Chronic renal failure

Lessons from the past and for the future[1]

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The author briefly describes the Medicare End-Stage Renal Disease Program, which has covered dialysis and kidney transplants for 12 years at a cost of $2 billion for 70,000 patients as of 1983. This program is used to illustrate the problems of patient selection for expensive treatment; the usefulness of self care in the home setting; the effects of funding on (*a*) the choice of treatment and the number of patients treated, (*b*) reimbursement and modalities of treatment, and (*c*) health care providers as well as the health care equipment supply industry; and the problems of collecting data on a national basis. Many of these lessons are important in view of the trend toward increasing use of home care in other fields of medicine.

Index term: Hemodialysis, home

Cleve Clin Q 52:285–290, Fall 1985

In March 1960, when Quinton et al described the development of the first successful cannula for long-term dialysis,[1] they had no idea that 24 years later more than 200,000 patients would be undergoing dialysis worldwide. They were also unaware that this development would result in a program costing the federal government more than $2 billion a year to treat 70,000 patients, or that this would not only create an extremely competitive marketplace for equipment and supplies but also a major factor in the development of what Relman has called the medical-industrial complex.[2] Nor were they aware that while the Medicare End-Stage Renal Disease (ESRD) Program would be seen as a prototype for national health insurance in view of the number of lives saved, the high cost involved might

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[1] Northwest Kidney Center, Seattle, Wash. Submitted for publication Nov 1984; accepted Feb 1985.

0009-8787/85/03/0285/06/$2.50/0

contribute to delay in considering any national health program in the United States. This paper is not a detailed review of the Medicare program, which has been described so well by Rettig,[3] but rather, deals with the role of home care in the treatment of ESRD and the lessons to be learned for other health care programs.

Patient selection

When Quinton et al started 3 patients on long-term dialysis, it soon became clear that this form of repetitive treatment was extremely expensive. They believed that the only way to pay for care was to make such treatment a community responsibility and realized that the costs could be diminished by having the dialysis done outside of the hospital. Consequently, they and Dr. James W. Haviland, then president of the King County Medical Society (KCMS), worked with that society as well as the Seattle Area Hospital Council to develop the first free-standing outpatient dialysis unit.[4] This facility, which became the Northwest Kidney Center (NKC), opened in January 1962 with support from the John A. Hartford Foundation, the U.S. Public Health Service, and public donations. However, the first problem was already apparent. Even with the restrictive selection criteria used at that time (age 20 to 40, primary renal failure without significant complications), there were too many candidates for the number of treatment openings available, making further selection essential. The KCMS came up with the concept of a committee representative of the community which would make the final selection. Patients who were medically acceptable were referred to this anonymous committee, which then selected individuals on the basis of many factors, including social worth. This "life and death" committee was written up in *Life*,[5] described in an NBC documentary, and copied in some other parts of the country. Elsewhere other physicians believed strongly that this approach was inappropriate, that the decision should be made by a physician, and that perhaps patients should be treated on a first-come, first-served basis. The Seattle committee remained in existence until 1971, when funding in the state of Washington was sufficient and all referred patients could be treated. Thus the first lesson to be learned from the dialysis subpopulation was the difficulty of selecting patients for expensive treatment when resources are limited. This is a problem which is again exercising minds in the United States and elsewhere, with regard to not only such costly forms of therapy as liver or heart transplants, but also how to generally control the cost of health care.[6]

Development of home hemodialysis

In 1963, in conjunction with A. L. Babb and the staff of the Nuclear Engineering Department, the University of Washington researchers developed a monitored and automated machine which would provide dialysate to three stations at the University Hospital. Concerned by the small number of patients who could be treated, they realized that costs might be reduced further by moving the machine from the outpatient setting to the home. Although they did not realize it, this had already been done in Japan two years earlier using a coil dialyzer and a washing machine.[7] At about the same time, Merrill et al in Boston[8] and Baillod et al in London[9] also began to experiment with home dialysis using the "twin coil" kidney which lacked a monitoring device. At the University of Washington, however, Curtis et al turned to the fluid supply system already developed, and they and the engineers produced a miniaturized version designed specifically for home dialysis.[10] This was the prototype of the single-patient dialysis machines now used around the world, both in the home and in outpatient centers.

