

ESRD as a Window into America's Cost Crisis in Health Care

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The United States is facing a severe crisis over health care costs. Although nearly 15% of the population—some 45 million people—lack health insurance,¹ per capita health care expenditures in the United States are approximately twice as high as in other industrialized countries,² most of which provide near-universal health insurance coverage. Despite these high per capita health care expenditures, health outcomes in the United States are no better, and arguably significantly worse, than in these other countries.³ Moreover, because health care expenditures in the United States have been rising at a rate almost 3% faster than the economy as a whole over the past 30 yr, health care expenses have been absorbing an ever-increasing fraction of the gross domestic product (GDP).⁴ Even before the current severe recession, it had been estimated that if current trends continue, health care expenses would represent 30% of the GDP within 30 yr, and that the Medicare hospital insurance trust fund would be exhausted within a decade.⁵

Some have argued that the projected increase in health care expenditures to consume a higher and higher fraction of GDP is not necessarily a problem.^{6,7} After all, the health care industry itself is an important driving force of the economy and its growth creates new jobs. Moreover, as long as the economy as a whole enjoys sufficient growth, devoting an increasing share of GDP to health care need not reduce absolute spending in areas other than health care, and therefore need not reduce the standard of living. But now that it represents over one-sixth of the national economy, the inefficiency of the American health care system represents a grave threat to America's economic competitiveness. Again, it should be emphasized that per capita health care expenditures in the United States are twice as high as in most other advanced economies, whereas health outcomes are no better.

Individuals, employers, and government using funds collected as taxes pay these health expenditures. Thus, compared with other countries, the poor cost-effectiveness of the American health care system raises the operating costs of employers in the United States and reduces the availability of private and public funds for investments in education, technology, and infrastructure to benefit future productivity. Recognition that these trends are unsustainable has motivated political action to reform America's health care system to achieve more effective cost control.^{8,9}

Although spending on care of patients with ESRD represents only a fraction of total health care costs, the rapid growth in spending on ESRD care, illustrated in Figure 1A, represents in microcosm the escalating costs of the overall health care system. The rapidly escalating total cost of ESRD is partly attributable to the growth of the prevalent ESRD population in the United States, as seen in Figure 1B. But the poor relative cost-effectiveness of the American health care system as a whole is mirrored by similarly poor relative cost-effectiveness of care for ESRD. The United States has one of the highest incidence rates of ESRD in the world and the highest annual expenditure per ESRD patient,¹⁰ yet outcomes of dialysis care are relatively poor compared with other countries, even after adjustment for case-mix differences.^{11–13} Given the increasing urgency of the health care crisis, it is instructive to review the history of ESRD care in the United States with respect to costs and benefits and to examine the opportunities for improvements in cost-effectiveness of kidney disease care.

The first facilities in the United States for long-term outpatient dialysis were established in the early 1960s, by which time kidney transplantation had also become available as a treatment modality for ESRD.¹⁴ But with the exception of a national dialysis program within the Veterans Administration Hospital system, there was no public mechanism to pay for the costs of dialysis and transplantation. Thus, access to these life-extending technologies was quite limited and tended to favor those of higher socioeconomic and educational status.¹⁴ The Bureau of the Budget established a panel of experts, the Committee on Chronic Kidney Disease, to evaluate the need for a national ESRD program. The eminent renal physiologist Carl Gottschalk chaired this committee. The report of the Gottschalk Committee in 1967 called for a federally funded program under Medicare to provide chronic dialysis and/or trans-

