

**Evaluation of End Stage Renal Disease (ESRD)
Measures Support
Task 10: Recommendations to Measures**

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In September 2006, six clinical technical expert panels (C-TEPs) were convened in a two-day meeting by Arbor Research Collaborative for Health, contractor to the Centers for Medicare & Medicaid Services (CMS). The C-TEPs were convened with the goal of reviewing and updating existing measures based on the revised NKF KDOQI guidelines. Each of the current measures was evaluated with respect to new evidence from the KDOQI guidelines published in 2006, recent publications, and current practices. The report resulting from the C-TEP meeting was put up for public comment from October 10 – November 15, 2006.

On October 11-12, 2006, a data technical expert panel (D-TEP) was convened by Arbor Research Collaborative for Health, with the goals of 1) reviewing the feasibility of collecting the data necessary for calculating the measures, 2) defining the specifications needed for business requirements and IT implementation, and 3) identifying practical problems of implementation.

This report reflects Arbor Research's preliminary recommendations for changes to the existing measures. Arbor Research has considered all input provided by the technical expert panels and by the public.

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Hemodialysis Adequacy Clinical Performance Measures

Background

The ESRD Clinical Performance Measures (CPMs) for hemodialysis (HD) adequacy were first published by the Centers for Medicaid & Medicare Services (CMS) in 1999. These CPMs have been updated several times since then, primarily driven by the National Kidney Foundation's Kidney Disease Outcomes Quality Initiative (KDOQI). In 2006, CMS contracted with Arbor Research Collaborative for Health (Arbor Research) to make recommendations for updating the CPMs, using:

- the 2006 K/DOQI Clinical Practice Guidelines (CPG) and Recommendations (CPR),
- a review of other relevant recent publications,
- a Clinical Technical Expert Panel (C-TEP) of five clinicians,
- a Data Technical Expert Panel (D-TEP) of data collection experts, and
- the expertise of Arbor Research staff in biostatistical analysis, clinical practice, management and integration of large data sets, economics, and public policy.

The CPMs that are currently related to Hemodialysis Adequacy are listed below.

CPM I: Measurement of Delivered HD Dose

The patient's delivered dose of hemodialysis is measured at least once per month.

Denominator: All adult (>18 years old) HD patients in the sample for analyses

Numerator: Number of patients in the denominator with documented monthly adequacy measurements (URR/spKt/V) during the study period

CPM II: Method of Measurement of delivered HD Dose

The patient's delivered dose of hemodialysis recorded in the patient's chart is calculated by using formal urea kinetic modelling (UKM) or the Daugirdas II formula for spKt/V.

Denominator: All adult (>18 years old) HD patients in the sample for analyses

Numerator: Number of patients in the denominator for whom delivered HD dose was calculated using formal UKM or Daugirdas II during study period

CPM III: Minimum Delivered HD Dose

The patient's (for those patients on hemodialysis six months or longer and dialyzing three times per week) delivered dose calculated from data points on the data collection form (monthly measurement averaged over the three-month period) of hemodialysis is $\text{spKt/V} \geq 1.2$ using the Daugirdas formula.

Denominator: All adult (>18 years old) HD patients in the sample for analysis who have been on HD for six months or more and dialyzing three times per week.

Numerator: Number of patients in denominator whose average delivered dose of HD (calculated from data points on the data collection form) was a $\text{spKt/V} \geq 1.2$ during the study period.

Salient Points of Discussion for Revising the Current HD Adequacy CPMs

Following is a summary of the key points that arose while revisions to the current CPMs were being discussed. Decisions about changes or modifications to the current CPMs were largely based on the 2006 KDOQI Clinical Practice Guidelines

CPM I: Frequency of Measurement of HD Dose

1. *Should this measure only be calculated for adult patients?*

There are no studies suggesting that dose of dialysis need not be measured regularly for pediatric patients, and therefore patients less than 18 years old should not be excluded from this performance measure.

2. *Some facilities measure dose at the “beginning of the month”, and some at the “end of the month”, thereby leading to missed measurements for certain patients depending on what time of the month they start treatment.*

The C-TEP recommended that the number of days between each measurement should be at least 31 days to reduce the number of missed monthly measurements caused due to the time of the month when patients start dialysis. The D-TEP brought to our attention the increase in burden of data collection that this 31-day interval would pose. Considering the data collection burden and the practical complexity of implementing this frequency of measurement, Arbor Research recommends that this specification remain “at least once per month” instead of “at least every 31 days.” The chair of the C-TEP has been notified of this recommendation and has consented to revert to the C-TEP’s suggestion.

CPM II: Method of Measurement of HD Dose

1. *Should alternative dose measures (e.g. eKt/V) and use of other formulas for calculation be allowed?*

The C-TEP discussed this issue at length. There is no evidence suggesting that the equilibrate Kt/V is a better measure of dose than the single pool Kt/V . Other formulas like Basile and Jindall, overestimate the dose. Conductivity methods of measuring the dose yield slightly lower Kt/V values and different manufacturer’s machines measure the Kt/V differently. Therefore, eKt/V or other formulas or conductivity based methods are less desirable and should not be allowed as a valid method of measurement of HD Dose for CPMs. The final decision was that only the formal Urea Kinetic Modeling or the Daugirdas II formula to calculate the $spKt/V$ method should be allowable for calculating this measure (CPG 2.4)

2. *Should daily or other than thrice weekly patients be included in this measure?*

There is no strong evidence/guideline suggesting that more frequent dialysis necessarily results in better outcomes. Frequency must be used to express the dose of dialysis and therefore must be reported. Patients for whom the frequency of dialysis is different from thrice weekly will not be a part of the CPM calculation, but the components for the Daugirdas II formula should be recorded for such patients. Patients whose frequency of dialysis is not specified are excluded from calculation of this measure (CPG 2.2)

3. *Should this measure only be calculated for adult patients?*

There are no studies suggesting that dose of dialysis should be measured differently for pediatric patients, and therefore patients less than 18 years old should not be excluded from this performance measure.

CPM III: Minimum Delivered HD Dose

1. *Should this measure only be calculated for adult patients?*

There are no studies suggesting that dose of dialysis should be different for pediatric patients. Additionally, children tend to have a higher metabolism than adults suggesting the need for at least the same dose as adults (CPG 4.1). Therefore patients less than 18 years old should not be excluded from this performance measure.

2. *Should patients that are on HD for less than 6 months be excluded from this calculation?*

There is no scientific evidence or guideline to support a six month rule. Therefore, based on expert opinion, and to discourage catheter use, the C-TEP recommended that only patients that have been on HD for less than 31 days be excluded from the calculation of this measure.

3. *Should patients with a Residual Renal Function (RRF) be excluded from this measure?*

Since the TEP made a recommendation to also include in this CPM, patients who have been on HD for only 2-6 months, the question of whether or not to give facilities credit for giving lower dose of dialysis to patients with Residual Renal Function arises. Based on CPG 4.1, Arbor Research recommends that this CPM include only patients whose RRF is less than 2 mL/min/1.73m². In order to be excluded from this CPM, the patient's RRF must be measured and reported at least quarterly and be ≥ 2 mL/min/1.73m.

Other topics of discussion:

The TEP also discussed the feasibility of developing a the following new CPMs that relate to Hemodialysis Adequacy

- *Minimum Time on Dialysis: Percent of patients receiving at least 3 hours per session*
The TEP decided not to make this a new CPM because, the 3 hour minimum time on dialysis is only a KDOQI recommendation and not a guideline that is based on evidence. Also, current trends in dialysis suggested that only about 5% of the HD patients receive < 3 hours of dialysis per session.
- *Prescribed/target Kt/V measure: Percent of patients achieving a target dose of Kt/V ≥ 1.4*
After detailed discussion, the TEP decided against proposing this measure as a new CPM because physicians for the most part do not calculate specifically a prescribed dose for a particular patient, but alter or adjust the dose based on the patient's response to the prescribed treatment.
- *Ultrafiltration Measure: Percent of patients achieving a target blood pressure range or remaining below a certain ultrafiltration goal*

The TEP decided not to make this a CPM because, there are too many blood pressure measurements and variables involved in calculation of these two goals and therefore are easy to game. Also, the blood pressure measure itself is widely varying and difficult to assess. Other issues also interfering with blood pressure targets are hypotension and interdialytic weight gain.

Recommended Revisions to the Current CPMs

CPM I: Frequency of Measurement of HD Dose

- Include all patients in calculating the frequency of measurement of the delivered dose, and not limit it only to adult patients.

CPM II: Method of Measurement of HD Dose

- Include all patients in the calculation of this CPM and not limit it only to adult patients.
- This measure should include patients on hemodialysis *31 days or longer*

CPM III: Minimum Delivered HD Dose

- The minimum delivered dose of dialysis should be calculated for all patients in the sample, not limited to only adult patients.
- This measure should include patients on hemodialysis *31 days or longer*
- The frequency of dialysis per week should be recorded for all patients
- The minimum delivered dose should only be calculated using either *the UKM or Daugirdas II formula*.

Recommended New CPM Hemodialysis Adequacy Measures: -None-

Revised Clinical Performance Measures for Hemodialysis Adequacy

CPM I: Measurement of Delivered HD Dose

The patient's delivered dose of hemodialysis is measured at least once per month.

Denominator: *All HD patients* in the sample for analyses

Numerator: Number of patients in the denominator with documented monthly adequacy measurements (URR/spKt/V) during the study period

Exclusions: None.

CPM II: Method of Measurement of delivered HD Dose

The patient's delivered dose of hemodialysis recorded in the patient's chart is calculated by using formal urea kinetic modelling (UKM) or the Daugirdas II formula for spKt/V.

Denominator: *All HD patients* in the sample for analyses

Numerator: Number of patients in the denominator for whom delivered HD dose was calculated using UKM or Daugirdas II during the study period *and for whom the frequency of HD per week is specified.*

Exclusions: None.

CPM III: Minimum Delivered HD Dose

The patient's (for those patients on hemodialysis *31 days or longer*, dialyzing thrice weekly and Residual Renal Function measured at least quarterly and is less than 2 ml/min/1.73m²) delivered dose calculated from data points on the data collection form (monthly measurement averaged over the three-month period) of hemodialysis is $spKt/V \geq 1.2$ using UKM or the Daugirdas II formula

Denominator: *All HD patients* in the sample for analysis who have been on HD for *31 days* or more and dialyzing thrice weekly, and for whom the RRF is either not reported or measured to be $< 2 \text{ ml/min/1.73m}^2$

Numerator: Number of patients in denominator whose average delivered dose of HD (calculated from data points on the data collection form *using the UKM or Daugirdas II formula*) was a $spKt/V \geq 1.2$ during the study period.

Exclusions: Patients on HD less than 31 days. Also excluded are patients for whom the RRF is measured at least quarterly and is reported to be $\geq 2 \text{ ml/min/1.73m}^2$

Recommended Changes to the CPM Data Collection Form (IN-CENTER HD Section)

Change Item 17H:

Current 17 H: Method used to calculate the single pool Kt/V

- Urea Kinetic Modeling
- Daugirdas II
- Depner
- Derived from URR no patient weights
- Other

Recommended 17 H: Method used to calculate the single pool Kt/V

- Urea Kinetic Modeling/Depner
- Daugirdas II
- *Derived from URR without patient weights (e.g. Jindall, Basile)*
- Other

Recommended additional question

Was Residual Renal function included in the calculation of reported $spKt/V$?

