

The organization and financing of kidney dialysis and transplant care in the United States of America

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Abstract

In the United States, end-stage renal disease (ESRD) patients are primarily insured by the publicly funded Medicare program. Compared to other countries in the International Study of Health Care Organization and Financing (ISHCOF), the United States has the highest health care expenditures for the general population and among ESRD patients. However, because the Medicare program is more influential in the market for ESRD-related services than for other medical services, ESRD price controls have been relatively stringent. Nonetheless, ESRD costs have grown substantially through increases in prevalence and use of ancillary services. Treatment costs are also controlled by the relatively high rate of transplantation. Proposed reforms include bundling more services into a prospective payment system, developing case-mix adjustments, and financially rewarding providers for quality.



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Introduction

Relative to individuals suffering from other clinical conditions, people with end-stage renal disease (ESRD) receive special treatment in the American health care system. Since 1972, ESRD patients have been eligible for heavily subsidized public health insurance conditional only on their disease status, regardless of age, income, or functional status. The public Medicare program, which otherwise provides coverage only to the elderly (aged 65 years and older) and those with other qualifying disabilities, covers people with kidney failure. Individuals who are not otherwise entitled to Medicare coverage face a three-month waiting period for coverage following the onset of chronic renal failure, and the relatively small number able to maintain private health care coverage face an additional 30-month period in which Medicare coverage is secondary to the private coverage.¹ The ESRD population is eligible for the same Medicare benefits as the elderly, with some special treatment for payments for dialysis, transplantation, and some drugs used largely by ESRD patients.

Because private insurance typically pays more than Medicare, patients in this waiting period are very attractive to dialysis facilities. A small proportion of the population is permanently ineligible for Medicare because of an insufficient time period of employment (own employment, spouse's employment, or parent's employment in the case of a child) in a job covered by the U.S. Social Security Administration (federal retirement benefits) system or in a government job that provides retirement benefits outside the Social Security system but pays Medicare payroll taxes. This means that, with only modest exceptions, both patient and provider incentives and the organizational structure for treating kidney disease are determined by the specifics of the Medicare program, and most of those program characteristics have not been modified for these beneficiaries compared with the much larger number of people who receive Medicare benefits in the other categories.

Specifically, the incentive structure for patients and providers in the Medicare ESRD program is based on administered fee-for-service payments by a government-managed insurance plan, subject to patient copayments. Copayments for most services are set at 20% of the Medicare allowable charges, and most patients hold a private or public secondary insurance plan that covers much of the copayments. However, patient out-of-pocket costs remain, particularly for outpatient prescription and over-the-counter pharmaceuticals.² The organization of supply of services is almost wholly private and is to some extent determined by the incentives present in the virtually universal payment system.

The Medicare program as a whole faces increasing financial pressures as rising expenditures for medical services combine with demographic changes, resulting in growth in the number of Medicare enrollees and in the number of enrollees with ESRD (who have per capita costs over seven times greater than the average Medicare beneficiary). As a result, many features of the program are coming under scrutiny and are potentially subject to change. This provides both a significant risk and a significant opportunity for the program.

¹ For an excellent history of the Medicare ESRD program, see Nissenson and Rettig (1999).

² Dykstra et al. (2003) report that relief from out-of-pocket costs was a primary reason that ESRD patients chose to participate in a Medicare Demonstration project on managed care. Those without secondary insurance potentially saved an average of \$9,000 annually in copayments by enrolling.

Methods

This paper is part of the International Study of Health Care Organization and Financing (ISHCOF), a substudy of the Dialysis Outcomes and Practice Patterns Study (DOPPS). The DOPPS is a multi-faceted, multi-year international study of the variations in practice patterns and treatment of ESRD patients on hemodialysis and their impact on clinical and other outcomes. The ISHCOF aims to characterize economic structures and their impact on the delivery of ESRD care. The study is based primarily on one-time commissioned surveys (2004–2005) and subsequent papers by authors from each of the 12 DOPPS countries.

The epidemiologic data for this report were drawn primarily from annual reports published by the American ESRD patient registry, the United States Renal Data System (USRDS, 2002, 2003, 2004 and 2005). Information regarding insurance coverage, policies, and demonstration projects was found on the Web site of the Centers for Medicare & Medicaid Services (CMS) (<http://www.cms.hhs.gov/default.asp>). Payment rates for various conditions were obtained from the Medicare Payment Advisory Commission reports. Due to the small number of economic investigators and countries in this study, all international comparisons reported here are informal and qualitative, unless otherwise noted.

The gross epidemiology of kidney disease and the provision of care in the United States

The measured prevalence and incidence of ESRD in the United States is moderately high by international standards (USRDS, 2004). In 2002, more than 400,000 people were counted as ESRD patients, which represents a prevalence rate of about 0.14%; of those patients, 28% are kidney transplant recipients. The prevalence of ESRD is increasing at an annual rate of about 4% (1998–2002), with modest growth in the number of transplantations performed. However, the increasing number of transplantations has not kept pace with the overall growth in the ESRD population. For a primer on clinical care for ESRD, see the ISHCOF summary article (Dor, Pauly, Eichleay, & Held, 2007).

ESRD patients receive care primarily from free-standing outpatient dialysis facilities. Hospitals provide about 16% of chronic dialysis care and, of course, are the site for transplantation. Dialysis facilities are largely private, for-profit organizations (76% of facilities and 79% of patients), with the remainder of dialysis treatments provided in private, nonprofit facilities and a very small number of public facilities. Corporate ownership is significant, with 53% of dialysis facilities owned by the four largest publicly traded dialysis chains. This percentage is growing, and two mergers have recently been consummated between the four largest chains, making two chains responsible for the majority of US dialysis care. Most facilities are located in urban rather than rural areas. However, to promote access to care in rural areas, Medicare provides higher payment rates to some rural facilities deemed to be essential, sole providers of dialysis services.

