



Measuring Dialysis Patients' Health-Related Quality of Life with the KDQOL-36™

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Clinical Performance Measure (CPM)

Effective April 1, 2008, the Centers for Medicare & Medicaid Services (CMS) adopted 26 new clinical performance measures to assess the quality of dialysis care in the United States. They include a requirement for annual measurement of health-related quality of life (HRQOL) in most dialysis patients.

The CPM for HRQOL requires clinics to report the **number of patients in a clinic who complete a KDQOL-36 annually (as a percent of the number of eligible prevalent dialysis patients**, including peritoneal dialysis, in-center hemodialysis, home hemodialysis)¹, with exclusions for:

- ✓ Patients under age 18
- ✓ Those who cannot complete a KDQOL-36 due to cognitive impairment, dementia, active psychosis
- ✓ Non-English speakers/readers (for whom there is no native language translation or interpreter)
- ✓ Patients on dialysis less than 3 months
- ✓ Patients who refuse to complete the KDQOL-36

CROWNWeb will collect data for this CPM.

Why Assess Health-Related Quality of Life

Dialysis is both life-saving and life-altering. It changes patients' eating, sleeping, medication use, and daily activities at home and in the community. Dialysis and associated symptoms can reduce the ability to work (50% of new patients each year are working-age). The degree of lifestyle change needed—following prescribed diet/fluid limits and medications and managing symptom burdens—depends considerably on the modality chosen, and affects patients' day-to-day health-related quality of



life. Per the U.S. Centers for Disease Control and Prevention, **health-related quality of life is the impact of a chronic disease and its treatment on patients' perceptions of their own physical and mental function.**² Among people on dialysis, HRQOL scores are both a critical outcome and a predictor of hospitalization and death.

A prospective study of 1,000 patients on standard in-center hemodialysis (HD) first linked low HRQOL scores with hospitalizations and death more than a decade ago.³ Patients with SF-36 scores below a center's median were twice as likely to be hospitalized as those above it. Each 5-point increase in physical component summary (PCS) score—a measure of patients' perceptions of their physical health—was associated with a 10% improvement in the chance of survival, and a 6% reduction in hospital days.

An analysis of nearly 14,000 Fresenius patients on standard in-center HD also found that SF-36 scores predicted hospitalizations and death.⁴ PCS scores <43 and mental component summary (MCS) scores—a measure of patients' perceptions of their mental health—<51 correlated with a higher risk of death. Each 1-point increase in PCS was associated with a 2% drop in the relative risk of death and hospitalization. Each 1-point increase in MCS was



History of the KDQOL-36

The Kidney Disease Quality of Life (KDQOL) survey was developed in 1994* as a kidney disease-specific measure of HRQOL. The KDQOL 1.2 and 1.3 include the Medical Outcomes Study Short Form 36 (MOS SF-36) as a generic chronic disease core, and added items relevant to patients with kidney disease, such as symptoms, burden of illness, social interaction, staff encouragement, and patient satisfaction. Currently, the KDQOL-36 uses the SF-12 (a shorter version of the SF-36) and 24 kidney disease specific questions.

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associated with a 2% drop in the relative risk of death and a 1% drop in the relative risk of hospitalization.⁴

The Dialysis Outcomes and Practice Patterns Study (DOPPS) is a prospective observational study of lab values, demographics, co-morbidities, dialysis parameters, and HRQOL. Among 10,030 patients in Europe, Canada, the U.S., New Zealand, and Japan, low HRQOL scores were linked with higher risks of death and hospitalization, independent of demographic factors and co-morbidities. As PCS and MCS scores fell, the risks of death and hospitalization rose significantly. Patients whose PCS scores were in the lowest quintile had a 56% higher risk of hospital stays and a 93% higher risk of death than those in the highest quintile. Researchers concluded that **low PCS and MCS scores were as powerful an independent predictor of hospitalization and death as serum albumin.**⁵

HRQOL is a unique dimension of chronic disease care—one whose data source is *patient perceptions* captured via a valid, reliable tool.

