

Socioeconomic impact of the End Stage Renal Disease Program in the USA. Payement and quality of care

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INTRODUCTION

In the early 1960s, the two treatments of chronic hemodialysis and kidney transplantation emerged, making it possible for patients with permanent kidney failure, previously certain to die, to be kept alive in a reasonably good state of health. In the initial decade, however, the high cost of these therapies and the few and fragmented sources for payment for them often limited severely the number of patients who were able to obtain medically appropriate treatment.

In 1972, Congress of the United States amended the Social Security Act to provide an entitlement to Medicare for persons with end-stage kidney failure regardless of age^{1,2}. This kidney disease entitlement, which became effective in mid-1973, is known as the end-stage renal disease (ESRD) program. It is unique in the US, in being based primarily on a medical diagnosis.

In the US, public health insurance involves two government programs - Medicare and Medicaid, both adopted in 1965. Medicare, financed by a combination of a payroll tax, general revenues, and beneficiary premiums, covers the elderly (those over 65 years of age), the disabled, and those with end-stage renal disease; Medicaid, jointly financed by the federal government and state governments, covers the poor. The federal agency administering these programs is the Health Care Financing Administration (HCFA), within the Department of Health and Human Services.

From the clinical perspective, the ESRD program has been very successful over two decades, saving several hundred thousand Americans from premature death. At present, more than 150,000 ESRD patients receive Medicare benefits. Moreover, from an ethical perspective the program has greatly enhanced equity of access to life-preserving therapy³.

The high and ever-growing cost of the ESRD component of the Medicare program, however, has made it quite visible. The cost to Medicare of maintaining a patient on chronic dialysis annually is about

\$32,000. The Medicare cost for a kidney transplant is about \$56,000 during the first year but falls to \$6,000 per year thereafter. These figures do not include additional costs for co-payments and deductibles not covered by Medicare, nor do they take into account the payment by employer health insurance plans in the eighteen months before Medicare benefits begin for some eligible patients.

The total costs of the ESRD program to the US government, which were 229 million dollars in 1974 (the first full year of the program), by 1988 had risen to 3.1 billion dollars. This is due largely to growth in the number of beneficiaries, which far outpaced initial expectations. However, the cost per treatment of dialysis, the largest component of ESRD expenditures, has actually fallen in constant dollars from \$138 in 1974 to approximately \$53 at present.

My purpose in this paper is to report briefly on major aspects of the United States' experience with the ESRD program of Medicare: the patient population, the provider community, access to care, the relation of reimbursement to the quality of care, and some ethical questions raised by the program. In doing so, I draw heavily on a study conducted in 1989-91 by an expert committee of the Institute of Medicine, of the National Academy of Sciences, for which I served as study director.

THE INSTITUTE OF MEDICINE STUDY

In May 1983, the Health Care Financing Administration (HCFA) issued a regulation regarding Medicare reimbursement of outpatient dialysis, implementing legislation enacted in 1978 and 1981. This new rule ended a decade of reimbursement policy under (interim) regulations of 1973. The interim rate had been set at \$138 per treatment and had remained unchanged for independent dialysis units; it had drifted up to an average of \$159 for hospital-based units. The new rate lowered average reimbursement for independent units to \$127 per treatment and for hospital based outpatient units to \$131. The

issuance of this regulation, controversial in its own right, ushered in a period of political conflict between HCFA and the provider community.

Three years later, in 1986, HCFA proposed to change the reimbursement methodology and to reduce the rate once again, on average, by \$6 per treatment. In response to a storm of protest, Congress limited the reduction to \$2 and fixed it for two years. This action froze the existing policy and postponed the revision of methodology; it meant that the data supporting the rate remained the audited costs for 1977, 1978, and 1979.

In this context, the IOM was asked by Congress, in late 1987, to study five aspects of the Medicare ESRD program: 1) epidemiologic and demographic changes in the ESRD patient population affecting access to treatment, quality of care, and resource requirements; 2) access to treatment, both for patients eligible for Medicare benefits and those not eligible; 3) the quality of care provided to ESRD beneficiaries; 4) the effect of reimbursement changes on quality of care; and 5) the adequacy of current data systems for monitoring these matters.

