The Effectiveness and Costs of Continuous Ambulatory Peritoneal Dialysis (CAPD)

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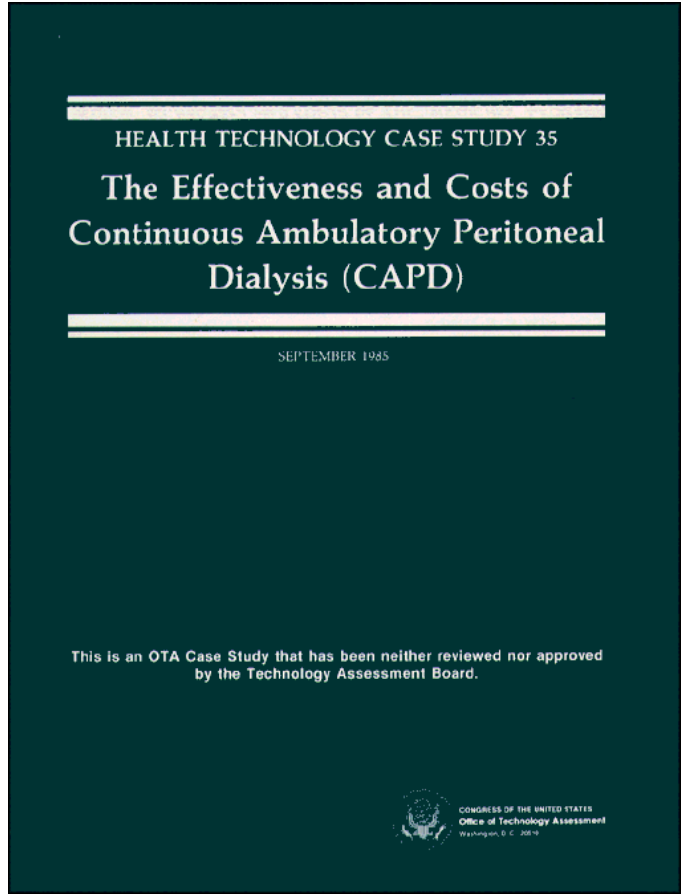

HEALTH TECHNOLOGY CASE STUDY 35

The Effectiveness and Costs of Continuous Ambulatory Peritoneal Dialysis (CAPD)

SEPTEMBER 1985

This case study was performed as part of OTA's Assessment of

Medical Technology and Costs of the Medicare Program

Prepared for OTA by:

William B. Stason, M. D., M.S.
Associate Professor, Harvard School of Public Health
Chief, Health Services Research
West Roxbury, VA Medical Center

Benjamin A. Barnes, M.D.
Associate Professor of Surgery, Harvard Medical School
Director, New England Organ Bank

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CONGRESS OF THE UNITED STATES
Office of Technology Assessment
Washington, D. C. 20510

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Preface

The Effectiveness and Costs of Continuous Ambulatory Peritoneal Dialysis (CAPD) is Case Study 35 in OTA's Health Technology Case Study Series. This case study, which was requested by the Senate Committee on Finance and its Subcommittee on Health, has been prepared in connection with OTA's project on *Medical Technology and Costs of the Medicare Program*, which was requested by the House Committee on Energy and Commerce and its Subcommittee on Health and the Environment and the Senate Committee on Finance, Subcommittee on Health. A listing of other case studies in the series is included at the end of this preface.

OTA case studies are designed to fulfill two functions. The primary purpose is to provide OTA with specific information that can be used in forming general conclusions regarding broader policy issues. The first 19 cases in the Health Technology Case Study Series, for example, were conducted in conjunction with OTA's overall project on *The Implications of Cost-Effectiveness Analysis of Medical Technology*. By examining the 19 cases as a group and looking for common problems or strengths in the techniques of cost-effectiveness or cost-benefit analysis, OTA was able to better analyze the potential contribution that those techniques might make to the management of medical technology and health care costs and quality.

The second function of the case studies is to provide useful information on the specific technologies covered. The design and the funding levels of most of the case studies are such that they should be read primarily in the context of the associated overall OTA projects, Nevertheless, in many instances, the case studies do represent extensive reviews of the literature on the efficacy, safety, and costs of the specific technologies and as such can stand on their own as a useful contribution to the field.

Case studies are prepared in some instances because they have been specifically requested by congressional committees and in others because they have been selected through an extensive review process involving OTA staff and consultations with the congressional staffs, advisory panel to the associated overall project, the Health Program Advisory Committee, and other experts in various fields. Selection criteria were developed to ensure that case studies provide the following:

- examples of types of technologies by function (preventive, diagnostic, therapeutic, and rehabilitative);
- examples of types of technologies by physical nature (drugs, devices, and procedures);
- examples of technologies in different stages of development and diffusion (new, emerging, and established);
- examples from different areas of medicine (e.g., general medical practice, pediatrics, radiology, and surgery);
- examples addressing medical problems that are important because of their high frequency or significant impacts (e. g., cost);
- examples of technologies with associated high costs either because of high volume (for low-cost technologies) or high individual costs;
- examples that could provide information material relating to the broader policy and methodological issues being examined in the particular overall project; and
- examples with sufficient scientific literature.

Case studies are either prepared by OTA staff, commissioned by OTA and performed under contract by experts (generally in academia), or written by OTA staff on the basis of contractors' papers.

OTA subjects each case study to an extensive review process. Initial drafts of cases are reviewed by OTA staff and by members of the advisory panel to the associated project. For commissioned cases, comments are provided to authors, along with OTA's suggestions for revisions. Subsequent drafts are sent by OTA to numerous experts for review and comment. Each case is seen by at least 30 reviewers, and sometimes by 80 or more outside reviewers. These individuals may be from relevant Government agencies, professional societies, consumer and public interest groups, medical practice, and academic medicine. Academicians such as economists, sociologists, decision analysts, biologists, and so forth, as appropriate, also review the cases.

Although cases are not statements of official OTA position, the review process is designed to satisfy OTA's concern with each case study's scientific quality and objectivity. During the various stages of the review and revision process, therefore, OTA encourages, and to the extent possible requires, authors to present balanced information and recognize divergent points of view.

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35	The Effectiveness and Costs of Continuous Ambulatory Peritoneal Dialysis (CAPD) William B. Stason and Benjamin A. Barnes (OTA-HCS-35)

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[b] Original publication numbers appear in parentheses.

[c] The first 17 cases in the series were 17 separately issued cases in *Background Paper #2: Case Studies of Medical Technologies*, prepared in conjunction with OTA's August 1980 report *The Implications of Cost-Effectiveness Analysis of Medical Technology.*

[d] Background Paper #3 t. *The Implications of Cost-Effectiveness Analysis of Medical Technology.*

[e] Background paper #5 t. *Th. Implications of Cost-Effectiveness Analysis of Medical Technology.*

[f] Background paper #1 to OTA's May 1982 report *Technology and Handicapped People.*

[g] Background Paper #2 to *Technology and Handicapped People.*

OTA Project Staff for Case Study #35

H. David Banta[1] and Roger C. Herdman,[2] *Assistant Director, OTA Health and Life Sciences Division*

Clyde J. Behney, *Health Program Manager*

Anne Kesselman Burns, *Project Director*

Pamela J. Simerly,[3] *Research Assistant*

Edward Seibert,[4] *Research Assistant*

Virginia Cwalina, *Administrative Assistant*

Beckie I. Erickson,[5] *P. C./Word Processor Specialist*

Brenda Miller,[6] *P. C./Word Processor Specialist*

Jennifer Nelson,[7] *Secretary*

Diann G. Hohenthaner,[8] *Secretary/Word Processor Specialist*

Carol A. Guntow,[9] *Clerical Assistant*

[1] Until August 1983
[2] Since December 1983.
[3] Until September 1984.
[4] September 1984
[5] Since January 1984.
[6] Until January 1985.
[7] Until January 1984.
[8] Since February 1985,
[9] Since October 1984

Medical Technology and Costs of the Medicare Program Advisory Panel*

Stuart Altman, *Panel Chair*
Dean, Florence Heller School, Brandeis University

Frank Baker
Vice President
Washington State Hospital Association

Robert Blendon
Senior Vice President
The Robert Wood Johnson Foundation

Jerry Cromwell
President
Health Economics Research
Chestnut Hill, MA

Karen Davis
Chair, Department of Health Policy and Management
School of Hygiene and Public Health
Johns Hopkins University

Robert Derzon
Vice President
Lewin & Associates
Washington, DC

Howard Frazier
Director
Center for the Analysis of Health Practices
Harvard School of Public Health

Clifton Gaus
President, Foundation for Health Services Research
Washington, DC

Jack Hadley
Director
Center for Health Policy Studies
Georgetown University

Kate Ireland
Chairman, Board of Governors
Frontier Nursing Service
Wendover, KY

Judith Lave
Professor
Department of Health Economics
University of Pittsburgh

Mary Marshall
Delegate
Virginia House of Delegates

Walter McNerney
Professor of Health Policy
J. L. Kellogg Graduate School of Management
Northwestern University

Morton Miller
Immediate Past President
National Health Council
New York, NY

James Mongan
Executive Director
Truman Medical Center
Kansas City, MO

Seymour Perry
Deputy Director
Institute for Health Policy Analysis
Georgetown University Medical Center

Robert Sigmond
Director, Community Programs for Affordable Health Care
Advisor on Hospital Affairs, Blue Cross/Blue Shield Associations

Anne Somers
Professor
Department of Environmental and Community and Family Medicine
UMDNJ–Rutgers Medical School

Paul Torrens
School of Public Health
University of California, Los Angeles

Keith Weikel
Group Vice President
AMI
McLean, VA

*The affiliations of the Panel members reflect their positions during the assessment (June 1982-July 1984).

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Introduction, Summary of Findings, and Suggested Future Directions

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.[1]

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, patient 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.[2] 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.

'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,

'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 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.

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

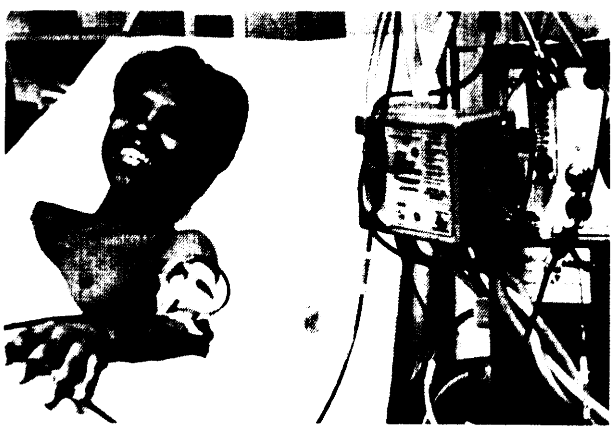

Photo credit: National Kidney Foundation

Young patient on chronic hemodialysis.

Photo credit: Travenol Laboratories, Inc.

Chrissy Sass, age 11, receives CAPD.

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 w-ho 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 average *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 bean 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.

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.

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 treatment 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.

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.

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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.

Chapter 2

End-Stage Renal Disease: Scope and Trends

Chapter 2

End-Stage Renal Disease: Scope and Trends

END-STAGE RENAL DISEASE DEFINED

The primary functions of the kidney are to remove waste products generated by the body's metabolism and to regulate the body's balance of fluid and electrolytes. *Chronic renal failure* refers to the permanent deterioration of the kidney's ability to adequately perform these functions, and *uremia* refers to the symptomatic phase of renal failure. The toxic products that cause the symptoms of uremia have not been fully elucidated. Candidates include small molecules such as urea and creatinine that come from the breakdown of proteins and so-called middle molecules (substances with molecular weights of around 5,000). The exact nature of middle molecules remains obscure as does their importance.

Renal function is classically measured in terms of the ability of the kidney to clear urea or creatinine from the blood. *Clearance* of a specific substance is defined as the volume of plasma containing an amount of the substance equal to that removed per unit of time into the urine or dialysate. For example, if in 1 minute the urine excreted by the kidneys contains 50 mg of urea (volume not considered), and if the concentration of urea in the plasma were 50 mg per 100 ml, then the clearance would be 100 ml/min. Normal clearance values are 40 to 80 ml/min for urea and 80 to 125 ml/min for creatinine. Values below 5 ml/min for creatinine are generally judged to be an absolute indication for dialysis treatment, though this criterion is not universally accepted. The presence of symptoms of uremia, such as nausea or shortness of breath, or deleterious physical findings, such as mental stupor, pleural fluid, or bone disease, may lead physicians to begin treatment at higher levels of residual renal function.

PREVALENCE OF END-STAGE RENAL DISEASE

The prevalence of end-stage renal disease (ESRD) is usually equated to the number of patients receiving chronic renal dialysis rather than to the number of people with any given level of renal failure. In the United States, where access to treatment has been made essentially universal because of Medicare's ESRD program, this assumption has some validity. Other countries, however, have established restrictive criteria for admission to chronic dialysis programs. In these countries, including several in Western Europe, dialysis rates substantially underestimate the true prevalence of disease. Moreover, patients who have undergone successful renal transplantation are removed from the ESRD pool of patients by this definition, even though they remain on immunosuppressive therapy and are susceptible to substantial risks and infectious complications as a result.

An estimated 70,000 persons in the United States were receiving chronic dialysis at the end of 1982, including 65,438 enrolled in the ESRD program and an additional 4,000 to 5,000 persons who are treated by the Veteran's Administration or by State programs. Patients diagnosed with ESRD for the first time during 1982 numbered slightly fewer than 23,000, and the net increase in patients on chronic dialysis during 1982 was 6,212 after accounting for deaths, transplants, and returns to chronic dialysis after rejection of transplanted kidneys (see table 2-1).

The size of the chronic dialysis population is projected to increase by about 5 percent per year

Table 2-1.–Estimated Prevalence and Incidence of End-Stage Renal Disease in the United States, 1982

Prevalence:	
Dialysis population on Jan. 1, 1982	58,948
Incidence:	
Started on dialysis for first time ever:	
Center dialysis	20,098
Home dialysis	2,699
Restarted on dialysis:	
Center dialysis	493
Home dialysis	53
Returned to dialysis after transplant:	
Center dialysis	1,415
Home dialysis	148
	24,906
Losses:	
Deaths:	
Center dialysis	11,018
Home dialysis	1,484
Recovered kidney function:	
Center dialysis	744
Home dialysis	78
Received transplant:	
From center dialysis	4,078
From home dialysis	682
Discontinued dialysis (? reason):	
Center dialysis	559
Home dialysis	51
	18,694
Prevalence:	
Dialysis population on Dec. 31, 1982	65,160[a]

[a]Differs from the 65,765 reported in the survey summary table for undefined reasons, perhaps related to Missing data for some categories

SOURCE: ESRD Medical Information System—Facility Survey Tables (Jan. I-Dec. 31, 1982).

between 1980 and 1990 and, thereafter, decline gradually to a growth rate of 1 percent per year by 2020 (11). Many factors will affect these projections, including changes in the age distribution of the population, changes in the incidence of ESRD, changes in the mortality rates of individuals on chronic dialysis, and changes in the use rate and success of renal transplantation.

MEDICARE'S END-STAGE RENAL DISEASE PROGRAM

The ESRD program was authorized in the Social Security Amendments of *1972* (Public Law *92-603)* and was implemented in 1973. The program recognized the availability of life-saving, though imperfect, treatment for ESRD by hemodialysis and renal transplantation and the catastrophic financial consequences of these treatments for the afflicted individuals. For some analysts, the ESRD program provided a limited test of issues relevant to universal national health insurance.

The program's growth has been dramatic. In 1974, 16,000 persons were enrolled, and the cost to U.S. taxpayers was about $250 million. By 1981, enrollees had grown to over 64,000 at a cost of $1.6 billion. The annual growth rate was 42 percent between 1974 and 1975, 24 percent between 1977 and 1978, and 11 percent between 1980 and 1981 (11). This decreasing rate of growth reflects primarily the success of the program in enrolling the pool of patients with ESRD who previously had been untreated or were defraying the cost of treatment in other ways.

