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Chapter 1

# **Introduction, Summary of Findings, and Suggested Future Directions**

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## INTRODUCTION

Thirty years ago end-stage renal disease (ESRD) was uniformly fatal. Today a variety of chronic renal dialysis techniques and renal transplantation offer the opportunity for markedly improved prognoses for afflicted individuals. Associated with the use of these technologies, however, have been formidable costs. Medicare's ESRD program was established in 1972 in recognition of the devastating financial consequences of ESRD treatment for the patient and his or her family (37). This program, which transferred the major financial burden from the individual to the taxpayer, has grown rapidly. In 1983, its estimated enrollment reached 73,000, including 68,000 persons on chronic dialysis and more than 5,000 who received renal transplants. Growth rates in enrollment are projected to be about 5 percent per year between 1980 and 1990.<sup>1</sup>

The historic standard chronic renal dialysis, the most common treatment for ESRD, is hemodialysis (HD) performed in the hospital or in independent dialysis centers (center HD). Home hemodialysis (home HD) has achieved only limited acceptance, in part because of the extensive home support that is required and in part because fiscal incentives have favored facility dialysis.

The advent of continuous ambulatory peritoneal dialysis (CAPD) in the late 1970s has dramatically changed treatment options available to the patient with ESRD. Since it was approved for reimbursement by Medicare in 1979, the use of CAPD has increased rapidly, and, by 1983, an estimated 8,000 patients, two-thirds of patients on home dialysis, or 12 percent of the entire chronic dialysis population were being treated by this modality. Diffusion has resulted from a combination of strong professional endorsement, pa-

tient acceptance, and vigorous marketing efforts by industrial producers of CAPD supplies and equipment. Some projections suggest that up to 40 percent of the ESRD population maybe suitable candidates for CAPD.

Congress' concern over the rising costs of the ESRD program led the Health Care Financing Administration (HCFA) in 1982 to propose prospectively set reimbursement rates designed to control these costs while providing incentives to increase the use of CAPD and other home dialysis techniques. This case study was initiated in response to controversy that surrounded the introduction of these new reimbursements rates to obtain an objective evaluation of the relative costs and medical effectiveness of the most commonly used techniques for renal chronic dialysis.

The request for this case study came from the Senate Committee on Finance to the Director of the Office of Technology Assessment in a letter that expressed concern over the rapid expansion in the use of CAPD despite the lack of conclusive evidence of its effectiveness in relation to HD.<sup>2</sup> The attention of the Senate Finance Committee, in turn, was attracted by public debate over regulations proposed by HCFA to establish prospective reimbursement for dialysis services "to encourage home dialysis and provide incentives for economy and efficiency in furnishing these services" (16). HCFA's rationale (15) was:

Since home dialysis is a less expensive alternative to dialysis conducted in facilities, its growth will help control the escalating cost of the ESRD Program.

CAPD is the preferred treatment for many patients because it causes relatively little disruption in the patient's life.

<sup>1</sup>These projections could be lower if preventive medical efforts, such as widespread hypertension treatment, reduce the incidence of ESRD or could be higher if more lenient patient selection criteria are adopted in the face of expanded treatment options.

<sup>2</sup>Letter from Senate Finance Committee to John H. Gibbons, Director, OTA, Apr. 26, 1982.

Because of the potential benefits to many patients, we would like to provide facilities and physicians with incentives to serve patients who are appropriate candidates for CAPD.

The new reimbursement rates that went into effect on August 1, 1983 do, in fact, appear to have created significant financial incentives for home

## SCOPE OF THE STUDY

This study:

- compares the medical effectiveness of HD performed in dialysis centers and hospitals with CAPD or HD performed at home;
- evaluates the costs of treatment by each of these modalities; and
- identifies critical issues that require further evaluation.

It does not, however, contain an actual cost-effectiveness analysis of CAPD relative to home and center HD. The data required to make the results of such an analysis meaningful simply do not exist. Furthermore, chronic renal dialysis is not compared to renal transplantation. Most experts believe that evidence is overwhelming that a transplant from a living related donor is the preferred treatment when circumstances permit. While the relative merits of cadaveric transplantation and chronic dialysis are more controversial, no explicit comparison is made in order to avoid the risk of diverting attention from the major pol-



*Photo credit: National Kidney Foundation*

Young patient on chronic hemodialysis.

dialysis. Significant questions have been raised, however, over the equity of these rates and the effects they may have on the quality of patient care and on the overall expenditures of the Medicare ESRD program. The Federal Government, medical community, and patients alike have important stakes in the answers to these questions.



