REPORT TO THE CONGRESS

Treatment Of Chronic Kidney Failure: Dialysis, Transplant, Costs, And The Need For More Vigorous Efforts

Department of Health, Education, and Welfare

BY THE COMPTROLLER GENERAL OF THE UNITED STATES

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COMPTROLLER GENERAL OF THE UNITED STATES
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To the President of the Senate and the
Speaker of the House of Representatives

This report presents the problems that people with chronic kidney failure face in obtaining treatment and paying the cost associated with the treatment. Various programs of the Department of Health, Education, and Welfare are related to this subject.

Our review was made pursuant to the Budget and Accounting Act, 1921 (31 U.S.C. 53), and the Accounting and Auditing Act of 1950 (31 U.S.C. 67).

We are sending copies of this report to the Director, Office of Management and Budget, and to the Secretary of Health, Education, and Welfare.

Comptroller General
of the United States

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ABBREVIATIONS

ACS	American College of Surgeons
GAO	General Accounting Office
HEW	Department of Health, Education, and Welfare
NIH	National Institutes of Health
VA	Veterans Administration

COMPTROLLER GENERAL'S REPORT TO THE CONGRESS

TREATMENT OF CHRONIC KIDNEY FAILURE: DIALYSIS, TRANSPLANT, COSTS, AND THE NEED FOR MORE VIGOROUS EFFORTS

Department of Health, Education, and Welfare

D I G E S T

WHY THE REVIEW WAS MADE

Under section 299I of the Social Security Amendments of 1972, the Federal Government, effective July 1, 1973, became responsible under the Medicare program for paying for chronic kidney disease treatment for persons under 65.

This is the first and only catastrophic illness for which the Government pays treatment costs for almost all Americans.

National health insurance bills introduced in the 93d Congress varied from providing a broad range of health services to programs which would pay the cost of all catastrophic illnesses.

Because chronic kidney disease is at present the only illness for which such insurance exists, GAO wanted to find out whether patients were getting the treatment needed and if the program should be improved.

FINDINGS AND CONCLUSIONS

Basic situation

Deaths related to kidney diseases in the United States have been estimated at about 50,000 to 55,000 each year. Dialysis and transplant can prolong the lives of persons afflicted. Dialysis performs the blood-purifying function of the kidneys through a machine.

As of January 1, 1974, over 10,000 persons were being dialized.

In the long run, a transplant is cheaper than continued dialysis. Home dialysis is cheaper than center dialysis. Center dialysis is any dialysis performed away from a patient's home, such as in a hospital.

Transplant replaces a patient's kidney with one obtained from a living donor or from a cadaver. From 1951 to June 30, 1973, more than 8,800 transplants were performed.

Before July 1973 the major funding sources available for paying treatment costs were such Federal agency programs as Medicare (for those over 65) and State programs, private health insurance programs, and patients' personal resources. (See pp. 5 to 9.)

The Department of Health, Education, and Welfare (HEW) estimated that the first year's cost of section 299I was about $240 million. GAO reviewed the treatment programs in 12 States and 2 counties.

HEW's role in kidney disease treatment includes:

--support of research into the cause, prevention, and treatment of the disease and

--the responsibility under Medicare of paying treatment costs for most patients.

HEW's policies and regulations directly affect the system of health care for kidney patients, the level of care provided, and the cost of treatment.

Access to dialysis

The incidence of dialysis treatment has increased rapidly since the first dialysis programs in 1962. In July 1974, 664 dialysis and 167 transplant facilities were eligible for Medicare reimbursement.

Nevertheless, several problems require HEW's attention to insure that everyone who needs treatment gets it.

In the 12 States and 2 counties reviewed, an average of 36 new patients per million population were treated during 1972. Treatment rates ranged from 68 in Los Angeles County to 14 in South Carolina. Variations occurred in part because:

--Doctors were not referring patients for treatment or dialysis facilities were rejecting patients because of stringent acceptance criteria. (See pp. 13 and 16.)

--Treatment facilities were concentrated in metropolitan areas. In general, the further one lived from dialysis facilities, the less chance he had to be treated. (See p. 18.)

--A balance of treatment programs was not provided. Some areas offered only home dialysis and patients not suited for it were not treated. (See p. 20.)

HEW could compare incidence and treatment rates for geographic areas to get indications of problems requiring the attention of HEW and the medical profession.

Access to transplants

Although kidney transplants have increased, the demand has not been satisfied because not enough cadaver kidneys are being donated. Partial data for 1972 showed that only 37 percent of over 3,000 persons awaiting the donation of a cadaver kidney got one.

Cadaver kidneys were used in about 59 percent of the 1,993 transplants performed in 1972. Most of these were from accident victims. National Safety Council statistics show that about 59,000 accident victims in 1972 were between 5 and 45 years old, which is within the age criteria for cadaver donors. So the problem appears to be one of getting cadaver kidneys donated.

Many kidney foundation officials believe that a massive public and medical education program is required to publicize the need for donated kidneys. (See p. 29.)

On the basis of 3-year data GAO reviewed, it appears that the death rates of transplant patients using cadaver kidneys are greater than those of transplant patients using living related donors or of dialysis patients.

In spite of the patient risk involved in transplanting cadaver kidneys, HEW should encourage their donation to assure that enough are available for patients who want such a transplant. (See p. 39.)

The data GAO obtained shows that the number of transplants performed by a hospital, donor and recipient ages, patient selection, and reaction-suppressant drugs all seem to affect transplant success. Additional factors that may affect success are the patient's physical condition, the length of time he has been on dialysis, and the proficiency of the transplant team. (See p. 30.)

The cost of treatment

The average cost of a successful transplant is comparable to that of home dialysis in an initial treatment year but is much less than that of center dialysis. A transplant which functions beyond the first year saves about $29,700 or $6,600 annually, depending on whether the patient would have been dialyzed in a center or at home. GAO estimates that second-year treatment cost savings of about $12 million could result from each 1,000 transplants. (See p. 42.)

Home dialysis costs much less than center dialysis. The average annual cost in 1972 for center dialysis was $30,100--about $15,200 more than home dialysis in the first year and $23,100 more than each succeeding year of treatment. For every 1,000 patients treated at home instead of at a center, there would be a significant annual savings. Even so, Medicare regulations do not require centers to provide training programs for home dialysis. (See p. 39.)

Improvements in the Medicare program

Although Medicare covers most people for chronic kidney disease, some changes should be considered.

The program discriminates against patients whose transplants fail after 12 months. Such patients are liable for the cost associated with the failure and any dialysis required during the waiting period before Medicare coverage resumes. Medicare eligibility begins with the third month after the month in which dialysis is started and ends with the twelfth month after the month a patient receives a kidney transplant.

Therefore, if a transplant functioned for 12 months and then failed, the patient would have to return to dialysis and start a new waiting period for Medicare coverage to resume. The waiting period would last until the third month after the month in which the patient began dialysis.

Also, the program does not provide incentives for home dialysis, the least expensive form of dialysis treatment. HEW should encourage those patients who wish to remain on dialysis to be treated at home rather than in a center if medical and other conditions permit. (See pp. 47 and 48.)

RECOMMENDATIONS

The Secretary of HEW should report annually to the Congress on the progress and problems of providing needed treatment.

This information could be incorporated into his annual report to the Congress on his continuing study of the operations and administration of the insurance programs under Parts A and B of Medicare.

To be able to prepare this report on the kidney treatment program and to administer this program properly,

the Secretary should provide for regular and systematic:

--Data-gathering on dialysis and transplant facilities, transplant donor and recipient characteristics, and survival and death rates.

--Data analysis to identify potential or actual problems, better or more cost-effective treatment, and geographic areas that may have special problems. (For details of factors to be considered, see pp. 53 to 54.)

The Secretary should also:

--Set new-patient treatment goals by geographic areas to determine whether persons considered treatable are being treated.

--Amend the Medicare regulations to require centers to provide training programs for home dialysis unless the Secretary determines on a case-by-case basis that such a requirement would not be warranted.

Because implementing the above recommendations will take time, the Secretary should act now to provide for:

--Educating the public on the nature of kidney disease and how and where it can be treated and financed under Medicare.

