

**Kidney Care Quality Alliance  
Summary Report  
Phase I Balloting**

**Phase I Starter Set Adult Clinical Measures**

**Phase I Starter Set Quality of Life Measures**

### **Kidney Care Quality Alliance Members**

Abbott Laboratories  
America's Health Insurance Plans  
American Kidney Fund  
American Regent, Inc.  
American Society of Nephrology  
Amgen, Inc.  
California Dialysis Council  
Centers for Medicare & Medicaid Services  
(Liaison)  
DaVita Patient Citizens  
Genzyme  
Nabi Biopharmaceuticals  
National Medical Association  
National Renal Administrators Association  
Renal Advantage, Inc.  
Renal Support Network  
Satellite Health Care  
Society of General Internal Medicine  
Watson Pharma, Inc.

American Health Care Association  
Federation of American Hospitals  
American Nephrology Nurses' Association  
American Renal Associates, Inc.  
American Society of Pediatric Nephrology  
Baxter Healthcare Corporation  
Centers for Dialysis Care  
DaVita, Inc.

Fresenius Medical Care North America  
Medical Education Institute  
National Kidney Foundation  
National Partnership for Women & Families  
Northwest Kidney Centers  
Renal Physician's Association  
Roche  
Sigma-Tau Pharmaceuticals, Inc.  
U.S. Renal Care

## EXECUTIVE SUMMARY

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The Kidney Care Quality Initiative (Initiative) seeks to encourage high-quality care for patients with kidney disease and kidney failure by developing payment reforms that directly link reimbursement to the quality of care provided in the Medicare End Stage Renal Disease (ESRD) program. In Phase I of the Initiative, members sought to develop a starter set of measures based upon existing measures and guidelines for which there is already community consensus. Phase II will build upon this foundation and propose appropriate revisions to the starter set of measures, as well as the addition of new measures.

Beginning in late 2005, two expert work groups examined current measures and guidelines to develop the starter set of measures. The Clinical Measures Work Group focused on developing recommendations for adult clinical measures based upon the Clinical Performance Measures (CPMs) developed by the Centers for Medicare and Medicaid Services (CMS), the National Kidney Foundations' (NKF) K-DOQI Guidelines, as well as measures developed by other organizations including the American Medical Association and the Renal Physicians Association. The Quality of Life/Patient Perspective Work Group examined existing quality of life instruments, peer-reviewed journal articles, and other relevant sources to develop its recommendations.

These work groups developed recommendations that were reviewed and commented upon by a Steering Committee. In March 2006, Kidney Care Partners (KCP), which launched the Initiative, reviewed the recommendations and approved the quality of life starter measures. They provided additional comments to the Clinical Measures Work Group, which continued its efforts throughout the summer. The final recommendations were presented to the KCP in July and approved.

To assure independence of the outcome – and to help build broad-based consensus for the ultimate recommendations – KCP also created the Kidney Care Quality Alliance (Alliance). The KCP took the initial step of creating the Initiative and pulling together the KCQA because ESRD is only a small part of the services provided by members of the broader health care community. KCP wanted to make sure that the needs of patients with kidney failure were addressed in a manner that recognizes the unique nature of this population.

The Alliance includes organizations that extend beyond the kidney care community. At this time, there are 30 members of the KCQA including: the Federal of American Hospitals, America's Health Insurance Plans, the Society of Internal Medicine, American Health Care Association, and the National Medical Association. A complete list is at the front of this report. This Alliance is extremely important; its role is to review, provide input, and ultimately to endorse or reject the final recommended measures.

In July 2006, the Alliance met in person to discuss the KCP-approved adult clinical and quality of life measures. The Alliance reviewed these starter measures, asked questions of the work group members, and submitted comments to them. The final sets of measures were balloted in November. For purposes of adopting recommendations, the following was required for approval: (1) a health majority of those voting; and (2) at least a majority of the non-kidney care community organizations. During the balloting process, members had the opportunity to review each others'

comments and to suggest modifications to the recommendations. The full Alliance development process is available at [www.kidneycarepartners.org/quality](http://www.kidneycarepartners.org/quality).

