicare & Medicaid Services (CMS) contracted with the Renal Network of the Upper Midwest, Inc. (Network 11) in June 2004 to develop new clinical performance measures (CPMs) for bone disease and mineral metabolism for inclusion in the CMS National ESRD CPM Data Collection Project.

CPMs Recommended by Network 11

The final report by Network 11 included recommendations for six CPMs, which included:

1. Serum phosphorus should be measured at least monthly in patients with CKD Stage 5 currently receiving renal replacement therapy with hemodialysis (HD) or peritoneal dialysis (PD).
2. Serum phosphorus concentration should be maintained between 3.5-5.5 mg/dL in patients with Stage 5 CKD currently receiving renal replacement therapy with HD or PD.
3. Serum calcium should be measured at least monthly in patients with CKD Stage 5 currently receiving renal replacement therapy with HD or PD.
4. Serum concentrations of appropriately adjusted total serum calcium should be maintained less than or equal to the upper limit of normal in patients with CKD Stage 5 currently receiving renal replacement therapy with HD or PD.
5. Serum PTH concentration should be measured at least every three months in patients with CKD Stage 5 currently receiving renal replacement therapy with HD or PD.
6. Serum intact PTH concentration should be maintained between 150-300 pg/mL in patients with CKD Stage 5 currently receiving renal replacement therapy with HD or PD.

Several among the NKF–KDOQI CPGs for bone metabolism and disease were excluded for CPM development by the TEP convened by the Network 11 workgroup, whose final report details the rationale for exclusion.

CPMs #1-4 above, related to phosphorus and calcium target concentrations and measurement frequency, were included in the ESRD CPM Data Collection Project. CPMs #5-6, related to frequency of testing and target concentrations of PTH, were not included.

In September 2006, multiple TEPs were convened to support Arbor Research/UM-KECC's work, with the goal of reviewing and updating existing CPMs. An additional TEP was convened to review and potentially revise the bone disease and mineral metabolism CPMs developed by Network 11. In addition, the Bone Disease and Mineral Metabolism TEP was tasked with review and recommendation of possible future CPMs for this area.

CPMs Recommended by 2006 TEP

The 2006 TEP reviewed and re-affirmed the prior decisions of the Network 11 TEP to exclude certain NKF-KDOQI CPGs from CPM development. In standing with the Network 11 recommendations concerning the four CPMs included in the ESRD CPM Data Collection Project, the 2006 TEP opined that recently published literature continued to support (i) at least monthly measurement of calcium and phosphorus and (ii) attainment of specified target serum concentrations as previously recommended by the Network 11 TEP (i.e., serum phosphorus should be maintained between 3.5-5.5 mg/dL; serum calcium should be maintained less than or equal to the upper limit of normal). In summary, the 2006 TEP did not recommend immediate development of any new measures, including those related to PTH.

The four CPMs which were reviewed and recommended by both the Network 11 TEP and the 2006 TEP were submitted to the National Quality Forum (NQF) for consensus endorsement. The two CPMs related

to measurement of serum phosphorus and serum calcium (CPMs #1 and 3 above) were subsequently endorsed by the NQF and adopted as Phase III ESRD CPMs in 2008. The two CPMs related to achievement of target levels for serum phosphorus and serum calcium phosphorus (CPMs #2 and 4 above) were not endorsed by the NQF but are included in CROWNWeb.

In 2009, Kidney Disease: Improving Global Outcomes (KDIGO) published the KDIGO Guideline for Chronic Kidney Disease – Mineral and Bone Disorder (CKD-MBD) [2]. These guidelines for CKD Stage 5D are summarized in the following table:

Summary of KDIGO Guidelines for CKD Stage 5D

	Frequency of Measurement	**Target Levels**
Calcium	Every 1-3 Months	Normal range
Phosphorus	Every 1-3 Months	Normal range
PTH	Every 3-6 Months	2-9 times upper limit for assay

2.1 Upper Limit for Total Uncorrected Serum Calcium

The TEP members recommended that a CPM for the upper limit of total serum calcium be calculated as the proportion of patients with 3-month rolling average of total serum calcium greater than 10.2 mg/dL. The numerator of this measure will be the number of patients with 3-month rolling average of total serum calcium greater than 10.2 mg/dL. If there are multiple serum calcium measurements within the month, the last value will be used for the calculation. The denominator of this measure will be the number of patients in an outpatient dialysis facility undergoing chronic maintenance dialysis (hemodialysis or peritoneal dialysis). The measure shall exclude the following populations: patients who are less than 18 years of age; incident patients on dialysis 90 days or less; patients having no calcium measurement during the prior 90 days; transient patients in a facility less than 30 days.

This recommendation is consistent with the value indicated by the 2006 TEP and with the recently published KDIGO guidelines [2], since 10.2 mg/dL is the considered the upper limit of the normal range in the majority of clinical laboratories.

Importance

Review of the currently available literature indicates that observational cohort studies show a consistent adverse association of hypercalcemia with cardiovascular events and all-cause mortality [3-7]. There is also clinical data demonstrating the association of increased serum calcium with vascular [8,9] and

valvular calcifications [10]. The basic science also supports a pathological role of high calcium in promoting soft tissue and vascular calcification [11-13]. Although there are no interventional studies demonstrating the benefit of correcting hypercalcemia, there was unanimous agreement among TEP members that calcium concentrations >10.2 mg/dL place the patient at increased risk of poor outcomes. Current guidelines indicate that clinical decision should be based on trends rather than single laboratory values [2]. Therefore, it was unanimously agreed to use a three-month rolling average for reporting.

Scientific Acceptability

A potential limitation of the current proposed quality measure is the recommendation to use total serum calcium. There are at least 3 possible measurements of serum calcium: ionized calcium, albumin-corrected calcium and total serum calcium. Although ionized calcium is the variable that is physiologically-regulated, current guidelines [1,2] do not recommend measuring it since reproducibility of ionized calcium measurement is worse than that of total serum calcium and because the technique is more expensive and not routinely available. In the presence of low serum albumin, the total serum calcium may be corrected for albumin. However, recent data indicate that albumin-corrected calcium offers no superiority over total calcium and is less specific than ionized calcium measurements [14]. In summary, at the present time there is no consensus as to the best technique for calcium measurement. Based on these data and the widespread availability in clinical practice, the TEP decided to base the CPM on total serum calcium, while also acknowledging that factors such as acidosis and low serum albumin levels will affect its interpretation and clinical utility.

It is likely that the percentage of patients within a facility with hypercalcemia is relatively low. However, the TEP members felt that this is a population with increased risk of cardiovascular events and needs to be identified and appropriately treated.

Hypercalcemia is usually an inadvertent complication of the management of CKD Mineral and Bone Disorder. The TEP members agree that therapy should be focused on preventing the development of a sustained serum calcium greater than 10.2 mg/dL.

Usability

Healthcare providers and patients can easily understand the meaning of a serum calcium concentration greater than 10.2 mg/dL. It is highly likely this measurement could be used for clinical decision-making.

Feasibility

The measurement of serum calcium is routinely performed and accurate, and thus makes this quality measure highly feasible.

Data TEP Recommendation

Specify in measure descriptions that no correction to Ca value is used to account for the impact of albumin level on the amount of bound calcium.

Exclusions should be included in the denominator and not as separate exclusions.

- ***C-TEP Response to D-TEP Recommendation***

The C-TEP agreed with the D-TEP recommendations. The measure definition was changed to the following:

Description: Proportion of patients with 3-month rolling average of total uncorrected serum calcium greater than 10.2 mg/dL

Numerator: Number of patients in the denominator with 3-month rolling average of total uncorrected serum calcium greater than 10.2 mg/dL

Denominator: Number of adult (>= 18 years old) hemodialysis or peritoneal dialysis patients treated at the outpatient dialysis facility for at least 30 days who are on dialysis for greater than 90 days with at least one calcium measurement during the prior 90 days

Exclusions: None

- ***D-TEP Response to C-TEP Response***

Not applicable.

- ***Final Reconciliation of C-TEP and C-TEP Comments***

The original measure developed by the C-TEP with minor edits as suggested by the D-TEP is submitted as the proposed quality measure for final endorsement.

2.2 Lower Limit for Serum Phosphorus

The TEP members recommended that a CPM for the lower limit of serum phosphorus be calculated as the proportion of patients with three-month rolling average of serum phosphorus less than 2.5 mg/dL. The numerator of this measure will be the number of patients with 3-month rolling average of serum phosphorus less than 2.5 mg/dL. If there are multiple serum phosphorus measurements within the month, the last value will be used for the calculation. The denominator of this measure will be the number of patients in an outpatient dialysis facility undergoing chronic maintenance dialysis (hemodialysis or peritoneal dialysis). The measure shall exclude the following populations: patients who are less than 18 years of age; incident patients on dialysis 90 days or less; patients having no phosphorus measurement during the prior 90 days; transient patients in a facility less than 30 days.

This recommendation is consistent with the value indicated by the recently published KDIGO guidelines [2], since 2.5 mg/dL is considered the lower limit of the normal range in the majority of clinical laboratories.

Importance

Review of the currently available literature indicates that observational studies showed a consistent adverse association of low serum phosphorus with all-cause mortality [3-5,7,15,16]. The basic science supports a pathological role of low serum phosphorus and intracellular phosphorus depletion in disturbed cellular function [17]. Although there are no interventional studies demonstrating the benefit of correcting hypophosphatemia, there was unanimous TEP agreement that phosphorus concentrations less than 2.5 mg/dL place the patient at increased risk of poor outcomes. It is recognized that a pre-dialysis serum phosphorus less than 2.5 mg/dL will result in interdialytic phosphorus levels recognized as deleterious in the general population [18]. Current guidelines indicate that clinical decision should be based on trends rather than single laboratory values [2]. Therefore, it was unanimously agreed to use a three-month rolling average for reporting.

Hypophosphatemia among patients with ESRD may be a marker of malnutrition or other morbid conditions [16,19]. Patients who are undergoing more intensive dialysis (nocturnal or daily hemodialysis) may experience hypophosphatemia as a result of the dialysis modality [20,21]. Thus, the etiology of the hypophosphatemia should be determined. In patients who are malnourished or have other morbid conditions, therapy should be directed to reverse the underlying condition. Patients undergoing more intensive dialysis may require dietary or other forms of phosphorus supplementation.

Scientific Acceptability

The percentage of patients within a facility with hypophosphatemia is low [7]. However, the TEP feels that this is a population with increased risk of cardiovascular events and needs to be identified and appropriately treated.

Usability

Healthcare providers and patients can easily understand the meaning of a serum phosphorus concentration less than 2.5 mg/dL. It is highly likely this measurement could be used for clinical decision making.

Feasibility

The measurement of serum phosphorus is routinely performed and accurate, and thus makes this quality measure highly feasible.

Data TEP Recommendations

Replace all instances of ‘phosphate’ with ‘phosphorus’.

Exclusions should be included in the denominator and not as exclusions.

- ***C-TEP Response to D-TEP Recommendations***

The C-TEP agreed with the D-TEP recommendations.

The denominator statement was changed to the following: Number of adult (>= 18 years old) hemodialysis or peritoneal dialysis patients treated at the outpatient dialysis facility for at least 30 days who are on dialysis for greater than 90 days with at least one phosphorus measurement during the prior 90 days.

- ***D-TEP Response to C-TEP Response***

Not applicable.

- ***Final Reconciliation of C-TEP and C-TEP Comments***

The original measure developed by the C-TEP with minor edits as suggested by the D-TEP is submitted as the proposed quality measure for final endorsement.

2.3 Process Measure for PTH

The C-TEP members recommend that a Process Quality Measure for serum PTH be calculated as the proportion of ESRD patients with monthly measurement of PTH. The numerator of this measure will be the number of patients with at least one measurement of PTH in the prior month. The denominator of this measure will be the number of patients in an outpatient dialysis facility undergoing chronic maintenance dialysis (hemodialysis or peritoneal dialysis). The measure shall exclude the following populations: patients who are less than 18 years of age; incident patients on dialysis 90 days or less; transient patients in a facility less than 30 days.

Importance

The TEP members recognized that very high and very low parathyroid hormone concentrations are associated with morbidity and mortality, including cardiovascular events [3-5,7,22]. The TEP also recognizes that there are substantial variations in specific PTH assay methodology which preclude identifying specific target values [23-25]. This TEP strongly recommends development of a standardized parathyroid hormone assay. This TEP also strongly recommends that CMS demand the adoption of such a standardized assay.

The consensus of this TEP is to recommend monthly parathyroid hormone measurement. The KDIGO guidelines support the evaluation of trends in parathyroid hormone over single PTH values but only recommend measuring PTH every 3 to 6 months [2]. However, currently there are no data to support any specific frequency of testing and the strength of this recommendation was not graded. The KDIGO guidelines further state, “In CKD patients receiving treatments for CKD–MBD, or in whom biochemical abnormalities are identified, it is reasonable to increase the frequency of measurements to monitor for trends and treatment efficacy and side effects.”

The TEP members felt that monthly measurement would provide practitioners the necessary information to guide therapy in a timely manner.

The TEP also recognizes that a small proportion of patients with ESRD are not receiving active therapy or have very low parathyroid hormone levels, and that monthly measurement in this population may not be required. However, the TEP feels that the logistic demands of identifying this small population are not feasible at this time. The risk of over-measurement is felt to be advantageous over under-measurement in the majority of patients. This is particularly true in light of the recommendations to follow trends in PTH rather than single values.

Scientific Acceptability

The proposed measure is well-defined and consistent with other process measures in this population.

Usability

Healthcare providers and patients can easily understand the need to assess changes in parathyroid hormone concentrations. This measurement could be used for clinical decision making.

Feasibility

Determination of PTH measurement frequency is readily available and can be easily performed, ensuring the feasibility of this process measure.

Data TEP Recommendations

Delete ‘serum’ so that either plasma or serum values may be submitted.

Change frequency from monthly to quarterly. This was recommended based on the fact that monthly testing is not the usual practice of facilities, the high cost of PTH testing, and to align with the previous two proposed Medicare Beneficiary Database (MBD) CPMs. If a percent of patients in range is calculated monthly for a test that is not performed monthly, then the patients in the denominator will change each month, potentially causing wide variation of the calculated percent of patients in range.

Remove data element of ‘Serum PTH.’

Exclusions should be included in the denominator and not as exclusions.

- ***C-TEP Response to D-TEP Recommendations***

The majority of C-TEP members felt that quarterly PTH measurement does not allow caregivers to monitor trends in PTH levels, as recommended by the KDIGO guidelines. The C-TEP recognizes that monitoring PTH for disease progression and for evaluating the response to therapy are both important. However, the frequency of these two monitoring purposes may be different and likely should be based on a patient's individual situation. The TEP recommends that CMS sets standards for the assay validity, but until more data is available we cannot set a recommended frequency measurement as a quality indicator.

- ***D-TEP Response to C-TEP Response***

Not applicable.

- ***Final Reconciliation of C-TEP and C-TEP Comments***

Due to the conflicting recommendations of the C-TEP and D-TEP regarding frequency of PTH measurement, the C-TEP concluded that no process quality measure for PTH measurement will be proposed at this time.

2.4 Other Recommendations

Rationale for Not Recommending a Target Value for Lower Limit of Serum Calcium

In the general population, serum calcium levels are tightly regulated within narrow limits of 8.5 to 10.2 mg/dL. Moderate hypocalcemia may be associated with symptoms such as paresthesias and tetany, while severe hypocalcemia may result in seizures and electrocardiographic abnormalities including QT prolongation and arrhythmias. In general, symptoms are more likely to occur as a result of acute changes in serum calcium as opposed to the more mild chronic reduction in serum calcium seen in patients with chronic kidney disease.

Dialysis patients have a high incidence of left ventricular hyperthrophy (LVH) [26] and cardiac arrhythmias [27,28]. They also may manifest mild to moderate hypocalcemia for a number of reasons, including reduced intestinal absorption as a result of vitamin D deficiency, hyperphosphatemia, calcimimetic therapy, and for other unknown reasons. The majority of these patients are asymptomatic. Severe symptomatic hypocalcemia is most commonly seen in patients with ESRD following parathyroidectomy.

While it is clear that moderate to severe acute hypocalcemia may be associated with adverse clinical events (including cardiovascular events) in the general population, observational data evaluating serum calcium levels in dialysis populations are mixed with regards to the relationship between hypocalcemia and adverse clinical outcomes. While some reports show an increased hazard in patients with the lowest serum calcium [5,7], other reports describe a survival benefit [3,4]. None of the observational reports to

date have included large numbers of subjects receiving Cinacalcet, which may be a proximate cause of hypocalcemia. Furthermore, there is no evidence available to determine if treatment to correct hypocalcemia is beneficial or harmful.

Therefore, the committee felt that all dialysis patients with hypocalcemia should be evaluated for the cause for their hypocalcemia and be managed on an individual basis. At the present time, there is insufficient evidence to support a specific level of hypocalcemia as a measure of quality of care.

Rationale for Not Recommending a Target Value for Upper Limit of Serum Phosphorus

The TEP members felt that there is not sufficient evidence to support a CPM related to a specific target phosphorus value for patients with hyperphosphatemia.

However, there was unanimous agreement among members that serum phosphorus is an important biomarker strongly associated with adverse cardiovascular outcomes [3-8, 10, 29], and that patients with hyperphosphatemia should be treated to lower their serum phosphorus.

In addition, the committee felt that the in-vitro and in-vivo animal data provide a solid foundation establishing the biologic plausibility of the adverse effects of serum phosphorus on cardiovascular outcomes [30]. Indeed, it is the general consensus of this TEP that the optimal serum phosphorus is likely to be in the normal range. Observational data consistently report an increased HR of cardiovascular events and mortality when serum phosphorus rises above this level in patients with CKD 5D [3-7].

The rationale for not providing a quality measure related to a precise target value is a result of a general agreement among all TEP members that the specific method employed to lower phosphorus might itself represent a risk to the patient. The TEP members agreed, for example, that while aluminum containing phosphate binders are remarkably effective at lowering phosphorus, their use may results in a net harm to the patient rather than a net benefit. Similar concerns were felt by all TEP members that currently available phosphate binders might similarly also be associated s with an increased risk of adverse cardiovascular outcomes (specifically, calcium containing phosphate binders were of a concern to this committee). If CMS were to implement a quality measure related to a precise target serum phosphorus value without any specific comment as to the manner in which this target is reached, the panel felt that there might be more risk than benefit.

The TEP recognizes that this is the third attempt to define quality measures related to optimal targets for phosphorus control, which is limited by the lack of interventional clinical trial data. The TEP strongly recommends that CMS consider support of a demonstration project addressing the treatment of hyperphosphatemia.

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3 Hemodialysis Vascular Access-Related Infections

The scope of the Hemodialysis Vascular Access-Related Infections (formally known as Dialysis Access Related Infections) C-TEP was limited to adult hemodialysis patient care, since it was felt that separate C-TEPs would be required to provide the necessary expertise to address access-related infections in peritoneal dialysis and pediatric patients. These additional C-TEPs are planned for the near future. Currently, no hemodialysis vascular access-related infection CPMs exist and data collected are limited. The C-TEP created a Data Ascertainment Algorithm to organize data collection of the data elements necessary for calculating seventeen proposed CPMs. The C-TEP intended for the elements on the form to be incorporated into CROWNWeb for facility-wide data collection. The C-TEP recommended that the seventeen proposed CPMs be used for: (1) quality improvement including comparisons among units; (2) assessment of change in vascular access-related infection rates over time within each dialysis unit; and (3) comparative effectiveness research. The panel emphasized that the vascular-access infection CPMs are inappropriate to use for reimbursement purposes.

In addition to the data ascertainment algorithm and the seventeen CPMs, the C-TEP created a list of proposed demonstration projects, and recommendations for clinical practice aimed at reducing catheters and reducing catheter-related bacteremia. Although there was consensus among C-TEP members that dialysis units should strive to reduce catheter use to levels as low as possible in view of the strong relationship between catheter use and mortality, unanimous C-TEP support could not be achieved for setting a target for catheter use.

Summary of Clinical Performance Measures Recommended for Hemodialysis Vascular Access-Related Infections

Description	Numerator	Denominator	Exclusions
CPM I – Presence of Suspected Infection During Reporting Month Express as: rate per 1000 HD patient days	Number of suspected infections among adult chronic hemodialysis patients during the reporting month	All adult chronic maintenance hemodialysis patient days	HD patients < 18 yrs old
CPM II – Presence of Clinically Established Infection During Reporting Month Express as: rate per 1000 HD patient days	Number of clinically established infections among adult chronic hemodialysis patients during the reporting month	All adult chronic maintenance hemodialysis patient days	HD patients < 18 yrs old

Description	Numerator	Denominator	Exclusions
CPM IIIa – Presence of Hemodialysis Vascular Access-Related Infection During Reporting Month Express as: rate per 1000 HD patient days	Number of clinically established hemodialysis vascular *access-related* infections among adult chronic hemodialysis patients during the reporting month	All adult chronic maintenance hemodialysis patient days	HD patients < 18 yrs old
CPM IIIb – Percent of Clinically Established Infections related to Hemodialysis Vascular Access During Reporting Month Express as: percentage	Number of clinically established hemodialysis vascular *access-related* infections among adult chronic hemodialysis patients during the reporting month	Number of clinically established infections during the reporting month for adult chronic maintenance hemodialysis patients	HD patients < 18 yrs old
CPM IVa – Presence of Hemodialysis Vascular *Access-Related* Bacteremia During Reporting Month Express as: rate per 1000 HD patient days	Number of clinically established hemodialysis vascular access-related infections WITH a positive blood culture among adult chronic hemodialysis patients during the reporting month	All adult chronic maintenance hemodialysis patient days	HD patients < 18 yrs old
CPM IVb – Percent of Hemodialysis Vascular *Access-Related* Infections with Bacteremia During Reporting Month Express as: percentage	Number of clinically established hemodialysis vascular *access-related* infections WITH a positive blood culture among adult chronic hemodialysis patients during the reporting month	Number of clinically established hemodialysis vascular *access-related* infections	HD patients < 18 yrs old

Description	Numerator	Denominator	Exclusions
CPM V – Six-Month Rolling Average Rate of Hemodialysis Vascular *Access-Related* Infections *Express as: rate per 1000 HD patient days*	Number of clinically established hemodialysis vascular access-*related* infections during the six-month period ending with the current reporting month.	All adult chronic maintenance hemodialysis patient days during the six-month period ending with the current reporting month	HD patients < 18 yrs old
CPM VI – Six-Month Rolling Average Rate of Hemodialysis Vascular *Access-Related* Bacteremia Express as: rate per 1000 HD patient days	Number of clinically established hemodialysis vascular *access-related* infections WITH a positive blood culture during the six-month period ending with the current reporting month	All adult chronic maintenance hemodialysis patient days during the six-month period ending with the current reporting month	HD patients < 18 yrs old
CPM VII – Six-Month Rolling Average Rate of Hemodialysis *Catheter-Related* Infections *Express as: rate per 1000 HD catheter days*	Number of clinically established hemodialysis *catheter-related* infections during the six-month period ending with the current reporting month	Number of hemodialysis catheter days during the six-month period ending with the current reporting month in adult chronic maintenance hemodialysis patients	HD patients < 18 yrs old
CPM VIII – Six-Month Rolling Average Rate of Hemodialysis *Catheter-related* Bacteremia *Express as: rate per 1000 HD catheter days*	Number of clinically established hemodialysis *catheter-related* infections with a positive blood culture during the six-month period ending with the current reporting month	Number of hemodialysis catheter days during the six-month period ending with the current reporting month in adult chronic maintenance hemodialysis patients	HD patients < 18 yrs old
CPM IX – Six-Month Rolling Average Rate of Hemodialysis *Arteriovenous Graft-Related* Infections *Express as: rate per 1000 HD graft days*	Number of clinically established hemodialysis *Arteriovenous Graft-related* infections during the six-month period ending with the current reporting month	Number of hemodialysis *Arteriovenous Graft* days during the six-month period ending with the current reporting month in adult chronic maintenance hemodialysis patients	HD patients < 18 yrs old

Description	Numerator	Denominator	Exclusions
CPM X – Six-Month Rolling Average Rate of Hemodialysis *Arteriovenous Fistula-Related* Infections *Express as: rate per 1000 HD fistula days*	Number of clinically established hemodialysis *Arteriovenous Fistula-related* infections during the six-month period ending with the current reporting month	Number of hemodialysis *Arteriovenous Fistula* days during the six-month period ending with the current reporting month in adult chronic maintenance hemodialysis patients	HD patients < 18 yrs old
CPM XI – Target for Hemodialysis Vascular Access-Related Infections Express as: rate per 1000 HD patient days	Number of clinically established hemodialysis vascular *access-related* infections	All adult chronic maintenance hemodialysis patient days	HD patients < 18 yrs old
CPM XII – Target for Six-month Rolling Average Rate of Hemodialysis *Catheter-Related* bacteremia rate Express as: rate per 1000 HD patient days	Number of clinically established hemodialysis *catheter-related* infections with a positive blood culture during the six-month period ending with the current reporting month	Number of hemodialysis catheter days during the six-month period ending with the current reporting month in adult chronic maintenance hemodialysis patients	HD patients < 18 yrs old
CPM XIII – Percent of Clinically Established Infections resulting in Hospitalization (Six-month rolling average) Express as: percentage	Number of clinically established infections requiring hospitalization during the six-month period ending with the current reporting month	Number of clinically established infections during the six-month period ending with the current reporting month	HD patients < 18 yrs old

Description	Numerator	Denominator	Exclusions
CPM XIV – Percent of Hemodialysis Vascular *Access-Related* Infections resulting in Hospitalization (Six-month rolling average) Express as: percentage	Number of clinically established hemodialysis vascular *access-related* infections requiring hospitalization during the six-month period ending with the current reporting month	Number of clinically established hemodialysis vascular *access-related* infections during the six-month period ending with the current reporting month	HD patients < 18 yrs old
CPM XV – Percent of Hemodialysis *Catheter-Related* infections resulting in Hospitalization (Six-month rolling average) Express as: percentage	Number of clinically established infections due to a hemodialysis catheter requiring hospitalization during the six-month period ending with the current reporting month	Number of established infections due to a hemodialysis catheter during the six-month period ending with the current reporting month	HD patients < 18 yrs old

Background

Currently, no hemodialysis vascular-access related infection CPMs exist and data collected are limited. Below is a summary of the discussions, recommendations and definitions of the seventeen CPMs proposed by the hemodialysis vascular access-related infection C-TEP members for hemodialysis practice, as well as descriptions of other non-measure recommendations relevant to this practice area.