If yes, provide the following information:

- Urine volume in ml
- Urine collection time in hours
- Urine urea level expressed as either mg/dl or total amount in mg
- Post-dialysis BUN (beginning of urine collection) and/or pre dialysis BUN (end of urine collection)

Peritoneal Dialysis Adequacy Clinical Performance Measures

Background

The ESRD Clinical Performance Measures (CPMs) for peritoneal dialysis (PD) adequacy were first published by the Centers for Medicaid & Medicare Services (CMS) in 1999. These CPMs have been updated several times since then, primarily driven by the National Kidney Foundation's Kidney Disease Outcomes Quality Initiative (KDOQI). In 2006, CMS contracted with Arbor Research Collaborative for Health (Arbor Research) to make recommendations for updating the CPMs. To this end, the following resources were utilized:

- The 2006 K/DOQI Clinical Practice Guidelines (CPG) and Recommendations (CPR),
- A review of other relevant recent publications,
- A Clinical Technical Expert Panel (C-TEP) of five clinicians,
- Public comments on the C-TEP summary,
- A Data Technical Expert Panel (D-TEP) of data collection experts, and
- The expertise of Arbor Research staff in biostatistical analysis, clinical practice, management and integration of large data sets, economics, and public policy.

Current CPMs for PD adequacy

CPM I: Measurement of total solute clearance at regular intervals

Numerator: Number of patients in the denominator with total solute clearance for urea and creatinine measured at least once in a 6 month time period

Denominator: All adults (≥ 18 years old) PD patients in the sample for analysis, excluding tidal dialysis patients

CPM II: Calculate weekly Kt/V_{urea} and creatinine clearance in a standard way

Numerator: The number of patients in the denominator with all of the following:

- a. Weekly creatinine clearance normalized to 1.73m^2 body surface area (BSA) and total weekly Kt/V_{urea} used to measure delivered PD dose
- b. Residual renal function (unless negligible*) is assessed by measuring the renal component of Kt/V_{urea} and estimating the patient's glomerular filtration rate (GFR) by calculating the mean of urea and creatinine clearance
- c. Total body water (V) estimated by either the Watson or Hume method using actual body weight, and BSA estimated by either the DuBois and DuBois method, the Gehan and George method, or the Haycock method of using actual body weight, during the study period

* Negligible = $< 200\text{mL}$ urine in 24 hours

Denominator: All adults (≥ 18 years old) PD patients in sample for analysis, excluding tidal dialysis patients

CPM III: Delivered dose of peritoneal dialysis

Numerator: a. For CAPD patients in the denominator, the delivered PD dose was a weekly Kt/V_{urea} of at least 2.0 and a weekly CrCl of at least $60 \text{ L/week}/1.73\text{m}^2$ or evidence that the prescription was changed according to NKF-KDOQI recommendations, during the study period

b. For cycler patients in the denominator without a daytime dwell (NIPD), the delivered PD dose was a weekly Kt/V_{urea} of at least 2.2 and a weekly CrCl of at

least 66 L/week/1.73m² or evidence that the prescription was changed according to NKF-KDOQI recommendations, during the study period

c. For cycler patients in the denominator with a daytime dwell (CCPD), the delivered PD dose was a weekly Kt/V_{urea} of at least 2.1 and a weekly CrCl of at least 63 L/week/1.73m² or evidence that the prescription was changed according to NKF-KDOQI recommendations, during the study period

Denominator: All adult (≥ 18 years old) PD patients in sample for analysis, excluding tidal dialysis patients.

Recommended Revisions to Current Peritoneal Dialysis CPMs

The table below summarizes the 2000 and 2006 K/DOQI Guidelines relating to these measures.

Table 1: K/DOQI Guidelines Relating to Peritoneal Dialysis Adequacy CPMs

PD CPM	2000 K/DOQI Guidelines	2006 K/DOQI Guidelines
I. Measurement of total solute clearance at regular intervals	<ul style="list-style-type: none"> At least twice within the first 6 months with first measurement at 2-4 weeks (Guidelines 3 and 10) At least once every 4 months thereafter (Guidelines 3 and 10) 	<ul style="list-style-type: none"> Once within the first month (CPG 2.1.2) At least once every 4 months thereafter (CPG 2.1.2)
II. Calculate total solute clearance in standard way	<ul style="list-style-type: none"> Measure PD dose using total weekly Kt/V_{urea} (Guideline 4) Measure PD dose using total weekly creatinine clearance, normalized to 1.73 m² BSA (Guideline 4) Measure residual renal function using renal component of Kt/V_{urea} and estimating GFR by mean of urea and creatinine clearances (Guideline 6) 	<ul style="list-style-type: none"> Measure PD dose using total weekly Kt/V_{urea} (CPG 2.1.1) Measure residual renal function using renal component of Kt/V_{urea} and estimating GFR by mean of urea and creatinine clearances (RRF considered significant if urine volume >100 mL/d) (CPG 2.1.3)
III. Delivered dose for peritoneal dialysis	<ul style="list-style-type: none"> <u>CAPD</u>: Total Kt/V_{urea} ≥ 2.0 per week and total C_{Cr} ≥ 60 L/week/1.73 m² (Guideline 15) <u>CCPD</u>: Total Kt/V_{urea} ≥ 2.1 per week and total C_{Cr} ≥ 63 L/week/1.73 m² (Guideline 16) <u>NIPD</u>: Total Kt/V_{urea} ≥ 2.2 per week and total C_{Cr} ≥ 66 L/week/1.73 m² (Guideline 16) 	<ul style="list-style-type: none"> <u>All PD</u>: Total Kt/V_{urea} ≥ 1.7 per week (CPG 2.1.1). <i>Note: the emphasis in the current guidelines is that all patients must exceed this threshold value as opposed to this being a target value as stipulated in the 2000 guidelines.</i>

Arbor Research recommends the following revisions to the current CPMs in order to make them consistent with the 2006 K/DOQI Clinical Practice Guidelines and Recommendations. The 2006 K/DOQI Peritoneal Dialysis Adequacy Guideline (CPG) supporting each recommendation is shown in parentheses. These recommendations are supported by K/DOQI, the C-TEP, and the D-TEP.

1. Include tidal dialysis patients in all three CPMs (CPG 2)
2. Define negligible residual renal function as $\leq 100\text{mL}$ urine in 24 hours in CPM II (rather than $<200\text{mL}$) (CPG 2.2)
3. No minimum target for creatinine clearance in CPM III (CPG 2)
4. Minimum delivered dose of dialysis is total Kt/V_{urea} of at least 1.7 for all peritoneal dialysis patients in CPM III (CPG 2.1.1)
5. Estimate total body water (V) using Watson or Hume method using *ideal* or *standard* (rather than *actual*) body weight in CPM II (CPR 2.6)

In addition to the five revisions recommended above, Arbor Research recommends retaining the following sections of the current CPM language. Although these recommendations are not specifically supported by the 2006 K/DOQI Clinical Practice Guidelines and Recommendations, they are supported by other relevant recent literature, the C-TEP, and the D-TEP. A detailed explanation of the difference between these recommendations and K/DOQI follows each recommendation.

6. *Measure total solute clearance at least once in a 6-month time period (rather than changing to a 4 month period) in CPM I*

Although the 2006 KDOQI Guidelines state that total solute clearance should be measured at least once every four months (CPG 2.1.2), Arbor Research decided against recommending a change to the frequency of measurement required by PD CPM I. There were two reasons for this recommendation. First, KDOQI recommends that total solute clearance measurements be done only on clinically stable patients and at least 1 month after resolution of an episode of peritonitis, because the test is unreliable in those with peritonitis or other acute illnesses (CPR 2.4). The 6-month time frame in PD CPM I will allow for some flexibility in the timing of the measurement in cases where the patient condition could cause the measurement to be unreliable at the 4-month time point. Second, the frequency of measurement in the 2006 KDOQI Guidelines was not evidence based. The 4-month interval was selected because that was the frequency used in one of the key studies cited. Another key study, however, used a 6-month interval.

7. *Measure Kt/V_{urea} and creatinine clearance (rather than only Kt/V_{urea}) in CPMs I and II*
Arbor Research, agreeing with K/DOQI, the C-TEP, and the D-TEP, recommended removing the creatinine clearance target values from PD CPM III (see recommendation 3, above). K/DOQI, however, does not explicitly recommend continued collection of creatinine clearance. Arbor Research recommends, however, that creatinine clearance measures remain part of PD CPMs I and II. The reasons for this recommendation are that (a) the ISPD and CARI Guidelines continue to recommend (based on weak evidence) minimum targets for creatinine clearance, (b) creatinine generation is an index of muscle

mass (CPR 2.7), and (c) creatinine clearance is a surrogate of larger molecular weight solute removal. This recommendation is supported by other literature, the C-TEP, and the D-TEP.

Recommended Revised Peritoneal Dialysis Clinical Performance Measures

The resulting revised version of the current Clinical Performance Measures recommended by Arbor Research are listed below:

CPM I: Measurement of total solute clearance at regular intervals

Numerator: Number of patients in the denominator with total solute clearance for urea and creatinine measured at least once in a 6 month time period

Denominator: All adult (≥ 18 years old) PD patients in sample for analysis

CPM II: Calculate weekly Kt/V_{urea} and creatinine clearance in a standard way

Numerator: The number of patients in the denominator with all of the following:

- a. Residual renal function (unless negligible*) is assessed by measuring the renal component of Kt/V_{urea} and estimating the patient's glomerular filtration rate (GFR) by calculating the mean of urea and creatinine clearance
- b. Total body water (V) estimated by either the Watson or Hume method using ideal or standard body weight, and BSA estimated by either the DuBois and DuBois method, the Gehan and George method, or the Haycock method of using actual body weight, during the study period
- c. Total weekly Kt/V_{urea} and weekly creatinine clearance normalized to 1.73m^2 body surface area (BSA) used to measure delivered PD dose

* Negligible is $\leq 100\text{mL}$ urine in 24 hours

Denominator: All adult (≥ 18 years old) PD patients in sample for analysis

CPM III: Delivered dose of peritoneal dialysis

Numerator: For peritoneal dialysis patients in the denominator, the delivered PD dose was a weekly Kt/V_{urea} of at least 1.7 or evidence that the prescription was changed according to NKF-KDOQI recommendations, during the study period.

Denominator: All adult (≥ 18 years old) PD patients in sample for analysis

Arbor Research additionally recommends new CPMs for consideration by CMS based on the 2006 KDOQI guidelines. These will form part of a separate document to be submitted later.

Vascular Access Clinical Performance Measures

Overview

This report focuses on the recommended revisions to the vascular access clinical performance measures taking into account 1) the proposed CPMs from the Clinical Technical Expert Panel (C-TEP) in collaboration with Arbor Research, 2) Comments and Feedback on these draft measures by the Data Technical Expert Panel (D-TEP), 3) Comments from the public on the proposed changes in the CPM measures, these comments were obtained from the public comments website and 4) Arbor Research's own review of the newly released KDOQI guidelines and the scientific literature, as well as our groups recognition of the broad criteria for clinical performance measures as proposed by the Measures Justification Form including each measure's Importance/Relevance, Scientific Soundness, Usability/Actionability and Feasibility. Furthermore, the data collection form was reviewed and revised in detail to take into account the recommended changes to the CPM. This report will present each recommended revision to the CPM using these same criteria contained in the Measures Justification Form.