The first Seattle patient, a 15-year-old girl who had been turned down for outpatient dialysis, was trained for home care in the summer of 1964. This proved so successful that for the next several years the University of Washington and the NKC trained patients from around the world to do home dialysis. In 1967, because of a shortage of funds for treatment in Seattle, it was decided to send all patients home on dialysis. Consequently, all new patients were trained for home care, and patients already on outpatient dialysis at the NKC were compelled to undergo training to treat themselves at home. This draconian measure was necessary to enable treatment of the maximum number of patients with the funds available. Yet, not only did the patients do extremely well, but patients of average or less than average intelligence performed dialysis at home equally as well as could more intelligent persons. Furthermore, once patients became confident and knowledgeable about their treatment, so that they could control their own therapy and scheduling, they were able to work and lead a much more active social life. It was also learned early on that it was important to make the patients primarily responsible for their own care rather than a spouse or other family member. This experience led to formulation of the philosophy that with any chronic disease, the more patients know about their disease and the more responsibility they take for their own care, the greater the opportunity for adjustment, improved quality of life, and rehabilitation. The teams at the University of Washington and the NKC worked to develop an effective home dialysis training program and support services. In 1972, with the assistance of an educational psychologist, the NKC developed a home dialysis training program using videotape and other audiovisual aids.[11] Thus another important lesson learned from the ESRD experience is that many patients are able to undertake a relatively complex technological procedure at home when provided with appropriate training and backed by an effective support and supply system.

What of the safety of home dialysis? In fact, survival with home dialysis is no different from that with in-center dialysis when adjustments are made for the patient population. With regard to quality of life, a recent study by Evans et al has shown that home hemodialysis patients are better adjusted in many respects than those treated by other modes and in this regard are closest to patients who have successfully undergone transplantation.[12]

Funding for treatment of ESRD

In 1973, Congress took the unprecedented step of covering treatment for patients with ESRD under the Medicare program, making it the first disease category to be funded in this fashion. This was widely regarded as a prototype of a national health program: in fact, however, there have been a number of problems, some of which may be applicable to present and future home health care programs. The major lesson learned from the ESRD experience is that the direction of a health care treatment system is determined to a large degree by available funding and by any associated restrictions. Initial reimbursement for outpatient dialysis was generous, whereas payment for home dialysis—while it covered equipment and supplies—was inadequate to cover the cost of necessary support services. As a result of the generous reimbursement for outpatient dialysis, the number of dialysis centers in the United States proliferated rapidly, two or three proprietary dialysis companies amassed large profits, nephrologists became extremely well paid for supervising outpatient dialysis, and the percentage of patients treated at home plummeted. That the level of outpatient dialysis reimbursement was set too high is borne out by the fact that the payment per dialysis in actual dollars in 1984 was generally slightly less than in 1973, despite increasing staff salaries and the effect of inflation. Thus the increase in ESRD cost to the present level of more than $2 billion a year reflects the unanticipated increase in the numbers of patients rather than higher treatment costs per se. This increase in the patient population was a direct result of the availability of funding and the consequent abrogation of the selection process.

In 1978, concerned about the cost of the program and the drop in home dialysis, Congress passed amendments to provide incentives, including early entitlement for patients entering home training, purchase of home dialysis equipment, and a fixed reimbursement per treatment set at 70% (later 75%) of the rate for outpatient care. Despite these changes, home dialysis did not increase significantly at first—although the financial situation of centers which still encouraged its use improved considerably—primarily because it was still simpler to profit by providing outpatient services than to establish and support a new home dialysis program. In addition, as a result of the rapid increase in the number of nephrologists trained in the several years following the availability of Medicare funding, many physicians graduated from programs which provided little or no experience with home care and subsidized their academic activies by outpatient dialysis.

The use of home dialysis began to increase in 1980–1981 with the use of continuous ambulatory peritoneal dialysis (CAPD), which now accounts for more than half of the patients being dialyzed at home in the United States. In 1982, as expenses continued to escalate, Congress passed legislation to lower the cost of hospital-based outpatient dialysis and encourage home dialysis by paying the same amount for both forms of treatment, both to the facility and to the physician. This measure was met with considerable opposition since at the same time the rate per treatment was reduced below that generally paid for outpatient care in the past, at least in many areas of the country. These new rates have been implemented for two years and do not appear to have had any marked impact on home dialysis. However, it is clear that prior to this legislation, home dialysis was not highly favored except in areas such as the Northwest and Indiana where there was already a strong commitment to this form of therapy.