Overview of Literature

A large body of literature exists showing strong associations between central venous catheter use in hemodialysis patients with poorer survival and greater morbidity [1-40]. Recent studies have shown a nearly 20% higher hazard of mortality for every 20% higher facility % catheter use [2]. The prevalence of numerous patient comorbidity indicators was similar in facilities with high versus low catheter use. Lower mortality has been observed with reduction in catheter use in facility and patient-level access use studies [7, 10, 13, 40, 41]. Furthermore, much of the 30-40% higher case-mix adjusted mortality rate for US hemodialysis patients compared to those in several European countries appears to be explained by differences in vascular access use between these two regions [2]. Rates of access-related infection, including septicemia, have been shown to be substantially higher for patients dialyzing with a central venous catheter versus an arteriovenous fistula or graft [2, 5, 9, 14, 19, 28, 34, 36, 42, 43]. Access-related septicemia is strongly associated with poor survival, high rates of hospitalization, and high treatment costs (>$25,000 per episode) [9, 15, 18-20, 27, 44-48]. Numerous clinical trials have demonstrated large variability in access-related infection rates among facilities treating HD patients,

while demonstrating large reductions in access-related infection rates through quality improvement programs focused on using certain anti-microbial lock solutions and/or other access-related infection control regimens [38, 49-91]. These trials provide strong evidence that access-related infection rates are modifiable with the possibility to reduce high rates of access-related infection to substantially lower levels. Several HD guideline committees and health care agencies have developed recommendations for either catheter use and/or access-related infection rates [92-95].

Data Collection Form

The C-TEP felt three factors were especially important in developing new vascular access-related infection measures for hemodialysis practice. These were: (1) evidence needed to determine whether a patient actually had an infection; (2) evidence necessary to determine whether an identified infection was due to a vascular access; and (3) type of vascular access to which the infection was related. In some cases the determination of an infection and its source is apparent, whereas in other cases this determination can be much more difficult to ascertain. The C-TEP members felt it would be most meaningful if a measure of total infections could first be obtained followed by an indication of those due to vascular access, and then if so, which type of vascular access. This approach would allow a determination of what percent of all suspected infections are due to vascular access. Although some of these data elements can be obtained through analyses of CMS claims data, the C-TEP felt there are inconsistencies in claims data reporting. Furthermore, claims data do not allow one to unequivocally determine the type of vascular access that an infection was due to. Therefore, to have reliable, higher quality data for measure evaluation, the C-TEP strongly recommended that the data be obtained through CROWNWeb, using claims data as an alternative source of information to support validation efforts. However, the C-TEP also was sensitive to not greatly increasing the work burden for facility staff in providing data needed for vascular access-related infections. Therefore, the C-TEP sought to minimize the amount of new data needed from dialysis units in order to calculate the newly proposed hemodialysis vascular access-related infection CPMs.

The C-TEP created a form (Figure I) to serve as a template for organizing data collection of the specific data elements necessary to calculate the 17 CPMs recommended by the C-TEP. The panel members intended for the elements on the form to be incorporated into CROWNWeb for facility-wide data collection. The C-TEP felt that expansion of the data collection for peritoneal dialysis-related infections should be addressed by a separate PD-related infection C-TEP.

Figure I
Collection Form for Data Ascertainment Algorithm

Facility #_____

Date of infection onset (mm/dd/yyyy):_____ Patient ID:_____

1) This patient has a NEW suspected infection because of:
- □ Clinical suspicion that warrants initiating antibiotic therapy
  And/Or
- □ Patient was discharged from hospital/other health care facility and already on antibiotics

2) The suspected infection is now clinically established: □ Yes □ No □ Pending
(should rollover and prompt again in one week)

If YES, the infection was established by (check all that apply):
- □ Positive blood culture
- □ Symptoms of clinical sepsis [e.g. fever (>38 C), rigors, blood pressure drop or altered mental status]
- □ Soft tissue (pus or exudate and 2 of: redness, pain, swelling)

3) The established infection required hospital admission: □ Yes □ No

4) The established infection is vascular access related: □ Yes □ No

If YES, the vascular access type this infection is attributed to is:
□ Temporary, uncuffed catheter □ Tunneled catheter
□ Arteriovenous FISTULA □ Arteriovenous GRAFT

Below are the seventeen CPMs created by members of the Hemodialysis Vascular Access-Related Infections C-TEP. The panel hopes that these measures will be used for: (1) quality improvement including comparisons among units, (2) assessment of change in vascular access-related infection rates over time within each unit, and for (3) comparative effectiveness research. The panel emphasized that the vascular access infection CPMs should not be used for reimbursement purposes.

3.1 CPM I – Presence of Suspected Infection During Reporting Month

Numerator: Number of suspected infections among adult chronic hemodialysis patients during the month; a suspected infection is defined as an episode that: (1) warrants empiric antibiotic therapy, or (2) is due to a patient being discharged from the hospital/other health care facility or provider during the reporting month with a new order for antibiotics.

Denominator: All adult chronic maintenance hemodialysis patient days

Inclusions: All adult chronic maintenance hemodialysis patients

Exclusions: HD patients < 18 yrs old

Unit of Measurement: *Express as number of suspected infections per 1000 HD patient days*

Importance

Infection-related death is the second most common cause of death among chronic hemodialysis patients after cardiovascular-related causes [14, 43]. Infection-related hospitalizations are associated with high health care costs [20, 47, 48, 96]. Furthermore, the rates of infection-related hospitalization vary substantially across dialysis units. The proposed CPM will provide important routine monthly reporting to dialysis units through CROWNWeb as a means to inform dialysis units of the rate of suspected infection among adult chronic hemodialysis patients in their facility. This measure will provide the capability for dialysis units to monitor infection rates over time thereby supporting local quality monitoring and improvement programs which may serve to decrease infection rates, lead to decreased mortality and morbidity, and lower overall costs.

Scientific Acceptability

This measure defines a suspected infection as an episode that: (1) warrants empiric antibiotic therapy, or (2) is due to a patient being discharged from the hospital/other health care facility or provider during the reporting month with a new order for antibiotics. It is generally accepted that antibiotics are only prescribed when a patient either has or is suspected of having an infection. There may be other situations in which an infection is suspected but antibiotics may not be prescribed until a more definitive diagnosis is obtained. However, the intent of the current measure was to limit the measure to infections displaying sufficient clinical symptomology and/or a high index of suspicion for significant risk to the patient to warrant antibiotic prescription thereby providing a greater level of reliability in the meaning of the measure.

Feasibility

The proposed measure offers a clear and unambiguous method for defining a suspected infection based upon whether a patient has been prescribed an antibiotic during the reporting month. Prescription of antibiotics is believed to be routinely reported in patient health records in a timely fashion.

Usability

The measure is applied to all adult chronic HD patients without differentiation between prevalent and incident hemodialysis patients so as to further increase the usability and actionability of this measure. Furthermore, the measure is expected to have operational relevance in that it will be informative to dialysis providers and can be incorporated into local quality improvement programs. The measure is expected to be understandable to different audiences (patients, providers, policy makers) who likely will find this measure useful in decision-making.

3.2 CPM II – Presence of Clinically Established Infection During Reporting Month

Numerator: Number of clinically established infections during the reporting month for adult chronic hemodialysis patients; an infection is defined as "clinically established" if meeting the following 2 requirements:
(1) Patients having a suspected infection as defined in CPM I , and patients have (2) (a) positive blood culture or
(2)(b) Symptoms of clinical sepsis [e.g. fever (>38 °C), rigors, blood pressure drop] or
(2)(c) Soft tissue (pus or exudate and two of: redness, pain, swelling)

Denominator: All adult chronic maintenance hemodialysis patient days

Inclusions: All adult chronic maintenance hemodialysis patients

Exclusions: HD patients < 18 yrs old

Unit of Measurement: *Express as number of clinically established infections per 1000 HD patient days*

Importance

Whereas CPM I provides a measure of overall suspected infections based upon whether a patient was prescribed an antibiotic, CPM II was recommended to provide a more reliable measure of infection (i.e., an infection which has been clinically established). Furthermore, the frequency of infection severity is poorly understood among hemodialysis patients, and was viewed by the C-TEP as an important factor for understanding the nature of infections experienced by hemodialysis patients and the percentage of suspected infections that are confirmed according to 3 clinical measures: (1) positive blood culture, (2) symptoms of clinical sepsis [e.g. fever (>38 C), rigors, blood pressure drop or altered mental status], and (3) Soft tissue (pus or exudate and two of: redness, pain, swelling). The collection of these data elements will make it possible to more accurately characterize the nature and severity of infections on a national level (e.g., positive blood culture plus symptoms of clinical sepsis versus soft-tissue infection without symptoms of clinical sepsis, etc), and relate these to mortality, morbidity, health care costs, and the focus of quality improvement programs.

Scientific Acceptability

The C-TEP felt it was important to have a measure to indicate that an infection had occurred based upon generally accepted clinical evidence. The C-TEP recognized the different degrees of severity and presentation of infections encountered in clinical practice. Consequently, the C-TEP has recommended an indication of whether a suspected infection has been clinically established according to 3 different criteria: (1) positive blood culture, (2) symptoms of clinical sepsis [e.g. fever (>38 C), rigors, blood pressure drop or altered mental status], or (3) Soft tissue (pus or exudate and two of: redness, pain, swelling). The recommendation is to indicate whether each criterion is applicable to each infection that

is suspected to have occurred in a hemodialysis patient during the reporting month. Many of the same criteria have been used in defining an infection as part of the Centers for Disease Control (CDC) National Healthcare Safety Network Outpatient Dialysis Event Surveillance program [97].

Feasibility

The proposed measure offers a clear and broadly encompassing method for defining a clinically established infection. C-TEP members felt that the requested information would be routinely available in patient medical records as part of treatment and evaluation of suspected and/or clinically established infections.

Usability

The measure is applied to all adult chronic HD patients without differentiation between prevalent and incident hemodialysis patients so as to further increase the usability and actionability of this measure. Furthermore, the measure is expected to have operational relevance in that it will be informative to dialysis providers, and can be incorporated into local quality improvement programs. The measure is expected to be understandable to different audiences (patients, providers, policy makers) who likely will find this measure useful for decision making.

3.3 CPM IIIa – Presence of Hemodialysis Vascular Access-Related Infection During Reporting Month

Numerator: Number of clinically established hemodialysis vascular access-related infections during the reporting month; where clinically established infection is defined as in CPM II and is attributed to the hemodialysis vascular access

Denominator: All adult chronic maintenance hemodialysis patient days

Inclusions: All adult chronic maintenance hemodialysis patients

Exclusions: HD patients < 18 yrs old

Unit of Measurement: *Express as # clinically established hemodialysis vascular access-related infections per 1000 HD patient days*

3.4 CPM IIIb – Percent of Clinically Established Infections Related to Hemodialysis Vascular Access During Reporting Month

Numerator: Number of clinically established hemodialysis vascular *access-related* infections during the reporting month

Denominator: Number of clinically established infections during the reporting month foradult chronic hemodialysis patients; a clinically established infection is defined as in CPM II.

Inclusions: All adult chronic maintenance hemodialysis patients

Exclusions: HD patients < 18 yrs old

Unit of Measurement: *Express as a percentage*

Importance

The average cost for vascular access-related infections has risen two-three fold since 1998 among US hemodialysis patients. In 2006, the average inpatient cost per patient per year for treating vascular access-related infections was $603 amounting to nearly $200 million dollars in overall costs for the US adult chronic HD patient population [43]. Furthermore, the per person per year total costs were substantially greater for patients with a catheter or a graft, $79,364 and $72,729, respectively, compared with patients dialyzing with an AV fistula (just under $60,000). In addition, prior studies have indicated the highest rates of access infection to be associated with central venous catheters, intermediate rates with AV grafts, and lowest rates of infection associated with native arteriovenous fistulae [2, 5, 9, 14, 19, 28, 34, 36, 42, 43]. Vascular access-related infections can lead to septicemia, especially for catheters, resulting in high rates of mortality and morbidity. Numerous clinical trials have demonstrated the ability to greatly diminish rates of hemodialysis vascular access-related infections through use of various infection control regimens [38, 43, 49-91]. Thus, vascular access-related infection rates are modifiable, with opportunities for substantial reductions in vascular access-related infection rates in some dialysis units. The proposed clinical performance measure will allow dialysis units to monitor their rates of hemodialysis vascular access-related infection which can be utilized for quality improvement programs aimed at decreasing vascular access-related infection rates. CPM III may be used in conjunction with CPM II, to determine the percentage of clinically established infections which are due to vascular access. Knowledge of overall clinically established infection rates (CPM II) and the proportion of clinically established infections due to vascular access (CPM III), will provide important information to caregivers for focusing and designing their overall infection control procedures to be as effective and impactful as possible. By decreasing vascular access-related infection rates, dialysis units will decrease overall costs, with the possibility for reductions in patient mortality and morbidity.

Scientific Acceptability

It is generally recognized that hemodialysis vascular access-related infections, particularly from catheters, are a major contributor to the total number of infections experienced by hemodialysis patients [2, 5, 9, 14, 19, 28, 34, 36, 42, 44, 98, 99]. Monitoring the level of hemodialysis vascular access-related infections at a national level will serve as an important step towards implementing quality improvement programs to diminish overall rates of hemodialysis vascular access-related infections. However, the C-TEP recognizes that it is not always possibly to know with complete certainty whether a particular infection is directly attributable to the patient's vascular access or due to some other source. Despite this uncertainty in some cases, the C-TEP felt that for the majority of clinically established infections, it is possible to determine whether or not the patient's vascular access was the main source for the development of the infection.

Feasibility

C-TEP members felt that the requested information would be routinely available in patient medical records as part of treatment and evaluation of suspected and/or clinically established infections.

Usability

The measure is applied to all adult chronic HD patients without differentiation between prevalent and incident hemodialysis patients so as to further increase the usability and actionability of this measure. Furthermore, the measure is expected to have operational relevance in that it will be informative to dialysis providers and can be incorporated into local quality improvement programs. The measure is expected to be understandable to different audiences (patients, providers, policy makers), who likely will find this measure useful for decision-making.

3.5 CPM IVa – Presence of Hemodialysis Vascular Access-Related Bacteremia During Reporting Month

Numerator: Number of clinically established hemodialysis vascular *access-related* infections with a positive blood culture during the reporting month; clinically established infection is defined as in CPM II and for which the blood culture is positive, and this infection is attributed to the hemodialysis vascular access

Denominator: All adult chronic maintenance hemodialysis patient days

Inclusions: All adult chronic maintenance hemodialysis patients

Exclusions: HD patients < 18 yrs old

Unit of Measurement: *Express as number clinically established hemodialysis vascular access-related infections with bacteremia per 1000 HD patient days*

3.6 CPM IVb – Percent of Hemodialysis Vascular Access-Related Infections with Bacteremia During Reporting Month

Numerator: Number of clinically established hemodialysis vascular *access-related* infections with a positive blood culture during the reporting month; clinically established infection is defined as in CPM II and for which the blood culture is positive, and this infection is attributed to the hemodialysis vascular access

Denominator: Number of clinically established hemodialysis vascular *access-related* infections

Inclusions: All adult chronic maintenance hemodialysis patients

Exclusions: HD patients < 18 yrs old

Unit of Measurement: *Express as a percentage*

Importance

Although CPMs I, II, and III are useful and meaningful CPMs for the reasons described in each of those measures, the C-TEP felt it was important to have a measure of HD vascular access-related infection that would be less subject to interpretation and based upon a specific, definitive, and standard measure of infection diagnosis. Thus, CPM IV was proposed to base one of the calculations of hemodialysis vascular access-related infection only upon those cases in which the blood culture is positive for an infection. This more specific measure of hemodialysis vascular access-related infections resulting in bacteremia will provide meaningful comparisons over time within and between dialysis units. Furthermore, infections resulting in bacteremia often represent more severe infections with greater potential for major adverse outcomes than seen in non-bacteremic infections and therefore are another important reason for specific monitoring of this important subset of infections. Besides its use as a stand-alone measure, CPM IV may also be used in conjunction with CPM III to determine the fraction of total hemodialysis vascular access-related infections that result in bacteremia.

Scientific Acceptability

Bacteremia is broadly accepted as a definitive and important measure of infection. Bacteremia has been used as a primary study end point in numerous studies of vascular access-related infection [22, 33-35, 39, 42, 44, 45, 49, 52-56, 58-62, 68, 69, 73, 74, 76, 79-82, 84, 87, 100, 101].

Feasibility

The requested information should be routinely available in patient medical records as part of treatment and evaluation of suspected and/or clinically established infections. No additional information would be required for CPM IV beyond that already necessary for proposed CPM II and CPM III.

Usability

The measure is applied to all adult chronic HD patients without differentiation between prevalent and incident hemodialysis patients so as to further increase the usability and actionability of this measure. Furthermore, the measure is expected to have operational relevance in that it will be informative to dialysis providers and can be incorporated into local quality improvement programs. The measure is expected to be understandable to different audiences (patients, providers, policy makers), who likely will find this measure useful in decision-making.

3.7 CPM V – Six-Month Rolling Average Rate of Hemodialysis Vascular Access-Related Infections

Numerator: Number of clinically established infections due to an HD access during the six-month period ending with the current reporting month; clinically established infection is defined as in CPM II and attributed to a hemodialysis vascular access

Denominator: Total number of patient days during the six-month period ending with the current reporting month in which the patient was considered a chronic maintenance hemodialysis patient

Inclusions: All adult chronic maintenance hemodialysis patients

Exclusions: HD patients < 18 yrs old

Unit of Measurement: Express as six-month average number HD vascular access-related infections per 1000 HD patient days

Importance

The expectation is that CPMs I-IV are designed to provide important infection-related information on a monthly basis which will be important for individual facilities and regional or national programs in monitoring overall infection rates and hemodialysis access-related infections with relatively quick feedback through CROWNWeb. However, the C-TEP felt it would also be informative to provide a measure of longer term vascular access-related infection control. To achieve this goal, the C-TEP recommended calculation of a six-month rolling average of hemodialysis vascular access-related infections and a six-month rolling average of hemodialysis vascular access-related bacteremia, as described for CPMs V, VI, VII, VIII, IX, and X. It is anticipated that these measures using a six-month rolling average will be most informative for monitoring overall quality of access-related infection control at dialysis units, and particularly for small dialysis units in which individual monthly infection rates may be highly variable due to the impact of one additional infection on the overall rate when calculated among a small number of patients in a dialysis unit. The six-month rolling average rates will be especially meaningful when comparing access-related infection associated with a particular type of vascular access (CPMs VII, VIII, IX, and X) since the individual monthly rates may be low and or highly variable, whereas the six-month rolling average will provide more stable estimates of infection control.

Scientific Acceptability

The use of rolling averages to describe practice achievement over a longer exposure period is scientifically acceptable and has previously been used by HCFA (e.g, three-month rolling average of achieved hematocrit in hemodialysis patients as part of the Hematocrit Management Audit (HMA) policy implemented in 1997 [102].

Feasibility

The requested information should be routinely available in patient medical records as part of treatment and evaluation of suspected and/or clinically established infections. No additional information would be required for CPM V beyond that already necessary for proposed CPM III and already being collected by CROWNWeb for other quality clinical performance measures.

Usability

The measure is applied to all adult chronic HD patients without differentiation between prevalent and incident hemodialysis patients so as to further increase the usability and actionability of this measure. Furthermore, the measure is expected to have operational relevance in that it will be informative to dialysis providers and can be incorporated into local quality improvement programs. The measure is expected to be understandable to different audiences (patients, providers, policy makers), who likely will find this measure useful in decision-making.

3.8 CPM VI – Six-Month Rolling Average Rate of Hemodialysis Vascular Access-Related Bacteremia

Numerator: Number of clinically established hemodialysis vascular access-related infections with a positive blood culture during the six-month period ending with the current reporting month; where a clinically established infection is defined as in CPM II and for which the blood culture is positive, and this infection is attributed to the hemodialysis vascular access

Denominator: Total number of patient days during the six-month period ending with the current reporting month in adult chronic maintenance hemodialysis patients

Inclusions: All adult chronic maintenance hemodialysis patients

Exclusions: HD patients < 18 yrs old

Unit of Measurement: express as six-month average number HD vascular access-related bacteremia infections per 1000 HD patient days

Importance

Please see “Importance” for CPM V.

Scientific Acceptability

Please see “Scientific Acceptability” for CPM V.

Feasibility

The requested information should be routinely available in patient medical records as part of treatment and evaluation of suspected and/or clinically established infections. No additional information would be required for CPM VI beyond that already necessary for proposed CPM IV and that already being collected by CROWNWeb for other quality clinical performance measures.

Usability

The measure is applied to all adult chronic HD patients without differentiation between prevalent and incident hemodialysis patients so as to further increase the usability and actionability of this measure.

Furthermore, the measure is expected to have operational relevance in that it will be informative to dialysis providers and can be incorporated into local quality improvement programs. The measure is expected to be understandable to different audiences (patients, providers, policy makers) who likely will find this measure useful in decision-making.

3.9 CPM VII – Six-Month Rolling Average Rate of Hemodialysis Catheter-Related Infections

Numerator: Number of clinically established infections due to a hemodialysis catheter during the six-month period ending with the current reporting month; clinically established infection is defined as in CPM II, and this infection is attributed to the central venous catheter used as hemodialysis vascular access

Denominator: Total number of hemodialysis catheter days during the six-month period ending with the current reporting month in adult chronic maintenance hemodialysis patients

Inclusions: All adult chronic maintenance hemodialysis patients

Exclusions: HD patients < 18 yrs old

Unit of Measurement: express as six-month average number HD catheter related infections per 1000 HD catheter days

Importance

The C-TEP felt it was important to determine rates of infection associated with different types of vascular access used for hemodialysis particularly since prior studies have shown much higher rates of access-related infections for central venous catheters versus native arteriovenous fistulae or prosthetic grafts. However, use of insertion/exit site disinfection and various anti-microbial lock solutions in the care of catheters along with other vascular access-related infection control practices have led to substantially reduced rates of access-related infection in numerous studies [38, 43, 49-91]. Knowledge of access-related infections by type of vascular access will serve as valuable information to dialysis units in optimizing infection control processes related to vascular access care. Furthermore, these national data will also serve to provide additional insights regarding aspects of access-related infections associated with the use of arteriovenous grafts since information in this regard is much more limited than currently exists for use of central venous catheters for vascular access. For the importance of using the six-month rolling average, please see the “Importance” criterion described for CPM V.

Scientific Acceptability

Reporting infection rates by type of vascular access has been standard practice in numerous studies for many years [49, 51, 53]. Furthermore, a similar approach has been used by the CDC [59] and suggested in several clinical practice guidelines [92-95].

Regarding use of the six-month rolling average, please see the "Scientific Acceptability" criterion described for CPM V.

Feasibility

The requested information should be routinely available in patient medical records as part of treatment and evaluation of suspected and/or clinically established infections. The additional information required for CPM VII beyond that already being collected by CROWNWeb and beyond that necessary for CPM III is an indication of the type of vascular access that caused the infection.

Usability

The measure is applied to all adult chronic HD patients without differentiation between prevalent and incident hemodialysis patients so as to further increase the usability and actionability of this measure. Furthermore, the measure is expected to have operational relevance in that it will be informative to dialysis providers and can be incorporated into local quality improvement programs. The measure is expected to be understandable to different audiences (patients, providers, policy makers), who likely will find this measure useful in decision-making.

