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PATIENTS, POPULATIONS AND POLICY: PATIENT OUTCOMES IN CHRONIC KIDNEY DISEASE

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INTRODUCTION

Before 1960, dialysis therapy for patients with End-stage Renal Disease, the most severe form of chronic kidney disease, was considered an experimental therapy. In the early 1960's several demonstrations tested the efficacy and feasibility of dialysis care. The first facility for long-term dialysis was established in 1962, and the Veterans Administration established a hospital dialysis program on a national level in 1963. In 1965, the United States Public Health Service established a research and demonstration project on dialysis care. This was the same year that Congress passed the Social Security Act that established Medicare (health insurance for the aged) and Medicaid (health insurance for low-income individuals). Two years later as a result of this early experience with dialysis therapy, a national committee on Chronic Kidney Disease declared that dialysis and transplantation were no longer experimental therapies. In 1972, in a striking move, Congress amended the 1965 Social Security Act (Public Law 92-603: section 2991) to provide health insurance for persons with ESRD under two conditions: a person must be eligible for Social Security benefits (or be the spouse or dependent of an eligible person) and a physician must certify that a person requires chronic dialysis of a kidney transplant to maintain life. Looking either forward or backward, this was a unique circumstance in American health care. Congress established eligibility criteria for health insurance on the basis of a pre-existing condition, an act that has not since been repeated for other chronic illnesses (e.g. HIV/AIDS, end-stage liver disease, cardiomyopathy).

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Prior to enactment of the ESRD amendments, the sociodemographic profile of the U.S. hemodialysis population was limited-only 25% were women, 7% African Americans, 27% had not completed high school, 7% were single or separated and 21% were divorced or widowed (1). Six years after passage of the ESRD amendments these statistics changed—51% of persons on hemodialysis were women, 35% African Americans, 46% had less than a high school education, 46% were single or separated and 38% were divorced or widowed. Thus, health insurance for chronic kidney disease had a dramatic effect on access to lifesaving kidney replacement therapy for particular segments of our population.

The Epidemic of Chronic Kidney Disease

The annual number of Medicare-eligible patients with chronic kidney disease has grown from approximately 20,000 persons in 1974 to more than 300,000 persons today (Figure 1) (2). The number of new cases, or incidence rate, of ESRD varies geographically across the U.S. by more than two-fold from below 150 persons affected per million population to more than 300 persons affected per million population (2). In part, this is due to the differences in the age distribution. A greater rise in incidence is occurring among those individuals 65 years of age or older. Diabetes mellitus is now the leading attributed cause of ESRD in the United States accounting for 39% of cases (2), followed by hypertension, 28% of cases and glomerulonephritis, 11% of cases. Among African-Americans, hypertension is more commonly attributed and among Native Americans diabetes mellitus accounts for nearly

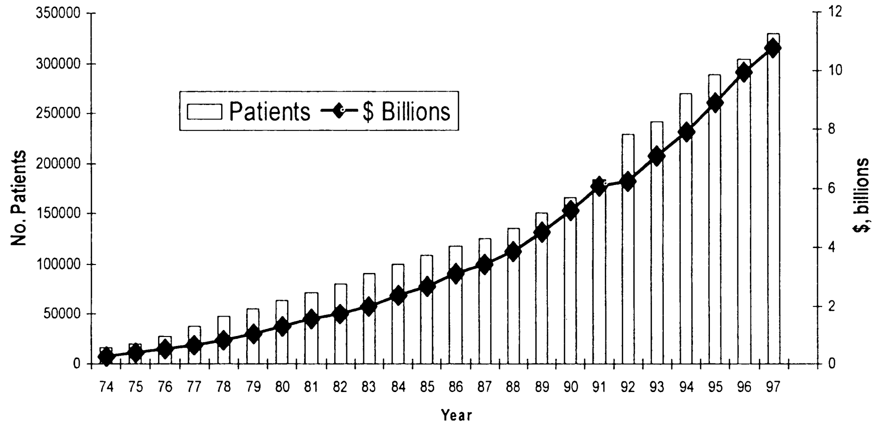

FIG. 1. Medicare endstage renal disease patients and payments ($ billions) from 1974 through 1997. Data are from the Health Care Financing Administration and the United States Renal Data System.

two thirds of cases. Other causes, interstitial disease or pyelonephritis, cystic/hereditary disease, secondary glomerulonephridities and neoplasms, each account for less than three–five percent of cases. The incidence of ESRD is far greater in African Americans than in whites (900 cases per million population versus less than 200 cases per million population, respectively) and does not appear to be fully explained by differences in sociodemographic, lifestyle or clinical factors (3,4,5,6).