The IOM Committee included experts in the treatment of end-stage renal disease— a patient, nephrologists and transplant surgeons, nurses, a social worker, a sociologist, an economist, and an epidemiologist, as well as others with broad expertise in internal medicine, quality assessment, bioethics, and economics who were not themselves immediately involved with dialysis or transplantation. Over the two years of the study, the committee held eight meetings, two public hearings, and three workshops — on kidney transplantation, the impact of changes in dialysis treatment personnel, and minority ESRD patient issues; it augmented its work by commissioned papers and by three patient focus groups. The committee released its report in April 1991 ⁴.

THE PATIENT POPULATION

When the Medicare ESRD entitlement became effective in 1973, the initial number of eligible beneficiaries was about 10,000 and approximately 3,000 transplants were performed in that year. Today over 150,000 dialysis and transplant patients are benefiting from the Medicare ESRD program.

Patient demographic characteristics have changed greatly over the duration of the program. The elderly (65 years and older) have increased from 5 percent of Medicare ESRD beneficiaries in 1973 to 27 percent in 1988. In 1988, 38 percent of all new patients who entered the program were 65 years or older. The proportion of the ESRD population with a primary diag-

nosis of diabetes mellitus or hypertension also has increased dramatically over time. Diabetes accounted for 31 percent and hypertension for 27 percent of new patients in 1988, up from 9 percent and 12 percent respectively in 1978.

Strikingly, kidney failure is much more frequent among black Americans than whites. Blacks, who constituted only about 10 percent of the treated population, in the late 1960s before the enactment of the Medicare ESRD entitlement ¹ increased to 26 percent of the patients in 1978 and today represent almost 30 percent of the prevalent population. Although the data are less clear but, several studies suggest that renal failure also is more frequent among Hispanic Americans than in the non-Hispanic-white population.

At the end of 1988, approximately three-quarters of ESRD patients were being treated with some form of dialysis, the remainder by transplantation. Slightly over 80 percent of all dialysis patients were treated in dialysis centers, 3 percent by home hemodialysis, and 14 percent by either continuous ambulatory peritoneal dialysis (CAPD) or continuous cycling peritoneal dialysis (CCPD). Kidney transplants increased from about 3,200 in 1974 to nearly 9,000 in 1986; the annual rate of increase in procedures from 1978 through 1986 was about 10 percent. The number has leveled off at about 10,000 because the supply of kidneys has not increased and there are few signs that the rapid growth of prior years will be resumed.

As part of its study, the IOM commissioned projections of the ESRD patient population to the year 2000. Three estimates were prepared by Eggers, of the HCFA. The middle estimate projected approximately 240,000 patients enrolled at the end of the decade. The high estimate of 270,000 patients is now believed to have been too conservative. The trends toward more elderly, more diabetic, more hypertensive, and more minority patients are expected to continue throughout the 1990s. The primary message for policy makers is that they *must* recognize how underlying epidemiological trends drive public policy, both with respect to quality of care and resources.

THE PROVIDER COMMUNITY

As the population of patients requiring treatment has grown, outpatient dialysis treatment capacity has increased at a proportionate rate. Most of the increase in outpatient dialysis facilities has been in independent units. Initially, hospital-based units provided the majority of dialysis treatment, by 1988 independent (free-standing, non-hospital) dialysis units were providing more than 60 percent of all treatments. Hospital-based outpatient dialysis units increased

slightly from 600 to 661 between 1980 and 1988. Independent dialysis units, both not-for-profit and for-profit, have increased rapidly in the past decade, but the rate of increase has been more rapid among for-profit units. From 1980 to 1988, the former grew from 79 to 185, while the latter increased from 325 to 894. No systematic examination has been conducted to elicit possible differences in quality between hospital-based and independent units, or between not-for-profit and for-profit independent units.

ACCESS TO CARE

The Medicare ESRD program removed most barriers to treatment for the great majority of United States citizens. In fact, treatment for ESRD is as close as the US has come until now to universal health insurance. However, the kidney entitlement is not universal; coverage extends to approximately 92 or 93 percent of the American public, but approximately 7 percent of dialysis patients treated in Medicare-certified facilities are routinely reported as not eligible for Medicare benefits.

Eligibility for Medicare coverage, in addition to a diagnosis of ESRD, is a function of Social Security insured status. Those ineligible include some state and federal government employees, some domestic, farm and other workers in covered occupations who may not have applied for benefits, and those who have never worked such as young unwed, non-working mothers and their children. Ineligible persons are concentrated disproportionately among the poor and minorities. Currently, public non-Medicare support for the treatment of such persons (Department of Veterans Affairs, Indian Health Service, state kidney programs, and state Medicaid programs) is either stable or shrinking, or varies as state Medicaid benefits vary.

