

## Measuring and Improving the Health Status of End Stage Renal Disease Patients

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*This highlight reports on recent efforts to develop and promote health status measurement instruments for use in dialysis units that treat end-stage renal disease (ESRD) patients, most of whom are covered for all medical services under Medicare. Readers interested in a more detailed discussion of instruments, including associated data collection and data processing aspects, should consult a recently published account, with its extensive references, of four instruments currently being used in dialysis units (Rettig et al., 1997). Those interested in early reports of the clinical utility of such instruments should consult the following references (Kurtin et al., 1992; Meyer et al., 1994; and DeOreo, 1997).*

### ESRD PATIENT POPULATION

The entire Medicare ESRD patient population is not "elderly, poor, or disabled," but it certainly includes many individuals who share those characteristics. The elderly (over 65 years of age) make up a large and growing proportion of the ESRD patient population: 47.1 percent of all new (incident) ESRD patients in 1993 were elderly; as were 32.1 percent of the prevalent patients at the end of 1993 (United States Renal Data System, 1996). There are no direct measurements of income of ESRD patients, but the economic consequences of kidney failure are very severe. More-

over, a disproportionate share of ESRD patients are drawn from minority populations known to have a higher than average incidence of poverty. African-Americans, with a kidney failure rate nearly four times that of the white population, constitute a major group within the ESRD patient population: 29.1 percent of all incident ESRD patients in 1993 and 31.4 percent of prevalent patients at the end of 1993 were African-American (United States Renal Data System, 1996). Klag and colleagues reported recently that lower income was as great a risk factor as high blood pressure among African-American male ESRD patients (Klag et al., 1997).

The original language of the Social Security Amendments of 1972, which extended Medicare benefits to the disabled, declared that ESRD patients "were deemed to be disabled" for purposes of Medicare coverage under Parts A and B. More importantly, a significant number of ESRD patients also receive disability benefits from Social Security, a result of the functional consequences of this organ's failure. Some of the ESRD patient population are elderly, poor, or disabled, some are not. All these individuals, however, clearly represent a vulnerable chronic disease patient population.

### MEASURING QUALITY IN ESRD: LAYING THE FOUNDATION

The Omnibus Budget Reconciliation Act of 1987, in which Congress requested the Institute of Medicine (IOM) to study aspects of

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the Medicare ESRD program, included the following two issues among those on which it sought advice: "the quality of care provided to ESRD beneficiaries, as measured by clinical indicators, functional status of patients, and patient satisfaction;" and "the effect of reimbursement on quality of care" (Rettig and Levinsky, 1991). At that time, little formal attention had been given within nephrology to the measurement of quality of care. Clinicians were concerned with patient mortality, as a measurable outcome, and the adequacy of dialysis, a process measure closely associated with mortality. "Adequacy," which was then emerging as a major preoccupation of nephrologists, addresses the optimal "dose" of dialysis.

Not surprisingly, given the salience of reimbursement issues, the IOM committee devoted more attention in its report to the impact of reimbursement on quality (three chapters) than to the formal evaluation of quality of care (one chapter) (Rettig and Levinsky, 1991). Data existed on mortality, on hospitalization, and on changing staffing patterns, and these could be examined for the effects of reimbursement changes. On measurement of quality of care, the report drew on the classical framework articulated by Donabedian of examining quality in terms of patient outcomes, processes of care, and structural variables (Donabedian, 1966). In addition, the committee commented on the quality assurance efforts of the federal government, focusing primarily on the Health Care Financing Administration but also including the National Institutes of Health. The IOM report made a number of recommendations, including a proposal to establish "a continuing program of ESRD QA research" (Rettig and Levinsky, 1991).

Concurrent with the IOM ESRD study were several other IOM efforts related to quality of care and health status measure-

ment. An IOM report, authorized by OBRA 1986, *Medicare: A Strategy for Quality Assurance*, published in 1990, was well received by the nephrology community (Lohr, 1990). It provided a conceptual and practical roadmap to quality assurance, quality assessment, and continuous quality improvement. This report defined quality of care as "the degree to which health services for individuals and populations increase the likelihood of desired health outcomes and that are consistent with current professional knowledge."