*Photo credit: Travenol Laboratories, Inc.*

Chrissy Sass, age 11, receives CAPD.

icy issues that surround the chronic dialysis end of the treatment spectrum for ESRD.

The major limitations of this study stem from shortcomings of available information on the effectiveness and costs of ESRD treatments. For example, most clinical studies fail to control adequately for differences in patient characteristics

that may have important effects on the outcomes of treatment. Hence, comparisons among dialysis modalities are tenuous. On the cost side, little is known of the true resource costs of treatment, and projections must be made from charge and reimbursement data.

Moreover, moving targets are being assessed. The technologies of CAPD and HD are evolving, and today's treatment results may be outdated

tomorrow. At the same time, the intricate interactions of technological factors, professional attitudes, and organizational relationships among health care institutions and health care industries are changing in a climate of altered financial incentives. This state of dynamic flux indicates the critical need to monitor carefully changes in ESRD treatment effectiveness and costs to better inform future clinical and policy decisions.

## ORGANIZATION OF THE CASE STUDY

In chapter 2, the dimensions of the ESRD problem are discussed, and in chapter 3 the major modalities of chronic dialysis treatment are described: center HD, home HD, and CAPD. Then, in chapter 4, evidence on the effectiveness and safety of each modality is examined, giving special emphasis to the important influences of the medical, sociodemographic, and psychological characteristics of patients on treatment outcomes. In chapter 5, the costs of treatment are estimated from cost audits performed by HCFA and the General Accounting Office (GAO); from average Medicare ESRD reimbursements rates; and from actual expenditures of the Medicare ESRD program.

Finally, in chapter 6, Medicare ESRD data for 1981 and 1982 are examined in detail to determine cost differences between patients who remain on a single dialysis modality and survive compared to those who change from one treatment modality to another ("the cost of changing") and to those who die while on a single modality ("the cost of dying").

The remainder of this chapter summarizes the major findings of the case study and suggests future directions.

## SUMMARY OF FINDINGS

### Effectiveness of Alternative Dialysis Modalities

Patient survival, morbidity from complications of treatment and related medical problems, and the quality of life experienced by patients on dialysis are all important measures of clinical effectiveness. The ability of a patient to continue on a prescribed treatment also is important because of the significant morbidity and costs associated with the need to change dialysis modalities.

Table 1-1 compares the characteristics of dialysis by CAPD and HD, and table 1-2 presents CAPD's most frequently mentioned advantages and disadvantages relative to HD. Arguments advanced in support of CAPD have focused on the freedom it allows the patient in controlling his or

her own treatment regimen and the continuous nature of the dialysis it provides. In many ways, CAPD's continuous treatment more closely approximates normal renal function than intermittent HD sessions. Countering arguments in favor of HD include its long-standing record of success, the more efficient clearance of low molecular weight toxins produced, and, in the case of center HD, the better medical supervision patients receive as a result of regular visits to dialysis centers.

These arguments, though germane, cannot be accepted as prima facie evidence supporting the superiority of one treatment modality or another without systematic demonstration of related objective health benefits. Unfortunately, evidence comparing the clinical effectiveness of the differ-

**Table 1-1.—Comparison of Continuous Ambulatory Peritoneal Dialysis (CAPD) and Hemodialysis (HD) as Currently Practiced**

|   | CAPD   | HD   |
|---|--|--|
| Estimated ESRD program beneficiaries in 1983 . . . . .  | 8,000  | 60,000   |
| Number of facilities providing therapy . . . . .  | 600  | 1,190  |
| Setting:  |  |  |
| Facility . . . . .  | 0  | 920/o  |
| Home . . . . .  | 100 %/0  | 80/0   |
| Dialysis . . . . .  | Continuous with three to five 2-liter peritoneal exchanges per day. Each exchange takes 30 minutes. Sterile technique critical | Intermittent with an average of three sessions per week each lasting 3 to 6 hours. Patient's circulation is connected to a dialysis machine                                  |
| Clearance of low molecular weight blood solutes . . . . .   | 70 liters per week   | 135 liters per week  |
| Clearance of higher molecular weight solutes (actual values not known because substances not identified chemically) . . . . . | More effective   | Less effective   |
| Access for dialysis . . . . .   | Catheter placement in abdomen requires a minor surgical procedure  | Creation of vascular arteriovenous fistula between a superficial artery and vein can be performed under local anesthesia   |
| Complications . . . . .   | Peritonitis. Exit or tunnel infections. Catheter obstruction. Hernias. Intestinal obstruction. Hydrothorax                     | Thrombosis of fistula. Sepsis related to the fistula. Accidental hemorrhage during dialysis. Vascular collapse following dialysis. Occasional failures of dialysis equipment |