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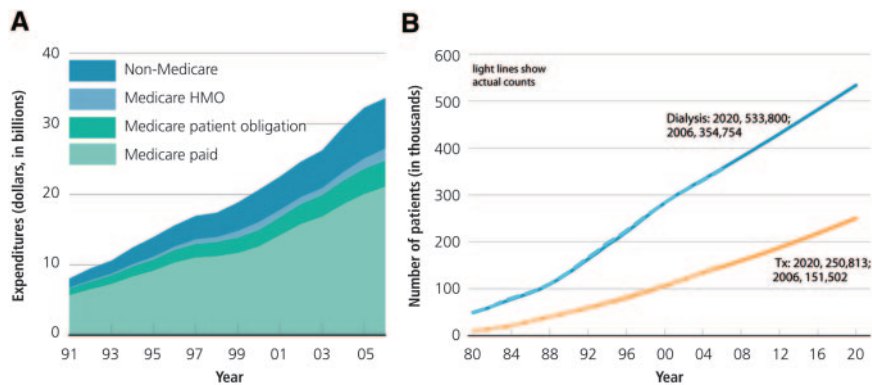


Figure 1. Rising cost of ESRD care in the United States is largely attributable to the growth of the prevalent ESRD population. (A) ESRD spending by payor.¹⁶ (B) Projected growth of prevalent dialysis and transplant populations in the United States.¹⁶

plantation services to all Americans in need of such care regardless of age or ability to pay.¹⁵ In 1972, the Medicare law was finally amended so that patients with ESRD were eligible for Medicare coverage. Patients with ESRD were defined as disabled by their chronic illness so they would qualify for Medicare independent of age.¹⁴ The Medicare ESRD Program then began operation in 1973, in essence providing near-universal catastrophic health insurance coverage for a single category of disease, renal failure.

As might be expected for a group convened by the Bureau of the Budget, the Gottschalk Committee devoted considerable effort to predicting the costs and benefits of the proposed ESRD care program. It is interesting to compare and contrast the key assumptions and predictions of the Gottschalk Committee with the Medicare ESRD Program as it functions today.

The Gottschalk Committee assumed that dialysis services would largely be limited to otherwise healthy patients under age 54 who were free of other severe illnesses, such as advanced cardiovascular disease.¹⁵ Thus, they assumed only about one in five patients with ESRD would be “medically suitable” candidates for dialysis and transplantation.¹⁵ On the basis of these assumptions, the committee predicted that the number of new patients per year suitable for dialysis would be less than 40 patients per million population.

Currently, as seen in Figure 2, the incidence rate for ESRD care is approximately 400 per million population, and the fastest growing subgroup of patients entering dialysis care represents those over 75 yr of age. Indeed, the median age of patients initiating treatment for ESRD is now over 64.¹⁶ Moreover, comorbidities among patients with ESRD are the norm rather than the exception. Among octogenarians and nonagenarians initiated on dialysis, almost half are suffering from congestive heart failure and one-third from diabetes mellitus or ischemic heart disease. More than four comorbid conditions are present in one-third of such patients.¹⁷ Broader access to ESRD therapy for older adults and for those with comorbid conditions has contributed greatly to the far higher incident and prevalent ESRD populations than predicted by the Gottschalk Committee. Although a component of the increased incidence of ESRD is attributable to the increasing prevalence of kidney disease

because of diabetes,¹⁸ the ESRD population in the United States has grown much faster over the past 30 yr than is attributable to changes in prevalence of chronic kidney disease (CKD) or risk factors for renal failure.¹⁹ Thus, an important additional factor contributing to the increasing incidence and prevalence of ESRD care in the United States is progressive liberalization of criteria for initiation of dialysis or transplantation.¹⁹ Of interest in this regard, there has been a dramatic increase over the past decade in the frequency of patients initiating dialysis with estimated GFR values above 10 ml/min/1.73 m².²⁰ For example, between 1995

and 2006 the fraction of patients starting dialysis with estimated GFR of 10 to 14.9 ml/min grew from 15% to 30%, and those starting dialysis with estimated GFR more than 15 ml/min increased from 4% to 15%.²⁰ These trends were even more pronounced in the elderly.¹⁷ Despite the absence of evidence of benefit, this trend toward early dialysis increased the incidence and prevalence of care for ESRD.²¹