The IOM committee concluded in its 1991 report that access to life-saving therapy should not be limited on any basis other than citizenship. Therefore, as a matter of equity, it recommended that entitlement to Medicare be extended to all US citizens and resident aliens who suffer from ESRD.

There have been two basic reactions to this recommendation. One policy response has been that such it violates the social insurance principle of work-related entitlement to Medicare and should be rejected on this basis. The second is simply that the country cannot afford to spend more money ESRD patients than it is doing at present. Of these, the fiscal argument is the primary political obstacle to expanded coverage.

Among those entitled to ESRD benefits, kidney transplant patients face two major additional restrictions to coverage.

First, Medicare eligibility is limited to a three year period following a successful transplant. This policy is built on the incorrect assumption that such patients do not require sustained support and reimbursement of immunosuppressive medications has been limited to one year after transplantation until 1993.

Transplantation is regarded as the best treatment for most patients with chronic renal failure. At least five times in the past dozen years Congress has passed legislation to encourage organ transplantation. The IOM committee, believing that Medicare reimbursement should foster transplantation rather than discourage it, recommended that kidney transplant patients be granted a lifetime entitlement comparable to that of dialysis patients; it also recommended that immunosuppressive drugs be covered for the period of entitlement. Happily, in the 1993 budget reconciliation act, Congress extended coverage for immunosuppressives by six months per year over the next several years up to a three year period.

Access to transplantation is limited primarily by a shortage of transplantable kidneys. Because transplantation is the preferred therapy for the great majority of patients, and because the long-term cost of transplantation is less than of dialysis, the IOM committee emphasized the importance of initiatives to increase the donation of kidneys. The recommendations broke no new ground but reflected the absence of consensus about how the supply of organs could be increased.

Black-white differences in kidney transplantation have received recently substantial attention. Black Americans constitute 12 per cent of the US population, but represent nearly 30 percent of the ESRD patient population. However, they received only 20 percent of kidney transplants in 1989 (12 percent of living donor and 22 percent of cadaver donor transplants) ⁵. They account for 30 percent of those wait-listed for a transplant, but wait nearly twice as long as whites ⁶. Graft survival rates for black transplant recipients are somewhat lower than for white recipients; two-year cadaver graft survival for those receiving a first transplant in 1987 was 70 percent for whites and 63 percent for blacks ⁷. The IOM committee encouraged continued active discussion of the equitable distribution of cadaver kidneys to clarify the extent and causes of inequitable distribution, and to design appropriate remedies.

REIMBURSEMENT AND QUALITY

As the cost of the ESRD program has grown, the federal government has faced an increasing tension between its responsibilities to constrain costs and to

provide the resources needed for adequate patient care. A key problem, however, is that few standards of quality for the ESRD program exist, especially with respect to patient outcomes, and quality is not systematically monitored. As reimbursement has been reduced over time, providers who are highly dependent on Medicare payments have confronted a conflict between remaining economically viable and providing appropriate care to patients. Available evidence, admittedly incomplete, suggests that prior reductions in real dollar reimbursement rates may have already eroded quality and that the ESRD program may be at the edge of a «slippery slope» of rapidly decreasing quality should reimbursement be reduced further. Consequently, the IOM Committee concluded that arbitrary further cuts were not justified.

HCFA cost data indicate major differences among dialysis units in the cost of treatments they offer. These data provide the opportunity for research to evaluate differences between high cost and low cost units, between independent and hospital-based providers, and between not-for-profit and for-profit providers, such research could in a relatively short period of time determine whether low cost units offer care of suitable quality through more cost-effective methods or whether, on the contrary lower costs reflect lower quality. Such research could also clarify whether patient severity differs by type of institutions provides. Armed with such information, a more rational, quality-based mechanism for setting payment rates for dialysis units could be implemented.

In addition, the committee recommended that, as in other areas of Medicare, the dialysis payment rate be updated yearly to reflect increasing costs. The Congress, in 1990, directed the Prospective Payment Assessment Commission (ProPAC) to study «the costs and services and profits» associated with the several dialysis treatment modalities and recommend payment methodology and levels in 1992, a step favored by the committee in its deliberations. ProPAC, in 1992, declared that the data were insufficient for it to make a recommendation but in 1993 did recommend that the dialysis reimbursement rate be increased by 2 and 1/2 percent. Given the pressures on all of Medicare from the overall fiscal difficulties of the US government and the need for severe cost containment measures as major health care reform (including financing) is debated, it is highly unlikely that the recommended increase will be enacted.