Recommended Revision to CPM I: Maximizing Use of Arterial Venous Fistula

A. Revisions to CPM

Current:

Maximizing Placement of Arterial Venous Fistulae

A primary arteriovenous fistula (AV fistula) should be the access for at least 50% of all new patients initiating hemodialysis. A native AV fistula should be the primary access for 40% of prevalent patients undergoing hemodialysis.

Recommended Revision:

Maximizing Use of Arterial Venous Fistulae

An arteriovenous fistula (AV fistula) should be in use with two needles as the access for greater than 65% of all chronic maintenance hemodialysis patients.

Recommendations:

Achievement of this target should occur incrementally based on annual goals set by the CMS ESRD network program. These incremental goals vary with region. For information specific to a given region, contact your local ESRD Network at www.esrdnetworks.org

There are three key recommended revisions to this CPM as proposed by the C-TEP. First, the increase in target for the use of AV fistula to greater than 65%; second, removing the differentiation between incident and prevalent patients in the achievement of this target; and third, the incorporation of the concept of AV fistula “in use” for chronic maintenance hemodialysis rather than simply requiring the placement of the fistula. In considering the feasibility of reaching the target of AV fistula use to greater than 65%, the panel considered the addition of a descriptive statement as shown above, which modifies the goal to that of an incremental target that should be defined by the local ESRD network.

B. Justification for Revisions

Arbor considers the recommended changes by the C-TEP as appropriate and justified. In reviewing the justifications for the revisions, Arbor Research, in collaboration with the C-TEP considered the broad criteria for clinical performance measures as proposed by the Measures Manager in the Measures Justification Forms. These are presented below:

1. Importance/ Relevance of the Measure

Numerous studies demonstrate that the use of AV fistulas have the best 5-year patency rates and require the fewest interventions compared with other access types. A study using data from the USRDS showed that patients receiving dialysis through catheters or AV grafts have greater mortality risk than patients dialyzed with fistula. Furthermore, infection-related deaths were significantly higher for catheters as compared to fistulas, in both diabetic and non-diabetic ESRD patients. Finally, the advantages of AV fistula over

other accesses are clearly delineated in the NKF KDOQI guidelines, summarized as follows: 1) AV fistulas have the lowest rate of thrombosis and require the fewest interventions, 2) cost of AV fistula use and maintenance is the lowest, 3) fistulas have the lowest rates of infection, and 4) Fistulas are associated with the highest survival and lowest hospitalization rates. Indeed, a number of epidemiologic studies consistently demonstrate the reduced morbidity and mortality associated with greater use of AV fistulas for vascular access in maintenance hemodialysis.

It has also been demonstrated that the use of AV grafts as compared to AV fistula are associated with increased patient care costs. Based on Medicare claims data, the cost of initiating hemodialysis using a fistula was \$68,002, as compared to grafts (\$75,611) and catheters (\$86,927). Canadian data similarly support the finding of a lower cost for vascular access care in patients who initiate dialysis with an AV fistula as compared to those with a catheter or an AV graft.

Finally, the aggressive policy for increasing AV fistula use is consistent with the U.S.'s overall goal of improving ESRD outcomes, as demonstrated by the Fistula First Breakthrough Initiative and the goals stated by the ESRD network program.

2. Scientific Soundness

Based on the recent revisions of the KDOQI guidelines for vascular access in hemodialysis, as well as other key literature reviewed by the panel, the modifications of this CPM are consistent with available evidence. Indeed, recent literature as reviewed by the KDOQI expert panel and even more recently published manuscripts have only confirmed the importance of this measure.

The panel also believed that this measure is reliable, particularly since the clinical community is already familiar with it and the data required for the measure is already submitted for the Fistula First Breakthrough Initiative.

The panel also believed that the addition of the term “in use with two needles” provides an explicit definition of what is being measured, thus removing any ambiguity in completing the data collection form. Furthermore, the positive clinical impact associated with AV fistulas is based on its use rather than on the fact that it is “in place.”

In considering the need for risk adjustment for this measure, the panel emphasized the fact that there is data which suggest that to a certain extent, regardless of patient mix and comorbidity, increasing AV fistula use is possible. For instance, a recent study demonstrated that a functioning AV fistula was achieved the majority of female patients who also have diabetes mellitus. Finally, setting the target at 65% allows a 35% window for the use of other accesses among patients in which a working fistula may be more difficult to sustain.

3. Usability/ Actionability

The panel believes that the revision of this CPM to that proposed offers a clear and unambiguous message and is a simplification of the prior CPM. Simplifying the measure to apply to all patients without differentiation between prevalent and incident hemodialysis patients further increases the usability and actionability of this measure, since setting of targets is clearer and tracking of the measure is easier. Furthermore, the measure is believed to have operational relevance in that it is under control of the dialysis provider once the hemodialysis patient is part of the dialysis program, and in fact, the measure can be incorporated into a quality improvement program.

4. Feasibility

The CPM specifications have been simplified in that 1) it provides a singular target for all chronic hemodialysis patients, removing any differentiation between incident and prevalent patients and 2) it specifies the definition of functionality of the AV fistula as being “in use with two needles.”

The components of this measure are:

Numerator: number of patients on maintenance hemodialysis (HD) using an AV fistula with two needles at last HD treatment of study period

Denominator: all patients on maintenance hemodialysis during the last HD treatment of study period

Exclusion criteria: patients on acute hemodialysis, peritoneal dialysis, or patients ≤ 18 years of age

These specifications can be used in any sampling frame

Because the data elements required for the calculation of this measure are already collected as part of the existing ESRD CPM project and the Fistula First Breakthrough Initiative, there will be no increase in burden of data collection.

Finally, increasing the specification of the measure to “in use with two needles” minimizes any possibility of gaming. Any such potential for distortion will be minimized even further if the measure is calculated at more frequent intervals.

C. Other Comments

C-TEP: In modifying this guideline, the panel removed the differentiation between AV fistula targets for prevalent and incident patients. Though the panel considered the fact that many ESRD patients receive no pre-ESRD care and therefore are not expected to have functional fistulas immediately upon entry into the ESRD program, it was believed that once a patient enters the program, the type of vascular access for maintenance hemodialysis is entirely within

the control of the dialysis provider. In addition, given the estimation for fistula failure rates, AV fistulas may even need to be placed in up to 85% of patients starting hemodialysis in order to reach the target of 65% for prevalent patients.

D-TEP: The D-TEP raised the following issues in regards to the data collection associated with CPM I: 1) should the data collection form include choices for other vascular accesses other than just fistulas with 2 needles (e.g., AV graft combined with AV fistula); 2) should ports and catheters still be reported together?

Arbor Research agrees with the D-TEP that it will be valuable to collect such information on vascular accesses other than the proposed “fistula with 2 needles”. In many cases, more than one access co-exist in a patient and it would be important to monitor the presence and potential impact, if any, of maintaining multiple accesses. Not only would it be valuable to monitor the presence of multiple accesses for tracking CPM measures, it would also be useful information for the Fistula First Initiative. In particular, it would be important to better define and understand the population of patients in whom AV fistulas are not used as long-term hemodialysis access.

Public Comments on this CPM: The majority of the public comments regarding this CPM relate to the feasibility of the target of >65% fistula use. We believe that the addition of the statements “Achievement of this target should occur incrementally based on annual goals set by the CMS ESRD network program. These incremental goals vary with region.” address this concern in two ways: first, by setting targets that increase incrementally allowing the targets to be achieved over time; second, by setting targets that are consistent with those set by the ESRD network program which by nature would take into account the current network achievement of the fistula use.

D. Recommended Changes to the Data Collection Form

For the modifications recommended in this measure, the data collection form will be simplified to remove question 19 (both 19A and 19B) which collects data required to differentiate between incident and prevalent hemodialysis patients.

A second change in the data collection form that will result from this measure is the revision of question 18 to incorporate the phrase “used” as follows:

18. VASCULAR ACCESS: What type of access was *used* on the last hemodialysis session on or before 10/1/20XX and 12/31/20XX at the patient’s primary in-center facility? Check only one of the following access types and follow the corresponding directions.

In addition, on the data collection form the choices for vascular access used will include the following:

AV Fistula (with 2 needles)

AV Fistula combined with an AV Graft

_ AV Fistula combined with a catheter

*_ AV Graft (with 2 needles)
_ with AV Fistula maturing*

*_ AV Graft combined with a catheter
_ with AV Fistula maturing*

This will be further clarified in the instructions to the data collection form with the following recommended revisions:

18. Check only one type of vascular access used on the last hemodialysis session on or between Oct 1, 20XX and Dec 31, 20XX at the patient's primary in-center facility and then complete the corresponding questions to the right of the access type. Exclude dialysis sessions performed at temporary facilities because of holiday travel or hospitalizations. ***An AV fistula or AV graft is considered as the access "used" only if both needles are being used.*** If a fistula and catheter are being used simultaneously for vascular access, the patient's access type should be considered catheter. "Port access" is considered a vascular access device which consists of a valve and cannula that is subcutaneously implanted and is accessed by dialysis needles.

As stated above, we believe that even though the CPM focuses solely on "AV Fistula use with two needles," it would be important to capture the presence and potential impact, if any of maintaining multiple accesses. Not only would it be valuable to monitor the presence of multiple accesses for tracking CPM measures, it would also be useful information for the Fistula First Initiative.

Recommended Revision to CPM II: Minimizing Use of Catheters as Chronic Hemodialysis Access

A. Revisions to CPM

Current:

Minimizing Use of Catheters as Chronic Dialysis Access

Less than 10% of chronic maintenance hemodialysis patients should be maintained on catheters continuously for ≥ 90 days as their permanent chronic dialysis access

Recommended Revision:

Minimizing Use of Catheters as Chronic Hemodialysis Access

Less than 10% of chronic maintenance hemodialysis patients should be maintained on catheters continuously for ≥ 90 days as their chronic maintenance hemodialysis access.

Recommendations:

Achievement of this measure is possible if all patients are evaluated for a permanent access. A permanent access (preferably AV fistula) should be placed within 30 days of initiating maintenance hemodialysis. All AV fistula not adequately maturing by 30 days or not usable (i.e., in use with two needles) by 60 days should be evaluated for remedial intervention.

There are no revisions to this CPM except to add the recommendation section for this measure. This recommendation facilitates the operationalization of this measure as it provides explicit landmarks so that the measure can be more readily attained.

B. Justification for Retaining this Measure

Arbor Research, in collaboration with the C-TEP and based on comments by both the D-TEP and the public, believes that this CPM is important and appropriate in its current form for the following reasons:

1. Importance/ Relevance of the Measure

Numerous studies demonstrate that the long-term use of venous catheters as hemodialysis access is associated with increased morbidity and mortality. Whereas it has the advantage of immediate use without need for maturation time, as enumerated in the KDOQI guidelines, the long-term use of catheters is associated with increased morbidity including infectious complications and increased risk for central venous thrombosis, stenosis and occlusion, etc. Finally, as shown by numerous studies, patients receiving dialysis using catheters have been found to have greater mortality risk than patients dialyzed with fistulas, whether or not diabetes mellitus was present.

It is also associated with the highest total costs for patients initiating hemodialysis therapy, with an estimate of \$86,927 as compared to AV fistulas at \$68,220 during the first year of treatment.

Finally, the aggressive policy for reducing catheter use is consistent with the U.S.'s overall goal of improving ESRD outcomes, as demonstrated by the Fistula First Breakthrough Initiative and the goals stated by the ESRD network program.