--Encouraging cadaver kidney donations.

--Keeping the medical profession advised on improvements in patient care and treatment equipment.

--Encouraging liberalized treatment criteria at facilities not accepting patients because of age, suitability for home dialysis, and diabetes and other diseases by establishing guidelines for treatment under Medicare.

--Evaluating dialysis and transplant facility needs by geographic areas, especially those with low new-patient treatment rates.

--Seeking to encourage patients who wish to remain on dialysis to be treated at home rather than in a center if their medical and other conditions permit.

AGENCY ACTIONS AND UNRESOLVED ISSUES

HEW concurred with most of these recommendations and, where administratively possible, has begun to implement them. Actions promised by HEW will correct many of the problems.

HEW did not agree with GAO's recommendations to set new-patient treatment goals by geographic areas and to require centers to provide training programs for home dialysis and advised GAO of other ways it plans to deal with the problems identified. GAO believes that such ways are consistent with the intent of the two recommendations. (See p. 55.)

MATTERS FOR CONSIDERATION BY THE CONGRESS

The Congress should consider legislation to

--eliminate the waiting period for Medicare coverage to resume for transplant patients who reject their transplants after 12 months and

--encourage greater use of home dialysis treatment by providing an incentive for medically and psychologically suited patients to select home over center dialysis.

Suggested legislative language to address the problem of the waiting period for transplant patients is included on pages 58 to 59.

Because there are a variety of ways to encourage greater use of home dialysis (see pp. 48 to 49), GAO did not develop specific legislative language to address this problem.

Tear Sheet

CHAPTER 1

INTRODUCTION

KIDNEYS AND THEIR FUNCTION

Each of us has two kidneys which maintain the delicate chemical balance required for all other body organs to function properly. They filter and return to the bloodstream almost three times the body weight in water and salts every day--about 200 quarts. About two quarts containing harmful substances are discharged as urine.

Because each kidney can process volumes many times greater than it normally does, one kidney can suffice if the other is removed.

If the kidneys do not remove wastes from the blood, uremia--urea in the blood--develops. Advanced uremia usually causes headache, nausea and vomiting, blurred vision, convulsions, and coma and will ultimately lead to death. The severity of uremia parallels the extent of kidney failure. The permanent loss of function of both kidneys is called chronic kidney failure.

TREATING CHRONIC KIDNEY FAILURE

Death certificates[1] show that about 50,000 to 55,000 deaths annually are related to kidney disease. A person with chronic kidney failure faces a serious but not hopeless situation. Two treatment methods--dialysis and transplant--enable some people with chronic kidney failure to live. The first step in obtaining treatment usually occurs when an attending physician refers a patient to a specialist. The patient is then referred to a hospital for evaluation as to suitability for dialysis.

More than half of the patients suitable for dialysis are also suitable for transplant.

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[1]Estimated deaths related to kidney disease are affected by physicians' reporting practices and diagnostic accuracy as well as by the association with hypertension and cardiovascular disease.

Dialysis

Dialysis performs the kidney's purifying function by circulating the patient's blood through a kidney machine (hemodialysis) or by using the membrane that lines the patient's abdominal cavity (peritoneal dialysis) to remove harmful substances. A patient must be dialyzed two or three times a week.

Dialysis was first used in the Netherlands in 1943. In early 1962 long term dialysis for treating chronic kidney failure was started in Seattle. The first home dialysis programs began in 1963 in Boston and in 1964 in Seattle.

Dialysis can be performed in a hospital, another properly equipped facility, or in the home. Dialysis performed in any location other than a patient's home is referred to as center dialysis in this report. The patient's condition and other factors generally govern the setting. Some physicians prefer home dialysis if the patient is psychologically and medically capable, has an assistant, and has adequate home facilities. Home patients are trained in self-treatment at dialysis centers.

Nonhospital settings range from centers with many dialysis machines to small centers with only a few. In some rural areas, trailers have been set up to treat patients. A hospital may be required if a patient is being treated to lower the toxic wastes to an acceptable level or requires constant medical attention.

No one knows the exact number of dialysis patients. According to the January 1, 1974, National Dialysis Registry, there were 10,164 dialysis patients. Sixty-six percent were being treated in centers and 34 percent at home. The registry was established by the National Institutes of Health (NIH) in 1969 but, because reporting has been voluntary, not all dialysis units report to the registry.

Transplant

Transplant is a surgical process which replaces diseased kidneys with healthy ones. Healthy kidneys are obtained

either from living donors or cadavers. The possible rejection of the transplant by the patient's body is a major disadvantage to this method.

Kidney transplants were experimental from 1945 to 1950, and the first life-sustaining transplant occurred after 1951. Transplants in the United States and Puerto Rico have been consistently increasing, particularly in recent years, and more hospitals have opened transplant units. Data reported voluntarily to the American College of Surgeons (ACS) by transplant hospitals shows that, of the 8,823 transplants from 1951 through June 1973, 65 percent, or about 5,700, occurred since 1970.

Transplants (note a)

			Increase over prior period	
	Number	Percent	Number	Percent
1951-62	75	1	-	-
1963	163	2	88	117
1964	239	3	76	47
1965	305	3	66	28
1966	338	4	33	11
1967	448	5	110	33
1968	676	8	228	51
1969	838	9	162	24
1970	1,091	12	253	30
1971	1,616	18	525	48
1972	1,993	23	377	23
1973 (6 mos.)	1,041	12	-	-
Total	8,823	100		

[a]ACS data is incomplete because not all transplant hospitals submitted data.

TREATMENT INNOVATIONS

Since the first long term dialysis program in 1962, many innovations have occurred. More efficient hemodialysis machines, for example, have reduced dialysis time. A single

needle is being used and home dialysis has become safer. In addition, work is being done or has been done to develop

--special diets for kidney disease patients,

--improved criteria for selecting patients who are less likely to reject a transplant,

--drugs for reducing transplant rejection,

--kidney-preserving devices which allow more time to better match cadaver kidneys with recipients, and

--improved dialysis machines which require only about one-half gallon of tap water rather than 80 to 100 gallons of specially demineralized water.

FEDERAL INVOLVEMENT

The Federal Government has been directly and indirectly involved in establishing and operating treatment centers, financing treatment, and conducting and sponsoring research into kidney disease since the early 1960s.

The Department of Health, Education, and Welfare (HEW) has a major role in the area of kidney disease, including (1) the support of research into the cause, prevention, and treatment of the disease and (2) the responsibility under Medicare of paying for treatment costs for most patients. In administering the kidney disease programs, HEW's policies and regulations directly affect (1) the system of health care for kidney patients, (2) the level of care provided, and (3) the cost of treatment. Because of HEW's responsibility and influence in these matters, our recommendations are directed to HEW wherever it has legislative authority to act. In cases where it does not have this authority, our recommendations are directed to the Congress.

Various HEW programs and other Federal programs that relate to kidney disease are described briefly below.

Medicare

Under the Social Security Amendments of 1972 (Public Law 92-603, Oct. 30, 1972), the Government, effective July 1, 1973, became responsible for the cost of treatment of chronic kidney disease through HEW's Medicare program. Most persons under age 65 with chronic kidney disease who undergo dialysis or transplant are covered for treatment costs. Before the 1972 amendments, Medicare helped finance health care for persons 65 and over. According to HEW, in July 1974, 664 dialysis centers and 167 hospitals in the United States and Puerto Rico were performing transplants and were eligibile for reimbursement under Medicare.

In general, Part A of Medicare covers inpatient hospital costs of dialysis and transplant and Part B covers physicians' services, outpatient hospital services, and other medical services and supplies. Most of the transplant and dialysis costs are paid for under Parts A and B, respectively.

Social security taxes finance Part A of the Medicare program, but Part B is financed by a monthly premium paid by beneficiaries and a matching Federal contribution from Federal revenues. HEW estimates that 5 to 8 percent of the under-65 population--about 9 to 15 million people--are ineligible for kidney treatment under Medicare because they are not currently or fully insured under social security or because they are the dependents or spouses of people who are not currently or fully insured under social security. These people are liable for Federal taxes, which are a source of the Government's contribution for Part B, but they are ineligible for Part B coverage.