This report provides a detailed summary of the results of the ballot on the Phase I Adult Clinical Starter Set and Quality of Life Starter Set measures and recommendations. All of the measures and recommendations submitted passed with a health majority of the kidney care community members approving the measures. As part of this process, the Alliance agreed that the physician measures for adequacy of dialysis and anemia management, which include both outcome and process components, be reported in way that each component can be identified independently. Physicians will still be evaluated on the combined measures, but there will be clarity as to the number of patients attaining the desired outcome. In addition, some members of the Alliance who are not actively involved in the kidney care community abstained from voting on particular measures. In these cases, the Alliance staff solicited their views on whether or not they agreed to move forward with all of the Phase I Clinical Measure and Quality of Life Recommendations. A majority agreed to move forward.

## PHASE I STARTER SET ADULT CLINICAL MEASURES

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### Phase I ACM 01F

**Ballot Release Date: 10/23/2006**

Summary: The recommendations describe general characteristics that will be applied to all of the facility measures. They address: (1) the threshold population; (2) the definition of facilities; (3) the reporting period; (4) global exclusions; (5) the patient population; (6) data sources for exclusions; (7) data sources; (8) the benchmarks.

Affirmative: 24

Negative: 1

Abstain: 4

### **SUMMARY OF COMMENTS:**

- Those who approved the measure made the following comments:
  - The measure should make clear that it only applies to facilities with more than 25 patients over the age of 18; not small facilities or pediatric units
- Those who opposed the measure made the following comments:
  - The measure should include facilities with less than 25 patients
  - The vote commented that long-term care facilities usually do not meet the 25 patient threshold for this measure
  - The vote commented that there were lingering questions about data sources

**Phase I ACM 02F**

**Ballot Release Date: 10/23/2006**

Summary: All participants agreed on the importance of addressing anemia among patients with ESRD. This facility measure captures patients whose Hgb level is greater than or equal to a threshold of 11.

$$\frac{\text{Number of patients whose Hgb} \geq 11}{\text{All ESRD patients receiving hemodialysis or peritoneal dialysis}}$$

Affirmative: 21

Negative: 6

Abstain: 2

**SUMMARY OF COMMENTS:**

- Those who approved the measure made the following comments:
  - The measure should also check for plans of care
  - Patients who are in their first 90 days of dialysis should be excluded since they require an adjustment period; this is consistent with USRDS and CMS data collection methods
  - There should be exclusions for patients with aplastic anemia, sickle cell anemia, thalassemias and other blood disorders built into the measure
- Those who opposed the measure made the following comments:
  - One member who voted in the negative commented that the measure should also check for plans of care
  - There should be an upper limit to the hemoglobin (Hgb)
- Those who abstained from voting on the measure made the following comments:
  - There were lingering questions about data sources

**Phase I ACM 03F**

**Ballot Release Date: 10/23/2006**

Summary: The facility measure below for hemodialysis captures patients whose Kt/V level is greater than or equal to a threshold of 1.2 and requires the measurement of Kt/V on a monthly basis.

Number of patients whose  $Kt/V \geq 1.2$  measured monthly

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All ESRD patients receiving hemodialysis

Summary: The facility measure below also captures patients whose Kt/V level is greater than or equal to a threshold of 1.7 and requires the measurement of Kt/V.

Number of patients whose  $Kt/V \geq 1.7$

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All ESRD patients receiving peritoneal dialysis

Affirmative: 24

Negative: 2

Abstain: 3

**SUMMARY OF COMMENTS:**

- Those who approved the measure made the following comments:
  - It may become necessary to separate the process component (frequency of collection) from the outcome component (Kt/V)
  - Both physicians and facilities should have two measures for anemia; one for measurement, as above, and another tracking plans of care
  - Patients who are in their first 90 days of dialysis should be excluded since they require an adjustment period; this is consistent with USRDS and CMS data collection methods
  
- Those who opposed the measure made the following comments:
  - The measure should include a plan of care
  - Patients who receive treatments five or more times a week should be excluded from the measure
  - There should be a time element, specifically three times per year, for measurement of Kt/V for peritoneal dialysis

**Phase I ACM 04F**

**Ballot Release Date: 10/23/2006**

Summary: The focus of this facility measure is to identify all patients who *received* an influenza vaccination (not just recommended to receive it). It is critically importance to vaccinate the ESRD population and the improved patient outcomes that are possible as a result of vaccination.