In addition, the IOM held two health status conferences, one in 1988 and the other in 1991, both of which proceedings were later published as supplements to *Medical Care* (Lohr, 1989; Lohr, 1992). These two conferences highlighted several themes that have been at the heart of the health status measurement agenda related to ESRD. First, they emphasized the importance of moving beyond lengthy research instruments to shorter ones that are acceptable to patients and busy clinicians. Second, these conferences raised the question, still being debated by nephrologists, whether generic instruments, which are designed for use with all patient groups and for all disease conditions, are adequate measures of functional and health status or whether disease-specific or disease-targeted instruments are needed for adequate sensitivity to the patients in question. Finally, the conferences underlined the importance of the practical issues facing prospective clinician users of functional and health status measures—What were the marginal costs of using such instruments? How much staff time was required to train unit personnel? How easily could patient reports be scored? Could the reports be entered into the clinical record? And—most importantly—functional and health status measures raised the fundamental issue of the utility of such instruments in the monitoring and

management of patients: Will patients accept these instruments? What does a numeric score on a functional status measure mean for a patient's health? How are functional status values correlated with clinical values? These developments set the stage for activity that has accelerated in the past five years.

## FROM RESEARCH TO CLINICAL USE

In September 1993, following a planning meeting in the prior year, the IOM held a conference on "Measuring, Managing, and Improving Quality in the End-Stage Renal Disease Treatment Setting." The meeting was sponsored by HCFA, the Agency for Health Care Policy Research, and the Department of Veterans Affairs, by the Renal Physicians Association, American Nephrology Nurses Association, and National Renal Administrators Association, by several dialysis provider chains (Dialysis Clinic Inc., National Medical Care, Kaiser Permanente, and Independent Dialysis Foundation) and by a number of manufacturers and suppliers,<sup>1</sup> indicating the broad interest in the subject. The proceedings were published in the August 1994 issue of the *American Journal of Kidney Diseases* (Schrier, 1994).

This 1993 conference reaffirmed the structure-process-outcomes conceptual framework, addressed severity adjustment, examined clinical processes (e.g., vascular access) and clinical outcomes (mortality, adequacy of dialysis) of importance. But strong arguments were also advanced urg-

ing the nephrology community to move beyond clinical outcome measures to also focus on functional and health status outcomes. Meyer et al. (1994), for example, reported additional data on the New England Medical Center dialysis unit experience with the SF-36, which has collected quarterly data on its patients since October 1990 (Kurtin, 1992). Considerable interest was expressed by the conferees in functional and health status measurement, but lack of experience with such measures led them to ask: "Suppose I wish to measure the functional status of my dialysis patients. How do I do it? What instrument should I use?"

The above question led the IOM to hold a workshop in December 1994 (Rettig, et al., 1997). The workshop considered three generic instruments—the Dartmouth COOP Charts (Nelson et al., 1987), the Duke Health Profile (Parkerson et al., 1990), and the SF-36 (Ware et al., 1993), all of which had been validated for use in clinical settings. It also considered the Kidney Disease Quality of Life™ instrument (KDQOL™) (Hays et al., 1994), which used the SF-36 as its generic core and added dialysis-targeted questions. Even though experience with these instruments was limited, early reports of benefits included improved diagnosis of depression secondary to ESRD and increased ease of patient communication—via a questionnaire—to physicians. Problems encountered included language barriers (not all patients speak English), literacy (not all read), and vision (many ESRD patients suffer from diabetic retinopathy). Practical responses to these problems were discussed.

In addition, the workshop participants heard a reports on two large, multi-center dialysis trials. The hemodialysis clinical trial, on dose and mortality and corollary outcomes, sponsored by the National Institute of Diabetes and Digestive and Kidney

<sup>1</sup> Both Amgen and Baxter have supported quality-of-life instrument development. Amgen did so for the original clinical trials of EPOGEN®, or erythropoietin, and it supported the development of the KDQOL™ in its Phase IV clinical studies program. Baxter has also supported adaptation of the KDQOL™ for its international studies of peritoneal dialysis. Other commercial sponsors of the IOM meetings included Althin Medical and CGH Medical. The sponsors of the HSO group included Amgen, Baxter, Althin, and Fresenius USA.

Diseases, reported on the trial's quality assessment component, which includes measurement of functional and health status. And representatives of the CHOICE study (Choices for Healthy Outcomes In Caring for ESRD) of the Johns Hopkins University's Patient Outcome Research Team, sponsored by the Agency for Health Care Policy and Research, laid out their plans for developing a disease-targeted functional and health status instrument, CHEQ (CHOICE Health Experience Questionnaire) that uses the SF-36 as its generic core.