Despite concern in the United States about impending shortages of nephrologists, given that the growth rate of ESRD exceeds the growth rate of newly trained nephrologists net of retirements (Osinski & Wish, 2005), the supply of personnel for ESRD treatment is currently generous by

international standards (data not shown). There is one specialized nephrologist per 48 dialysis patients.³ Of course, nephrologists are engaged in a variety of activities other than clinical care of dialysis patients (e.g., care of transplant and pre-ESRD patients, research, and administration).

In terms of transplantation procedures, there are sufficient physician resources to treat the population (the supply of transplantable organs is the only significant constraint on transplant capacity). If half of ESRD patients were candidates for transplantation and organs were available, the stock of transplant surgeons could complete the task of transplanting all of them at a rate of one surgery per day in 228 working days.

Physician incomes in the United States are generally high by international standards (data not shown) and relative to the rest of the US population. In 2002, the median nephrologist income of \$227,385 (mean of \$261,919) fell between the median income of primary care physicians (\$153,231) and all specialists (\$274,639) (MGMA, 2003). In the general US workforce, median earnings among full-time, full-year workers were about \$36,000.

This adequate supply comes from a mixed public and private educational system that imposes no limits on the total number of physicians or specialist physicians who are trained in the United States, combined with a substantial (though regulated) inflow of foreign-trained doctors. There is believed to be a shortage of registered nurses, which probably extends to dialysis nurses. In the past such shortages have been temporary, but there is considerable concern about the current situation.

As a result of the availability of supply, there are no waiting lists for dialysis or access placement. There is a shortage of transplant opportunities, but that has resulted from a shortage of organs, not from any scarcity of facilities or personnel to perform transplants.

Expenditures

The combination of a high prevalence of ESRD patients in the general population, virtually universal insurance coverage, and high cost (or at least highly paid) inputs means that total spending on the ESRD population is high by international standards. For ESRD patients, spending in 2003 was about \$27 billion total, equivalent to \$55,000 per patient per year for Medicare patients and \$72,000 per patient per year for employee group health plans (USRDS, 2005). However, the spending is not out of proportion to other medical care spending in the United States, despite the absence of universal insurance for the nonelderly who have other diseases. In 2002, national health expenditures in the United States were about \$1.5 trillion (14.6% of the gross domestic product), or about \$5,274 per capita, much higher than the overall medical spending rates observed in other ISHCOF countries (WHO, 2005).

³ On December 31, 2003, there were 324,826 point-prevalent ESRD patients treated with dialysis (USRDS, 2005). The American Medical Association database listed 6800 nephrologists (Osinski & Wish, 2005), resulting in a ratio of 48 dialysis patients per nephrologist.

Both overall medical care and ESRD expenditures have been advancing faster than population, inflation, or real income growth. From 1999 to 2005, private and public expenditures have been growing at similar rates (CMS, 2005). The introduction of outpatient drug coverage into Medicare in 2006 may have some impact on this trend by shifting some of these costs from the private to the public sector. Total spending for ESRD has, however, increased a little faster in that time period than overall medical spending and spending in other parts of the Medicare program. Two factors that may explain the higher cost growth for ESRD are the faster growth in the number of enrollees in this part of the program and the mix of services used by ESRD patients relative to other Medicare enrollees. Hospital inpatient and physician office services, which are subject to a variety of financial controls by Medicare, account for a smaller percentage of the services used by ESRD patients compared with non- ESRD patients. Conversely, use of injectable medications, which have been subject to only limited controls, represent a larger share of services received by ESRD patients. Using a purchasing power parity (PPP) price index to convert all currencies to United States dollars, United States expenditure levels exceed those in every other ISHCOF country, both in the general population and among ESRD patients (Dor et al., 2007). On a per ESRD patient-year basis, US spending (\$58,115 in 2002; \$60,337 in 2003) is higher than all ISHCOF countries. However, while the United States is a clear outlier in terms of health expenditures in the general population (\$5,274 per capita in the United States versus \$2,222 per capita in next highest spending country, Canada (WHO, 2005)), ESRD expenditures per capita are only marginally higher than those in the median ISHCOF country. This indicates that the controls in the Medicare program (e.g., increases in payments for dialysis treatments have fallen far short of both medical and general inflation rates) have resulted in ESRD spending being relatively “efficient” compared with the very high overall medical spending in the United States.

Total US medical care spending is almost evenly divided between public and private spending. Public spending goes for insurance to cover the elderly, the disabled, those with ESRD, some poor adults, and children in low-income families. For ESRD patients, all medical services (whether for kidney disease or other illness) are covered, along with some outpatient drugs (primarily, injectable medications and immunosuppressive medications are covered). Health insurance does not compensate ESRD patients for lost wages, but disability and welfare programs provide payments for a fraction of patients.

Private insurance and public insurance combined cover 85% of the general US population, leaving about 45 million people without formal health insurance at any point in time. Private insurance is largely supplied as part of the benefits offered by firms to attract workers. Private insurance pays for treatment of kidney disease and is even required to pay for those with kidney failure who are eligible for Medicare. Preexisting private coverage for patients under age 65 is considered primary to Medicare for up to 33 months (3-month waiting period for Medicare coverage plus 30-month coordination of benefits period). During this coordination of benefits period, Medicare remains the secondary payer, covering items such as the patient’s copayments and any services covered by Medicare but not by the private insurance plan. Because relatively few ESRD patients, particularly those who require dialysis, can maintain full-time employment, less than 20% of patients hold such coverage. Nonetheless, because private insurance generally pays more than Medicare, dialysis facilities that can attract an above average percentage of privately insured patients can attain significant financial benefits.

Once Medicare becomes the primary payer, any existing private insurance may cover the Medicare copayments and often pay for outpatient drugs that Medicare does not cover. It does not pay for amenities. Because virtually all providers of ESRD care accept public insurance, having private insurance does not appear to improve access to covered services.