About 93 percent of persons with ESRD are eligible for benefits (9). Persons covered by the armed services, or by certain State or private insurance programs are exceptions, while many veterans have dual entitlement to the Veteran's Administration health care system and Medicare's ESRD program,

The ESRD program covers not only the costs of dialysis or renal transplantation but also provides the full spectrum of Medicare benefits whether or not they directly relate to the care of ESRD or its complications. In 1979, 55 percent of ESRD program costs were estimated to be for outpatient dialysis services, 29 percent for hospital care, 15 percent for physician services, and 1 percent for other miscellaneous items (12). Escalation in the total costs of the program reflects primarily the increasing numbers of persons enrolled and the increasing costs of hospitalization rather than increases in the costs of dialysis. Reimbursement rates for dialysis have, in fact, been frozen since 1979.

CLINICAL CHARACTERISTICS AND OUTCOMES OF PERSONS ENROLLED IN THE ESRD PROGRAM

New enrollees in *1980* were older, more likely to be black, and more likely to have diabetic nephropathy than enrollees in earlier years. The proportion of the ESRD population having diabetic nephropathy, for example, increased from **7** percent in 1973 to 16 percent in 1977 and to 22 percent in 1980 (11). This trend toward increased enrollment of diabetics in the United States stands in contrast to other countries where diabetes, until recently, has often been an indication for withholding therapy.

Survival of patients on chronic dialysis remained stable between **1977** and 1980, with slightly over *80* percent of patients surviving 1 year and 54 to 57 percent surviving 3 years (11). Survival varied considerably according to the age of the patient, however, with l-year survival after the onset of renal failure during 1973-79 ranging from *88* percent in patients **24** years of age or younger to **64** percent in those over **75** years of age. Corresponding 5-year survival rates were **64** and **22** percent, respectively. These figures exclude renal transplant patients (11). Patients with a primary diagnosis of glomerulonephritis fared considerably better than those with a diagnosis of diabetic nephropathy (5-year survival of **47** percent vs. **21** percent).

The survival rates between 1977 and *1980* were stable despite trends toward enrolling persons who were at higher risk of mortality by virtue of being older and more likely to have diabetic nephropathy. Compensatory improvements in dialysis technology or general medical management may account for the stability of survival rates, but no direct evidence on this point is available.

Persons enrolled in the ESRD program, excluding those receiving renal transplants, were hospitalized an average of 1.6 times during 1981 for a total of 16,7 days (11). Hospitalization rates were age dependent and ranged from an average of 12.8 days in persons 25 years of age or younger to 20.3 days in persons **65** years or older. ESRD program beneficiaries spent more than four times as many days in the hospital than other Medicare recipients (45).

TRENDS IN THE USE OF CHRONIC DIALYSIS MODALITIES

Dialysis can be provided either in centers located in hospitals or in independent facilities or can be performed at home. Hemodialysis (HD) and intermittent peritoneal dialysis (IPD) may be performed either in centers or in the home, while continuous ambulatory peritoneal dialysis (CAPD) is solely a home technique. In 1980, 47 percent of the chronic dialysis population received dialysis in hospital centers, 39 percent in independent centers, and 14 percent at home. Since that time, the proportion of patients on home dialysis has increased steadily to 18 percent in 1982, primarily as a result of the increased use of CAPD. About 32 percent of home dialysis patients were on CAPD at the end of 1980, 47 percent by the end of 1981, and 56 percent at the end of 1982. More than two-thirds of all home dialysis patients were estimated to be on CAPD by March **1983** **(46).**

Dialysis rates and the utilization of home dialysis techniques vary widely among the States *(38)*. In 1979, the number of patients dialyzed per million of population ranged from a low of **20** (Wyoming) to a high of *383* (Hawaii). Even among States with populations of 3 million or more (a population size chosen to minimize statistical fluctuations), the rate varied from 119 per million (Kentucky) to *282* per million (New York). Use of home dialysis at the same time varied from zero (North Dakota, South Dakota, and Wyoming) to over 40 percent (Indiana, Utah, and Washington).

Complex interactions of patient characteristics, demographic factors, physician acceptance, and entrepreneurial motivations, no doubt, underlie both variations in dialysis rates and variations in the popularity of home dialysis.

Future increases in the use of home dialysis will depend on these same factors and well may be influenced by the financial incentives created by Medicare's 1983 composite reimbursement rates that favor home dialysis.

Chapter 3

Physiology and Techniques of Modalities for Chronic Renal Dialysis

Chapter 3

Physiology and Techniques of Modalities for Chronic Renal Dialysis

The purpose of this chapter is to acquaint the nonmedical reader with the methods of dialysis that have been developed to substitute for kidneys whose function has deteriorated below a level that can support life.[1] Most attention is focused on hemodialysis (HD), the historical standard of medical treatment for renal failure, and on continuous ambulatory peritoneal dialysis (CAPD). Only brief mention is made of the less widely used approaches (e.g., continuous cycling peritoneal dialysis [CCPD] and intermittent peritoneal dialysis [IPD]).

[1] See Appendix B.—*Glossary of Acronyms and Terms* for definitions of selected medical terms.

HEMODIALYSIS

Principles and Physiology

HD depends on the concept of circulating a patient's blood outside the body through a thin-walled synthetic tube or group of tubes (dialyzer), which are bathed in aqueous solution (dialysate). The semipermeable properties of the dialyzing membrane permit the exchange of selected dissolved substances (solutes) between the dialysate and the blood. Dialysis, crudely, may be likened to the exchange that takes place through the screen of a porch. The screen permits free passage of air to and from, since air molecules are much smaller than the screen's mesh. Large insects are totally unable to pass through the screen, but smaller insects or other airborne particles may be able to penetrate with some difficulty or delay. With current HD technology, blood circulates through thousands of hollow capillary fibers which are bathed in a continuously flowing dialysate that is discarded after a single passage past the fibers.

During HD, small molecules (e.g., urea and creatinine) diffuse rapidly from the blood through the membrane and into the dialysate. HD, therefore, is ideally suited to adjust the concentration of these small molecules in the blood and in other extracellular fluid compartments of the body that are in free communication with the blood. Equilibrium occurs more slowly, however, with body compartments that are more remote from the circulating blood, including intracellular fluid and cerebrospinal fluid. Middle molecules diffuse through the dialyzing membrane more slowly, and large molecules such as proteins (molecular weight 50,000 and greater) are effectively blocked.

In clinical practice, the composition of the dialysate is adjusted carefully to minimize excessive disturbances in the water and salt balance of the body and, hence, to reduce the small but finite risk of hypertensive crises, cardiac arrhythmias or circulatory collapse. The volume of dialysate, the surface area of the dialyzer, the rate of flow of blood through the dialysis tubing, and the duration and frequency of dialysis sessions are tailored to the needs of the individual patient.

Technique

The application of HD requires access to the patient's circulation. Originally, this was accomplished by inserting a cannula into a superficial artery, which was then connected by external tubing to a cannula in an adjacent vein. These connections formed an arteriovenous connection, or fistula. In recent years, the cannula and external tubing have been replaced by a direct anatomosis between the artery and vein beneath the skin which is accessed by large bore needles at the time of dialysis. This latter technique has greatly reduced the risk of infection. Most commonly, the arteriovenous fistula is placed in the forearm, but other sites are possible if occlusion of the fistula or local infection requires its relocation.

HD requires two or three dialysis sessions per week, each lasting 3 to 5 hours. During dialysis the arteriovenous fistula is connected to the dialyzer, and dialysis solution is circulated past the dialyzer at an average rate of about 500 ml/min. The patient usually is given an anticoagulant, heparin, to prevent the blood from clotting as it circulates through the dialyzer.

HD may be administered in a hospital, in an independent dialysis center, or at home. The first two options are collectively referred center *HD* or *facility HD*. Alternatively, the patient may purchase or lease the dialysis equipment and receive dialysis treatments at home with the aid of family, friends, or salaried assistants. This is known as *home HD*.

CONTINUOUS AMBULATORY PERITONEAL DIALYSIS

Principles and Physiology

Like HD, CAPD is based on the principles of diffusion of fluids and solutes across a semipermeable membrane. In the case of CAPD, however, the dialyzing membrane is the membrane lining the abdominal cavity (peritoneum). Instead of the patient's blood being circulated outside the body, the normal capillary circulation that supplies the peritoneum is used. During each exchange, up to 2 liters of dialysate is introduced into the peritoneal cavity through a catheter that penetrates the abdominal wall and is left for 4 to 8 hours before being removed through the same catheter by gravity drainage.

The composition of the dialysate is adjusted so that the transfer of fluid and solutes favors normalization of the patient's fluid and electrolyte balance. The transfer of water across the peritoneum is controlled by the concentration of glucose in the dialysate. Higher concentrations of glucose favor the transfer of water into the peritoneal cavity. Thus, if a patient is overhydrated, excess water can be removed. This feature of CAPD can be particularly advantageous in the patient with hypertension or edema. In some diabetics, insulin may be introduced into the dialysate, thereby obviating the need for daily insulin injections.

The small volume of dialysate used in CAPD results in a rapid decrease in the concentration gradient during an exchange. Since a high gradient favors the diffusion of low molecular weight solutes from the patient to the dialysate, transfer will be rapid initially but will then decrease to the point that relatively little net transfer takes place towards the end of a period. CAPD, therefore, is less efficient than HD in eliminating low molecular weight solutes. The "middle" molecules mentioned previously are removed more effectively, however, because the effective pore size of the peritoneum is larger than that of the HD dialyzing membrane.

In contrast to the intermittent nature of HD, the multiple daily exchanges of CAPD result in essentially continuous dialysis. There are several consequences. Fluctuations in concentrations of solutes are relatively small during CAPD, and rapid changes of fluid volume are avoided. Furthermore, the equilibrium between body fluid compartments (blood, extracellular fluid, intracellular fluid, and cerebrospinal fluid) is disturbed less than with HD. The clinical significance of this latter phenomenon is not completely known but is at least a theoretical advantage of CAPD.

Although changes in the filtration characteristics of the peritoneal membrane might be expected to occur during the long-term use of CAPD, observations over intervals of months to several years have not consistently demonstrated measurable effects.

Technique

Analogous to the need for vascular access in HD, CAPD requires that a catheter be placed in the peritoneal cavity to permit exchanges of dialysate. The original technique to insert the catheter (a Tenckhoff® catheter with multiple terminal perforations or some modification) required a hospital admission and a "mini''-laparotomy. A more recent technique permits the catheter to be placed percutaneously through a stylus, thus avoiding the need for a laparotomy and hospitalization.

The catheter is placed in a dependent position in the peritoneal cavity in a manner that minimizes the likelihood of catheter obstruction and the risk of erosion into other abdominal organs. It is then led out obliquely through a subcutaneous track to decrease the risk of subsequent infection. There are several types of devices that place flanges and spongy materials around the catheter to reduce the likelihood of fluid leaks from the peritoneal cavity and to impede the migration of bacteria.

When CAPD is first begun in a patient, an automated cycling machine is often used to facilitate exchanges. Thereafter, exchanges are performed by gravity feed. The volume of fluid exchanged depends on the size and tolerance of the patient and ranges from 500 cc in children to 3,000 cc, with an average for adults being between 1,500 and 2,000 cc. Four or five exchanges are performed daily, including one exchange in which the dialysate remains in the abdomen overnight. The exchange procedure takes 30 to 45 minutes and requires a moderate amount of physical dexterity. Meticulous, sterile techniques must be followed while connecting the dialysate bag to the peritoneal catheter (a process called "spiking") to prevent infection of the peritoneal cavity (peritonitis). The long-term compliance required with these exacting procedures may be extremely difficult for some patients.

Recent technical advances in CAPD have centered on reducing the risk of peritonitis. Several approaches have been proposed, including:

- *Sterile Connection Device (SCD)® (Dupont Co.):* This device eliminates the need to manually "spike" the dialysate bags to connect them to the peritoneal catheter tubing by performing a sterile "heat-weld" between the tubes of the dialysate bag and that of the catheter.
- *Peridex CAPD Filter Set® (Millipore Co.):* A filter is placed in the line conveying dialysate to the peritoneum to remove bacteria or fungi that may have contaminated the system during "spiking." Each filter is designed for 2 weeks of use.
- *CAPD UV Germicidal System® (Travenol Laboratories, Inc.):* Ultraviolet light is used to sterilize the connection between the dialysate bag and the catheter or its extension. This system improves sterile technique but does not eliminate the need for the manual "spiking" procedure.

Although each of these approaches has promise, none has yet been shown to actually reduce peritonitis rates in properly controlled studies.

Two other relatively infrequently used techniques for peritoneal dialysis deserve mention:

- *Intermittent Peritoneal Dialysis (IPD):* This technique is similar in principle to CAPD but involves intermittent dialysis sessions of up to 10 hours each 3 or 4 days a week during which dialysate exchanges are cycled at rates of about 2 liters per hour. Schedules are highly individualized to the needs of the individual patient.
- *Continuous Cycling Peritoneal Dialysis (CCPD):* CCPD is very similar to CAPD but employs a machine that permits continuous dialysate exchanges to be performed automatically during sleep. Dialysate volumes of 10 liters or more are cycled, but not more than 2 liters are in the abdominal cavity at any one time. This technique obviates the inconvenience of multiple daily exchanges and may reduce the risk of peritonitis.

COMPARATIVE EFFICIENCY OF DIALYSIS BY HEMODIALYSIS AND CONTINUOUS AMBULATORY PERITONEAL DIALYSIS

Table 3-1 provides comparisons between the efficiency of dialysis by HD, CAPD, and IPD as measured by urea clearance (ml/min) and weekly urea clearance (L/week). The results are from a single study (29) and are based on the dialysis requirements of a 70 kg individual with a urea gen-

Table 3-1.-Strategies for Solute Removal With Hemo- or Peritoneal Dialysis to Maintain Average BUN = 80 mg/dl[a]

Method of dialysis	Urea clearance during treatment (ml/min)	Treatment (hr/wk)	Urea clearance (L/wk)
Hemodialysis	150	15	135
Intermittent peritoneal dialysis	22	64	85
Continuous cycling or continuous	35	40	85
ambulatory peritoneal dialysis	7	168	70

[a]BUN (Blood Urea Nitrogen). The source from which this table was taken does not make the distinction between a time averaged BUN and predialysis BUN for patients receiving hemodialysis. Lowrie indicates that a predialysis BUN of 60 mg/dl is equivalent to an average BUN of 50-60 mg/dl in patients being treated with hemodialysis.

SOURCE: A. S. Levy and J. T. Barrington, "Continuous Peritoneal Dialysis for Chronic Renal Failure," *Medicine* 61:330-339, *1962.*

eration rate of 5.7 mg/min and no residual renal function. Other studies provide similar, though not identical, findings.

HD is the more efficient method of dialysis. Urea clearance per unit of time by HD is twice that of two normal kidneys and more than 20 times that with CAPD. Because dialysis treatment time with CAPD (168 hours per week) is much longer than that with HD (9 to 15 hours per week), the weekly urea clearance by CAPD is slightly *over* half that provided by HD (70 vs. 135 L/wk).

Controversy is brisk over whether the amount of dialysis provided by CAPD is clinically adequate, since it is less than that provided by HD as measured by urea clearance (30). This controversy, in large part, is related to uncertainty over the nature of the toxic substances responsible for the signs and symptoms of the uremic state. Nephrologists who believe that urea clearance serves as an appropriate marker for the removal of other toxic substances point to the greater efficiency of HD, while other nephrologists who believe that "middle molecules" are important emphasize the greater ability of CAPD to remove these substances and downplay implications of differences in urea clearances. As of this writing, this controversy is unresolved.

Chapter 4

Clinical Effectiveness of Continuous Ambulatory Peritoneal Dialysis and Hemodialysis

Chapter 4

Clinical Effectiveness of Continuous Ambulatory Peritoneal Dialysis and Hemodialysis

Comparison of the effectiveness of chronic dialysis modalities requires information from controlled trials that involve patients with similar clinical characteristics. To date no such trials have been performed. In their absence, this case study takes information from reported clinical observations to draw qualitative conclusions on the relative effectiveness of continuous ambulatory peritoneal dialysis (CAPD), home hemodialysis (HD), and center HD. Further, the influence of case-mix differences on clinical outcomes is assessed from those few studies that have retrospectively examined the influence of patient characteristics on medical outcomes.

