



Measure Information

This document contains the information submitted by measure developers/stewards, but is organized according to NQF's measure evaluation criteria and process. The item numbers refer to those in the submission form but may be in a slightly different order here. In general, the item numbers also reference the related criteria (e.g., item 1b.1 relates to subcriterion 1b).

Brief Measure Information

NQF #: 0260

Corresponding Measures:

De.2. Measure Title: [Assessment of Health-related Quality of Life in Dialysis Patients](#)

Co.1.1. Measure Steward: [Witten and Associates, LLC](#)

De.3. Brief Description of Measure: Percentage of eligible dialysis patients who complete a health-related quality of life assessment with or without assistance using the KDQOL-36 (36-question survey that assesses patients' functioning and well-being) at least once during a calendar year.

1b.1. Developer Rationale: Assessing functioning and well-being (health-related quality of life) will help health care providers monitor the impact of kidney disease on the daily lives of persons on dialysis.

S.4. Numerator Statement: Number of eligible (not excluded) individuals with ESRD (ICD-10 N18.6) on dialysis who complete a KDQOL-36 with or without assistance at least once per calendar year

S.7. Denominator Statement: Number of individuals with ESRD (ICD-10 N18.6) on peritoneal dialysis, in-center hemodialysis, and home hemodialysis treated by the dialysis facility during the calendar year minus those dialysis patients who meet exclusion criteria in S.10.

S.10. Denominator Exclusions: Patients with ESRD (ICD-10 N18.6) on dialysis who are <18 years old; who are unable to complete the survey due to mental status that could invalidate the results; who are non-English speaking/reading and no native language translation or interpreter is available; or who have been on dialysis for <3 months. A patient who declines to complete one survey but completes one survey during the calendar year is counted as having a completed survey.

De.1. Measure Type: [Process](#)

S.23. Data Source: [Instrument-Based Data](#)

S.26. Level of Analysis: [Facility](#)

IF Endorsement Maintenance – Original Endorsement Date: [Nov 15, 2007](#) **Most Recent Endorsement Date:** [Nov 15, 2007](#)

IF this measure is included in a composite, NQF Composite#/title:

IF this measure is paired/grouped, NQF#/title:

De.4. IF PAIRED/GROUPED, what is the reason this measure must be reported with other measures to appropriately interpret results?

1. Evidence, Performance Gap, Priority – Importance to Measure and Report

Extent to which the specific measure focus is evidence-based, important to making significant gains in healthcare quality, and improving health outcomes for a specific high-priority (high-impact) aspect of healthcare where there is variation in or overall less-than-optimal performance. ***Measures must be judged to meet all subcriteria to pass this criterion and be evaluated against the remaining criteria.***

1a. Evidence to Support the Measure Focus – See attached Evidence Submission Form
[0260-MeasSubmEvidence-2016.docx](#)

1b. Performance Gap

Demonstration of quality problems and opportunity for improvement, i.e., data demonstrating:

- considerable variation, or overall less-than-optimal performance, in the quality of care across providers; and/or
- disparities in care across population groups.

1b.1. Briefly explain the rationale for this measure (e.g., the benefits or improvements in quality envisioned by use of this measure)

Assessing functioning and well-being (health-related quality of life) will help health care providers monitor the impact of kidney disease on the daily lives of persons on dialysis.

1b.2. Provide performance scores on the measure as specified (current and over time) at the specified level of analysis. (This is required for endorsement maintenance. Include mean, std dev, min, max, interquartile range, scores by decile. Describe the data source including number of measured entities; number of patients; dates of data; if a sample, characteristics of the entities included). This information also will be used to address the subcriterion on improvement (4b.1) under Usability and Use.

Using KDQOL-Complete data, we are able to test whether there are statistically significant differences in the performance measure between facilities with at least 10 patients.

2013

N=1,240; Mean=85.4; Median=91.8; Range=0-100; Interquartile Range=78.3-100; 100% Max=100; 99%=100; 95%=100; 90%=100; 75% Q3=100; 50% Median=91.8; 25% Q1=78.3; 10%=59.4; 5%=46.9; 1%=28.1; 0% Min=0

2014

N=1,222; Mean=85.5; Median=92.1; Range=0-100; Interquartile Range=78.3-98.1; 100% Max=100; 99%=100; 95%=100; 90%=100; 75% Q3=98.1; 50% Median=92.1; 25% Q1=78.3; 10%=61.4; 5%=50.0; 1%=29.1; 0% Min=0

2015

N=1,261; Mean=85.6; Median=91.8; Range=16.7-100; Interquartile Range=78.3-100; 100% Max=100; 99%=100; 95%=100; 90%=100; 75% Q3=97.9; 50% Median=91.8; 25% Q1=78.3; 10%=61.2; 5%=48.9; 1%=29.3; 0% Min=16.7

1b.3. If no or limited performance data on the measure as specified is reported in 1b2, then provide a summary of data from the literature that indicates opportunity for improvement or overall less than optimal performance on the specific focus of measurement.