The overall cost of care for ESRD depends not only on the incidence and prevalence of ESRD patients, but also the health care cost per ESRD patient. As mentioned above, the fraction of dialysis patients who are elderly and have major comorbid conditions is rapidly rising. But chronic dialysis is far less cost-effective in the case of the elderly with multiple comorbidities. For example, as shown in Figure 3, annual per person Medicare expenditures are greater the older the patient, and costs are twice as high for those with both diabetes and congestive heart failure than for those without these comorbidities. Moreover, as compared with the cost-benefit analysis of the Gottschalk Committee that estimated that the average increase in life expectancy from chronic hemodialysis would be 9 yr, the life expectancy of the elderly receiving chronic dialysis is very poor. In particular, the 1-yr mortality rate for octogenarians and nonagenarians starting dialysis is almost 50%, and the median survival for patients greater than 85 yr is less than 1 yr.¹⁷ Clinical characteristics associated with an increased risk of death are older age, nonambulatory status, and higher number of comorbid conditions.¹⁷ Indeed, in certain subgroups of patients it is questionable whether dialysis improves quantity and quality of life at all.

One recent study reported the survival advantage of dialysis compared with conservative management is only minimal in patients 75 yr of age and older who have CKD stage V and either ischemic heart disease or high comorbidity scores.²² Another study found in high-risk, medically compromised patients with ESRD that the initiation of dialysis had little effect on survival but increased the chance of dying in the hospital rather than in the community.²³ Whereas the Gottschalk Committee assumed ESRD care would be limited to patients who would benefit in terms of extension of life of high quality, phy-

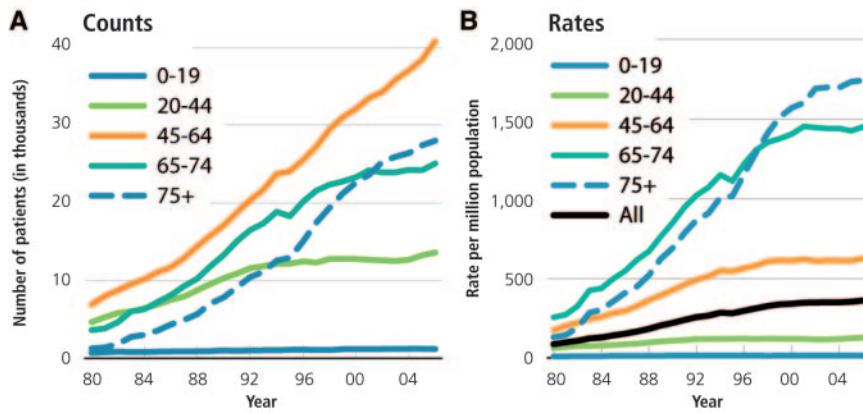


Figure 2. The fastest growing subgroup of patients starting dialysis care is the elderly. (A) Incident counts¹⁶ and (B) adjusted rates of ESRD patients in the United States.¹⁶

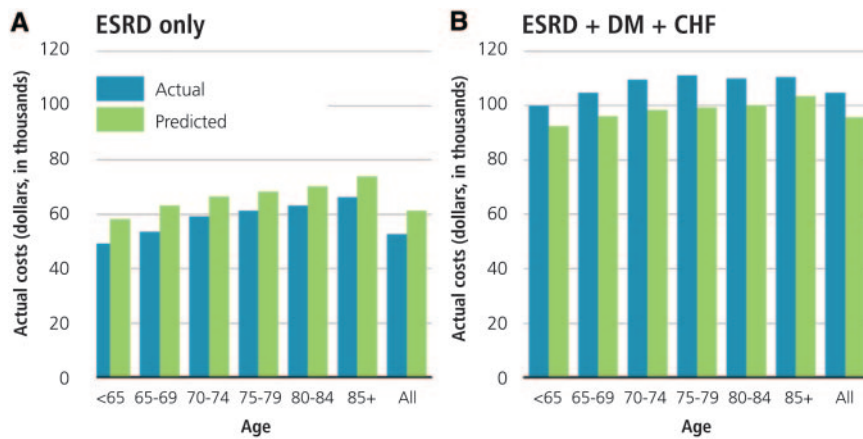


Figure 3. Cost of dialysis care increases with age and number of comorbidities. (A) Annualized actual and predicted payments for dialysis patients with ESRD only for different age groups¹⁶ and (B) for patients with ESRD, diabetes, and congestive heart failure.¹⁶