Lives are short for persons with ESRD, with five-year survival rates below 50% for persons on dialysis. Persons who are fortunate enough to get one of the approximately 12,000 kidney transplants available each year, which offers the potential of a more normal life free from the daily or weekly routine of dialysis, have an 80 percent five-year survival.

Cost of ESRD Care

With the growth in persons with chronic kidney disease in the U.S., the total annual cost of the Medicare ESRD program has gone from approximately $250,000 to more than $11 billion (Figure 1). The annual cost of care for an individual with ESRD is over $50,000 per year, or 8–10 times that of other persons with Medicare insurance. While persons with chronic kidney disease have high individual costs, the large increase in aggregate costs is due in large part to the increasing numbers of patients, rather than an increase in per patient costs. In fact, Medicare payment policy for ESRD services provided by both physicians and dialysis facilities has used a per-case reimbursement scheme or capitated amount, similar to that used by managed care for their predominately healthy individuals. From a Medicare cost- containment perspective this has been a success, because unlike other medical payments, per case payments for ESRD care have been nearly frozen in nominal or real terms. Accounting for inflation in the medical care sector, payment rates have profoundly declined (Figure 2).

Providers of ESRD Care

Despite payment levels, over the 1980's, with the growth in the number of patients, the number of dialysis facilities providing care doubled from approximately 1000 to more than 2000 facilities by 1990 (Figure 3). In 1980, the majority of facilities were hospital-based and non profit (Figures 3 and 4). By 1990 the majority of facilities were freestanding units with for-profit ownership. This shift is very striking if one considers that by 1997, two-thirds of prevalent patients in the U.S. were being treated at for-profit, freestanding centers.

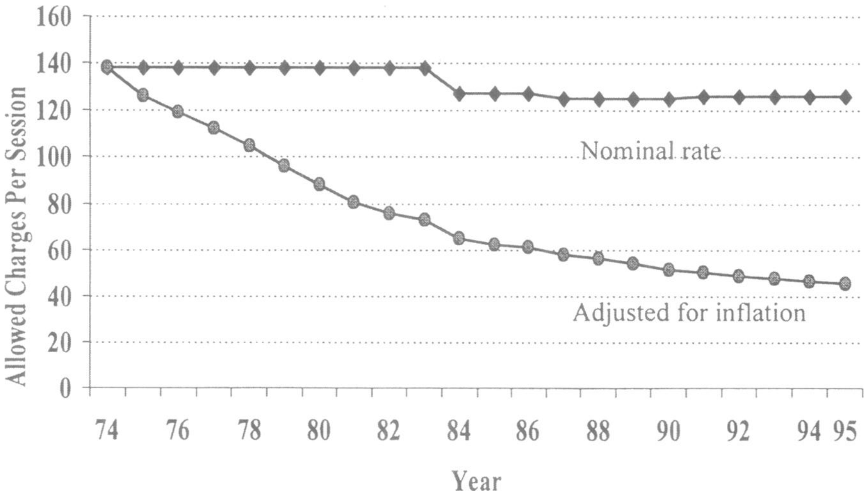

FIG. 2. Dialysis reimbursement rate (allowed charges per dialysis session) from 1974 through 1995 in nominal terms and adjusted for inflation. Data are from the Health Care Financing Administration.

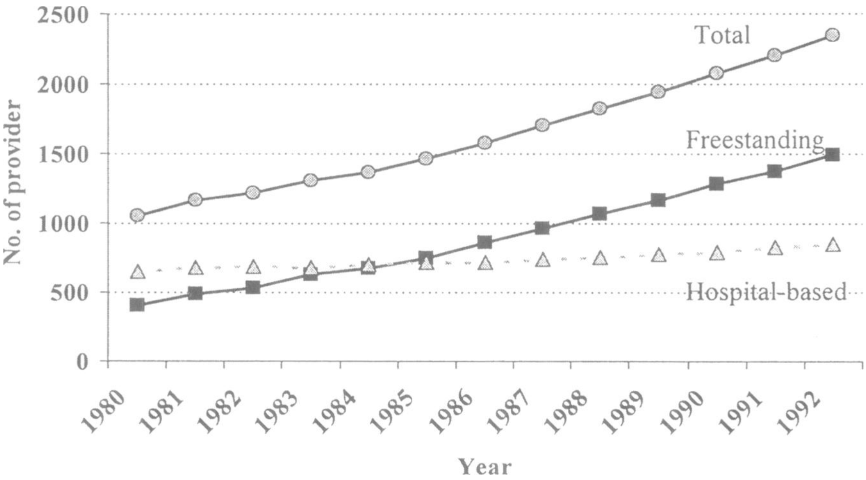

FIG. 3. Providers of treatment for end-stage renal disease from 1980 through 1992 by profit status. Data are from the Health Care Financing Administration and the United States Renal Data System.