Medicaid

Under Medicaid, a grant-in-aid program administered by the Social and Rehabilitation Service of HEW, the States can pay for treating chronic kidney failure. Generally, eligible persons are those who receive public assistance under certain titles of the Social Security Act or, in 20 States, those who have income and resources insufficient to meet medical needs. Services vary among States, and the Federal Government pays 50 to 81 percent of the Medicaid costs, depending on the State's per capita income.

Vocational Rehabilitation Act

The Vocational Rehabilitation Act of 1920 authorizes Federal grants to the States to help rehabilitate handicapped persons for gainful employment. The Rehabilitation Services Administration, an agency of the Social and Rehabilitation Service, helps the States plan, develop, and coordinate State programs. An Administration official estimated that the program helps 300 to 400 individuals with kidney disease annually at a cost of about $1 million.

Comprehensive health planning

On June 30, 1974, authorization for the comprehensive health planning program expired. Administered by HEW's Health Resources Administration, the program helped States and local communities, through Federal grants, to develop continuing processes to produce comprehensive plans for meeting their current and future health needs.

Responsibilities of the Health Resources Administration included (1) maintaining liaison with other Federal agencies and national organizations, (2) assessing the progress of State and areawide planning agencies for use in guiding Federal policy, and (3) administering section 221 of Public Law 92-603, which limits Federal reimbursement for health facility construction costs disapproved under the comprehensive planning program.

The program's primary purpose was to promote adequate health care for all persons through effective and efficient use of all health resources.

According to HEW, the Regional Medical Program of the Health Resources Administration was, as of April 1975, investing $4.8 million in grants to develop chronic kidney disease treatment services reimbursable under the Medicare program. These funds were principally aimed at startup costs of cadaver kidney procurement systems and associated specialized laboratory services required for efficiently evaluating and distributing cadaver kidneys.

In January 1975, the President signed Public Law 93-641 which, among other things, combined the planning functions

of the comprehensive health planning program with the planning function of certain other HEW programs, such as the Hill-Burton program which helps States plan, construct, modernize, and equip health facilities.

Veterans Administration

The Veterans Administration (VA) provides dialysis and transplant for all qualified veterans with chronic kidney failure whether the failure is service connected or not. Public Law 89-785 (38 U.S.C. 5053), dated November 7, 1966, provides that nonveterans may also receive such services from VA hospitals if facilities are available but VA must be reimbursed for the full cost of services rendered under agreements with other hospitals.

As of March 1973, 44 VA hospitals had 501 dialysis beds, of which 123 were for home training. Ten hospitals also operated branch dialysis centers. As of March 1973, 979 patients were being treated in the 44 VA hospitals and 26 patients were being treated in the 10 branch centers. Of the 979 hospital patients, 173 were being trained for home dialysis. VA was also providing backup medical services for 766 patients being dialyzed at home. Thirty-three VA hospitals reported a total of 327 transplants performed in 1972.

At the end of 1972, nearly 18 percent of all dialysis patients in the 12 States and 2 counties reviewed were being treated by VA. (See ch. 6.) Nine VA hospitals in these locations performed 94 transplants in 1972.

Availability of VA hospitals has affected the number of patients being treated in an area--particularly in States having few non-VA treatment facilities. (See app. II.) In Massachusetts, which had 16 non-VA facilities, VA was treating slightly more than 5 percent of the dialysis patients as of the end of 1972. On the other hand, in Arkansas, which had 3 non-VA facilities, VA was treating nearly 64 percent of the dialysis patients as of the end of 1972.

Military

The Army, Navy, and Air Force have also provided a limited number of dialysis machines for home and center programs. Home dialysis training is done through the Civilian Health and Medical Program of the Uniformed Services.

Research

The National Institute of Arthritis, Metabolism, and Digestive Diseases is the NIH component primarily responsible for supporting kidney disease research and research training and the related field of urology. NIH has requested $17,355,000 for its fiscal year 1975 program.

The National Institute of Allergy and Infectious Diseases of NIH supports research on the infectious and immunological aspects of kidney disease. It also provides (1) contract support for research and development projects in the transplant immunology field and (2) the materials used for tissue matching in most U.S. transplant centers.

Four other NIH components involved to varying degrees in research related to kidney disease are the National Heart and Lung Institute, the National Cancer Institute, the National Institute of Child Health and Human Development, and the National Institute of General Medical Sciences.

The Air Force and the Army have also done some research on kidney disease.

STATE AND PRIVATE INVOLVEMENT

Eight of the 14 States reviewed--including the 2 where the counties reviewed were located--appropriated funds to directly assist patients with kidney disease. These funds varied considerably. In fiscal year 1973, one State legislature appropriated $200,000 for treating patients, which averaged about $4,400 per 100,000 population on the basis of 1970 census data. Another State legislature appropriated $1,220,000, which averaged about $11,000 per 100,000 population. Two of the States operate dialysis facilities. As noted earlier, some States also pay for treatment through their Medicaid and vocational rehabilitation programs.

Private sources of financial aid to patients with chronic kidney failure include private health insurance, kidney foundations, and local community organizations.

CHAPTER 2

DIALYSIS TREATMENT--ACCESSIBILITY AND PROBLEMS

The system for delivering dialysis treatment has expanded rapidly since the first program in 1962, indicating that the medical profession, the Federal Government, and State governments have taken steps to treat chronic kidney failure.

Nevertheless, several problems require HEW's attention to insure that everyone needing treatment gets it. These problems include patients not being referred for treatment, stringent treatment criteria in some areas, location of facilities, and an imbalance of available programs.

NUMBER OF NEW PATIENTS TREATED

We tried to obtain the number of new patients who began treatment for chronic kidney failure during 1972 in the 14 jurisdictions reviewed. To do this, we contacted all facilities--Federal and non-Federal--involved with dialysis and transplants in these jurisdictions.

According to the data obtained from 121 dialysis centers and 48 transplant hospitals, 1,642 new patients were treated for chronic kidney failure during 1972. To get more meaningful information and to compare one geographic area with another, we converted the number of new patients treated to a rate per million of population on the basis of 1970 census data.

	Number of new patients treated in 1972		
	Total		Per million of 1970 population
Los Angeles County, Calif.	475		68
Cook County, Ill.	235		43
Massachusetts	218		38
Minnesota	164		43
Missouri	124		27
Washington	114		33
Georgia	77		17
Arizona	55		31
Oregon	53		25
Arkansas	40		21
South Carolina	35		14
Maine	23		23
New Hampshire	18		24
Vermont	11		25
Total	1,642	Average	36

We asked 43 physicians--including dialysis center directors and transplant surgeons--whether the incidence of chronic kidney failure should vary by location. They responded as follows:

--22 said the incidence should not vary.

--10 said the incidence should vary.

--7 said it may vary.

--4 did not give an opinion.

Among the reasons given by 17 physicians as to why variations should or may occur were that (1) blacks have a higher incidence and (2) the rate is higher in urban and poverty areas.

We asked 56 physicians to estimate new annual treatable rates per million population, regardless of the availability of treatment facilities, and 47[1] responded as follows.

Number	Percent	Estimated new annual treatable rate per million population
11	23	Under 50
30	64	50 to 70
6	13	Over 70

Seventy-seven percent of these physicians estimated the new annual treatable rate to be over 50 per million population. In the jurisdictions reviewed, the rates for 4 metropolitan areas did exceed 50, indicating that these estimates are reasonable.

Metropolitan area	New patients treated per million population in 1972
Los Angeles County	68
Tucson	58
Minneapolis-St. Paul	55
Boston	52

The overall average rate of new patients treated in the 14 jurisdictions was only 36 in 1972; actual rates ranged from 68 to 14. We identified some factors which contributed to the wide variations in new-patient treatment rates. These factors are:

--Patients were not being referred for treatment.

--Treatment criteria keep some patients from being treated.

--Treatment facilities were not dispersed in proportion to the population.

--A balance of treatment programs was not provided.

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[1]Includes 35 physicians who commented on whether incidence should vary and 12 others.