Medicare beneficiaries can choose between a single government-managed fee-for-service insurer and a number of private (mostly managed care) Medicare plans, all financed with public funds. However, 85% of all beneficiaries, and a larger proportion of ESRD patients, select the government-managed plan. Only 6% of Medicare ESRD patients are enrolled in managed care plans (USRDS, 2003). Further, because of uncertainties surrounding the suitability of managed care options for high-intensity ESRD patients, Medicare beneficiaries with ESRD are currently prohibited from enrolling in Medicare managed care options. However, those who were enrolled in Medicare managed care options before the onset of ESRD can, by their own choice, remain in managed care. As a result of this requirement that Medicare managed care enrollment predate ESRD, those patients enrolled in managed care tend to be older than the average ESRD patient. For this reason, ESRD providers, almost all in the private sector, must continue to work with a single large buyer if they wish to have business for the foreseeable future. A recent, federally funded demonstration project has evaluated managed care for Medicare enrollees as a possible precursor to the elimination of the enrollment prohibition.

The government-managed Medicare plan usually pays on a fee-for-service or a provider-specific, prospective basis for its beneficiaries. Payment for hemodialysis and related services for ESRD is a blend of the fee-for-service and prospective approaches. For dialysis facilities, there is a single “composite rate” payment per dialysis treatment, which covers the basic services rendered in connection with dialysis; no separate billing by the facility is permitted for these core services within the dialysis “bundle.” This bundle includes labor, equipment, and supplies associated with the dialysis treatment along with specified routine laboratory tests and drugs. In 2006, the base level for the composite rate was \$132 for hospital-based facilities and \$128 for free-standing facilities (MedPAC, 2006). These base composite rates vary across dialysis facilities according to (1) area health care wages, subject to a floor and a ceiling on the allowed extent of adjustment, (2) ownership, with hospital-based facilities receiving payments 2%-3% higher than free-standing facilities, and (3) exceptions made for facilities showing unusually high costs. These exceptions often result from atypical patient mix or small facility size due to essential rural provider status; however, new payment exceptions are no longer being granted except in the case of facilities serving disproportionately pediatric populations. Generally, hemodialysis payments are limited to three sessions per week, and peritoneal dialysis payments are limited to the equivalent of the payment for three hemodialysis sessions per week. Dialysis facilities can bill separately for services outside the composite rate bundle, primarily injectable medications and non-routine lab tests. Anemia management, erythropoietin (EPO) and iron, accounts for more than two-thirds of Medicare payments to dialysis facilities for items billable separately from the composite rate (USRDS, 2005).

Physicians (usually nephrologists) are paid on a fixed monthly capitation basis for routine outpatient services to ESRD patients. In 2004, this payment was \$303 per month for four or more visits, \$252 for two to three visits, and \$201 for one visit. In addition, nephrologists are paid on a

fee-for-service basis for services provided when a patient is hospitalized. All other physicians are paid on a fee-for-service basis for inpatient or outpatient care. Fixed capitation payments for outpatient care may discourage nephrologists from providing primary care services. Hospitals are paid a fixed rate for inpatient care depending on the diagnosis related group (DRG) to which the patient is assigned, with outlier payments possible for very expensive cases. Outpatient facility payments were recently changed from fee for service to a prospective payment system analogous to DRGs.

There is growing interest from the Medicare program and other payers in linking provider payments to measures of performance. Such a link has not yet been created for dialysis providers, but many of the requisite data are being collected and published. Since 1999, the Medicare program has been collecting data on 18 ESRD-related clinical performance measures (<http://www.cms.hhs.gov/CPMProject>). These measures are collected for a nationally representative sample of patients and are intended to track national trends, identify opportunities for improvement, and facilitate regional comparisons. At the provider level, Medicare's Dialysis Facility Compare project provides a Web-based interface that allows patients to assess different dialysis providers in terms of services provided and several outcome measures that can be compared with those of other facilities and with state and national averages (Medicare, 2007). The publication of these data, while not providing a direct financial incentive to raise quality, creates an indirect incentive to the extent that the data are used by patients to select a provider and could be used in the future as a basis for a pay-for-performance system.

Finally, beneficiaries potentially pay for their care in four major ways: (1) a premium (\$78.20 per month in 2005, up from \$66.60 in 2004) for Medicare insurance, (2) a copayment of 20% for covered outpatient services, (3) a deductible approximately equal to the cost of a one-day hospitalization for inpatient care, and (4) most outpatient prescription drugs. However, a large majority of ESRD patients have supplementary insurance to cover the copayments and most of the cost of drugs; if they have a low income they may also have their premium paid by the government and qualify for public coverage through the Medicaid program or charitable write-offs from providers to cover many of their remaining expenses. Thus, the average percentage of care paid out of pocket for ESRD patients, for all medical goods and services other than outpatient prescription drugs, is relatively low. Based on data from the DOPPS, patient-reported out-of-pocket costs for dialysis averaged \$10 per month versus \$113 per month for prescription and over-the-counter medications (personal unpublished data).

The Medicare program that covers ESRD patients is financed by a wage tax, by general tax revenues, and by modest beneficiary premiums (less than 10% of total costs). It covers everyone who has worked for more than a minimum number of calendar quarters in covered employment (including the self-employed), so that it covers almost all people with ESRD except those who never worked and never had a spouse who worked, and children whose parents never worked.

Reimbursement incentives and their effects

These payment systems are thought to affect the amount, source, and type of care patients receive. For all practical purposes, patients do not pay for care and therefore are not motivated to

limit spending on their behalf or to seek out lower-cost sources of care. They are, however, usually able to choose among competing sources of supply and do so to some extent based on their perception of the quality and amenity levels of the care they receive. Especially in large cities where there are many facilities, the competition for patients serves to limit profits that can be earned (regardless of the level of reimbursement). Some of the competition for patients may involve amenities (e.g., convenience of scheduling) (Hirth, Chernew, & Orzol, 2000). Thus, there exists a kind of conflict between patients and the Medicare program, with each group wanting to benefit from efforts to squeeze out provider profits.