The following paragraph, which is intended to facilitate the operationalization of the measure, will also be included in the description of the CPM:

Achievement of this measure is possible if all patients are evaluated for a permanent access. A permanent access (preferably AV fistula) should be placed within 30 days of initiating maintenance hemodialysis. All AV fistula not adequately maturing by 30 days or not usable (i.e., in use with two needles) by 60 days should be evaluated for remedial intervention.

2. Scientific Soundness

Similar to the modifications recommended to CPM I described above, this measure is consistent with available evidence. This is reviewed extensively in the recent revisions of the KDOQI guidelines for vascular access in hemodialysis, as well as other key literature reviewed by the panel. Indeed, literature recently reviewed by the KDOQI expert panel and more recent publications (since January 2006) have only confirmed the importance of this measure.

Reliability of the completion of this CPM is assured by the fact that the clinical community is already familiar with this measure and the data required for the measure is already submitted for the Fistula First Breakthrough Initiative.

The measure's validity is linked to the increased validity of the prior related measure (CPM I), which specifically defines use of AV fistula.

With regards to the possible need for risk adjustment of this measure, data suggest that to a certain extent, regardless of patient mix and co-morbidity, reducing catheter use and increasing AV fistula use is possible. Again, recent findings demonstrated that a functioning AV fistula was achieved in a majority female patients with diabetes mellitus. Finally, setting the target of catheter use at <10% allows a window for the use of other accesses among patients in which a working fistula may be more difficult to sustain.

3. Usability/ Actionability

The CPM will be applied to “all” patients, without differentiation between prevalent and incident hemodialysis patients. This allows the clear setting of targets that are actionable and that are easy to track. In addition, the inclusion of the descriptive paragraph “**Achievement of this measure is possible if all patients are evaluated for a permanent access. A permanent access (preferably AV fistula) should be placed within 30 days of initiating maintenance hemodialysis. All AV fistula not adequately maturing by 30 days or not usable (i.e., in use with two needles) by 60 days should be evaluated for remedial intervention.**” facilitates the operationalization of this CPM as it sets intermediate targets before the 90 day limit on catheter use is reached.

The statement of the CPM offers a clear and unambiguous message and is a simplification of the prior CPM.

The measure has operational relevance in that it sets clear improvement targets, is under the control of the dialysis provider once the hemodialysis patient is part of the dialysis program, and can be incorporated into a quality improvement program.

4. Feasibility

The CPM specifications have been simplified in that it provides a singular target for all chronic hemodialysis patients, removing any differentiation between incident and prevalent patients.

The components of this measure are:

Numerator: number of patients on maintenance hemodialysis using a catheter for ≥ 90 days before the last HD treatment of study period

Denominator: all patients on maintenance hemodialysis at the last HD treatment of study period

Exclusion criteria: patients on acute hemodialysis, peritoneal dialysis, or patients ≤ 18 years of age

These specifications can be used in any sampling frame.

Because the data elements required for the calculation of this measure are already collected as part of the existing ESRD CPM project and the Fistula First Breakthrough Initiative, there will be no increase in burden of data collection.

C. Other Comments

C-TEP: The C-TEP had no additional comments outside of those already discussed above.

D-TEP: The D-TEP agreed with the wording of CPM II, but in addition, suggested that in order to address the needs of the Fistula First Initiative, more information should be collected on the data collection form regarding vascular access (see CPM I, Section C).

Arbor Research believes that the specifics of multiple accesses as proposed by the D-TEP would be useful for both the CPM measures and the Fistula First Initiative.

Public Comments: A public comment raised the issue of the feasibility of the statement “All AV fistula not adequately maturing by 30 days or not usable (i.e., in use with two needles) by 60 days should be evaluated for remedial intervention.” Arbor Research would like to clarify that this explanation is NOT part of the measure but is simply a recommendation to help facilitate the operationalization of the actual measure, which is the percent catheter use. As such, the addition of the statements provides a guide to the clinician for early and remedial intervention before the 90-day cut-off for catheter use is met.

D. Recommended Changes to the Data Collection Form

There will be no changes to the data collection form as it relates to this measure, except for the changes already indicated for CPM I above.

Recommended Revision to CPM III: Routine Monitoring and Surveillance of Permanent Vascular Access for Access Dysfunction

A. Revisions to CPM

Current:

Surveillance of Arterial Venous Grafts for Stenosis

A patient's AV graft should be routinely monitored for stenosis.

The following were suggested methods:

1. intra-access flow
2. static venous pressure
3. dynamic venous pressures
4. measurement of access recirculation using urea concentrations
5. unexplained decrease in the measured amount of URR or Kt/V
6. physical findings of persistent swelling of the arm, clotting of the graft, prolonged bleeding after needle withdrawal or altered characteristics of pulse or thrill in a graft
7. Doppler ultrasound

(Source: 2005 CPM Annual Report, Appendix 1, pg 72)

Recommended Revision:

Routine Monitoring and Surveillance of Permanent Vascular Access for Access Dysfunction

A patient's permanent access (AV fistula or AV graft) should be monitored for access dysfunction. Physical examination (abnormalities, such as persistent swelling, prolonged bleeding after needle withdrawal or altered characteristics of pulse or thrill in the outflow vein) and pre-pump arterial pressure should be done at every treatment.

In addition, for AV graft surveillance, one of the following should routinely be included:

1. intra-access flow measurements
2. static venous pressure
3. duplex Doppler ultrasound

Recommendations:

Routine surveillance of grafts should be performed in a prospective trend analysis.

There are several key revisions recommended to this CPM as follows: 1) The addition of AV fistula as a vascular access that requires routine monitoring and surveillance, 2) The revision of the term "access stenosis" to "access dysfunction" to allow for the early detection of any reduced functionality of the access, 3) the requirement for using physical examination at every treatment in the assessment of both AV fistula and AV graft, 4) the requirement for using pre-pump arterial pressure at every treatment in the assessment of both AV fistula and AV graft, and 5) the shortening of the acceptable methodologies for the surveillance of AV grafts.

B. Justification for Revisions

Arbor Research is in agreement with the C-TEP with the modifications of this third CPM for reasons stated below. In addition, the D-TEP is in agreement with the general contents of this CPM.

1. Importance/ Relevance of the Measure

The routine monitoring and surveillance of vascular access in use for maintenance hemodialysis is clinically relevant in that its patency and function are essential for the adequate delivery of hemodialysis dose. Early detection of access dysfunction provides an opportunity to salvage the vascular access and allows for the appropriate planning for access replacement. This is especially relevant in patients dialyzed with an AV graft, for which part of graft surveillance is to facilitate planning for AV fistula placement.

There is also sufficient evidence to support the use of routine physical examination in monitoring vascular accesses. For instance, it has been shown that physical examination may be comparable to the measurement of static venous pressures. Similarly, there is available evidence to support the routine measurement of pre-pump arterial pressure. Indeed it has been shown that pressure more negative than 250 mmHg at a blood flow of 250 ml/min suggests poor access function, and that a pressure more negative than 300 mmHg may be dangerous for the patient.

The goal of monitoring and surveillance of vascular access is to reduce costly complications. Indeed, some studies show that thrombosis of long-term accesses is associated with increased health care spending, in addition to increasing access-related hospitalization rates.

Finally, the routine monitoring and surveillance of vascular access is consistent with the U.S.'s overall goal of improving ESRD outcomes, as demonstrated by the Fistula First Breakthrough Initiative and the goals stated by the ESRD network program.

The following paragraph, which is intended to facilitate the operationalization of the measure, will also be included in the description of the CPM:

Routine surveillance of grafts should be performed in a prospective trend analysis.

2. Scientific Soundness

Similar to the modifications recommended to CPM I described above, this measure is consistent with available evidence. This is particularly the case for the routine use of physical examination and measurement of pre-pump arterial pressure for the evaluation of AV fistula and AV graft. This is reviewed extensively in the recent revisions of the KDOQI guidelines for vascular access in hemodialysis, as well as other key literature reviewed by the panel.

The first half of this measure regarding the use of physical examination and arterial pre-pump pressure measurement at every treatment may be less reliable, since data documenting the routine use of both monitoring techniques is not currently available. The recommended changes in the data collection form attempts to increase the likelihood that this measure is reliable. With regards to the second half of the measure (AV graft surveillance), the current version of this CPM has already included this measure (with a kappa statistic of 0.58 for the presence of AV graft surveillance). This recommended modification of the CPM simplifies the previous CPM in the use of AV graft surveillance.

Scientific evidence exists that supports the use of the measure, both physical examination and the AV graft surveillance techniques, in predicting access dysfunction. This CPMs validity in capturing access monitoring and surveillance is increased by the changes recommended in the data collection form. In the form, we have provided several options for reporting frequency of access monitoring and surveillance.

This CPM is important to measure across all demographic and clinical subgroups, and the issue of risk adjustment is not applicable.

3. Usability/ Actionability

The CPM seeks to identify whether standard policies for access monitoring are in place. This measure is actionable in the setting of a clinical quality improvement initiative.

The statement of the CPM offers a clear and unambiguous message and the second part of the CPM is a simplification of the prior CPM.

4. Feasibility

The following specifications facilitate the feasibility of this measure.

- A. Routine physical examination of the AV graft of AV fistula
 - i. **numerator**: number of patients who are monitored at every session (whether AV graft or AV fistula) until the last HD treatment of study period
 - ii. **denominator**: everyone with AV graft or AV fistula at the last HD treatment of study period
- B. Routine measurement of Pre-pump pressure of the AV graft or fistula
 - i. **numerator**: number of patients who are monitored at every session (whether AV graft or AV fistula) until the last HD treatment of study period
 - ii. **denominator**: everyone with AV graft or AV fistula at the last HD treatment of study period
- C. Routine surveillance of AV graft using the three methodologies listed in the CPM
 - i. **numerator**: number of patients who undergo specific surveillance tests, according to defined frequencies, until the last HD treatment of study period
 - ii. **denominator**: everyone with AV graft at the last HD treatment of study period

D. **Exclusion:** patients on acute hemodialysis, peritoneal dialysis, or patients ≤ 18 years of age

E. These specifications can be used in any sampling frame

Data collection for this measure is believed to be reasonable, and has in fact been simplified. In order to increase the simplicity, reliability and validity of this measure, additional questions are recommended in the section on data collection below. The periodic monitoring and surveillance of accesses are clearly supported by the KDOQI guidelines and the frequency of such surveillance should be captured.

The increase in the number of questions for this CPM reduces the likelihood of distortion. The specifications in the choices of frequency of monitoring and surveillance increase the likelihood of accurate capture of information.

C. Other Comments

C-TEP: The C-TEP re-emphasized the goal of increasing AV fistula use. As such, the goal of AV graft surveillance is not merely to prolong AV graft function, but rather to help in planning for fistula creation among patients in whom there is adequate vasculature.

D-TEP: The D-TEP raised concerns over the CMS data collection form for CPM III. They recommended deleting question 2 (Section D below) and rewording questions 1, 3, and 4 (Section D below) to only include the choice “At each treatment.”

In line with the concerns of the C-TEP, Arbor Research believes that it is important to keep the wording of these questions as originally recommended in order to cut down on gaming by facilities and to better capture the practice of monitoring vascular access in the U.S.