WHY PATIENTS ARE NOT BEING REFERRED FOR TREATMENT

According to an official of the Health Services and Mental Health Administration,[1] HEW, the referral problem is, in part, the "failure to refer patients on the part of physicians who do not have the expertise to assess and treat properly."

On February 26, 1973, a Senate bill (S. 994) was introduced in the first session, 93d Congress, to amend the Public Health Service Act to provide assistance for kidney transplant, hemodialysis, and related facilities and services. As of December 1974, no action had been taken on this bill. One of the bill's sponsors included an article from the 1971 issue of "Social Problems" on the referral problem in the Senate Congressional Record of February 26, 1973. An excerpt follows:

> "* * * Without question, the technological potential seems to have outstripped the communication networks in medicine, as well as the resources.
>
> * * * In addition, it is likely that many physicians are unaware of (a) the success of kidney transplantation and dialysis, (b) the categories of patients who can benefit, (c) the presence of the nearest center, and (d) the fact that some centers are not overcrowded. Even if the physician is aware of the therapeutic success of the procedures, he may be afraid the patient will be denied treatment. He may believe that the patient is too old, or that children cannot be dialyzed, or that the sacrifices in travel and expense are too great for the family."

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[1] Reorganized in 1973 into other Public Health Service components.

Of 53 physicians[1] we asked, 33 indicated that the lack of patient referrals is a problem, 4 indicated it may be a problem, and 16 indicated that it is not. According to them, some patients are not being referred for treatment because some general practitioners are not aware of available treatment programs, facilities, or criteria and some are not aware of available financial aid.

Officials of dialysis centers told us of patients who sought treatment themselves:

--In Georgia, several patients got dissatisfied with their family doctors and went to an Atlanta center after their condition failed to improve and they feared for their lives.

--A patient in a northern New Hampshire hospital was not referred to a center for treatment and was told he was going to die. He left the hospital and received treatment at a center in Vermont.

--A patient's wife wrote to the director of a Maine facility explaining that her husband had chronic kidney failure and their family doctor offered no help and did not refer her husband. The patient later started treatment at the facility.

Others have also recognized the referral problem. In its kidney disease plan submitted to the Regional Medical Programs Service of the Health Services and Mental Health Administration in 1973, the tristate region of Missouri, Kansas, and Southern Illinois stated that:

"Both in the large urban areas and the rural communities throughout this region as well as nationally, there is a kidney disease management delivery gap when one leaves the medical centers. In large part, this is because the increased body of scientific, technical and

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[1]Includes 45 who commented on whether incidence rates should vary or on new annual treatable rates. (See pp. 11 to 12.)

clinical knowledge in nephrology has mushroomed, particularly during the past decade and health care personnel who are not recent graduates have not kept pace with the expanding body of knowledge. In part, this reflects sadly on our ability to accomplish postgraduate education. Further, to relieve the demand on physicians, this region has a critical need for increasing the number capable of functioning as physician's assistants and nurse associates in the overall management of patients with end-stage renal (kidney) failure."

What can be done to increase referrals?

Solving the referral problem will not be easy. Twenty-six dialysis center directors and physicians we talked to said the solution may be to educate local general practitioners and the general public on the disease, the treatment criteria, and the availability of treatment facilities and programs. Generally, these physicians feel the education can be accomplished through the following methods.

General practitioner:

Postgraduate courses
Kidney foundation symposiums
Lectures
Professional publications
Updated listings of available treatment facilities

General public:

Radio and television public service announcements
Newspaper and magazine articles

Four of these physicians believe that the problem can best be overcome by educating the public so that it will put pressure on physicians to refer patients for treatment. They believe that physicians are difficult to educate and have been unwilling to learn about treating kidney disease.

TREATMENT CRITERIA KEEP SOME PATIENTS FROM BEING TREATED

According to a 1967 report,[1] some criteria for selecting patients were that the patient (1) be 15 to 45 years old, (2) be of good physical condition (free from irremediable diseases and from illnesses such as severe hypertension), (3) live sufficiently close to a dialysis center, and (4) have adequate financial resources.

We asked officials at 47 of the 121 dialysis units reviewed what would preclude treatment. Some would not accept patients with diabetes or other life-threatening diseases, patients who were considered too old or too young, or patients not suitable for home dialysis.

Patients with diabetes

Although 40 of the 47 centers treated patients with diabetes, 4 strongly discouraged diabetics from seeking treatment and 13 considered each diabetic individually.

Most of the 40 centers that treated diabetics would not treat those who had severe cases or were blind. Because diabetics have done poorly on dialysis, those centers that would treat such patients either strongly discouraged them from seeking treatment or considered each patient individually.

Patients with other life-threatening diseases

Generally, the 47 centers would not treat patients with other life-threatening diseases, such as cancer, cardiac disease, or liver disease. However, 20 centers would provide treatment on an individual basis and some would treat these patients if they were expected to have about 6 months of "reasonably good life."

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[1] Report of the Committee on Chronic Kidney Disease-1967 (commonly referred to as the Gottschalk Report).

Patient's age

Generally, a patient's age based on physiological or medical condition rather than chronological age is a treatment criterion. However, a few centers were reluctant to treat patients younger than about 10 or older than about 65 because children develop growth and emotional problems and require special equipment and older patients historically do poorly on dialysis.

Patient suitability for home dialysis

Centers in South Carolina, Vermont, and all but one in Washington have only home dialysis programs. In accepting a patient for home training these centers generally consider

--the patient's medical and psychological stability,

--the availability of a suitable assistant to help administer the treatment,

--the degree of motivation of the patient and his family, and

--the adequacy of home facilities to support the dialysis equipment.

Following are two examples of patients who did not meet these criteria and were not accepted for treatment:

--In Washington, a man who could have been treated in a center program was not accepted for treatment because he was medically and sociologically unsuitable for home dialysis.

--In Washington, a 70-year-old widow who was medically suitable for center dialysis was not accepted for treatment because she lived alone and was not capable of dialyzing herself at home. She died in a nursing home.

FACILITIES NOT DISPERSED IN PROPORTION TO POPULATION

In the 12 States reviewed, about 41 percent of the population lived less than 20 miles from major cities where about 75 percent of the kidney disease treatment centers were located. About 12 percent of the population lived from 20 to 40 miles from these major cities in areas which had only about 4 percent of the centers. The availability of facilities is disproportionate to the population distribution and contributes to the problem of nontreatment. The difference in the number of new patients treated per million population in 1972, based on the distance that these patients lived from major treatment centers, is shown below. (See app. III.)

	1972 new treatment rate (per million)
Less than 20 miles from major treatment centers	39
20 to 40 miles from major treatment centers	25

In other words, patients living in areas having major treatment centers were treated at a rate of 14 patients per million more than those living 20 to 40 miles away. In general, the further away one lives from chronic dialysis facilities, the less chance he or she has of being treated.

Other States

We wanted to determine what States had few dialysis centers and how many patients these centers were treating. As of May 1973, 13 States had less than 3 dialysis centers. Three of these States--New Hampshire, South Carolina, and Vermont--were included in our review. Data on the other 10 follows.

	Number of dialysis centers	Dialysis patients as of 12-31-72	1970 population (000 omitted)
Kansas	2	32	2,247
South Dakota	2	7	666
Utah	2	70	1,059
Alabama	1	58	3,444
Alaska	1	10	300
Delaware	1	10	548
Idaho	1	4	713
North Dakota	1	7	618
Montana	-	-	694
Wyoming	-	-	332
Total		198	10,621

We don't know how many new patients were treated in the dialysis centers in these States in 1972. As of December 31, 1972, however, only 198 were being treated, or an average of 19 patients per million population of these States. The States and counties reviewed averaged 62 patients per million population as of December 31, 1972. Although some patients in the States with less than three dialysis centers were going to other States for treatment, health officials in these States did not think very many were doing so.

State health officials in several of the 10 States said their State's population centers were not large enough to support a dialysis center. Dialysis patients may travel great distances, therefore, to centers in their own or neighboring States. Several of the 10 States plan to expand or establish centers soon.

On April 16, 1975, HEW stated that, since the advent of kidney disease treatment legislation, it is no longer aware of grossly underserved areas.