About the KDQOL-36

The Kidney Disease Quality of Life (KDQOL) survey is a kidney disease-specific measure of HRQOL. The first version contained the Medical Outcomes Study 36 (MOS SF-36) as a generic chronic disease core, plus items relevant to patients with kidney disease, such as symptoms, burden of illness, social interaction, staff encouragement, and patient satisfaction.⁶

The KDQOL-36, available since 2002, is a reliable and valid 36-item HRQOL survey with five subscales:

- **SF-12: Physical Component Summary (PCS) subscale (Questions 1-12) and SF-12: Mental Component Summary (MCS) subscale (Questions 1-12)**, include items about general health, activity limits, ability to accomplish desired tasks, depression and anxiety, energy level, and social activities.
- **Burden of Kidney Disease subscale (Questions 13-16)**, includes items about how much kidney disease interferes with daily life, takes up time, causes frustration, or makes the respondent feel like a burden.
- **Symptoms and Problems subscale (Questions 17-28)**, includes items about how bothered a respondent feels by sore muscles, chest pain, cramps, itchy or dry skin, shortness of breath, faintness/dizziness, lack of appetite, feeling washed out or drained, numbness in the hands or feet, nausea, or problems with dialysis access.
- **Effects of Kidney Disease on Daily Life subscale (Questions 29-36)**, includes items about how bothered the respondent feels by fluid limits, diet restrictions, ability to work around the house or travel, feeling dependent on doctors and other medical staff, stress or worries, sex life, and personal appearance.

Administering the KDQOL-36

The survey takes about 10-15 minutes. Provide a pencil or pen. If the survey is completed on paper, you can enter the responses into **KDQOL COMPLETE** manually, or send the surveys to the Medical Education Institute (MEI) for entry (\$2/survey). **KDQOL COMPLETE** also allows patients to take the survey online, eliminating data entry. Patient scores will go into your clinic's records and the patient will receive his/hers scores upon completion. Additional tips include:

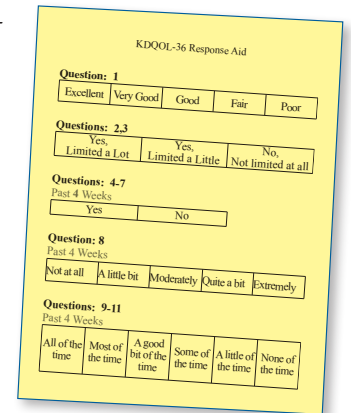


- ✔ Explain the purpose of the survey, and ask patients to complete it. (The KDQOL-36 is optional; patients can refuse. If your clinic requires a written consent, obtain the consent.) Tell patients that Medicare wants to focus on their quality of life to help them feel better and live as long as they can. Explain that the interdisciplinary team considers the KDQOL-36 an important measure of their well-being, and will work with the patient to address needs identified with the tool.
- ✔ If patients are not sure how to answer, explain that there are no “right or wrong” answers—just how they think or feel. Advise patients to choose the first answer that comes to mind and not to “over-think”.
- ✔ Verify that all items—or at least the first 12—have been completed prior to scoring. NOTE: The KDQOL-36 cannot provide PCS and MCS scores if the first 12 items are not completed.
- ✔ Provide the Patient Report and discuss the scores and individual responses as soon as you can, focusing on areas where patients are doing well along with areas that need improvement. Rapid feedback improves future KDQOL-36 participation.
- ✔ When possible, have in-center patients take the survey independently during the first 2 hours of dialysis. Ask home dialysis patients to fill out the survey during a clinic visit. Discourage patients from taking the survey outside of the clinic, since you cannot know how involved the patient was in completing the survey and you may not get the survey returned. In-center hemodialysis patients who were interviewed for HRQOL in the HEMO study had higher PCS scores (despite multiple and more severe co-morbidities) than those who self-administered.⁷ This suggests that response bias (telling the interviewer what s/he might want to hear) can occur when the survey is not self-administered.