The level of Medicare payments is set on an administered price basis, depending on data collected annually about the costs incurred by dialysis facilities, whether barriers exist to accessing care (particularly, whether new facilities are opening at a pace comparable to the growth of the ESRD population), the cost impact of new technologies, governmental budgetary objectives, and supplier political pressure. The Medicare Payment Advisory Commission (MedPAC), an independent advisory commission for the Medicare program, issues recommendations about payment updates and program design for ESRD benefits. However, any recommended payment change is subject to legislative approval, generally as a component of a much broader Medicare or budget bill. Several increases in payment levels recommended by MedPAC in recent years were not implemented by legislation. Because of the competition noted above, the level of payment in a meaningful sense determines the cost that is incurred and the maximum quality or intensity of services provided. Providers seeking to generate profit (in the case of for-profit firms) or net revenues to invest in their operations (in the case of nonprofit firms) have an incentive to minimize cost subject to regulatory constraints on quality and subject to any effects of quality on the ability to attract and retain patients.

Within this framework, some aspects of the publicly set prices probably work to increase the quality of care, relative to a benchmark of minimal acceptability, while others work to reduce it. Analyses of cost data from dialysis facilities indicate that the composite rate payment for the basic bundle of services for a dialysis treatment falls short of the input costs incurred to produce the treatment. However, the payments for separately billable items such as injectable medications exceed their input costs, cross-subsidizing losses incurred on composite rate services (MedPAC, 2003). While this system provides a powerful incentive to economize on the dialysis treatment itself, it also provides a strong incentive to aggressively manage concurrent clinical conditions such as anemia through the use of separately billable drugs.

One unintended consequence of the payment system may be that few patients receive peritoneal dialysis or other home therapies. Payment for the basic dialysis service (whether in-center hemodialysis, home hemodialysis, or peritoneal dialysis) is based on the composite rate derived from a weighted average of provider-reported costs for different dialysis modalities. Ironically, this system was actually designed to encourage peritoneal dialysis, which typically has lower costs than hemodialysis. However, the erosion of the composite rate (in real terms) over time increased dialysis providers' reliance on profitable, separately billable items. Because peritoneal dialysis patients tend to use fewer of these items (and are less likely to use them in the injectable forms covered by Medicare) and because home hemodialysis payments are limited to three weekly sessions, the financial incentive to use home therapies has eroded. On net, in-center

hemodialysis now appears to be more financially advantageous to providers than home therapies, and the share of patients on home therapies has eroded substantially.

More generally, patients and their families view the availability of coverage and care to anyone with kidney failure and the possibility of choice as desirable, even though it can lead to expensive care for people with a poor prognosis, low current quality of life, and little ability to benefit from care. There are no age cutoffs, and all patients have realistic access to specialist physicians and high technology. The result of such broad access, compared with countries that restrict access, is that the average quality of life and life years added per patient treated may be lower. However, broad access may result in a high aggregate number of quality-adjusted life years gained because of the large number of patients undergoing treatment.

On the downside, payment rates for dialysis, once set by the public program, are rarely raised in the face of rising costs of inputs for dialysis. Since the current composite rate system was implemented in 1983, there have been only four modest payment updates, resulting in a substantial real (inflation-adjusted) decline in the payment for services covered by the composite rate. To some extent this process has undoubtedly stimulated providers to adopt productivity-improving measures and to minimize costs for whatever they do. But, sooner or later, relatively low and rigid prices lead to lower levels of quality than firms would find it both possible and rewarding to provide if payment rates were higher. Research on the relationship between payment for dialysis and the quality and nature of the process is not definitive, but there is evidence that practices such as dialyzer reuse, staffing reductions, and scheduling inflexibilities (fewer dialysis stations per patient) were encouraged by financial pressures (Hirth, Held, Orzol, & Dor, 1999; Hirth et al., 2000). Both the relatively low payment per dialysis session and the limit of that payment to three treatments per week may have contributed to inadequate dialyzing of at least some patients and failure to adopt dialysis schedules with shorter but more frequent treatments.

Nonetheless, patient outcomes (survival) and clinical indicators of therapy [percent of patients receiving the target dose of dialysis ($Kt/V > 1.20$) and achieving hematocrit targets (hematocrit > 33 g/dL)] have improved substantially in recent years. The percentage of adult hemodialysis patients receiving the target dose increased from 74% in 1996 to 91% in 2003, while the percentage achieving hematocrit targets improved from 43% in 1997 to 80% in 2003 (CMS, 2004). Several factors most likely contributed to this success in the face of declining real payment rates for dialysis. Certainly, improved dialysis technologies and knowledge played a role. In addition, Medicare quality initiatives such as generating and disseminating unit-specific reports on a variety of outcome measures and the clinical performance measures project described earlier sought to enhance clinical care. ESRD facilities also report to one of eighteen regional “networks” charged with data collection and facilitating quality improvements. These regulatory efforts, when combined with the development of widely respected clinical practice guidelines (particularly, the National Kidney Foundation’s Kidney Disease Outcomes Quality Initiative, or KDOQI, guidelines) that focused professional attention on quality improvement, appear to have offset or at least mitigated the potential threat to quality posed by declining real payment rates. It remains to be seen whether more recent guidelines on mineral metabolism, nutrition, and vascular access will result in similar improvements.

Payment to the surgeon for placement of an arteriovenous (AV) access for hemodialysis is almost the same regardless of the type of access placed. Compared with more targeted methods, this has probably led to less use of fistulae relative to synthetic grafts, although there are many reasons other than reimbursement that affect the choice of access.