Patient survival is undeniably the central measure of treatment effectiveness in end-stage renal disease (ESRD). Chronic dialysis techniques (and renal transplantation) have markedly enhanced survival in patients with ESRD. Survival alone is an inadequate yardstick, however, and factors that relate to quality of life on dialysis also need to be considered. To this end, the following factors are examined in addition to survival: the ability of the patient to tolerate and remain on a dialysis modality (referred to as "procedure survival"), morbidity as measured by complication rates and the need for hospitalization, and proxies for the "quality of life" such as physical activity levels and ability to return to work. The "burden of treatment" as perceived by the patient and his or her family is also important, especially for a chronic illness such as ESRD. Information on this point is extremely limited, however.

PATIENT SURVIVAL

Tables 4-1, 4-2, and 4-3 present survival data for patients receiving CAPD or HD. Where possible, the differences between center HD and home HD are distinguished. All results are unadjusted for differences in the duration of ESRD, age, or other risk factors. Furthermore, these results do not account for the effects of varying actuarial methods. Overall, l-year survival on CAPD ranges from 74 percent in the Registry of the European Dialysis and Transplant Association (EDTA) (28) to 86 percent in the most recent results from the National Institutes of Health (NIH) CAPD Registry (46) (table 4-l). Single institution studies give higher figures, perhaps due to special local expertise or patient selection factors. Two-year survival on CAPD in the EDTA registry is 60 percent, while 2 year data had not been reported by the NIH CAPD Registry by 1983.

Survival estimates for HD are from ESRD program enrollees (27), the Michigan Kidney Registry (50), and the EDTA Registry (51) (table 4-2). In the ESRD program, survival on chronic dialysis was reported as 81 percent at 1 year and 56 percent at 3 years, but this report did not break results down by dialysis modality. It can be assumed that, in the period 1977-80 to which the results apply, the overwhelmingly dominant modality was HD and that the ratio of center HD to home HD was about 9 to 1. The Michigan Kidney Registry survival rates of 78 percent at 1 year and 61 percent at 2 years are for center HD alone,

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Table 4-1.—Patient Survival and the Ability of Patients to Continue CAPD

				Patient survival			Continued on CAPD[b]		
Source[a] and population	Calendar year(s)	Number of patients	Patient-years	0.5 yr	1 yr	2 yr	0.5 yr	1 yr	2 yr
Nolph, et al., 1983 (NIH CAPD Registry). .	1981	567	320	930/0	900/0	—	79%0	600/0	—
NIH CAPD Registry, 1982	1981-82	4,858	—	93	86	–	76	62	56 (18 mo)
							88	82	76 (18 mo)[c]
Kramer, et al., 1982 (EDTA Registry)	1979-81	2,905	—	80	74	60	53	41	28
							62	53	46[c]
Oliver, 1983 (Churchill Hospital, Oxford) .	1978-82	126	124	91	86	80	72	57	38
Rubin, 1983	1979-81	56	—	—	—		80	50	35
Amair, 1982[d]	1978-81	20	24	—	92	81	—	87	76
Baum, 1983[e]	1979-82	20	—	95	95	95	78	78	53

[a] Full citations found in the References.
[b] Refers t. th. percent of the initial cohort who remain on CAPD. Hence, the denominator includes deaths and patients undergoing transplantation, as well as patients who change from one dialysis modality to another.
[c] Percent of patients still on chronic dialysis who remain in CAPD. Excludes deaths and transplants.
[d] All patients were diabetics.
[e] Patients were children with a mean age of 11.9 years. The mean period of observation was 0.95 years.

SOURCE: Office of Technology Assessment

Table 4-2.—Patient Survival on HD

Source[a] and population	Calendar years	Dialysis modality	Number of patients	Survival 1 yr	2 yr	3 yr	Comment
Krakauer, et al., 1983. .	1977-80	Predominantly HD	65,270	81 0/0	—	56°/0	ESRD program enrollees beginning dialysis in 1977-80. Results overestimate survival in ESRD, because they exclude deaths during the 3-month period following diagnosis before the patient becomes eligible for enrollment in the ESRD program. The vast majority (98+ °/o) of patients would have been on home or center HD in these years in an approximate ratio of 10:90
Weller, et al., 1982 (Michigan Kidney Registry)	1974-78	Center HD only	1,560	70.80/o	53,20/o	—	Actuarial survival curves were calculated separately for patients on center HD only and all patients on center HD including those subsequently transplanted or changed to another dialysis modality
		All center HD	2,396	78.1	61.2		

[a]Full citations found in the References.

SOURCE' Office of Technology Assessment

Table 4.3.—Comparisons of Patient Survival on CAPD and HD

Source[a] and population	Calendar years	Dialysis modality	Number of patients	Survival 1 yr	Comments
Wing, et al., 1983 (EDTA Registry)	1979-81	HD	–	840/o	Results apply to a low-risk "standard population" ages 20 to 60. Reference does not specify whether HD was in the home or in a center
		CAPD	–	78	
Bovbjerg, et al., 1983 (ESRD program)	1981	Home HD	109	91	ESRD program enrollees who began dialysis between 1/1/81 and 3/31/81. The reference does not state whether survival rates are annualized or merely refer to survival in calendar year 1981 following enrollment
		Center HD	2,929	86	
		CAPD	174	87	

[a]Full citations found in the References.

SOURCE' Office of Technology Assessment.

and the EDTA Registry reported an 84 percent 1-year survival on HD in a low-risk "standard population."

First-year survival after the 3-month preenrollment period required by the ESRD program is greater in patients on home HD (91 percent) than for those on CAPD or center HD (87 and 86 percent, respectively) (8) (table 4-3). The better result in the home HD group is consistent with other reports and has been attributed to the selection of younger and healthier patients for home HD.

On balance, these results suggest that early survival on CAPD is equivalent to that on HD. This conclusion must be considered tentative, however, because studies of HD generally apply to earlier time periods, and because none of these studies takes into account the characteristics of the populations being dialyzed.

ABILITY TO CONTINUE ON A DIALYSIS MODALITY

The ability of a patient to remain on a dialysis modality over a prolonged period of time is important both because failures usually reflect treatment-related morbidity and because the cost of treating complications or changing modalities may be considerable.

For this study, systematic information on abandonment rates for HD was unobtainable. For example, no recent reports from sizable patient populations or registries could be found that described the frequency of transfer from HD to peritoneal dialysis or to cadaveric renal transplantation because of vascular access or other complications of dialysis. That failure rates of HD may be appreciable, however, can be inferred from the NIH CAPD Registry results that indicate that, among patients beginning CAPD between January 1, 1981, and March 31, 1982, 48.3 percent had previously received HD (table 4-4). Presumably, these patients either had vascular access problems, or for some other reason, preferred to change to CAPD.

Abandonment rates of patients on CAPD, on the other hand, have been well documented (table 4-1), and in fact, constitute the main argument against its proliferation. Patients still on CAPD after 1 year range from 41 percent in the European experience (28) to 62 percent in the 1983 report from the NIH CAPD Registry (46). The corresponding 2-year rate is 28 percent in Europe, and the 18-month rate is 56 percent in this country (28).

Calculation of abandonment rates depends importantly on whether elective transfers, deaths not directly related to procedure complications, transplanted patients, and patients who spontaneously recover renal function are counted in the population at risk. Hence, results must be examined closely. The above figures include in the denominator all patients starting on CAPD regardless of the reason for departure. Therefore, they significantly overestimate departures for reasons of procedure-related morbidity alone. When deaths and transplanted patients are removed, 1-year continuation rates for CAPD become 53 and 82 percent for the European and U.S. experiences, respectively.

Excessive peritonitis or noncompliance was the reason given for discontinuing CAPD in 27 percent of patients in the NIH CAPD Registry, and peritonitis alone was the reason in 50 percent of those in EDTA (see table 4-5). Inability to control "fluid/chemistry" or inadequate dialysis was the reason given for 12 and 10 percent of patients in these two registries, respectively.

Table 4-4.—Prior Treatment Modalities in Patients Entering the NIH CAPD Registry

Prior treatment	Number of patients	Percent
Hemodialysis	1,225	48.30/o
None	749	29.5
Intermittent peritoneal dialysis	483	19.0
Transplant	61	2.4
Continuous cycling peritoneal dialysis	20	0.8
Totals	2,538	100.0%

SOURCE: U.S. Department of Health and Human Services, National Institutes of Health, "CAPD Patient Registry Patient Population Demographics and Selected Outcome Measures, " Report No. 82-83, July 1, 1983.

Table 4-5.—Reasons for Leaving CAPD Other Than Transplantation or Return of Renal Function

Reason	Number of patients	Percent
NIH CAPD Registry:[a]		
Medical (not lack of fluid or chemical control)	257	39%0
Noncompliance or excessive peritonitis	176	27
Patient or family choice	101	16
CAPD not able to control fluid/chemistry	80	12
Other	30	5
Socioeconomic	8	1
Totals	652	100%
European Dialysis and Transplant Association (EDTA):[b]		
Peritonitis	153	50%
Other abdominal	43	14
Inadequate dialysis	31	10
Inability to cope	28	9
Other	28	9
Patient's request	22	7
Family's request	3	1
Totals	308	100%0

aU.S. Department of Health and Human Services, National Institutes of Health, "CAPD Patient Registry Patient Population Demographics and Selected Outcome Measures," Report No. 82-83, July 1, 1983.
bp. Kramer, M. Broyer, F. P, Brunner, et al., "Combined Report on Regular Dialysis and Transplantation in Europe, XII, 1981 ," presented at the XIXth Congress of the European Dialysis and Transplantation Association, Madrid, Spain, September 1982.

Better information on failures of HD will be required to permit valid comparisons with CAPD. Nonetheless, the high failure rates on CAPD give rise to justifiable concern that needs to be addressed through a combination of better patient selection, better patient training, and improved sterile techniques.

PATIENT MORBIDITY

Hospitalization Rates

Comparison of hospitalization rates indicates that patients receiving CAPD are hospitalized about 20 days per patient-year (range 19.7 to 23.2 days); those on center HD about the same or somewhat less (19.3 and 13.4 days in two studies); and patients on home HD about 9 days per patient-year (tables 4-6 and 4-7). About half of hospital stays in patients on CAPD were for complications of treatment, especially peritonitis, and the rest were for a variety of medical problems (33,51). No population-based data comparable to those in the NIH CAPD Registry are available for HD in the United States.

Although they are useful benchmarks, these crude hospitalization rates provide only a tentative basis for comparing morbidity among dialysis modalities. Most important, they do not account for differences among the treated populations that may influence the need for hospitali-

Table 4-6.—Hospitaiization Rates by Dialysis Modality

Source[a] and population	Calendar year	Number of patient-years	Days of hospitalization per patient-year			
			Center HD	Home HD	CAPD	Home IPD
Blagg and Wahl, 1983[b] (Northwest Kidney Center) . .	1982	430	19.3	9.2	19.7	26.3
Evans, 1983 (National Kidney Dialysis and Kidney Transplantation Study).	1981	859	13.4	8.2	20.6	—

[a]Full citations found in the References.
[b]Updated hospitalization rates areas follows: CAPD—16.2 days/pt-yr; center HD—9.1 days/pt-yr; home HD—9.1 days/pt-yr; and IPD—28.1 days/pt-yr. (C. Blagg, Personal communication, 1983).

SOURCE: Office of Technology Assessment.

Table 4-7.—Hospitalization and Complication Rates in Patients on CAPD

Source[a] and population	Calendar year(s)	Hospitalizations per patient-year			Complications per patient-year		
		Number	Admissions	Days	Peritonitis	Exit or tunnel infections	Catheter replacement
Nolph, 1983, (NIH CAPD Registry)	1981	567	2.5	25.9	2.0	0.7	0.4
NIH CAPD Registry, 1982	1981-82	4,858	—	23.2	1.8	0.7	0.3
Kramer, 1982	1981	895	—	—	0 41.80/o 1-3 49.7 4-6 7.0 >6 1.5	—	—
Wing, et al., 1983[b] (EDTA)	1981	1,504	—	20	Males 1.4 Females 1.6	—	—
Oliver, 1983 (Churchill Hospital, Oxford).	1981-82	126	—	—	1.6	—	—
Amair, et al., 1982[c].	1978-81	20	–	–	0.6	—	—

[a]Full citations found in the References.
[b]Figures are for a "standard population" that includes only patients 20 to 60 years of age, without diabetes, malignancy, or other severe systemic illness, Or a primary diagnosis of ESRD having systemic disease implications (e.g., collagen disease).
[c]All patients were diabetics.

SOURCE: Office of Technology Assessment.

zation. The shorter periods of hospitalization experienced by patients on home HD, in particular, have been attributed to favorable patient selection factors. Age is one such factor, and the existence of comorbid conditions is another.

Furthermore, interpretation of hospitalization rates requires consideration of the length of time patients have been on a dialysis modality. For example, annualized hospitalization rates are considerably higher during the first 3 months of CAPD than in subsequent months. These higher rates reflect the hospital days required to initiate dialysis, the fact that patients starting out on dialysis are usually ill and require time to stabilize prior to discharge, and the days for treatment of complications that occur early in the course of dialysis. The same considerations apply to HD. A comparison of annualized days of hospitalization between two groups of patients which differ only in the proportion of patients beginning on dialysis would indicate a deceptive differential.

Finally, interpretation of reported hospitalization rates is complicated by methodological problems, including differences in the criteria used for including a patient in the study and differences in the method for dating the onset of dialysis. For example, a criterion that requires a patient to be on a dialysis modality for *30* days to qualify for entry into a study will result in a different casemix from one that counts all patients started on a dialysis modality regardless of the duration of treatment.

Complications of Dialysis

Many patients on chronic renal dialysis have underlying medical problems such as hypertension, diabetes, and cardiovascular disease. Some treatment complications, therefore, may be more accurately regarded as part of a preexisting disease process than as a consequence of the treatment itself. Patients with ESRD due to diabetic nephropathy, for example, are at a higher than normal risk of developing cerebrovascular disease and suffering strokes. A high incidence of such a complication should be attributed at least in part to the diabetic disease process rather than to the specific technique of dialysis. Treatment complications, as other health outcomes, therefore, must be examined in the context of the population treated.

Complications of Hemodialysis

Complications of HD can be broadly classified into those occurring during dialysis, complications related to vascular access, and late complications seen in chronically treated patients. Although all are well known to occur, systematic data describing their frequencies could not be found for this case study.

The intermittent nature of HD and its efficiency as a method of dialysis can cause fluctuations in vascular-volume and serum chemistries that may lead to hypotension or cardiac arrhythmias or make hypertension more difficult to control. Associated shifts in central nervous system fluid balance have been alleged to contribute to some of the neurological symptoms that have been observed.

Extracorporeal circulation of the patient's blood through the dialyzer traumatizes and causes some destruction of red blood cells. Although' usually not serious, this red cell destruction, coupled with the loss of residual blood left in the dialyzer, blood loss due to numerous laboratory tests, and occasional blood leakage through the dialysis membrane, may aggravate the anemic state in ESRD. Blood transfusions occasionally are needed, and they increase the risk of serum hepatitis.

Patients are usually given the drug heparin during center HD to prevent coagulation of blood as it circulates extracorporeally. Careful medical supervision is required to restore normal coagulation as the blood returns to the body to minimize the risk of internal hemorrhage. This appears to be particularly important in diabetic patients who may be prone to ocular hemorrhages when repeatedly given anticoagulant drugs. Patients on home HD rarely receive heparin, because of the meticulous monitoring that is required.

There have been several deaths reported to have resulted from failures of the temperature regulating devices in the dialysis equipment. Clearly, equipment failures represent another potential complication of HD.

Vascular access is an absolute requirement of HD. The subcutaneous arteriovenous fistulae that are created for this purpose are subject to thrombosis and, rarely, to septic complications from repeated needle punctures. Replacement or transfer of the fistula to another site maybe required, and eventual depletion of convenient anatomical sites may necessitate change to another dialysis modality or renal transplantation. Access difficulties are only rarely encountered in young adults but are more likely in older patients with arteriosclerotic vessels and in diabetics. Children are also at higher risk of this complication because of the smaller sizes of their blood vessels.