sicians are often willing to provide dialysis care to patients with greatly diminished quality of life. For example, a survey of nephrologists found that almost half would be willing to continue dialysis in a patient who develops permanent and severe dementia.²⁴

What can be done to reduce the rate of rise of the cost of ESRD in the United States and improve its cost-effectiveness? The principal cost-control measure up to now has been simply to steadily decrease the reimbursement rate per dialysis treatment as expressed in constant dollars.²⁵ The net effect has been to spur the development of a highly consolidated for-profit industry capable of generating volume-based cost-efficiencies for outpatient dialysis.²⁵ Dialysis providers are not at financial risk for the high health care costs generated by dialysis patients with multiple comorbidities who require extensive medical services and frequent hospitalization. Thus, the current model of ESRD care in the United States arguably incentivizes the provision of chronic dialysis services to as many patients as possible, including those with high health care costs above and beyond the direct cost of dialysis itself.

Of course, the most effective strategy to improve health outcomes and limit the need for expensive ESRD care is to reduce the incidence of ESRD. Here too, the Medicare program for ESRD represents in microcosm a major deficiency of our current health care system, namely the lack of universal insurance coverage for primary care and early-stage disease management. Thus, although Medicare provides near-universal catastrophic insurance for dialysis and transplantation, it does not provide payment for screening of patients at high risk for development of kidney disease, or for treatment of hypertension and use of angiotensin converting enzyme inhibitors or angiotensin II receptor antagonists in patients identified with CKD. Indeed, uninsured patients with CKD are at increased risk for renal progression but are less likely to receive recommended interventions known to slow this progression.²⁶

Provision of near-universal health insurance is a key feature of current proposals for health care reform in the United States. But providing insurance coverage for primary care and early-stage disease management will not necessarily increase their availability, especially if financial incentives continue to more highly reward procedures and treatment of severe illness. Specifically with regard to kidney disease, there are major structural and organizational barriers that will need to be overcome to provide effective screening of high-risk patient groups, and then to provide coordinated

disease management to delay if not prevent ESRD in patients identified with early stages of CKD.²⁷

For patients who do progress to ESRD, it is important that ESRD care be as cost-effective as possible. The Gottschalk Committee recognized transplantation as being more cost-effective than chronic dialysis,¹⁵ and this remains the case today,¹⁶ as illustrated in Figure 4. Although transplantation is clearly the preferred modality for treatment of ESRD, its utilization is limited primarily by the availability of donor organs. Strategies to increase the supply of kidneys by using expanded criteria donors, systematic programs to improve consent rates, increased donation after cardiac death, and paired living donor kidney donation are important efforts to fight the organ shortage.^{28,29} In addition, the enormous benefits of transplantation with regard to outcomes and cost have led to proposals for development of a regulated system of compensation for organ donation.^{29,30} It should be noted that kidney transplant recipients currently lose Medicare coverage for immunosuppressive drugs 3 yr after transplantation whereas extended coverage would likely result in better transplant outcomes and be cost-effective at the same time.³¹