Number of patients who receive an influenza vaccination  
All ESRD patients receiving hemodialysis or peritoneal dialysis

Affirmative: 27

Negative: 0

Abstain: 2

**SUMMARY OF COMMENTS:**

- Those who approved the measure made the following comments:
  - Patients who have received vaccination outside the facility should count for the measure
  - The exclusions to the measure should be mentioned in the summary
  - The period of time in the numerator and denominator should be the same

**Phase I ACM 05F**

**Ballot Release Date: 10/23/2006**

Summary: The goal for vascular access is simultaneously to decrease the number of patients with catheters and to increase the number of patients with AV fistulas. Because both of these components are important to track, there are two measures for vascular access. This facility measure looks at the whole ESRD population.

Number of patients who have a functioning AV fistula or are referred for permanent access  
All ESRD patients receiving hemodialysis

Affirmative: 26

Negative: 1

Abstain: 2

**SUMMARY OF COMMENTS:**

- Those who approved the measure made the following comments:
  - Patients who have already been referred for a fistula, but still have a catheter, should be excluded from the measure
  - Patients without viable sites for a fistula or graft should be excluded from the denominator
  - The acceptable methods of referring patients must be specified
  - Once a patient has been referred for evaluation of a permanent access that this process does not have to recur every year
- Those who opposed the measure made the following comments:
  - Patients with fistulas should be separated from patients referred for permanent access
  - They should be counted as if they have a fistula or permanent access – or the measure should be split in two

## Phase I ACM 06F

Ballot Release Date: 10/23/2006

Summary: The goal for vascular access is simultaneously to decrease the number of patients with catheters and to increase the number of patients with AV fistulas. Because both of these components are important to track, there are two measures for vascular access. This facility measure focuses on patients with catheters.

Number of patients who are referred for permanent access  
All ESRD patients receiving hemodialysis who have a catheter

Affirmative: 24

Negative: 3

Abstain: 2

### **SUMMARY OF COMMENTS:**

- Those who approved the measure made the following comments:
  - The acceptable methods of referring patients must be specified
  - Patients who have already been referred for a fistula, but still have a catheter, should be excluded from the measure
  - Once a patient has been referred for evaluation of a permanent access that this process does not have to recur every year
  
- Those who opposed the measure made the following comments:
  - The measure should gauge simply the number of patients with catheters over the total number of hemodialysis patients; not all patients can or should be referred for permanent access
  - The measure should track assessments for vascular access along with referral; the assessment should include a discussion of all modalities
  - Patients who have already been referred for a fistula, but still have a catheter, should be excluded from the measure

**Phase I ACM 07P**

**Ballot Release Date: 10/23/2006**

Summary: The physician recommendations describe general characteristics that will be applied to all of the measures. They address: (1) the threshold population; (2) the level of aggregation; (3) the reporting period; (4) global exclusions; (5) the patient population; (6) data sources for exclusions; (7) feedback; (8) data sources.

Affirmative: 24

Negative: 1

Abstain: 4

**SUMMARY OF COMMENTS:**

- Those who opposed the measure made the following comments:
  - The measure should include facilities with less than 25 patients
- Those who abstained from voting on the measure made the following comments:
  - There were lingering questions about data sources

## Phase I ACM 08P

Ballot Release Date: 10/23/2006

Summary: This physician measure captures both patients whose Hgb level is greater than or equal to a threshold of 11 and patients whose Hgb is < 11 with a documented plan of care.

Number of patients whose Hgb  $\geq 11$  AND number of patients whose Hgb < 11 with a plan of care

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All ESRD patients receiving hemodialysis or peritoneal dialysis

Affirmative: 18

Negative: 9

Abstain: 2

### **SUMMARY OF COMMENTS:**

- A significant number of members who voted in the affirmative agreed to it only if reporting of the outcome and plan of care were separate and then combined later.
- In addition, individual members who approved the measures made the following comments:
  - The outcomes and process measures should be separate measures
  - There should also be a process measure for both physicians and facilities tracking the establishment of a plan of care for patients not meeting the parameter
  - Patients who are in their first 90 days of dialysis should be excluded since they require an adjustment period; this is consistent with USRDS and CMS data collection methods
- Those who opposed the measure made the following comments:
  - There should be an upper limit to the hemoglobin (Hgb)
  - The measure should be outcome only
  - The measure fails to address safety issues, particularly package inserts
  - The outcomes and process measures should be separated
  - The measure should be separated between patients with an Hgb > 11 and patients with an Hgb > 11
- Those who abstained from voting on the measure made the following comments:
  - There should be an upper limit to the Hgb