Cost versus Quality of Care

The number of dialysis providers, and disproportionately the number of for-profit providers, has continued to grow despite the stagnant reimbursement levels. One study examining the relative efficiency of

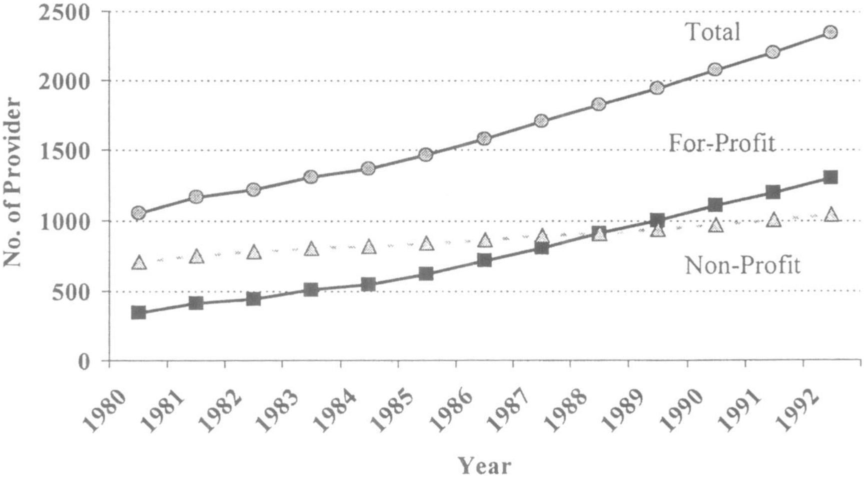

FIG. 4. Providers of treatment for end-stage renal disease from 1980 through 1992 by affiliation. Data are from the Health Care Financing Administration and the United States Renal Data System.

different types of dialysis providers (7) found that with an equivalent level of labor and capital inputs for profit providers were able to produce 100–150 more treatments per month than not for profit facilities, approximately 13–19 percent more monthly treatments. However, some have speculated that the advantages of efficiency may have down sides in patient care. Efforts to maintain income by cutting costs and increasing volume could eventually compromise the quality of care. While the pressures of a declining inflation-adjusted value of payments exist for all types of dialysis providers, it is possible that for-profits may be more sensitive than not for profits providers to such economic pressures. A careful look at the potential tradeoffs in efficiency versus quality of care is warranted.

TABLE 1

The dimensions for assessing quality of care and examples of their application to medical care for chronic kidney disease

Structure	Process	Outcomes
Facility size	Dialysis modality	Mortality
Facility location	Dose of dialysis	Morbidity
Facility staffing	Medications	Symptoms
Facility profit status	Dialysis membrane reuse	Quality of life
		Satisfaction with care

Assessing Quality of Care for Chronic Kidney Disease

The well-known dimensions along which quality of health care can be evaluated include structure, process and outcomes [Table 1] (8). Structure refers to aspects such as staffing, equipment and location. Process includes the practices of medicine including type of treatments (e.g. peritoneal and hemodialysis), the amount of treatment (dialysis dose), medications use (e.g. recombinant human erythropoietin and immunosuppressives) and dialyzer reuse. Outcomes include traditional measures sure as mortality and morbidity, but also patient views of their quality of life and satisfaction with care. I will describe some of the evidence in chronic kidney disease care along these dimensions.

Structure and Process of Care

One study indicates that the structure of staffing varies by profit status. Farley found that for-profit facilities are more likely to employ lower levels of staffing, such as the use of technicians versus registered nurses (9). Studies have also suggested that process of care varies by profit status of facilities. Furth showed that children with chronic kidney disease are almost three times more likely to receive peritoneal dialysis if they are dialyzed in a not-for-profit versus for-profit facility (10) . Another study indicates that for-profit facilities are more likely to reuse dialysis membranes than not-for-profit facilities, although the gap has been narrowing over time, raising the question of whether not-for-profit facilities are slower adopters of cost-efficient practices (11).