If you must complete a KDQOL-36 with a patient for any reason:

- ✔ Speak clearly and confirm that the patient can hear you.
- ✔ Do not interpret any item. Ask the patient to respond to what *he or she believes* the question asks.

- ✔ Repeat response options as often as needed, keeping any frustration out of your voice.
- ✔ Consider using a visual aid to help patients track the questions and possible answers. (See Response Aid located under the Tools Tab)
- ✔ Be sure the patient knows the time frame for each question. Some ask for the past 4 weeks; others have no time frame.
- ✔ Be sure the patient knows which questions ask about *general health* (Questions 1-12 and 17-28) and which ask about *kidney disease* (13-16 and 29-36).



KDQOL-36 Response Aid

Question: 1
Excellent | Very Good | Good | Fair | Poor

Questions: 2,3
Yes, Limited a Lot | Yes, Limited a Little | No, Not limited at all

Questions: 4-7
Past 4 Weeks
Yes | No

Question: 8
Past 4 Weeks
Not at all | A little bit | Moderately | Quite a bit | Extremely

Questions: 9-11
Past 4 Weeks
All of the time | Most of the time | A good bit of the time | Some of the time | A little of the time | None of the time

How to Score the KDQOL-36

Scores are reported separately for each of the five KDQOL-36 subscales. The KDQOL-36 *cannot be hand-scored*—the item weighting is too complex.

KDQOL COMPLETE 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. (NOTE: Race was examined, but did not contribute as much variation as the others).

KDQOL COMPLETE is case-mix adjusted, which means it automatically compares patients to others of the same age, gender, and diabetes status. It reports individual patient subscale scores by tertiles (thirds):

- » **“Above average”**: More than one standard deviation *above* the mean
- » **“Average”**: The mean +/- one standard deviation
- » **“Below average”**: More than one standard deviation *below* the mean



Interpreting KDQOL-36 Scores and Risk

PCS and MCS scores from the KDQOL-36 or other HRQOL surveys are associated with aggregate hospitalization and mortality for *groups*—not individuals. However, on the presumption that scores *more than one standard deviation below the mean* may signify a degree of health risk that could perhaps be preventable, the patient scoring language in the **KDQOL COMPLETE** is deliberately cautionary for those with lower scores.

Where possible, the Patient Report suggests “tips to feel better” based on available evidence. Others were based on known contributors to dialysis morbidity and mortality, such as serum albumin levels,⁸ and interdialytic weight gain.⁹ Finally, the remaining tips were based on factors known to contribute to HRQOL and derive directly from items in the KDQOL-36, such as malnutrition, poor serum phosphate control, dialysis dose, hemodialysis catheters,¹⁰ sleep problems¹¹, sexual dysfunction,¹² symptoms.¹³

Talking with Patients about Low Scores

Key points to remember about the **KDQOL COMPLETE** scoring include:

- ✔ The range of average scores is *very* broad, so someone who falls in the “below average” tertile is at *significantly higher risk of hospitalization and/or death*.
- ✔ The predictive value of these scores has been proven in multiple studies with tens of thousands of dialysis patients. Patients who respond to questions with the low options know that they don’t feel good. We are not telling them anything they don’t already know. Sensitivity to fear of debilitation and death is key to the helping relationship.
- ✔ Just as the social worker intervenes in mineral bone disease, fluid management, and other adherence issues, other team members may have ideas for exploring contributors to low scores.
- ✔ There is hope. Share with patients that research has found that some things help to improve health. As HRQOL research goes on, other interventions may be found to be effective.

Definitions

KDQOL-36 – a 36 item survey for dialysis patients to measure quality of life.

KDQOL COMPLETE – service used by a clinic to score and store the KDQOL-36 data.