The development of cardiovascular morbidity including myocardial infarctions, cerebrovascular accidents, and advanced peripheral vascular disease in patients on HD may result from the progression of preexisting disease, but at least circumstantial evidence suggests that the pace of these disorders may be accelerated by HD. Similarly, some reports attribute the occurrence of dementia to the presence of excessive amounts of aluminum in the dialysate. The possible importance of aluminum in antacid preparations taken by patients with ESRD also needs to be further evaluated.

Finally, the patient's dependence on a machine and reliance on the services of others when on HD, together with his/her awareness of social, parental, and conjugal inadequacies have been implicated as causes of severe depression and occasional suicides reported in patients on chronic HD.

Complications of CAPD

Peritonitis, or infection of the abdominal cavity, is far and away the most important complication of CAPD. The average patient in the NIH CAPD Registry suffered 1.8 episodes of peritonitis per patient-year (table 4-7), even though one-third of patients had no episodes during their first year of treatment **(46).** Peritonitis led to an average of slightly more than 10 days of hospitalization per patient-year and to occasional deaths. If detected and treated early, in some cases, peritonitis may be treated at home and cause minimal morbidity.

Peritonitis often results from a failure of the patient to adhere strictly to sterile procedures in effecting dialysate exchanges. Inadequate understanding of what is required, impaired manual dexterity, poor vision, and poor or inconsistent motivation all may be contributing factors.

A variety of approaches have been tried to improve CAPD techniques and to reduce the risk of peritonitis *(10,21,35,44).* To date, there is no evidence that the rates of the disease have been materially affected.

Reported peritonitis rates must be interpreted with caution because of widely varying definitions of what constitutes an episode. The presence of symptoms and signs such as fever and abdominal pain, cloudy dialysate effluent, a white cell count greater than 100 per cubic millimeter in the effluent, or a positive culture for bacteria, fungi, or other infectious agents all have been used individually or collectively. Causative organisms include a wide variety of bacteria and fungi **(3,25, 36,41,46).**

A second complication of CAPD has been infection of the subcutaneous tunnel in which the peritoneal catheter lies. Treatment with antibiotics or replacement of the catheter may be required. The NIH CAPD Registry indicates that these "exit or tunnel infections" occur an average of *0.7* times per patient-year (table 4-7).

Leakage of fluid around peritoneal catheter, obstruction to flow of dialysate in or out of the abdomen due to adherent organs or fibrous adhesions, inadequate circulation of the dialysate throughout the peritoneal cavity, adhesions, deep pelvic pain, intestinal obstruction, and perforation of neighboring abdominal viscera are additional reported complications of CAPD *(23,40).* For one reason or another, catheter replacement is required *0.3* to *0.4* times per patient-year (table 4-7).

In some patients, the peritoneum may undergo chronic changes during CAPD that reduces its effectiveness as a dialyzing membrane *(48).* These changes are incompletely understood at the present time, but many cases have been reported in which dialysis efficiency decreased over a period of months (19). Moreover, during acute peritonitis, changes in the vascularity and dialyzing characteristics of the peritoneum may require alteration in the dialysis regimen or temporary discontinuation of CAPD. Usually this is required only if the infection is severe or resistant to antibiotic treatment.

Several metabolic effects of CAPD require mention even though they do not necessarily constitute complications. CAPD results in the loss of 8 to 10 grams of protein per day into the dialysate, more than half of which is albumin (6,7, 18,26). Hence, protein depletion can become a clinically important problem unless dietary intake compensates for this loss. Daily diets of 1.2 to 1.5 grams of protein per kilogram of body weight have been recommended (18) and generally can be achieved. A second metabolic effect of CAPD is weight gain due to absorption of glucose from the dialysate. This high carbohydrate intake also may induce elevation of serum triglycerides in susceptible patients, and potentially, accelerate atherogenesis. These metabolic effects require further study.

A variety of abdominal hernias have developed in patients on CAPD due to increased pressure created in the abdominal cavity by the dialysate. Preexisting weakness of the abdominal wall and poor muscle tone are predisposing causes, and women and older men seem especially prone to this complication. In one report involving 51 patients, 12 hernias were observed, but only 7 of these developed after the start of CAPD (40a). Other studies have reported up to an 11 percent incidence of abdominal hernias, many of which developed at the site of the peritoneal catheter insertion (17). Rarely, a hiatus hernia has been noted to develop or increase in size during CAPD.

Pleural effusions may occur even in the absence of any obvious opening in the diaphragm, presumably due to fluid transfer through transdiaphragmatic lymphatic and other pathways (31, 42,43).

Other rare complications include: the development of ascites, dialysate draining from the vagina, uterine prolapse, rectocystocoeles, hemorrhoids, and chronic low back pain.

QUALITY OF LIFE ON DIALYSIS

Enthusiasm for the benefits of chronic renal dialysis in terms of improved survival must be tempered by the imperfect ability of treatment to free the patient from the symptoms of uremia, to ensure full participation in desired physical and social activities, and to maintain normal economic productivity. Even individuals who have undergone successful renal transplants do not lead normal lives, and patients on chronic dialysis are even more restricted. An important consideration is whether patients with ESRD may place less value on future years of life than healthy persons do and much greater value on the near-term balance between life's satisfactions and the frustrations of chronic illness and its treatment. Stated in economic terms, the pragmatic discount rate the patient intuitively applies to a life dominated by ESRD maybe so large that differences in survival may be given little weight in decisions about therapeutic choices. Although difficult to quantify, this tradeoff between future years of life and the present quality of life is a very real one that must be faced in any realistic evaluation of treatments for ESRD.

Available information does not definitively support one or another dialysis modality as being superior in terms of the ensuing quality of the patient's life on dialysis. Individuals' values vary widely, and it is probable that selection factors play a decisive role. Several studies do provide some useful insights, however (13,14,20,24).

These studies all focus on relatively objective measures of the quality of life, including the degree of functional impairment the patient experiences and his or her employment status. More subjective phenomena such as satisfaction with life, the sense of well-being, the relative value of different activities, and the perceived burden of treatment (physician visits, machine dependency, ritualism) on the patient and the family have received less attention.

Gutman (20) evaluated 2,481 patients on chronic HD in selected facilities and found that only *60* percent of nondiabetics and only *23* percent of diabetics were “normally active, ” while 21 and 51 percent, respectively, were severely debilitated or moribund. Of the nondiabetics, only 34 percent were employed full-or part-time, and 14 percent worked at home. Return to full- or part-time employment depended importantly on pretreatment employment status, and while 55 percent of patients with a previous skilled job returned to work, only **27** percent of those with an unskilled job and 16 percent of those who were previously unemployed did so.

Johnson’s study *(24)* provides complementary information by comparing quality of life measures of patients on chronic HD with those patients who either were awaiting a first transplant, had had a successful transplant, or had a failed transplant. Patients on chronic dialysis were more likely to feel tired, engaged in fewer physical activities, were less sexually active, and felt more tied down by their treatment than did patients with successful transplants. They were also less likely to be employed full-time or do full-time housework.

A summary of studies reporting employment status in ESRD patients compiled by Evans (13) is presented in table 4-8. Results vary widely. Differences no doubt reflect variations in casemix, prior employment status, definitions of what constitutes full- or part-time employment, dialysis modality, and quality of ESRD treatment.

The National Kidney Dialysis and Kidney Transplantation Study is the first attempt to directly compare quality of life measures among different dialysis modalities and transplantation. Information is currently available only for functional impairment and current employment status, although future publications will evaluate differences on subjective and psychological measures as well. Table 4-9, which is adapted from a report of this study, indicates that fewer patients on center HD and CAPD were “able to carry on normal activities and to work” *(67* and 71 percent, respectively) than home HD patients (83 percent) or successful transplant (88 percent). Patients on CAPD were less likely to be employed (16 percent) than those on center HD **(24** percent), home HD **(40** percent), or those who had had a successful renal transplant (54 percent). These differences are impressive until they are adjusted by multiple regression analysis for differences among populations in age, sex, education, and perceived health status. After adjustment, the employment rate of patients on CAPD was still lower than on

Table 4-8.—Summary of Studies of the Employment Status of ESRD Patients

Study reference	Year	Number of patients	Place of Dialysis	Employment status: Full-time	Part-time	Not employed
Baillod, et al.	1969	60	Mostly at home	920/o		
Cameron, et al.	1970	24	Facility	77%		
		25	Home	920/o		
Pendras and Pollard	1970	110	Home	73%	240/o	3%
Strauch, et al.	1971	178	Facility	28.90/o		71.1%
Freyberger	1973	48	Facility	550/0	240/o	21"!0
Reichsman and Levy	1972	25	Facility	560/o		44%
Malmquist	1973	17	Facility	47 "/0		53%
Foster, et al.	1973	21	Facility	47 "/0		53%
Cadnapaphornchoi, et al.	1974	41	Home	31 .9 "/0	31 .60/0	36.50/o
Kaplan DeNour and Czaczkes	1976	95	Facility	28.40/o	36.80/o	34.70/0
Disney and Row	1974	300	Facility	51 .2 "/0	31.4%	17.4"!0
		123	Home	81 .30/0	10.40/0	8.30/o
Brunner, et al.	1976	9,000	Facility	36.80/o	30.80/o	32.40/o
		2,500	Home	68.00/0	16.8 "/0	15.20/.
Bryan, et al.	1978	3,462	Facility	5.7%	7.1 "/0	87.20/o
		1,198	Home	20.8%	10.3 "/0	68.9%
Tews, et al.	1980	227	Hospital	23.00/o	27.00/o	50.0 "/0
		65	Limited care	40.00/0	20.0%	40.0%
		190	Home	56.00/o	19.0"/0	25.00/o

SOURCE: The full citations of the studies can be found in R. W. Evans, “Health Services Utilization and Disability Days: Indicators of the Quality of Patient Care Among ESRD Patients,” ***Battelle Human Affairs Research Centers Update No 18,*** Jan. 6, 1983,

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Table 4-9.—National Kidney Dialysis and Kidney Transplantation Study: Functional Impairment and Current Employment Status by Type of Dialysis (unadjusted for differences in case-mix)

Condition	Percent in category			
	Home HD	Center HD	CAPD	Transplant
Functional impairment (Karnofsky Index)[a]:				
Able to carry on normal activity and to work. No special care is needed	83%	67%	71%	88%
Unable to work. Able to live at home and care for most personal needs. A varying degree of assistance is needed	16	26	26	12
Unable to care for self. Requires equivalent of institutional or hospital care. Disease may be progressing rapidly	2	7	3	0
Totals	101%	100%	100%	100%
Work disability—current employment status[b]:				
Employed full-time or part-time or seeking employment	40%	24%	16%	54%
Unemployed or unable to work because of health (disabled)	37	49	55	28
Homemaker	12	10	11	13
Retired	8	16	16	1
Student full-time	4	1	1	5
Totals	99%	100%	99%	101%

[a]Adapted from: R.W. Evans, "Functional Impairment, Work Disability, and the Availability and Use of Rehabilitation Services by Patients With Chronic Renal Failure," *Battelle Human Affairs Research Centers Update* No. 16, December 20, 1982.
[b]Adapted from: R. W. Evans, "Health Services Utilization and Disability Days: Indicators of the Quality of Patient Care Among ESRD Patients," *Battelle Human Affairs Research Centers Update* No. 18, Jan. 8, 1983.

center HD but only marginally so. Inclusion of previous employment status might have affected comparisons even more.

The National Kidney Dialysis and Kidney Transplantation Study is an important one. It is cross-sectional, however, and relies primarily on self-reported information. A prospective, longitudinal study will be required to confirm and extend its findings.

Burden of Treatment

Some argue that the quality of life maybe better on CAPD than on HD because of the freedom it permits from chronic symbiosis with a machine and its relatively flexible schedule of treatments. On CAPD, dialysate exchanges can be performed at the convenience of the patient, while HD sessions must be scheduled in advance with the dialysis center. CAPD, however, imposes the burden of performing four or five daily exchanges, each of which requires meticulous attention to sterile technique. Center HD, on the other hand, frees the patient from responsibility for successful dialysis and places this responsibility on the professional staff. Home HD lies between CAPD and center HD by permitting more flexibility in scheduling dialysis sessions. It encourages self-responsibility, but at the cost of machine dependency and the need for considerable support by family of home health aides. Clearly, tradeoffs exist, and different value judgments on the part of the patients will favor one method of treatment or the other. The physician often plays an important role in clarifying these choices and helping the patient through a perplexing and unfamiliar decision process.

EFFECTS OF CASE= MIX DIFFERENCES ON THE OUTCOMES OF CHRONIC DIALYSIS

Whether patient survival, hospitalization or complication rates, the quality of life, or some combination is used as the outcome measure of interest, patient characteristics may have a profound influence on results. Some characteristics, such as age and the presence of diabetes, will affeet several of these outcomes regardless of the modality of treatment. Other patient characteristics, however, may be treatment specific in the sense that they adversely affect outcomes on one type of treatment but not on another. Socioeconomic and psychological characteristics of the patient also may be critical determinants of success. Differences in patient characteristics *must* be taken into account if valid comparisons between treatment modalities are to be achieved.

All studies cited thus far in this case study were uncontrolled. They were performed in populations that differed widely in age, sex, race, comorbidity, and prior treatment for ESRD. Also, the calendar years of treatment varied, and undoubtable, so did the techniques and quality of treatment. Only the NIH CAPD and EDTA Registries report annual results from broadly representative populations of patients and providers. Other studies are either series of patients from single institutions or from selected multiple institutions and involve potential biases in patient selection and in the selection of "better" institutions and providers.

A randomized clinical trial would be the most definitive approach to resolving controversy over the relative merits of different treatment modalities for ESRD. In the absence of such a study, the best that can be done is to examine available information critically in an attempt to make the comparisons among studies more valid. '

Characteristics of ESRD Populations

Tables 4-10, 4-11, and 4-12 summarize the characteristics of patients in three distinct but overlapping ESRD populations: those enrolled in the NIH CAPD Registry, those who enrolled in the ESRD program early in 1981, and those sampled in the National Kidney Dialysis and Kidney Transplantation Study. All three studies include patients on CAPD. The age, sex, and race distributions of patients on CAPD in the three reports are very similar. Information on primary ESRD diagnosis and comorbidity is variable, however.

The two studies that compare CAPD to home HD and center HD reveal several important differences in the characteristics of populations treated (tables 4-11 and 4-12):

- Patients on center HD are, on average, slightly older than those on CAPD and definitely older than those on home HD.

Table 4-10.—NIH CAPD Registry: Characteristics of CAPD Population Enrolled in the NIH CAPD Registry in 1981 and 1982

Size of population	4,858
Demographics:	
Age:	
<20 yr.	5%
20-39	25
40-49	15
50-59	25
60-69	22
70+	9
	101%
Race:	
White	77 "/0
Black	16
Other	7
	100 "/0
Sex:	
Male	57 "/0
Female	43 "/0
	100 "/0
Primary diagnosis:	
Diagnosis available in	66 "/0
When diagnosis available:	
Glomerulonephritis	23
Diabetic nephropathy	19
Hypertensive renal disease	17
Polycystic kidney disease	8
Chronic pyelonephritis	4
Systemic immunologic diseases	3
Interstitial nephritis	3
Obstructive uropathy	3
Rapidly progressive GN	2
Miscellaneous	12
Unknown	6
	100 "/0

SOURCE: U.S. Department of Health and Human Services, National Institutes of Health, "CAPD Patient Registry Patient Population Demographic and Selected Outcome Measures," Report No. 82-83, July 1, 19S3.

- Patients on CAPD or home HD are much less likely than center HD patients to be black.
- The proportion of patients on home HD who are male is much higher than that on the other types of dialysis.
- The proportion of patients with diabetes is higher in the CAPD population than in the center HD or home HD populations.