SOURCE: Office of Technology Assessment.

ent dialysis modalities is incomplete at the present time. All available information comes either from small clinical series, dialysis registries, or the Medicare ESRD data system. No controlled clinical trial has been performed to compare CAPD and HD directly. In the absence of such a trial, case-mix differences among populations studied, differences in the expertise of providers, and differences in definitions and data collection techniques obscure comparisons. Moreover, since experience with CAPD in substantial numbers of patients is limited to the past 2 or 3 years, long-term effects cannot be evaluated. Conversely, most information on HD dates from the 1970s and does not necessarily reflect current technology.

Despite the caveats, the following conclusions appear justified:

- One- and two-year survival rates *on* CAPD and HD are comparable.
- Annual hospitalization rates, as one measure of morbidity, are somewhat higher for CAPD than HD. The higher rate for CAPD appears primarily to reflect days of hospitalization required to train patients in the use

of the technique, to initiate dialysis, and to treat episodes of peritonitis. Patients who are successful in being able to continue on CAPD experience about the same hospitalization rates as do patients on HD. These findings emphasize the "startup costs" of CAPD treatment and the importance of selecting patients with the motivation and physical abilities required to perform repetitive sterile dialysate exchanges over long periods of time.

- Both survival and hospitalization rates are better for patients on home HD than either CAPD or center HD, but these differences can be attributed to favorable case selection.
- Peritonitis and infections around the peritoneal catheter are the most important complications of CAPD. The several technologies that have been developed to facilitate sterile dialysate exchanges have not yet been tested sufficiently to determine whether their use will actually reduce rates of peritonitis.
- Thrombosis and infection of vascular access sites, accidental hemorrhage, and vascular collapse after dialysis sessions are the most frequently mentioned complications of HD.

**Table 1-2.—Advantages and Disadvantages of CAPD Relative to HD**

**Advantages of CAPD:**

- CAPD is continuous and avoids the fluctuations of fluid and body chemistries associated with intermittent HD sessions. This is of particular advantage in patients with cardiovascular disease and hypertension.
- CAPD allows patients flexibility in adapting dialysate exchanges to their daily schedules.
- CAPD avoids dependency on a dialysis machine.
- CAPD avoids the problems of vascular access and accidental hemorrhage that accompany HD.
- CAPD provides more clearance of higher molecular weight toxins.
- CAPD permits improved blood sugar control in diabetics through the intraperitoneal administration of insulin.
- CAPD may be accompanied by a greater sense of well-being and improved appetite and permits a more liberal dietary protein intake.
- CAPD does not require the extensive family support that home HD does.

**Disadvantages of CAPD:**

- CAPD is complicated by frequent episodes of peritonitis in many patients.
- CAPD provides less dialysis than HD in terms of the elimination of low molecular weight toxins.
- CAPD results in the loss of 8 or more grams of protein per day in the dialysate that must be compensated for by additional dietary intake.
- CAPD may lead to obesity or increased serum triglycerides and, hence, to the possibility of accelerated atherogenesis.
- CAPD may be complicated by infection around the peritoneal catheter or by obstruction of the catheter.
- CAPD requires faithful long-term compliance with meticulous aseptic techniques.
- CAPD patients may receive less rigorous medical supervision than that provided by thrice-weekly center HD sessions.

SOURCE: Off Ice of Technology Assessment.

The frequency of these complications, however, is not well documented in studies that reflect current technology.

- Excluding deaths and patients who subsequently receive renal transplants, only 50 to 80 percent of patients who start on CAPD are still on it at the end of 1 year. This relatively high failure rate is an important problem for CAPD and underscores the need to establish carefully defined patient selection criteria.
- Failure rates for HD could not be documented. To be meaningful, such results would have to coincide with the period of time that CAPD has been available as an alternative form of treatment.