In this very difficult fiscal context, there is general acceptance of the need for effective systems to assess and guarantee quality in all areas of medicine⁵. This is especially the case for the ESRD program, which provides life-extending treatment to a large group of patients at high cost.

The question arises, then, as to the current quality of care afforded to ESRD patients and how have reimbursement changes affected this quality? The IOM committee considered these issues mainly in relation to dialysis, but confronted several basic facts. First, reimbursement rates for outpatient dialysis had decreased steadily in constant dollars over the 18 year history of the ESRD program, both from a lack of an inflation adjustment and from explicit rate reductions, second, quality had not been systematically measured or monitored by HCFA or by the provider community. Consequently, though many providers, patients, and investigators believe that quality has been eroded already by progressive reductions in reimbursement, existing data are inadequate to determine how quality has changed over the years or to assess definitively the present level of quality. Third, the committee noted the polar views of HCFA -that provider cost reports justified further reimbursement cuts- and the equally strong beliefs of many patients and providers -that further cuts would erode quality dangerously.

To determine the effect of reimbursement on quality, the committee examined several quality measurements: mortality, morbidity (hospitalization), treatment time, staffing patterns of dialysis units, and treatment innovations. Mortality has received much attention during the past decade as an index of ESRD program quality. Increasing unadjusted mortality rates (sometimes described as crude mortality rates) in the 1980s appear to be related to the changing composition of the ESRD patient population, e.g., more elderly patients and patients with diabetic kidney disease. When mortality data are adjusted for age and primary renal diagnosis, they show stability over time.

In assessing the impact of reimbursement on mortality, the committee reviewed studies (both existing and commissioned) of the impact of the 1983 major reimbursement policy change that reduced reimbursement for many providers. Although earlier studies did not detect any effect on mortality, a commissioned study suggested, but not conclusively, that there may be an inverse relation between reimbursement (payment) and mortality among dialysis units affected by the 1983 rate reduction.⁹

Also during the past decade, treatment times of dialysis patients had become shorter, in part due to pressure to reduce costs. Although an inverse relation between reimbursement and mortality was not proven, shorter treatment time has found to be associated with decreased reimbursement and has also been implicated in higher mortality. Thus, the committee concluded that there was a possible, although unproven, two-step relation between reimbursement and mortality.

Although a useful and easily quantifiable patient outcome, mortality alone is not an adequate indicator of quality. Physicians and treatment units confronted with increasingly severe resource constraints presumably would adapt if necessary to preserve the lives of their patients even at the potential cost of diminished quality as reflected in increased morbidity, inadequate dialysis, reduced staffing patterns and lower patient health status. The committee also reviewed hospitalization as an index of quality. A study¹⁰ found some evidence that lower dialysis reimbursement rates were associated with higher frequency of hospitalization, but these results were suggestive rather than conclusive. Shorter treatment time, already noted as correlated with reduced reimbursement also correlated with increased hospitalization. Thus, indirect evidence exists that reimbursement reductions may be associated with excess morbidity.

A structural measure of quality is treatment unit staffing. One study¹¹ found that units receiving higher payment had more total staffing hours per patient and more registered nurses per patient, while the converse was true for treatment units receiving lower payment. The composition of dialysis unit staff has changed as well in the 1980s, with the proportion of nurses decreasing and that of technicians increasing. Replacement of nurses trained to care for patients with technicians trained only to perform the dialysis procedures obviously decreases the clinical training and skill level of the personnel who directly treat patients. Staffing by social workers and dietitians also decreased dramatically during the 1980s. In many units, staff-to-patient ratios for these workers of between 1 to 100 and 1 to 200, which are now common, reduce the activities of social workers and dietitians to minimal routine functions.

Admittedly, optimal patterns for staffing are not known and no effect of observed changes on patient outcomes has been demonstrated. However, in view of the reasonable presumption that professional capability to treat a patient population of increasing complexity has been eroded, the committee felt that HCFA had to recognize the likely impact of further reimbursement reductions on staffing and, at minimum, not cut payment further until it was able to monitor the effects on patients outcomes.