Implications of Differences in Patient Characteristics for Health Outcomes

If the population differences noted above were generally applicable to patients on dialysis, what would be their impact on the outcomes of treatment? Several recent studies address this question by examining the individual effects of age, sex,

Table 4.11.—Patients Beginning Chronic Dialysis in 1981 Under the ESRD Program

	CAPD	Home HD	Center HD
Size of population	174	109	***2,929***
General demographics:			
Mean age (yr)	51	47	55
Race (o/o):			
Black	17	13	27
White	78	84	67
Other	3	2	3
Sex (0/0):			
Female	49	29	*42*
Male	51	71	*58*
Medical diagnosis recorded (Al")	69	72	67
When diagnosis available (o/o):			
Diabetes (10 or 2°)	36	14	24
Hypertension (10 or 2°)	72	70	71
Malignant disease, past or present.	2	1	6
Number of associated diseases present:			
1	25	35	25
2-4 : : : : : : : : : : : : : : : :	39	43	46
5+	30	18	24
First year outcomes:			
Died (o/o)	13	9	14
Hospitalization:			
Hospitalized (o/o). . . .	71	55	***56***
Hospital days	22	15	***16***
Hospital stays	1.7	1.3	***1.2***

SOURCE: R. R. **Bovbjerg**, L. H. Kiamond, P. J. Held, and M. V. **Pauly**, "Continuous Ambulatory Peritoneal Dialysis: Preliminary Evidence in the Debate Over Efficacy and Cost," ***Health Affairs*** 96-102, summer 1983, Includes only patients whose "first dialysis was in the period from **January-March** 19S1 ." The paper did not state whether the 3-month waiting period prior to eligibility for the **ESRD** program was taken into account. Nor did it state whether first year outcomes were annualized or limited to calendar year, 1981.

race, primary diagnosis of ESRD, or comorbidity on patient survival (5,11,22,27):

- *Age:* Patient survival unequivocally and importantly is influenced by age. The magnitude of the age effect is exemplified by the survival statistics from the ESRD program *(27):*

	Survival	
Age (years)	l-year	3-year
11-20	95%	88%
21-30	91%	78%
31-40	89%	71%
41-50	88%	68%
over ***50***	***77%***	***48%***

  Older patients also have markedly higher rates of hospitalization even in the absence of renal disease (45).

- Cause of *ESRD:* Patients with ESRD due to diagnoses of diabetic nephropathy or primary hypertensive disease experience poorer survival than patients with glomerulonephritis.
- Comorbidity: Survival is adversely influenced by the number of coexisting serious diseases such as ischemic heart disease, prior myocardial infarction, hypertension, congestive heart failure, or complications of diabetes.
- Sex and *Race:* The effects of race and sex appear to be small and inconsistent. The finding that black individuals with primary hypertension seem to survive better than their white counterparts is interesting, but may be explained by age or comorbidity differences.

The above results describe only the relationship between a single patient characteristic and survival. Determination of the relative importance of various characteristics in combination, however, is obviously critical if case-mix differences are to be removed from outcome measures in order to permit valid retrospective comparisons between treatment modalities.

A limited number of published studies address this issue in multivariate analyses. In one, Vollmer found striking independent effects on survival of age and the number of associated diseases at the inception of treatment (49). In another, Hutchinson demonstrated significant effects of age, duration of diabetes, and presence of left-sided heart failure on survival (22). These studies offer some important insights and, hopefully, will stimulate further similar efforts.

Finally, "time to treatment bias" or "time-dependence" *(50)* may exert important effects on comparisons among dialysis modalities or between dialysis and transplantation over and beyond those created by differences in patient characteristics. ESRD treatment begins at the time of diagnosis and often involves several sequential treatment modalities. A patient must survive a period of dialysis, for example, before he or she can receive a transplant or may have survived a period of HD before being transferred to CAPD. In either case, survival experience on the prior treatment must be taken into account when evaluating outcomes on the second treatment. When adjustments are made for time to treatment, differences in survival between home HD and cen-

Table 4-12.—National Kidney Dialysis and Kidney Transplantation Study: Population Characteristics of Random Samples of Prevalent Patients Undergoing Chronic Dialysis in Eleven Selected Dialysis Facilities, in 1981

	Dialysis type and location		
	CAPD/CCPD[a]	Home HD	Center HD
Sample size	61(CAPD) 20(CCPD)	287	347
General demographics:			
Mean age (yr)	52	49	54
Race(%)			
Black	10	8	42
White	84	87	54
Other	6	5	4
Sex (O/0)			
Male	46	61	50
Female	54	39	50
Education	12	13	11
Primary renal diagnosis (%)			
Interstitial nephritis	13	11	7
Polycystic kidney disease	10	17	8
Disease involving glomerular structures	30	44	34
Hypertensive renal disease	10	5	19
Nephrosclerosis	7	4	1
Diabetes	16	8	12
Other	13	11	10
Morbidity (%)[b]:			
Angina or myocardial infarction	20	15	25
Other cardiovascular problem	19	25	35
Respiratory disease	7	6	17
Gastrointestinal problems	12	9	25
Neurological problems, including stroke	7	10	14
Musculoskeletal disorders including bone disease	21	21	30
Other	7	13	31
Average number of comorbid conditions	0.94	0.98	1.77

[a]CAPD is continuous ambulatory peritoneal dialysis; CCPD is continuous cycling peritoneal dialysis.
[b]Totals may be greater than 100 percent because patients may have more than one comorbid condition.

SOURCE: R. W. Evans, "Health Services Utilization and Disability Days: indicators of the Quality of PatientCareAmong ESRD Patients/' *Battelle Human Affairs Research* Centers Update No. 18, Jan. 6, 1963.

ter HD and between center HD and cadaveric transplantation are markedly narrowed, especially if age is simultaneously controlled. Thus, the time to initiation of a treatment following the diagnosis of ESRD, as well as the demographic and medical characteristics of patients, are critical considerations.

Use of a "Standard Population" to Report Outcomes

The only systematic attempt to take case-mix considerations into account was reported at a symposium conducted by the American Society for Artificial Internal Organs at its meeting in April 1983. At this meeting, several dialysis program directors presented their results for a ''standard population" of patients 20 to 60 years of age at the onset of treatment. This standard population excluded patients who were "high risk, " either by virtue of having primary ESRD diagnoses with systematic implications such as primary hypertension, diabetic nephropathy and collagen diseases, or by having severe comorbidity such as cardiovascular disease or malignancy. The goal of the presentations was to minimize population differences and obtain comparable results for CAPD and HD.

The results of available reports' from these presentations are summarized in table 4-13. Both patient survival and the ability of patients to re-

'As of May 1984, when this case study was received for final editing.

Table 4-13.—Patient Survival and Ability to Continue on a Dialysis Modality in "Standard Population" of ESRD Patients[a]

Modality of dialysis	Source[b]	Calendar year(s)	Number of patients	Patient survival 0.5 yr	Patient survival 1 yr	Patient survival 2 yr	Patient survival 5 yr	Continued on modality[c] 0.5 yr	Continued on modality[c] 1 yr	Continued on modality[c] 2 yr
CAPD	Nolph, et al., 1983[d]	1981-82	2,137	97 ”/0	94%	—	—	88 ”/0	830/o	—
CAPD	Wing, et al., 1983[e]	1976-81	1,504	—	78	—	—	—	63	—
HD	Wing, et al., 1983[e]			—	84	—	—	—	64	—
HD	Blagg and Wahl, 1983	1976-82	367	—	96	88	73	—	—	—

Modality of dialysis	Source	Calendar year(s)	Number of patients	Interval mortality—3-mo intervals[f] 3 mo	6 mo	12 mo	24 mo	Interval procedures failure—3-mo intervals 3 mo	6 mo	1 yr	2 yr
CAPD	Wing, et al., 1983	1976-82	1,504	7.80/o	4.9 ”/0	5.30/0	10.0 ”/0	25.30/o	11.4%	11 .2 ”/0	13.4 ”/0
HD	Wing, et al., 1983	1976-82	35,532	5.3	3.9	3.6	3.3	15.1	11.4	6.8	5.2

[a]The "standard population" is defined as one 20 to 60 years of age at the date of first treatment; which does not have diabetes, malignancy, or other severe systemic illness; excludes primary diagnoses for ESRD such as collagen disease, primary hypertension, oxalosis, and/or myloidosis; and excludes high risk patients with cardiovascular disease.
[b]Full citations found in the References,
Calculations reflect both deaths and treatment failures resulting in transfers to other forms of chronic dialysis. Transplants are excluded and hence, are not considered to repreSent failures Of dialysis.
[d]Deaths are ascribed to CAPD if they occurred within 2 weeks of change to any other treatment modality.
[e]In survival calculations patients were censored on the day of change in treatment modality.
[f]Three-month interval rates are estimated from bar graphs and, therefore, are approximate. Populations at risk at each interval were not specified, but presumably excluded those removed at previous intervals.

SOURCE: Office of Technology Assessment.

main on CAPD after 1 year of treatment appears to be better in the United States than in Europe. One possible explanation for these differences is that the European Registry did not permit the exclusion of patients at high risk of cardiovascular events. Patient survival at 1 year on HD in a single U.S. center (5) appeared to be similar to that for CAPD in the NIH CAPD Registry *(33)*.

Examination of survival within discrete intervals of followup in the European registry provides some interesting contrasts between CAPD and HD (table 4-13). The mortality rate on HD was highest in the first 3 months of treatment and then quickly plateaued, while mortality on CAPD fluctuated at higher levels than HD over the entire period of observation. Procedure failure was higher in the first *3* to *6* months of treatment for both modalities, but remained higher for CAPD than for HD during subsequent time periods.

This effort to “compare” outcomes of dialysis in a standard population, though commendable, falls far short of what is needed to establish credible comparisons among dialysis modalities. For example, important residual differences in age were found between patients on CAPD and HD in the EDTA Registry (51). Furthermore, there is a possible deception in limiting comparisons to a low risk population. Subtle differences between dialysis techniques, if they exist, are more likely to become manifest in patients at a higher risk of mortality or morbidity. An analysis confined to low risk patients may obscure these differences.

Chapter 5

Costs of Treatment End-Stage Renal Disease

Chapter 5

Costs of Treatment for End- Stage Renal Disease

INTRODUCTION

The rapidly escalating expenditures of the End-Stage Renal Disease (ESRD) program have been well recorded. Less attention has been given, however, to how these expenditures distribute among the components of care involved—dialysis treatments themselves, physician services, and hospitalizations. Furthermore, the relationship between ESRD program expenditures and the resource costs of the services they cover has been virtually unexplored. Better cost information is urgently needed.

Preliminary insights can be gained, however, from existing information. To this end, this chapter examines the results of the cost audits of dialysis treatment facilities that have been performed and projects the costs of dialysis from these audits and from average Medicare ESRD reimbursement rates. These results refer only to the cost of dialysis treatments themselves, with or without physician supervision, and do not include hospitalizations or medical care unrelated to dialysis. In chapter 6, Medicare ESRD reimbursement data for 1981 and 1982 are analyzed, and the total costs of treatment of ESRD, including hospitalizations, are compared for continuous ambulatory peritoneal dialysis (CAPD), center hemodialysis (HD), and home HD.

The diverse sources of information and diverse measures of cost used create a confusing array of results. To help clarify interpretation the following definitions are used:

- Cost: The dollar value of a product or service determined by audit or special investigation. The word cost is also used in a generic sense.
- Charge or Price: The dollar value placed on a product or service by a supplier or provider.
- *Reimbursement Rate:* The dollar value of a product or service as determined by a Federal program (or health insurer) based either on costs or charges or on some proportion of costs or charges.
- *Projected Cost:* The dollar value of a service calculated as the product of unit cost or average reimbursement rate and assumed utilization.
- *Expenditure:* The dollars actually paid for a product or service based on costs, charges, reimbursement rates, or some combination. Expenditures usually take the perspective of a particular program (e. g., the ESRD program), the individual payor, or some combination of payers.

PROJECTED COST OF DIALYSIS FROM COST AUDITS

In response to the ESRD Program Amendments of 1978 (Public Law 98-292), the Health Care Financing Administration (HCFA) performed an audit in 1980 of a selected sample of 105 facilities (66 hospitals and 39 independent dialysis centers). From this audit, HCFA estimated a median cost of $135 per HD treatment in a hospital center and $108 per treatment in an independent dialysis center (15). Home dialysis costs were not assessed. The Omnibus Budget Reconciliation Act of 1981 (Public Law 97-35) promoted home dialysis and led to a subsequent HCFA audit of 23 centers and 2 State programs that provided both center dialysis and supervised home dialysis. The centers selected were from those having large patient populations. Cost estimates obtained were $87 per treatment for home HD and $114 per “treatment equivalent” for home CAPD. (Because CAPD treatments are given daily, the the weekly costs of dialysis were divided by three to provide a cost equivalent to that for a single HD treatment, since HD treatment schedules generally call for three treatments per week.)

In 1981, the General Accounting Office (GAO) performed an independent audit of home dialysis costs from data provided by carriers and financial intermediaries on 656 randomly selected patients (47). This audit estimated costs of $103 per treatment for home HD and $110 for CAPD (47). An interesting finding of the GAO audit was that 70 percent of home dialysis patients were purchasing their supplies and equipment directly from commercial suppliers rather than through supervising dialysis centers. The question arises as to whether the higher estimate obtained for home HD in the GAO audit may, at least in part, reflect higher prices of supplies to individual purchasers. Alternative explanations, of course, might be differences in sampling techniques and the audit methodology.

The HCFA audit has been widely criticized, because its sample of dialysis centers was not representative, and because it used less than optimal auditing techniques. This is particularly true for the examination of home dialysis costs, which HCFA admits was done hastily under considerable time pressure. Despite their limitations, HCFA figures were used as the basis for calculating Medicare's recently implemented composite reimbursement rates.

Table 5-1 presents projections of the yearly cost of dialysis treatments based on HCFA and GAO audits. These figures refer only to the cost of the dialysis treatments and do not include physician fees. They assume full compliance with prescribed dialysis treatments. The yearly cost of HD in a hospital center is slightly over $4,000 more expensive than HD in an independent dialysis center. CAPD appears to cost about the same as HD in an independent center, and home HD is less expensive than either CAPD or center HD (how much depends on whether one prefers the HCFA or GAO audit results). If the cost of a home health aide to assist with home HD were added, any cost savings from home HD would be greatly reduced or eliminated.

Table 5-1.—Cost of Dialysis per Patient-Year as Estimated From Health Care Financing Administration and General Accounting Office Cost Audits

Dialysis modality	Cost/day[a]	Cost/yr[b]
Health Care Financing Administration Audit:		
Center HD:		
Hospital center	$135	$21,060
Independent center	108	16,848
Home HD	87	13,572
CAPD	114	17,784
General Accounting Office Audit:		
Home HD[c]	$103	$16,068
CAPD[c]	110	17.160

[a] Represents median costs from 1980 data for center HD (67 hospital and 38 independent centers) and 1981 data for home dialysis (23 centers).
[b] Assumes full compliance with regimens of 3 dialysis treatments or "treatment equivalents" (CAPD) per week,
[c] Represents mean costs of home dialysis in 1981 .

SOURCE: Office of Technology Assessment,

PROJECTED COST OF DIALYSIS FROM 1982 MEDICARE ESRD REIMBURSEMENT RATES

Reimbursement rates paid by the ESRD program provide a second method by which to assess the projected costs of dialysis. Differences between estimates based on ESRD reimbursement rates and cost audit results would reflect profit margins (revenues minus costs), if the cost audit results accurately reflect resource costs and if complete collection of deductibles and the 20 percent coinsurance required by Medicare were achieved.

Medicare's ESRD reimbursement rates in 1982 averaged $159 per treatment in a hospital center and $138 in an independent center. No comparable figures exist for home dialysis. Multiple formulae have been used to determine reimbursements for home dialysis, which alternatively, have been based on reasonable costs to the hospital or independent center, negotiated Target Rate Reimbursement Agreements with centers, or reasonable charges for supplies and equipment billed by the patient or the commercial supplier.

Physician supervision of dialysis is not included in these reimbursement rates and has averaged $220 per month for center dialysis and $154 for home dialysis under the cavitation-based "alternative reimbursement method" option. Average estimates for physician services billed under the "fee for service" option were not obtained for this study.

Table 5-2 shows projected yearly costs of $24,804 for HD in a hospital center and $21,528 in an independent center. These figures, which are *18* percent and **28** percent higher than costs projected from the HCFA cost audit for hospital and independent centers, respectively, provide crude estimates of the magnitude of "profits" enjoyed by dialysis centers.