Another lesson to be learned from the ESRD program is the impact of federal funding on health care providers. As noted, the initially generous reimbursement for outpatient treatment resulted in the proliferation of dialysis centers, particularly free-standing proprietary units. Arguments over the benefits (or lack of them) of proprietary dialysis remain unresolved.[13,14] While many of these units provide good care, the concern is that in the final analysis these facilities are responsible to their stockholders rather than to their patients. Conflict is likely to ensue as continuing reductions in federal support exert pressure on such facilities.

It is evident from the ESRD program that quality of care is difficult to evaluate. Despite the limited number of treatment options for ESRD, as yet there appears to be no adequate quality assessment program in widespread use, even with efforts to monitor quality by establishing Network Coordinating Councils which are representative of regional providers and patients and have a medical review board. In fact, network councils have proved to be self-perpetuating bureaucracies in much the same mold as previous federal agencies such as the Regional Medical Program.

Another effect of the availability of funding for dialysis was that as the market rapidly grew, industry also expanded to provide supplies and equipment. During the later 1970s in particular, manufacturers' exhibits at meetings such as that of the American Society of Nephrology were lavish, even though there was little in the way of new development. Marketing of expensive technology by commercial interests without adequate assessment has continued, especially since the abolishment of the National Center for Health Care Technology (at least in part because it was a threat to these vested interests).[15] With budgetary tightening, a life-and-death struggle is now being played out among the various manufacturers to see which few will remain in the dialysis business. However, manufacturers are also responding to the pressure to increase the use of home dialysis. This response has taken two forms. First, CAPD was developed in the late 1970s as the result of the work of Popovich et al.[16] This has become the most rapidly growing form of treatment in recent years, due at least in part to aggressive marketing by its proponents and the companies providing CAPD supplies. While CAPD is a form of home dialysis, most patients cannot continue on it for more than two or three years because of recurrent episodes of peritonitis. Despite concern on the part of the National Institutes of Health and the Health Care Financing Administration (HCFA), CAPD was marketed so aggressively both to the public and to the medical profession that in 1979 the government had no choice but to accept it as included under Medicare. The HCFA was so impressed by the information it received on the potential savings with CAPD, as well as its benefits, that the 1982 regulations were written to imply that CAPD was the preferred form of treatment. In fact, savings are less than with home dialysis, unless competition should lower the cost of fluid and other supplies in the future. At this time, the long-term role of CAPD is still not fully established. Thus another lesson from the ESRD program is that aggressive marketing by suppliers can have an impact on the type of treatment used as well as on government reimbursement. However, problems may develop later. For example, in Ontario, Canada, and Australia, where large numbers of patients have been treated by CAPD in order to make the best use of restricted government funding, several of them are now returning to outpatient hemodialysis, putting severe pressure on existing facilities. Nor is aggressive marketing limited to dialysis supplies. Introduction of the immunosuppressive agent cyclosporine has been accompanied by massive publicity, both professional and among the general public. As a result, this drug has been approved by the FDA even though transplant surgeons are still learning which is the best regimen to use. Cyclosporine will almost certainly benefit from recent "orphan drug" legislation, and indeed because of pending legislation, may become the first outpatient drug to be paid for with federal funding. The second way in which manufacturers have responded to pressure to increase home dialysis is by offering package deals providing machines and supplies to patients. Generally, they cost more than one would pay directly for the same materials, as the package price has been set as high as possible consistent with the availability of reimbursement and competition. In addition, some manufacturers are exploiting a loophole which permits patients to buy directly from the supplier rather than through a dialysis facility, thereby allowing the manufacturer to set the cost of supplies independently of the fixed rate of reimbursement applicable to facilities.

Another lesson from the ESRD program is that once a benefit becomes available, it is impossible to forecast how many patients will ultimately require it. The change in the patient population with the availability of funding for ESRD is well known.[17] Once a given form of treatment is accepted and supported by federal funding, it becomes impossible to put rigid restrictions on patient access to care. For this reason, Aaron and Schwarz have expressed the concern that some form of rationing may eventually develop in the United States in order to contain health care costs, and they have discussed some of the problems inherent to this approach in their recent book.[6]

Finally, it is apparent from the ESRD experience that the federal government cannot run a data collection system efficiently. The fiasco of the ESRD Medical Information System has been documented elsewhere[18, 19] and remains a matter of shame in comparison with data collection and analysis by the European Dialysis and Transplant Association. One can only presume that the government merely gives lip service to the need for medical data, having neither any real interest in establishing an effective data system nor the capability to do so.