Public Comments: Comments from the public on this recommended CPM generally focused on the specifications for the physical examination and pre-pump arterial measurement as incorporated in the CPM. In response to this, Arbor Research believes that the goal of the recommended CPM is to ensure, through documentation, that standard physical assessment and assessment of pre-pump pressures occur at each dialysis treatment. We believe that a standard physical examination is dictated by good clinical practice and would naturally include visual examination, palpation and auscultation. With regards to pre-pump arterial measurement, Arbor Research considers such pressures to be more relevant in a trending fashion (continued rise, or sudden increase), and it is not appropriate, nor feasible, to define absolute levels. We believe that it is to the clinician’s discretion to define an actionable pressure and that the measure simply requires that it be evaluated at each treatment.

D. Recommended Changes to the Data Collection Form

In order to reliably capture the frequency of access surveillance and monitoring, the C-TEP recommends the following changes to number 18 of the data collection form:

If patient had an AV Fistula or Graft:

1. Was routine physical examination of the access performed?
 Yes No
2. If Yes to Question 1, how often was this performed?
 At each treatment
 Weekly
 Monthly
 Other
3. Was routine measurement of arterial pre-pump pressure performed?
 Yes No
4. If Yes to Question 3, how often was this performed?
 At each treatment
 Weekly
 Monthly
 Other

If patient had an AV graft

5. Was routine surveillance of the AV graft for access dysfunction performed?
 Yes No
6. If Yes to Question 5, please check all methods of AV graft surveillance (below) that were utilized:
 Static Venous Pressure (check how often this was performed)
 Every 2 weeks
 Monthly
 Quarterly
 Other
 Doppler Duplex Ultrasound (check how often this was performed)
 Every 2 weeks
 Monthly
 Quarterly
 Other
 Intra-access Flow ((check how often this was performed)
 Every 2 weeks
 Monthly
 Quarterly
 Other

In addition, the instruction section that relates to this CPM will be revised as follows:

AV Fistula or Graft

Question 1:

If the vascular access marked for question 18 was an AV fistula or graft (with or without AV fistula), indicate if physical examination of the vascular access site was done routinely.

- *Indicate “Yes” for this question if physical examination of the vascular access site was done at least monthly.*
- *Indicate “No” for this question if physical examination of the vascular access site was done less than monthly.*

Question 2:

If Question 1 was marked “Yes”, mark the box that most closely approximates the frequency of physical examination performed.

Question 3:

If the vascular access marked for question 18 was an AV fistula or graft (with or without AV fistula), indicate if measurement of pre-pump arterial pressure was done routinely.

- *Indicate “Yes” for this question if pre-pump arterial measurement was done at least monthly.*
- *Indicate “No” for this question if pre-pump arterial measurement was done less than monthly.*

Question 4:

If Question 3 was marked “Yes”, mark the box that most closely approximates the frequency of measurement of pre-pump arterial pressure.

For AV Graft

Question 5:

If the vascular access marked for question 18 was an AV graft, indicate if routine surveillance of the AV graft for access dysfunction was done. Routine surveillance is the sequential measurement for access dysfunction.

- *Indicate “Yes” for this question if surveillance was done using any of the following:*
 - *Static Venous Pressure*
 - *Doppler Duplex Ultrasound*
 - *Intra-Access Flow*
- *Indicate “No” for this question if surveillance was done using any other methodology*

Question 6:

Continue with question 6 if answered “Yes” to question 5 and check all surveillance methods utilized. Under each method used, mark the box that most closely approximates the frequency of surveillance.

Mineral Metabolism Clinical Performance Measures

Background

Since 1998, clinical performance measures (CPMs) addressing anemia management, hemodialysis (HD) adequacy, peritoneal dialysis (PD) adequacy, and vascular access in patients receiving chronic dialysis have been available. These CPMs have generally been based upon clinical practice guidelines (CPGs) developed by the National Kidney Foundation (NKF) Kidney Disease Outcomes Quality Initiative (KDOQI).

In June 2004, CMS contracted with the Renal Network of the Upper Midwest, Inc. (Network 11) to develop new CPMs for bone disease and mineral metabolism based on the NKF-K/DOQI guidelines for Bone Metabolism and Disease in CKD published in 2003. Network 11 utilized targeted literature reviews (2001-2004) and solicited community, Technical Expert Panel (TEP) and stakeholder input in selecting suitable CPGs for development into CPMs. A detailed description of the processes used in completing the work is available at www.esrdnet11.org/quality/bone_project.asp.

Network 11 Recommended CPMs

The final report included recommendations for six CPMs, including:

1. S. phosphorus should be measured at least monthly in patients with CKD Stage 5 currently receiving renal replacement therapy with HD or PD.
2. S. phosphorous 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. S. 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 S. 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. S. PTH concentration should be measured at least every 3 months in patients with CKD Stage 5 currently receiving renal replacement therapy with HD or PD.
6. S. 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.

Status of CPMs Recommended by Network 11

CPMs #1-4 above, related to calcium and phosphorus target concentrations and measurement frequency, are being pilot tested in the Q4 2005 ESRD CPM Project data collection. Preliminary data from the pilot test were not yet available for review by the current 2006 TEP. CPMs #5 and 6, related to frequency of testing and target concentrations of PTH, were not included in the Q4 2005 data collection.

Current Objectives

In September 2006, multiple Clinical Technical Expert Panels (C-TEPs) were convened by Arbor Research Collaborative for Health (Arbor Research), with the goal of reviewing and updating existing CPMs. An additional C-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 C-TEP was tasked with the review and recommendation of possible future CPMs for this area.

CPMs were to be developed from evidence-based CPGs (especially those set forth by NKF-K/DOQI). In addition, CPM development was to be supported by a systematized review of medical literature pertinent to bone disease and mineral metabolism published since the 2003 publication of the NKF-K/DOQI CPGs. The deliberations of the C-TEP built upon the thorough body of work originated by the Network 11 workgroup.

Deliberations of the C-TEP

The C-TEP first 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 currently being pilot tested, the C-TEP opined that recently published literature continues to support (i) at least monthly measurement of calcium and phosphorus and (ii) attainment of specified target serum concentrations as previously recommended.

Recommended Mineral Metabolism Clinical Performance Measures

The CPMs proposed by the C-TEP are listed below.

I: **Measurement of Serum Phosphorus Concentration**: S. phosphorus should be measured at least monthly in patients with CKD Stage 5 currently receiving renal replacement therapy with HD or PD.

Numerator: Number of adult dialysis patients included in denominator with serum phosphorus measured at least once within month.

Denominator: All adult peritoneal dialysis and in-center hemodialysis patients included in the sample for analysis.

II: **Evaluation of Serum Phosphorus Concentration**: S. 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.

Numerator: Number of adult dialysis patients included in denominator with serum phosphorous concentration of A) < 3.5 mg/dl, B) 3.5-5.5 mg/dl, C) > 5.5 mg/dl, and D) phosphorous concentration missing.

Denominator: All adult peritoneal dialysis and in-center hemodialysis patients included in the sample for analysis.

III: **Measurement of Serum Calcium Concentration**: S. calcium should be measured at least monthly in patients with CKD Stage 5 currently receiving renal replacement therapy with HD or PD.

Numerator: Number of adult dialysis patients included in denominator with serum calcium measured at least once within month.

Denominator: All adult peritoneal dialysis and in-center hemodialysis patients included in the sample for analysis.

IV: **Evaluation of Serum Calcium Concentration**: Serum concentrations of appropriately adjusted total S. 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.

Numerator: Number of adult dialysis patients included in denominator with appropriately adjusted serum calcium concentration of a) < 8.4 mg/dl, b) 8.4-9.5 mg/dl, c) 9.6-10.2 mg/dl, d) 10.3-11 mg/dl, e) > 11 mg/dl, and f) calcium concentration missing. *The NKF-K/DOQI equation for calcium correction should be used when the serum albumin concentration is below normal.*

Denominator: All adult peritoneal dialysis and in-center hemodialysis patients included in the sample for analysis.

Furthermore, the C-TEP recommended reporting facility results categorically (in contrast to in-/out-of-range) for calcium and phosphorus concentrations to describe the population. Such representation will allow for more detailed evaluation of mineral metabolism outcomes in U.S. dialysis facilities. Finally, the C-TEP recommended early re-evaluation of these four guidelines. In recommending early review, the C-TEP acknowledged the ongoing review/revision of current NKF-KDOQI bone and mineral metabolism CPGs by KDIGO. In addition, the C-TEP cited recent clinical developments, including new medical therapies and the emerging recognition of important associations between mineral metabolism parameters and cardiovascular morbidity/mortality in chronic dialysis patients.

New CPM Development

The C-TEP did not recommend immediate development of any new measures beyond those included in the original Network 11 report, including those related to PTH. While the C-TEP recognizes PTH as an important component of the treatment of ESRD patients, a preponderance of recent literature describing the significant inter-assay variation between currently available PTH assays contributed to the C-TEP's decision to recommend against implementation of PTH-specific CPMs at this time. The C-TEP cited the absence of adequate literature associating PTH concentrations measured with assays currently in widespread use with relevant bone and mineral metabolism endpoints.

Arbor Research Recommendation

Arbor Research agrees with the recommendations put forth by the Mineral Metabolism C-TEP, as described above.

Dialysis Facility Compare Measures

Background

In 1999, the Centers for Medicare & Medicaid Services (CMS) funded the development of dialysis facility-specific measures that could be released in reports to the public for their use in making dialysis treatment choices. The Dialysis Facility Compare (DFC) website (www.medicare.gov) began providing information on nine facility characteristics and three quality measures on dialysis facilities in the United States in 2001. The three ESRD quality measures that are currently publicly reported on the Dialysis Facility Compare website are related to adequacy of hemodialysis (urea reduction ratio), anemia management (hematocrit level), and patient survival.

In 2006, CMS contracted with Arbor Research Collaborative for Health (Arbor Research) to make recommendations for updating these three measures, using:

- the 2006 KDOQI Clinical Practice Guidelines (CPG) and Recommendations (CPR),
- a review of other relevant recent publications,
- a Clinical Technical Expert Panel (C-TEP) of four members in the ESRD community,
- Public comments on the C-TEP summary,
- the expertise of Arbor Research staff in biostatistical analysis, clinical practice, management and integration of large data sets, economics, and public policy.

The DFC measures differ from other CPM measures because they are based on Medicare claims data. Consequently, the source data cannot be changed or augmented with the same flexibility that is present for other CPM data elements discussed in this report.

Recommendations for Current Publicly Reported Quality Measures

Hemodialysis Adequacy

Current Measure

Hemodialysis adequacy is reported as the percentage of the facility's Medicare hemodialysis patients with a urea reduction ratio (URR) of 65% or more in a calendar year. URR is reported monthly on Medicare dialysis claims in five categories: <60%, 60-64.9%, 65-69.9%, 70-74.9%, 75+%. Each patient is assigned to the URR category most commonly reported for them during the year (ties go to the lower category). Medicare claims starting before day 365 of ESRD and claims with a missing URR category were excluded from the calculation. In order to be included in a facility's calculation, a patient must have 4 or more eligible claims from the facility. If a patient is treated at more than one facility during the year, the most common URR category reported is calculated for that patient separately for each facility based on the claims from each facility only.