BALANCE OF DIALYSIS PROGRAMS NOT PROVIDED

Whether a patient is placed on a home or center dialysis program depends on his or her medical, mental, and sociological suitability and the availability of each program. This availability varies greatly within the United States and is strongly influenced by the philosophies of treating physicians. Some areas emphasize home programs and have mostly home dialysis training programs, and other areas emphasize center programs and have mostly center dialysis. Furthermore, as discussed earlier, some States have few or no centers and others have many.

Physicians' opinions differ on how many patients are suitable for home dialysis. Thirty-six physicians associated with dialysis centers gave us estimates on the percentage of patients they believe to be suitable. The estimates ranged from about 10 percent to 90 percent and averaged about 50 percent. They believe the remaining patients are more suitable for center dialysis. About 36 percent of the patients in the areas we reviewed were on home dialysis at the end of 1972.

Where home programs are emphasized and center programs are few or nonexistent, patients requiring center dialysis either accept home dialysis, for which they may not be suited, or go untreated. Conversely, where center programs are emphasized and facilities are abundant or concentrated, patients may be receiving care above the level needed, resulting in higher costs.

Georgia and Washington emphasize[1] and South Carolina and Vermont offer only home dialysis programs. On the other hand, Cook County, Los Angeles County, Massachusetts, and Minnesota emphasize center dialysis programs. Following are the percentages of new patients who went on home and center dialysis during 1972 in the States and counties reviewed.

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[1]States and counties in which 75 percent or more of the dialysis patients were on a home or a center program.

	Home dialysis	Center dialysis
South Carolina	100	-
Vermont	100	-
Georgia	92	8
Washington	85	15
Arkansas	73	27
Missouri	68	32
Arizona	50	50
Maine	43	57
Oregon	29	71
Minnesota	24	76
Los Angeles County	13	87
Massachusetts	13	87
Cook County	11	89

In States where the home program is emphasized or the only one offered, six physicians we contacted believe it is better than center dialysis. Some of their reasons are:

--Many patients live too far from dialysis facilities and travel and weather could be a problem.

--Home dialysis allows more patients to be treated with given resources.

--Home dialysis is less costly.

--Home dialysis allows the patient more convenience and a greater opportunity to seek employment.

Some of the physicians cited disadvantages to home dialysis, such as mental and psychological problems for the patient and his or her family, dependence on an assistant, and potential medical complications.

Some centers in Washington, South Carolina, and Arkansas have refused dialysis treatment to patients because they were not suitable for home dialysis and center programs were not available. Some require patients to be capable of going on home dialysis as a condition of treatment.

On the average, the four States that emphasize or offer only home dialysis programs treated fewer new patients than the other jurisdictions.

	1972 new-treatment rate (per million)
Areas offering both home and center dialysis (7 States and 2 counties)	41
Areas offering mostly or only home dialysis (4 States)	21

In our opinion, the imbalance of dialysis programs offered in the areas reviewed affected the number of patients treated. Generally, those areas that offer only, or nearly only, home dialysis programs are not treating as many new patients as the areas that emphasize center dialysis programs and have home dialysis programs as well. Thus, to satisfy dialysis treatment needs, a strong center program complimented by a home program seems necessary.

CHAPTER 3

ACCESS TO KIDNEY TRANSPLANTS

Kidney transplants have increased in recent years. A successful transplant permits the patient to live a more normal life than dialysis does.

The demand for kidneys has not been satisfied because not enough cadaver kidneys are being donated. An education program is needed to publicize the need for kidneys.

The major disadvantage to a transplant is that the patient's body may reject it. When this occurs, the patient returns to dialysis, receives another transplant, or dies. On the basis of 3-year data we reviewed, it appears that the death rates for transplants using kidneys from cadaver and living unrelated donors are greater than for transplants from living related donors or for dialysis patients.

However, analyzing transplant data over a longer period could find a change in these rates.

Treatment	Percent of patients who died within 12 months	24 months
Dialysis (note a)	13	23
Transplant--overall (note b)	21	29
Living related donors	10	14
Cadaver and living unrelated donors	30	41

[a]"Mortality from Kidney Diseases," Statistical Bulletin, Vol. 52, Metropolitan Life Insurance Company, July 1971.
[b]Based on 1970 transplant data reported to ACS.

Even with maximum use of transplant, long term dialysis capability will still be needed, particularly for patients who cannot receive transplants for medical reasons.

ADDITIONAL KIDNEYS NEEDED FOR TRANSPLANT

Because of the shortage of donated kidneys, not as many transplants are being performed as could be. Programs to obtain kidneys have generally not met the demand. An HEW education program aimed at the general public and the medical profession might help.

Criteria for obtaining a transplant

Estimates from 39 physicians in 13 States indicated that most treatable patients are suitable for transplant. Thirty-four of the 39 gave estimates that ranged from 40 percent to 90 percent, and 22 of the estimates fell in the 60- to 90-percent range. Of the remaining five physicians, one indicated virtually all patients were suitable, two indicated a majority were, and two had no idea.

Twenty-two physicians identified the specific factors that would keep a patient from receiving a transplant. Their comments are summarized below.

--11 cited malignancy because rejection-suppressive drugs accelerate the spread of cancer.

--9 cited other life-threatening diseases, such as chronic liver disease, severe heart disease, and chronic lung disease.

--4 cited psychological problems.

--13 cited age. The ages given were as follows.

Over	Number of physicians (note a)
50	2
55	5
60	5
65	2
Under	
5	1
2	1

[a]One gave two "over" ages--depending on whether a cadaver or living related donor was available. Two gave an "under" and an "over" age.

Criteria for donating a kidney

Ten of the 11 organ-sharing groups--loosely affiliated hospitals that cooperate in procuring, preserving, and distributing cadaver kidneys--that we identified throughout the country indicated that criteria for rejecting donors are fairly uniform. Among the major diseases mentioned that would preclude a donation were cancer, kidney disease, and diabetes. The groups indicated that age was also a criterion and 4 of the 10 gave an upper and lower age limit as follows.

Upper age limit	Number of organ-sharing groups
70	2
65	2
60	2
55	3
40	1
Lower age limit	
10	1
5	1
3	2

The age criteria of the organ-sharing groups and of the 13 physicians that cited age as a factor in precluding a patient from receiving a transplant generally conform to the actual ages of donors and recipients in 1972.

Of 1,993 transplants reported to ACS, less than 9 percent of the donors and less than 12 percent of the recipients were 51 years of age or older.

Age range	Percent of transplants	
	Recipients	Donors
51 to 55	8.5	4.9
56 to 60	2.7	2.2
61 to 65	.5	1.3
Over 65	.2	.4
Total	11.9	8.8

In addition, less than 5 percent of the donors and less than 4 percent of the recipients were 10 years of age or less.

Kidney sources

Transplant kidneys come from living donors--usually a close relative of the patient--and cadavers. Cadaver kidneys are usually obtained through permission granted to an attending doctor by the donor's next of kin.

The length of time that a kidney can be preserved before transplant varies with the preservation method used. Kidneys can be preserved up to 72 hours in a machine or for 24 hours or more on ice.

The 8,823 transplants performed in the United States and Puerto Rico from 1951 through June 30, 1973, as reported to ACS, show the use of cadaver kidneys is rising. During 1951 through 1966, about 38 percent of the reported transplants used cadaver kidneys. In 1972 the percentage was about 59. Accident victims supplied 60 percent of the cadaver kidneys used in 1972 transplants.

The principal living kidney donors are patients' brothers and sisters (other than twins) and parents. About 40 percent of the 8,823 transplants used these donors and about 54 percent used cadaver donors. The remaining transplants (about 6 percent) used kidneys of other living donors--twins, sons, daughters, other relations, spouses, and unrelated persons.

Wide variations exist in the use of cadaver kidneys in the United States. For example, 90 percent of the 230 transplants reported from Tennessee during 1951 through June 30, 1973, used cadaver kidneys. In contrast, of the 109 transplants reported from Alabama for the same period, only 31 percent used them.

Shortage of donated kidneys

We don't know how many patients are waiting for a donated kidney. Partial data available at the University of California at Los Angeles, which maintains a national transplant communications network, shows that 3,156 patients were awaiting donated cadaver kidneys in 1972. However, not all transplant hospitals participate in the network. Only 37 percent of the 3,156 patients received transplants during the year.