3.10 CPM VIII – Six-Month Rolling Average Rate of Hemodialysis Catheter-Related Bacteremia

Numerator: Number of clinically established **infections** due to a hemodialysis catheter with a positive blood culture during the six-month period ending with the current reporting month; clinically established infection is defined as in CPM II and for which the blood culture is positive, and this infection is attributed to the central venous catheter used as hemodialysis vascular access

Denominator: Total number of hemodialysis catheter days during the six-month period ending with the current reporting month in adult chronic maintenance hemodialysis patients

Inclusions: All adult chronic maintenance hemodialysis patients

Exclusions: HD patients < 18 yrs old

Unit of Measurement: express as six-month average number hemodialysis catheter-related bacteremia episodes per 1000 HD catheter days

Importance

Same as the "Importance" criterion described for CPM VII. In addition, available CMS billing data indicate that catheter-associated bacteremia comprises the bulk of vascular access-related infections and likely is the main driver for morbidity, mortality, and resource utilization. It is also arguably the most well-studied outcome measure, albeit with varying rigor for criteria used to define it in the literature.

Scientific Acceptability

Same as the "Scientific Acceptability" criterion described for CPM VII except with the more specific focus on bacteremia.

Feasibility

The requested information should be routinely available in patient medical records as part of treatment and evaluation of suspected and/or clinically established infections. The additional information required for CPM VIII beyond that already being collected in CROWNWeb and beyond that necessary for CPM IV is an indication of the type of vascular access that caused the infection.

Usability

The measure is applied to all adult chronic HD patients without differentiation between prevalent and incident hemodialysis patients so as to further increase the usability and actionability of this measure. Furthermore, the measure is expected to have operational relevance in that it will be informative to dialysis providers and can be incorporated into local quality improvement programs. The measure is expected to be understandable to different audiences (patients, providers, policy makers), who likely will find this measure useful in decision-making.

3.11 CPM IX – Six-Month Rolling Average Rate of Hemodialysis Arteriovenous Graft Related Infections

Numerator: Number of clinically established infections due to a hemodialysis arteriovenous graft used as hemodialysis vascular access during the six-month period ending with the current reporting month; clinically established infection is defined as in CPM II

Denominator: Total number of hemodialysis arteriovenous graft days during the six-month period ending with the current reporting month in adult chronic maintenance hemodialysis patients

Inclusions: All adult chronic maintenance hemodialysis patients

Exclusions: HD patients < 18 yrs old

Unit of Measurement: express as six-month average number hemodialysis AV graft-related infections per 1000 HD graft access days

Importance

Please see "Importance" from CPM VII.

Scientific Acceptability

Please see "Scientific Acceptability" for CPM VII.

Feasibility

The requested information should be routinely available in patient medical records as part of treatment and evaluation of suspected and/or clinically established infections. The additional information required for CPM IX beyond that already being collected by CROWNWeb and beyond that necessary for CPM III is an indication of the type of vascular access that caused the infection.

Usability

The measure is applied to all adult chronic HD patients without differentiation between prevalent and incident hemodialysis patients so as to further increase the usability and actionability of this measure. Furthermore, the measure is expected to have operational relevance in that it will be informative to dialysis providers and can be incorporated into local quality improvement programs. The measure is expected to be understandable to different audiences (patients, providers, policy makers) who likely will find this measure useful for decision making.

3.12 CPM X – Six-Month Rolling Average Rate of Hemodialysis Arteriovenous Fistula-Related Infections

Numerator: Number of clinically established infections due to a hemodialysis native arteriovenous fistula used as hemodialysis vascular access during the six-month period ending with the current reporting month; clinically established infection is defined as in CPM II

Denominator: Total number of hemodialysis native arteriovenous fistula days during the six-month period ending with the current reporting month in adult chronic maintenance hemodialysis patients

Inclusions: All adult chronic maintenance hemodialysis patients

Exclusions: HD patients < 18 yrs old

Unit of Measurement: express as six-month average number hemodialysis AV *Fistula*-related infections per 1000 HD fistula access days

Importance

Please see “Importance” for CPM VII.

Scientific Acceptability

Please see “Scientific Acceptability” for CPM VII.

Feasibility

The requested information should be routinely available in patient medical records as part of treatment and evaluation of suspected and/or clinically established infections. The additional information required

for CPM X beyond that already being collected by CROWNWeb and beyond that necessary for CPM III is an indication of the type of vascular access the infection is due to.

Usability

The measure is applied to all adult chronic HD patients without differentiation between prevalent and incident hemodialysis patients so as to further increase the usability and actionability of this measure. Furthermore, the measure is expected to have operational relevance in that it will be informative to dialysis providers and can be incorporated into local quality improvement programs. The measure is expected to be understandable to different audiences (patients, providers, policy makers), who likely will find this measure useful for decision-making.

3.13 CPM XI – Target for Hemodialysis Vascular Access Related Infections

Measure Description: Hemodialysis Vascular *Access-related* Infections is the most important measure. The target will be established pending the first year of complete data collection

Numerator: All clinically established HD vascular *access-related* infections

Denominator: All adult chronic maintenance hemodialysis patient days

Inclusions: All adult chronic maintenance hemodialysis patients

Exclusions: HD patients < 18 yrs old

Length of time over which the measure will be calculated: six-month rolling average

Importance

The C-TEP felt it was important for a target to be established to help guide improvements in vascular access-related infection control. Even though there have been numerous studies published indicating large variation in vascular access-related infection rates within dialysis units [38, 43, 49-91], uncertainties remain regarding the generalizability of study findings either to studies having been performed in single center settings or due to other concerns. The C-TEP feels that two of the most important CPMs for monitoring and focusing upon improvements in hemodialysis vascular access-related infection are CPMs XI and XII which will establish targets, respectively, for hemodialysis access-related infection rates and for hemodialysis catheter-related bacteremia rates. However, the C-TEP felt that even though claims data have provided some insights into variability in access-related infection rates among hemodialysis patients, inconsistencies and questions remain regarding the completeness of claims data reporting. Specifically, there are far fewer publications on the frequency of fistula or graft infections, as compared with catheter infections. Therefore, the C-TEP felt it would be prudent to wait until data from recommended CPMs I-X have been collected for at least one year to guide the C-TEP's future decision regarding meaningful targets to establish for HD access-related infection rates and hemodialysis catheter-related bacteremia rates.

Scientific Acceptability

Target rates for access-related infection have been used in a number of infection quality improvement programs [42], and use of targets or monitoring rates of access-related infection have been recommended by some clinical practice guideline committees, the CDC, and other health quality improvement programs [92-95, 103, 104].

Feasibility

The requested information should be routinely available in patient medical records as part of treatment and evaluation of suspected and/or clinically established infections. The data required for CPM XI are either already being collected by CROWNWeb or requested for CPM III.

Usability

The measure is applied to all adult chronic HD patients without differentiation between prevalent and incident hemodialysis patients so as to further increase the usability and actionability of this measure. Furthermore, the measure is expected to have operational relevance in that it will be informative to dialysis providers, and can be incorporated into local quality improvement programs. The measure is expected to be understandable to different audiences (patients, providers, policy makers), who likely will find this measure useful in decision-making.

3.14 CPM XII – Target for Hemodialysis Catheter-Related bacteremia rate

Measure Description: The initial target for hemodialysis catheter bacteremia rate is less than 3.0 episodes per 1000 catheter days calculated as a six-month rolling average. This initial target is subject to change as data become available.

Numerator: Number of clinically established infections due to a hemodialysis catheter with a positive blood culture during the six-month period ending with the current reporting month; clinically established infection is defined as in CPM II and for which the blood culture is positive, and this infection is attributed to the central venous catheter used as hemodialysis vascular access.

Denominator: Total number of hemodialysis catheter days during the six-month period ending with the current reporting month in adult chronic maintenance hemodialysis patients

Inclusions: All adult chronic maintenance hemodialysis patients

Exclusions: HD patients < 18 yrs old

Unit of Measurement: express as six-month average number hemodialysis catheter-related bacteremia episodes per 1000 HD catheter days

Importance

Please see "Importance" for CPM XI.

Scientific Acceptability

Please see "Scientific Acceptability" for CPM XI.

Feasibility

The requested information should be routinely available in patient medical records as part of treatment and evaluation of suspected and/or clinically established infections. The data required for CPM XII are either already being collected by CROWNWeb or requested for CPM IV.

Usability

The measure is applied to all adult chronic HD patients without differentiation between prevalent and incident hemodialysis patients so as to further increase the usability and actionability of this measure. Furthermore, the measure is expected to have operational relevance in that it will be informative to dialysis providers and can be incorporated into local quality improvement programs. The measure is expected to be understandable to different audiences (patients, providers, policy makers) who likely will find this measure useful for decision making.

3.15 CPM XIII – Percent of Established Infections Resulting in Hospitalization

Numerator: Number of established infections requiring hospitalization

Denominator: Number of clinically established infections

Inclusions: All adult chronic maintenance hemodialysis patients

Exclusions: HD patients < 18 yrs old

Unit of Measurement: *Express as a percentage*

Importance

Dialysis patients experience a mean of nearly two hospitalizations per year [43], with hospitalizations associated with substantial morbidity for patients and substantial costs for patients, providers, and the health care system. In 2005-2007, there were 10.5 and 8.0 hospitalizations, respectively, for bacteremia/septicemia and pneumonia, for every 100 hemodialysis patient years with the reported rates of hospitalization due to bacteremia/septicemia having risen from 8.2 in 1999-2001 [43]. An important quality measure of the severity of infections and quality of infection management is to monitor the rates of infections resulting in a hospitalization.

Scientific Acceptability

Rate of hospitalization in conjunction with other measures such as length of hospital stay and survival have been accepted, long-standing measures of quality of care and health-care related costs. Conclusions regarding quality of care and health-care costs based solely upon rates of hospitalization need to be interpreted with caution, as this may reflect, not only severity of infection, but also differences in practice patterns. Nonetheless, health-care system improvements in infection management, particularly in infection prevention and early identification/treatment, would be expected to decrease overall rates of hospitalization due to infection.

Feasibility

The requested information should be routinely available in patient medical records.

Usability

The measure is applied to all adult chronic HD patients without differentiation between prevalent and incident hemodialysis patients so as to further increase the usability and actionability of this measure. Furthermore, the measure is expected to have operational relevance in that it will be informative to dialysis providers, and can be incorporated into local quality improvement programs. The measure is expected to be understandable to different audiences (patients, providers, policy makers) who likely will find this measure useful in decision-making.

3.16 CPM XIV – Percent of Hemodialysis Vascular Access-Related Infections resulting in Hospitalization

Numerator: Number of clinically established hemodialysis vascular *access-related* infections requiring hospitalization during the reporting month

Denominator: Number of clinically established hemodialysis vascular *access-related* infections

Inclusions: All adult chronic maintenance hemodialysis patients

Exclusions: HD patients < 18 yrs old

Unit of Measurement: *Express as a percentage*

Importance

In 2007, there were 13.3, 2.8, and 1.2 hospitalizations, respectively, due to vascular access-related infections associated with catheters, arteriovenous grafts, and native arteriovenous fistulae, respectively, for every 100 hemodialysis patients [43]. Furthermore, in 2007, there were 14.3, 6.5, and 4.5 hospitalizations, respectively, due to vascular access-related episodes of sepsis associated with catheters, arteriovenous grafts, and native arteriovenous fistulae, respectively, for every 100 hemodialysis patients [43]. The much higher infection-related rates of hospitalization seen for catheters

compared with arteriovenous fistulae and grafts suggest that reductions in catheter use and/or improvements in catheter care provide opportunities for decreasing hospitalization rates due to vascular access-related infection.

Scientific Acceptability

Rate of hospitalization in conjunction with other measures such as length of hospital stay and survival have been accepted, long-standing measures of quality of care and health-care related costs. Conclusions regarding quality of care and health-care costs based solely upon rates of hospitalization need to be interpreted with caution. Nonetheless, health care system improvements in infection management particularly in infection prevention and early identification/treatment of infections would be expected to decrease overall rates of hospitalization due to infection.

Feasibility

The requested information should be routinely available in patient medical records.

Usability

The measure is applied to all adult chronic HD patients without differentiation between prevalent and incident hemodialysis patients so as to further increase the usability and actionability of this measure. Furthermore, the measure is expected to have operational relevance in that it will be informative to dialysis providers, and can be incorporated into local quality improvement programs. The measure is expected to be understandable to different audiences (patients, providers, policy makers), who likely will find this measure useful in decision-making.

3.17 CPM XV – Percent of Hemodialysis Vascular Access-Related Infections resulting in Hospitalization

Numerator: Number of established infections due to a hemodialysis catheter requiring hospitalization during the six-month period ending with the current reporting month

Denominator: Number of established infections due to a hemodialysis catheter during the six-month period ending with the current reporting month

Inclusions: All adult chronic maintenance hemodialysis patients

Exclusions: HD patients < 18 yrs old

Unit of Measurement: Express as a percentage

Importance

Please see “Importance” for CPM XIV.

Scientific Acceptability

Please see "Scientific Acceptability" for CPM XIV.

Feasibility

The requested information should be routinely available in patient medical records.

Usability

The measure is applied to all adult chronic HD patients without differentiation between prevalent and incident hemodialysis patients so as to further increase the usability and actionability of this measure. Furthermore, the measure is expected to have operational relevance in that it will be informative to dialysis providers and can be incorporated into local quality improvement programs. The measure is expected to be understandable to different audiences (patients, providers, policy makers), who likely will find this measure useful in decision-making.

3.18 Other Recommendations

Recommended Demonstration Project Proposal from the Hemodialysis Vascular Access Related Infection C-TEP

In addition to new CPMs for infection control, the C-TEP recommended several demonstration projects to be considered by CMS. Following are the C-TEP's recommendations to CMS for possible demonstration projects to be considered which would support improvements in vascular use and infection control for U.S. HD patients.

On March 23, 2010, Dr. Michael Allon- chair of the Hemodialysis Vascular Access Related Infection TEP sent CMS an email regarding demonstration projects that were proposed during the TEP. Dr. Allon listed several items that the TEP was able to unanimously agree, these items are listed below.

1. Dialysis catheters are the major source of vascular access-related infection.

2. At present, 80% of new hemodialysis patients start dialysis with a catheter.

3. The delay in achieving a mature dialysis AV fistula in patients with advanced chronic kidney disease (CKD) prior to or shortly after initiating hemodialysis is a major reason for the high catheter use.

4. Placement of fistulas in pre-dialysis patients decreases the likelihood of a patient starting dialysis with a catheter.

5. New fistulas frequently require a few months and one or more surgical or radiologic interventions before they are suitable for dialysis use.

6. A major barrier to increasing fistula use in new dialysis patients is the lack of reimbursement for fistula placement and/or revision in uninsured patients who are predialysis or in their first 3 months of dialysis (before they qualify for Medicare coverage). Specifically, surgeons and radiologists are unwilling to perform fistula procedures in these patients until they are insured.

Dr. Allon went on to explain that to accelerate the early use of fistulas and reduce catheter use in hemodialysis patients, the TEP proposed a few items that should be considered for future demonstration projects. The TEP also suggested that their suggested changes will remove financial barriers and provide economic incentives to reduce catheter use in new hemodialysis patients, and thus minimize access-related infections. Additional costs incurred would be easily offset by the savings realized from the reduction in access-related infections.

Dr. Allon also included three additional topics of discussion in his email to CMS. These topics were 1) Earlier disbursement of Medicare benefits to uninsured patients requiring fistula placement, 2) Changes to the current surgeon and hospital reimbursement for AV fistula placement, and 3) Increased involvement of the ESRD Networks in facilitating decreased catheter use.

1) Earlier disbursement of Medicare benefits to uninsured patients requiring fistula placement

- Uninsured individuals with CKD prior to requiring dialysis (ESRD): Provide payment for surgical and radiological procedures necessary for the **creation** of native arteriovenous (AV) fistulae and surgical and/or radiologic modifications necessary to achieve fistula maturation during the pre-ESRD period for uninsured CKD patients who ultimately would qualify for the Medicare ESRD benefit after the commencement of chronic hemodialysis.

- Uninsured new ESRD patients within the first 90 days of hemodialysis: For uninsured new dialysis patients who initiate dialysis with a catheter only, and who would be eligible for the Medicare ESRD benefit at 90 days after initiating hemodialysis, provide immediate payment for surgical and radiological procedures necessary for the creation of native arteriovenous fistulae (AV fistula) and surgical and/or radiologic modifications necessary to achieve fistula maturation.

- New uninsured hemodialysis patients who initiate hemodialysis with a fistula or whose fistula is used for dialysis prior to the first 90 days of dialysis, would qualify for immediate, full Medicare coverage during the first 90 days of dialysis, similar to the benefit for patients who begin a period of home dialysis training prior to the end of the 90-day waiting period.

2) Changes to the current surgeon and hospital reimbursement for AV fistula placement

- If both a dialysis catheter and AV fistula are placed during the same hospitalization, current Medicare payment policy results in only partial payment, reimbursing fully for only one of the two accesses placed on that day. We recommend that CMS provide a

full rate of payment to the surgeon and to the hospital for both accesses placed during the same hospitalization, when one of the procedures is creation of an AV fistula. This incentive will discourage delays in permanent access placement (AV fistula) among hemodialysis patients, by avoiding scheduling of the fistula placement to a date later than that of catheter placement.

- For incident hemodialysis patients, we recommend an additional incentive payment to surgeons for any AV fistula that is used for hemodialysis within 4 months of its creation.

- For patients who initiate hemodialysis urgently in the hospital, we recommend an expanded DRG reimbursement to allow for prolonging the hospitalization to accommodate surgery for placement of an AV fistula, AV graft, or peritoneal dialysis catheter.

3) Increased involvement of the ESRD Networks in facilitating decreased catheter use

- The C-TEP recommends that CMS involve the Dialysis Networks in promoting an initiative to decrease catheter use ("Catheter Last") by providing regular feedback and specific advice on achieving this goal. The Networks can play a role in the consolidation of this initiative with the Fistula First program, promoting the alignment of incentives and goals and, in an individualized approach, adapting strategies that have been successful elsewhere to dialysis facilities that may be having greater difficulty.

Lastly, Dr. Allon noted that given the extensive factors that are not modifiable by the dialysis unit or the physicians, the C-TEP strongly believes that this initiative should not be tied to reimbursement to the dialysis units or nephrologists.

Recommendations for Clinical Practice for Reducing Catheters

Although there was consensus among C-TEP members that dialysis units should strive to reduce catheter use to levels as low as possible in view of the strong relationship between catheter use and mortality, the C-TEP felt uncomfortable in setting a target for catheter use. Below are recommendations made by the C-TEP for reducing catheter use in the clinical setting:

1. Catheters last- consider graft in high risk patients on HD after a failed fistula rather than placement of a catheter

2. Consider peritoneal dialysis as an option to HD catheter use in new HD pts if dialysis initiation is required and there has been insufficient time for creation and maturation of an arteriovenous fistula or graft

3. If patient is an urgent start, consider a graft with subsequent conversion to fistula (avoid catheter use)

4. Evaluate fistulas for maturation within 4-6 weeks and every two weeks thereafter, with appropriate referral for diagnostic tests or surgical consultation if failing to mature.

Recommendations for Clinical Practice for Reducing Catheter Related Bacteremia in Catheter Patients

Below are suggestions made by the C-TEP for reducing catheter related bacteremia in catheter patients in the clinical setting:

1. Enhance patient and staff education regarding access care – Include education on proper documentation of vascular access infections including the use of specific ICD-9 codes for catheter-related bacteremia and sepsis (e.g., 996.62, 999.31, V8 modifier, etc).
2. Infection control HD precautions
3. Use of chlorhexidine for exit site and hubs as long as it is not contraindicated by catheter manufacturer
4. Use of polysporin at exit sites if not contraindicated by catheter manufacturer
5. Consider use of prophylactic antimicrobial (but not antibiotic) lock solutions— None are currently approved by the FDA but we recommend that the definition of catheter-related bacteremia as currently described by the panel be adopted by DHHS (includes CMS/CDC/FDA etc.) as a special case for the hemodialysis population to facilitate uniformity in clinical trials and comparative effectiveness research.
6. Increase the availability of ESRD Network support for providing consultations to dialysis units, particularly for facilities having high rates of vascular access infection

- ***D-TEP Recommendations***

Vascular Access Infection proposed measures were not discussed individually by the Data TEP. The data collection form was reviewed. The D-TEP felt that the information required on the form presented a substantial data collection burden regardless of LDO or non LDO and needed to be simplified. The D-TEP agreed upon revisions to the data elements that would be collected to assess vascular access infections. The new data elements would include:

#1: Was patient started on antibiotics during the month?

-This would be used to define patients with any known infection.

#2: If yes to #1, was there a positive blood culture?

#3: If yes to #1, was the infection access-related?

-Items 2 and 3 allow classification of the infections in a 2x2 matrix

Other concerns raised regarding the vascular access infection measures:

Determining if an infection is attributable to a vascular access is not always possible. Also, many patients have more than one access in place, and deciding which access is the cause of infection can be difficult. These data would be based on clinician opinion.

Facilities can reliably report if a patient is on IV antibiotics, but may not consistently report whether a patient is on oral antibiotics. When a facility is not administering a medication, it is hard to track.

Many infections are not within the facility's sphere of influence.

Dates of hospital admission are hard to obtain, unless the facility sends the patient to the hospital.

Prescription of antibiotics is a somewhat subjective indicator of infection; some physicians are more likely to prescribe than others.

- *D-TEP General Discussion/Recommendations*

The D-TEP discussed the proposed CPMs individually. However, during those discussions several issues were raised that were more widely applicable, and are described below:

  - Definitions for what constitutes an in center patient needs to be standardized across all measures. When modality is an issue (in-center HD, PD, HHD) make sure that definitions and calculations clearly identify modalities included and excluded
  - The D-TEP suggested that facilities should be able to access a list of qualifying and non-qualifying patients for each measure for use in quality improvement activities.
  - The D-TEP recommended excluding transient patients from all measures.
  - D-TEP members would like to see revisions to measures language prior to finalization.

- ***C-TEP Response to D-TEP Recommendations***

A series of emails were exchanged among the C-TEP members after receiving the D-TEP recommendations. A summary of the changes that the C-TEP members agreed to in response to the D-TEP recommendations and provided as part of a joint teleconference held on June 22, 2010 are below.

Changes from the proposed data collection form reviewed by D-TEP in April, 2010:

(1) Have deleted the collection of "oral" antibiotic therapy.
(2) Have deleted question whether patient had a new suspected infection this month.
(3) No longer requesting the date the infection was clinically established.
(4) No longer requesting information regarding:
    (a) Symptoms of clinical sepsis [e.g. fever (>38 ˚C), rigors, blood pressure drop or altered mental status] □ Yes □ No
    (b) Soft tissue infection (pus or exudate and 2 of: redness, pain, swelling) □Yes □No

Other Discussion Points:

- views/feasibility of collecting information regarding type of organism causing infection
- estimate of what % of hospitalized patients for whom admission diagnosis is not captured and date of hospital admission is not captured
- estimate of what % of patients for whom a blood specimen is drawn for infection evaluation for whom results of blood cultures are not available in patient records by end of following month
- The intention of the first question was to limit the data collection to patients who potentially ***may have*** a serious infection as suggested by the action of the physician to prescribe intravenous antibiotics for the patient. However, the presence of an infection may not become manifested in all patients prescribed an IV antibiotic, which is the purpose of question #2 to help discriminate between cases in which an infection was confirmed versus those in which an infection was not confirmed, realizing there will be some subjectivity in this latter determination depending on patient symptoms, blood culture results, etc. However, there is a possibility that could result in over-counting the number of infections, in the case when a patient initiates a new IV antibiotic therapy near the end of 1 month for a suspected infection, and then after positive blood culture results come back in the early part of the next month, the patient is switched to a different IV antibiotic which may be more effective for treating the infection. With the current wording of question #1, one may answer "Yes" for each month since this would be consistent with a patient initiating a new IV antibiotic therapy even though the patient has had only one infection. Question #1 could potentially be modified to indicate:
  "**Did this patient initiate a new intravenous (IV) antibiotic therapy this month? Yes/No**
  "Did the patient have a new suspected infection? this month?" Yes/No.

  If answer is "Yes" to both questions then proceed to remaining questions.

▪ *C-TEP and D-TEP Teleconference*

A teleconference with members of the C-TEP and the D-TEP was held on June 22, 2010 in which nearly all TEP members were able to participate. Below is a list of key points discussed during the teleconference and versions of the data collection form before and after the conference.

Key Points discussed during Teleconference

(numbers and letters below correlate with data collection sheet emailed by Dr. Ron Pisoni on 6/21/10)

1. Revision of Question A to "initiation of new IV antibiotics."

In the originally proposed data collection for the dialysis access-related infection measures, the first question was: "Did this patient have a NEW suspected infection during this month" which was to be answered for each patient. To allow data collection for the new hemodialysis vascular access-related infection measures to be less burdensome, with greater reliability, and greater uniformity in reporting, a revision of the first question from: "did patient have a new suspected infection" to "did

patient start new IV antibiotics" was discussed. The rationale for the revision was that any patient who is started on a new IV antibiotic therapy is suspected of having an infection. Moreover, the series of subsequent questions would be triggered only for patients with a new IV antibiotic start during the month. Furthermore, the old question "did the patient have a new suspected infection" during the reporting month was felt to require physician input in order to answer the question. Obtaining this type of physician input was viewed by some D-TEP members to be difficult with great variability across facilities in the extent to which reporting would be uniform and reliable, and it would take considerable effort to obtain this type of reporting by physicians at each dialysis unit. Consequently, there were strong recommendations by D-TEP members to replace the question regarding suspected infection with the question as to whether a patient initiated IV antibiotic therapy for a newly suspected infection during the month. There was some concern about missing less serious infections because the revised question only includes IV antibiotics and not oral. Other panel members responded that capturing IV antibiotic starts would cover most serious infections. Several panel members commented that the revised question allows facility staff to answer the question using currently available data instead of requiring physician input for each patient in the unit resulting in significantly less data burden for the facility staff.