Another national study examined how medication prescribing practices may differ between for-profit and non-profit facilities (12,13,14). In June of 1989 the U.S. Food and Drug Administration approved recombinant human crythropoietin (rHuEPO) for routine use in treatment of the anemia of ESRD. rHuEPO increases hematocrit, decreases red blood cell transfusions and improves quality of life for ESRD patients. Recognizing the substantial benefits of rHuEPO, Medicare provided coverage for this outpatient prescription drug in June 1989. The cost was large, \$4000–6000 per patient per year cost (15,16). Building on its economic success with per-case (capitated) payment for dialysis care, the Health Care Financing Administration (HCFA) which administers the Medicare program, decided to reimburse dialysis providers for rhuEPO with a fixed payment for case (\$40 per < 10,000 units administered). Per-case payment mechanisms contain a financial incentive to providers for under-use of services, while variable, fee-for-service payment mechanisms potentially encourage overuse of services.

The early experience indicated that doses far lower than were administered in early clinical trials were used in routine practice. Recognizing these low doses, HCFA revised its payment policy in January 1991 to variable payment per dose ($11 per 1000 units). Of note is that for-profit facilities administered the lowest doses under the early fixed payment per case. While all types of facilities, (both for-profit and not-for-profit) increased doses after the change in payment policy, the largest increases in doses occurred among the for-profit facilities (14). This suggested that for-profit facilities are more sensitive than not-for-profit facilities to the financial incentives inherent in payment policy.

Outcomes of Care

A recent study has examined patient outcomes of for-profit and not-for-profit care (17). This national longitudinal study of adult patients with onset of ESRD in the early 1990's examined the relation between both facility ownership and competition in local dialysis markets on mortality and placement on the renal transplant waiting list over six years of follow-up. Because transplantation offers patients increases in quantity and quality of life, placement on the renal transplant waiting list serves as surrogate outcome measure. The study accounted for potential selection bias in where patients were treated by adjusting for a wide range of sociodemographic factors, comorbid disease factors and system factors such as facility occupancy, volume of patients treated, distance from facility and geography. Mortality was 20-percent greater for patients treated in for-profit dialysis facilities, and rates of placement on the kidney transplant waiting list were 25% lower for patients treated in for-profit facilities. The negative outcomes were accentuated in a dose-dependent fashion when competition from nearby not-for-profit facilities was absent in a local health care market. Whether health care competition on quality of care versus cost of care will be the predominant theme in future health care policy is a paramount issue for American health care.

Summary and Conclusions

Chronic kidney disease represents an interesting illustration for evaluating an epidemic of chronic illness, the impact of care processes and technology on health outcomes, the impact of financial incentives and cost containment on health outcomes, and the choices society must consider in responding to a chronic illness.

The evidence suggests that strong economic pressures exist in the care of chronic kidney disease and that cost containment is important. The results in large part reflect the impact of economic pressures on clinical decision making in the absence of good evidence on outcomes.

To improve clinical decision making we need valid evidence linking specific processes of care to patient outcomes. Specific processes amenable to study include the provision of preventive services, physician and nurse technical and interpersonal care and adherence to clinical practice guidelines. The ESRD Quality Study (EQUAL) currently underway and supported by the National Institutes of Diabetes and Digestive and Kidney Diseases, may help to guide physicians and centers in caring for their patients with chronic kidney disease. This investigation examines the relation between process of care and outcomes and expands outcomes measure to include disease-specific quality-of-life measures and patient satisfaction and accounts for case mix using the Index of Co-Existent Disease, a measure of the extent of different comorbid diseases as well as their severity (18,19,20). Better data on how processes of care are linked to health outcomes can inform decision making and allow educated cost cutting and quality maintenance.

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DISCUSSION

Cohen, Washington: Let me thank you again for a marvelous set of studies. I think your work is shining a very important light on an issue, as you pointed out, that's not just restricted to end stage renal disease, but has important implications for a broad range, perhaps ubiquitous issues with respect to management of chronic disease as we are entering an era that's more dominated by the management of chronic disease. And also, it seems to me that your work fits into a broader context of conflict of interest considerations that are being raised across a wide spectrum of activities within the health care system, both in clinical care in as well as in research. I wondered if you have seen any difference in behavior on the part of the providers of dialysis treatments now that the insights from these data are evident. What you suggested was that for-profit dialysis units that are in close proximity to not-for-profit facilities seem to emulate some of the behavior of the not-for-profit providers as opposed to those that are in more isolated locations. Has there been any reaction to that observation?