Of 37 physicians contacted to determine why more transplants were not being done, 31 said there were not enough donated kidneys.

Some of these physicians said the demand for kidneys may be affected by the fact that:

--Physicians are reluctant to transplant a cadaver kidney on the basis of the poor success rate.

--Patients are not being referred from dialysis centers.

Some reasons given for why enough kidneys were not donated were:

--Attending physicians find it difficult to ask for kidneys (four responses).

--Some people don't want to give away a dead relative's organs (two responses).

--The problems of defining death (four responses).

In cases in which the cause of a donor's death was reported to ACS, the major sources of cadaver kidneys have been victims of accidents (59 percent) and of vascular disorders (about 23 percent). The known causes of donor death for reported cadaver transplants from 1951 through June 1973 are as follows.

	Number	Percent
Accidents	1,735	58.9
Vascular disorders	663	22.5
Central nervous system	147	5.0
Brain tumor	134	4.5
Other	268	9.1
Total	2,947	100

According to the National Safety Council, there were 117,000 accidental deaths in 1972. About 50 percent, or about 59,000, of these involved people between 5 and 45 years old, which is within the age criteria for donors cited by most organ-sharing groups. (See p. 25.) The problem in obtaining cadaver kidneys appears to be donations rather than availability.

Effect of donor card programs

All States have adopted the Uniform Anatomical Gift Act,[1] which provides a uniform favorable legal environment for donating and using organs and tissues for medical research and therapy. Generally, local kidney foundations have publicized and disseminated donor cards so people can

[1]The National Conference of Commissioners on Uniform State Laws, on July 30, 1968, approved the draft of a uniform donation statute to serve as a model for all States relative to the donation and use of organs and tissues for medical research and therapy.

consent to the use of parts of their bodies. We could identify very little direct effect of donor card programs on increasing the supply of cadaver kidneys.

Thirty-nine of the 48 donor card programs we contacted distributed about 2 and 4 million donor cards in 1971 and 1972, respectively. Most of the 1972 donor cards--about 3.4 million--were distributed by the seven kidney foundations of northern California, the District of Columbia, Illinois, Michigan, Oklahoma, Tidewater (eastern Virginia), and Wisconsin. Although a large number of donor cards have been distributed, no one knows how many persons actually carry them.

The donor programs generally do not record the number of kidneys actually donated as a result of them. However, three programs were able to identify two donors in 1971 and five in 1972 who did carry donor cards.

Some reasons why few donor cards are associated with donors include:

--Medical personnel may not look for donor cards.

--Records are not kept on kidneys obtained through donor cards.

--Some physicians would require approval of the next of kin even if the donor carried a card.

Although many organizations contacted agree that donor card programs are valuable for educating the public about the need for donated kidneys, such programs probably will not immediately make enough kidneys available.

Arkansas and Tennessee include a donor card on driver permits which can be filled out if the driver desires. Many kidney foundation officials feel that a massive public and medical education program also is needed to demonstrate the need for donated kidneys.

Time of death--
a potential problem

Because kidneys deteriorate quickly after circulation stops, they must be removed as soon as possible after death if they are to be transplanted. A few physicians told us of concern over the potential liability of physicians who remove cadaver kidneys. This concern centers on whether courts would hold that death legally occurs when the heart stops beating and respiration ends or when irreversible coma from brain death occurs. A vegetable-like physical existence may be sustained after brain death by mechanically maintaining respiration and circulation.

FACTORS AFFECTING TRANSPLANT SUCCESS

Transplant success can be measured by the functioning rates of transplanted kidneys and death rates of transplant patients. Functioning rates are based on the length of time a transplanted kidney keeps functioning in a recipient's body, and death rates are based on the length of time between a transplant and the recipient's death. Patients who live after their body rejects the transplant return to dialysis.

Many factors affect transplant success. The type of donor used clearly affects functioning and death rates. Several other factors which also seem to affect one or both of these rates are

--number of transplants performed by a facility,

--age of donors and recipients,

--likelihood of patient not rejecting a transplant (nonsensitivity), and

--reaction-suppressant drugs.

Some physicians indicated still other factors for which we did not obtain data, including the patient's physical condition, the transplant team's proficiency, and the length of time the patient has been on dialysis.

Effect of donor types

The more successful transplants, it seems, use kidneys from living related donors. For example, on the basis of data reported to ACS on 3,545 transplants performed during 1969-71, we developed death and functioning rates for 12, 24, and 36 months after transplant from two categories of donors--living related, and cadaver or living unrelated. Because ACS did not have death and functioning data on all transplant patients, the total number of patients analyzed for functioning rates differed from the number of patients analyzed for death rates.

Donor	Percent of transplanted kidneys functioning after 12 months	24 months	36 months
Living related	74	69	59
Cadaver and living unrelated	49	40	34
Overall	60	53	45

This data shows that, for transplants performed during 1969-71, the functioning rates 1 year after transplant were 74 percent when kidneys from living related donors were used and only 49 percent when kidneys from cadavers or living unrelated donors were used.

Analyzing the number of known deaths, as shown below, revealed a similar but more exaggerated situation. The death rate at 1 year after transplant was about 14 percent for patients whose kidneys were donated by a living relative; however, it was about 32 percent for patients whose kidneys came from a cadaver or living unrelated donor.

Donor	Percent of transplant patients who died within (note a) 12 months	24 months	36 months
Living related	14	19	30
Cadaver and living unrelated	32	44	54
Overall	24	33	43

[a]ACS data showed that the remaining patients were alive but their kidney may have failed, requiring them to return to dialysis.

One transplant surgeon said death rates are biased because a disproportionate percentage of transplant patients are those who do badly on dialysis and are poor risks from the start. Two other transplant surgeons said that some patients who do poorly on dialysis are either proposed for or are given priority for transplant.

Effect of the number of transplants performed by a facility

The number of transplants performed by a transplant hospital seems to affect both the functioning rate of the transplanted kidneys and the death rate of transplant patients. Of the 107 hospitals reporting to ACS in 1971, 52 performed 86 percent of the transplants and 55 performed 14 percent. The 55 hospitals each performed 10 or fewer transplants.

Appendixes IV and V show analyses of functioning and death rates by number of transplants performed during 1969-71. With some notable exceptions, the better functioning rates (1 year after transplant) were found in hospitals that performed more than 15 transplants in 1969 and 1970 and more than 20 in 1971. A numerical ranking of the patients in those years, in terms of functioning and death rates 1 year after transplant, is shown in the following table. "1" is the highest rating given.

Number of transplants performed	1969		1970		1971	
	Functioning	Death	Functioning	Death	Functioning	Death
1 to 5	4	4	7	7	11	8
6 to 10	6	7	8	8	7	9
11 to 15	7	6	4	5	6	7
16 to 20	1	1	3	3	10	11
21 to 25	5	5	6	6	5	5
26 to 30	8	8	9	9	4	6
31 to 40	-	-	5	4	3	2
41 to 50	2	3	2	2	8	4
51 to 75	3	2	1	1	1	1
76 to 100	-	-	-	-	2	3
Over 100	-	-	-	-	9	10

The 51-to-75 transplant range had the best rates in 1970 and 1971 and also did well in 1969.

Generally, the transplant ranges that had an above-average number of living related donors had higher functioning and lower death rates at the end of 1 year than those ranges that had fewer. The ranges having the best and worst rates at the end of 1 year had the following mix of donor types.

Period	Transplant range	Rates		Donor percentage (note a)	
		Functioning	Death	Living related	Cadaver and living unrelated
1969:					
Worst	26 to 30	44	39	52	48
Best	16 to 20	71	18	66	34
Average		59	28	44	56
1970:					
Worst	26 to 30	32	48	14	86
Best	51 to 75	73	15	43	56
Average		62	21	43	57
1971:					
Worst	1 to 5	39	-	37	63
	16 to 20	-	33	29	71
Best	51 to 75	73	12	62	38
Average		58	23	44	56

[a]May not total 100 percent because donor types were not known for some transplants.