1b.4. Provide disparities data from the measure as specified (current and over time) by population group, e.g., by race/ethnicity, gender, age, insurance status, socioeconomic status, and/or disability. (This is required for endorsement maintenance. Describe the data source including number of measured entities; number of patients; dates of data; if a sample, characteristics of the entities include.) This information also will be used to address the subcriterion on improvement (4b.1) under Usability and Use.

We used the full KDQOL-Complete dataset, counting only the first KDQOL-36 survey for patients who completed the survey more than once in a calendar year. We compared the data for All, Completed, Refused, and Excluded for 2013, 2014, 2015.

2013:

All-79,872; Mean Age 62.4+ (14.9); Male-55.5%; White-45.4%; Black-26%; Asian-4.5%; Native Am-1.6%; Pacific Island-1.8%; Missing-20.8%; Diabetes 52.7%

Completed-62,620; Mean Age 61.9 (14.7); Male-55.7%; White-46.3%; Black-25.9%; Asian-4.3%; Native Am-1.8%; Pacific Island-1.8%; Missing-20.2%; Diabetes 52.8%

Refused-11,790; Mean Age 61.9 (15.1); Male-49.9%; White-43.7%; Black-25.3%; Asian-3.7%; Native Am-1.3%; Pacific Island-2.4%; Missing-23.5%; Diabetes 51.6%

Excluded-5,462; Mean Age 69.2 (14.5); Male-59.1%; White-38.6%; Black-28.5%; Asian-8.0%; Native Am-2.6%; Pacific Island-1.3%; Missing-21.0%; Diabetes 54.6%

2014

All-84,167; Mean Age 62.4 (14.9); Male-56.3%; White-45.4%; Black-25.8%; Asian-5.5%; Native Am-1.5%; Pacific Island-1.9%; Missing-19.9%; Diabetes 52.6%

Completed-66,386; Mean Age 62.0 (14.7); Male-56.2%; White-46.6%; Black-25.8%; Asian-5.4%; Native Am-1.5%; Pacific Island-1.8%; Missing-18.9%; Diabetes 52.9%

Refused-12,015; Mean Age 61.7 (15.1); Male-51.2%; White-42.5%; Black-25.5%; Asian-4.4%; Native Am-1.5%; Pacific Island-1.7%; Missing-24.3%; Diabetes 50.5%

Excluded-5,756; Mean Age 69.2 (14.6); Male-59.1%; White-37.8%; Black-27.4%; Asian-9.4%; Native Am-0.6%; Pacific Island-2.5%; Missing-22.3%; Diabetes 54.1%

2015

All-87,892; Mean Age 62.4 (14.7); Male-56.4%; White-45.1%; Black-26.6%; Asian-5.4%; Native Am-1.5%; Pacific Island-1.9%; Missing-

19.5%; Diabetes 52.5%

Completed-69,746; Mean Age 62.0 (14.5); Male-56.4%; White-45.9%; Black-27.0%; Asian-5.1%; Native Am-1.5%; Pacific Island-1.9%; Missing-18.7%; Diabetes 52.4%

Refused-12,475; Mean Age 61.7 (15.0); Male-59.2%; White-43.3%; Black-24.7%; Asian-5.2%; Native Am-1.7%; Pacific Island-1.9%; Missing-23.1%; Diabetes 51.6%

Excluded-5,671; Mean Age 69.5 (14.6); Male-50.4%; White-38.8%; Black-26.5%; Asian-9.9%; Native Am-0.7%; Pacific Island-2.2%; Missing-21.9%; Diabetes 55.3%

1b.5. If no or limited data on disparities from the measure as specified is reported in 1b4, then provide a summary of data from the literature that addresses disparities in care on the specific focus of measurement. Include citations.

1c. High Priority (previously referred to as High Impact)

The measure addresses:

- a specific national health goal/priority identified by DHHS or the National Priorities Partnership convened by NQF; OR
- a demonstrated high-priority (high-impact) aspect of healthcare (e.g., affects large numbers of patients and/or has a substantial impact for a smaller population; leading cause of morbidity/mortality; high resource use (current and/or future); severity of illness; and severity of patient/societal consequences of poor quality).

1c.1. Demonstrated high priority aspect of healthcare

A leading cause of morbidity/mortality, Patient/societal consequences of poor quality, Severity of illness

1c.2. If Other:

1c.3. Provide epidemiologic or resource use data that demonstrates the measure addresses a high priority aspect of healthcare.

