

Why we need a health-related quality of life CPM

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Introduction

In 2007, the Centers for Medicare & Medicaid Services commissioned the National Quality Forum (NQF) to “achieve voluntary consensus on a set of performance measures that can be used to assess the quality of end-stage renal disease care in the United States.”¹ Among the 24 standards recently recommended by the NQF are some that mirror current

ity of dialysis care: regular assessment of health-related quality of life (HRQOL).

Specifically, the proposed NQF standards for ESRD recommend “dialysis facilities administer the Kidney Disease Quality of Life survey (KDQOL-36) to assess patients’ functioning and well-being at least once a year.”² In other words, for the first time ever, we will be asking patients how they are doing, instead of

is so urgently needed. This article will provide an overview of what HRQOL is, how it is measured, why it makes sense to use it as a clinical performance measure, and the next steps.

Defining health-related quality of life

The term “health-related quality of life” is often misunderstood. In casual conversation, “quality of life” is taken to mean “standard of living,” like whether you have a comfortable home, a nice car or access to good educational and recreational activities. HRQOL is none of those things. The U.S. Centers for Disease Control and Prevention defines it as “the extent to which patients’ perceived physical and mental functioning are affected on a day-to-day basis by a chronic disease.”⁴

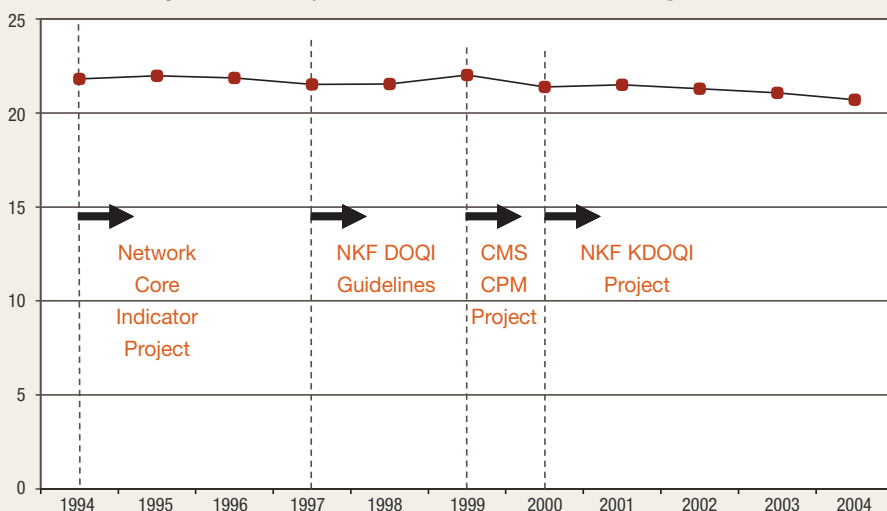
HRQOL can be measured only by obtaining patient self-reports, typically with paper-and-pencil surveys.

How HRQOL measurement began

In 1986-87, RAND, a nonprofit global policy think tank, developed the Medical Outcomes Study (MOS) core survey to assess the impact of chronic disease on patients’ lives. While the Karnofsky scale from the 1940s was a staff assessment of patient functioning, the MOS tool had 116 patient self-report questions like: “During the past four weeks, how much did pain interfere with your normal work?” and “How much of the time during the past four weeks have you felt down or blue?” This tool was the first instance of a HRQOL measurement from the patients’ own perspective.

Shorter forms (SF) of the survey have been developed throughout the years, and now there is an SF-36, an SF-12, and even an SF-8.⁵ Scoring yields a total of eight domains, with two summary scores that turn out to be key: a physical component summary (PCS) and a mental component summary (MCS).

Figure 1. Adjusted Annual Mortality Rate



USRDS 2006 Annual Data Report

From day 1 to 1 year + 90 days, by age, gender, race, ethnicity, primary diagnosis, vintage

clinical performance measures (CPMs), such as hemodialysis and peritoneal dialysis adequacy.^{2,3} New measures were also endorsed as potential CPMs—like patient satisfaction with care, modality education, and one new standard in particular that represents a quantum leap forward in the decades-old effort to assess the qual-

relying solely on lab values. From patient-centered care and rehabilitation perspectives, this is the Holy Grail.