Finally, the public Medicare program is an island of universal insurance coverage in a sea of uncertain and incomplete private insurance. Especially for economically vulnerable populations, this means that the care they receive for their kidney disease before reaching ESRD may be limited. Delayed referral to nephrology has been implicated as a cause of delayed diagnosis or renal failure and the loss of opportunities to slow progression to end-stage renal failure. In addition, late referral and lack of insurance coverage have been implicated as causes of the high percentage of US patients who begin dialysis with a temporary vascular access or with a polytetrafluoroethylene graft rather than a native fistula (Pisoni et al., 2002).

Specific aspects of treatment and financing

Having outlined the broad patterns of financing and incentives in the care of patients with kidney disease, I now turn to the specific types of care.

Prescription drugs

Even before the implementation of a broader Medicare prescription drug benefit in 2006, the Medicare program covered specific drugs used in connection with kidney disease (especially immunosuppressive medications for transplant patients and injectable medications such as EPO, iron, and vitamin D for dialysis patients). However, there are no general limits on reimbursement for prescription drugs, potentially covered by a wide variety of public and private insurances or paid out of pocket. Physicians have no external limits placed on what drugs they can use or in what way, and they need not consult with anyone else. Except for EPO and other injectables that are dispensed by the dialysis unit, drugs are generally obtained in private pharmacies. Medication use in the US hemodialysis population is very high, with an average of 9.4 prescriptions per patient (Bragg-Gresham et al., 2003).

ESRD beneficiaries often have supplemental insurance that covers what Medicare does not cover, especially outpatient drugs. Low-income patients are covered by the federal- and state-funded Medicaid program, which usually employs formularies and requires drug companies to charge the lowest price they accept from any payer. Private supplemental insurance provided by the patient's or a family member's employer sometimes has formularies and sometimes does not, and also pays in a wide variety of ways. Many drug plans have tiered copayment structures that require higher copayments for brand name drugs and drugs not on the plan's preferred formulary than for generic or preferred formulary drugs. Those who have no supplemental insurance coverage for drugs are a small fraction of ESRD patients, but they face serious financial challenges. Even those with supplemental coverage face, on average, a higher out-of-pocket cost burden than do residents of other countries included in the DOPPS (Young et al., 2003).

For most injectable and non-immunosuppressive drugs that Medicare did not cover before the 2006 implementation of the prescription drug benefit, the pattern is mixed. Many ESRD patients have coverage for most of the cost, with varying degrees of limitation. In contrast, a subset of patients has no coverage; these patients have no externally imposed limits on what they can get—if they can pay for it.

Medicare reform legislation enacted in November 2003 provides, for the first time, a limited outpatient prescription drug benefit for Medicare enrollees. This benefit was phased in, with optional prescription discount cards made available in May 2004 and replaced by the permanent benefit in 2006. The permanent benefit is administered by competing private insurers, and enrollment is voluntary. In exchange for an enrollee-paid premium (estimated to be \$37 per month, with subsidies available to low-income enrollees), the benefit partially covers 75% of the first \$2,250 of expenses in excess of a \$250 deductible and then provides no coverage until an out-of-pocket maximum expenditure of \$3,600 is reached; at that point, the benefit covers 95% of any additional expenditures.

With regard to Medicare payment for EPO, each dialysis unit is permitted to set its own guidelines for anemia control, subject to review by Medicare. Many units follow the KDOQI recommendations, but there are no mandated rules or procedures. The only major constraint Medicare imposes is that EPO be paid for if the hematocrit level falls below 37%. Before the implementation of the Medicare prescription drug benefit, Medicare also generally paid for injectable iron and vitamin D, but not for oral iron and vitamin D or other vitamins. There are target levels for iron stores, but no rules on how iron must be administered. EPO and iron play complementary roles in controlling anemia. Because fee-for-service payment for EPO is a major revenue source for dialysis facilities, there is a potential economic disincentive for optimal iron dosing (which could reduce the required EPO dose).

The 2003 Medicare reform legislation also changed the manner in which EPO and other injectable medications are paid for. Following a study of drug acquisition costs, payments for these medications were reduced, with the savings channeled to an increase in the composite rate for dialysis. This change was intended to remedy the situation in which composite rate payments fall short of the input costs incurred in providing dialysis, forcing providers to make up the losses by (possibly) overusing profitable, injectable medications. These changes were implemented on January 1, 2005, and their impact has not yet been evaluated.

To summarize, the use of prescription drugs for ESRD patients in the United States is limited more by financial incentives to patients and providers than by administrative rules or restrictions on physicians' decisions. The addition of limited outpatient prescription coverage to Medicare in 2006 should benefit a large number of ESRD patients, many of whom have significant prescription expenditures for treating co-existing illnesses such as diabetes and heart disease. Peritoneal dialysis patients are likely to be particularly affected because they typically receive oral iron and vitamin D therapy (which was not previously covered by Medicare), while hemodialysis patients typically receive injectable versions of those drugs (which were previously covered). Changes in the use of injectable medications, and subsequent clinical outcomes, will have to be monitored following the implementation of the Medicare policy change intended to eliminate the cross-subsidization between separately billable items and composite rate services.

Likewise, almost all EPO received by hemodialysis patients is delivered intravenously, which may be attributable at least in part to the profitability of higher EPO doses. The attempts to eliminate the cross-subsidy from separately billable items will lessen the incentive to avoid subcutaneous administration of EPO (which requires a slightly lower dose but subjects patients to extra injections).

Hospitalization

Even with the substantial expense of outpatient dialysis, expenditures for inpatient hospital care still make up a major part of the health care cost of the ESRD population. Hospital stays for ESRD patients, like those for other patients, are short in the United States by international standards. The average length of stay is generally 7.2 days for ESRD patients and 6.6 days for a kidney transplantation (USRDS, 2003).