- Documentation of quality of life differences among patients on CAPD, home HD, and center HD are sparse. Information from the only study that directly addresses this issue (the National Kidney Dialysis and Kidney Transplantation Study) suggests that patients on CAPD are less likely to be employed and have greater functional impairment than patients on either home HD or center HD. These differences are largely eliminated when adjustments are made for case-mix variables, however, and should not be construed to indicate a poorer quality of life attributable to CAPD.
- No systematic information could be found that assesses the relative “burdens of treatment” of CAPD and HD. Critical determinants appear to be the relatively inflexible treatment schedule and machine dependency in the case of HD and the requirement for long-term compliance with multiple daily dialysis exchanges in the case of CAPD. The burden on the family may be considerable, especially for home HD.
- Patient characteristics that appear to be particularly important determinants of outcomes on chronic renal dialysis are age, the cause of ESRD, the presence of comorbid medical conditions, and the time elapsed since the diagnosis of ESRD.

## Costs of Treatment for ESRD

Treatment for patients on chronic renal dialysis includes the dialysis treatments themselves, physician services both for the supervision of dialysis and for the treatment of other medical problems, any required hospitalizations, and ancillary services such as laboratory tests and medications. In this case study, estimates of the costs of one or more of these components of care are derived from three separate sources: cost audits performed by HCFA and the GAO, Medicare’s average reimbursement rates for dialysis, and information on actual expenditures of the ESRD program. Each of these sources has its limitations, and no one source can be pointed to as providing the “best” estimate. The distinction between the costs of dialysis projected from *cost audit figures* or aver-

age reimbursement rates, and actual ESRD program expenditures are important ones. The former assumes average treatment regimens and full compliance, while the latter refers only to services actually billed for and, hence, reflects variations in treatment regimens among patients and patient compliance failures.

Despite the vicissitudes of cost estimates, the following conclusions seem warranted:

- The cost of HD performed in hospital-based dialysis centers is higher than that in independent centers. Whether this higher cost can be justified by a “sicker case-mix” of patients treated in hospitals, as hospitals claim, or is due to higher overhead and failures to take advantage of economies of scale cannot be judged from existing information.
- The results of HCFA’s and GAO’s cost audits do not justify the claim that home dialysis (CAPD or home HD) is less expensive than HD in an independent center.
- Analysis of 1981 and 1982 Medicare ESRD expenditures provide estimates of the annual cost of dialysis that are considerably lower for each dialysis modality than those projected from the cost audits. The figure for CAPD, in fact, is less than half that from the cost audits and must be considered suspect. Aberrances in billings for CAPD, factors related to CAPD’s status as a new technology,

and failures of compliance all are possible explanations.

- The cost of home dialysis (CAPD or home HD) to the ESRD program may depend importantly on whether the patient purchases supplies through a bulk purchaser such as a dialysis center or directly from the supplier. Alternative price lists for CAPD supplies and equipment suggest that the cost of CAPD could vary by as much as \$6,000 per year. The higher prices would seem likely to be applied to the individual purchaser unless Medicare were to negotiate a preferred customer relationship.
- Medicare’s ESRD expenditures for hospitalizations are similar in patients able to continue on CAPD or center HD (about \$3,000 per patient-year) but are higher than those of patients who are stable on home HD (**\$2,400** per patient-year). Hospital costs double, however, in patients who have to change from one modality to another. These “costs of changing” underscore the cost implications of proper patient selection for a dialysis modality.
- Reasonable estimates of the average annual cost of treatment of a patient on chronic renal dialysis range from **\$20,000 to \$30,000 (1982 dollars)**. Dialysis treatments themselves account for at least **70** percent of this total.

## CONCLUSIONS

### Clinical Effectiveness

CAPD appears to be an acceptable alternative to HD for, at least, selected persons with ESRD. Survival rates on the two modalities appear similar, but somewhat higher overall morbidity occurs in patients on CAPD due to the frequent episodes of peritonitis that occur in some patients. These conclusions must be considered tentative in view of the relatively short-term experience with CAPD and the case-mix differences among populations from which results have been reported.

### Quality of Life

No conclusion is warranted that a patient’s quality of life is better (or worse) on CAPD than on HD. Each modality has its advantages and disadvantages. Individual preferences for one form of therapy or the other undoubtedly vary widely among patients and among families,

### Costs of Treatment

Differences in the cost of treatment by CAPD, by HD performed in independent dialysis centers,

and by home HD are sufficiently small that they can be accounted for by the variations in methods used in the available cost estimates and by case-mix differences. A conclusion that home dialysis (CAPD or home HD) is less expensive than HD in an independent center appears unwarranted. Treatment by HD in hospital dialysis centers, however, is more expensive than in other settings.