## Phase I ACM 09P

**Ballot Release Date: 10/23/2006**

Summary: The physician measure below for hemodialysis captures both patients whose Kt/V level is greater than or equal to a threshold of 1.2 and patients whose Kt/V level is  $< 1.2$  with a documented plan of care.

Number of patients whose  $Kt/V \geq 1.2$  measured monthly AND number of patients whose  $Kt/V < 1.2$  with a plan of care

All ESRD patients receiving hemodialysis

Summary: The physician measure also captures both patients whose Kt/V level is greater than or equal to a threshold of 1.7 and patients whose Kt/V level is  $< 1.7$  with a documented plan of care.

Number of patients whose  $Kt/V \geq 1.7$  AND number of patients whose  $Kt/V < 1.7$  with a plan of care

All ESRD patients receiving peritoneal dialysis

Affirmative: 21      Negative: 5      Abstain: 3

### **SUMMARY OF COMMENTS:**

- A significant number of members who voted in the affirmative agreed to it only if reporting of the outcome and plan of care were separate and then combined later.
- In addition, individual members who approved the measures made the following comments:
  - There should also be a process measure for both physicians and facilities tracking the establishment of a plan of care for patients not meeting the parameter
  - Daily dialysis patients should be excluded or captured under a separate measure
  - Patients who are in their first 90 days of dialysis should be excluded since they require an adjustment period; this is consistent with USRDS and CMS data collection methods.
  - The outcomes and process measures metrics should be separated
- Those who opposed the measure made the following comments:
  - That there should be an outcomes measure in addition to this clinical measure
  - The measure should be split into two; patients with  $Kt/V > 1.2$  and those with plans of care
  - Data should be collected to incorporate the outcomes and process aspects separately
  - The Kt/V should actually be higher
  - The measure should be outcome only
  - There should be a time element, specifically three times per year, for measurement of Kt/V for peritoneal dialysis

**Phase I ACM 10P**

**Ballot Release Date: 10/23/2006**

Summary: The focus of this measure is to identify all patients who *received* an influenza vaccination (not just recommended to receive it). The group discussed the critical importance of vaccinating the ESRD population and the improved patient outcomes that are possible as a result of vaccination.

Number of patients who receive an influenza vaccination  
All ESRD patients receiving hemodialysis or peritoneal dialysis

Affirmative: 27

Negative: 0

Abstain: 2

**SUMMARY OF COMMENTS:**

- Those who approved the measure made the following comments:
  - Patients who have received vaccination outside the facility should count for the measure
  - The exclusions to the measure should be mentioned in the summary
- Those who opposed the measure made the following comments:
  - The period of time in the numerator and denominator to be the same

## Phase I ACM 11P

**Ballot Release Date: 10/23/2006**

Summary: The goal for vascular access is simultaneously to decrease the number of patients with catheters and to increase the number of patients with AV fistulas. Because both of these components are important to track, there are two measures for vascular access. This facility measure looks at the whole ESRD population.

Number of patients who have a functioning AV fistula or are referred for permanent access  
All ESRD patients receiving hemodialysis

Affirmative: 26

Negative: 1

Abstain: 2

### **SUMMARY OF COMMENTS:**

- Those who approved the measure made the following comments:
  - Patients who are not candidates for a fistula should be excluded from this measure
  - The acceptable methods of referring patients must be specified
  - Patients who have already been referred for a fistula, but still have a catheter, should be excluded from the measure or counted separately
  
- Those who opposed the measure made the following comments:
  - Patients who have already been referred for a fistula, but still have a catheter, should be excluded from the measure or counted separately

**Phase I ACM 12P**

**Ballot Release Date: 10/23/2006**

Summary: The goal for vascular access is simultaneously to decrease the number of patients with catheters and to increase the number of patients with AV fistulas. Because both of these components are important to track, there are two measures for vascular access. This facility measure focuses on patients with catheters.