2. Data collection burden vs. importance of questions requiring physician input: clinical confirmation of infection (B) and is infection related to dialysis access (3).

Numerous concerns were raised by panel members regarding infections that might be incorrectly identified by measures based only upon antibiotic start and blood culture data. For example, a subset of patients is started on IV antibiotics and later a decision is made that they don't have an infection. There was concern that if the extra step of physician confirmation is not taken, antibiotics would be equated with infection and result in overestimating infection rates. Some members responded that blood culture results from the lab would clarify the presence of infection but others disagreed that you could have an infection with a negative blood culture result. Others said that if a patient ended up not having an infection, the physician stops antibiotic use and that information would be readily available for use in a confirmation of infection decision. Another related issue is that some infections are not access-related. For example, a patient with pneumonia may have negative blood cultures and the infection is not related to the dialysis access. Cases similar to this can't strictly be distinguished simply by blood culture results advocating for the necessity for physician input regarding clinical confirmation of the infection and whether the cause of the infection was related to the dialysis access.

Several other examples of the importance of a critical assessment of patients by physicians were given. Some people stated that physician input data on infection are required and collected in most dialysis units for Quality Improvement programs. However, other panel members indicated that physician reporting of infection status and physician reporting of whether an infection was associated with the dialysis access would be highly variable across different dialysis units, and would require substantial efforts to develop a systematic approach to obtain this input in a uniform and reliable manner. Furthermore, a concern was voiced that small facilities manually enter over 250

data elements into CROWNWeb each month and adding data elements will require more work for them compared to LDOs that submit CROWNWeb data electronically. However, other panel members indicated that most of the questions being proposed for the current dialysis access-related infection measures would only need to be completed for a small percentage of facility patients each month, i.e. only for those patients having a new IV antibiotic start (implying that the additional work burden would not be large). The question was raised whether statistics were available regarding the number of new IV antibiotic starts expected in a month. Arbor Research/UM-KECC has offered to look at CMS claims data to provide an indication of number of new IV antibiotic starts in a monthly time period. However, in the mean time, the Klevens et al. paper [59] has indicated the following values for the 10th, 25th, 50th, 75th, and 90th percentiles of the distribution of number of new IV antibiotic starts per month for HD patients using a cuffed, tunneled catheter at 32 facilities participating in the CDC's National Healthcare Safety Network program: 0, 2.2, 4.8, 10.5, and 12.8 IV antibiotic starts per 100 patient months. The number of IV antibiotic starts per month for patients dialyzing with an AV graft or AV fistula was approximately one-third of the values seen for catheter patients. When one considers that currenlty 27% of US patients use a catheter, 55% dialyze with an AV fistula, and 18% with an AV graft, then one would expect that in a facility with 100 patients that a median of only 2.5 patients per month would be initiated on a new IV antibiotic, and with facilities in the 90th percentile of the distribution for IV antibiotic starts, only 7 patients per month would be initiated on a new IV antibiotic per month in facilities having 100 patients. Of course, facilities with higher catheter use will have more IV antibiotic starts to report due to the higher rates of infection associated with catheter use. However, that is one main focus area of these measures which is to provide a means to monitor and provide feedback to facilities regarding how a facility's infection rates are related to dialysis access use at the facility. Thus overall, it would appear that the work burden for completing the proposed questions beyond the IV antibiotic start question would be limited to a very small number of patients at each facility.

3. Two Time Limited CPMs result from the addition of "unavailable" to answer choices.

Concerns were expressed about the ability of facilities to design and implement a system to obtain physician input for two questions per month per patient with a new antibiotic start. TEP members provided 3 proposals to address this issue:

- Create a physician level measure using NPI numbers for measuring how often physicians complete the questions. The NPI is a 10-digit, numeric identifier (10 digit number) required for health care providers that remains with the provider regardless of job or location changes.
- Tie the physician input questions to physician or facility payment.
- Add "unavailable" as a response option for the two questions requiring physician input and to create an additional Time-limited process measure that would measure the percentage of "unavailable" at the facility level. If the percentage is high, it would signal that the facility has improvements to make regarding physician reporting concerning the two infection measures requiring physician input [**clinical confirmation of (1) infection, and (2) whether cause of infection was related to dialysis access]**. Several agreed that this would be a good

first step since these are new data elements and it would help facilities to focus on reducing the number of "unavailable". It was suggested to add "unavailable" to the blood culture question as well since it takes some time for results to return from the lab and will require some effort in entering the data into the system. An additional Time Limited process measure would be added for this answer choice as well. In addition, the group proposed that the order of these questions be switched because blood culture results from the lab take some time to return to the facility.

4. Combining the questions that require physician input.

Suggestions were made to reduce the burden related to collecting data requiring physician input. These suggestions were to combine "suspected infection confirmed" and "infection VA-related" into one question. The proposition was made to use the following question and answer choices:

Was the infection related to the dialysis access?

□ No, but infection was confirmed

□ Yes HD- Catheter

□ Yes HD-Arteriovenous FISTULA

□ Yes HD-Arteriovenous GRAFT

□ Yes PD- Catheter (Use of this choice to be evaluated later by PD-specific C-TEP and D-TEP)

□ No: tests/symptoms failed to confirm infection

□ Unavailable

This approach still results in obtaining physician input for answering only one question, typically for only 1 to 5 patients per month for a facility treating 100 patients.

5. Deletion of the hospitalization question (2).

In order to make data collection less burdensome, both C-TEP and D-TEP members who took part in the teleconference approved the decision to remove the hospitalization question. They agreed that it wasn't the initial focus of the measure development task and that claims data could be analyzed for hospitalization information. This decision eliminated three proposed CPMs related to hospitalizations and infection.

6. Summary

Below in this report are the following: the latest version of the data elements as proposed by the C-TEP and D-TEP members to be collected for the dialysis access-related infection measures, and older versions of the data collection form for comparison.

Revision of Proposed Collection Form for Dialysis Access-related

Infection ESRD Measures

(version after C-TEP and D-TEP teleconference 6/22/10)

(A) Did this patient initiate a new intravenous (IV) antibiotic therapy this month for a newly suspected infection? (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

If YES, please answer remaining questions:

(B) Date new IV antibiotic was prescribed:_____

(C) Was the infection related to the dialysis access?

□ No, but infection was confirmed

□ Yes HD- Catheter

□ Yes HD-Arteriovenous FISTULA

□ Yes HD-Arteriovenous GRAFT

□ Yes PD- Catheter (Use of this choice to be evaluated later by PD-specific C-TEP and D-TEP)

□ No: tests/symptoms failed to confirm infection

□ Unavailable

(D) Was the blood culture positive for infection? □ Yes □ No □ Unavailable

OUTDATED Proposed Collection Form for Dialysis Access-related

Infection ESRD Measures

(Old version emailed by Ron Pisoni on 6/21/10 for comparison)

(A) 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

If YES, please answer remaining questions:

Date new IV antibiotic was prescribed:_____

(B) Was the suspected infection confirmed for this patient? □ Yes □ No

If YES, please answer remaining questions:

(1) Was the blood culture positive for infection? □ Yes □ No □ Unavailable
(2) Did the infection require hospital admission? □ Yes □ No
If Yes, date of hospital admission: ___ ___ _____
(mm -dd - yyyy)

(3) Was the infection related to the dialysis access? □ Yes □ No
If Yes, to which access do you attribute this infection?

□ HD- Catheter
□ HD-Arteriovenous FISTULA
□ HD-Arteriovenous GRAFT
□ PD- Catheter (Use of this choice to be evaluated later by PD-specific C-TEP and D- TEP)

Following the distribution of the summary, an email was sent on July 17, 2010 to C-TEP and D-TEP members with data on the facility rate of IV antibiotic starts for 2008:

> We have performed a preliminary analysis of 2008 claims data on number of IV antibiotic prescriptions per month and those data suggest a median of 5% of patients with an IV antibiotic prescription each month (10th and 90th percentiles = 0, 12.5); these preliminary data along with those reported by CDC from their NHSN pilot program (Klevens paper, 32 facilities but not nationally representative) [59] suggest that the questions after our IV antibiotic prescription would have to be completed for only a small fraction of patients at each facility each month.

▪ *Final Reconciliation of C-TEP and D-TEP Comments*

Below are the final versions of the data collection form (data elements will be collected in CROWNWeb), overview of measures, and the proposed measure descriptions as a result of email communication with the C-TEP and D-TEP after the teleconference on 6/22/10.

Revision of Proposed Collection Form for Hemodialysis Access-related Infection ESRD Measures

(version after C-TEP and D-TEP teleconference 6/22/10)

(A) 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

If YES, please provide date of prescription, and answer remaining questions:

Date of IV antibiotic prescription: ____ - ____ - ____ (mm-dd-yy)

Date Unknown □

(B) Were the blood cultures consistent with bacteremia?

□ Yes □ No □ Unavailable □ Not collected

(C) Was the suspected infection clinically confirmed?

□ Yes □ No □ Unavailable

If YES, please answer remaining question:

(D) Was the infection 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

Final List of Proposed Hemodialysis Vascular Access-Related Infection CPMs

Description	Numerator	Denominator	Exclusions
CPM I – Six-Month rolling average rate of initiating IV antibiotic prescription therapy for newly suspected infection among adult chronic HD patients *Express as: rate per 1000 HD patient days*	Number of months that HD patients initiated a new IV antibiotic therapy for a newly suspected infection among adult chronic hemodialysis patients during the six-month period ending with the current reporting month	All adult (age 18+) chronic maintenance HD patient days during the six-month period ending with the current reporting month	HD patients < 18 yrs old
CPM II – Six-Month rolling average prevalence of clinically confirmed infection among HD patients prescribed IV antibiotics *Express as: percentage*	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 clinically confirmed	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	HD patients < 18 yrs old, or not prescribed an IV antibiotic for a newly suspected infection
CPM III – 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*	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 clinically confirmed	All adult (18+) chronic maintenance HD patient days during the six-month period ending with the current reporting month	HD patients < 18 yrs old
CPM IV – Six-Month rolling average rate of bacteremia with IV antibiotic therapy, among adult chronic HD patients *Express as: rate per 1000 HD patient days*	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 cultures were consistent with bacteremia.	All adult (18+) chronic maintenance HD patient days during the six-month period ending with the current reporting month	HD patients < 18 yrs old

Description	Numerator	Denominator	Exclusions
CPM V – Six-Month rolling average prevalence of bacteremia among adult chronicHD patients prescribed IV antibiotics *Express as: percentage*	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 cultures were consistent with bacteremia.	Number of months that adult (18+) chronic maintenance HD patients initiated a new IV antibiotic therapy for a newly suspected infection during the six-month period ending with the current reporting month.	HD patients < 18 yrs old
CPM VI – Six-Month rolling average rate of hemodialysis vascular access-related infection with IV antibiotic therapy among adult chronic HD patients *Express as: rate per 1000 HD patient days*	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 hemodialysis access	All adult (18+) chronic maintenance HD patient days during the six-month period ending with the current reporting month	HD patients < 18 yrs old
CPM VII – Six-Month rolling average prevalence of hemodialysis access-related infection among adult chronic HD patients with a clinically confirmed infection and prescribed IV antibiotics *Express as: percentage*	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 clinically confirmed infection was related to the hemodialysis access	Number of months that adult (18+) chronic maintenance 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.	HD patients < 18 yrs old, or not prescribed an IV antibiotic, or infection not clinically confirmed
CPM XVIII – Six-Month rolling average prevalence of bacteremia among adult chronic HD patients with a hemodialysis access-related infection and prescribed IV antibiotics *Express as: percentage*	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 cultures were consistent with bacteremia and infection was hemodialysis access-related.	Number of months that adult (18+) chronic maintenance 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 hemodialysis access.	HD patients < 18 yrs old, or not prescribed an IV antibiotic, or infection not related to HD access

Description	Numerator	Denominator	Exclusions
CPM IX – Six-Month rolling average prevalence of hemodialysis catheter-related infection among adult chronic HD patients with a HD access-related infection and prescribed IV antibiotics *Express as: percentage*	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 clinically confirmed and related to the catheter used as hemodialysis access.	Number of months that adult (18+) chronic maintenance 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.	HD patients < 18 yrs old, or not prescribed an IV antibiotic, or infection was not related to HD access
CPM X – Six-Month rolling average prevalence of hemodialysis arteriovenous graft-related infection among adult chronic HD patients with a HD access-related infection and prescribed IV antibiotics *Express as: percentage*	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 clinically confirmed and related to the arteriovenous graft used as hemodialysis access.	Number of months that adult (18+) chronic maintenance 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.	HD patients < 18 yrs old, or not prescribed an IV antibiotic, or infection was not related to HD access
CPM XI – Six-Month rolling average prevalence of hemodialysis arteriovenous fistula-related infection among adult chronic HD patients with a HD access-related infection and prescribed IV antibiotics *Express as: percentage*	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 clinically confirmed and related to the arteriovenous fistula used as hemodialysis access.	Number of months that adult (18+) chronic maintenance 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.	HD patients < 18 yrs old, or not prescribed an IV antibiotic, or infection was not related to HD access
CPM XII – Six-Month rolling average rate for access-related infection with IV antibiotic therapy, among adult chronic HD patients using a catheter for hemodialysis access *Express as: rate per 1000 HD catheter days*	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 *catheter* used as hemodialysis access.	Number of HD *catheter* days during the six-month period ending with the current reporting month in adult (18+) chronic maintenance HD patients.	HD patients < 18 yrs old

Description	Numerator	Denominator	Exclusions
CPM XIII – Six-Month rolling average rate for access-related infection with IV antibiotic therapy, among adult chronic HD patients using an arteriovenous graft for hemodialysis access *Express as: rate per 1000 HD arteriovenous graft days*	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 *arteriovenous graft* used as hemodialysis access.	Number of HD *arteriovenous graft* days during the six-month period ending with the current reporting month in adult (18+) chronic maintenance HD patients.	HD patients < 18 yrs old
CPM XIV – Six-Month rolling average rate for access-related infection with IV antibiotic therapy, among adult chronic HD patients using an arteriovenous fistula for hemodialysis access *Express as: rate per 1000 HD arteriovenous fistula days*	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 *arteriovenous fistula* used as hemodialysis access.	Number of HD *arteriovenous fistula* days during the six-month period ending with the current reporting month in adult (18+) chronic maintenance HD patients.	HD patients < 18 yrs old
CPM XV – Six-Month rolling average rate for access-related bacteremia with IV antibiotic therapy, among adult chronic HD patients using a catheter for hemodialysis access *Express as: rate per 1000 HD catheter days*	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 *catheter* used as hemodialysis access, and blood cultures were consistent with bacteremia.	Number of HD *catheter* days during the six-month period ending with the current reporting month in adult (18+) chronic maintenance HD patients.	HD patients < 18 yrs old
CPM XVI – Six-Month rolling average rate for access-related bacteremia with IV antibiotic therapy, among adult chronic HD patients using an arteriovenous graft for hemodialysis access *Express as: rate per 1000 HD arteriovenous graft days*	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 *arteriovenous graft* used as hemodialysis access, and blood cultures were consistent with bacteremia.	Number of HD*arteriovenous graft* days during the six-month period ending with the current reporting month in adult (18+) chronic maintenance HD patients.	HD patients < 18 yrs old

Description	Numerator	Denominator	Exclusions
CPM XVII – Six-Month rolling average rate for access-related bacteremia with IV antibiotic therapy, among adult chronic HD patients using an arteriovenous fistula for hemodialysis access *Express as: rate per 1000 HD arteriovenous fistula days*	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 *arteriovenous fistula* used as hemodialysis access, and blood cultures were consistent with bacteremia.	Number of HD *arteriovenous fistula* days during the six-month period ending with the current reporting month in adult (18+) chronic maintenance HD patients.	HD patients < 18 yrs old
CPM XVIII – Six-Month rolling average prevalence of "unavailable" information regarding clinical confirmation of infection among adult chronic HD patients with new IV antibiotic prescription *Express as: percentage*	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.	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.	HD patients < 18 yrs old, or not prescribed an IV antibiotic
CPM XIX – Six-Month rolling average prevalence of "unavailable" blood culture results for adult chronic HD patients prescribed IV antibiotics *Express as: percentage*	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".	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.	HD patients < 18 yrs old, or not prescribed an IV antibiotic

The target measures below will need to be defined in the future after data is collected. They will be submitted to NQF in a later measure development cycle.

Description	Numerator	Denominator	Exclusions
CPM XX *(to be defined by C-TEP in future)* – Target for CPM VI: six-month rolling average rate of hemodialysis vascular access-related infection with IV antibiotic therapy among adult chronic HD patients *Express as: rate per 1000 HD patient days*	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 hemodialysis access.	All adult (18+) chronic maintenance HD patient days during the six-month period ending with the current reporting month.	HD patients < 18 yrs old
CPM XXI *(to be defined by C-TEP in future)* – Target for CPM XV: six-month rolling average rate for bacteremia among adult chronic HD patients using a catheter for hemodialysis access *Express as: rate per 1000 HD catheter days*	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 *catheter* used as hemodialysis access, and blood cultures were consistent with bacteremia during this time.	Number of HD catheter days during the six-month period ending with the current reporting month in adult (18+) chronic maintenance HD patients.	HD patients < 18 yrs old

3.19 References

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4 Pediatric Hemodialysis Adequacy Clinical Performance Measures

Currently CPMs do not exist for the pediatric age group (<18 years old). Due to the low prevalence of stage 5 CKD among pediatric patients, high transplantation rate, and difficulty of determining measurable study end points, longitudinal studies on pediatric HD adequacy have not been performed. HD adequacy studies among the pediatric population that have been performed are largely observational studies, thus making evidence based measures difficult to establish. Furthermore, existing clinical practice guidelines for the management of pediatric ESRD patients are largely opinion- rather than evidence-based.

The pediatric measures were also framed in the context of the unique aspects of the management of pediatric ESRD patients. Firstly, for adult hemodialysis and peritoneal dialysis patients, outcome measures including mortality and hospitalizations are assessed in the development of quality measures. Among children, however, these outcomes occur less frequently and other outcomes such as linear growth, school performance and attendance, and cognitive development should be considered. Second, many pediatric patients do not have Medicare as primary coverage, making data collection less complete. Additionally, pediatric patients have a wide variation in physiology by age and the requirements for optimal outcome may differ particularly in younger pediatric patients. Finally, the majority of patients below 20 years of age are dialyzed in primarily adult hemodialysis units, and even within pediatric units wherein greater than 50% of patients are of pediatric age, the number of pediatric patients within each unit is small. Indeed, analysis of claims data suggests that the majority of non-pediatric units dialyze one or two patients under the age of 18 years, so that the impact of each patient on a facility-level measure needs to be taken into consideration. Despite this, the C-TEP discussed that in these primarily adult units, even greater attention should be provided to the one or two pediatric patients who are treated. Furthermore, the C-TEP agreed that the pediatric hemodialysis adequacy measures should not be stratified by number of pediatric patients, and exclusions should be avoided when possible.

Prior to discussing specific pediatric HD adequacy measures, the TEP members agreed that since CPMs for pediatric patients currently do not exist, measures should be developed even if they are based on preliminary or limited available data. Furthermore, the TEP agreed the initial pediatric targets should be set to ensure delivery of at least the minimum required care for this population if not optimal care. In addition, these adequacy targets should be no lower than existing adult hemodialysis targets since generally, pediatric patients' greater metabolic demands require higher hemodialysis adequacy targets in terms of small solute clearance. It is the intent that over time the initial measures will be improved, and additional targets established, resulting in improved quality of care for pediatric patients.

Summary of Quality Measures Recommended for Pediatric Hemodialysis Adequacy

Description	Numerator	Denominator	Exclusions
Percentage of all pediatric (<18 years) patients receiving in-center hemodialysis (irrespective of frequency of dialysis) with documented monthly adequacy measurements	Number of patients in the denominator with monthly adequacy measurements	Number of pediatric patients (<18 years) receiving in-center hemodialysis (irrespective of frequency of dialysis	Patients on home dialysis
Percentage of pediatric <18 years) in-center hemodialysis 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	Number of patients in the denominator for whom delivered HD dose was measured by spKt/V as calculated using UKM or Daugirdas II during the reporting period	Number of pediatric patients (<18 years) receiving in-center hemodialysis (irrespective of frequency of dialysis	Patients on home dialysis
Percentage of pediatric (<18 years) in-center hemodialysis patients who have been on dialysis for 90 days or longer and dialyzing 3 or 4 times weekly who received a delivered hemodialysis dose (spKt/V) of at least 1.2 during the reporting period	Number of patients in the denominator who received a delivered hemodialysis dose (spKt/V) of at least 1.2 during the reporting period	Number of pediatric patients <18 years receiving in-center hemodialysis 3 or 4 times weekly	Patients on home hemodialysis, patients receiving dialysis 2x/week and patients receiving dialysis 5x or greater/week

Description	Numerator	Denominator	Exclusions
Percentage of all pediatric (<18 years) in-center hemodialysis patients (irrespective of frequency of dialysis) with documented monthly nPCR adequacy measurements	Number of patients in the denominator with documented monthly nPCR measurements	Number of all pediatric (<18 years) in-center hemodialysis patients (irrespective of frequency of dialysis) with documented monthly nPCR measurements	Patients on home dialysis

4.1 CPM I – Frequency of HD Adequacy Measurement

Percentage of pediatric patients <18 years old receiving in-center hemodialysis (irrespective of frequency of dialysis) with documented monthly adequacy measurements.

Denominator: Number of patients <18 years old receiving in-center hemodialysis (irrespective of frequency of dialysis)

Numerator: Number of patients in the denominator with documented monthly adequacy measurements

Exclusions: Patients on home HD

Importance

The incidence and prevalence rates of pediatric ESRD continue to increase with 7209 pediatric patients with ESRD in 2007 [1]. Although the majority of these patients are managed with kidney transplantation, approximately 2000 pediatric patients receive maintenance dialysis. Data also reveal that the five-year survival among pediatric patients receiving maintenance dialysis has not improved [1], demonstrating the need to improve the quality of dialysis care in this fragile patient group, particularly since no dialysis quality measures have been in place for the pediatric ESRD population. Finally, improving patient outcomes in pediatric patients is a priority particularly since the cost of care for a pediatric ESRD patient is markedly higher than for an adult patient [2].

The dose of dialysis is used to estimate the ability of hemodialysis to clear the blood of accumulated toxins. In the adult population, outcome studies have shown an association between dose of hemodialysis in terms of small solute removal and clinical outcomes [3,4]. No equivalent large scale clinical trials have been conducted in the pediatric hemodialysis population but smaller scale observational studies support the association between delivered hemodialysis dose and patient outcomes [5] including the potential for improved growth with intensive HD regimens [6,7].

Prior studies have used a monthly interval of measurement of hemodialysis dose [3,4]. Furthermore, since pediatric patients are in a growth phase, a minimum of monthly evaluation of HD adequacy is critical to ensure timely dose adjustment as needed. The C-TEP discussed the possibility of more frequent monitoring of HD dose but concluded that there is insufficient evidence to suggest that pediatric patients would benefit from being monitored more than once per month.

Currently there is variation in the frequency of measurement of hemodialysis adequacy among the pediatric population. Analysis of CPM data demonstrate that during the 3 month study period, dialysis adequacy using spKt/V was not measured at any time in 20% of pediatric patients. For all of these reasons, the C-TEP believed that monthly measurement of HD adequacy is an important measure in the pediatric population.

Scientific Acceptability

The measure specification is well defined and the required data elements are of high quality as defined in the measure evaluation tool. Reliability and validation studies for this measure have not been conducted in the pediatric population. However, a similar measure was evaluated as part of the adult measures on dialysis adequacy, vascular access, anemia management, serum albumin, mineral metabolism and other data elements such as ethnicity. This ESRD CPM Reliability Report is a validation study that evaluates the concurrence between facility-abstract data and Network re-abstracted data. For more information on this report, please see link below:

http://www.cms.hhs.gov/CPMProject/Downloads/ESRD2006ReliabilityReport.pdf

This measure does not require risk adjustment. The measure excludes patients on home hemodialysis since measurement of adequacy has not been adequately studied in this population.

Usability

Dialysis adequacy measurement in the adult population has been demonstrated to inform quality improvement programs as it has been a part of the CMS' CPM project as well as the Dialysis Facility Reports. There is no reason to believe that this would be any different for the pediatric population. This measure is in harmony with other related measures.

Feasibility

Data are readily available since dialysis adequacy (spKt/V) is a required data element for CROWNWeb. There are no potential barriers to retrieving data necessary for this measure, and there are no data availability issues.

Data TEP Recommendations

The D-TEP suggested that if urea reduction ratio (URR) doesn't count, then change measure description to specify 'Kt/V' adequacy measurements.