### **Effects of Medicare's 1983 Composite Reimbursement Rates**

These rates were designed to encourage home dialysis by providing equal reimbursement for home and center dialysis. They dramatically reduced reimbursement for HD in hospital dialysis centers (from an averaged \$159 to \$131 per treatment) and in independent dialysis centers (from \$138 to \$127 per treatment), and, simultaneously, adjusted physician cavitation rates for dialysis supervision to provide incentives for home dialysis.

## **SUGGESTED FUTURE DIRECTIONS**

Efforts to compare alternative dialysis modalities more conclusively and, ultimately, to contain the costs of the ESRD program without compromising health benefits depend on the availability of better medical and cost information and better definition of criteria for program eligibility.

### **Better Medical Information**

The most critical need is for better information by which to judge the relative effectiveness of dialysis modalities. Better information on survival, medical morbidity, and quality of life parameters all are needed.

Two approaches are possible. One would be to create a dialysis registry that would enroll patients as they begin on any one of the three major chronic dialysis modalities. This registry could be similar to the present National Institute of Health (NIH) CAPD Registry, but would include additional information on patients' clinical characteristics, such as comorbidity and ESRD treat-

ment history. Such data are essential to adjust for case-mix and for achieving valid comparisons among treatment modalities. The advantages of this approach are that it would benefit from the experience already gained in the NIH CAPD Registry and would be relatively inexpensive.

Their impact on the balance between home dialysis (CAPD and home HD) and center HD can only be speculated upon, however. The financial disincentive provided for hospital-based HD is strong, and suggests that hospitals may well find it necessary to discontinue outpatient dialysis and either transfer patients to independent dialysis centers for HD or put them on CAPD or home HD. Incentives for independent centers are less clear. If the HCFA audit results accurately reflect dialysis centers' resource costs, centers may respond by attempting to increase the efficiency of center HD, while at the same time reducing marginal costs by accepting transfers from hospital units that close. Alternatively, they may increase the use of home dialysis, especially if favorable prices can be obtained from suppliers of CAPD and home dialysis equipment and supplies. The possibility that dialysis centers will see it to be in their best interests to "assign" purchase of supplies, and hence bypass the new prospective payment rates, is a real one that will need to be carefully monitored.

A more scientifically rigorous approach would be a randomized clinical trial (RCT) in which dialysis modalities were compared directly. Obstacles to such a trial involve its relatively high cost, the risk that changes in technology might render findings of the trial obsolete, and whether an RCT is actually feasible. Since each major dialysis modality is well established and has its strong advocates, it is not certain whether randomization of treatments would be acceptable or, if the study was accepted, whether patient selection criteria could be agreed upon that would permit enrollment of a sufficiently broad spectrum of the ESRD population that the results would be widely generalizable. Despite these drawbacks, the feasibility of a controlled clinical trial should be carefully explored.

## Better Cost Information

Better cost information is needed both to evaluate HCFA's 1983 reimbursement regulations and to guide future policy decisions. Three issues seem central.

The first is the need to better define the relationship between the resource costs of component medical services (dialysis treatments, dialysis supplies and equipment, physician care, and days of hospitalization) and reimbursement rates. Carefully conceived and executed cost audits are one means to this end.

Second, better information is needed on actual expenditures for the treatment of ESRD, including the dialysis treatments themselves, resulting complications, and associated medical problems. Costs of treatment to the ESRD program for each patient depends both on the unit costs of component services and on their utilization. Refinement of Medicare's ESRD information system would appear to be the most practical way to monitor utilization and expenditures.

Third, a broader economic study should be undertaken to better understand the societal burden of ESRD compared to the economic and health

benefits of treatment. This study would examine social costs, such as lost wages and disability pensions, and opportunity costs, such as those of family support, in addition to medical care costs.

## Eligibility for the ESRD Program

Finally, the fundamental question of who should qualify for ESRD treatment needs attention. The cost implications of expanding enrollment in the ESRD program far exceed those of the costs of treatment for any individual patient. As the effectiveness, safety, and acceptability of treatment technologies improve, there will be a natural inclination among physicians and among patients to apply them earlier and earlier in the natural history of chronic renal failure and for more and more marginal indications. This same tendency has been observed in the case of other medical technologies, such as coronary artery bypass surgery and total hip replacement. If cost containment in the ESRD program is to be achieved, the problem of defining medical criteria for eligibility will have to be explicitly addressed. A consensus conference that involves ethicists, lawyers, and economists, as well as physicians, would be a reasonable first step in this direction.