Physician supervision of dialysis adds *$2,640* to the average yearly cost of center HD and $1,848 per year for supervision of home dialysis.

Table 5-2.—Cost of Dialysis Per Patient-Year From 1982 Medicare Reimbursement Rates

	Projected yearly cost[a]		
Dialysis modality	Dialysis	Physician	Total
HD—Hospital center	$24,804[b]	$2,640'	$27,444
HD—independent center	21,528[d]	2,640	24,168

[a]Assumes 156 dialysis treatments Per Year (3 per week)
[b]Based on a reimbursement rate of $159 per treatment for HD in a hospital dialysis center,
[c]Based on the average monthly physician reimbursement rate of $220 per patient for supervision of dialysis in a center
[d]Based on the ESRD "screen" or maximum allowed reimbursement rate Of $138 per treatment for HD performed in an independent center Most centers obtained the maximum rate

SOURCE" Office of Technology Assessment

PROJECTED COSTS OF DIALYSIS UNDER HCFA's 1983 COMPOSITE REIMBURSEMENT RATES

The composite reimbursement rates that were implemented on August 1, 1983 were designed to encourage home dialysis and, at the same time, to help contain the costs of the ESRD program. Under this rate structure, a single rate is applied to all dialysis performed under the supervision of a center, and a single monthly rate is paid for physician supervision regardless of whether the treatment is furnished in the center or at home. The regulation does not in any way alter the ability of the patient to purchase equipment and supplies directly from the supplier. Reasonable charges continue to be the basis for these purchases.

HCFA's assumptions are that dialysis centers will be provided an incentive to offer home dialysis alternatives to their patients because of the lower resource cost of home dialysis. In addition, HCFA assumes that physicians will encourage home dialysis because they will be reimbursed the same amount for the lesser effort required to supervise home patients than is required by dialysis treatments performed three times a week in a center.

Average reimbursement rates were set at $127 per treatment for dialysis supervised by an independent center and $131 per treatment supervised by a hospital center. The rates were based on a formula that took into consideration the distribution of dialysis among home and center dialysis settings and relied heavily on the HCFA cost audit results. Adjustments are to be made to these average rates to adjust for geographic wage differences. Furthermore, dialysis training sessions are to be reimbursed at an additional *$20* per session. Exceptions to the above rates will be granted under special circumstances. Physicians are reimbursed at an average rate of $184 per patient per month, again adjusted for geographic wage differences.

Table 5-3 shows the projected average yearly costs of dialysis under the 1983 HCFA prospective reimbursement formula. Compared to cost estimates based on 1982 ESRD reimbursement rates (table 5-2), the yearly cost of center HD will be reduced by 18 percent in hospital centers and by 8 percent in independent centers.

Table 5-3.—Estimated Projected Cost of Dialysis Per Patient-Year Under HCFA's 1983 Composite Reimbursement Rates

Dialysis modality and location	Projected yearly cost[a] Dialysis[b]	Physician[c]	Total
Center HD:			
Hospital	$20,436	$2,208	$22,644
Independent	19,812	2,208	22,020
Home HD or CAPD:			
Supervised by hospital	$20,436	$2,208	$22,644
Supervised by independent center	19,812	2,208	22,020

aAssumes full compliance with 156 treatments per year (3 Per week × 52 weeks) or, in the case of CAPD, "treatment equivalents."
bBased on average per treatment reimbursement rates Of $131 and $127 in hospital and independent centers, respectively, regardless of dialysis modality or location
cBased on an average monthly capitation rate of $184 for Supervision of dialysis.
SOURCE" Office of Technology Assessment.

Average physician cavitation fees under the 1983 composite rate formula will increase from $1,848 per year to $2,208 per year (19 percent) for supervision of home dialysis and decrease from *$2,640* per year to $2,208 (16 percent) for center dialysis.

The most obvious effect of the new rates is to reduce the level of reimbursement for center dialysis from $159 to $131 in hospitals and from *$138* to $127 in independent centers.

FINANCIAL INCENTIVES CREATED BY HCFA's 1983 COMPOSITE REIMBURSEMENT RATES

If the HCFA cost audit results represent valid estimates of the average resource costs of dialysis treatments, financial incentives favoring one dialysis modality or another should operate in relation to differences between reimbursement rates and the unit costs determined by the audits. The validity of the cost audit results can be questioned, but, pending better cost information, no better assumption is obvious.

The estimated yearly costs of dialysis from the cost audits and from the *1983* composite reimbursement rates are compared in table 5-4.

Three observations are germane:

1. a strong disincentive has been created for performing HD in hospital dialysis centers;
2. approximately similar incentives exist in independent centers for center HD and CAPD; and
3. a very strong incentive has been created for home HD that would be mitigated if unit costs rise as a result of the need to furnish more home health aides when home HD is offered to a broader spectrum of patients with more comorbidity or less than adequate home support.

If these incentives alone were to drive utilization, center HD, home HD, and CAPD all would be expected to increase under the *1983* rates largely at the expense of HD in hospital dialysis centers.

Table 5-4.—Comparison Between Estimates of the Projected Cost of Dialysis Per Patient-Year Based on HCFA and GAO Cost Audits and HCFA's 1983 Composite Reimbursement Rates

Dialysis type and location	Projected yearly cost: cost audits[a]	1983 Composite rates[b]	Percent difference
Center HD:			
Hospital	$21,060	$20,436	–3%
Independent center	16,848	19,812	18
Home HD:			
Supervised by hospital center	13,572	20,436	51
Supervised by independent center	13,572	19,812	46
Direct purchase[c]	16,068	7	?
CAPD:			
Supervised by hospital center	17,784	20,436	15
Supervised by independent center	17,784	19,812	11
Direct purchase	17,160	?	?

aFrom table 5-1
bFrom table 5-3.
cFrom the results of the GAO audit in which 70 percent of the patient sample were purchasing supplies directly from the supplier.
SOURCE: Office of Technology Assessment.

Many factors other than financial incentives created by the 1983 rates, of course, may affect patterns of utilization. The change in cavitation rates for physician supervision of dialysis, for example, clearly favors home dialysis over center dialysis. Because the physician plays a major role in the selection of dialysis modality, this financial incentive may be at least as powerful as that operating on dialysis centers, Physician acceptance of home dialysis techniques will be strongly influenced by convictions about patient suitability and medical effectiveness, in addition to financial considerations. Finally, patient acceptance almost certainly will become an increasingly important determinant as public information on medical effectiveness and quality of life considerations become more widely distributed.

COST IMPLICATIONS OF THE DIRECT PURCHASE OF SUPPLIES FOR HOME DIALYSIS

HCFA's 1983 rates apply only to the reimbursement of dialysis centers and do not affect the ability of the patient to purchase equipment and supplies for home dialysis directly from suppliers. The GAO cost audit indicated that *70* percent of home dialysis patients were direct purchasers under previous regulations. Questions that need to be raised include:

1. Are prices for supplies purchased directly by the patient higher than those for supplies purchased by a hospital or independent dialysis center?
2. If so, will the new reimbursement rates affect the number of direct purchasers and in what direction?

Higher prices for direct purchasers and any increase in their numbers, obviously, will be inflationary for the ESRD program.

In the absence of regulations to the contrary, suppliers probably do charge individuals higher prices than they do bulk purchasers such as dialysis centers or hospitals. CAPD provides an example of the possible consequences. Patients on CAPD require nearly *3,000* liters of sterile dialysate solution per year packaged in plastic bags plus a variety of ancillary supplies, including sterilization or "prep" kits, connecting tubes, and other apparatus. Two estimates of the yearly cost of supplies, provided by Travenol Laboratories, Inc., the supplier with the dominant market share, range from $13,000 per year (1) to over $19,000 per year (Travenol Price List, November 1, 1982). The details of these estimates appear in table 5-5. This wide range suggests that prices to direct purchasers may, in fact, be considerably higher.

Table 5.5.—Estimates of the Annual Cost of CAPD Supplies and Equipment

Travenol Laboratories Testimony to Congress (1982)[a]	13,147
Travenol Price List–Nov. 1, 1982[b]	19.688

aBased on four exchanges per day or 1,460 per year at $732 Per bag, $100 for a prep kit for each exchange, and $1,000 for other ancillaries
bBased on 1,460 exchanges per year with Dianeal 137 Solution, 1 5 or 2 liters, at $64,20 for case of 6 and Prep Kit Model 3 at $6300 for case or 30 wit h each exchange, and $1,000 for other ancillaries,

SOURCE Off Ice of Technology Assessment

Furthermore, it suggests that, if Medicare is to retain the direct purchase option, it should establish limits on allowable charges that are directly linked to production costs, and at the same time, ensure a preferred customer relationship for persons enrolled in the ESRD program.

It is difficult to predict how many home dialysis patients will select the direct purchase option under the new rates. On the one hand, dialysis centers may find the new reimbursement rates and financial arrangements with suppliers sufficiently attractive that they will actively encourage patients to obtain their supplies through the center. In this case, the proportion, and even the total number, of direct purchasers might fall. If, however, centers see the financial incentives created by the new rates to be insufficient to offset the operational problems of distributing supplies, they might take actions to "assign" supply functions to the supplier or encourage direct purchase. This latter scenario would create the risk for ESRD program cost escalation.

In summary, it appears highly likely that HCFA's intent to encourage diffusion of home dialysis techniques will be fulfilled. Far less certain, however, are the effects this diffusion will have on stemming the rising tide of ESRD costs. As a prudent purchaser of services, HCFA should consider taking the necessary steps to reassess the equity of the new rates in relation to the resource costs of the services they cover; to monitor changes in the organization and patterns of utilization of dialysis services as they occur; and to devise mechanisms for determining the effects of these reimbursement decisions on the quality of ESRD treatment as well as its costs.

Chapter 6

Analysis of End-Stage Renal Disease Expenditures

Chapter 6

Analysis of End-Stage Renal Disease Expenditures

INTRODUCTION

The End-Stage Renal Disease (ESRD) program reimburses its beneficiaries for dialysis treatments, for physician services, and for hospital care. Analysis of data collected in conjunction with monitoring expenditures of the program, therefore, provides an alternative method by which to estimate the costs of treatment by different dialysis modalities.

Two major distinctions must be kept in mind when the results of this analysis are compared to those projected from cost audits or average ESRD program reimbursement rates presented in chapter 5. First, projected costs assume full compliance with average prescribed dialysis regimens, while *dialysis costs estimated from Medicare Part B expenditures* reflect actual billings and, therefore, any deviations from average regimens or failures in compliance. Part B expenditures include physician services and ancillaries in addition to those of dialysis treatments per se.

Second, the ESRD program, by recording the frequency of hospitalizations, allows estimation of hospital costs. The *total* costs of medical care, therefore, can be calculated as the basis for comparing dialysis modalities and thereby offset any lower dialysis costs by any higher costs of hospitalization identified. In the case of continuous ambulatory peritoneal dialysis (CAPD), for example, some claim that any savings in the cost of dialysis are negated by added hospitalizations due to frequent bouts of peritonitis.

This analysis examines expenditures by the Medicare ESRD program on behalf of its beneficiaries during 1981 and 1982. The primary objective is to compare the cost of uninterrupted treatment by center hemodialysis (HD), home HD, and CAPD. In addition, any increases in costs incurred by patients who are unable to tolerate one modality of treatment and are changed to another modality, and the costs associated with dying are examined . These incremental "costs of changing" or "costs of dying" are particularly important to the extent that "procedure survival" or patient survival differ among dialysis modalities.

Although many questions have been raised about the reliability of Medicare ESRD reimbursement data, there is no reason to believe a priori that comparisons among dialysis modalities should be biased even though *actual* dollar figures may be suspect.

METHODS OF THE ANALYSIS

ESRD Program Data Files

The ESRD program records the following information on each beneficiary:

- Patient characteristics such as age, sex, race, and primary ESRD diagnosis.
- Time in the program (a 3-month waiting period is required after the diagnosis of ESRD before enrollment occurs).
- Aggregated Medicare payments under Part B for dialysis treatments, supplies and equipment, and physician services. These figures exclude a 20 percent coinsurance and deductibles.
- Admission and discharge dates for hospitalizations related to the treatment or complications of ESRD. This criterion is very broadly interpreted because of the widespread systemic manifestations of renal disease. Days of hospitalization are converted to dollars by using the national average Medicare per diem rate for the year in question.

The data files obtained for this analysis included all persons enrolled in the ESRD program, with the exception of patients who had undergone renal transplantation at any time and patients who first enrolled in the ESRD program during 1981 or 1982. Transplanted patients were excluded because of the special problems that maybe encountered in the dialysis of patients with failed transplants. Newly enrolled patients were excluded because of concern that the startup costs of dialysis might obscure differences in costs of maintenance treatment.

Patient Subgroups for Analysis

The 1981 and 1982 files were merged and 10 subgroups of patients were identified:

Continuous Dialysis on a Single Modality From January 1, 1981 to December 31, 1982 and Survived:

1. Center HD (hospital or independent center)
2. Home HD
3. CAPD

Single Change of Dialysis Modality Between January 1, 1981 and December 31, 1982 and Survived:

4. CAPD to center HD
5. Center HD to CAPD
6. CAPD to home HD
7. Home HD to CAPD

Continuous Dialysis on a Single Modality From January 1, 1981 Until Death Between July 1, 1982 and December 31, 1982:

8. Center HD
9. Home HD
10. CAPD

In all *survivor* subgroups (subgroups 1 to 7), the analysis was limited to data that applied to the 18-month period from April 1, 1981 to October 31, 1982. The first 3 months of 1981 and the last 3 months of 1982 were excluded to eliminate any expenditures for hospitalizations that might have been associated with the startup of therapy or with complications that might have led to a change in therapy or death after December 31, 1982. Another exclusion was *deaths* before July 1, 1982; this was done to ensure a sufficiently long period of observation prior to death that stable estimates of expenditures prior the terminal costs of dying would be obtained.

Variables examined in each subgroup were:

- age on July 1, 1981;
- sex;
- race;
- time in ESRD Program prior to January 1, 1981;
- aggregate Medicare Part B reimbursements;
- number of hospitalizations; and
- duration of each hospitalization.

Dates of change of dialysis modality depend on information provided in claims submitted by dialysis centers or physicians. Change dates tended to clump around the end of quarters (March 31, June 30, September 30, December 31). The listed date was accepted if it were other than the end of a quarter, but the date of the midpoint of the preceding quarter was arbitrarily assigned for changes reported in claims dated within 3 days of the end of the quarter on the assumption that actual dates of change were randomly distributed.

Dates of hospital admission and discharge were provided only for the first five hospitalizations in any calendar year for any given patient. In those few patients with more than five hospitalizations, the average length of stay of the first five hospitalizations was used as an estimate of the duration of hospitalization on subsequent admissions,

Costs of Hospitalizations

Hospital days per patient-year are converted to dollars as follows:

$$\text{Hospital days in the period of observation} \times \frac{365}{\text{length of period of observation}} \times \text{Average hospital per diem rate} \times 0.68 \times 1.047 \times 1.07$$

The average national hospital per diem rate for Medicare patients was $348 in 1981 and $412 in 1982. The factor 0.68 is the proportion of the hospital per diem rate that Medicare reimburses. The factor 1.047 adjusts for hospital administrative and overhead costs not otherwise included in the per diem rate, and the factor 1.07 adjusts for the average coinsurance and deductibles patients pay towards the cost of their Part A Medicare treatment. Adjusted average per diem rates are $265.11 for 1981 and $313.86 for 1982.

This formulation assumes that days of hospitalization for patients with ESRD are of average intensity and, hence, average cost. To the extent that ESRD patients may require more days in intensive care units, more ancillary services, or more nursing services than the average patient, this assumption will underestimate the true cost of hospitalizations. Similarly, to the extent that renal dialysis during hospitalizations is billed separately under Medicare Part B, costs of hospitalization will be further underestimated. No reliable information is currently available on either issue.