Although this indicates the type of donor has a major effect on functioning and death rates without regard to the number of transplants performed by the hospitals, it also indicates other factors may affect the rates. The 31-to-40 transplant range illustrates this. It had the highest percentage of living related donors in 1970 but did not have the best rates.

	Range	Percent of living related donors	Rates	
			Functioning	Death
	31 to 40	59	65	20
Best rates	51 to 75	43	73	15
Average		43	62	21

Also, some of the ranges in the 1969-71 period that had above-average percentages of living related donors had lower-than-average functioning and higher-than-average death rates. (See apps. IV and V.)

Effect of donor's and recipient's age on functioning rates

On the basis of an analysis of transplants performed during 1951-69, donor and recipient ages affect the functioning rates of transplants. In general, the younger the recipients and donors, the better the functioning rates at the end of 1, 2, and 3 years. An exception is the 1-to-10 age group that used cadaver or living unrelated donors. This group generally did not do as well as the 11-to-50 age group that used cadaver or living unrelated donors.

The functioning rates of donor and recipient age groups by donor type follow.

Recipient age group	Functioning rates after 12 months	24 months	36 months
Living related donors used:			
1 to 10	70	66	59
11 to 20	73	65	60
21 to 30	72	65	60
31 to 40	67	62	59
41 to 50	68	60	54
51 to 60	50	30	30
61 to 70	-	-	-
71 to 80	-	-	-
80 plus	-	-	-
Cadaver and living unrelated donors used:			
1 to 10	33	22	18
11 to 20	41	33	29
21 to 30	38	31	28
31 to 40	41	34	30
41 to 50	37	28	22
51 to 60	28	16	12
61 to 70	-	-	-
71 to 80	-	-	-
80 plus	-	-	-
Donor age group			
Living related donors:			
1 to 10	100	100	100
11 to 20	74	64	61
21 to 30	76	69	67
31 to 40	69	64	59
41 to 50	71	61	56
51 to 60	63	57	50
61 to 70	65	62	52
71 to 80	-	-	-
80 plus	50	50	50

Donor age group (Cont.)	Functioning rates after 12 months	24 months	36 months
Cadaver and living unrelated donors:			
1 to 10	32	27	25
11 to 20	46	36	32
21 to 30	45	35	29
31 to 40	38	30	25
41 to 50	33	28	25
51 to 60	35	26	22
61 to 70	30	23	13
71 to 80	13	13	13
80 plus	-	-	-

The effect of the donor type was also shown in this age analysis. Recipients of kidneys from living related donors in all age groups except 51 to 60 had better functioning rates at the end of 1, 2, and 3 years than recipients of kidneys from cadaver or living unrelated donors.

Recipient sensitivity affects transplant success

Available tests help predict a potential recipient's reaction--whether he is sensitized or unsensitized--to a donated kidney.

Potential recipients who are tested and found unsensitized (not allergic) may have a high degree of success. An article in the "New England Journal of Medicine," July 29, 1971, cited a comparison of sensitized and unsensitized recipients who received transplants between February 1966 and December 1970 and stated:

> "* * * it is our clinical impression that results of kidney transplantation in sensitized recipients are inferior to those in unsensitized recipients."

A University of California report covering the period June 1969 to June 1973 also indicated that unsensitized patients have higher transplant acceptance rates than sensitized patients.

ACS has been gathering data on the degree of sensitivity of transplant recipients but it was not in usable form at the time of our review.

Effect of reaction-suppressant drugs

Rejection by the recipient's body is the principal reason why transplanted kidneys fail to function. Reaction-suppressant drugs are used to combat rejection. One hospital using an experimental drug--antilymphocyte globulin[1]--had, according to its records, great success in achieving high functioning and low death rates on its transplants performed during 1971, particularly those using cadaver kidneys.

Type of donor	Number of transplants	Percentages 1 year after transplant	
		Functioning	Death
Living related	48	77	13
Cadaver	37	62	24
Total	85		

Comparable rates on all 1971 transplants reported to ACS follow.

All transplants	Percentages 1 year after transplant	
	Functioning	Death
Living related	72	14
Cadaver/living unrelated	48	31

The hospital's rates cannot be attributed solely to the drug since other factors, such as nonsensitized patients, might have been involved.

Twenty-two transplant surgeons were asked if they used antilymphocyte globulin. Ten said they were using it, and

[1]"Antilymphocyte-globulin" refers to a group of experimental biological products. According to HEW, no standards of purity or accurate means of evaluating the immunosuppressive activity of these experimental products exist.

one said he was using a derivative. Three others said they had stopped using it because of adverse side effects; one, however, said he planned to use it in a future study.

Of the eight who had not used it, three thought other drugs were just as good, two had reservations about using it until it is conclusively proven safe and effective, and three said they would use it if it were readily available.

CHAPTER 4

THE COST OF TREATMENT

The cost of treating chronic kidney failure depends on the type of treatment--dialysis or transplant--and on the type of dialysis program--home or center. In the long run, a transplant is less costly than continued dialysis and home dialysis is less costly than center (hospital or non-hospital) dialysis.

Transplant using living related donors appears to be more successful than dialysis, but the death rate of patients with transplanted cadaver kidneys appears to be much higher than that of dialysis patients during the early years of treatment. In spite of the apparent patient risk involved in transplanting cadaver kidneys, HEW should, as a minimum, encourage their donation to assure that enough are available for patients who want such a transplant and are medically suitable. HEW should also encourage home dialysis instead of center dialysis for dialysis patients who are medically and psychologically suitable for it and who have assistance at home.

POTENTIAL SAVINGS THROUGH HOME DIALYSIS

Physicians interviewed (see p. 20) estimated that about half of all treatable patients are suitable for home dialysis. Because home dialysis is so much cheaper than center dialysis, patients who are medically and psychologically suitable for home dialysis and who will have assistance at home should be encouraged to choose or change to a home program.

For every 1,000 patients dialyzed at home instead of at a center, there would be a significant annual savings. Even so, Medicare regulations do not require centers to provide training programs for home dialysis.

However, a National Dialysis Registry report showed that as of January 1, 1973, 36.5 percent of dialysis patients were in home programs and as of January 1, 1974, 33.7 percent were in home programs. Only about 30 percent of the new dialysis patients in 1972 in the 12 States and 2 counties reviewed went on home dialysis.

The average 1972 cost of home dialysis, on the basis of data from 10 home dialysis programs in 6 States, was about $14,900 for the first year of treatment and $7,000 for each succeeding year. First-year costs are higher because of the cost of home training and the dialysis machine. With three treatments per week, the average treatment cost of home dialysis would be about $96 in the first year and $45 in succeeding years.

The average charge during 1972 for center dialysis at 96 centers--81 hospital and 15 nonhospital--in 11 of the States and the 2 counties reviewed was $203 a treatment, or about $30,100 a year. (See app. VI.) This is $15,200 more than the average charge for home dialysis in the first year and $23,100 more than the average charge in each succeeding year.

The charge for dialysis at the 81 hospital centers ranged from $111 to $315 a treatment and averaged $206 as shown in the following table. The lowest charge was in Georgia and the highest in Los Angeles County. The annual charge for hospital dialysis ranged from $11,500 to $49,100 and averaged about $30,500.[1]

	Number of hospital centers	Range of charges		
		Low	High	Average
Georgia	3	$111	$150	$132
Oregon	2	125	160	143
Arizona	2	140	157	148
South Carolina	1	-	-	154
Washington	1	-	-	160
Cook County	15	150	200	178
Minnesota	10	134	259	188
Massachusetts	13	125	315	199
Missouri	7	114	242	199
Arkansas	1	-	-	200
Vermont	1	-	-	206
Maine	1	-	-	251
Los Angeles County	24	150	315	259
Overall	81	$111	$315	$206

[1]The annual charge is based on the actual number of dialysis treatments a patient received--usually two or three per week.

The charge for dialysis at the 15 nonhospital centers ranged from $120 to $300 a treatment and averaged $186. The lowest charges were in Minnesota and Washington, and the highest was in Los Angeles County. The annual charge for nonhospital dialysis ranged from $12,800 to $46,800 and averaged $27,600.