List citations in 1c.4.

The United States Renal System reported that in 2013 over 468,000 patients were on dialysis. African Americans, Hispanics, Pacific Islanders, Native Americans and older Americans are at increased risk. Kidney disease is a leading cause of hospitalization and death. Low HRQOL scores predict higher relative risk of death and hospitalization. Healthy People 2020 will monitor progress toward improving HRQOL as one of its 4 foundation health measures.

1c.4. Citations for data demonstrating high priority provided in 1a.3

United States Renal Data System. 2015 USRDS annual data report: Epidemiology of kidney disease in the United States. National Institutes of Health, National Institute of Diabetes and Digestive and Kidney Diseases, Bethesda, MD, 2015.

Lopes AA, Bragg-Gresham JL, Satayathum S, McCullough K, Pifer T, Goodkin DA, Mapes DL, Young EW, Wolfe RA, Held PJ, Port FK; Worldwide Dialysis Outcomes and Practice Patterns Study Committee. (2003). Health-related quality of life and associated outcomes among hemodialysis patients of different ethnicities in the United States: the Dialysis Outcomes and Practice Patterns Study (DOPPS). Am J Kidney Dis 2003 Mar; 41(3):605-15.

Mapes DL, Lopes AA, Satayathum S, McCullough KP, Goodkin DA, Locatelli F, Fukuhara S, Young EW, Kurokawa K, Saito A, Bommer J, Wolfe RA, Held PJ, Port FK. (2003). Health-related quality of life as a predictor of mortality and hospitalization: the Dialysis Outcomes and Practice Patterns Study (DOPPS). Kidney Int. 2003 Jul; 64(1):339-49.

Walters BA, Hays RD, Spritzer KL, Fridman M, Carter WB. (2002). Health-related quality of life, depressive symptoms, anemia, and malnutrition at hemodialysis initiation. American Journal of Kidney Disease, 40 (6), 1185-94.

HealthyPeople.gov

1c.5. If a PRO-PM (e.g. HRQoL/functional status, symptom/burden, experience with care, health-related behaviors), provide evidence that the target population values the measured PRO and finds it meaningful. (Describe how and from whom their input was obtained.)

The ESRD Conditions for Coverage published in 2008 requires administration of a "standardized mental and physical assessment tool...at regular intervals, or more frequently on an as-needed basis" at 42 CFR 494.90(a)(6). Further, Dialysis Therapies: A National Dialogue published by Mehrotra et al. in CJASN in 2014 states, "The National Institute of Diabetes, Digestive, and Kidney Diseases-supported Kidney Research National Dialogue asked the scientific community to formulate and prioritize research objectives that would improve our understanding of kidney function and disease. Kidney Research National Dialogue participants identified the need to improve outcomes in ESRD by decreasing mortality and morbidity and enhancing quality of life as high priority areas in kidney research."

2. Reliability and Validity—Scientific Acceptability of Measure Properties

Extent to which the measure, as specified, produces consistent (reliable) and credible (valid) results about the quality of care when implemented. **Measures must be judged to meet the subcriteria for both reliability and validity to pass this criterion and be evaluated against the remaining criteria.**

2a.1. Specifications The measure is well defined and precisely specified so it can be implemented consistently within and across organizations and allows for comparability. eMeasures should be specified in the Health Quality Measures Format (HQMF) and the Quality Data Model (QDM).

De.5. Subject/Topic Area (check all the areas that apply):

Renal, Renal : End Stage Renal Disease (ESRD)

De.6. Non-Condition Specific (check all the areas that apply):

Health and Functional Status : Change

S.1. Measure-specific Web Page (Provide a URL link to a web page specific for this measure that contains current detailed specifications including code lists, risk model details, and supplemental materials. Do not enter a URL linking to a home page or to general information.)

www.rand.org/health/surveys_tools/kdqol.html

S.2a. If this is an eMeasure, HQMF specifications must be attached. Attach the zipped output from the eMeasure authoring tool (MAT) - if the MAT was not used, contact staff. (Use the specification fields in this online form for the plain-language description of the specifications)

This is not an eMeasure Attachment:

S.2b. Data Dictionary, Code Table, or Value Sets (and risk model codes and coefficients when applicable) must be attached. (Excel or csv file in the suggested format preferred - if not, contact staff)

No data dictionary Attachment:

S.3. For endorsement maintenance, please briefly describe any changes to the measure specifications since last endorsement date and explain the reasons.

- We revised the exclusion of "<3 months at the facility" to "<3 months on dialysis." The ESRD Conditions for Coverage at 42 CFR 494.90 require the dialysis interdisciplinary team to perform a reassessment during the 4th month of dialysis and to use results of that reassessment for the patient plan of care meeting that is held 15 days after the team completes that reassessment. Excluding patients during the first 3 months of dialysis will align the survey with the first reassessment.