In summary, the analyses of specific effects of previous reimbursement reductions suggested but did not prove that quality of care had been reduced. Some data suggested that decreased reimbursement may have increased mortality, either directly or indirectly, but available studies were not conclusive. Some studies also suggested, but not conclusively, a direct or indirect effect of reimbursement reductions on increased morbidity (measured by hospitaliza-

tion). Dialysis treatment time has decreased in the past decade; and shorter time has been associated with increased mortality and hospitalization. Although shorter treatment time appears to correlate with decreased reimbursement, clinical practice and patient preferences are other possible causes¹². Data indicate that decreased reimbursement has led to decreased dialysis unit staffing and to reductions in nurses, social workers, and dietitians.

Overall, the committee concluded that the evidence deserved attention in setting future reimbursement because all results pointed in the same direction, the changes in quality measures were associated with temporal changes in reimbursement, and the effects appeared plausible on a priori grounds. Professional opinion clearly holds that these changes have been adverse to quality care. As dialysis is life-sustaining therapy, the committee concluded that some weight must be given even to imperfect data pointing to possible adverse effects.

To date, no systematic guidelines for evaluating quality have been developed for the ESRD program and support for quality assessment research in this area has been quite limited. The IOM committee reviewed current quality assessment and assurance mechanisms in the light of modern concepts in these areas; these had been evaluated recently by another IOM committee¹³.

The committee emphasized the importance of outcome measures of quality, but underlined the need to link these to measures of the processes of care. In addition to patient mortality, clinical outcomes and processes, the committee recommended that patient functional outcomes, health status, and patient satisfaction also be monitored. It emphasized the need for effective measures to adjust for patients severity.

Although the IOM committee was critical of HCFA's approach to quality assurance, did not propose an alternative system, a task that was beyond its mandate and a very complicated in its own right. However, the institute of Medicine has organized a Conference for September 1993 on «Measuring, Managing, and Improving Quality in the End-Stage Renal Disease Treatment Setting». The agenda of this meeting will consider the measurement of patient outcomes of care (both clinical and functional), processes of care that are related critically to outcomes, adjustment for patient severity, variations in outcomes among treatment units, and practical problems of instituting effective systems for measuring and managing quality. The results of this meeting will be published in the *American Journal of Kidney Diseases* sometime in the Spring of 1994.

ETHICS

The increasing size and changing age and composition of the ESRD patient population has led to a growing concern in the US that patient acceptance criteria have changed over time to include an increasing number of patients with limited survival possibilities and relatively poor quality of life. Although not asked by Congress to address this issue, the committee believed it was obliged to consider it.

The IOM committee took the position that, in 1991, this issue should not become a matter of public policy. It stated that actions by the Congress or the HCFA to limit access were not warranted «until and unless the federal government undertakes explicit rationing of beneficial care» more broadly. Rather, it emphasized that these ethical issues were properly «the domain of patients, families, physicians, and other caregivers».

The committee strongly believed that patient acceptance criteria should be medical, not derived from economic considerations, and should be determined by the best interests of individual patients. Studies indicate that ESRD patients usually rate their quality of life higher than do «objective» observers¹⁴. Therefore, patient preferences must be emphasized in making decisions about care of individuals with ESRD. The focus of diagnosis and discussion with the patient and his or her ought to center on the relative benefit and burdens of treatment of the given patient.

Much discussion in recent years has centered on age as a criterion for limiting the use of advanced medical technology. The IOM committee explicitly rejected chronological age as a patient acceptance criterion because it did not measure the ability of an individual to benefit from treatment. Rather, comorbidities at any age are the determinants of prognosis and course of treatment.

On the other hand, the committee stated that the existence of a public entitlement did not mean that physicians were obligated to treat all patients who presented with kidney failure. The choice was not between treatment and abandonment, but rather between different goals of treatment. Patient-family preferences and clinical judgment sometimes will indicate that withdrawal or terminal palliative care is more appropriate than initiating or continuing life-extending care. Indeed, patients do sometimes withdraw voluntarily from treatment: in 1988, reported withdrawal from dialysis accounted for 9 percent of all deaths, and nearly 12 percent of those over 65 years of age and over⁵.

The committee recommended that patients, nephrology clinicians, and bioethicists should develop guidelines for evaluating patients for whom the bur-

dens of treatment may outweigh the benefits, that such guideline be flexible and exercised with discretion by physicians in individual cases, and that clinicians discuss with all ESRD patients their wishes about dialysis, cardiopulmonary resuscitation and other life-sustaining treatments and encourage documented advance directives. In 1993, there is evidence of increasing public discussion of these issues, although they remain difficult ones for patients, physicians, other clinicians, and the society to confront.

Endnotes

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