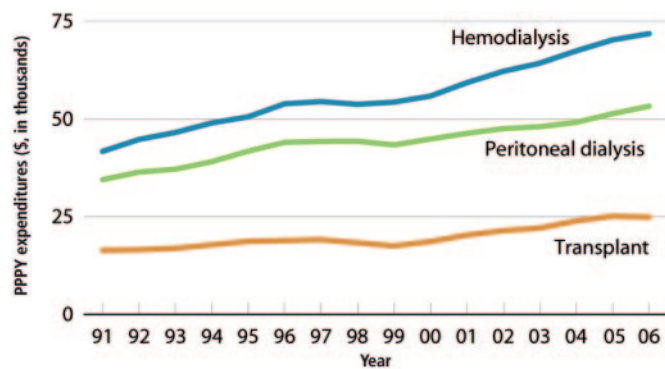


Figure 4. Total Medicare expenditures per person per year vary depending on the modality of renal replacement therapy. Kidney transplantation is by far the most cost-effective modality, followed by peritoneal dialysis. In-center hemodialysis is the least cost-effective renal replacement modality.¹⁶

Although in-center hemodialysis remains by far the most common renal replacement modality in the United States, peritoneal dialysis is less costly, as also shown in Figure 4.¹⁶ Even after accounting for such factors as patient selection, there is general agreement that peritoneal dialysis is more cost-effective than in-center hemodialysis.^{32–34} Accordingly, utilization of peritoneal dialysis as an alternative to in-center hemodialysis should be maximized. A shift from in-center hemodialysis to home-based hemodialysis is another potential strategy to enhance the cost-effectiveness of ESRD care.³⁵ Furthermore, as discussed above, the recent trend of initiating dialysis at higher GFR should be re-evaluated as potentially leading to overutilization of resources with no outcome benefit.^{36,37}

In principle, the cost-effectiveness of care for ESRD could be improved by limiting care of patient subgroups with exceptionally high cost in relation to benefit. In 2000, the Renal Physician Association and American Society of Nephrology issued guidelines for shared medical decision-making by patient and physician regarding the appropriate initiation of and withdrawal from dialysis, but there was no consideration of cost.³⁸ An example of an attempt to factor cost into medical decision-making is the establishment in Britain of an independent agency to assess the incremental cost-effectiveness ratio, or the cost per quality-adjusted life-year (QALY), gained through use of new medications and treatments.³⁹ These assessments are used to determine which new treatments are recommended for coverage by the National Health Service, with the goal of restricting care to those treatments for which the incremental cost-effectiveness ratio is less than an arbitrary maximal value of approximately \$50,000/QALY. The problem of applying such a methodology to ESRD care is that the incremental cost/QALY varies widely among patient subgroups, as discussed earlier with reference to Figure 3.

Assigning individual patients to subgroups for estimation of cost-effectiveness ratios would be difficult at best, and such a scheme for strict rationing of care would almost certainly be

politically unacceptable in the United States. Nevertheless, as noted above, there are patient subgroups, such as the frail elderly with severe comorbidities, for whom dialysis may not prolong life and instead may reduce the quality of life.²² For these patients, the management of end-of-life is often done poorly and there is a need to increase awareness of palliative care in managing ESRD.^{40,41} A survey of nephrology fellows indicates few thought themselves prepared to provide end-of-life care and most fellowship programs do not offer this training.⁴² Accordingly, training of nephrologists in palliative care should be enhanced to provide optimal end-of-life care while at the same time avoiding overutilization of dialysis in patients for whom there is little or no benefit.

Limiting the need for chronic dialysis also requires better preventive and therapeutic approaches to reduce the incidence of CKD and ESRD. Expansion of health services research in kidney disease is needed to address not only comparative effectiveness but also cost-effectiveness of preventive and therapeutic strategies in different subgroups of patients. However, such expansion of health services research should parallel growth of basic research on underlying disease mechanisms. One can look forward to the day that dialysis machines will be considered a costly halfway technology of the past like the iron lung. As has been argued in these pages previously,⁶ although we can seek to deploy halfway technologies like dialysis with greater cost-effectiveness, only basic research on disease mechanisms can lead to discovery of the nephrologic analogues of polio vaccine that will completely rid us of halfway technology. It is therefore critically important to expand federal support for both health services and basic research on kidney disease because together they offer the best hope to improve health outcomes while enhancing the cost-effectiveness of the health care system.

DISCLOSURES

None.

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