- We revised the exclusion of "cognitive impairment, dementia, psychosis" to "unable to complete due to mental status" to incorporate those diagnoses as well as others that make completion impossible or unreliable.

- We removed patients who refuse to complete the survey from the exclusions from the denominator. Facilities need to track and make efforts to to increase the number of patients completing the survey.

- We broadened the target populations to include more than just seniors since dialysis patients are populations at risk, dual eligible beneficiaries, individuals with multiple chronic illnesses, veterans.

S.4. Numerator Statement (Brief, narrative description of the measure focus or what is being measured about the target population, i.e., cases from the target population with the target process, condition, event, or outcome)

IF an OUTCOME MEASURE, state the outcome being measured. Calculation of the risk-adjusted outcome should be described in the calculation algorithm.

Number of eligible (not excluded) individuals with ESRD (ICD-10 N18.6) on dialysis who complete a KDQOL-36 with or without assistance at least once per calendar year

S.5. Time Period for Data (What is the time period in which data will be aggregated for the measure, e.g., 12 mo, 3 years, look back to August for flu vaccination? Note if there are different time periods for the numerator and denominator.)

Annually

S.6. Numerator Details (All information required to identify and calculate the cases from the target population with the target process, condition, event, or outcome such as definitions, specific data collection items/responses, code/value sets – Note: lists of

individual codes with descriptors that exceed 1 page should be provided in an Excel or csv file in required format at S.2b)
IF an OUTCOME MEASURE, describe how the observed outcome is identified/counted. Calculation of the risk-adjusted outcome should be described in the calculation algorithm.

Number of eligible (not excluded) individuals with ESRD (ICD-10 N18.6) on peritoneal dialysis, in-center hemodialysis, and home hemodialysis who complete a KDQOL-36 survey with or without assistance during the calendar year. A patient who declines to complete one survey but completes one survey during the calendar year is counted as having a completed a survey that year. A patient who completes more than one survey in a calendar year is counted only once.

S.7. Denominator Statement *(Brief, narrative description of the target population being measured)*

Number of individuals with ESRD (ICD-10 N18.6) on peritoneal dialysis, in-center hemodialysis, and home hemodialysis treated by the dialysis facility during the calendar year minus those dialysis patients who meet exclusion criteria in S.10.

S.8. Target Population Category *(Check all the populations for which the measure is specified and tested if any):*

Elderly, Populations at Risk, Populations at Risk : Dual eligible beneficiaries, Populations at Risk : Individuals with multiple chronic conditions, Populations at Risk : Veterans

S.9. Denominator Details *(All information required to identify and calculate the target population/denominator such as definitions, specific data collection items/responses, code/value sets – Note: lists of individual codes with descriptors that exceed 1 page should be provided in an Excel or csv file in required format at S.2b)*

Total number of individuals with ESRD (ICD-10 N18.6) on all types of dialysis at the dialysis facility minus patients who meet exclusion criteria in S.10.

S.10. Denominator Exclusions *(Brief narrative description of exclusions from the target population)*

Patients with ESRD (ICD-10 N18.6) on dialysis who are <18 years old; who are unable to complete the survey due to mental status that could invalidate the results; who are non-English speaking/reading and no native language translation or interpreter is available; or who have been on dialysis for <3 months. A patient who declines to complete one survey but completes one survey during the calendar year is counted as having a completed survey.

S.11. Denominator Exclusion Details *(All information required to identify and calculate exclusions from the denominator such as definitions, specific data collection items/responses, code/value sets – Note: lists of individual codes with descriptors that exceed 1 page should be provided in an Excel or csv file in required format at S.2b)*

- 1 - Age <18 calculated by date of exclusion minus date of birth in the medical record
- 2 - Unable to complete due to mental status (revised exclusion) from the medical record
- 3 - Non-English speaking/reading (no language translation or interpreter available) from medical record and RAND translations for KDQOL-36 and interpreter resources like www.LanguageLine.com or other service
- 4 - <3 months on dialysis (revised exclusion) calculated by date of exclusion minus date of first dialysis on Form CMS 2728 in medical record

S.12. Stratification Details/Variables *(All information required to stratify the measure results including the stratification variables, definitions, specific data collection items/responses, code/value sets – Note: lists of individual codes with descriptors that exceed 1 page should be provided in an Excel or csv file in required format with at S.2b)*

NA

S.13. Risk Adjustment Type *(Select type. Provide specifications for risk stratification in S.12 and for statistical model in S.14-15)*

No risk adjustment or risk stratification

If other:

S.14. Identify the statistical risk model method and variables *(Name the statistical method - e.g., logistic regression and list all the risk factor variables. Note - risk model development and testing should be addressed with measure testing under Scientific Acceptability)*

NA

S.15. Detailed risk model specifications *(must be in attached data dictionary/code list Excel or csv file. Also indicate if available at measure-specific URL identified in S.1.)*

Note: Risk model details (including coefficients, equations, codes with descriptors, definitions), should be provided on a separate

worksheet in the suggested format in the Excel or csv file with data dictionary/code lists at S.2b.