MOS SF-36 – a 36-item HRQOL survey for adults with chronic conditions.

Some social workers have expressed concern about telling patients their risk levels. However, we owe our patients the truth. If we shy away from bad news, *who* are we protecting—our patients or ourselves? A doctor would not keep a treatable condition from a patient because the news might be upsetting. Indeed, knowing one’s risk level and what actions may reduce that risk could motivate a patient to take action to feel better.

Social workers who use KDQOL COMPLETE tell MEI that when they present the Patient Report (available in multiple languages) in a positive way, it has led to positive behavior change.

One way to present the information to the patients is:

“I looked at your survey and noticed that you marked several survey questions low. Can we talk about that? What affected how you marked your survey?” (Probe for reasons.)

“My concern is that the way you marked your survey lowered your scores in these areas.” (Describe.)

“Research has shown that low scores are linked to higher risk of hospitalizations and even death. We want to help you avoid those things. There are things you can do that research has shown can improve scores.” (Discuss and personalize patient behaviors that may contribute to lower scores, e.g., being on a type of treatment that is too limiting, skipping or shortening treatments, not taking prescribed medications, being sedentary, avoiding people due to depression, etc.)



“What goal would you be willing to set to improve these scores? How can we help you do that? We’ll be planning for your care at a meeting on (date). We’d like you to be there in person or by phone to help us help you. Will you do that?” (Discuss how to set a goal and help the patient identify how to achieve them.)

Talking with patients about Average to Above Average scores

Discussing average and above average scores with patients is as important as discussing the low scores. It is important for patients to understand how their health behaviors prevent health deterioration and maintain stability.

One way to present the information to the patient is:

“I looked at your survey and notice that your scores are similar to other patients in your age group with [or without] diabetes. In this particular area, your scores were all very positive. What do you think contributes to these high scores?” (Probe for reasons)

“Research has shown that low scores are linked to higher risk of hospitalizations and even death, therefore it is important to maintain these positive scores. What do you think needs to happen to maintain your current quality of life?”

“Is there an area of this survey that you feel has changed in the last year? In what way has it changed? What goal would you be willing to set to prevent this score from decreasing or help it to improve?”

Interventions that Improve HRQOL

Certain interventions have been found to improve HRQOL scores among people with chronic kidney disease (most often on dialysis) in randomized, controlled trials. Some of these include:

- ✔ **Automated (vs. manual) peritoneal dialysis.**
After 6 months, APD patients had higher SF-36 scores. Treatments when sleeping allowed time for work, family, and social life.¹⁴
- ✔ **Icodextrin peritoneal dialysis fluid.**
After 13 weeks, patients using icodextrin had fewer dialysis symptoms and higher mean change scores on the KDQOL than those on usual care.¹⁵

- ✔ **More frequent hemodialysis.** Short daily or long nocturnal HD reduced cramping, headaches, hypotension, shortness of breath and other common dialysis symptoms and improved SF-36 scores in patients who switched from standard in-center HD.^{16,17}
- ✔ **Goal-setting.** An intervention with interdisciplinary collaboration and support, significantly improved role physical and role emotional scores on the SF-36.¹⁸
- ✔ **Help with coping.** Adaptation training to help patients cope with the stresses of ESRD significantly improved SF-36 scores vs. usual care,¹⁹ as did group psychosocial counseling.²⁰
- ✔ **Exercise training.** Exercise programs have significantly improved exercise duration and peak workload, reduced depression, and improved both PCS and MCS on the KDQOL-36 in people on standard in-center HD²¹⁻²⁵ and peritoneal dialysis.²⁶
- ✔ **Anemia treatment.** Significant improvements in SF-36 scores were found in dialysis patients whose anemia was treated with ESAs²⁷ or IV (vs. oral) iron.²⁸

Scoring the KDQOL-36

KDQOL COMPLETE

Subscription service used to score, report, and store clinic KDQOL-36 data. Prices range from \$100 - \$350 per year per clinic. This service provides reports for the medical record and for the patient. It also allows clinicians to view how one patient has done over time, as well as scores for the entire clinic.