The D-TEP also suggested that the C-TEP should use identical language as current adult CPM and replace 'adult' with 'pediatric'.

- ***C-TEP Response to D-TEP Recommendations***

The C-TEP agreed that the use of spKt/V should be specified in this measure specification. The C-TEP also agreed to include 'spKt/V or its components' to the measure definition, thus harmonizing this measure with the adult HD adequacy CPM I.

The measure definition was changed to the following:

Percentage of all pediatric (<18 years old) patients receiving in-center hemodialysis (irrespective of frequency of dialysis) with documented monthly adequacy measurements (spKt/V) or its components in the calendar month

Denominator: Number of pediatric (<18 years old) patients receiving in-center hemodialysis (irrespective of frequency of dialysis) who are in the facility and on hemodialysis for the entire study period

Numerator: Number of patients in the denominator with documented monthly (spKt/V) adequacy measurements or its components in the calendar month

Exclusions: Patients on home dialysis, patients who are not in the facility for the entire one-month study period

- ***D-TEP Response to C-TEP Response***

The D-TEP had no objections to the C-TEP revisions.

4.2 CPM II – Method of Hemodialysis Adequacy Measurement

Percentage of pediatric (<18 years) in-center hemodialysis patients (irrespective of frequency of dialysis) for whom delivered hemodialysis dose was measured by spKt/V as calculated using urea kinetic monitoring (UKM) or Daugirdas II during the reporting period.

Denominator: Number of patients <18 years receiving in-center hemodialysis (irrespective of frequency of dialysis)

Numerator: Number of patients in the denominator for whom delivered hemodialysis dose was measured by spKt/V as calculated using UKM or Daugirdas II during the reporting period

Exclusions: Patients on home hemodialysis

Importance

Urea clearance estimated as Kt/V is currently the standard of measurement of dialysis dose [8]**.** Although Kt/V does not represent clearance of all uremic toxins, it has been used as the index of dialysis dose in prospective randomized controlled studies [3,9].

The C-TEP considered various methods for estimating urea clearance (Kt/V). Firstly, the second generation natural logarithmic (Daugirdas II formula) has been shown to approximate Kt/V obtained from formal urea kinetic modeling [10-12]. In addition, data from a single-center pediatric study showed that calculation of spKt/V using urea kinetic monitoring (UKM) or Daugirdas II was reliable [13]. The use of an equilibrated two-compartment model eKt/V was also evaluated. The C-TEP considered that although eKt/V has some advantage over spKt/V in that it takes into account urea rebound, data suggest a low rate of spKt/V and eKt/V discordance (defined as spKt/V > 0.2 higher than eKt/V) [14]. The use of standardized Kt/V was considered but not accepted by the C-TEP due to potential difficulty in interpreting this metric as it is currently not widely used in patients receiving less than five times weekly hemodialysis. Surface area normalized Kt/V [15] was also discussed but not included in the measure because this has not been studied in the pediatric population, and the implications of its use including the need for more frequent and intensified dialysis may not be feasible. Finally, the use of spKt/V as calculated using formal urea kinetic modeling or the Daugirdas II formula is consistent with clinical practice guidelines in the pediatric population, as well as with the clinical performance measures in the adult population.

Scientific Acceptability

The measure specification is well defined and the required data elements are of high quality as defined in the measure evaluation tool. Reliability and validation studies for this measure have not been conducted in the pediatric population. However, a similar measure was evaluated as part of the adult measures on dialysis adequacy, vascular access, anemia management, serum albumin, mineral metabolism and other data elements such as ethnicity. This ESRD CPM Reliability Report is a validation study that evaluates the concurrence between facility-abstract data and Network re-abstracted data. For more information on this report, please see link below:

http://www.cms.hhs.gov/CPMProject/Downloads/ESRD2006ReliabilityReport.pdf

This measure does not require risk adjustment. The measure excludes patients on home hemodialysis since measurement of adequacy has not been adequately studied in this population.

Usability

Dialysis adequacy measurement in the adult population has been demonstrated to inform quality improvement programs as it has been a part of the CMS' CPM project as well as the Dialysis Facility Reports. There is no reason to believe that this would be any different for the pediatric population. This measure is in harmony with other related measures.

Feasibility

Data are readily available since dialysis adequacy (spKt/V) is a required data element for CROWNWeb. There are no potential barriers to retrieving data necessary for this measure, and there are no data availability issues.

Data TEP Recommendation

The D-TEP suggested that the C-TEP should use identical language as current adult CPM and replace 'adult' with 'pediatric'.

- ***C-TEP Response to D-TEP Recommendations***

The D-TEP proposes using identical language as the current adult CPM. However, the current adult CPM limits the measure only to patients in "whom the frequency of HD per week is specified" thus excluding patients in whom facilities fail to specify frequency of HD sessions or if the data regarding this is missing. The C-TEP felt it was important to apply this measure to all pediatric in-center HD patients regardless of whether the dialysis facility specified the frequency of HD sessions or not.

The measure description has been modified to the following:

Percentage of all pediatric (<18 years old) in-center HD patients (irrespective of frequency of dialysis) for whom delivered HD dose was calculated using UKM or Daugirdas II during the reporting period

Denominator: Number of pediatric (<18 years old) in-center HD patients (irrespective of frequency of dialysis) in the sample for analysis

Numerator: 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

Exclusions: Patients on home dialysis, patients not on HD for the entire one-month study period.

- ***D-TEP Response to C-TEP Response***

The D-TEP had no objections to the C-TEP revisions.

4.3 CPM III- Minimum Target spKt/V

Percentage of pediatric (<18 years) in-center hemodialysis patients who have been on dialysis for 90 days or longer and dialyzing 3 or 4 times weekly who received a delivered hemodialysis dose (spKt/V) of at least 1.2 during the reported period

Denominator: Number of patients <18 years receiving in-center hemodialysis 3 or 4 times weekly

Numerator: Number of patients in the denominator who received a delivered hemodialysis dose (spKt/V) of at least 1.2 during the reporting period

Exclusions: Patients on home hemodialysis, patients receiving dialysis either less than 3x/week or greater than 4x/week, transient hemodialysis patients

Importance

In the adult population, outcome studies have shown an association between dose of hemodialysis and clinical outcomes [3,4]. No equivalent large scale clinical trials have been conducted in the pediatric population but smaller scale observational studies support the association between delivered dialysis dose and patient outcomes [5] including the potential for improved growth with intensive hemodialysis regimens [6]. In considering target spKt/V, the C-TEP believed that the pediatric population should receive at least an spKt/V of 1.2, which is the minimum requirement for the adult population in order to allow for the increased nutritional needs of children. Analysis of CPM data further support this cut-off since adolescents with spKt/V below 1.2 were found to have significantly increased risk of hospitalization as compared to those with spKt/V of 1.2-1.4 [5]. The C-TEP evaluated whether a higher target Kt/V may be necessary in the pediatric population given the increased dietary needs to ensure growth.

However, there is insufficient evidence to support increasing target Kt/V based on hospitalization rates and mortality, although the C-TEP wishes to state that there is evidence that increasing target Kt/V may improve growth in pediatric dialysis patients [6]. Furthermore, a proportion of pediatric patients receive a dialysis dose below the target adult spKt/V suggesting that even with this target, there is room for improvement in quality of care.

This proposed measure differs from the corresponding adult adequacy measure in that the measure applies to patients receiving four dialysis treatments a week. Analysis of 2007 claims data suggest that in 5.6% of patient-weeks, dialysis sessions occurred four times per week. Given that this is not an insignificant proportion, the C-TEP concluded that these patients should be included in this measure.

As seen in Table 1, there were three or four dialysis sessions in approximately 88% of patient-weeks. Based on these results, the TEP concluded that by defining the denominator as hemodialysis patients receiving dialysis three or four times weekly, the measure will be applicable to most pediatric hemodialysis patients. 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 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. 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.

Table 1. Dialysis sessions per patient week among all HD pediatric patients < 20 years old

Sessions per Week	Number of Patient-Weeks	Percent
1	211	2.6
2	614	7.5
3	6712	82.2
4	533	6.5
5	60	0.7
6	36	0.4
7	3	0.04

N=312 patients with first Medicare dialysis claim on or before January 1, 2007

Scientific Acceptability

The measure specification is well defined and the required data elements are of high quality as defined in the measure evaluation tool. Reproducibility of spKt/V was found to be high in a published study [16]. Additionally, a similar measure was evaluated as part of the adult measures on dialysis adequacy, vascular access, anemia management, serum albumin, mineral metabolism and other data elements such as ethnicity. This ESRD CPM Reliability Report is a validation study that evaluates the concurrence between facility-abstract data and Network re-abstracted data. For more information on this report, please see link below:

http://www.cms.hhs.gov/CPMProject/Downloads/ESRD2006ReliabilityReport.pdf

This measure does not require risk adjustment. The measure excludes patients on home hemodialysis since measurement of adequacy has not been adequately studied in this population. Other exclusions are based on evidence and are clinically appropriate.

Usability

Dialysis adequacy measurement in the adult population has been demonstrated to inform quality improvement programs as it has been a part of the CMS CPM project as well as the Dialysis Facility Reports. There is no reason to believe that this would be any different for the pediatric population. This measure is in harmony with other related measures.

Feasibility

Data are readily available since dialysis adequacy (spKt/V) is a required data element for CROWNWeb. There are no potential barriers to retrieving data necessary for this measure, and there are no data availability issues.

Data TEP Recommendations

The D-TEP suggested that the C-TEP- use identical language as current adult CPM and replace 'adult' with 'pediatric', except for frequency of dialysis sessions.

The D-TEP also suggested that the C-TEP change the wording of frequency of dialysis sessions to be 'dialyzing three to four times weekly' to capture patients dialyzing every other day (3.5 sessions per week).

An additional recommend included that all elements for calculating the Kt/V be collected in CROWNWeb and value be calculated by system so methodology is uniform.

D-TEP suggested to add residual renal function so that can be included in calculation of adequacy.

- ***C-TEP Response to D-TEP Recommendations***

The C-TEP believes it is more appropriate to maintain the current wording of 3 or 4 times/week dialysis rather than "every other day (3.5 sessions per week)" as proposed by the D-TEP, since patients do not generally receive hemodialysis treatments every other day. By stating 3 or 4 days in the measure description and adding 'patients receiving dialysis every other day' to the inclusion criteria, this will ensure that all intended patients are included in the denominator.

With regards to the incorporation of residual renal function in the calculation of adequacy, the C-TEP does not agree that residual renal function (RRF) should be added to the measure description for several reasons: 1) Published studies evaluating dialysis adequacy in the pediatric population do not include residual renal function, 2) RRF changes continuously with age in the pediatric population and 3) RRF is difficult to measure among pediatric patients.

With regards to the use of identical language as the current adult CPM, the C-TEP agreed that the addition of the modifier "calculated from the last measurements of the month using UKM or Daugirdas II formula" was appropriate. The measure description was modified as follows:

Percentage of all pediatric (<18 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/V>= 1.2 during the reporting period

Denominator: Number of pediatric (<18 years old) in-center HD patients who have been on hemodialysis for 90 days or more and dialyzing 3 or 4 times weekly.

Numerator: 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/V>=1.2

Exclusions: Patients on home hemodialysis, patients on HD less than 3x/week or greater than 4x/week, patients on HD<90 days, patients who are not in the facility for the entire one-month study period

- ***D-TEP Response to C-TEP Response***

The D-TEP had no objections to the C-TEP revisions.

4.4 CPM IV- Measurement of nPCR

Percentage of pediatric (<18 years) in-center hemodialysis patients (irrespective of frequency of dialysis) with documented monthly nPCR measurements

Denominator: Number of patients <18 years receiving in-center hemodialysis (irrespective of frequency of dialysis)

Numerator: Number of patients in the denominator with documented monthly nPCR measurements

Exclusions: Patients on home hemodialysis

Importance

In the pediatric population, the assessment of dialysis adequacy requires an evaluation of both small solute clearance and nutritional status [8,17]. This is because both adequate solute clearance and nutrition are essential for growth and visceral weight gain. Whereas there are several potential measures of nutritional status, these are outside the scope of hemodialysis adequacy measures with the exception of nPCR (normalized protein catabolic rate), a value that is a fundamental component of and already readily available from urea kinetics. This allows the use of nPCR along with spKt/V as measures of dialysis adequacy.

nPCR provides an estimate of dietary protein intake and has been shown to provide additional information to spKt/V. In malnourished adolescent patients who achieved target spKt/V levels, nPCR, but not serum albumin, was associated with nutritional status [18,19]. In adolescent patients, nPCR levels < 1 gram/kg/day were found to be an earlier and more sensitive marker than serum albumin levels in predicting malnutrition and sustained weight loss [20]. There is currently no evidence that supports specific nPCR targets, although age-specific protein intake targets exist.

Scientific Acceptability

The measure specification is well defined and the required data elements are of high quality as defined in the measure evaluation tool. Reliability and validation studies for this measure have not been conducted in the pediatric population. However, since calculation of nPCR uses data elements used for urea kinetics, its reliability should estimate that of spKt/V.

Usability

nPCR measurements in the pediatric population may inform quality improvement programs. However, actual interpretation of nPCR values may be less straightforward in younger age groups.

Feasibility

Although this measure is not currently is use, the panel agrees it can be implemented with minimal difficulty, since nPCR is readily available from urea kinetics.

Data TEP Recommendations

The D-TEP recommend adding data element 'number of days between dialysis sessions' instead of 'interdialytic time', and removing data elements nPCR and Date nPCR Collected.

They also recommend that all elements for calculating the nPCR be collected in CROWNWeb and value be calculated by system so methodology is uniform.

- ***C-TEP Response to D-TEP Recommendations***

The C-TEP does not agree with the replacement of 'interdialytic time' with 'number of days between dialysis sessions'. In order to calculate nPCR using the modified Borah equation [21], the time from the end of the last session to the beginning of the next session is needed and is indicated as hours or minutes. Days between sessions would yield less accurate calculations of nPCR. Furthermore, the C-TEP believes it is important to capture the data element nPCR in CROWNWeb and not exclude this as suggested by the D-TEP. By requiring a facility to report actual nPCR values, attentiveness to nPCR values by the clinical team will be increased.

The measure description was not modified from the initial description and is as follows:

Percentage of pediatric (<18 years) in-center HD patients (irrespective of frequency of dialysis) with documented monthly nPCR measurements

Denominator: Number of pediatric patients (<18 years) receiving in-center hemodialysis (irrespective of frequency of dialysis) in the sample for analyses

Numerator: Number of patients in the denominator with documented monthly nPCR measurements

Exclusions: Patients on home hemodialysis, patients who are not in the facility for the entire one-month study period

- ***D-TEP Response to C-TEP Response***

The D-TEP had no objections to the C-TEP revisions.

4.5 Data TEP General Discussion/Recommendations

The D-TEP discussed the proposed CPMs individually. However, during those discussions several issues were raised that were more widely applicable, and are described below:

- Definitions for what constitutes an in center patient needs to be standardized across all measures. When modality is an issue (in-center HD, PD, HHD) make sure that definitions and calculations clearly identify modalities included and excluded.
- Where measures are process measures (i.e., was a test done) then requiring the actual dose of drug administered or biochemical value is not required.
- The D-TEP recommends that all clinical values be accepted in CROWNWeb by removing limitations on the ranges of values accepted in the system. They felt that it would be preferable to allow all data to be submitted, and any necessary cleaning of the data could be performed in the system.
- The D-TEP also felt it would be preferable to have all data accepted into CROWNWeb, not just the last values of the month.
- For all measures with a laboratory value, the D-TEP recommends including a data element indicating the laboratory that performed the analysis, with a drop-down list of the largest 9-10 labs + other, with a facility default auto-populated. This was the recommendation to address concerns over variability of laboratory measurements, which was discussed with respect to hemoglobin, ferritin and transferrin saturation (TSAT). For certain measurements, accuracy of measurements is not well defined, and the total analytical error that is allowed is quite large. D-TEP members agreed that better standards need to be developed for these analytes, and while this is not the responsibility of the dialysis facilities, there is concern that facilities are treating patients based on these data.
- The D-TEP suggested that facilities should be able to access a list of qualifying and non-qualifying patients for each measure for use in quality improvement activities.
- The D-TEP recommended including significant digits to the hundredths for lab values (currently only to tenths) to allow for future improvements in lab precision. If that level of detail is not needed for the measures, the rounding off could occur in the system, rather than at entry.
- The D-TEP recommended excluding transient patients from all measures.
- Clarify that data element 5.3.3 is Kt/V HD ‘result’ or ‘value’.
- Rename data element 4.8.7 to remove ‘(delivered)’.
- The D-TEP recommended that pediatric measures should be made consistent with existing or proposed adult measures. Some exceptions are justified, but should be kept to a minimum.

- D-TEP members would like to see revisions to measures language prior to finalization.

▪ *C-TEP Responses to D-TEP Recommendations*

The C-TEP agreed to revise the measures to be consistent with the adult measures when possible, but in some instances (as described above), the adult measure specifications were not applicable to the pediatric population. The modality inclusions are stated in all measure specifications (in-center HD patients). Home dialysis patients and patients not in the facility for the entire month are excluded for all pediatric adequacy measures. The table below is a summary of the revised proposed measures for pediatric hemodialysis adequacy.

Revised Summary of Quality Measures Recommended for Pediatric Hemodialysis Adequacy

Description	Numerator	Denominator	Exclusions
Percentage of all pediatric (<18 years old) patients receiving in-center hemodialysis (irrespective of frequency of dialysis) with documented monthly adequacy measurements (spKt/V) or its components in the calendar month	Number of patients in the denominator with documented monthly (spKt/V) adequacy measurements or its components in the calendar month	Number of pediatric patients (<18 years old) receiving in-center hemodialysis (irrespective of frequency of dialysis) who are in the facility and on hemodialysis for the entire study period	Patients on home dialysis, patients not in the facility for the entire one-month study period
Percentage of pediatric (<18 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	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 pediatric (<18 years old) in-center HD patients (irrespective of frequency of dialysis) in the sample for analysis	Patients on home dialysis, patients not on HD for the entire one-month study period
Percentage of all pediatric (<18 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/V>= 1.2	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/V>=1.2	Number of pediatric (<18 years old) in-center HD patients who have been on hemodialysis for 90 days or more and dialyzing 3 or 4 times weekly	Patients on home hemodialysis, patients on HD<90 days, patients receiving dialysis <3x/week or greater than 4x/week, patients not in the facility for the entire one-month study period

Description	Numerator	Denominator	Exclusions
during the reporting period			
Percentage of pediatric (<18 years old) in-center HD patients (irrespective of frequency of dialysis) with documented monthly nPCR measurements	Number of patients in the denominator with documented monthly nPCR measurements	Number of all pediatric (<18 years old) in-center hemodialysis patients (irrespective of frequency of dialysis) with documented monthly nPCR measurements	Patients on home dialysis, patients not in the facility for the entire one-month study period

- ***D-TEP Responses to C-TEP Response***

The D-TEP had no objections to the C-TEP revisions.

4.6 References

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5 Pediatric Anemia Clinical Performance Measures

Currently CPMs do not exist for the pediatric age group (<18 years old). As such, the C-TEP took into consideration the adult anemia CPMs approved by CMS in 2008, and the 2006 pediatric KDOQI guidelines in the development of pediatric anemia measures. The pediatric measures were also framed in the context of the unique aspects of the management of pediatric ESRD patients. Firstly, for adult hemodialysis and peritoneal dialysis patients, outcome measures including mortality and hospitalizations are assessed in the development of quality measures. Among children, however, these outcomes occur less frequently, and other outcomes such as linear growth, school performance and attendance, or cognitive development should be considered. Second, many pediatric patients do not have Medicare as primary coverage, making data collection less complete. Additionally, pediatric patients have a wide variation in physiology by age and requirements for optimal care may differ, particularly in younger pediatric patients. Finally, the majority of patients are dialyzed in primarily adult hemodialysis units, and even within pediatric units wherein greater than 50% of patients are of pediatric age, the number of pediatric patients within each unit is small. Indeed, analysis of claims data suggests that the majority of non-pediatric units dialyze 1 or 2 patients under the age of 18 years, so that the impact of each patient on a facility-level measure needs to be taken into consideration. Despite this, the C-TEP discussed that in these primarily adult units, even greater attention should be provided to the one or two pediatric patients who are treated.

Summary of Quality Measures Recommended for Pediatric Anemia

Description	Numerator	Denominator	Exclusions
Percentage of all pediatric (<18 years) hemodialysis and peritoneal dialysis patients who have monthly measures for hemoglobin	Number of patients in the denominator who have monthly measures for hemoglobin	Number of pediatric (<18 years) hemodialysis and peritoneal dialysis patients	None
Percentage of pediatric patients (<18 years) on hemodialysis or peritoneal dialysis for 90 days or more with a mean hemoglobin<10 g/dL for a 3 month reporting period, irrespective of ESA use	Number of pediatric patients (<18 years) in the denominator with a mean hemoglobin<10 g/dL for a 3 month reporting period, irrespective of ESA use	Number of pediatric patients (<18 years) on hemodialysis or peritoneal dialysis for 90 days or more	None

Description	Numerator	Denominator	Exclusions
Percentage of all pediatric patients (<18 years) on hemodialysis and peritoneal dialysis prescribed an ESA at any time during the reporting period or who have a hemoglobin<11 g/dL in at least one month per quarter for whom serum ferritin concentration and percent transferrin saturation are measured at least once in a three-month period for all hemodialysis and peritoneal dialysis patients	Number of patients in the denominator for whom serum ferritin concentration and percent transferrin saturation are measured at least once in a three-month period for all hemodialysis and peritoneal dialysis patients	Number of pediatric patients (<18 years) on hemodialysis and peritoneal dialysis prescribed an ESA at any time during the reporting period or who have a hemoglobin<11 g/dL in at least one month per quarter	None
Percentage of all pediatric patients (<18 years) on hemodialysis or peritoneal dialysis with hemoglobin<11 g/dL and in whom serum ferritin<100 ng/ml and TSAT<20% who were prescribed iron therapy	Number of pediatric patients (<18 years) on hemodialysis or peritoneal dialysis with hemoglobin<11 g/dL and in whom serum ferritin <100 ng/ml and TSAT<20%	Number of patients in the denominator who were prescribed iron therapy	None

5.1 *CPM I – Hemoglobin Process Measure*

Percentage of all pediatric (<18 years) hemodialysis and peritoneal dialysis patients who have monthly measures for hemoglobin

Denominator: Number of pediatric (<18 years) hemodialysis and peritoneal dialysis patients

Numerator: Number of patients in the denominator who have monthly measures for hemoglobin

Importance

Kidney disease results in a deficiency of erythropoietin, a hormone which stimulates the production of red blood cells, leading to the development of anemia. The presence of anemia in the pediatric population has been associated with increased morbidity and mortality [1,2]. Lower hemoglobin levels have also been associated with cardiovascular disease [3] and quality of life [4].

Additionally, prior studies show a high prevalence of anemia in the pediatric ESRD population [5,6]. Furthermore, analysis of the 2008 CPM project, in which hemoglobin data were collected over a six month period (October 2007 through March 2008), indicated 29% of pediatric ESRD patients had fewer

than three hemoglobin values, with 11% (N=81) missing hemoglobin in all six study months. These suggest the clinical importance of developing a measure that ensures regular monitoring of hemoglobin values.

Scientific Acceptability

The measure specification is well defined and the required data elements are of high quality as defined in the measure evaluation tool. Reliability and validation studies for this measure have not been conducted in the pediatric population. However, a similar measure was evaluated as part of the adult measures on dialysis adequacy, vascular access, anemia management, serum albumin, mineral metabolism and other data elements such as ethnicity. This ESRD CPM Reliability Report is a validation study that evaluates the concurrence between facility-abstract data and Network re-abstracted data. For more information on this report, please see link below:

http://www.cms.hhs.gov/CPMProject/Downloads/ESRD2006ReliabilityReport.pdf

This measure does not have any exclusions and does not require risk adjustment.

Usability

Hemoglobin measurement in the adult population has been demonstrated to inform quality improvement programs as it has been a part of the CMS' CPM project as well as the Dialysis Facility Reports. There is no reason to believe that this would be any different for the pediatric population.

Feasibility

Data are readily available since hemoglobin is a required data element for CROWNWeb. There are no potential barriers to retrieving data necessary for this measure, and there are no data availability issues.

Data TEP Recommendations

The D-TEP noted that Peritoneal Dialysis (PD) patients may not be in clinic monthly and therefore may be less likely to have hemoglobin measured.

They also suggest that the C-TEP clarify that they intended to evaluate the suggested measures for each modality separately.

The D-TEP noted that one month study period is in contrast to other Anemia Management measures which have a three-month study period.

- ***C-TEP Response to D-TEP Recommendations***

The C-TEP notes the D-TEP comment regarding PD patients not being seen in the clinic monthly. Even if this were the case, the C-TEP believes that monthly hemoglobin measurements should be obtained, as blood sample for measurement can be drawn in local clinics.

With regards to the D-TEP comment on separating HD and PD patients in the measure, the C-TEP believes that since monthly hemoglobin measurement is important in both populations, it is not necessary to evaluate patients receiving each modality separately.