Key Differences between Previous and Current and KDOQI Guidelines for this Measure

Guideline	2000	2006
Minimum Delivered Dose of Hemodialysis	<ul style="list-style-type: none"> ▪ The dialysis care team should deliver a Kt/V of at least 1.2 (single-pool variable volume) for both adult and pediatric Hemodialysis patients. ▪ For those using URR, the delivered dose should be equivalent to a Kt/V of 1.2, i.e., an average URR of 65% 	<ul style="list-style-type: none"> ▪ The minimally adequate dose of HD given 3 times per week to patients with Kr less than 2 mL/min/1.73 m² should be an spKt/V (excluding RKF) of 1.2 per dialysis. ▪ For treatment times less than 5 hours, an alternative minimum dose is a URR of 65%.

C-TEP Recommendations for Changes to Measure

1. Hemodialysis adequacy could be measured more accurately by using Kt/V instead of URR. Kt/V calculations should be either derived from UKM or Daugirdas II formulae.
2. Patient URR category assignment should be based on the median URR category (%) rather than by the modal URR category.
3. The requirement for inclusion of claims should be changed from starting after day 365 of ESRD for a patient to starting after 31 days of ESRD therapy.
4. The measure should be as consistent as possible with the Clinical Performance Measures, subject to constraints of the claims data.

Arbor Research Recommendations for Changes to Measure

1. Arbor Research recognizes that hemodialysis adequacy could be measured more accurately by using Kt/V instead of URR. However, since the current data source for this measure is the Medicare hemodialysis patient claims, the data element that can currently be reported are the 5 categories of URR: <60%, 60-64.9%, 65-69.9%, 70-74.9%, 75+%.
2. Arbor Research agrees that the patient URR category assignment should be based on the median URR category (%) rather than by the modal URR category. We will revise the measure for the 2007 Dialysis Facility Report and Dialysis Facility Compare.
3. Arbor Research recommends that the requirement for inclusion of claims should be changed from starting after day 365 of ESRD for a patient to starting after 90 days of ESRD therapy due to the constraints of the dialysis claims (completeness of data in the first 90 days).

Recommended Measure Specifications (changes from current specifications in bold)

NUMERATOR: Number of eligible Medicare hemodialysis patients at the facility during the calendar year with a **median** URR value of 65% or higher

DENOMINATOR: Number of eligible Medicare hemodialysis patients at the facility during the calendar year

ELIGIBILITY: Calculated on all Medicare hemodialysis claims submitted by the dialysis facility, with the following exclusions: (1) claims for periods before **day 90** of ESRD for any patient; and (2) claims with missing URR category. In order to be included in a facility's calculation, a patient must have 4 or more eligible claims from that facility. If a patient is treated at more than one facility during the year, the **median** URR category reported is calculated for him/her separately for each facility based on ≥ 4 claims from each facility only.

Anemia Management

Current Measure

The anemia management measure is reported as the percentage of epotein or darboepotein treated Medicare patients with a hematocrit level of 33 or higher in a calendar year among patients at that facility treated for epotein or darboepotein. Hematocrit is reported monthly to CMS on Medicare dialysis claims (UB-92). For each patient, the average hematocrit reported on these claims is calculated. Medicare dialysis claims that did not indicate epotein or darboepotein treatment, claims starting before day 90 of ESRD, and claims with hematocrit values less than 14 or greater than 60 were excluded from the calculation. In order to be included in a facility's calculation, a patient must have 4 or more such eligible claims from the facility. If a patient is treated at more than one facility during the year, the average hematocrit is calculated for him/her separately for each facility based on the claims from each facility only.

Key Differences between Previous and Current and KDOQI Guidelines for this Measure

Guideline	2000	2006
Target Hb	11 - 12 g/dl	≥ 11 g/dl, caution when intentionally maintaining Hb > 13g/dl

C-TEP Recommendations for Changes to Measure

1. Hemoglobin is the preferred measure for anemia management rather than hematocrit.
2. Inclusion criteria should include all ESAs because new products have been developed (ex. Darboepotein). The definition for drug therapy should be based on type of drug activity rather than upon drug name.
3. The measure should be as consistent as possible with the Clinical Performance Measures, subject to constraints of the claims data.

Arbor Research Recommendations for Changes to Measure

1. Arbor Research recognizes that hemoglobin is the preferred measure for anemia management rather than hematocrit. However, only 1% of claims, the current data source for this measure, reported hemoglobin in 2005. Approximately 90% of claims report hematocrits instead.
2. Arbor Research agrees that the inclusion criteria should include all ESAs. We will continue to check for new ESAs as they come on the market.
3. The KDOQI guidelines specify that the goal for anemia management should be to achieve a hemoglobin concentration of 11 g/dL or higher, but cautioning not to routinely maintain Hb levels greater than 13.0 g/dL. However, the recent CHOIR clinical trial published since the C-TEP meetings has pointed to higher composite events for chronic kidney disease patients when the target for anemia correction was to elevate and maintain patient hemoglobin concentrations at a level of 13.5 g/dL. The results of the CHOIR trial are reminiscent of those observed in the earlier normal hematocrit trial by Besarab et al in dialysis patients with heart disease (Ref). In contrast, the recent CREATE trial did not observe higher mortality risk for chronic kidney disease patients targeted to have a hemoglobin concentration of 13 g/dL. However, no benefit was observed in the high hemoglobin group. In view of these new studies it may be difficult to embrace a CPM of ≥ 11 g/dL as a goal for anemia management in dialysis patients since this CPM of good practice would also include patients with a Hb level > 13 g/dL. Arbor Research has recommended an Anemia Management CPM of percent of patients with a Hb < 11 g/dL as a measure of inadequate anemia control. Since there appears to be agreement that a Hb concentration < 11 g/dL is undesirable, this new CPM would serve as a meaningful measure of inadequate anemia control. Thus, Arbor Research recommends that the DFC Anemia Management measure be the percentage of ESA treated Medicare patients with an average hematocrit level lower than 33 in a calendar year.

Measure Specifications (changes from current specifications in bold)

NUMERATOR: number of eligible **ESA-treated** Medicare dialysis patients at the facility during the calendar year with an average hematocrit **lower than 33**

DENOMINATOR: number of eligible **ESA-treated** Medicare dialysis patients at the facility during the calendar year

ELIGIBILITY: Calculated on all Medicare hemodialysis claims submitted by the dialysis facility, with the following exclusions: (1) Medicare dialysis claims that did not indicate **ESA** treatment; (2) claims starting before day 90 of ESRD; and (3) claims with hematocrit values less than 14 or greater than 60. In order to be included in a facility's calculation, a patient must have 4 or more such eligible claims from the facility. For each patient, the average hematocrit reported on these claims is calculated. If a patient is treated at more than one facility during the year, the average

hematocrit is calculated for him/her separately for each facility based on ≥ 4 claims from each facility only.

Patient Survival

Current Measure

The patient survival classification (based on facility Standardized Mortality Ratio (SMR)) is reported as "Better than Expected", "Worse than Expected", and "As Expected" on DFC. The classifications are determined by the upper and lower confidence interval of the SMR. If the upper confidence limit for the facility SMR is less than 0.8, the patient survival classification is "Better than Expected". If the lower confidence limit is greater than 1.2, the patient survival classification is "Worse than Expected". Otherwise, the patient survival classification is "As Expected". The SMR calculation is based on a 4-year period and adjusts for patient age, sex, race, Hispanic ethnicity, diabetes as a cause of ESRD, duration of ESRD, BMI at incidence, and comorbidities at incidence, as well as state population death rates by comparing actual to expected deaths at the facility (indirect method of standardization). The number of expected deaths for patients at the facility is based on a Cox model accounting for these patient characteristics.

The number of facilities that fell into each patient survival classification for the 2006 DFC are shown in the table below.

Category Definition	Number of Facilities in 2006 DFC		
	Better Than Expected	As Expected	Worse Than Expected
At least 20% Different	109	4365	208

C-TEP Recommendations for Changes to Measure

1. The TEP strongly recommended that more categories (5 instead of 3) of survival be considered for display. Since the majority of facilities receive an "as expected" designation under current cutoff rules, additional categories of outcomes should be considered.
2. If only three categories are to be used, the TEP recommended that the categories be reviewed to consider using less stringent criteria for being classified in the extreme categories.
3. The TEP would also like to convert the display to bar graphs instead of check boxes. The bar graphs should be analogous to the anemia management and adequacy measures.
4. The TEP recommended no changes to the current SMR methodology, however, there is room for improvement in better capturing elements for risk adjustment as data becomes available. The current measures are reasonably risk adjusted based upon the constraints of the existing data in the 2728 form. In the future, further analysis should be done with the level of acuity of patients, especially with nursing home patients.

Arbor Research Recommendations for Changes to Measure

1. Arbor Research strongly recommends that 5 categories of survival be considered for display, using one of 2 potential category definitions:

Number of Facilities for Two Potential Category Definitions Using a 5-Category System

Category Definitions

Number of Facilities in 2006 DFC

	Much Better Than Expected *	Better Than Expected**	As Expected	Worse Than Expected**	Much Worse Than Expected*
Definition 1:	596	83	3329	28	646
*Statistically significant SMR (p<0.05) greater than 1.2 or less than 0.8					
**Statistically significant SMR (p<0.05) greater than 1.0 but less than 1.2 or less than 1.0 but greater than 0.8					
Definition 2:	109	487	3440	438	208
*Statistically greater than 1.2 or statistically less than 0.8					
**Statistically significant SMR (p<0.05) and SMR is greater than 1.2 or less than 0.8, but not statistically greater than 1.2 or statistically less than 0.8					

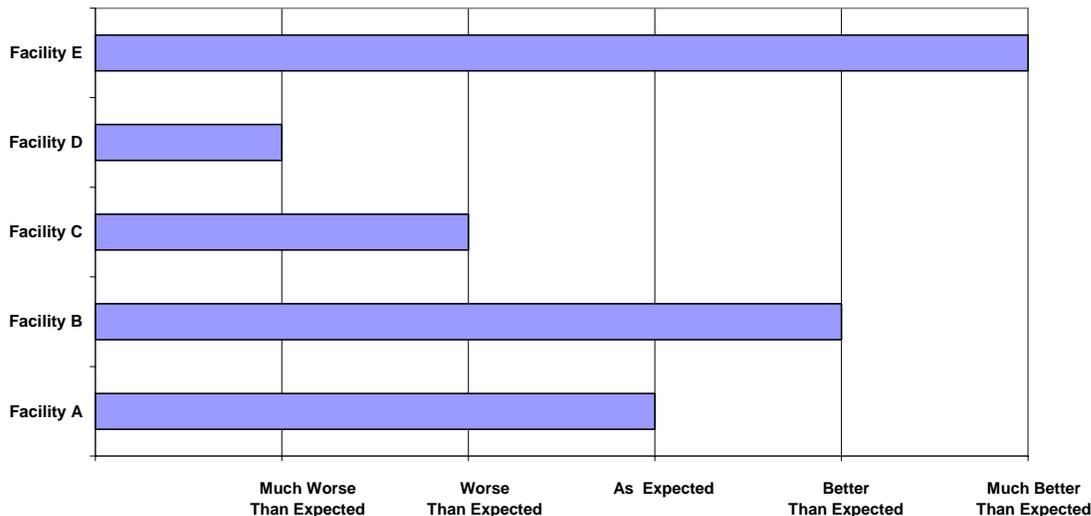
- Using less stringent criteria for three categories, the Arbor Research recommends using one of the following 3 potential category definitions:

Number of Facilities for Three Potential Category Definitions Using a 5-Category System

Category Definitions	Number of Facilities in 2006 DFC		
	Better Than Expected	As Expected	Worse Than Expected
20% Different (Null Hypothesis SMR=1.0)	596	3440	646
10% Different (Null Hypothesis SMR=1.0) *	679	3329	674
Significantly Different from 1.0*	679	3329	674

*Minimum statistically different “worse” SMR is equal to 1.12. Maximum statistically different “better” SMR is equal to 0.86.