Excel Spreadsheet

You can download an Excel scoring template for free from the RAND website at www.rand.org/health/surveys_tools/kdqol. To determine level of risk, manually compare scores on the 5 subscales to the DOPPS table of means and standard deviations (SDs) by age and gender for each patient.



- ✓ **Echocardiogram adjustment of dry weight.**
Reaching ideal dry weight as measured by the size of the inferior vena cava was associated with SF-36 score improvements compared to usual care.²⁹
- ✓ **Improving bone mineral metabolism.**
Compared to placebo, use of cinacalcet to reduce parathyroid hormone levels was associated with significantly lower risk of parathyroidectomy, cardiac-related hospitalization, fracture, and significantly higher PCS scores on the KDQOL.³⁰
- ✓ **Treatment of Restless Legs Syndrome.**
Treatment of RLS with gabapentin significantly relieved symptoms and improved several subscales of the SF-36.³¹
- ✓ **Treatment of carnitine deficiency.** Patients randomized to receive carnitine for 24 weeks showed significant SF-36 score improvements over treatment with a placebo.³²

Incorporating the KDQOL-36 into Psychosocial Needs Assessment

Each survey is a patient contact the social worker can document in the medical record. KDQOL-36 scores enhance the social workers' assessment of patients' psychosocial needs and identification of areas where a patient is doing well and areas where improvement is needed. The survey and patient responses can help the interdisciplinary team more effectively evaluate clinical outcomes and barriers to achieving established goals and help patients establish individualized goals and choose interventions to achieve them.

Using the KDQOL-36 for the Patient Plan of Care

The Conditions for Coverage expect the dialysis team to use KDQOL-36 results when they develop a plan of care. In the Plan of Care meeting, explain the scores and what they mean for adjusted risk, and point out the reported symptoms or problems and other areas the patient marked low. This should help the team brainstorm actions they can take to improve a patient's scores and outcomes.

Patients need to be more involved in planning their care than simply signing a form. Some team goals may not be patient goals. Patients may be less willing to take some actions staff members want them to take if those actions are not relevant to them. Interventions must be workable and goals achievable to help patients achieve the best outcomes possible.

Using the KDQOL-36 in Quality Assessment and Performance Improvement (QAPI)

Each facility must have an ongoing data-driven QAPI program that uses clinical performances measures (CPMs). The CPM associated with health outcomes is the facility-level KDQOL-36 scores. (Reporting on patients' physical and mental functioning). Some examples of possible facility-level measures the QAPI team could evaluate include:

- ✓ What percentage of new patients completed the survey at the initial reassessment (4th month of dialysis)? All eligible patients should be offered the survey that month.
- ✓ What percentage of eligible patients completed the survey within 12 months of an initial survey? This is a CMS CPM requirement.
- ✓ How many patients were excluded? Why? This information would identify patients who need to be monitored in another way.
- ✓ What percentage of patients low KDQOL-36 score had at least a 1-point gain in PCS or MCS on the next survey? Improving scores by even 1 point significantly reduces the relative risks of death and hospitalization.
- ✓ Do certain scores relate to certain behaviors, e.g., low MCS and high PCS with skipping/shortening treatments?
- ✓ How many patients who were hospitalized more than twice in the last 12 months had low KDQOL-36 scores?
- ✓ How many patients who died in the last 12 months had low KDQOL-36 scores?
- ✓ What interventions have successfully improved scores in your clinic?



The **KDQOL COMPLETE** clinic reports can help your team evaluate multiple patients' scores for your QAPI program.

Other than the CPM requirement, each clinic can choose QAPI measures that are relevant for its patients.

Conclusion

HRQOL monitoring and use have great potential to improve patient outcomes, yielding benefits that exceed burdens for patients and clinics.

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