While the public comments sent to the NQF were overwhelmingly in favor of including HRQOL as a measure of dialysis quality,² many in the dialysis community don’t yet understand why such a measure

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In 1994, with Amgen's support, RAND went on to develop the kidney-specific "Kidney Disease Quality of Life" (KDQOL) survey,⁶ which combined the MOS 36-Item Short Form Health Survey (the same as the SF-36, but with simplified scoring) with 98 kidney-specific questions to yield these domains:

- ▶ Physical functioning
- ▶ Role limitations (physical)
- ▶ Role limitations (emotional)
- ▶ Bodily pain
- ▶ General health
- ▶ Vitality
- ▶ Social functioning
- ▶ Mental health
- ▶ Symptoms/problems
- ▶ Work status
- ▶ Sleep
- ▶ Burden of kidney disease

In 2000, RAND developed the KDQOL-36. This was revised in 2002 to include the SF-12 plus kidney disease inquiries like, "During the past four weeks, to what extent were you bothered by itchy skin?" and "Too much of my time is spent dealing with my kidney disease (true/false)."

Why HRQOL matters:

The link to outcomes

Researchers have promoted the use of HRQOL surveys for more than a decade. Kutner⁷ suggested that HRQOL scores can help identify necessary care and track changes based on treatment. According to Rettig et al,⁸ HRQOL scores should be one-third patient assessment, while physical findings and lab tests make up the other two-thirds.

The most compelling reason to measure HRQOL scores is their proven ability to predict the ultimate clinical outcomes: morbidity and mortality. A prospective study of 1,000 hemodialysis patients at three facilities first established the link between HRQOL scores and hospitalizations, death, missed treatments, and depression.⁹ Patients with SF-36 scores below the center's median were twice as likely to be hospitalized than those above

the median. Each five-point increase in PCS score improved the chance of survival by 10% and reduced hospital days by 6%.

A review of 13,952 Fresenius Medical Care patients in 1996 demonstrated a strong association among HRQOL, hospitalizations, and mortality.¹⁰ PCS scores below 43 and MCS scores below 51 predicted a higher risk of death. With each one-point increase in PCS, the relative risk of death or hospitalization declined by 2%. Each additional MCS point

reduced the relative risk of death by 2% and of hospitalization by 1%.

More recently, the Dialysis Outcomes and Practice Patterns Study (DOPPS) confirmed a strong link between HRQOL measures and outcomes. DOPPS is an observational prospective study in representative hemodialysis centers in Europe, Canada, the United States, New Zealand, and Japan. In addition to patient demographics, lab values, comorbidity profiles, and treatment parameters, DOPPS has gath-

ered HRQOL data from more than 10,000 patients who completed the KDQOL-36.¹¹ This data were used to calculate PCS and MCS scores, as well as a kidney disease component summary (KDCS) score.

Low PCS, MCS, and KDCS scores predicted a higher risk of death and hospitalization in all countries, independent of demographic factors and comorbidities. As PCS, MCS, and KDCS scores fell, statistically significant risks of death and hospitalization rose.¹² A 10-point drop in PCS score increased the risk of death by 25%, and of hospitalization by 15%. Patients with PCS scores in the lowest quintile had a 56% higher risk of hospitalization and a 93% higher risk of death than those in the highest quintile. When researchers compared the value of HRQOL scores (PCS, MCS, KDCS) with serum albumin (a known morbidity and mortality predictor), they concluded that low PCS, MCS, and KDCS scores were at least as powerful in independently predicting hospitalization and death as

Health-related quality of life resources

- ▶ <http://gim.med.ucla.edu/kdqol> (official KDQOL website)
- ▶ www.rand.org/health/surveys_tools.html
RAND Corporation site with list and links to various quality survey tools
- ▶ www.qualityforum.org/projects/ongoing/esrd/index.asp
National Quality Forum Consensus Standards for end-stage renal disease care
- ▶ www.cms.hhs.gov/ESRDQualityImprovement/03_Quality%20Measures.asp
Information from CMS about clinical performance measures for ESRD care already in place

albumin.¹² The logical conclusion is that it is just as important to collect and respond to patient self-report FWB—functioning and well-being, another term for HRQOL—scores as it is to collect and respond to laboratory data.

Why choose the KDQOL-36?