### **BROADENING AND DEEPENING CLINICAL USE**

The IOM does not maintain a continuing involvement with a given area of medicine and its functional and health status measurement efforts ended with the 1994 workshop. One result was the formation of the End-Stage Renal Disease Health Status Outcomes (ESRD HSO) Group. This group included three experts on measurement and instrument development, four nephrologists, and one policy analyst, all of whom had participated in prior IOM activities.

The purpose of the ESRD HSO group was to encourage the further development and use of functional and health status measures in dialysis. The initial focus was to generate a clinical literature that reported on the use of such measures. Over 1½ years, quarterly meetings heard reports on the following topics: additional data and experience from current nephrology users of health status measures (New England Medical Center Hospital, Centers for Dialysis Care of Cleveland); extension of the Duke Health Profile, a generic instrument, to use in the dialysis setting; adaptation of the Dartmouth COOP Charts for dialysis use; and shortening of the disease-targeted KDQOL™ to the KDQOLSF™.

The HSO Group met with HCFA in May 1966 at the end of 1 year of work. The presentations emphasized the following: functional and health status outcome measures are the logical third element of patient assessment, along with laboratory data and physical findings; the routine use of such measures adds a real but modest cost; and patients appreciate the use of these instruments, especially if accompanied by direct feedback and interpretation of results.

A fundamental point put forward by the HSO Group members was that there was no single best instrument. A number of validated instruments exist and each has its uses: The SF-36 is widely used and recognized; the Duke Health Profile is the shortest well-validated generic instrument; the Dartmouth COOP Charts are easy to use, patient-friendly, have automated methods for prompt scoring and reporting of results during the encounter, and a dialysis adaptation has been developed; the KDQOL™ and the KDQOLSF™ obtain data on kidney disease and dialysis treatment that are not obtainable from generic instruments; the CHEQ instrument has been developed and validated but is not yet widely used; and methods have been developed to compare scores from instrument to instrument. The group concluded that the selection by HCFA of one functional and health status measurement instrument would be premature and would stop the development of a not-yet-mature field.

The final activity of the ESRD HSO Group was a February 1997 meeting in Phoenix, Arizona. Participants included renal physicians, nurses, and social workers, representatives of all major dialysis provider chains, ESRD network professionals, and major dialysis suppliers. Reports presented from both U.S. and international speakers addressed the following issues: the breadth of clinical applications of these instruments by groups of facilities; the vari-

ety of instruments in use and developments underway; and the correlation of health status and clinical outcomes. There was a strong sense of shared experience among U.S., Canadian, and European participants. The meeting concluded with consensus that an annual conference would be useful to clinicians and researchers alike.

In the last analysis, the justification for these measures must be their usefulness in patient care and their contribution to improving its outcomes. Decisive evidence of this clinical benefit is still lacking, but early experience is promising. Meyer (1994) found that patients communicated their condition through a questionnaire in ways that differed from how they spoke to physicians and that this enabled clinicians to modify and focus their efforts on improving outcomes. He found that serial measurements in individuals tracked other morbid events or improvements in condition. DeOreo (1997) found that summary physical and mental scores for the SF-36 predicted risk-increasing behaviors, such as missing dialysis, and thus pointed to specific patient situations that needed attention. He also found that these summary scores related to survival. Both programs from which these publications come use these scores as a focus for clinical staff discussion of a patient's course and condition and have concluded that the instruments aid communication between patients and clinicians as well as clinical strategy. Most of the more than 100 facilities of Dialysis Clinic, Inc. have routinely used the SF-36 as a patient assessment tool for clinical management over the past one to two years. Other large chains have also begun this practice. Results from these experiences will soon be available and these large groups are expected to provide statistical evidence of clinical utility, or the lack thereof, for dialysis patients' outcomes.

## FUTURE DIRECTIONS

The use of functional and health status and health-related quality of life measures by clinical nephrologists has begun. That use must grow if health status measurement is to survive as a useful clinical practice. A literature review on clinical use of functional and health status measures is being produced; reference values for ESRD patients have been established; and clinical experience with health status outcomes is increasing. All major dialysis chains are examining the use of health status measures and many are moving to implement widespread use as supporting data for quality of care assessment. Several research endeavors are expanding the knowledge base.

As experience grows, the criteria for assessing functional and health status results as a performance measure useful to monitor and improve care will be clarified, the limited clinical correlations with clinical outcomes already realized can be expected to increase and become accepted clinical knowledge, and the scope of ESRD patient assessment will routinely include patient-reported information because it is useful. This development, in concert with established clinical indicators, promises practical methods for monitoring quality of care through outcomes.

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