However, though stays are short, they are frequent and expensive. Hospital admissions per patient-year have remained relatively stable over the past decade at about two hospitalizations per ESRD patient-year at risk (1.98 in 1993 versus 1.93 in 2003), but hospital days per year have declined by 17% percent (16.6 days in 1993 versus 13.8 days in 2003) due to a drop in average length of stay (USRDS, 2005). Admissions and hospital days are greatest for older and diabetic patients. For ESRD patients with Medicare as the primary insurer, hospitalization costs are about \$19,000 per year, representing nearly \$10,000 per admission and accounting for nearly 40% of total Medicare expenditures (USRDS, 2004). Medicare pays hospitals on a diagnosis-related group (DRG) basis, with a few separate DRGs for ESRD patients. Decisions to hospitalize are under physician control; there is generally no review of the necessity of an admission and typically no shortage of hospital beds to discourage it.

The DRG system does appear to put in place strong incentives to minimize the cost per hospital stay (conditional on the high wages paid to hospital personnel in the United States compared with those in other countries). However, few incentives directly affect the use of hospitalization. Indirect incentives include the effects of hospitalization on the dialysis facility. Because payment for dialysis for an inpatient is made to the hospital, a free-standing outpatient dialysis facility can gain by hospitalizing a patient who is very costly to dialyze in the outpatient setting due to some acute clinical episode. Conversely, hospitalizing a patient creates a “hole” in the outpatient facility’s dialysis schedule that may be impossible to fill in short run, resulting in a greater loss of revenue than the avoided variable costs of dialysis. Similarly, the nephrologist is paid a flat monthly rate for dialysis-related outpatient care. If the patient is hospitalized, the nephrologist’s flat payment is prorated for the fraction of the month spent in the hospital, but the nephrologist can then bill separately for any care provided to the patient during hospitalization.

Transplantation

Kidney transplantation is performed at about 5% of American hospitals, and about 28% of ESRD patients eventually receive a transplant (USRDS, 2004). The organ procurement and distribution system is operated by 58 private organizations (organ procurement organizations, or OPOs) contracted to the federal government. Each OPO is granted a regional “monopoly” in organ procurement and works with one or more transplant center hospital, with arrangements for some

sharing of organs across regions using explicit criteria for wait-listing and organ allocation. Reimbursement for these organizations is primarily on a cost basis. Given the existence of a large transplant waiting list, it is clear that substantially more of the ESRD population might be clinically appropriate for transplantation. Comparing the number of patients wait-listed with the number of dialysis patients can generate a crude estimate of the proportion of dialysis patients who might benefit from transplantation. This is likely to yield a reasonable approximation, because even if some wait-listed patients have had clinical deteriorations that make them poor transplant candidates, it is also likely that some appropriate candidates are discouraged from joining the waiting list due to its length. In 2003, the list was 17.4% as large as the number of dialysis patients. Restricting this comparison to wait-listed patients and dialysis patients under age 65, the waiting list was 27.1% as large as the number of dialysis patients.

There is no shortage of financing for transplantation, hospital units, or (as noted above) transplant surgeons. Regional organ procurement organizations (OPOs, discussed below), hospitals, and individual surgeons each have some discretion over the criteria they use to define organs acceptable for transplantation. Patient copayment (the rough equivalent of one hospital day) does apply to admissions for transplantation, but this deductible is generally covered by secondary insurance. The public Medicare program has found that transplantation generally reduces long-term program costs. The primary constraint is on the availability of organs. Direct payment for organ donation is not permitted in the United States. Donations by family members and other living donors have become more common but still constitute only about one-third of all transplants. Living donation is still somewhat controversial, in part because little long-term follow-up data are available about the risks to donors. Unlike transplant recipients, transplant donors have no registry or public outcomes tracking and reporting measures. Thus, the system relies primarily on deceased-donor organs. Despite increasing discussion of the use of financial incentives to encourage organ donation, this decision remains an altruistic one made by the donor or the decedent's family. There is no presumed consent to donate, nor are an individual's wishes, as expressed on an organ donation card, enforceable after death.

Because organs are in short supply, they must be allocated. This is done largely through nongovernmental organizations (i.e., OPOs) based on policies of the Organ Procurement and Transplantation Network (OPTN) that try to take into account the quality of the clinical match (with relative emphasis on these criteria shifting back and forth over time), preformed antibodies, and waiting time. Substantial regional variations exist in the average time spent waiting for a kidney, and alternative allocation algorithms for sharing organs across regions are being considered.

Among those clinically eligible for transplantation, younger patients and white males are more likely to receive donated organs. Substantial regional variations exist in the length of the waiting list, average time to transplant, and OPO performance in acquiring transplantable organs. Efforts to better evaluate and improve the performance of the organ procurement process are under way. However, more radical changes, such as fundamentally restructuring the basic organ acquisition process (i.e., the relationships between OPOs, transplant hospitals, and transplant surgeons) or providing financial rewards to living donors or to families of deceased donors, are quite controversial and are not being strongly pursued despite the persistent and growing shortage of organs.

Dialysis

Of the patients being treated with dialysis, about 10% receive peritoneal dialysis and the remainder receive hemodialysis. Less than 1% of patients now receive hemodialysis at home. The average cost per dialysis treatment for items covered by the composite rate is estimated to be about \$141 in the 2003 Medicare Cost Reports. This compares with an average reimbursement rate of \$128 from Medicare for free-standing facilities. Thus, facilities lose money on average by providing composite rate services to Medicare beneficiaries. They do earn profits from providing separately billable services (primarily injections of EPO, iron, and vitamin D) to partially or wholly offset any losses on composite rate services.