Powe, Baltimore: Well there has been. Some of you may know that the Medical Payment Advisory Commission has recommended that HCFA actually increase slightly its reimbursement for dialysis facilities to take some of the pressure and the heat off in this case. There is a lot of competition in the dialysis industry. My feeling is that we need to learn better and do more work looking at what improves patients' outcomes through studies linking processes to outcomes. I haven't seen a lot of movement. It's been more rhetoric than movement to the data that I have shown you. One of the things that I think is really interesting is that we haven't had the ability to look at is whether a for-profit facility in association with the not-for-profit like an academic medical center emulates the academic medical center rather than the for-profit corporation. That's something I think would be worthy of looking at in the future.

Falk, Chapel Hill: Lovely talk. At the University of North Carolina, we have relationships with for-profit and not-for-profit dialysis facilities. In these facilities, we have the same group of medical directors. The staff-to-patient ratios differ between these units, but are not better in the not-for-profit units. For-profit groups want as many patients in their dialysis facility as possible, and higher death rates in those units would certainly countervail that goal. With the advent of the DOQI Guidelines by the National Kidney Foundation, have you compared units with respect to guideline adherence in profit versus non-profit units? Is there any separation of non-profit units managed by for-profit companies?

Powe: That's an important question. There have been a number of initiatives in the renal community like the Dialysis Outcomes Quality Initiative Guidelines, work being done by the ESRD forum and networks and the Health Care Financing Administration's core indicator project to look at outcomes. At the American Society of Nephrology last weekend, Al Collins who heads the US Renal Data System mentioned he has actually replicated these findings, as well as the old USRDS researchers at the University of Michigan. So I think the data are real. The replications suggest though (although they use limited data) that the differences have narrowed over time, which may be due to efforts to raise overall quality of care within the community through the DOQI Guidelines or other efforts as well. But I think this bears continual watching and more work in the future.

Thibault, Boston: Neil that's wonderful work. There's one other aspect of this whole area that you didn't comment on. We still have a major problem with the large number of medically uninsured in this country. This experiment was launched 30 years ago to extend coverage in a disease specific way. Would you make any comment on that from a policy standpoint? Do you think this has been a success or a failure, or do you think we should be thinking about this as a way of addressing the problem of the uninsured?

Powe: We certainly haven't done this for any other disease. We haven't done it for HIV and AIDS, we haven't done it for end-stage cardiomyopathy for younger individuals. It is unique in our history and people wonder why we did it especially when you look back at the dollars that have been spent. There's been a lot of lives that have been extended as a result of that, but you might say unfairly compared to other diseases. That was a political process. We are now going through another political process and there is not always reason in political processes. And so I think we will have to watch in the future. But it is an interesting issue of why for this one disease Congress capitulated and actually provided health insurance coverage on the basis of pre-existing conditions. It's very interesting.

Winchester, New York: If indeed you are right that there is a lesser survival in the for-profit dialysis units, one assumes that these patients have been rendered poorer substrates. What happens to those patients who do get put forward for transplantation from the for-profits vs. the non-profit dialysis unit?

Powe: I don't think anyone knows that. I should have mentioned in regard to the other question, why would a facility want to kill its patients to derive revenue from it. But it also derives revenue from keeping its patients and not referring them to transplantation. So there is logic in the data that you've seen. But I haven't seen any work demonstrating that for-profits, or not-for-profit better prepare individuals for transplantation and improve outcomes.

Winchester: Do you have enough numbers to do an analysis?

Powe: You could certainly do that. Yes, through some of the current data that is available to look at.

Glassock, Laguna Niguel: Again Neil I enjoyed your presentation here and at other meetings. I wanted to try to address Jordy Cohen's question a little bit. I also want to announce that I have a bit of conflict of interest. I am on a Medical Advisory Board of a Disease Management Co., and I think basically the development of disease management strategy for end-stage renal disease is going to be one of the outcomes of this macroepidemiologic examination of differences and variations of outcomes. There is a rapidly growing industry of disease management as applied to end-stage renal disease and they are trying to address some of these process and outcome issues that you identified in your epidemiologic studies. This includes an intensive look at the factors that are associated with good and poor outcomes and applying practice guidelines and other kinds of detailed information to see if poor outcomes can be remedied. This approach is equally applicable in the private as well as the public sector. But it is information which you have presented here and at other meetings, that has galvanized the community to really examine itself in a more thorough manner. So thanks again for your work.

Powe: Thank you. I think we need to figure out what works best for our patients by generating the best scientific evidence.