- Arbor Research recommends that the display be converted to bar graphs instead of check boxes. An example is shown below.



- During the C-TEP deliberations, the C-TEP discussed the possibility of putting up the entire Dialysis Facility Report on the website like the Transplant Center Specific Report, since the DFR shows the Standardized Mortality Ratio and other mortality data annually in more explicit detail. They felt that one possibility, in addition to having a graphical display, is linking to the report for the audience that desires more information. Arbor Research recommends that a link to the entire report also be considered as an option.

Recommended Measure Specifications (no changes to calculation of measure)

SMR=observed deaths/ expected deaths

NUMERATOR for SMR: Number of deaths among eligible patients at the facility during the 4-year time period

DENOMINATOR: Number of deaths that would be expected among eligible patients at the facility during the 4-year time period, given the patient mix at the facility.

ELIGIBILITY: For each patient, the dialysis provider was identified using a combination of the Medicare paid dialysis claims, the Medical Evidence Form, and data from the Standard Information Management System (SIMS) maintained by the ESRD Networks. Treatment facility histories were determined for each patient starting at day 91 of ESRD. Patients are assigned to a facility only once they have been treated there for 60 days. Similarly, patients remain assigned to a facility for 60 days after transfer out of the facility. The continued tabulation of the time at risk for 60 days after transfer out of the facility ensures that the sequelae of treatment at a facility are attributed to that facility, even if the patient is transferred to another facility, such as a hospital-based facility, after the patient's condition worsens. In particular, patients are placed in their initial facility on day 91 of ESRD if they have been treated for at least 60 days at the facility. If on day 91, the patient has been treated at the facility for less than 60 days, the patient is not placed in any facility until they reach day 60 of treatment at a facility. Paid dialysis claims and SIMS data are used to determine that a patient has transferred to another facility. Patient outcomes are attributed to the original facility for 60 days after transfer out. On day 61 after transfer out of a facility, the patient will be placed in the new facility if they have been treated there for 60 days. If the patient has not been treated for 60 days at the new facility (for instance, if there were 2 switches within 60 days of each other), the patient is not placed in any facility until they reach day 60 of treatment at a facility. Patients who receive a transplant are removed from the facility on the day of transplant. Patients who withdraw from dialysis or recover renal function remain assigned to the facility of treatment for 60 days after withdrawal or recovery. Patients are considered lost to follow-up and are removed from the analyses for a facility 1 year after the last evidence of dialysis treatment. In other words, if there is a 1 year period where there are no paid dialysis claims and no SIMS information indicating that a patient is receiving dialysis treatment, the patient is considered lost to follow-up and is not used in the analysis unless dialysis claims or other evidence of dialysis reappears. Only deaths during the time at risk described above are included for each facility. Deaths from street drugs or accidents unrelated to treatment are excluded from the calculation (corresponding time at risk is not excluded).

Anemia Management Clinical Performance Measures

In 1998, in response to the Balanced Budget Act 1997, CMS developed sixteen Clinical Performance Measures (CPMs) based on the NKF DOQI clinical practice guidelines, which was released in the fall of 1997. In 2006, CMS contracted with Arbor Research Collaborative for Health (Arbor Research) to make recommendations for updating the CPMs, using:

- the updated 2006 KDOQI Clinical Practice Guidelines (CPG) and Recommendations (CPR),
- a review of other relevant recent publications,
- a Clinical Technical Expert Panel (C-TEP) of four clinicians,
- a Data Technical Expert Panel (D-TEP) of data collection experts, and
- the expertise of Arbor Research staff in biostatistical analysis, clinical practice, management and integration of large data sets, economics, and public policy.

The following table lists the key difference between the 2000 and 2006 KDOQI guidelines relating to these measures:

Guideline	2000	2006
Definition of Anemia by Hb	< 12.0 g/dl in males and postmenopausal females < 11.0 g/dl in premenopausal females and prepubertal patients	< 13.5 g/dl males < 12.0 g/dl females
Target Hb	11 - 12 g/dl	>=11g/dl, insufficient evidence to maintain Hb >13 g/dl
Target Iron Status	TSAT(%) lower limit 20 upper limit 50 Ferritin (ng/ml) lower limit 100	TSAT(%) lower limit 20 No upper limit Ferritin lower limit 200 HD-CKD 100 non HD-CKD > 500 not routinely recommended

The current CPMs and the recommended revisions are listed below.

CPM I:

Current CPM I: Target hemoglobin for epoetin therapy

The target hemoglobin for patients prescribed epoetin is 11-12 g/dL (110-120 g/L).

Patients with a mean hemoglobin > 12 g/dL (120 g/L) and not prescribed epoetin are excluded from the calculation of this CPM.

New CPM I Recommended by C-TEP: Hb goal for anemia management

The lower limit of Hb among adult dialysis patients is ≥ 11.0 g/dL.

Patients on dialysis < 90 days are excluded from the calculation of this CPM.

Other recommendations:

- Use hemoglobin (Hb) exclusively in measuring, reporting and billing
- Use the last Hb of month or “End-of-Month” Hb.
- Remove reference to “hematocrit” from CPM

Recommended Change to Anemia Management CPM:

1. CPM of Inadequate Anemia Control: percent of patients with a Hb < 11 g/dl

The KDOQI guidelines specify that the goal for anemia management should be to achieve a hemoglobin concentration of 11 g/dl or higher, but cautioning not to routinely maintain Hb levels greater than 13.0 g/dl. However, the recent CHOIR clinical trial [Singh et al, NEJM 355: 2085-98 (2006)] published since the C-TEP meeting has pointed to a higher risk of composite events for death, myocardial infarction, or hospitalization for congestive heart failure or stroke for certain chronic kidney disease patients when the target for anemia correction was to elevate and maintain patient hemoglobin concentrations to a level of 13.5 g/dl. The results of the CHOIR trial are reminiscent of some findings from the earlier Normal Hematocrit Trial by Besarab et al [NEJM 339: 584-90 (1998)] in dialysis patients with cardiac disease. In contrast, the recent CREATE trial did not observe higher mortality or cardiovascular event risk for chronic kidney disease patients targeted to have a hemoglobin concentration of 13 - 15 g/dl compared with patients maintained at a Hb

level of 10.5-11.5 g/dl. Furthermore, the high Hb group displayed significantly higher scores for a number of quality of life measures in the CREATE Trial. However, the prevalence of cardiovascular disease among patients in the CREATE Trial was considerably lower than that of patients in the CHOIR Trial and lower than that observed in most US hemodialysis patients.

In view of these new studies, it may be difficult to embrace a CPM of ≥ 11 g/dl as a goal for anemia management in dialysis patients since this CPM of good practice would also include patients with a Hb level > 13 g/dl, with uncertainty remaining regarding the benefits/risks associated with a Hb level > 13 g/dl. We therefore recommend that one solution to this problem is to use a CPM of percent of patients with a Hb < 11 g/dl as a measure of inadequate anemia control. Since there appears to be agreement that a Hb concentration < 11 g/dl is undesirable, this new CPM would serve as a meaningful measure of inadequate anemia control, and is in agreement with the KDOQI guideline.

2. Annual reporting of percent of patients with a Hb ≥ 13 g/dl

Even though additional research is still required to understand adverse outcomes for some patients with CKD when targeting Hb levels ≥ 13.5 g/dl, we recommend annual reporting to monitor the percent of ESA-treated patients with a Hb ≥ 13.0 g/dl. This will be useful for determining if the percent of ESA-treated patients with a Hb > 13 g/dl changes over time, and thus would also be in agreement with KDOQI which had recommended that patients should not be routinely maintained at a Hb concentration > 13 g/dl. Although there is evidence from some RCTs that maintaining some ESA-treated patients at a Hb > 13 g/dl can be associated with adverse outcomes, there is a lack of evidence whether there is any risk for patients to occasionally have a Hb > 13 g/dl for short periods of time. Furthermore, it is well recognized that in trying to keep a patient's Hb level ≥ 11 g/dl that there is wide variation in response by hemodialysis patients within the population such that a standard deviation of ~ 1.2 g/dl has been observed. As a result of this variation in response to anemia management protocols, it is not uncommon for some patients to occasionally exceed 13 g/dl as part of the effort of dialysis units to maintain patient Hb levels above 11.0 g/dl. Even though it is difficult at the present time to determine an acceptable percentage of ESA-treated patients to have a Hb > 13 g/dl, there is

value associated with monitoring this practice and determine time trends. However, due to insufficient generalizable evidence regarding the risks and benefits associated with Hb > 13 g/dl, and the need for further discussions and review by expert panels as additional data are published, the C-TEP is reluctant to recommend a CPM for > 13 g/dl for ESA-treated patients at the present time.

Since Hb levels and ESA prescription are expected to be collected each month in the near future, another possible measure for consideration would be the percent of ESA-treated patients with an end of the month Hb \geq 13 g/dl for 3 or 4 consecutive months as this would provide an indication of whether certain ESA-treated patients are routinely being maintained at this higher Hb concentration.

It is noteworthy that some patients such as those with polycystic kidney disease are able to spontaneously maintain Hb levels > 13 g/dl without receiving exogenous ESAs. The recommendation that annual reporting of Hb levels > 13 g/dl be restricted to patients receiving ESA therapy is based on lack of any evidence for worse outcomes for patients such as polycystic kidney disease patients who are able to maintain higher Hb levels without use of exogenous ESAs. In fact, in observational studies, polycystic kidney disease patients show lower relative risks of mortality even after adjusting for differences in numerous patient characteristics.

3. The C-TEP recommended that patients on dialysis < 90 days should be excluded from the calculation of the CPM for anemia management. Arbor Research recommends that this exclusion be changed to “< 3 months” instead of “< 90 days” to fit more closely with how the data would be collected and analysed.
4. It is also recommended that the data collection form be designed to address use of all different forms of ESAs – those known presently, and those entering into the market in the future.

As a summary, the following table displays perceived risk associated with patients being maintained at different Hb levels for patients receiving or not receiving ESA/iron therapy:

	Patient Hemoglobin Level Maintained			
ESA/Iron Therapy	Hb < 11 g/dl	11.0 ≤ Hb < 12 g/dl	12.0 ≤ Hb < 13 g/dl	Hb ≥ 13.0 g/dl
Yes	Higher Risk	No evidence for higher risk	Uncertainty about risks	Higher Risk in some studies; benefits or no risk in others
No	Higher Risk	No evidence for higher risk	No evidence for higher risk	No evidence for higher risk

The newly recommended CPM and annual reporting would provide a means to monitor the cells circled in the above table, while collecting data that allow categorizing patients into these eight cells.

Recommended Measure Specifications for Newly Proposed CPMs:

CPM I: The percentage of patients with Hb < 11.0 g/dL.

Numerator: Patients on dialysis ≥ 3 months and with documented Hb < 11.0 g/dL during a study month.

Denominator: All adult (≥18 yrs old) HD or PD patients in the sample for analysis and who have been on dialysis ≥ 3 months.

For CPM I, use the last Hb of the month or “End-of-Month” Hb for purposes of calculation.