S.15a. Detailed risk model specifications (if not provided in excel or csv file at S.2b)

NA

S.16. Type of score:

Categorical, e.g., yes/no

If other:

S.17. Interpretation of Score (Classifies interpretation of score according to whether better quality is associated with a higher score, a lower score, a score falling within a defined interval, or a passing score)

Passing score defines better quality

S.18. Calculation Algorithm/Measure Logic (Describe the calculation of the measure score as an ordered sequence of steps including identifying the target population; exclusions; cases meeting the target process, condition, event, or outcome; aggregating data; risk adjustment; etc.)

Number of completed surveys divided by the number of eligible dialysis patients (all treatment types) treated at the dialysis facility during the calendar year. Exclusion criteria are described in S.10.

S.19. Calculation Algorithm/Measure Logic Diagram URL or Attachment (You also may provide a diagram of the Calculation Algorithm/Measure Logic described above at measure-specific Web page URL identified in S.1 OR in attached appendix at A.1)

No diagram provided

S.20. Sampling (If measure is based on a sample, provide instructions for obtaining the sample and guidance on minimum sample size.)

IF a PRO-PM, identify whether (and how) proxy responses are allowed.

NA

S.21. Survey/Patient-reported data (If measure is based on a survey, provide instructions for conducting the survey and guidance on minimum response rate.)

IF a PRO-PM, specify calculation of response rates to be reported with performance measure results.

At each dialysis facility, dialysis staff (usually the social worker) offers the survey to those dialysis patients who are not excluded.

Dialysis staff describe the purpose of the survey, how to complete it alerting the patient to pay close attention to the time period related to each question. Staff collect the survey, score it, and report results to the patient and dialysis team.

The survey downloaded from the RAND site states, "This survey asks for your views about your health. This information will help keep track of how you feel and how well you are able to do your usual activities."

The survey downloaded from the KDQOL-Complete site states, "The KDQOL-36 survey lets you rate your quality of life with kidney disease. Hundreds of studies have found that how you view your physical and mental function is vital. People who had a poor view of their lives were more likely to need hospital care and less likely to live a long time. You are the only one who can tell us how you feel about your life. In fact, how you rate your quality of life is one of the best ways to know how you are doing. The Dialysis Outcomes and Practice Patterns Study (DOPPS) looks at people who are on dialysis around the world. The DOPPS found a strong link between how people feel, their quality of life, and how well they do on dialysis. We ask you to take this survey so you can share things that may affect how well you feel while you receive dialysis treatment. At the end of the survey, we will provide a report that will tell you information about:

* Your scores on each of 5 subtests

* How your scores compare to others like you with regard to age, sex, and diabetic status

* Things you can do to improve your scores

Over time, tracking your scores will help you learn how taking care of yourself affects how you feel.

Help us to help you feel your best with kidney failure."

S.22. Missing data (specify how missing data are handled, e.g., imputation, delete case.)

Required for Composites and PRO-PMs.

Anecdotally, dialysis facility staff report that completion rates are higher when the patient understands the survey purpose and how

it will be used, when survey is completed at the dialysis facility rather than taken home to complete and return, when staff provide help as needed, when results are shared with patients in a timely manner, and when the patient is involved in goal setting to address problems related to the patient's health-related quality of life.

S.23. Data Source (Check *ONLY* the sources for which the measure is SPECIFIED AND TESTED).

If other, please describe in S.24.

[Instrument-Based Data](#)

S.24. Data Source or Collection Instrument (Identify the specific data source/data collection instrument e.g. name of database, clinical registry, collection instrument, etc.)

If a PRO-PM, identify the specific PROM(s); and standard methods, modes, and languages of administration.

[Kidney Disease Quality of Life \(KDQOL-36\) survey](#)

S.25. Data Source or Collection Instrument (available at measure-specific Web page URL identified in S.1 OR in attached appendix at A.1)

[Available at measure-specific web page URL identified in S.1](#)

S.26. Level of Analysis (Check *ONLY* the levels of analysis for which the measure is SPECIFIED AND TESTED)

[Facility](#)

S.27. Care Setting (Check *ONLY* the settings for which the measure is SPECIFIED AND TESTED)

[Post-Acute Care](#)

If other:

S.28. COMPOSITE Performance Measure - Additional Specifications (Use this section as needed for aggregation and weighting rules, or calculation of individual performance measures if not individually endorsed.)