As already noted, the provision of dialysis is largely at the discretion of the unit providing it, given the reimbursement rate. There are national standards for Kt/V (≥ 1.20), but the average value achieved is higher (1.40), with the minimum acceptable at 1.20 and the maximum at 1.75. The associated range of acceptable time per dialysis session is from 189 min to 270 min (Rajiv Saran, MD, personal communication, October, 2004). The maximum seems to be determined by a combination of patient reluctance to accept longer treatment times, lack of conclusive evidence that increasing Kt/V to the high end of the range improves clinical outcomes, and costs to the facility of extending treatment times. Federal law mandates that the dialysis dose be measured monthly and reported on Medicare claims, but there are no links between reimbursement (or continued certification of a unit) and the dose actually achieved. Instead, such incentives for a more adequate dose come from competition for patients and peer pressure on providers. CMS is conducting a demonstration project on quality incentive payments to explore dialysis pay-for-performance concepts. Bonus payments in this demonstration are based in part on the proportion of patients achieving Kt/V > 1.20 . The KDOQI standard provides the most visible version of the latter. Facilities make their own choices as to staffing, type of dialyzer, frequency of reuse, and sterilant, although research results on the adverse effects of some options have altered behavior. One response to the declining real value of the composite rate has been a decrease in overall staffing and a shift in the staffing mix from higher-paid (e.g., RN) to lower-paid (e.g., technician) classes of staff.

The incentives offered facilities and patients are well known, but their strength and ultimate impact on outcomes are still being researched. Because dialysis is paid on a fixed-price basis, facilities of all types of ownership have an incentive to minimize cost, although the emphasis on cost minimization may vary with type of ownership and level of cost relative to the payment rate. Ownership is controversial; several studies show that for-profit facilities score somewhat lower in quality on several measures, but other studies have not corroborated these findings and this issue remains unsettled. Patients have short-term incentives to shorten and skip dialysis treatments because time used for treatment may be costly to family members and bothersome to patients, and travel to the dialysis unit sometimes must be arranged and paid for by the patient. Overall, 8.5% of patients skip at least one session in a month and another 20% shorten at least one session (Leggat et al., 1998). African Americans, younger patients (20–39 years of age), and smokers were most likely to skip a treatment (Leggat et al., 1998).

One important class of ancillary services that is included in the composite rate bundle is vascular access monitoring. Dialysis facilities or other providers cannot separately bill routine monitoring of vascular access function, including noninvasive studies such as Doppler sonography. Presumably, this discourages use of such studies relative to a system that allows them to be billed separately, but the cost-effectiveness of increased use in routine monitoring is not a settled issue. In cases where there are signs of vascular access problems and where such studies may directly influence the treatment of the access dysfunction, they can be billed separately with appropriate documentation (CMS, 2003).

Trends and outcomes

As with so many other issues in the United States, the question of the effectiveness of the ESRD treatment system is confounded by the diversity, in terms of race, socioeconomic status, and comorbidity status, of the patient population, and by the variety of treatment types even for apparently similar patient populations. As the US population ages and as diabetes becomes more prevalent, the ESRD population is likely to continue its growth. Therefore, the effectiveness of care for conditions that predispose individuals to suffer loss of renal function (e.g., diabetes, hypertension) can substantially affect the number and types of patients entering the dialysis facility. The age-adjusted mortality rate is very strongly related to race (with minority patients having lower death rates on dialysis than white patients) and age, and somewhat related to sex and socioeconomic status (SES)(USRDS, 2004). However, given the universal coverage of this population by Medicare, it is more difficult to attribute these differences to treatment per se. The absence of universal coverage for all drugs may have some impact. But if the provision of care has a substantial causal effect on patient outcomes by race or SES, it would arise primarily from differences in utilization by race or SES given uniform insurance coverage; that is, it is related to incentives and choices unrelated to financing per se.

The ESRD mortality rate in the United States, unadjusted for international differences in age and comorbidities, is high by international standards and is especially high for whites (USRDS, 2004). Asian-Americans have the longest life expectancy of any racial/ethnic group (USRDS, 2004). The lower life expectancy of whites on dialysis is not fully understood, but it may arise partially from whites' higher transplantation rates (USRDS, 2004). Patients eligible for transplantation are healthier than the average ESRD patient (Wolfe et al., 1999). Therefore, the greater transplantation rate among whites implies that the white dialysis population may represent a more "adverse" draw in terms of comorbidities relative to the African American dialysis population, from which fewer low-comorbidity patients are removed for transplantation. However, this cannot be a complete explanation because the overall white death rate among all ESRD patients (dialysis and transplantation) of 193 per 1,000 patient years at risk exceeds the rate of 162 per 1,000 patient-years at risk for African Americans (USRDS, 2002). The race-mortality relationship also varies substantially by age. Younger whites (20–44 years of age) have lower mortality rates (48 per 1,000) than African Americans (70 per 1,000). Rates are comparable for middle-aged (45–64 years of age) patients (137 per 1,000 for whites versus 133 per 1,000 for African Americans). Therefore, the entire aggregate mortality disadvantage for white patients is attributable to the over-65 age group, in which whites face a risk of 365 per 1,000 versus 294 per 1,000 for African Americans (USRDS, 2002).

It is theoretically possible to restructure financial incentives in the United States to target care improvement efforts to those patient subgroups who suffer unusually high mortality rates (for example, by increasing cost sharing or lowering reimbursement for services for advantaged subpopulations and changing in the opposite direction for disadvantaged subpopulations). However, such targeting would conflict with the presumed uniform nature of the Medicare benefit. Directing spending toward more effective methods of treatment would probably be the best strategy if those methods can be identified. Given the success of the efforts described earlier to improve the percentage of patients achieving target doses of dialysis and target levels of hematocrit, it is unlikely that further substantial improvements in outcomes can be achieved by efforts (e.g., via pay for performance) to push these percentages even higher. Rather, it is important to continue to measure these processes to guard against any decline in achievement while focusing on improving quality in areas where the United States continues to lag in the best, evidence-based practices (e.g., encouraging the timely creation of permanent vascular access and using a native fistula as the preferred type of access whenever possible).