Arbor Research Note:

For the remaining CPMs recommended by the C-TEP, the D-TEP asked for clarification of what was meant by the 3 month study period (for HD patients) and the 6 month study period (for PD patients) particularly when data collection changes from the current system to the monthly data collection which is expected to begin in 2008.

The three CPMs to which this are relevant (CPM IIa, CPM IIb, and CPM III) are shown below. Since each of these three CPMs require that a patient either be prescribed an ESA or have a Hb < 11 g/dl, we recommend that the three-month study period (for HD patients) for purposes of these CPMs be defined as the 3 month period consisting of the month in which a patient's Hb level and ESA use are reported and the 1 month preceding and 1 month following the month of Hb and ESA use measurement. This calculation methodology essentially represents a 3 month rolling quarter, with 12 calculations per year. As an example, if an HD patient's Hb level and ESA use are measured in the month of July, then the 3 month study period would pertain to the period from June 1st through August 31st. This methodology inherently provides dialysis units at least one month to take action following a measured Hb value.

For PD patients, we recommend that the six-month study period for purposes of these CPMs be defined as the 6 month period consisting of the month in which a patient's Hb level and ESA use are reported and the 2 months preceding and 3 months following the month of Hb and ESA use measurement. This calculation methodology essentially represents a 6 month rolling time period. As an example, if a PD patient's Hb level and ESA use are measured in the month of May, then the 6 month study period would pertain to the period from March 1st through August 31st.

CPM IIa:

Current CPM IIa: Assessment of iron stores among anemic patients or patients prescribed Epoetin.

For anemic patients (hemoglobin < 11 g/dL (110 g/L) in at least one study month) or patients prescribed epoetin, the percent transferrin saturation and serum ferritin concentration are assessed (measured) at least once in a three-month period for hemodialysis patients and at least two times during the six month study period for peritoneal dialysis patients.

Recommended CPM IIa by C-TEP: Assessment of iron stores among anemic patients or patients prescribed ESAs

For patients with Hb < 11.0 g/dL in at least one study month or patients prescribed ESAs, the serum ferritin concentrations and either percent transferrin saturation or reticulocyte Hb content

(CHr) are assessed (measured) *at least once in a three-month period* for hemodialysis patients and *at least two times during the six month study period* for peritoneal dialysis patients.

Numerator:

a. Number of HD patients in the denominator with at least one documented serum ferritin concentration and either percent transferrin saturation or reticulocyte Hb content (CHr) result during every 3 month period.

b. Number of PD patients in the denominator with at least two documented serum ferritin concentrations and either percent transferrin saturation or reticulocyte Hb content (CHr) results over the 6-month study period.

Denominator:

a. All adult (≥ 18 years old) HD patients included in the sample for analysis, if last reported Hgb in a study month is < 11 g/dL (110 g/L) or if prescribed an ESA in a study month.

b. All adult (≥ 18 years old) PD patients included in the sample for analysis, if last reported Hgb in a study month is < 11 g/dL (110 g/L) or if prescribed an ESA in a study month.

Basis for CPM IIa revision:

The recommendation to allow for use of reticulocyte Hb content (CHr) in assessment of iron stores is based on the 2006 KDOQI anemia management guidelines.

CPM IIb:

Current CPM IIb: Maintenance of iron stores.

For anemic patients (hemoglobin < 11 g/dL (110 g/L) in at least one study month) or patients prescribed epoetin, at least one serum ferritin concentration ≥ 100 ng/mL and at least one transferrin saturation $\geq 20\%$ were documented during the three-month study period for hemodialysis patients or during the six-month study period for peritoneal dialysis patients.

Recommended Revised CPM Iib by C-TEP: Maintenance of iron stores.

For patients with Hb < 11.0 g/dL in at least one study month or receiving ESA at any Hb level, at least one serum ferritin ≥ 200 ng/mL (≥ 100 ng/mL for peritoneal dialysis) and either one transferrin saturation $\geq 20\%$ or one CHr ≥ 29 pg were documented during the three-month study period (or six-month study period for peritoneal dialysis).

Numerator:

a. Number of HD patients in the denominator with at least one documented serum ferritin ≥ 200 ng/ml and either one transferrin saturation $\geq 20\%$ or one CHr ≥ 29 pg during a three-month period.

b. Number of PD patients in the denominator with at least one serum ferritin ≥ 100 ng/ml and either one transferrin saturation $\geq 20\%$ or one CHr ≥ 29 pg during the six-month study period.

Denominator:

- a. All adult (>18 years old) HD patients included in sample, if last reported Hgb in a study month is < 11 g/dL (110 g/L) or if prescribed an ESA in a study month.
- b. All adult (>18 years old) PD patients included in sample, if last reported Hgb in a study month is < 11 g/dL (110 g/L) or if prescribed an ESA in a study month.

Basis for CPM IIb revision:

The 3 major recommended changes in this CPM are:

- use of any ESA rather than only epoetin
- allow for use of reticulocyte Hb content (CHr \geq 29 pg) as one indicator of adequate iron stores
- changing the minimum target for serum ferritin from 100 to 200 ng/mL for hemodialysis patients

All recommended changes are based on the 2006 KDOQI anemia management guidelines.

CPM III:

Current CPM III: Administration of supplemental iron.

All anemic patients (hemoglobin < 11 g/dL (110 g/L) in at least one study month) or patients prescribed epoetin, and with at least one transferrin saturation < 20% or at least one serum ferritin concentration < 100 ng/mL during the study period are prescribed IV iron.

Current Exclusions:

- Mean transferrin saturation was \geq 50% or the mean serum ferritin concentration was \geq 800 ng/mL;
- Patient was in the first three months of dialysis and was prescribed oral iron.

Recommended CPM III by C-TEP: Administration of supplemental iron.

All hemodialysis and peritoneal dialysis patients with Hb < 11.0 g/dL or receiving ESA therapy at any Hb level are prescribed IV iron if they also meet at least one of the following conditions at any time during the study period:

- TSAT < 20%
- CHr < 29 pg
- Serum ferritin concentration < 200 ng/mL for hemodialysis patients or < 100 ng/mL for peritoneal dialysis patients.

Numerator:

- a. The number of HD patients in the denominator prescribed intravenous iron in at any time during 3 month study period.
- b. The number of PD patients in denominator prescribed intravenous iron at any time during the 6 month study period.

Denominator:

a. All adult (> 18 years old) HD patients included in the sample for analysis, if last reported Hgb in a study month is < 11 g/dL (110 g/L) or if prescribed an ESA in a study month, AND with at least one transferrin saturation < 20%, CHr < 29 pg, or serum ferritin concentration < 200 ng/mL.

b. All adult (> 18 years old) PD patients included in the sample for analysis if last reported Hgb in a study month is < 11 g/dL (110 g/L) or if prescribed an ESA in a study month, AND with at least one transferrin saturation < 20%, CHr < 29 pg, or serum ferritin concentration < 100 ng/mL.

Recommended Exclusions:

Patients with TSAT > 50% or serum ferritin concentration > 500 ng/mL and who have not received IV iron at any time during the study period are excluded from the calculation of this CPM

Basis for CPM III revision:

The major recommended changes in this CPM are:

- use of any ESA rather than only epoetin
- allow for use of reticulocyte Hb content (CHr < 29 pg) as an indication of iron deficiency
- changing the minimum target for serum ferritin from 100 to 200 ng/mL for hemodialysis patients
- making the CPM applicable to all dialysis patients, even those patients on dialysis < 90 days
- designing the exclusion criteria to be consistent with the 2006 KDOQI guideline regarding serum ferritin levels and iron replete status

Recommendation for Additional Figure in Annual Report

In Annual Report include a figure of:

The percentage of patients with Hb \geq 13.0 g/dL and prescribed an ESA in the same month as the Hb measurement.

Numerator: ESA-treated HD or PD patients on dialysis \geq 3 months and with documented mean Hb \geq 13.0 g/dL during a study month.

Denominator: All adult (\geq 18 yrs old) HD or PD patients on dialysis \geq 3 months and who have been prescribed an ESA in the same month as the Hb measurement.

Use the last Hb of the month or “End-of-Month” Hb for purposes of calculation.

APPENDIX A: ESRD Measures Clinical Technical Expert Panel (C-TEP) Members

Anemia Management C-TEP

Dr. David VanWyck, panel chair (University of Arizona Department of Medicine, Tucson, AZ)
Dr. Nathan Levin (Renal Research Institute, New York, NY)
Dr. Gerald Schulman (Vanderbilt University School of Medicine, Nashville, TN)
Dr. Jay Wish (University Hospital of Cleveland, Cleveland, OH)

Hemodialysis Adequacy C-TEP

Dr. Mike Rocco, panel chair (Wake Forest University, Salem, NC)
Dr. Richard Goldman (Renal Medicine Associates, Albuquerque, NM)
Dr. Tom Depner (University of California, Davis, CA)

Peritoneal Dialysis Adequacy C-TEP

Dr. Fred Finkelstein, panel chair (Yale University, New Haven, CT)
Dr. John Burkart (Wake Forest University, Salem, NC)
Dr. Ramesh Khanna (University of Missouri-Columbia, Columbia, MO)
Raynel Kinney, RN, CNN (The Renal Network, Network 10, Indianapolis, IN)
Barbara Prowant, MS, RN, CNN (University of Missouri-Columbia, Columbia, MO)

Vascular Access C-TEP

Dr. Anatole Besarab, panel chair (Henry Ford Hospital, Detroit, MI)
Evelyn Butera, MS, RN, CNN (Mills-Peninsula Health Services, San Mateo, CA)
Shu-Cheng Chen, MS (USRDS, Minneapolis, MN)
Dr. Eduardo Lacson (Fresenius Medical Care, Lexington, MA)
Dr. Vo Nguyen (Memorial Nephrology Association, Olympia, WA)
Dr. Lawrence Spergel (Dialysis Management Medical Group, San Francisco, CA)
Dr. Jack Work (Emory University School of Medicine, Atlanta, GA)

DFC Measures C-TEP

Dr. Derrick Latos, panel chair (Wheeling Renal Care, Wheeling, WV)
Dr. Paul Eggers (NIH-NIDDK, Bethesda, MD)
Dr. John Newmann (Health Policy Research & Analysis, Inc., Reston, VA)
Susan Stark (The Renal Network, Network 10, Indianapolis, IN)

Mineral Metabolism C-TEP

Dr. Curt Johnson, panel chair (University of Wisconsin, Verona, WI)
Jan Deane, RN, CNN (ESRD Network 11, St. Paul, MN)
Dr. Donna Mapes (Moore Park, CA)
Dr. James McCarthy (Mayo Clinic, Rochester, MN)

APPENDIX B: ESRD Measures Data Technical Expert Panel (D-TEP) Participants

Members:

Matt Howard (Network 15)
Raynel Kinney (Network 9)
Chris Lovell (DCI)
Norma Ofsthun (FMCHP)

Other Attendees:

Jackie Abt (CMS)
Brady Augustine (CMS)
Maria Ciccanti (CMS)
Gina Clemons (CMS)
Diane Frankenfield (CMS)
Pamela Frederick (CMS)
Judy Goldfarb (CMS)
Melinda Jones (CMS/QMHAG)
Vicki Schlining (CMS/ISG)

Andy Hanks (CSC)

Janet Hutchinson (Network 7)
H. Anthony Seabrook (Network 7)

Valarie Ashby (UM-KECC)
Charlene Cole (Arbor Research)
Erik Roys (Arbor Research)
Randy Webb (UM-KECC)