[NA](#)

2a. Reliability – See attached Measure Testing Submission Form

2b. Validity – See attached Measure Testing Submission Form

[0260-Measure-Testing-Attachment-2016.docx](#)

3. Feasibility

Extent to which the specifications including measure logic, require data that are readily available or could be captured without undue burden and can be implemented for performance measurement.

3a. Byproduct of Care Processes

For clinical measures, the required data elements are routinely generated and used during care delivery (e.g., blood pressure, lab test, diagnosis, medication order).

3a.1. Data Elements Generated as Byproduct of Care Processes.

[Generated or collected by and used by healthcare personnel during the provision of care \(e.g., blood pressure, lab value, diagnosis, depression score\)](#)

If other:

3b. Electronic Sources

The required data elements are available in electronic health records or other electronic sources. If the required data are not in electronic health records or existing electronic sources, a credible, near-term path to electronic collection is specified.

3b.1. To what extent are the specified data elements available electronically in defined fields? (i.e., data elements that are needed to compute the performance measure score are in defined, computer-readable fields)

3b.2. If ALL the data elements needed to compute the performance measure score are not from electronic sources, specify a credible, near-term path to electronic capture, OR provide a rationale for using other than electronic sources.

3b.3. If this is an eMeasure, provide a summary of the feasibility assessment in an attached file or make available at a measure-specific URL.

Attachment:

3c. Data Collection Strategy

Demonstration that the data collection strategy (e.g., source, timing, frequency, sampling, patient confidentiality, costs associated with fees/licensing of proprietary measures) can be implemented (e.g., already in operational use, or testing demonstrates that it is ready to put into operational use). For eMeasures, a feasibility assessment addresses the data elements and measure logic and demonstrates the eMeasure can be implemented or feasibility concerns can be adequately addressed.

3c.1. Describe what you have learned/modified as a result of testing and/or operational use of the measure regarding data collection, availability of data, missing data, timing and frequency of data collection, sampling, patient confidentiality, time and cost of data collection, other feasibility/implementation issues.

IF a PRO-PM, consider implications for both individuals providing PROM data (patients, service recipients, respondents) and those whose performance is being measured.

- Data collection: Although self-administration is encouraged, staff may assist patients who need it. The response rate is lower when patients require help to complete the survey and don't get it. Patients should be encouraged to complete the survey at the clinic during dialysis or during a home clinic visit. When patients take the survey home they frequently fail to return it and when they return it, there is no guarantee the answers are the patient's. Staff need to explain the survey's purpose and use. Patients may decline to complete the survey if they don't believe it is relevant to them or their care. During dialysis fluid and electrolyte shifts contribute to changes in cognition. Patients may decline to complete the survey late if they don't feel well or during dialysis when their brain is "foggy." Staff should offer the survey at a different time during the dialysis or on a different day rather than waiting a year.
- Availability of Data: KDQOL-Complete reports data on survey completions and exclusions by category.
- Missing data: Data completeness relies on dialysis facility staff entering data completely and accurate reporting of patients on the facility census. On the KDQOL-36, the first 12 questions yield the physical component summary (PCS) score and a mental component summary (MCS) score and must all be completed to get these scores. Otherwise, missing data is handled by averaging completed responses in each domain.
- Timing/Frequency: The minimum frequency of survey is annually. A patient can complete the survey in <30 minutes. If the social worker assists, it may take longer and the patient may provide the social worker with a fuller picture of his/her life and HRQOL.
- Patient confidentiality: Survey instructions inform patients that the survey is used internally to help plan care. Some providers require signed patient consent while others accept completion of the survey as implied consent.

3c.2. Describe any fees, licensing, or other requirements to use any aspect of the measure as specified (e.g., value/code set, risk model, programming code, algorithm).

The RAND website posts the survey instrument, instructions, and a free Excel template that staff can download to the facility computer for scoring and retention. Large dialysis organizations have developed their own scoring and reporting programs. KDQOL-Complete is a subscription-based data management and analysis service offers online scoring of the KDQOL-36 in multiple languages. Arbor Research Collaborative for Health collected KDQOL-36 data from 1,282 U.S. prevalent in-center hemodialysis (HD) patients. Arbor statisticians determined that gender (M/F), diabetes (Y/N), and age (<45, 45-64, 65-74, 75+) were the demographic characteristics associated with the greatest variability in KDQOL-36 scores. Using the case mix adjustment, KDQOL-Complete reports individual patient domain scores by tertiles (thirds): Above average (color coded green) = More than one standard deviation above the mean; Average (color coded yellow) = The mean +/- one standard deviation; Below average (color coded red) = More than one standard deviation below the mean. KDQOL-Complete also provides facility-level reports and a report with aggregate data for all facilities using KDQOL-Complete that allow dialysis facilities using KDQOL Complete to compare their population demographics, response rate, and scores to others.