African Americans are at particularly high risk of ESRD. While this group represents only about one-eighth of the US population, it accounts for more than one-third of the patients with ESRD. There are many, controversial reasons for the high incidence and prevalence among African Americans. Norris and Agodoa (2002) summarize research in this area in their introduction to a journal issue devoted to the “epidemic” of ESRD among African Americans. Leading explanations include a higher prevalence of key predisposing conditions (most significantly, hypertension and diabetes). Diabetes is about 50% more prevalent among African Americans than among whites and is even more prevalent in Hispanics and Native Americans. However, African Americans are the only major racial/ethnic group in the United States with elevated hypertension rates. It is unclear how much these higher rates of predisposing conditions and of ESRD itself arise because race is an independent risk factor rather than a proxy for differences in other factors such as insurance status, education, income, diet, environmental exposures, or health care attitudes/beliefs. Interventions that might help reduce these racial/ethnic disparities include clinical measures (e.g., tighter glucose control and better hypertension control), health care financing reforms (e.g., improving financial access to care in the pre-ESRD period), and public health measures (e.g., education and screening programs).

Efforts to increase deceased-donor and living-kidney donations are also expected to improve ESRD survival given the long and growing waiting list of qualified recipients. One interesting, new effort to increase transplant rates focuses on developing an “exchange” system to match willing living donors to clinically appropriate recipients. For example, suppose patient A has found a willing donor, but the donor is not a suitable match for patient A. Under this system, the prospective donor would agree to donate to patient B if a different donor in the system provided a better matched organ for patient A.

Conclusion

Financial incentives play an important role in shaping the dialysis care system and practice patterns in the United States. Overall, the United States has achieved broad access to renal

replacement therapy through its policies on eligibility for public funding and its lack of restrictions on who can receive care (e.g., there is no cutoff based on age or comorbidities that formally or informally excludes patients from being referred for renal replacement therapy).

US health care costs are quite high overall compared with those of other ISHCOF countries, but ESRD spending appears reasonably efficient relative to spending in the U.S. health care system generally. This is likely due to incentives inherent in the flat rate payment for composite rate dialysis services and Medicare's strong controls on the price paid for these services over the past two decades. The percentage of patients achieving anemia management targets (hematocrit >33%) has risen substantially from 43% in 1997 to 80% in 2003. Part of this increase is plausibly attributable to generous payment to dialysis facilities for injectable medications. The United States has also achieved high doses of dialysis (Kt/V) by ISHCOF standards, though it is less clear that direct financial incentives explain this because payments do not rise in response to higher-delivered doses. Rather, widely accepted clinical guidelines and indirect financial incentives created by monitoring and public reporting might be relatively more important explanations.

Some economically driven practices, such as dialyzer reuse (encouraged by the prospective payment for the dialysis treatment) and intravenous administration of EPO (encouraged by the fee-for-service payment for EPO dose), are more prevalent in the United States than in many other ISHCOF countries. Home therapies are less prevalent in the United States than in many other nations. In part, these differences are likely to arise due to patient preferences and clinical opinions about outcomes of different modalities, but they also arise in part from financial incentives. US dialysis facilities rely heavily on profits from injectable medications to offset losses in providing dialysis to their Medicare patients. Because home therapies, on average, make less use of injectable medications, this cross-subsidization is harder to achieve. Recently implemented payment changes have sought to make the incentives more neutral by reducing payments for medications and, at the same time, raising payments for the dialysis treatment.

US patients are also less likely than their international counterparts to have native fistulae for vascular access. This may result, in part, from a lack of incentives for surgeons to choose fistulae over synthetic grafts. (Payments are similar, but creating a native fistula is somewhat more involved and there is no device manufacturer promoting its use, as there is for synthetic grafts.) Guideline-based efforts to increase use of native fistulae could potentially be enhanced by financial incentives or global capitation.

One of the primary gaps in coverage is for pre-ESRD care. ESRD patients under age 65 are not entitled to Medicare coverage until three months after the onset of ESRD, and ESRD disproportionately strikes lower-income people who are more likely than average to be uninsured or underinsured. Therefore, many patients do not have their kidney failure identified early enough to slow its progression, plan for modality choice, and have a functioning, permanent vascular access in place upon the initiation of dialysis. Inadequate pre-ESRD care and late referral to specialty care are also barriers to the creation of native fistulae, which take longer than synthetic grafts to mature. However, despite the financial pressures created by the lack of substantial, nominal increases in the composite rate, the US dialysis system has seen improved

outcomes, increased compliance with guidelines such as KDOQI, and the adoption of several technical advances in care.

Nonfinancial incentives such as patient education, education of primary care physicians on the value of early diagnosis and referral to specialty care, and education of surgeons about the importance of creating native fistulae whenever possible can play important roles in improving practice patterns.

After two decades of relative stability in the payment system, several important changes are being implemented or are under consideration. The addition of a prescription drug benefit, though limited, to the Medicare program will reduce a gap in coverage that has become increasingly important given the rapid growth in drug costs. As noted, the reallocation of payments from currently profitable separately billable items to currently unprofitable composite rate services, effective January 1, 2005, has helped make financial incentives more neutral with regard to both the use of separately billed items and the choice of dialysis modality. Further, limited case mix adjustment to the composite rate was implemented on April 1, 2005, to guard against barriers to access for patients who are more costly than average (Hirth et al., 2005; Wheeler et al., 2006). Based on a study of the relationships between patient characteristics and facility input costs, higher payments are being targeted to the youngest and oldest patients, larger patients, and malnourished patients. As noted earlier, a Medicare demonstration project is studying tying payments to clinical performance measures. Finally, the largest change being considered is bundling separately billable items (primarily injectable medications and nonroutine laboratory tests) along with composite rate services into a dialysis prospective payment system. Medicare is currently funding a demonstration project to study the effects of broader bundling. Such a change would significantly alter facilities' incentives to manage anemia and vitamin D deficiencies aggressively and should be accompanied by clinical quality monitoring. Another ongoing CMS-funded demonstration, the quality incentive payment project, allows facilities to earn back a small, withheld payment by complying with national and improvement targets. Thus, efforts continue to improve patient care through refinements in the payment structure.

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