The C-TEP believes that maintaining this measure at a frequency of one month does not contradict the other anemia measures. Consistent with adult measures, the other anemia measures will be modified to state that the "end of each reporting month is used for the calculation" which similarly requires a monthly measurement as indicated in this measure. The revised proposed measure description is as follows:

Percentage of all pediatric (<18 years old) hemodialysis patients and peritoneal dialysis patients with ESRD >= 3 months 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.

Denominator: All pediatric (<18 years old) hemodialysis and peritoneal dialysis patients with ESRD >=3 months

Numerator: Number of pediatric (<18 years old) hemodialysis and peritoneal dialysis patients with ESRD >=3 months 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.

Inclusions: Patients receiving in-center hemodialysis, peritoneal dialysis, and home hemodialysis

Exclusions: Patients on dialysis <3 months at the start of the reporting period, patients who are not in the facility for the entire one-month study period

- ***D-TEP Response to C-TEP Response***

The D-TEP had no objections to the C-TEP revisions.

5.2 CPM II – Lower Limit of Hemoglobin

Percentage of pediatric patients (<18 years) on hemodialysis or peritoneal dialysis for 90 days or more with a mean hemoglobin <10 g/dL for a three-month reporting period, irrespective of ESA use

Denominator: Number of pediatric patients (<18 years) on hemodialysis or peritoneal dialysis for 90 days or more

Numerator: Number of pediatric patients (<18 years) in the denominator with a mean hemoglobin <10 g/dL for a three month reporting period, irrespective of ESA use

Importance

The hemoglobin cut-off for this measure was based on the following considerations:

- Recent studies suggest that among CKD pediatric patients, anemia is associated with adverse outcomes including increased mortality risk and hospitalizations [1,2,7]. Staples et al analyzed stage II-V predialysis CKD patients and found that anemic children, defined as hematocrit <33%, were 55% more likely to be hospitalized compared to non-anemic children. Warady and Ho studied pediatric hemodialysis and peritoneal dialysis patients at the initiation of dialysis and showed that 68% of patients were anemic (hematocrit <33%), and that anemia was associated with a 55% increase in mortality risk. Mortality and hospitalization rates among adolescent hemodialysis patients were assessed in the Amaral et al study, and an increased risk of mortality with lower hemoglobin levels was observed. The mortality risk among adolescent hemodialysis patients with Hgb 11-12 g/dL was 70% lower compared to patients with Hgb<10 g/dL. These studies therefore suggest that a hematocrit <33% (approximately equal to Hgb<10 g/dl) is associated with adverse outcomes.

- Because the normal range of hemoglobin levels varies in the pediatric population according to age group and gender, the C-TEP believes that ideally, the definition of anemia should be age- and gender-dependent, with anemia being defined as below 5th percentile for hemoglobin levels in each age and gender category from the National Health and Nutrition Examination Survey (NHANES) III study [8]. This is consistent with the definition of anemia in the pediatric population based on the KDOQI guidelines [9]. However, having an age and gender-specific hemoglobin target will be difficult to implement, and identification of a single lower bound limit is appropriate. Across the NHANES III categories, cut-off levels for the definition of anemia are all above 10 g/dl. Thus, using a cut-off of 10 g/dl is a feasible and achievable target regardless of the pediatric age and gender category.

- The panel discussed whether an upper limit for hemoglobin targets should be developed as a measure. However, there is insufficient evidence to set an upper bound for hemoglobin targets in the pediatric population, and a measure was therefore not developed.

- The NQF endorsed adult anemia measure also uses a hemoglobin lower bound of 10 g/dl. There is no evidence to approach anemia differently in the pediatric population.

For these reasons, the lower bound for hemoglobin targets was defined as 10 g/dl.

Table 1. Hgb Levels (g/dL) in Children Between 1 and 19 years for Initiation of Anemia Workup[a]

All Races/Ethnic Groups	Number of Subjects	Mean	Standard Deviation	Anemia Definition Met if Value is <5th Percentile
BOYS				
1 yr and over	12,623	14.7	1.4	12.1
1-2 yr	931	12	0.8	10.7
3-5 yr	1,281	12.4	0.8	11.2

All Races/Ethnic Groups	Number of Subjects	Mean	Standard Deviation	Anemia Definition Met if Value is <5th Percentile
6-8 yr	709	12.9	0.8	11.5
9-11 yr	773	13.3	0.8	12
12-14 yr	540	14.1	1.1	12.4
15-19 yr	836	15.1	1	13.5
GIRLS				
1 yr and over	13,749	13.2	1.1	11.4
1-2 yr	858	12	0.8	10.8
3-5 yr	1,337	12.4	0.8	11.1
6-8 yr	675	12.8	0.8	11.5
9-11 yr	734	13.1	0.8	11.9
12-14 yr[b]	621	13.3	1	11.7
15-19 yr[b]	920	13.2	1	11.5

[a]Based on NHANES III data, United states, 1988-94

[b]Menstrual losses contribute to lower mean and 5th percentile Hgb values for group

Scientific Acceptability

The measure specification is well defined and the required data elements are of high quality as defined in the measure evaluation tool. Reliability and validation studies for this measure have not been conducted in the pediatric population. However, a similar measure was evaluated as part of the adult measures on dialysis adequacy, vascular access, anemia management, serum albumin, mineral metabolism and other data elements such as ethnicity. This ESRD CPM Reliability Report is a validation study that evaluates the concurrence between facility-abstract data and Network re-abstracted data. For more information on this report, please see link below:

http://www.cms.hhs.gov/CPMProject/Downloads/ESRD2006ReliabilityReport.pdf

This measure does not have any exclusions and does not require risk-adjustment. Consideration was given to the use of this measure on patients with sickle cell anemia. After discussion, the C-TEP believed that the small number of patients affected does not warrant measure exclusion.

Usability

Hemoglobin measurement in the adult population has been demonstrated to inform quality improvement programs as it has been a part of the CMS' CPM project as well as the Dialysis Facility Reports. There is no reason to believe that this would be any different for the pediatric population.

Feasibility

Data are readily available since hemoglobin is a required data element for CROWNWeb. There are no potential barriers to retrieving data necessary for this measure, and there are no data availability issues.

Data TEP Recommendation

The D-TEP suggested that the study period should be consistent with CPM I process measure.

The D-TEP aso suggested that the C-TEP should use identical language as current adult Anemia Management CPM and replace 'adult' with 'pediatric'.

- ***C-TEP Response to D-TEP Recommendations***

The C-TEP does not see an inconsistency in study periods for CPM I and CPM II. This measure uses hemoglobin value from the end of each reporting month, or the monthly hemoglobin values. The revised measure description (see below) uses similar language as the adult AM CPM I, except for the omission of '…and who had Hb values reported for at least 2 of the 3 study months.' Since CPM I requires monthly Hb measurements, this clause is not applicable. Additionally, by specifying the end-of-month Hb value in the measure description, the pediatric measure is harmonized with the adult anemia CPM and takes into account the need for repeating laboratory values for various clinical reasons. The following is the revised measure description:

Percentage of pediatric (<18 years old) hemodialysis and peritoneal dialysis patients, with ESRD >=3 months, who have a mean hemoglobin <10 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.

Denominator: All pediatric (<18 years old) hemodialysis and peritoneal dialysis patients with ESRD >= 3 months

Numerator: Number of pediatric (<18 years old) hemodialysis and peritoneal dialysis patients, with ESRD >= 3 months, who have a mean hemoglobin <10.0 g/dL for a 3 month reporting period, irrespective of ESA use. The hemoglobin value reported for the end of each reporting month (end-of-month hemoglobin) is used for the calculation.

Inclusions: Patients receiving in-center hemodialysis, peritoneal dialysis, and home hemodialysis

Exclusions: Patients on dialysis <3 months at the start of the reporting period, patients who are not in the facility for the entire three-month study period

- ***D-TEP Response to C-TEP Response***

The D-TEP had no objections to the C-TEP revisions.

5.3 CPM III – Anemia Process Measure

Percentage of all pediatric patients (<18 years) on hemodialysis and peritoneal dialysis prescribed an ESA at any time during the reporting period or who have a hemoglobin <11 g/dL in at least one month per quarter for whom serum ferritin concentration and percent transferrin saturation are measured at least once in a three-month period for all hemodialysis and peritoneal dialysis patients.

Denominator: Number of pediatric patients (<18 years) on hemodialysis and peritoneal dialysis prescribed an ESA at any time during the reporting period or who have a hemoglobin <11 g/dL in at least one month per quarter

Numerator: Number of patients in the denominator for whom serum ferritin concentration and percent transferrin saturation are measured at least once in a three-month period for all hemodialysis and peritoneal dialysis patients

Importance

As discussed previously, ESRD leads to a deficiency in the hormone erythyropoietin, resulting in anemia. The use of erythropoiesis-stimulating agents and iron supplementation are effective therapies for correcting anemia in children with ESRD [10,11]. However, erythropoietin therapy will not result in an increase in hemoglobin if iron stores are deficient. As such, assessment of iron stores is important to ensure success of anemia management.

The C-TEP considered a level of hemoglobin of 11 g/dL as the cut-off point for evaluation of iron deficiency. This is based on the aforementioned NHANES III age- and gender-specific definition of anemia in the pediatric age group, where only two age and gender categories had cut-off points below 11g/dL. Furthermore, using 11g/dL instead of 10 g/dL, which was the cut-off used in the Pediatric Anemia CPM II proposed above, allows for the earlier assessment of iron deficiency. Finally, there is no evidence that suggests that pediatric guidelines should differ from the adult population, especially since the corresponding adult measure is fully endorsed by the NQF. The only modification from the adult CPM is that reticulocyte Hgb content is excluded from the recommended assessment of iron stores since this has not been well-studied in the pediatric population [12].

Scientific Acceptability

The measure specification is well defined and the required data elements are of high quality as described in the measure evaluation tool. Reliability and validation studies for this measure have not

been conducted in the pediatric population. Furthermore, the C-TEP discussed considerations in the use of TSAT and serum ferritin to determine iron stores. For instance, TSAT follows a circadian rhythm and serum ferritin, an acute phase reactant, may be increased in response to inflammatory processes. However, a similar measure was evaluated as part of the adult measures on dialysis adequacy, vascular access, anemia management, serum albumin, mineral metabolism and other data elements such as ethnicity. This ESRD CPM Reliability Report is a validation study that evaluates the concurrence between facility-abstract data and Network re-abstracted data. For more information on this report, please see link below:

http://www.cms.hhs.gov/CPMProject/Downloads/ESRD2006ReliabilityReport.pdf

This measure does not have any exclusions and does not require risk-adjustment.

Usability

The TEP agrees that this CPM is meaningful, understandable, and useful for both public reporting and informing quality improvement. Measurement of iron stores in the adult population has been demonstrated to inform quality improvement programs as it has been a part of the CMS' CPM project. There is no reason to believe that this would be any different for the pediatric population. It should be pointed out that the Hgb cut-off for this measure at 11 g/dL differs from the Hgb cut-off for the previously defined Pediatric Anemia CPM II measure. However, similar cut-off points have been used in the adult population and are therefore harmonized.

Feasibility

Data are readily available since hemoglobin, TSAT and serum ferritin levels are required data elements for CROWNWeb. There are no potential barriers to retrieving data necessary for this measure, and there are no data availability issues.

Data TEP Recommendation

The D-TEP suggested that the C-TEP use identical language as current adult Anemia Management CPM and replace 'adult' with 'pediatric'.

The D-TEP does not see need to use data element Date ESA Prescription Changed.

- ***C-TEP Responses to D-TEP Recommendations***

The revised measure proposed by the C-TEP uses similar but not identical language for two reasons: (1) the use of reticulocyte Hb content (CHr) as a measure of iron stores has not been adequately tested in the pediatric population and should be excluded from the measure description; and (2) the measurement period of 3 months applies to both HD and PD pediatric patients, whereas in the adult measure, 3 months is used as the reporting period for HD patients and 6 months for PD patients.

The revised CPM proposed by the C-TEP is as follows:

Percentage of all pediatric (<18 years old) hemodialysis and peritoneal dialysis patients prescribed an ESA at any time during the study period or who have a Hb<11.0 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.

Denominator: All pediatric (<18 years old) hemodialysis and peritoneal dialysis patients prescribed an ESA at any time during the study period or who have a Hb<11.0 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 Hb) is used for this calculation.

Numerator: 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.

Inclusions: Patients receiving in-center hemodialysis, peritoneal dialysis, and home hemodialysis

Exclusions: Patients on dialysis <3 months at the start of the reporting period, patients who are not in the facility for the entire three-month study period

- ***D-TEP Response to C-TEP Response***

The D-TEP had no objections to the C-TEP revisions.

5.4 CPM IV – Iron Therapy

Percentage of all pediatric patients (<18 years) on hemodialysis or peritoneal dialysis with hemoglobin <11 g/dL and in whom serum ferritin <100 ng/ml and TSAT <20% who were prescribed iron therapy

Denominator: Number of pediatric patients (<18 years) on hemodialysis or peritoneal dialysis with hemoglobin <11 g/dL and in whom serum ferritin <100 ng/ml and TSAT <20%

Numerator: Number of patients in the denominator who were prescribed iron therapy

Importance

Anemia management requires the presence of sufficient iron stores. Iron deficiency is a leading cause of non-response to ESA therapy [13], and several studies demonstrate the effectiveness of oral or IV iron in correcting iron deficiency in the pediatric population [11,14]. With regards to defining iron deficiency, a TSAT less than 20% was shown to be predictive of iron deficiency in at least one study in the pediatric population [5]. Furthermore, in a clinical trial evaluating the impact of iron supplementation on improving iron stores, a TSAT less than 20% was used as indication for iron therapy [11]. A ferritin level of 100 ng/ml was used even though clinical studies are mixed with regards to the level of ferritin which

is predictive of iron deficiency [5,15], since this cut-off was used in the KDOQI clinical practice guidelines for the pediatric population.

Scientific Acceptability

The measure specification is well defined and the required data elements are of high quality as described in the measure evaluation tool. However, reliability and validation studies for this measure have not been conducted in the pediatric population. Furthermore, the C-TEP discussed considerations in the use of TSAT and serum ferritin to determine iron stores. For instance, TSAT follows a circadian rhythm and serum ferritin, an acute phase reactant, may be increased in response to inflammatory processes.

Usability

The panel agreed the information obtained from this measure will be meaningful and understandable for both public reporting and for quality improvement initiatives. This measure is in harmony with the current KDOQI guidelines for targets of iron therapy in pediatric patients.

Feasibility

The required data for this measure are readily available. All required data elements, with the exception of oral iron therapy, are collected in CROWNWeb. Although this measure is not currently in use, the panel agrees it can be implemented with minimal difficulty.

Data TEP Recommendation

The D-TEP suggested that the C-TEP use identical language as current adult Anemia Managment CPM and replace ‘adult’ with ‘pediatric’, except also include oral iron.

The D-TEP does not see need to use data elements Date ESA Prescription Changed or Date Oral Iron Changed.

The D-TEP noted that facilities’ ability to track oral medications varies widely, and is especially difficult with over the counter medications. Even if facility personnel know that patient is prescribed a medication, they may be unable to know if patient takes it.

- ***C-TEP Response to D-TEP Recommendations***

The C-TEP agrees that the dialysis team may not be able to determine whether a patient is taking prescribed oral iron. To address this, the C-TEP changed the measure from “who received IV or oral iron” to “who received IV iron or were prescribed oral iron.”

The C-TEP also revised the wording for the pediatric measure as compared to the adult measure adult measure to provide clarity with the descriptor “simultaneous”, which applies to simultaneous values of

serum ferritin <100ng/ml and TSAT <20%, but not necessarily a simultaneous measurement of Hb<11g/dl. The revised proposed measure is as follows:

Percentage of all pediatric (<18 years old) hemodialysis and peritoneal dialysis patients with hemoglobin <11.0 g/dL and in whom simultaneous values of serum ferritin concentration was <100 ng/ml and TSAT <20% who received IV iron or were prescribed oral iron within the following three months

Denominator: All pediatric (<18 years) hemodialysis and peritoneal dialysis patients in the facility for the entire three-month reporting period with hemoglobin <11 g/dL and in whom simultaneous values of serum ferritin was <100 ng/mL and TSAT <20% during the three-month study period. Simultaneous measurements are serum ferritin and TSAT measurements reported with the same collection date.

Numerator: 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 TSAT <20% during the study period

Inclusions: Patients receiving in-center hemodialysis, peritoneal dialysis, and home hemodialysis

Exclusions: Patients on dialysis <3 months at the start of the reporting period, patients who are not in the facility for the entire three-month study period

- ***D-TEP Response to C-TEP Response***

The D-TEP had no objections to the C-TEP revisions.

5.5 Data TEP General Discussion/Recommendations

The D-TEP discussed the proposed CPMs individually. However, during those discussions several issues were raised that were more widely applicable, and are described below:

- Definitions for what constitutes an in-center patient need to be standardized across all measures. When modality is an issue (in-center HD, PD, HHD), make sure that definitions and calculations clearly identify modalities included and excluded.
- Where measures are process measures (i.e., was a test done) then requiring the actual dose of drug administered or biochemical value is not required.
- The D-TEP recommends that all clinical values be accepted in CROWNWeb by removing limitations on the ranges of values accepted in the system. They felt that it would be preferable to allow all data to be submitted, and any necessary cleaning of the data could be performed in the system.
- The D-TEP also felt it would be preferable to have all data accepted into CROWNWeb, not just the last values of the month.

- For all measures with a laboratory value, the D-TEP recommends including a data element indicating the laboratory that performed the analysis, with a drop-down list of the largest 9-10 labs + other, with a facility default auto-populated. This was the recommendation to address concerns over variability of laboratory measurements, which was discussed with respect to hemoglobin, ferritin and transferrin saturation (TSAT). For certain measurements, accuracy of measurements is not well defined, and the total analytical error that is allowed is quite large. D-TEP members agreed that better standards need to be developed for these analytes, and while this is not the responsibility of the dialysis facilities, there is concern that facilities are treating patients based on these data.

- The D-TEP suggested that facilities should be able to access a list of qualifying and non-qualifying patients for each measure for use in quality improvement activities.

- The D-TEP recommended including significant digits to the hundredths for lab values (currently only to tenths) to allow for future improvements in lab precision. If that level of detail is not needed for the measures, the rounding off could occur in the system, rather than at entry.

- The D-TEP recommended excluding transient patients from all measures.

- Clarify that data element 5.3.3 is Kt/V HD 'result' or 'value'.

- Rename data element 4.8.7 to remove '(delivered)'.

- The D-TEP recommended that pediatric measures should be made consistent with existing or proposed adult measures. Some exceptions are justified, but should be kept to a minimum.

- D-TEP members would like to see revisions to measures language prior to finalization.

▪ *C-TEP Response to D-TEP Recommendations*

The C-TEP agreed to revise the measures to be consistent with the adult measures when possible, but in some instances (as described above), the adult measure specifications were not applicable to the pediatric population. The modality inclusions are specified in the inclusion/exclusion section rather than in the measure description in order to limit the length of the measure description.

The following table presents a summary of the revised proposed measures for pediatric anemia.

Revised Summary of Quality Measures Recommended for Pediatric Anemia

Description	Numerator	Denominator	Inclusions	Exclusions
Percentage of all pediatric (<18 years old) hemodialysis patients and peritoneal dialysis patients with ESRD >=3 months 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	Number of pediatric (<18 years old) hemodialysis and peritoneal dialysis patients with ESRD >=3 months 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	All pediatric (<18 years old) hemodialysis and peritoneal dialysis patients with ESRD>=3 months	Patients receiving in-center hemodialysis, peritoneal dialysis, and home hemodialysis	Patients on dialysis >3 months at the start of the reporting period, patients who are not in the facility for the entire one-month study period
Percentage of pediatric (<18 years old) hemodialysis and peritoneal dialysis patients, with ESRD >=3 months, who have a mean hemoglobin <10 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.	Number of pediatric (<18 years old) hemodialysis and peritoneal dialysis patients, with ESRD >= 3 months, who have a mean hemoglobin <10.0 g/dL for a 3 month reporting period, irrespective of ESA use. The hemoglobin value reported for the end of each reporting month (end-of-month hemoglobin) is used for the calculation.	All pediatric (<18 years old) hemodialysis and peritoneal dialysis patients with ESRD >= 3 months	Patients receiving in-center hemodialysis, peritoneal dialysis, and home hemodialysis	Patients on dialysis <3 months at the start of the reporting period, patients who are not in the facility for the entire three-month study period

Description	Numerator	Denominator	Inclusions	Exclusions
Percentage of all pediatric (<18 years old) hemodialysis and peritoneal dialysis patients prescribed an ESA at any time during the study period or who have a Hb<11.0 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	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.	All pediatric (<18 years old) hemodialysis and peritoneal dialysis patients prescribed an ESA at any time during the study period or who have a Hb<11.0 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 Hb) is used for this calculation.	Patients receiving in-center hemodialysis, peritoneal dialysis, and home hemodialysis	Patients on dialysis <3 months at the start of the reporting period, patients who are not in the facility for the entire three-month study period
Percentage of all pediatric (<18 years old) hemodialysis and peritoneal dialysis patients with hemoglobin<11.0 g/dL and in whom simultaneous values of serum ferritin concentration was <100 ng/ml and TSAT<20% who received IV iron or were prescribed oral iron within the following three months	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 TSAT <20% during the study period.	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 simultaneous values of serum ferritin was <100 ng/mL and TSAT<20% during the three-month study period. Simultaneous measurements are serum ferritin and TSAT measurements	Patients receiving in-center hemodialysis, peritoneal dialysis, and home hemodialysis	Patients on dialysis <3 months at the start of the reporting period, patients who are not in the facility for the entire three-month study period

Description	Numerator	Denominator	Inclusions	Exclusions
		reported with the same collection date.		

- ***D-TEP Response to C-TEP Response***

The D-TEP had no objections to the C-TEP revisions.

5.6 References

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4) Gerson A, et al. Anemia and health-related quality of life in adolescents with chronic kidney disease. *Am J Kidney Dis* 44:1017-1023, 2004.

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6 Fluid Weight Management

The C-TEP deliberations resulted in the development of ten Quality Measure recommendations for Fluid Weight Management as summarized in the table below. The specifications were refined over teleconferences held April 20 and April 27, 2010.

Quality Measures Initially Proposed by the Fluid Weight Management C-TEP

Description	Numerator	Denominator	Exclusions
Dietary Sodium Reduction Advice for Patients New to Dialysis	Number of patients in denominator who have received formal advice on dietary sodium restriction by the renal dietician within the first 90 days of starting dialysis	Number of patients new to dialysis (at least 90 days but not greater than six months since initiation of dialysis) in an outpatient dialysis facility undergoing chronic maintenance dialysis (hemodialysis or peritoneal dialysis)	Patients in a facility for less than 30 days
Dietary Sodium Reduction Advice for Dialysis Patients	Number of patients in denominator having received formal advice on dietary sodium restriction by the dialysis unit's renal dietician in the prior six months	Number of patients who have been on dialysis for greater than or equal to 90 days since initiation of dialysis) in an outpatient dialysis facility undergoing chronic maintenance dialysis (hemodialysis or peritoneal dialysis)	Patients in a facility for less than 30 days
Sodium Profiling Practice for Hemodialysis	Number of patients in denominator who were prescribed sodium profiling at least once in the reporting month	Number of patients in an outpatient dialysis facility undergoing chronic maintenance hemodialysis	Patients in a facility for less than 30 days
Restriction of Dialysate Sodium	Number of patients in denominator who were prescribed a dialysate sodium concentration greater than or equal to 138 mEq/L in the reporting month	Number of patients in an outpatient dialysis facility undergoing chronic maintenance hemodialysis	Patients in a facility for less than 30 days

Description	Numerator	Denominator	Exclusions
Utilization of Echocardiogram at Initiation of Dialysis	Number of patients in denominator with an echocardiogram performed within the 90-day period prior to or after the initiation of dialysis	Number of patients new to dialysis (less than 90 days since initiation of dialysis) in an outpatient dialysis facility undergoing chronic maintenance dialysis (hemodialysis or peritoneal dialysis)	Patients in a facility for less than 30 days
Utilization of Echocardiogram	Number of patients in denominator with an echocardiogram performed within the three-year period prior to the reporting date	Number of prevalent patients (greater than or equal to three months since initiation of dialysis) in an outpatient dialysis facility undergoing chronic maintenance dialysis (hemodialysis or peritoneal dialysis)	Patients in a facility for less than 30 days
Utilization of Dialysis Duration of Four Hours or Longer for Patients New to Dialysis	Number of patients in denominator whose delivered dialysis session length is at least 240 minutes	Number of patients new to dialysis (i.e., within the first 90 days since initiation of dialysis) in an outpatient dialysis facility undergoing chronic maintenance hemodialysis	Patients in a facility for less than 30 days Patients receiving dialysis treatment greater than three times per week
Periodic Assessment of Post-Dialysis Weight by Nephrologists	Number of patients in denominator who received a clinical assessment of target post-dialysis weight by a nephrologist in the reporting month	Number of patients in an outpatient dialysis facility undergoing chronic maintenance hemodialysis	Patients in a facility for less than 30 days
Utilization of High Ultrafiltration Rate for Fluid Removal	Number of patients in denominator who received an ultrafiltration (UF) rate greater than or equal to 15 ml/kg/hr in the reporting month	Number of patients in an outpatient dialysis facility undergoing chronic maintenance hemodialysis	Patients in a facility for less than 30 days

Description	Numerator	Denominator	Exclusions
Utilization of Home Blood Pressure Monitoring	Number of patients in denominator who have been trained in the use of home blood pressure monitoring and provide blood pressure values to the dialysis unit for the management of hypertension in the reporting month	Number of patients in an outpatient dialysis facility undergoing chronic maintenance dialysis (hemodialysis or peritoneal dialysis)	Patients in a facility for less than 30 days Patients on dialysis for 90 days or less

Additional teleconferences were held in order to address modifications suggested by the Data Technical Expert Panel (D-TEP). A subset of the D-TEP was invited to participate in the first of these calls, held June 22, 2010. The second call was held on July 7, 2010.