4. Usability and Use

Extent to which potential audiences (e.g., consumers, purchasers, providers, policy makers) are using or could use performance results for both accountability and performance improvement to achieve the goal of high-quality, efficient healthcare for individuals or populations.

4a. Accountability and Transparency

Performance results are used in at least one accountability application within three years after initial endorsement and are publicly reported within six years after initial endorsement (or the data on performance results are available). If not in use at the time of initial endorsement, then a credible plan for implementation within the specified timeframes is provided.

4.1. Current and Planned Use

NQF-endorsed measures are expected to be used in at least one accountability application within 3 years and publicly reported within 6 years of initial endorsement in addition to performance improvement.

Planned	Current Use (for current use provide URL)
Public Reporting	Quality Improvement (Internal to the specific organization) KDQOL-Complete www.kdqol-complete.org Other dialysis facilities http://www.rand.org/health/surveys_tools/kdqol.html Large dialysis organizations use their own scoring programs internal to those dialysis facilities

4a.1. For each CURRENT use, checked above, provide:

- Name of program and sponsor
- Purpose
- Geographic area and number and percentage of accountable entities and patients included

For 4.1f and g above, over 6,000 U.S. dialysis facilities treat almost 500,000 dialysis patients. The Federal regulation, ESRD Conditions for Coverage at 42 CFR 494.90(a)(6), requires dialysis facilities to assess each eligible (not excluded) U.S. dialysis patient's physical and mental functioning (HRQOL) at least annually. Further, there is a requirement at 42 CFR 494.110(a) for dialysis facilities to have a quality assessment and performance improvement program that "achieves measurable improvement in health outcomes." To do this, the facility must "measure, analyze, and track quality indicators." State ESRD surveyors use the CMS Measures Assessment Tool and the ESRD Core Survey Field Manual's interview worksheets ask patients and staff about the survey and its use (<https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/GuidanceforLawsAndRegulations/Dialysis.html>) as part of all dialysis facility recertification surveys that determine compliance with the individual patient plan of care requirement (V552) and the facility-level Quality Assessment and Performance Improvement (V628).

4a.2. If not currently publicly reported OR used in at least one other accountability application (e.g., payment program, certification, licensing) what are the reasons? (e.g., Do policies or actions of the developer/steward or accountable entities restrict access to performance results or impede implementation?)

Dialysis facilities are required to offer the health-related quality of life survey and use the results of the survey plan care for patients under 42 CFR 494.90(a)(6) in the ESRD Conditions for Coverage (CfC). State Agency ESRD surveyors review facilities requesting recertification and cite facilities that are not in compliance with the ESRD CfC.

4a.3. If not currently publicly reported OR used in at least one other accountability application, provide a credible plan for implementation within the expected timeframes -- any accountability application within 3 years and publicly reported within 6 years of initial endorsement. (Credible plan includes the specific program, purpose, intended audience, and timeline for implementing the measure within the specified timeframes. A plan for accountability applications addresses mechanisms for data aggregation and reporting.)

Janis Grady, CMS project officer for CROWNWeb, has been contacted and has shared our desire for CROWNWeb to collect data on health-related quality of life with multiple CMS program directors.

The Kidney Disease Quality of Life (KDQOL) survey is administered by IMPAQ International, LLC, on behalf of the Centers for Medicare & Medicaid Services (CMS), to assess self-reported quality of life among Medicare end-stage renal disease (ESRD) beneficiaries included in the Comprehensive ESRD Care (CEC) Model. IMPAQ will use data from the two censuses to further develop and test quality of life measures suitable for monitoring changes in the impact of ESCO-provided care on the health and well-being of aligned beneficiaries over time.

4b. Improvement

Progress toward achieving the goal of high-quality, efficient healthcare for individuals or populations is demonstrated. If not in

use for performance improvement at the time of initial endorsement, then a credible rationale describes how the performance results could be used to further the goal of high-quality, efficient healthcare for individuals or populations.

4b.1. Progress on Improvement. (Not required for initial endorsement unless available.)