Number of patients who are referred for permanent access  
All ESRD patients receiving hemodialysis who have a catheter

Affirmative: 24

Negative: 3

Abstain: 2

**SUMMARY OF COMMENTS:**

- Those who approved the measure made the following comments:
  - The acceptable methods of referring patients must be specified
  - Patients who have already been referred for a fistula, but still have a catheter, should be excluded from the measure
  - A patient has been referred for evaluation of a permanent access that this process does not have to recur every year
- Those who opposed the measure made the following comments:
  - Patients who do not have other possible access sites should be excluded from the measure
  - The measure should track assessments for vascular access along with referral; the assessment should include a discussion of all modalities
  - Patients who have already been referred for a fistula, but still have a catheter, should be excluded from the measure

## PHASE I STARTER SET QUALITY OF LIFE MEASURES

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### Phase I QOL 01

**Ballot Release Date: 10/23/2006**

A process measure that requires an ongoing educational effort beginning with Stage 4 and 5 CKD patients about the different treatment modality options available to them. (Number of patients with documentation regarding discussion of renal replacement therapy (RRT) modalities (including transplants and identification of potential living donors)/number of patients with advanced CKD; outcome measure; input measured; documentation regarding discussion of RRT modalities; source of input: chart reviews).

Affirmative: 23

Negative: 4

Abstain: 2

### **SUMMARY OF COMMENTS:**

- Those who approved the measure made the following comments:
  - The measure is insufficiently developed with the numerator and denominators along with their data sources being unclear
  - This should be considered a clinical measure
  - There should be clarification of the term “ongoing”
  - It was "too easy to check the box" rather than actually counsel the patient
  
- Those who opposed the measure made the following comments:
  - Chart reviews are notoriously inaccurate
  - The measure is insufficiently developed with the numerator and denominators along with their data sources being unclear

## Phase I QOL 02

**Ballot Release Date: 10/23/2006**

A process measure that identifies whether or not facilities and providers are measuring patient satisfaction and quality of life. Until appropriate patient satisfaction and quality of life tools have been identified, facilities and providers should be attentive to patient satisfaction and quality of life issues through whatever mechanisms/tools they have determined are appropriate. The process of measuring quality of life should entail using either the SF-36 or KDQOL.

Affirmative: 24

Negative: 4

Abstain: 1

### **SUMMARY OF COMMENTS:**

- Those who approved the measure made the following comments:
  - Other tools, beyond SF-36 or KDQOL, may be more appropriate in the future
  - The measure is insufficiently developed with the numerator and denominators along with their data sources being unclear
  
- Those who opposed the measure made the following comments:
  - The measure was too formal for many cases
  - Other tools, beyond SF-36 or KDQOL, may be more appropriate in the future
  - The measure is insufficiently developed with the numerator and denominators along with their data sources being unclear

## Phase I QOL 03

**Ballot Release Date: 10/23/2006**

Based upon current literature, quality of life tools strongly correlate with hospitalization and mortality rates. However, there is no evidence of a causal relationship between specific actions and improvements in quality of life. Therefore, the Work Group recommends an evaluation/pilot study to be conducted to determine if scores on one or more of the patient quality of life tools correlate with processes of care in dialysis facilities and/or improved outcomes (as directly related to facility activities) and to evaluate the cost and burden of implementing such tools. The evaluation of these tools should be conducted by the USRDS Quality of Life Special Study Center, the Agency for Healthcare Research and Quality, MedPAC, and/or the Institute of Medicine with consultation from the kidney care community. The National Institutes of Health should fund a study examining the role and usefulness of quality of life measures in the management of ESRD patients.

Affirmative: 26

Negative: 2

Abstain: 1

### **SUMMARY OF COMMENTS:**

- Those who approved the measure made the following comments:
  - The measure is insufficiently developed with the numerator and denominators along with their data sources being unclear
  - The measure should track patients utilizing all modalities and encompass the physicians role in care for both CKD and ESRD patients
- Those who opposed the measure made the following comments:
  - The measure is insufficiently developed with the numerator and denominators along with their data sources being unclear