Based on the feedback from the D-TEP, modifications were made to several of the proposed Fluid Weight Management Quality Measures. The revised measures were then ratified by the C-TEP, resulting in the final set of six measures as shown in the table below. Rationales for the modifications are described in each measure's respective section below.

Quality Measures Ratified by the Fluid Weight Management C-TEP

Description	Numerator	Denominator	Exclusions
Dietary Sodium Reduction Advice	Number of patients in denominator who have received formal advice on dietary sodium restriction by the renal dietician within the past 90 days	Number of patients in an outpatient dialysis facility undergoing chronic maintenance dialysis (hemodialysis or peritoneal dialysis)	Patients in a facility for less than 90 days
Sodium Profiling Practice for Hemodialysis	Number of patients in denominator who were not prescribed sodium profiling in the reporting month	Number of patients in an outpatient dialysis facility undergoing chronic maintenance hemodialysis	Patients in a facility for less than 30 days

Description	Numerator	Denominator	Exclusions
Restriction of Dialysate Sodium	Number of patients in denominator who were prescribed a dialysate sodium concentration less than or equal to 138 mEq/L in the reporting month	Number of patients in an outpatient dialysis facility undergoing chronic maintenance hemodialysis	Patients in a facility for less than 30 days
Utilization of Dialysis Duration of Four Hours or Longer for Patients New to Dialysis	Number of patients in denominator whose prescribed dialysis session length is at least 240 minutes	Number of patients new to dialysis (i.e., within the first 90 days since initiation of dialysis) in an outpatient dialysis facility undergoing chronic maintenance hemodialysis	Patients in a facility for less than 30 days Patients receiving dialysis treatment greater than three times per week Pediatric patients
Periodic Assessment of Post-Dialysis Weight by Nephrologists	Number of patients in denominator who have documentation of receiving a new post-dialysis weight prescription from a nephrologist in the reporting month	Number of patients in an outpatient dialysis facility undergoing chronic maintenance hemodialysis	Patients in a facility for less than 30 days
Utilization of High Ultrafiltration Rate for Fluid Removal	Number of patients in denominator who did not receive an ultrafiltration (UF) rate greater than or equal to 15 ml/kg/hr in the reporting month	Number of patients in an outpatient dialysis facility undergoing chronic maintenance hemodialysis	Patients in a facility for less than 30 days

Background

Fluid Weight Management is a singularly important issue for dialysis patients, going beyond dialysis dose. It is essential to the quality of dialysis that patients receive and is strongly associated with patient survival. The maintenance of stable normal extracellular fluid volume is challenging under standard thrice-weekly hemodialysis. Hypertension, volume overload, left ventricular hypertrophy, inflammation,

malnutrition, congestive heart failure, quality of life, and mortality are issues inextricably linked to salt and water excess and its management.

Despite the importance of this topic, there are few clinical practice guidelines regarding the management of fluid weight. At present, there are no endorsed Quality Measures related to this aspect of dialysis patient management, and few metrics have enough evidence to support an endorsement of a new Quality Measure.

Clinical Practice Guidelines

Although there are no guidelines that specifically address fluid weight management, there are pertinent guidelines for cardiovascular disease management and dialysis adequacy from the National Kidney Foundation (NKF) Kidney Disease Outcomes Quality Initiative (KDOQI). Additional guidelines on blood pressure management were available from the 2009 Kidney Disease: Improving Global Outcomes (KDIGO) report.

Under the 2006 KDOQI guidelines for hemodialysis adequacy [1], the following guidelines are relevant:

> 4.9 - The minimum HD treatment time for thrice-weekly dialysis in patients with K_r less than 2 mL/min should be at least 3 hours.
>
> 5.1 - The ultrafiltration component of the HD prescription should be optimized with a goal to render the patient euvolemic and normotensive. This includes counseling the patient on sodium and fluid restriction, adequate ultrafiltration, and the use of diuretics in patients with Residual Kidney Function (RKF). (Evidence Level A)
>
> 5.2 - Daily dietary sodium intake should be restricted to no more than 5 g of sodium chloride (2.0 g or 85 mmol of sodium). (Evidence Level A)
>
> 5.3 - Increasing positive sodium balance by “sodium profiling” or using a high dialysate sodium concentration should be avoided. (Evidence Level B)

Under the 2009 KDIGO report on blood pressure in chronic kidney disease stage 5D [2], the following guidelines are pertinent:

> Although a worthy goal, neither measurement of APBM nor self measured home BP may be feasible for most patients throughout the world, leaving pre-HD and post-HD BP measurements to be used, but with caution and with the knowledge that these are inferior.
>
> A high prevalence of isolated systolic HTN exists in the stage 5D CKD population. Clinical decisions in managing interdialytic BP should be based on SBP and DBP, but not on mean arterial BP.
>
> The recent National Kidney Foundation Kidney Disease Outcomes Quality Initiative guidelines suggest that pre-HD and post-HD BP should be < 140/90 and < 130/80 mmHg, respectively.

> Whether the definition of HTN on the basis of home BP should be the same as that for the general population, as outlined in the Seventh Report of the Joint National Committee (JNC 7),21 with SBP > 139 mmHg or DBP > 89 mmHg, can only be decided by future research.

Under the 2005 KDOQI guidelines for the management of cardiovascular disease in dialysis patients [3], the following guidelines are relevant:

> 1.1.a - Echocardiograms should be performed in all patients at the initiation of dialysis, once patients have achieved dry weight (ideally within 1-3 months of dialysis initiation) (Evidence Level A), and at 3-yearly intervals thereafter (see Guideline 6) (Evidence Level B)
>
> 6.1.a - Dialysis patients should be evaluated for the presence of cardiomyopathy (systolic or diastolic dysfunction) in the same manner as the general population, using echocardiographic testing. (Evidence Level C)
>
> 6.2.a - Congestive heart failure unresponsive to changes in target dry weight may also be a complication of unsuspected valvular heart disease (VHD) or ischemic heart disease (IHD); clinical re-evaluation should be considered in these patients. (Evidence Level C)
>
> 6.2.b - Dosing of therapeutic agents may need to be empirically individualized to hemodialysis schedules (in hypotensive patients). (Evidence Level C)
>
> 6.2.c - The consistent maintenance of euvolemia is a cornerstone of treatment of CHF in dialysis patients. (Evidence Level C)
>
> 6.3 - Target “hemodynamic dry weight” may need to be adjusted to compensate for hemodynamic effects of therapeutic agents. (Evidence Level C)
>
> 6.1.d - As in the general population, dialysis patients identified with significant reduction in LV systolic function (EF < 40%) should be evaluated for CAD (if not done previously). This evaluation may include both noninvasive testing (stress imaging) and invasive testing (coronary angiography). In patients at high risk for CAD (e.g., those with diabetic CKD), coronary angiography may be appropriate, even in patients with negative stress imaging tests, due to lower diagnostic accuracy of noninvasive stress imaging tests in CKD patients. (Evidence Level C)
>
> 6.1.b - Patients should be re-evaluated if there is change in clinical status (e.g., symptoms of CHF, recurrent hypotension on dialysis, postcardiac events) or considered for kidney transplant. (Evidence Level C)
>
> 6.1.c - Echocardiograms should be performed in all patients at the initiation of dialysis, once patients have achieved dry weight (ideally within 1-3 months of dialysis initiation) (A), and at 3-yearly intervals thereafter. (Evidence Level B)

Existing Quality Measures

At present, there are no endorsed Quality Measures for Fluid Weight Management.

6.1 Dietary Sodium Reduction Advice to Patients in Dialysis Units

Dietary Sodium Reduction Advice to Patients in Dialysis Units measures the proportion of patients new to dialysis who received formal advice on dietary sodium restriction by the renal dietician in the prior three months.

This measure is related to the following 2006 KDOQI guidelines [1]:

> 5.1 - The ultrafiltration component of the HD prescription should be optimized with a goal to render the patient euvolemic and normotensive. This includes counseling the patient on sodium and fluid restriction, adequate ultrafiltration, and the use of diuretics in patients with Residual Kidney Function (RKF). (Evidence Level A)
>
> 5.2 - Daily dietary sodium intake should be restricted to no more than 5 g of sodium chloride (2.0 g or 85 mmol of sodium). (Evidence Level A)

Based on the above guidelines, the formal advice measured here should emphasize a daily limit of no more than 5 grams of sodium chloride (2.0 grams of sodium) in all dialysis patients.

Discussion of this Measure

The panel noted that excess sodium intake, mainly from diet and possibly the dialysis treatment, is the primary cause of excessive fluid weight. Because dietary sodium intake is directly influenced by patient behavior, a measure was proposed that documents whether the patient has received educational instruction on the importance of limiting sodium intake.

In support of this measure, the panel considered a paper that showed significant differences in cardiac-related outcomes in facilities practicing salt restriction versus those that do not [4]. The panel also considered evidence from DOPPS I and DOPPS II suggesting that time spent with highly trained staff and unit dieticians was associated with lower interdialytic weight gain [5]. The panel cited this piece as evidence that patient education could be effective.

Under this measure, the panel suggested that “advice” would be intended to provided focused educational material and counseling on the dangers of excess sodium ingestion. However, one panelist noted that advice given during dialysis sessions is difficult for patients to retain, and suggested that the message be repeated regularly. Based on this recommendation, and the KDOQI guidelines, the panel recommended that the sodium intake advice be administered on a regular basis and at least documented once within the first three-months and every six-months thereafter. The panel also noted that the advice could be administered after changes in patient status, such as after a cardiovascular-related hospitalization.

The panel voted unanimously that this measure should be implemented.

Other Recommendations for this Measure

As sodium intake occurs both inter- and intra-dialysis, the panel recommended that this measure be implemented in conjunction with the *Sodium Profiling Practice for Hemodialysis* and the *Restriction of Dialysate Sodium* measures.

Data TEP Recommendation

The D-TEP agreed that the data elements would be easy to collect and recommended no changes.

- ***C-TEP Response to D-TEP Recommendations***

On the April 20 teleconference, in an effort to harmonize the two sodium reduction advice measures (for new patients and for existing dialysis patients) the C-TEP considered combining them into a single measure, using 90 days as the interval for all patients. Although some expressed concern that the 90 day interval would be too frequent, others suggested that the intensity of the advice may freely vary according to the provider's judgment.

The panel ultimately agreed that the two measures be combined into a single sodium reduction advice measure, using the past 90 days as the measurement period.

- ***D-TEP Response to C-TEP Response***

Not applicable.

- ***Final Reconciliation of C-TEP and C-TEP Comments***

As the D-TEP had no recommendations for this measure, it was ratified as described above, with a single measure for all patients using the past 90 days as the measurement period. The measure for all dialysis patients was eliminated by the C-TEP.

6.2 Sodium Profiling Practice for Hemodialysis

Sodium Profiling Practice for Hemodialysis measures the proportion of hemodialysis patients who received sodium profiling in the reporting month.

This measure is related to the 2006 KDOQI guideline [1] below, which suggests that the practice of sodium profiling be avoided:

> 5.3 - Increasing positive sodium balance by "sodium profiling" or using a high dialysate sodium concentration should be avoided (Evidence Level B).

Discussion of this Measure

The panel noted that excess sodium intake, mainly from diet and possibly the dialysis treatment, is the primary cause of excessive fluid weight. The panel also noted that sodium profiling is one source of

excess sodium. Sodium profiling raises the serum sodium to a high level, and although the intent is to lower the serum sodium at the end of the treatment, in practice this rarely occurs [6-7].

The panel voted unanimously that this measure should be implemented.

Other Recommendations for this Measure

As sodium intake occurs both inter- and intra-dialysis, the panel recommended that this measure be implemented in conjunction with the *Dietary Sodium Reduction Advice to Patients in Dialysis Units* and the *Restriction of Dialysate Sodium* measures.

Data TEP Recommendations

The D-TEP noted that the measure should be framed positively so that high attainment of the measure is the desired behavior.

The D-TEP also noted that facilities that enter data manually into CROWNWeb are concerned about data entry burden for this measure. The data for this measure would have to be abstracted from medical records, which is not uniformly collected across facilities.

Additionally, the D-TEP argued that in order to evaluate the effect of sodium modeling on net sodium accumulation, and in turn fluid management, it would necessitate at a minimum to record the maximum dialysate sodium concentration during the treatment. At least one BSO captures this information. Other parameters required for true quantification would be the minimum sodium concentration, the profile type (step change, linear, or exponential), and the time over which the modeling is performed. None of the clinical systems employed by the BSO's are currently capturing all of this information.

▪ *C-TEP Response to D-TEP Recommendations*

This measure was discussed during the teleconference held June 22 with members of the D-TEP. During this call, the C-TEP noted the concerns about the measure, particularly with regard to the data collection burden. However, the C-TEP felt that this measure would result in significant improvements in dialysis care; therefore, the importance of reducing intradialytic sodium justifies the additional data burden.

The C-TEP also confirmed that certain data elements that were initially requested for validation purposes are unnecessary for this measure and would therefore be dropped. The C-TEP noted that this measure would remain otherwise as-is, as a simple yes/no process measure.

▪ *D-TEP Response to C-TEP Response*

During the joint teleconference, the D-TEP raised no further objections.

▪ *Final Reconciliation of C-TEP and C-TEP Comments*

Based upon the consensus reached during the June 22 joint teleconference, the Sodium Profiling Practice measure was ratified as a simple yes/no process measure, with no additional data elements

requested for validation purposes, and the measure re-stated such that positive achievement is measured.

6.3 Restriction of Dialysate Sodium

The *Restriction of Dialysate Sodium* measure was intended to indicate the proportion of hemodialysis patients who received a "high" dialysate sodium concentration, i.e., 138 mEq/L or greater.

This measure is related to the following 2006 KDOQI volume and blood pressure guideline [1]:

> 5.3 - Increasing positive sodium balance by "sodium profiling" or using a high dialysate sodium concentration should be avoided (Evidence Level B).

Discussion of this Measure

The panel noted that based on available evidence, patients receiving high dialysate sodium concentrations were receiving an excessive sodium load and that larger sodium gradients were associated with greater interdialytic weight gain, hospitalization rates, and mortality rates [8-9].

One panelist presented unpublished data, which showed results from a sample of 8,000 patients illustrating that when dialysate sodium is greater than the patient's serum sodium, hospital admissions, fluid overload, and cardiovascular-related hospitalizations all increase.

The panel voted unanimously that this measure should be implemented.

Other Recommendations for this Measure

As sodium intake occurs both inter- and intra-dialysis, the panel recommended that this measure be implemented in conjunction with the *Dietary Sodium Reduction Advice to Patients in Dialysis Units* and the *Sodium Profiling Practice for Hemodialysis* measures.

Data TEP Recommendations

The D-TEP had recommended that this measure be re-stated such that achievement of the measure is positive rather than negative. The panel also needed clarifications on whether the measure was intended to restrict dialysate sodium to levels greater than or equal to 138 mEq/L or only greater than 138 mEq/L.

The D-TEP also recommended that the measure refer specifically to prescribed sodium concentration and not received sodium concentration.

Data elements requested for validation purposes were recommended to be dropped.

- ***C-TEP Response to D-TEP Recommendations***

The C-TEP agreed with each of these recommendations and clarified that the measure would be stated as follows: "Number of patients in denominator who were prescribed a dialysate sodium concentration less than or equal to 138 mEq/L in the reporting month." Under this language, facilities may utilize dialysate sodium levels of at most 138 mEq/L and still meet the guideline.

- ***D-TEP Response to C-TEP Response***

During the joint teleconference, the D-TEP raised no further objections.

- ***Final Reconciliation of C-TEP and C-TEP Comments***

Based upon the consensus reached during the June 22 joint teleconference, the Restriction of Dialysate Sodium measure was ratified as described above, with no additional data elements requested for validation purposes.

6.4 Utilization of Echocardiogram at Initiation of Dialysis

Utilization of Echocardiogram at Initiation of Dialysis measures the proportion of patients with an echocardiogram performed at recommended intervals. For new patients, the echocardiogram should be performed within 90 days of initiating dialysis treatment based on Level A evidence cited in the KDOQI guidelines from 2005; echocardiograms should be performed every three years thereafter (Level B evidence).

This measure is related to the following 2005 KDOQI guidelines [3]:

> 1.1.a - Echocardiograms should be performed in all patients at the initiation of dialysis, once patients have achieved dry weight (ideally within one to three months of dialysis initiation) (Evidence Level A), and every three years thereafter (see Guideline 6) (Evidence Level B)
>
> 6.1.a - Dialysis patients should be evaluated for the presence of cardiomyopathy (systolic or diastolic dysfunction) in the same manner as the general population, using echocardiographic testing. (Evidence Level C)
>
> 6.1.b - Patients should be re-evaluated if there is change in clinical status (e.g., symptoms of CHF, recurrent hypotension on dialysis, postcardiac events) or considered for kidney transplant. (Evidence Level C)
>
> 6.1.c - Echocardiograms should be performed in all patients at the initiation of dialysis, once patients have achieved dry weight (ideally within one to three months of dialysis initiation) (A), and at 3-yearly intervals thereafter. (Evidence Level B)

Discussion of this Measure

There was some discussion regarding what data elements from echocardiographic procedures should be collected. However, the panel felt that this information would be difficult to collect in CROWNWeb and it should be left to the dialysis facilities to utilize the test in the manner they deem fit toward fluid weight management.

Six of seven panelists voted that this measure should be implemented.

Other Recommendations for this Measure

There was generally less enthusiasm for the echocardiogram every three years. Panelists felt that an echocardiogram within the first 90 days was potentially more valuable as a guide to fluid weight management.

Data TEP Recommendations

The D-TEP did not feel getting echocardiogram data would be feasible for three reasons: (1) the limited availability of echocardiogram records to the dialysis facility; (2) the lack of specificity for the proposed data elements; and (3) issues regarding payment and how to justify requisition of test under current payment guidelines.

Specifically, the D-TEP noted that unless the dialysis facility ordered the echocardiogram for a patient, it would be very hard to obtain the record from the test. Even in the cases where a facility orders the test, many patients, especially when initiating dialysis, do not actually receive the procedure. There was discussion about whether the measure would be more appropriately measured at the physician level. The D-TEP members felt that the dialysis facility had little influence over getting the echocardiogram test done, and would not have access to the results. The D-TEP also noted that several years ago, the predecessor of Fresenius implemented a program in which echocardiogram equipment was brought to dialysis facilities to perform testing. However, payment for these tests was later rescinded based on the principle that screening tests are not billable to Medicare.

- ***C-TEP Response to D-TEP Recommendations***

Some members of the C-TEP also noted concerns about this measure in light of recent literature suggesting that 2-D echocardiogram may not be very useful at monitoring left ventricular hypertrophy. Several panelists agreed, but others noted the KDOQI evidence level A guidelines recommending the use of the procedure. The guideline was based on the high prevalence of cardiovascular disease and left ventricular hypertrophy in dialysis patients.

Based on these concerns, the June 22 teleconference with members from both the C-TEP and D-TEP concluded that the measure was flawed. However, members of the C-TEP had reservations about eliminating it entirely.

- ***D-TEP Response to C-TEP Response***

The D-TEP did not change its position that the measure was infeasible as proposed.

- ***Final Reconciliation of C-TEP and C-TEP Comments***

Given the continued contention both from the D-TEP and within the C-TEP, the C-TEP discussed the echocardiogram measure again on a teleconference held July 7. The panel considered several arguments while discussing the merits of the echocardiogram measures as proposed. First, recent literature suggests that 2-D echocardiography may be less valuable than combined use of electrocardiography (EKG) and brain natriuretic peptide (BNP), and is certainly less valuable than the "gold standard" of cardiac magnetic resonance imaging (MRI). Additionally, the panel noted the lack of accountability for changing the fluid management approach and the lack of clinical trials.

Based upon these arguments, the echocardiogram measures were put to a vote via electronic mail. Four of seven TEP members did not feel that the measures were ready for submission to the NQF, while three did. Therefore, the C-TEP eliminated these measures.

6.5 Utilization of Dialysis Duration of Four Hours or Longer for Patients New to Dialysis

Utilization of Dialysis Duration of Four Hours or Longer measures the proportion of hemodialysis patients whose delivered dialysis session length is at least 240 minutes (four hours).

Current clinical practice guidelines related to hemodialysis adequacy recommend a minimum duration of three hours for all patients on thrice weekly dialysis. This is in recognition of observational data suggesting that longer time is associated with improved patient outcomes.

Discussion of this Measure

The panel considered data from the DOPPS [10] that showed that longer treatment time was associated with reduced mortality. The panel also noted another recent paper, which found that treatment times of less than four hours were associated with poorer patient outcomes [11]. The panel agreed that this general conclusion has been known for some time including studies from New Zealand [12] and Japan [13]. The panel also recalled the National Cooperative Dialysis Study (NCDS), a randomized trial with a 2×2 factorial design that showed lower risk of hospitalization with longer dialysis session duration that was significant to a p-value of 0.06 and therefore dialysis session duration or 'time' did not receive much attention in its aftermath [14]. The U.S. dialysis community then increasingly adopted mostly a purely urea kinetic modeling based approach to dialysis adequacy.

The panel considered the potential impact of longer treatment time for patients, as this might lead to pushback or increased skipping of sessions, although it was generally agreed that longer treatment times are known to be better.

Panelists noted that the 2006 KDOQI guidelines on hemodialysis adequacy suggest a minimum of three hours a session [1], and considered whether a recommendation of four hours would be feasible in practice. However, according to some panelists, some US dialysis facilities now recommend starting all their new hemodialysis patients at a minimum of four hours treatment time. This is in contrast to DOPPS I and II data that suggest that few patients in the US were dialyzed for sessions of four hour or longer, whereas in other countries (Europe, Japan) four hour treatments are quite common [10]. The DOPPS study showed that for every 30 minutes longer on dialysis there was on average, associated with 7% lower mortality risk, independent of case-mix, body size, and Kt/V [10].

Two of the panelists expressed concern whether a blanket application of four hours was appropriate for all patients, including those with residual renal function, different body size, or other clinical and demographic factors. Six of seven panelists voted that a measure of four hour treatment time should be implemented, if it were based on initiating patients new to dialysis with four hours of treatment time.

Other Recommendations for this Measure

There was some disagreement among the panel whether the treatment time measure should be for *new* patients only versus *all* hemodialysis patients. The former was favored, however, some panel members cited logistic difficulties with a blanket implementation of a minimum treatment time of 4 hours which, amongst other things, was likely to be associated with increase an in costs for dialysis facilities. Some panelists also felt that a four-hour treatment session was unnecessary once normal extracellular fluid volume was achieved.

Data TEP Recommendations

The D-TEP had three recommendations for this measure: (1) to use prescribed treatment time and not delivered time; (2) to include home hemodialysis patients as long as they have three sessions per week; and (3) to include only adult patients. The D-TEP also expressed concern whether the measure was appropriate for adult patients with low body mass.

- ***C-TEP Response to D-TEP Recommendations***

The C-TEP agreed that the measure should utilize prescribed session length rather than delivered time. As the proposed measure covers only patients new to dialysis, the C-TEP decided not to include home hemodialysis patients, as few patients begin treatment on home hemodialysis. The C-TEP agreed that the measure should only cover adult patients, but did not feel that exclusions based on body mass should be added.

- ***D-TEP Response to C-TEP Response***

During the joint teleconference on June 22, the D-TEP expressed no other objections to this measure.

- ***Final Reconciliation of C-TEP and C-TEP Comments***

The measure was clarified to utilize prescribed session length rather than delivered time and exclude pediatric patients. The measure was then ratified by the C-TEP.

6.6 Periodic Assessment of Post-Dialysis Weight by Nephrologists

Periodic Assessment of Post-Dialysis Weight by Nephrologists measures the proportion of hemodialysis patients who received a clinical assessment of target post-dialysis weight by a nephrologist during the reporting month.

This measure is related to the following 2006 KDOQI guideline [1]:

> 5.1 - The ultrafiltration component of the HD prescription should be optimized with a goal to render the patient euvolemic and normotensive. This includes counseling the patient on sodium and fluid restriction, adequate ultrafiltration, and the use of diuretics in patients with Residual Kidney Function (RKF) (Evidence Level A).