Performance results on this measure (current and over time) should be provided in 1b.2 and 1b.4. Discuss:

- Progress (trends in performance results, number and percentage of people receiving high-quality healthcare)
- Geographic area and number and percentage of accountable entities and patients included

Looking at all patients in each calendar year, we calculated the patient level completion rate. In 2013, 62,620 patients out of 74,410 eligible (not excluded) patients (84.2% completed the survey. In 2014 66,386 patients out of 78,401 eligible (not excluded) patients (84.7%) completed the survey. In 2015, 69,746 patients out of 82,221 eligible (not excluded) patients (84.8%) completed the survey.

If completion rates are calculated within each facility and averaged over all facilities, completion rates were 85.4% in 2013, 85.5% in 2014, and 85.6% in 2015. These completion rates do not take into account differences in patient mix across time. Therefore we calculated the odds of KDQOL-36 survey completion over time using a logistic model adjusted for age, gender, race, and diabetes status and found that patients were 3% more likely to complete the survey each year ($p < 0.0001$).

4b.2. If no improvement was demonstrated, what are the reasons? If not in use for performance improvement at the time of initial endorsement, provide a credible rationale that describes how the performance results could be used to further the goal of high-quality, efficient healthcare for individuals or populations.

KDQOL-Complete data showed improvement.

4c. Unintended Consequences

The benefits of the performance measure in facilitating progress toward achieving high-quality, efficient healthcare for individuals or populations outweigh evidence of unintended negative consequences to individuals or populations (if such evidence exists).

4c.1. Were any unintended negative consequences to individuals or populations identified during testing; OR has evidence of unintended negative consequences to individuals or populations been reported since implementation? If so, identify the negative unintended consequences and describe how benefits outweigh them or actions taken to mitigate them.

None reported

5. Comparison to Related or Competing Measures

If a measure meets the above criteria and there are endorsed or new related measures (either the same measure focus or the same target population) or competing measures (both the same measure focus and the same target population), the measures are compared to address harmonization and/or selection of the best measure.

5. Relation to Other NQF-endorsed Measures

Are there related measures (conceptually, either same measure focus or target population) or competing measures (conceptually both the same measure focus and same target population)? If yes, list the NQF # and title of all related and/or competing measures.

5.1a. List of related or competing measures (selected from NQF-endorsed measures)

5.1b. If related or competing measures are not NQF endorsed please indicate measure title and steward.

5a. Harmonization

The measure specifications are harmonized with related measures;

OR

The differences in specifications are justified

5a.1. If this measure conceptually addresses EITHER the same measure focus OR the same target population as NQF-endorsed measure(s):

Are the measure specifications completely harmonized?

5a.2. If the measure specifications are not completely harmonized, identify the differences, rationale, and impact on interpretability and data collection burden.

5b. Competing Measures

The measure is superior to competing measures (e.g., is a more valid or efficient way to measure);

OR

Multiple measures are justified.

5b.1. If this measure conceptually addresses both the same measure focus and the same target population as NQF-endorsed measure(s):

Describe why this measure is superior to competing measures (e.g., a more valid or efficient way to measure quality); OR provide a rationale for the additive value of endorsing an additional measure. (Provide analyses when possible.)

Appendix

A.1 Supplemental materials may be provided in an appendix. All supplemental materials (such as data collection instrument or methodology reports) should be organized in one file with a table of contents or bookmarks. If material pertains to a specific submission form number, that should be indicated. Requested information should be provided in the submission form and required attachments. There is no guarantee that supplemental materials will be reviewed.

Attachment:

Contact Information

Co.1 Measure Steward (Intellectual Property Owner): [Witten and Associates, LLC](#)

Co.2 Point of Contact: [Beth, Witten, beth@wittenllc.com, 913-642-0269-](#)

Co.3 Measure Developer if different from Measure Steward: [UCLA](#)

Co.4 Point of Contact: [Ron, Hays, drhays@ucla.edu, 310-794-2294-](#)

Additional Information

Ad.1 Workgroup/Expert Panel involved in measure development

Provide a list of sponsoring organizations and workgroup/panel members' names and organizations. Describe the members' role in measure development.

[NA](#)

Measure Developer/Steward Updates and Ongoing Maintenance

Ad.2 Year the measure was first released: [1994](#)

Ad.3 Month and Year of most recent revision: [04, 2016](#)

Ad.4 What is your frequency for review/update of this measure? [Ad hoc](#)

Ad.5 When is the next scheduled review/update for this measure? [02, 2017](#)

Ad.6 Copyright statement: [The KDQOL-36 survey states: "Copyright © 2000 by RAND and the University of Arizona"](#)

Ad.7 Disclaimers: [NA](#)

Ad.8 Additional Information/Comments: [The release date for KDQOL-SF survey was 1994 and the KDQOL-36 was published in January 2004. The date the NQF endorsed the measure of percent of eligible patients who completed the HRQOL survey was 2007. 4/2016 IS most recent date for this measure maintenance.](#)