Costs of Outpatient Dialysis and Physician Services

Medicare Part B reimbursements are assumed to represent 80 percent of all bills for dialysis and physician services rendered in both outpatient and inpatient sites. To estimate total costs, adjustment is made for the 20 percent coinsurance that must be borne by the patient or another payor, but the annual deductible of $75 is ignored. Part B costs are assumed to accrue at a uniform rate throughout the year. The cost of outpatient care and physician services per patient-year, therefore are calculated as:

$$\text{Medicare Part B reimbursements in period of observation} \times \frac{365}{\text{length of period of observation}} \times 1.25$$

Total Costs of Care

Total costs are presented as the sum of the costs of hospitalizations and Part B costs per patient-year of treatment.

Costs of Changing Dialysis Modality and Costs of Dying

The "cost of changing" and the "cost of dying" are estimated as the difference between the actual total cost and the total cost predicted from the relevant dialysis subgroup(s) that survived on a single dialysis modality (subgroups 1 to 3). For change subgroups, predicted expenditures are weighted by the number of days a patient was on each dialysis modality.

RESULTS

Population Characteristics

The distribution of the ESRD population among defined subgroups for the 1981 and 1982 files separately and for the merged file are shown on table 6-1. Patients remaining continuously on one dialysis modality predominate in each file, and include 90.9 percent of patients in the merged file. The number of deaths in the merged file are about half those in the 1981 or 1982 files, because only deaths between July 1, 1982 and December 31, 1982 were included. Fewer than 1 percent of patients experienced multiple changes in dialysis modality. Of note is that among patients who changed dialysis modality, many more change from center HD to CAPD than in the reverse direction. This finding no doubt reflects both the larger population of center HD patients at risk for change and the increasing acceptance of CAPD as a viable alternative. Sample sizes in the merged file are of tolerable size for analysis except for the change group of CAPD to home HD.

Table 6-2 shows the demographic characteristics of patient subgroups for the merged file. Patients who are continuously on CAPD are, on average, slightly younger than those on center HD (49.7 years vs. 53.9 years), while the age of patients on home HD is intermediate (51.0 years). Patients who die are, on average, 6 to 8 years older than their surviving counterparts. A markedly higher proportion of ESRD program participants on continuous center HD are black (37 percent) than those on either home HD (20 percent) or CAPD (16 percent). Modest male predominance is seen among patients on home HD (57 percent) and CAPD (55 percent).

Costs of Dialysis and Physician Services (Part B Costs)

The estimated cost per patient-year of continuous dialysis is $16,915 for center HD, $12,024 for home HD and $7,631 for CAPD (table 6-3). For center HD, this amount is about 60 percent

Table 6-1.—Distribution of the ESRD Population by Clinical Subgroup and Dialysis Modality for 1981 and 1982 Files and for the Merged File

Clinical and dialysis subgroups	1981		1982		Merged file[a]	
Continuous dialysis on a single modality and survived:						
Center HD[b]	25,583		30,075		20,186	
Home HD[b]	1,216		1,463		418	
CAPD[b]	627		1,693		357	
Other[c]	217		293		—	
Subtotals	27,697	81.3%	33,524	83.7%	20,967	90.9%
Single change of dialysis modality and survived:						
CAPD to center HD	113		292		108	
Center HD to CAPD	433		438		388	
CAPD to home HD	36		31		9	
Home HD to CAPD	93		81		49	
Other[d]	413		385		—	
Subtotals	1,088	3.2%	1,227	3.1%	554	2.4%
Continuous dialysis on a single modality but died:[e]						
Center HD	4,825		4,664		1,499	
Home HD	173		218		21	
CAPD	104		252		29	
Other	179		171		—	
Subtotals	5,281	15.5%	5,305	13.2%	1,549	6.7%
Totals	34,066	100.0%	40,056	100.0%	23,070	100.0%

[a]Merged file includes only patients who remained in the specified subgroup from 4/1/81-9/30/82 inclusive or who were on one modality of dialysis after 4/1/81 and died between 7/1/82 and 12/31/82.
[b]Center HD may be at either a hospital or independent dialysis center. Home HD and CAPD are supervised by a hospital or independent center or, rarely, by individual physicians.
[c]Includes intermittent peritoneal dialysis or simultaneous combinations of dialysis modalities.
[d]Includes multiple changes in dialysis modality.
[e]For 1981 and 1982 files, the patient may have died any time in the specified year; for merged file the patient died between 7/1/82 and 12/31/82.

SOURCE: Office of Technology Assessment.

Table 6-2.—Demographic Characteristics of ESRD Program Participants by Clinical Subgroup and Dialysis Modality for the Merged File

Clinical and dialysis subgroups[a]	Number	Mean age (on 7/1/81)	Sex		Race			
			Male	Female	White	Black	Other	Unknown
Continuous dialysis on a single modality and survived:								
Center HD	20,192	53.9	50%	50%	58%	37%	3%	2%
Home HD	418	51.0	57	43	75	20	3	2
CAPD	357	49.7	55	45	79	16	3	2
Single change of dialysis modality and survived:								
CAPD to center HD	108	49.2	54	46	63	32	3	2
Center HD to CAPD	388	49.6	49	51	70	25	3	2
CAPD to home HD	9	46.8	33	67	56	22	11	11
Home HD to CAPD	49	49.3	45	55	86	10	2	2
Continuous dialysis on a single modality but died:								
Center HD	1,499	61.1	54	46	66	29	3	2
Home HD	21	57.0	38	62	76	10	10	4
CAPD	29	56.3	48	52	90	3	7	0

[a]Center HD may be at either a hospital or independent dialysis center. Home HD and CAPD are supervised by a hospital, independent center or, rarely, by individual physicians.

SOURCE: Office of Technology Assessment.

Table 6-3.—Mean Costs of Dialysis and Physician Services by Clinical Subgroup and Dialysis Modality

Clinical and dialysis subgroups[a]	Mean costs per patient-year: ESRD reimbursements	Mean costs per patient-year: Estimated total cost[b]
Continuous dialysis on a single modality and survived:		
Center HD.	$13,532	$16,915
Home HD	9,619	12,024
CAPD	6,105	7,631
Single change of dialysis modality and survived:		
CAPD to center HD.	10,833	13,604
Center HD to CAPD	10,549	13,186
CAPD to home HD	5,331	6,664
Home HD to CAPD	7,626	9,533
Continuous dialysis on a single modality but died:		
Center HD.	14,086	17,608
Home HD	11,675	14,594
CAPD	6,058	7,573

[a]Center HD may be at either a hospital or independent dialysis center. Home HD and CAPD are supervised by a hospital, independent center or, rarely, by individual physicians

[b]ESRD reimbursements multiplied by 1.25 to adjust for the 20 percent coinsurance charged to the patient under Part B of the Medicare ESRD program.

of yearly costs projected from average ESRD program reimbursement rates for dialysis plus the average cost of physician supervision. For home HD and CAPD, they are about 80 percent and 40 percent, respectively, of those projected from the HCFA cost audit results plus the estimated average cost of physician supervision (table 6-4).

Several explanations are possible to account for these differences. One is that ESRD enrollees who are stable on a single dialysis modality require less frequent dialysis and less physician supervision than the "average" ESRD patient. Although this may be true, it could account for only a small fraction of the discrepancies, because costs in the subgroups of patients who changed modalities (weighted by the time on each modality) and in the subgroups of patients who died are only slightly higher than in the continuous dialysis subgroups.

A second explanation maybe that a significant proportion of patients have dialysis prescribed less frequently than the assumed three times a week for HD and four times per day for CAPD. Some estimates suggest that this may occur in 20 to 25 percent of patients, and especially in those with some residual renal function.

Third, failures in compliance maybe important. Compliance with treatment regimens for chronic diseases has been well demonstrated to be extremely difficult; that with treatment for ESRD, undoubtable, is no exception.

Fourth, incomplete rendering of bills to the ESRD program may occur either because of dual entitlement to coverage or, in the case of a new technology such as CAPD, because of cost incentives offered by industrial suppliers. Nearly 4,000 patients have dual entitlement to coverage by the Veterans Administration and by the ESRD program. ESRD reimbursements for these individuals, naturally, would be low. Data files do not permit identification and exclusion of these patients.

Finally, some bills submitted by providers may not be recorded in the Part B data system. Even though physicians have been instructed to submit all bills for ESRD patients to this system, they may not always do so.

Whatever their explanations, discrepancies between projected dialysis costs and actual costs de-

Table 6-4.—Comparisons of the Estimated Costs of Dialysis From Different Data Sources by Dialysis Modality

Dialysis type	Cost audits (1980-81): HCFA[a]	Cost audits (1980-81): GAO[a]	Average Medicare reimbursement rates (1982)	Medicare ESRD reimbursements under Part B (1981 -82)[b]
Center HD[c]:				
Hospital center	$21,060	—	$24,804	$16,915
Independent center	16,848	—	21,528	16,915
Home HD	13,572	16,068	—	12,024
CAPD	17,784	17,160	—	7,631

[a]Excludes physician services not billed through the facility.

[b]Estimates are for patients who continue on a single form of dialysis for at least 2 years and include physician services

[c]Medicare part B data did not permit differentiation of center HD by whether it was performed in a hospital or independent dialysis center.

SOURCE: Off Ice of Technology Assessment termined from the ESRD data system require further evaluation, especially in the case of CAPD.

Rates and Costs of Hospitalization

Patients on any one dialysis modality who survived averaged slightly over one hospitalization per patient-year (table 6-5), Patients who changed dialysis modality or died had nearly double these rates of hospitalization. Somewhat more CAPD patients had at least one hospitalization during the 18 months of observation than center HD patients (76 vs. 69 percent), and patients on home HD were least likely to have been hospitalized (58 percent).

Hospital days per patient-year among survivors on a single dialysis modality were higher for center HD (11.9 days) than either CAPD (10.6 days) or home HD (8.9 days) (table 6-6). These hospitalization rates are lower than those reported in chapter 4, because they are for patients who are on

Table 6-5.—Mean Frequency of Hospitalizations by Clinical Subgroup and Dialysis Modality

	All patients		Patients with one or more hospitalization	
Clinical and dialysis subgroups	Number	Mean number of hospitalizations per patient-year	Percent of all patients	Mean number of hospitalizations per patient-year
Continuous dialysis on a single modality and survived:				
Center HD	20,192	1.3	690/o	1.9
Home HD	418	1.0	58	1.7
CAPD	357	1.3	76	1.7
Single change of dialysis modality and survived:				
CAPD to center HD	108	2.4	96	2.5
Center HD to CAPD	388	2.3	93	2.5
CAPD to home HD	9	1.3	78	1.7
Home HD to CAPD	49	1.6	84	2.0
Continuous dialysis on a single modality but died:				
Center HD	1,499	2.5	94	2.7
Home HD	21	2.1	81	2.6
CAPD	29	2.4	90	2.7

[a]Center HD may be at either a hospital or independent dialysis center. Home HD and CAPD are supervised by a hospital, independent center or, rarely, by individual physicians.

SOURCE: Office of Technology Assessment.

Table 6-6.—Mean Number of Hospital Days and Estimated Hospital Costs per Patient-Year by Clinical Subgroup and Dialysis Modality

	All patients		Patients with one or more hospitalization
Clinical and dialysis subgroups	Hospital days per patient-year	Annual hospital costs	Hospital days per patient-year
Continuous dialysis on a single modality and survived:			
Center HD	11.9	$3,342	17.1
Home HD	8.9	2,443	15.3
CAPD	10.6	2,953	14.0
Singe change of dialysis modality and survived:			
CAPD to center HD	23.1	6,655	23.9
Center HD to CAPD	17.6	5,151	18.9
CAPD to home HD	9.9	2,806	12.8
Home HD to CAPD	11.4	3,340	13.7
Continuous dialysis on a single modality but died:			
Center HD	31.1	9,205	33.2
Home HD	21.4	6,403	26.5
CAPD	26.0	7,763	29.0

[a]Center HD may be at either a hospital o, independent dialysis center. Home HD and CAPD are supervised by a hospital, independent center or, rarely, by individual physicians.

SOURCE: Office of Technology Assessment.

continuous dialysis and exclude hospitalizations related to startup of dialysis or change in modality. Patients changing from CAPD to center HD had more hospital days than those changing from center HD to CAPD or from home HD to CAPD (23.1, 17.6, and 11.4 days, respectively). Patients who remained on a single dialysis modality, but died, were hospitalized between two and three times as many days as their surviving counterparts. Distributions of lengths of hospital stays are shown in table **6-7.** The highest proportions of patients with long periods of hospitalization occur in the group changing from CAPD to center HD and in nonsurvivors.

In nonsurvivors, hospitalization rates in the last 3 months of life were three times those experienced earlier in the last year in life, but during the preceding months were more than twice those in stable survivors. This pattern of increasing hospital utilization reflects the crescendo of complications and medical interventions that often precede death.

Annual hospital costs directly reflect lengths of stay because of the assumption that the average Medicare per diem rate applies to each hospital day (table 6-8). Hence, any differences between patient groups in the intensity of care required,

Table 6-7.—Distribution of Lengths of Hospital Stay by Clinical Subgroup and Dialysis Modality

		Days per patient-year[b]									
Clinical and dialysis subgroups	Number	O	1-3	4-6	7-9	10-19	20-29	‘30-39	40-49	50-59	>60
Continuous dialysis on a single modality and survived:											
Center HD	20,192	31%	14%	12%	7%	17%	80/0	5%	3%	2%	30/0
Home HD.	418	42	11	13	5	14	7	3	3	1	2
CAPD	357	24	16	18	9	17	8	4	1	3	1
Single change of dialysis modality and survived:											
CAPD to center HD	108	4	9	9	7	23	19	14	7	5	4
Center HD to CAPD	388	7	11	14	12	23	14	7	6	3	3
CAPD to home HD.	9	22	11	11	11	33	11	0	0	0	0
Home HD to CAPD	49	16	12	12	14	25	14	4	0	2	0
Continuous dialysis on a single modality but died:											
Center HD	1,499	6	6	6	6	19	15	12	9	6	15
Home HD.	21	19	0	5	10	19	24	14	5	0	5
CAPD	29	10	4	4	7	28	4	17	17	7	4

[a]Center HD may be at either a hospital or independent dialysis center Home HD and CAPD are supervised by a hospital, independent center or, rarely, by Individual physicians
[b]Rows may not add to 100 percent because of rounding

SOURCE Off Ice of Technology Assessment

Table 6-8.—Total Costs of Care Per Patient-Year by Clinical Subgroup and Dialysis Modality

Clinical and dialysis subgroups	Costs of dialysis and physician services[b]	costs of hospitalization	Total costs
Continuous dialysis on a single modality and survived:			
Center HD	$16,915	$3,342	$20,257
Home HD	12,024	2,443	14,485
CAPD	7,631	2,953	10,584
Single change of dialysis modality and survived:			
CAPD to center HD	13,604	6,655	20,259
Center HD to CAPD	13,186	5,151	18,337
CAPD to home HD	6,664	2,806	9,470
Home HD to CAPD	9,533	3,340	12,873
Continuous dialysis on a single modality but died:			
Center HD	17,608	9,205	26,813
Home HD	14,594	6,403	20,997
CAPD	7,573	7,763	15,336

‘Center HD may be at either a hospital or Independent dialysis center. Home HD and CAPD are supervised by a hospital, independent center or, rarely, by individual physicians
[b]ESRD reimbursements multiplied by 125 to adjust for the 20 percent coinsurance charged to the patient under Part B of the Medicare ESRD Program calculated Using adjusted average national Medicare Per diem rate

SOURCE Off Ice of Technology Assessment

operating room use, and diagnostic test requirements are not captured. Costs per year for hospital care range from $2,443 in patients continuously on home HD to $9,205 in patients on center HD who die; and costs are slightly lower in patients continuously on CAPD than those who remain on center HD ($2,953 vs. $3,342 per year).

Total Costs of Care

The total cost of care per patient-year in "continuous survivors" was *$20,257* for center HD, $14,485 for home HD, and $10,584 for CAPD (table 6-8). Interpretation of the low figure for CAPD again must be tempered by concern over the reliability of the unexpectedly low Part B reimbursements recorded for this modality. Patients who changed from CAPD to center HD experienced higher costs than for the reverse direction of change ($20,259 vs. $18,337) due primarily to differences in the cost of hospitalizations.