And the following 2005 KDOQI guidelines on the management of cardiovascular disease [3]:

> 6.2.a - Congestive heart failure unresponsive to changes in target dry weight may also be a complication of unsuspected valvular heart disease (VHD) or ischemic heart disease (IHD); clinical re-evaluation should be considered in these patients (Evidence Level C).
>
> 6.3 - Target "hemodynamic dry weight" may need to be adjusted to compensate for hemodynamic effects of therapeutic agents (Evidence Level C).

Discussion of this Measure

The panel noted that periodic assessment and challenging of the patient's post-dialysis weight is the only practical method for lowering fluid overload as has been recommended by repeated observations from France [16], and more recently in the form of a randomized clinical trial that utilized frequent clinical probing of the target weight versus usual management with progressive post dialysis weight and blood pressure reduction [17]. In general, the approach is a method to slowly achieving euvolemia. The technique can be implemented in clinical practice with or without techniques such as blood volume monitoring (using online hematocrit monitoring), or by monitoring patients' hydration status using bioimpedance analysis. Practices likely vary considerably in this regard across dialysis facilities, and the use of blood volume monitoring while available on dialysis machines is not frequently used or understood by dialysis staff in relation to achievement of target post dialysis weight or euvolemia. Bioelectrical impedance techniques are also not routine practice, and while promising as a measure of patient's hydration status, remain in the realm of research at present.

The panelists discussed the fact that some clinics assess the weight of stable patients once every two weeks. Furthermore, panelists noted that, for new patients, additional assessments at every session for an initial period of two or more weeks is not unusual. For patients coming back after hospitalization,

more frequent re-assessment is practiced, as re-admissions rates are high. It was felt that a formal assessment of post dialysis weight by the nephrologist was essential at least once monthly and should be documented as such. Additional assessments should be administered after changes in patient status, such as a cardiovascular-related hospitalization.

The panel voted on this measure and determined unanimously that periodic assessment of post-dialysis weight should be a process measure related to fluid weight management.

Other Recommendations for this Measure

The panel suggested that this measure would be most effective as part of a package with blood pressure monitoring and sodium restriction measures, and potentially complemented by a technology assisted measure of fluid volume such as bioimpedance analysis or blood volume monitoring. However, it was recognized that there was not sufficient published evidence yet to introduce either blood volume monitoring or bioimpedance assessment as quality measures, and that these would require a demonstration project and more research.

Some panelists felt that this measure should stress the importance of a Nephrologist evaluating the post-dialysis weight, while others felt that this might exclude physician assistants or nurse practitioners.

Data TEP Recommendations

The D-TEP was concerned that the definition of "assessment" used in the proposed measure was vague. They were unsure that a yes/no check box of whether the patient was assessed is a meaningful data element. The D-TEP suggested to use a new data element—downward target weight prescription change—as one indicator of assessment. However, this alone would not be sufficient to define assessment but does constitute the endpoint of an assessment. The restriction to downward adjustment was specified to avoid potential gaming of the system by changing the dry weight slightly upward or downward each month in alternate fashion.

▪ *C-TEP Response to D-TEP Recommendations*

The C-TEP shared the D-TEP's concern that the measure would result in 100 percent compliance, as periodic assessment of post-dialysis weight is part of the dialysis treatment standard of care. However, the C-TEP noted that periodic weight assessment is crucial for managing fluid weight, and despite being standard of care, careful re-assessment of post-dialysis weight was not routinely and diligently performed.

▪ *D-TEP Response to C-TEP Response*

The D-TEP suggested during the June 22 joint teleconference to utilize language measuring whether the patient has a "new post-dialysis weight prescription" for each reporting month, which would necessitate a signed order.

- ***Final Reconciliation of C-TEP and C-TEP Comments***

The C-TEP discussed this measure again on the July 7 teleconference. The panel noted that the key data elements for periodic weight assessment are (1) a measure of the patient's post-dialysis weight and (2) an indicator of whether the weight had been re-assessed for the month.

The C-TEP then proposed language for the measure that for compliance would require (1) a new post-dialysis weight prescription in the reporting month, as well as (2) documentation in the patient's chart that the post-dialysis weight assessment was in fact carried out by a nephrologist.

This measure was then ratified by the C-TEP.

6.7 Utilization of High Ultrafiltration Rate for Fluid Removal

Utilization of High Ultrafiltration Rate for Fluid Removal measures the proportion of patients who received an ultrafiltration (UF) rate greater than or equal to 15 ml/kg/hr in the reporting month.

This measure is related to the following 2006 KDOQI guideline [1]:

- 5.1 - The ultrafiltration component of the HD prescription should be optimized with a goal to render the patient euvolemic and normotensive. This includes counseling the patient on sodium and fluid restriction, adequate ultrafiltration, and the use of diuretics in patients with Residual Kidney Function (RKF) (Evidence Level A).

Discussion of this Measure

The panel considered an article, which suggested that aggressive volume reduction through ultrafiltration can result in the progressive loss of residual renal function [18].

Rather than increasing the UF rate, the panel agreed that if a target post-dialysis weight cannot be reached due to a hypertensive episode or other reason, then a longer treatment time or an additional treatment session should be prescribed. The panel suggested that the available evidence supports this conclusion, both in the DOPPS and elsewhere [10].

The panel considered this measure, and five of seven members voted that a measure related to estimation of the fraction of patients being treated with high ultrafiltration rates at dialysis facilities should be implemented. A value of 15 ml/min/kg was chosen based on data published on the distribution of ultrafiltration rate in dialysis facilities in the U.S. in a DOPPS analysis [10]. In this analysis, higher ultrafiltration rate (> 10 ml/min/kg) was associated with higher mortality and greater odds of intradialytic hypotension.

Data TEP Recommendations

The D-TEP noted that dialysis session data is available only over a single treatment each month, and asked whether the C-TEP has considered which treatment should be used. The D-TEP also suggested that the measure be framed positively so that high attainment of measure is what is desired.

- ***C-TEP Response to D-TEP Recommendations***

The C-TEP agreed with these suggestions, noting that the data in CROWNWeb is for the last treatment session of each month, and the measure can be calculated from this data. The measure can also be re-stated such that high attainment of the measure is desirable.

- ***D-TEP Response to C-TEP Response***

The D-TEP expressed no other objections to this measure.

- ***Final Reconciliation of C-TEP and C-TEP Comments***

The measure was revised to be stated such that high attainment of the measure is desirable and then ratified by the C-TEP.

6.8 Utilization of Home Blood Pressure Monitoring

Utilization of Home Blood Pressure Monitoring measures the proportion of patients (or patients' caregivers) that have been trained by the dialysis facility to use home blood pressure monitors and provide blood pressure measurements to the dialysis unit for the management of hypertension. Hence it is being recommended as a process measure currently.

This measure is based on the following recommendations from the 2009 KDIGO report on blood pressure [2]:

> Although a worthy goal, neither measurement of APBM nor self measured home BP may be feasible for most patients throughout the world, leaving pre-HD and post-HD BP measurements to be used, but with caution and with the knowledge that these are inferior.
>
> Whether the definition of HTN on the basis of home BP should be the same as that for the general population, as outlined in the Seventh Report of the Joint National Committee (JNC 7), 21 with SBP > 139 mmHg or DBP > 89 mmHg, can only be decided by future research.

Discussion of this Measure

The panel considered that home blood pressure monitoring was endorsed by American Heart Association and renal societies, and can be deployed as a cost-effective strategy for improving the outcomes of dialysis patients. The panel also suggested that home blood pressure monitoring empowers the patient.

One panelist suggested that the feasibility issues have been evaluated in trials in England and in the United States. Another panelist, however, cautioned that in previous trials of technological interventions (weight monitoring scales) patient adherence has been a major barrier to feasibility, in addition to various technical issues. Furthermore, some patients think home monitoring is a violation of privacy. This problem may be mediated by blood pressure monitors that automatically record the measurements.

The scientific acceptability of home blood pressure monitoring was also discussed. According to the KDIGO blood pressure guidelines in 2009 [2], "Hemodialysis BP and ABPM correlation is poor. A recent meta-analysis showed that pre- and post-HD BP are imprecise estimates of interdialytic ambulatory BP. A single-center cross-sectional study showed that home BP measured by the patients was better than pre-HD in predicting LVH." The DRIP study, a randomized control trial, also found a link between volume and blood pressure [17].

However, several panelists suggested that high blood pressure is not necessary or sufficient for demonstrating that a patient is volume overloaded. Hence, any measure based on blood pressure might miss the fraction of the population that is fluid overloaded but does not exhibit signs of hypertension. The panel noted a paper, which suggested that successful cardiovascular care must consist of both fluid weight management and blood pressure management [19]. The panel agreed that blood pressure alone was not sufficient for managing fluid weight, and that a composite measure should be suggested.

The panel debated whether several papers provide enough evidence to support the scientific acceptability of home blood pressure monitoring for measuring hypertension and left ventricular disease [20-22].

A recent randomized trial [23] also concluded, "Decision-making based on HBPM among hemodialysis patients has led to a better BP control during the interdialytic period in comparison with predialysis BP measurements. HBPM may be a useful adjuvant instrument for blood pressure control among hemodialysis patients."

The panel considered the importance of blood pressure control by reviewing a paper, which found a strong relationship between increased mortality and high post-HD systolic blood pressure [24]. Two meta-analyses published 2009 showed that use of antihypertensive drugs is associated with lower risk of mortality [25-26]. However the trials included in these meta analyses did not target specific blood pressure levels, nor did they investigate which blood pressure (home vs. in center) was superior. Furthermore, the possibility of publication bias may have contributed to a favorable result.

Finally, a 2008 article [27] suggested that "HBPM is of value in patients with diabetes, in whom tight BP control is of paramount importance; Other populations in whom HBPM may be beneficial include pregnant women, children, and patients with *kidney disease*; and HBPM has the potential to improve the quality of care while reducing costs and should be reimbursed."

Some panelists insisted that in center dialysis blood pressure readings were also immensely valuable and should not be automatically eschewed, as they had shown strong associations with hard patient

outcomes in large observational studies. Moreover, targets for optimal blood pressure control are currently unclear in dialysis patients and standards from the general population cannot automatically be extended to the dialysis population.

The panel voted on this measure and five of seven panelists voted that a measure related to home blood pressure monitoring could be implemented immediately—contingent on CMS' reimbursement for the devices. However, all seven panelists agreed that further demonstration of the importance, feasibility, usability, and acceptability would be necessary before widespread adoption of this practice in hemodialysis patients.

Other Recommendations for this Measure

The panel suggested that this measure not be implemented without reimbursement from CMS for the cost of the home blood pressure monitoring device.

The panel also suggested that this measure would be most effective as part of a package with sodium restriction measures, and potentially complemented by a technology assisted measure of fluid volume such as bioimpedance analysis or blood volume monitoring, should one be proven effective.

Data TEP Recommendations

The D-TEP shared several concerns about the feasibility of this measure. In particular, the D-TEP noted that (1) there is little availability of home blood pressure information to the dialysis facility; (2) the service is not in current range of services that facilities offer; (3) the service is not currently reimbursed by CMS; and (4) at present, facilities are not equipped to train patients in the use of home blood pressure monitors.

The D-TEP also requested clarification on whether this was only ambulatory BPM or included any type of home monitoring. They felt that the numerator required more definition as to what type of equipment is used, and what constituted 'training' and 'reporting of blood pressure values'.

- ***C-TEP Response to D-TEP Recommendations***

The C-TEP clarified that the measure was intended not to cover ambulatory blood pressure monitoring, but rather standardized home blood pressure monitoring as described in literature from the American Heart Association and others.

The C-TEP also considered whether the concerns presented by the D-TEP were significant enough to consider dropping the Home Blood Pressure Monitoring measure for submission to the NQF. They agreed that a major barrier to the implementation of home blood pressure monitoring is the issue of reimbursement. The devises also require a secular change in behavior by physicians and facilities, which may limit the feasibility of the measure.

As a result of these concerns, the measure was put again to vote via email, and four of seven TEP members indicated that the measure was not ready for submission to NQF.

- ***D-TEP Response to C-TEP Response***

Not applicable.

- ***Final Reconciliation of C-TEP and C-TEP Comments***

The Home Blood Pressure monitoring measure was eliminated from consideration due to feasibility concerns from both the D-TEP and the C-TEP.

6.9 Other Measures Discussed

At the in-person meeting, the Fluid Weight Management C-TEP also discussed practices that, at present, do not have a high enough level of evidence to justify as being the basis for implementation of quality measures. It is the recommendation of the panel that further study is needed to demonstrate the usability, feasibility, importance, and scientific acceptability of the measures below.

Use of Blood Volume Monitoring

The panel reviewed findings from the CLIMB Crit-Line trial, which found increased hospitalization with the use of plasma volume monitoring. Some panelists argued that until the CLIMB trial is superseded, it is difficult to accept measures based on blood volume monitoring as valid.

Other panelists presented unpublished data demonstrating decreased hospitalizations with the use of blood volume monitoring. Two published studies were noted as showing improved outcomes [28-29]. The panel also reviewed a paper [30] that concluded, "The assessment of dry weight in patients on long-term hemodialysis has been a long-term challenge… Periodic monitoring of RPV may assist in the management of dry weight and control of hypertension among long-term hemodialysis patients… Although RPV slope may serve as a marker of volume, its utility needs to be confirmed in clinical trials." Yet another paper [31] concluded that "RPV slope monitoring is a valid method to assess dry weight among hypertensive hemodialysis patients."

The panel also considered competing measures of patient hydration status, such as bioimpedance analysis, which can also determine whether a patient is overhydrated, and debated the scientific validity of the blood volume monitoring technique.

In light of this contradictory evidence regarding the use of blood volume monitoring, the panel agreed that the published research is incomplete and/or non-conclusive, and a clinical performance measure in this regard was not yet ready for prime time. All panelists recommended that this method be studied further in a demonstration project.

Use of Bioimpedance Analysis

Bioimpedance analysis has been used for a long time for monitoring fluid volume/hydration status, particularly in Europe. The panel considered a bioimpedance volume measure that continuously

monitors the resistance in the calf, as this is the last place to lose water. When there is no more fluid to be removed, a flat line was observed.

The panel considered data illustrating the use of the bioimpedance analysis measurement technique described above, which led to a reduction in blood pressure. Over a series of dialysis treatments, the target post-dialysis weight was reduced until the resistivity indicated that the patient was nearing "dry weight."

The panel also considered competing measures of volume, such as blood volume monitoring, which can also determine whether a patient is overloaded, and debated the scientific validity of the bioimpedance analysis technique.

The panel voted on this measure and determined unanimously that additional research was necessary before the measure could be recommended for implementation. Five of seven panelists recommended that this method be studied further in a demonstration project.

Proportion with Very High Pre-Hemodialysis Blood Pressure

This measure is based on the following recommendations from the 2009 KDIGO report on blood pressure [2]:

> Although a worthy goal, neither measurement of APBM nor self measured home BP may be feasible for most patients throughout the world, leaving pre-HD and post-HD BP measurements to be used, but with caution and with the knowledge that these are inferior.
>
> A high prevalence of isolated systolic HTN exists in the stage 5D CKD population. Clinical decisions in managing interdialytic BP should be based on SBP and DBP, but not on mean arterial BP.
>
> The recent National Kidney Foundation Kidney Disease Outcomes Quality Initiative guidelines suggest that pre-HD and post-HD BP should be < 140/90 and < 130/80 mmHg, respectively.

The panel noted that all dialysis patients have pre and post-dialysis blood pressure data, so it is feasible for dialysis facilities to collect.

The panel debated the scientific validity of pre and post-dialysis blood pressure data. For instance, the KDIGO meta-analysis of pre-HD systolic BP showed high variability between the pre-HD BP reading and ambulatory reading [2]. Two articles also questioned the utility of dialysis blood pressure measurements for managing hypertension [32-33].

The panel agreed upon the importance of blood pressure control. One paper showed a strong relationship between increased mortality and high post-HD systolic blood pressure [24]. Several large observational studies since then have also consistently shown a relationship between low blood pressure and higher mortality and neutral to only minimally increased risk associated with high blood pressure. Two meta-analyses showed that lowering BP does not hurt, and may in fact help [25-26]. The

panel also considered DOPPS I, II, and III data on the association between blood pressure and mortality. At baseline, low and high blood pressure values were associated with higher mortality—the traditional U-shaped curve. The longitudinal data suggest that changes in blood pressure were important to monitor in addition to cross-sectional blood pressure measurements.

The panel discussed whether there is some level of blood pressure that a clinical performance measure could be developed. One panelist suggested that the upper limit for systolic blood pressure should be set at 160 mmHg, but others suggested 170 or 180 mmHg. It was recognized, however, that blood pressure targets had not yet been clarified in the published literature to date.

The panel voted on this measure, and although one panelist believed that a measure could be developed now, five panelists suggested that a demonstration project is needed to determine the usability, acceptability, and feasibility of such a measure.

Missed or Shortened Dialysis Treatments

The panel considered data from the DOPPS on non-adherence in dialysis treatment. Noncompliance was defined as skipping one or more sessions a month or shortening one or more sessions a month by more than 10 minutes. These measures were significantly associated with an increased risk of mortality and hospitalization [10].

One panelist suggested that their experience has shown that congestive heart failure is often due to missed or shortened treatments. The panel agreed, but thought that a measure would be difficult to develop. All panelists agreed on the importance of patient adherence, but considered that the facility has little control over “problem patients.” Some also expressed concern that this measure might burden patients, as it would create additional pressure on dialysis units to drop or stigmatize patients who miss or shorten treatments.

The panel voted on this measure and unanimously determined that further research was needed before a measure could be widely implemented. Five of seven panelists recommended that a demonstration project be conducted for the study of this potential measure.

Interdialytic Weight Gain

The panel noted that the evidence is mixed on interdialytic weight gain (IDWG), as some studies have shown better outcomes with greater weight gain, and others show better outcomes with lesser weight gain. The panel also noted that the relationship between IDWG and clinical outcomes is possibly a U-shaped curve. IDWG does not define volume, as it is not a direct measure of dry weight.

The panel reviewed international data from the DOPPS (I and II) on non-adherence in dialysis treatment [10]. In the DOPPS study, IDWG noncompliance was defined as a gain of more than 5.7%. This measure was not significantly associated with hospitalization, but was associated with mortality. Three papers linked IDWG to outcomes [5, 34-35].

Some panelists expressed concern that an emphasis on IDWG might compromise nutritional intake by the patients.

The panel considered the interdialytic weight gain measure and two of seven members voted that the metric was ready to be implemented. Four of seven, however, voted that the measure should be evaluated further in a demonstration project.

This measure would be calculated based on intradialytic weight loss divided by the treatment time, and as such these data elements are currently being collected in CROWNWeb. This fact was not known to the C-TEP members at the time of the meeting.

General Recommendations

Implementation of evidence based fluid-weight management related measures are vital toward enhancing greater awareness in the community regarding this critical issue in dialysis patients and would be a definite way forward toward reducing the high mortality and morbidity for this high risk population.

Data TEP Recommendation

Regarding the measures for future consideration described above, the D-TEP was generally concerned that many of these measures had variable degrees of supporting evidence and did not seem to be prioritized. The D-TEP suggested that the C-TEP may want to prioritize which of these moves forward.

- ***C-TEP Response to D-TEP Recommendations***

These measures were not discussed further by the C-TEP.

6.10 References

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Appendix A: Key to Selected Acronyms and Abbreviations

Acronyms/ Abbreviations	Description
Arbor Research	Arbor Research Collaborative For Health
AV	Arteriovenous
AV fistula	Arteriovenous Fistulae
BNP	Brain Natriuretic Peptide
CAD	Coronary artery disease
CDC	Centers for Disease Control
CHF	Congestive Heart Failure
CHOIR	Correction of Hemoglobin and Outcomes in Renal Insufficiency
CHr	Reticulocyte Hb Content
CKD	Chronic Kidney Disease
CKD-MBD	Chronic Kidney Disease – Mineral and Bone Disorder
CMS	Centers for Medicare & Medicaid Services
CPGs	Clinical Practice Guidelines
CPM	Clinical Performance Measures
CROWNWeb	Consolidated Renal Operations in a Web-Enabled Network
C-TEP	Clinical Technical Expert Panel
DOPPS	Dialysis Outcomes and Practice Patterns Study
D-TEP	Data Technical Expert Panel
EKG	Electrocardiography
ESA	Erythropoiesis-Stimulating Agent
ESRD	End-Stage Renal Disease
Hb	Hemoglobin
HD	Hemodialysis
HD-CKD	Hemodialysis Dependent – Chronic Kidney Disease
Hgb	Hemoglobin
HHD	Home Hemodialysis
HMA	Hematocrit Management Audit
IDWG	Interdialytic Weight Gain
IHD	Ischemic Heart Disease
IT	Information Technology
JNC	Joint National Committee
KDIGO	Kidney Disease: Improving Global Outcomes
KDOQI	Kidney Diseases Outcomes Quality Initiative
LDO	Large Dialysis Organizations
LVH	Left Ventricular Hyperthrophy

Acronyms/ Abbreviations	Description
MBD	Medicare Beneficiary Database
MRI	Magnetic Resonance Imaging
NCDS	National Cooperative Dialysis Study
ND-CKD	Non Dialysis – Chronic Kidney Disease
NHANES	National Health and Nutrition Examination Survey
NKF	National Kidney Foundation
NKF – DOQI	National Kidney Foundation – Dialysis Outcomes Quality Initiative
NQF	National Quality Forum
PD	Peritoneal Dialysis
PD-CKD	Peritoneal Dialysis – Chronic Kidney Disease
PSR	Practice-Related Risk Score
PTH	Parathyroid Hormone
QMs	Quality Measures
RKF	Residual Kidney Function
RRF	Residual Renal Function
TEP	Technical Expert Panel
TREAT	Trial to Reduce Cardiovascular Endpoints with Aranesp Therapy
TSAT	Transferrin Saturation
UF	Ultrafiltration
UKM	Urea Kinetic Monitoring
UM-KECC	University of Michigan Kidney Epidemiology and Cost Center
URR	Urea Reduction Ratio
VHD	Valvular Heart Disease

Appendix B: C-TEP Members

Name	Title	Organization	Measure Area
Stuart Sprague, DO - *TEP CHAIR*	Chief, Division of Nephrology and Hypertension; Professor of Medicine	NorthShore University HealthSystem, University of Chicago Pritzker School of Medicine	Mineral and Bone Disorder
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Linda McCann, RD	Senior Director of Quality	Satellite Healthcare	Mineral and Bone Disorder
Jan Deane, RN, CNN	Director, Quality Improvement and Consumer Services	Renal Network of the Upper Midwest, Inc. (Network 11)	Mineral and Bone Disorder
David Spiegel, MD	Professor of Medicine	University of Colorado, Denver	Mineral and Bone Disorder
Dennis Andress, MD	Senior Medical Director	Abbott Global Pharmaceutical Research & Development	Mineral and Bone Disorder
David Van Wyck, MD - *TEP CHAIR*	Vice President, Clinical Services	DaVita	Anemia Management
Lynda Szczech, MD	Assistant Professor of Medicine	Duke University School of Medicine	Anemia Management
John Stivelman, MD	Professor of Medicine; Chief Medical Officer	University of Washington, School of Medicine; Northwest Kidney Centers	Anemia Management
David Gilbertson, PhD	Director of Epidemiology and Biostatistics	USRDS Coordinating Center	Anemia Management
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Name	Title	Organization	Measure Area
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Theodore Steinman, MD	Clinical Professor of Medicine; Senior Physician	Harvard Medical School/Beth Israel Deaconess Medical Center	HD Vascular Access-Related Infections
Derrick Latos, MD, MACP	Board Member	Forum of ESRD Networks	HD Vascular Access-Related Infections
Eduardo Lacson Jr, MD, MPH	Vice President, Clinical Science, Epidemiology and Research	Fresenius Medical Care NA	HD Vascular Access-Related Infections
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Name	Title	Organization	Measure Area
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Douglas Silverstein, MD	Medical Director, Dialysis Services	Children's National Medical Center	Pediatric Anemia; Pediatric Adequacy (HD)
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Stuart Goldstein, MD	Professor of Pediatrics	Baylor College of Medicine	Pediatric Anemia; Pediatric Adequacy (HD)
Irene Restaino, MD	Division Director, Division of Nephrology	Children's Hospital of The King Daughters	Pediatric Anemia; Pediatric Adequacy (HD)
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Nathan Levin, MD	Medical and Research Director	Renal Research Institute, NY	Fluid Weight Management
John Daugirdas, MD	Professor of Medicine	University of Illinois at Chicago	Fluid Weight Management
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Name	Title	Organization	Measure Area
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Allen Nissenson, MD	Chief Medical Officer	DaVita	Fluid Weight Management

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Name	Title	Organization
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Gordon Kapke, PhD	Clinical Science Fellow	Covance Central Laboratories
Mahesh Krishnan, MD	Vice President of Clinical Research	DaVita
Chris Lovell, RN, MSN, CNN	Director of Medical Informatics	DCI
Norma Ofsthun, PhD	Vice President of Corporate Research	Fresenius
Audrianne Stromski, RN, CNN	Vice President of Clinical Services	Affiliated Dialysis Centers
Raynel Wilson, RN, CNN	Quality Improvement Director	The Renal Network