Home health care in the future

To a nephrologist with a strong belief in the value of home treatment based on self care, it has been interesting to watch the developments of the past few years. Proponents of home care for hemophilia and chronic obstructive pulmonary disease, home parenteral nutrition, and other modalities have rediscovered all of the advantages first noted for home hemodialysis, including not only reduced cost but also the benefit of allowing the patient to be directly involved in his or her own care at home. More recently, cancer chemotherapy and terminal care have generally been moving into the home or hospice setting, and there has been an increased interest in supporting the elderly in their own environment rather than having them committed to nursing homes. It is interesting to observe how legislation for federal funding of any of these activities immediately attracts great interest from providers and suppliers. For example, with current efforts to limit hospital reimbursement by means of diagnostic-related groups (DRGs) and other measures, hospitals are searching for means to offset these financial restrictions. Home health care appears to be an ideal solution. At the same time, the medical equipment and supply industry is making great efforts to work with providers to develop such programs. In the field of parenteral nutrition, to give one example, manufacturers are developing fluids containing specific medications for home use; moreover, as with dialysis, they will ship packets of all necessary supplies directly to the patient's home while ensuring that both supplier and referring institution receive some financial return. As long as institutions and industry can be encouraged to work in the best interests of the patient rather than primarily on the basis of maximizing profits, and the government can exercise wisdom in the development and regulation of funding programs, the "crisis" in health care costs may turn out to be less severe than many have feared.

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References

1. Quinton W, Dillard D, Scribner BH. Cannulation of blood vessels for prolonged hemodialysis. Trans Am Soc Artif Intern Organs 1960; **6**:104–113.
2. Relman AS. The new medical-industrial complex. N Engl J Med 1980; **303**:963–970.
3. Rettig RA. Implementing the End-Stage Renal Disease Program of Medicare. R-2505-HCFA/HEW. Santa Monica, Calif., Rand Corp., 1980.
4. Haviland JW. Experiences in establishing a community artificial kidney center. Trans Am Clin Climatol Assoc 1965; **77**:125–136.
5. Alexander S. They decide who lives, who dies. Life 1962; **53**:102–125.
6. Aaron HJ, Schwartz WB. Painful prescription: rationing hospital care. Washington, D. C., Brookings Institution, 1984.
7. Nosé Y. [Discussion of] Tenckhoff H, Shilipetar G, Boen ST. One year's experience with home peritoneal dialysis. Trans Am Soc Artif Intern Organs 1965; **11**:11–14.
8. Merrill JP, Schupak E, Cameron E, Hampers CL. Hemodialysis in the home. JAMA 1964; **190**:468–470.

9. Baillod RA, Comty C, Ilahi M, Konotey-Ahulu FID, Sevitt L, Shaldon S. Overnight haemodialysis in the home. Proc Eur Dial Transplant Assoc 1965; **2**:99–103.
10. Curtis FK, Cole JJ, Tyler LL, Scribner BH, et al. Hemodialysis in the home. Trans Am Soc Artif Intern Organs 1965; **11**:7–10.
11. Stinson GW, Clark MF, Sawyer TK, Blagg CR. Home hemodialysis training in 3 weeks. Trans Am Soc Artif Intern Organs 1972; **18**:66–69.
12. Evans RW, Manninen DL, Garrison LP Jr, et al. The quality of life of patients with end-stage renal disease. N Engl J Med 1985; **312**:553–559.
13. Lowrie EG, Hampers CL. Medicare's end-stage renal disease program: historical and policy considerations. [In] Narins RG, ed. Controversies in Nephrology and Hypertension. New York, Churchill Livingstone, 1984, pp 5–25.
14. Blagg CR. Cost-effective treatment of chronic renal disease. [In] Narins RG, ed. Controversies in Nephrology and Hypertension. New York, Churchill Livingstone, 1984, pp 27–43.
15. Jennett B. High technology medicine benefits and burdens. Rock-Carling Fellowship, 1983. London, Nuffield Provincial Hospitals Trust, 1984.
16. Popovich RP, Moncrief JW, Nolph KD, Ghods AJ, Twardowski ZJ, Pyle WK. Continuous ambulatory peritoneal dialysis. Ann Intern Med 1978; **88**:449–456.
17. Evans RW, Blagg CR, Bryan FA Jr. Implications for health care policy: a social and demographic profile of hemodialysis patients in the United States. JAMA 1981; **245**:487–491.
18. Blagg CR, Scribner BH. Long–term dialysis: current problems and future prospects. Am J Med 1980; **68**:633–635.
19. Blagg CR. After ten years of the Medicare End-Stage Renal Disease Program (editorial). Am J Kidney Dis 1983; **3**:1–2.