There are many excellent measures of HRQOL. A Health and Status Outcomes Group convened by the Institutes of Medicine in 1994 determined that the MOS SF-36, KDQOL, Dartmouth COOP Charts, and DUKE Health Profiles were all reliable, valid, easy to use, patient-friendly, and economical.⁸

However, the NQF process did not permit endorsement of proprietary measures (such as the SF-36 or shorter SF-12). The non-proprietary KDQOL-36 has been used extensively for years. It is available online, with free registration, at <http://gim.med.ucla.edu/kdqol>, and includes detailed instructions and an Excel spreadsheet for scoring. The tool is comprised of the SF-12 plus 24 items covering symptoms/problems, effects of and burdens of kidney disease, and takes just 10 to 15 minutes to complete. It has also been translated into multiple languages.

The NQF ESRD Measures Steering Committee evaluated each of the new ESRD measures using standardized NQF selection criteria, including importance, scientific acceptability, usability, and feasibility.¹³ The Steering Committee submitted and endorsed the use of the KDQOL-36 in September 2007. Subsequent endorsement by the full NQF indicates that this measure meets all of the evaluation criteria.

Staff assessment vs. patient reports

Staff and patients have very different perceptions of patients' HRQOL. Indeed, one 1995 study found significant differences between patients, nurses, and doctors on four of the eight domains of the RAND 36-Item Health Survey. On seven-of-eight domains, patient self-reported scores were higher than scores doctors and nurses assigned to them.¹⁴ Some may believe the potential exists for patients to overestimate their HRQOL. However, it is patients' perceptions of their own HRQOL, not clinicians', that has been linked in numerous studies with hospitalizations and mortality.

HRQOL as a CPM

Research proving the value of HRQOL measures convinced the National Kidney Foundation's Kidney Disease Outcomes Quality Initiative work groups to include assessment of HRQOL in the CKD guidelines.¹⁵ The same logic argues in favor of going on to include HRQOL assessment as a CPM—which would add teeth to the NQF endorsement. And, there are two further reasons:

1. Research shows that clinicians can intervene to improve PCS and/or MCS scores. For example, Patricia Painter, PhD, who has extensively studied the effects of exercise in dialysis patients, has demonstrated that exercise can improve PCS scores by as much as seven points.¹⁶ A study of 169 dialysis facilities in the ESRD Network of Texas, conducted by the Medical Education Institute for the Life Options program, linked greater numbers of rehabilitation activities with higher MCS scores.¹⁷

2. What we have been doing has not substantially improved dialysis. Since the late 1980s, the federal government and renal community have invested heavily in efforts to improve dialysis outcomes. Virtually all of these quality initiatives

have focused on clinical indicators, from anemia to dialysis adequacy, vascular access, nutrition, and medical conditions that contribute to or result from kidney damage. Yet, in the decade from 1994 to 2004, while the ESRD Network Core Indicators, DOQI and K/DOQI clinical performance measures were implemented, U.S. annual adjusted dialysis mortality rate declined by a mere 1.1%^{11,18} Despite all of the attention we have given to clinical and lab markers in the United States, more than 21% of dialysis patients still die each year (see Fig. 1).

It is time to expand our efforts to the whole patient, by including a valid and reliable measure of HRQOL as a CPM. Results of the KDQOL-36 can be used by clinicians to assess patients' status, identify needs and risks, and set goals. Interdisciplinary teams at dialysis clinics can use the results to develop or modify patient care plans, identify areas for Clinical Quality Improvement (CQI) focus, and track the effectiveness of interventions.

What's next?

The NQF recommendations for performance measures have been submitted to CMS for review and approval.

As of this writing, the review process is underway. Although the value of collecting HRQOL data has been officially recognized, the process could be challenging and slow; administering and collecting survey data will require new systems and procedures that will take time to put into place. The CMS review process will take all these factors into consideration. CMS approval, if granted, would put the KDQOL-36 and HRQOL on track to become a new CPM. The proposed Conditions for Coverage, published on Feb. 5, 2005, charged facilities with collecting and reporting CPM data. The final regulations have been delayed for one year.

Conclusion

The time for use of a standardized measurement of HRQOL has arrived. Research supports it, the National Quality Forum recommends it, and we anticipate a favorable review by CMS. A U.S. dialysis mortality rate of nearly 21% is far too high when validated surveys are available to identify at-risk patients and guide the development of individualized, multidisciplinary interventions to help them feel better and live longer.¹¹ **N**

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