Total costs distribute widely. Higher proportions of patients with costs above *$25,000* per patient year are notable for continuous survivors on center HD, changes from CAPD to center HD or the reverse, and for patients who die (table *6-9).*

"Cost of Changing" Dialysis Modality

Estimated costs of changing dialysis modality are shown in table *6-10.* Predicted costs are those that would have applied if the patient accrued costs at the rates of patients on continuous dialysis by each of the dialysis modalities involved. Change dates were used to time-weight predicted costs. Total change costs range from $1,621 in patients who change from home HD to CAPD, and to *$4,922* for those who change from CAPD to center HD. By far the largest contribution to the costs of change involving CAPD and center HD arise from additional days of hospitalization. No doubt these days reflect both requirements to treat complications of the previous treatment and those to begin the new treatment. Results in the group who changed from CAPD to home HD are suspect because of the small numbers of patients involved.

"Cost of Dying"

The incremental cost of dying, shown in table 6-11, ranges from $4,752 in patients on CAPD to $6,556 in patients on center HD. These costs relate only to death in patients on a single modality of dialysis for 18 months prior to death and exclude those whose terminal events led to either a change in chronic dialysis modality or to transplantation.

Predictors of Hospitalization in Survivors Who Continue on a Single Dialysis Modality

Case-mix differences, as well as dialysis modality, may influence the need for hospitalization, To examine the independent effects of sociodemo-

Table 6.9.—Distribution of Total Costs of Care per Patient-Year by Clinical Subgroup and Dialysis Modality

Clinical and dialysis subgroups	Number	<$5,000	$5,000-9,999	$10,000-14,999	$15,000-19,999	$20,000-24,999	$25,000-29,999	$30,000-39,999	$40,000-49,999	>$50,000
Continuous dialysis on a single modality and survived:										
Center HD	20,192	7%	16%	17%	13%	11 %	14 %	17%	4%	1%
Home HD	418	12	28	18	17	13	5	5	1	1
CAPD	357	19	36	24	13	6	1	1	0	0
Single change of dialysis modality and survived:										
CAPD to center HD	108	5	11	21	18	12	12	18	3	0
Center HD to CAPD	388	4	15	24	20	14	12	8	3	0
CAPD to home HD	9	0	56	33	11	0	0	0	0	0
Home HD to CAPD.	49	16	21	27	16	14	6	0	0	0
Continuous dialysis on a single modality but died:										
Center HD	1,499	1	8	13	14	12	13	23	11	5
Home HD	21	5	19	9	19	24	10	0	14	0
CAPD	29	7	27	10	28	14	7	7	0	0

[a]Center HD may be at either a hospital or independent dialysis center. Home HD and CAPD are supervised by a hospital, independent center or, rarely, by individual physicians

SOURCE: Office of Technology Assessment,

Table 6-10.—Mean Costs Per Patient-Year of a Single Change in the Modality of Dialysis Among Survivors

Dialysis change	Number	Actual	Predicted	Difference
Costs of dialysis and physician services:				
CAPD to center HD	108	$13,604	$12,599	$1,005
Center HD to CAPD	388	13,186	12,463	723
CAPD to home HD	9	6,664	8,733	–2,069
Home HD to CAPD	49	9,533	8,741	792
Hospitalization costs:				
CAPD to center HD	108	$6,655	$2,738	$3,917
Center HD to CAPD	388	5,151	2,681	2,470
CAPD to home HD	9	2,806	2,333	473
Home HD to CAPD	49	3,340	2,511	829
Total costs:				
CAPD to center HD	108	$20,259	$15,337	$4,922
Center HD to CAPD	388	18,337	15,144	3,193
CAPD to home HD	9	9,470	11,066	– 1,596
Home HD to CAPD	49	12,873	11,252	1,621

SOURCE Office of Technology Assessment.

Table 6-11 .—Mean Costs of Dying in Patients on a Single Dialysis Modality

	Total costs per patient-year		
Dialysis modality	Died	Survived	Difference
Center HD	$26,813	$20,257	$6,556
Home HD	20,997	14,485	6,512
CAPD	15,336	10,584	4,752

SOURCE: Office of Technology Assessment

graphic characteristics, lengths of time on chronic dialysis, and dialysis modality on days of hospitalization, a multiple regression analysis was performed using the number of hospital days during 18 months of observation as the dependent variable (table 6-12). Longer length of time on dialysis and female gender were significantly associated ($p < 0.05$) with more days in the hospital. Older age was less strongly associated ($p < 0.06$), and race was not associated with longer periods of hospitalization. After adjustment for these patient characteristics, home HD patients still experienced fewer hospital days, but no difference in hospital days was seen between patients on CAPD and center HD.

These findings reemphasize the importance of case-mix differences in explaining differences in costs and morbidity among patients on chronic dialysis.

Table 6-12.—Predictors of Days of Hospitalization in Survivors on Continuous Dialysis by a Single Modality[a]

Factor	Coefficient	Standard error	F value	Level of significance
Age[b]	0.02103	0.01104	3.63	p <0.06
Sex[c]	0.73479	0.32495	5.11	p <0.03
Race[d]	0.07393	0.33034	0.05	p <0.83 n.s.
Length of time on dialysis[e]	0.00038	0.00013	7.73	p <0.01
Dialysis group[f]			3.23	p <0.04
Home HD	–2.83343	1.16193	5.95	p <0.02
CAPD	–0.97231	1.25590	0.59	p <0.44 n.s.
Center HD	—	—	—	—

[a]Patients who continued on a single dialysis modality from 1/1/81 to 12/31/82 and survived, persons with no hospitalizations are entered as zero days Sample sizes are: Center HD 20,192; home HD 418; CAPD 357.
[b]As of 711181.
[c]Female = 1; male = O.
[d]NOn.White = 1; white = O.
[e]Length of time in ESRD program prior to 1/1/81.
[f]Compared to center HD as referent.

SOURCE: Office of Technology Assessment.

DISCUSSION

This analysis of Medicare ESRD reimbursement data provides the only available estimates of actual expenditures for chronic renal dialysis which distinguishes between the costs of dialysis itself and those for associated hospitalizations. The focus on three distinct clinical populations—patients who are able to continue for a prolonged period of time on one dialysis modality and survive, those who require a single change in modality, and those who remain on a single modality but die—facilitates cost comparisons by creating relatively homogeneous subgroups. Costs of continuous dialysis, costs associated with changing dialysis modality, and the added costs incurred by ESRD patients who die, therefore, can be estimated.

The costs of dialysis alone estimated from ESRD reimbursement data differ substantially from those projected from cost audits or average ESRD program reimbursement rates (table *6-4).* Despite the vagaries of these comparisons the following conclusions seem warranted:

- Hemodialysis in hospital centers is the most expensive form of dialysis treatment.
- Home HD appears less expensive than center HD, although much or all of the difference probably would be nullified if health aides to assist with home dialysis treatments were required or if opportunity costs were assigned to the time family members must spend learning and assisting the patient with home HD.
- The cost of CAPD is uncertain. Estimates from Medicare ESRD program data are markedly lower than those projected from cost audits or from the prices of supplies and equipment. One can only speculate on possible explanations for this discrepancy. Underreporting of dialysis costs in the Medicare data system seems most likely.

Perhaps the most important finding of this study is that patients who are able to remain on CAPD experience no more days of hospitalization than those who continue on center HD (although more than patients on home HD). The higher hospitalization rates for CAPD reported in the literature, therefore, probably reflect days of hospitalization related to startup of dialysis or early failures.

This result, coupled with the demonstration of the high costs associated with changing dialysis modalities, underscores the importance of carefully selecting those patients most likely to succeed on a given treatment modality. *Public policy decisions on financial incentives for one or another type of dialysis treatment need to take into account the likelihood of changes in treatment modality and the cost of change.*

Finally, this study demonstrates the effects of patient characteristics, such as sex, age, and total length of time on dialysis, on the need for hospitalization. Case-mix differences have important effects on hospitalization rates, and hence, on the costs of ESRD treatment and on survival that are independent of the dialysis modality. To facilitate valid comparisons, future cost studies need to include consideration of differences in population characteristics.

The total costs of care for ESRD patients estimated in this analysis are similar to those by Eggers (12) using 1979 Medicare ESRD data (table 6-13). The slightly lower costs in the 1981-82 data, despite inflation, are probably due to the fact that the figures were obtained in clinically stable patients and exclude the additional costs of dying or changing from one dialysis modality to another.

The limitations of this analysis of Medicare ESRD reimbursement data need to be acknowledged. These limitations relate both to the fact that the patient samples used in the analysis were

Table 6-13.—Estimated Total Costs Per Patient-Year of Care by Modality of Dialysis

	Medicare (ESRD) data	
Dialysis modality	1979[a]	1981-82
Center HD	$23,562	$20,257
Home HD	18,629	14,485
CAPD	–	10,584

[a]P.W. Eggers, unpublished paper on the ESRD program, Office Of Research and Demonstration, Health Care Financing Administration, U.S. Department of Health and Human Services, 1983.

SOURCE: Office of Technology Assessment

selected subsets of the ESRD population and to deficiencies of the Medicare ESRD medical information system.

Patients were included in the analysis only if they had remained on one or another dialysis modality for at least 1 year; hence, early procedure failures and patients newly enrolled in the ESRD program were excluded. Similarly excluded were patients who had previously undergone renal transplantations and those with multiple changes in dialysis modality. The rationale was to focus attention on the costs of treatment in groups that were relatively homogeneous in terms of the clinical course of dialysis. The tradeoff is that the results can be generalized only to about two-thirds of ESRD program beneficiaries on chronic dialysis.

Deficiencies of the Medicare ESRD data system include, first, that dates of change in dialysis modality are often inaccurate, and, hence, compromise calculations of the "cost of changing." Second, significant delays are often experienced in receiving or recording bills that are submitted. The effects of this problem were minimized, so far as hospital costs were concerned, by terminating the period of observation 3 months prior to the end of 1982. Third, Part B reimbursements are reported only in aggregate for the calendar year and do not permit dissection either by their rate of accrual during the year or according to source (dialysis center, physician, commercial supplier). The aberrant result for Part B CAPD costs is particularly troublesome. Fourth, the extent to which the hospital per diem rates used to estimate hospitalization costs also capture dialysis treatments in hospitals could not be ascertained.

Finally, information on patient characteristics is limited. The primary ESRD diagnosis was available for only slightly more than 60 percent of patients, and no information was available on comorbidity. This last deficiency compromised the extent to which case-mix differences could be explored. Relatively *straightforward changes in the Medicare ESRD data collection methods could rectify many of these deficiencies and greatly facilitate future assessments of the ESRD program and chronic renal dialysis in general.*

Appendixes

Appendix A.—Acknowledgments and Health Program Advisory Committee

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National Institute of Arthritis, Diabetes, and Digestive and Kidney Diseases
National Institutes of Health
Bethesda, MD

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Henry Ford Hospital
Detroit, MI

Edmund Lowrie
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National Center for Health Services Research
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D. Oliver
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Oxford, England

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Wilmington, DE

Lester B. Salans
National Institute of Arthritis, Diabetes, and Digestive and Kidney Diseases
National Institutes of Health
Bethesda, MD

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Appendix B.—Glossary of Acronyms and Terms

Glossary of Acronyms

CAPD—continuous ambulatory peritoneal dialysis
CCPD—continuous cycling peritoneal dialysis
EDTA —European Dialysis and Transplant Association
ESRD —end-stage renal disease
GAO —General Accounting Office
HCFA —Health Care Financing Administration
HD —hemodialysis
IPD —intermittent peritoneal dialysis
NIH –National Institutes of Health
RCT —randomized clinical trial
SCD —sterile connection device

Glossary of Terms

Anticoagulant: Any substance that suppresses, delays, or nullifies the coagulation or clotting of blood.

Arteriosclerotic: Pertaining to or affected with arteriosclerosis. A group of diseases characterized by thickening and loss of elasticity of arterial walls.

Arteriovenous: Pertaining to or affecting an artery and a vein.

Ascites: The excessive accumulation of fluid in the abdominal cavity.

Atherogenesis: The formulation of masses of degenerated fatty or lipid material in the arterial wall associated with atherosclerosis.

Cannula: A tube for insertion into a duct or cavity. This is used to attain a continuous flow of liquid into and out of an organ.

Cardiac arrhythmias: Variations from the normal rate or rhythm of heart beats.

Dementia: A general designation for mental deterioration; also referred to as aphrenia, aphronesia, and athymia.

Diabetic nephropathy: A disease of or an abnormal state of the kidneys caused by diabetes.

Effectiveness: Same as efficacy except that it refers to ". . . average or actual conditions of use."

Efficacy: The probability of benefit to individuals in a defined population from a medical technology applied for a given medical problem under ideal conditions or use.

Electrolyte balance: The state in which the body has the correct amount of positively and negatively charged ions in its system.

End-stage renal disease: Chronic renal failure that occurs when an individual irreversibly loses a sufficient amount of kidney function so that life cannot be sustained without treatment intervention. Hemodialysis, continuous ambulatory peritoneal dialysis, and kidney transplant surgery are forms of therapy.

Fistula: An abnormal passage between two organs or from an internal organ to the surface of the body.

Glomerulonephritis: Inflammation of the kidneys characterized by the inflammation of the capillary loops in the glomeruli of the kidneys. It occurs in acute, subacute, and chronic forms.

Hemorrhage: The escape of blood from the blood vessels, either into surrounding tissues or into the environment.

Heparin: A substance occurring in various tissues or produced artificially that renders the blood unable to coagulate.

Hydrothorax: An abnormal accumulation of watery fluid within the pleural cavity.

Hypertension: A common and significant cardiovascular disorder characterized by persistently high arterial blood pressure, ranging from 140 to 200 mm Hg systolic and 90 to 110 mm Hg diastolic pressure.

Hypotension: Abnormally low blood pressure that is seen in shock but not necessarily indicative of it.

Immunosuppressive: Pertaining to or inducing the artificial prevention or diminution of the immune response.

Incidence: The frequency of new occurrences of disease within a defined time interval. Incidence rate is the number of new cases of specified disease divided by the number of people in a population over a specified period of time, usually 1 year.

Laparotomy: Surgical incision through the abdominal section.

Medicare: A nationwide, federally administered health insurance program authorized in 1965 to cover the cost of hospitalization, medical care, and some related services for eligible persons over age 65, persons receiving Social Security Disability Insurance payments for 2 years, and persons with end-stage renal disease. Medicare consists of two separate, but coordinated programs—Hospital Insurance (Part A) Program and the Supplementary Medical Insurance (Part B) Program. Health insurance protection is available to insured persons without regard to income.

Modality: A possible or preferred manner or procedure used in order to carry out a particular function.

Peritoneum: The smooth transparent serous membrane that lines the cavity of the abdomen.

Peritonitis: Inflammation of the peritoneum.

Pleural effusion: The accumulation of fluid within the pleural spaces that occurs either as a result of disease involving the pleurae (the serous membranes investing the lungs and lining the thoracic cavity) or as a result of diseases of other organs that affect the dynamics of pleural fluid production.

Prevalence: In epidemiology, the number of cases of disease, infected persons, or persons with disabilities or some other condition, present at a particular time and in relation to the size of the population. It is a measure of morbidity at a point in time.

Prima facie: True, valid, or self-evident.

Serum triglycerides: Neutral fats synthesized from carbohydrates for storage in animal fat cells.

Symbiosis: In parasitology, the living together or close association of two dissimilar organisms.

Thrombosis: The formulation, development, or presence of a solid mass in a blood vessel or in the heart. It is composed of fibrin, platelets, and, in most instances, erythrocytes,

Uremia: The retention of excessive byproducts of protein metabolism in the blood, and the toxic condition produced thereby.

Uterine prolapse: Protrusion of the uterus through the vaginal orifice.

Validity: A measure of the extent to which an observed situation reflects the “true” situation,

Internal validity: A measure of the extent to which study results reflect the true relationship of a “risk factor” (e.g., treatment or technology) to the outcome of interest in study subjects.

External validity: A measure of the extent to which study results can be generalized to the population that is represented by individuals in the study, assuming that the characters of that population are accurately specified.

Vascular access site: Pertaining to entry into the blood vessel system.

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