	Number of nonhospital centers	Range of charges		
		Low	High	Average
Minnesota	1	$ -	$ -	$120
Washington	1	-	-	120
Georgia	1	-	-	124
Cook County	2	140	140	140
Massachusetts	1	-	-	160
Oregon	1	-	-	175
Arkansas	1	-	-	195
Los Angeles County	7	185	300	230
Overall	15	$120	$300	$186

On the basis of the 1972 average charges--$203 a treatment at a center and $96 a treatment for home dialysis in the first year and $45 in succeeding years--every 1,000 patients dialyzed at home rather than in a center would save a total of about $15.2 million in the first year and about $23.1 million in each succeeding year.

On April 16, 1975, HEW told us, however, that due to the establishment of reimbursement controls under Medicare, center dialysis now averages about $160 a treatment and home dialysis averages about $100 a treatment after the first year. It said that first-year treatment costs for home dialysis are slightly higher than second-year costs because of home dialysis training. HEW also told us that the difference in home dialysis costs between the first and second years is not occurring because most dialysis equipment is being leased or rented. In our calculations, we assumed that such equipment would be purchased during the first year of dialysis.

We have not analyzed the average-cost-per-treatment information supplied by HEW, but the information indicates

an annual savings for every 1,000 patients dialyzed at home rather than in a center of about $9.4 million.

POTENTIAL SAVINGS THROUGH TRANSPLANT

The average charge for a successful transplant, including preoperative and postoperative dialysis, is comparable to that for home dialysis in the first treatment year but is much less than the center dialysis charge. The major differences between the cost of transplant and the cost of dialysis occur in succeeding years.

On the basis of 1970 transplant data, 620 of every 1,000 transplant patients can be expected to have functioning transplants at the end of the first year after the operation. This decreases to 547 at the end of the second year. Patients whose transplants function beyond the first year save about $29,700 or $6,600 during the second and succeeding years, depending upon whether they were dialyzed in a center or at home. The second-year savings for these 547 patients is close to $12 million, calculated as follows.

Original dialysis location	Number of patients (note a) with functioning transplants	Dialysis costs saved (note b)
Center	350	$10,535,000
Home	197	1,379,000
Total	547	$11,914,000
Less the estimated second-year cost of $400 per patient for drugs and clinic visits		218,800
Potential savings		$11,695,200

[a]Relationship of home and center dialysis patients is based on dialysis methods being used in reviewed areas as of December 31, 1972.

[b]The dialysis charges are based on center facilities' fees during 1972 and do not consider limitations imposed by the Medicare program. (See apps. VII and VIII.)

Using current charges supplied by HEW of $160 a treatment for center dialysis and $100 a treatment for home dialysis would result in an estimated second-year savings of about $11.6 million.

Transplant charges

Twenty-four of the transplant facilities reviewed provided estimates of transplant charges for 1973 which ranged from $5,500 to $20,500 and averaged about $12,800. The facilities were in California, Arizona, Minnesota, Washington, Oregon, Georgia, Illinois, Massachusetts, Arkansas, and Missouri. Ten of them supplied estimates averaging $10,600 and $12,400, respectively, for transplants using kidneys from cadavers and living related donors.

HEW stated that preliminary analysis of current information indicates the cost for a transplant from a living donor would be about $14,000.

Cost items included were hospital room, board, ancillary charges, and professional fees.

Analysis of transplant charges at two facilities

We analyzed actual charges at 2 facilities that performed 52 transplants during 1972 (36 cadaver and 16 living donor). The charges included hospital room, board, ancillary charges, and professional fees for the transplant patient and similar charges for living related donors who had to be hospitalized for kidney removal.

The average charge for a cadaver kidney transplant was $10,915 at facility I and $16,154 at facility II. The average charges for living donor transplants were $10,139 and $15,874, respectively. The average cost of a successful transplant was less than that of an unsuccessful transplant at both facilities.

Average Transplant Charges

Donor	Status of transplant (note a)	Facility I	Facility II
Cadaver		$10,915	$16,154
	Successful	10,067	11,884
	Unsuccessful	14,873	18,645
Living related		$10,139	$15,874
	Successful	10,139	15,805
	Unsuccessful	-	16,047

[a]At time of discharge from the hospital.

Actual charges ranged from $6,410 to $30,275 at facility I and from $5,332 to $46,236 at facility II. The wide variance is due principally to the length of the hospital stay. Stays ranged from 8 to 116 days at facility I and from 2 to 122 days at facility II. The average stays at facility I were much shorter than at facility II for all types of transplants--regardless of donor type and success.

Average Hospital Stay

	Facility I		Facility II		Total	
	Number of transplants	Average stay	Number of transplants	Average stay	Number of transplants	Average stay
Cadaver:	17	28	19	45	36	37
Successful	14	26	7	36	21	29
Unsuccessful	3	40	12	50	15	48
Living related:	9	22	7	44	16	32
Successful	9	22	5	51	14	32
Unsuccessful	-	-	2	26	2	26

The average stay at both facilities was much longer for unsuccessful cadaver transplants (48 days) than for successful cadaver transplants (29 days).

IMPROVEMENTS NEEDED IN FINANCING THE TREATMENT OF CHRONIC KIDNEY FAILURE UNDER MEDICARE

Effective July 1, 1973, section 299I of the Social Security Amendments of 1972 (Public Law 92-603) provided for the financing of chronic kidney disease treatment through Medicare for eligible persons under 65. HEW is responsible for implementing this law, which alleviated a major problem confronting most victims of the disease. Although treatment

was technologically available, the costs were staggering. In April 1974 HEW estimated the first year cost of section 299I would be about $240 million.

In general, Part A of Medicare--Hospital Insurance Benefits for the Aged and Disabled (hospital insurance)--covers inpatient hospital costs of dialysis and transplant and Part B--Supplementary Medical Insurance Benefits for the Aged and Disabled (supplementary medical insurance)--covers physicians' services, outpatient hospital services, and medical services and supplies. Most of the transplant and dialysis costs, therefore, are paid under Part A and Part B, respectively. (See app. VII.)

HEW estimates that between 92 and 95 percent of people under 65--about 168 to 174 million people, on the basis of 1970 census data--will be eligible for Medicare coverage under section 299I. A person with chronic kidney failure is eligible if he or she has not reached 65 and is currently or fully insured,[1] is entitled to monthly insurance benefits under the social security program, or is the spouse or dependent of such an insured or entitled individual. Public Law 93-58, effective July 1, 1973, modified section 299I to extend coverage to railroad employees and their spouses and dependent children.

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[1]Fully insured--a person with 40 quarters of coverage under the social security program. One quarter is a 3-month period during which (a) a person has earned $50 or more subject to social security taxes or (b) a self-employed person has reported income of $400 or more subject to social security taxes.

--a person who has one quarter of coverage for each year after 1950 or for each year after becoming 21 and prior to the year he attained age 62 or became disabled.

Currently insured--a person who earned at least 6 quarters of coverage during the 13-quarter period ending with (1) the calendar quarter in which age 62 is attained or (2) the calendar quarter in which disability began.

Some changes in coverage should be considered because the program

--discriminates against those who receive a transplant which fails after 12 months and

--does not provide specific incentives for home dialysis, the least expensive form of dialysis.

In addition, treatment costs for which the patients are still liable, particularly the Medicare co-insurance and the waiting period, may be a limiting factor for some patients in obtaining treatment.

The program discriminates against those who receive transplants which fail after 12 months

Section 299I(f) of the act states:

"Medicare elibibility on the basis of chronic kidney failure shall begin with the third month after the month in which a course of renal (kidney) dialysis is initiated and would end with the twelfth month after the month in which the person has a renal transplant or such course of dialysis is terminated." (Underscoring supplied.)

Regulations published in the "Federal Register" of June 29, 1973, eliminated or reduced the 3-month waiting period for transplant patients by providing Medicare's hospital insurance benefits in the month the patient entered the hospital in preparation for the transplant if it was performed in that or in the following month.

Results of transplants performed in 1969, 1970, and 1971 indicate that about 40 percent of all transplants fail during the first year. (See p. 31.) The costs related to these failures and subsequent treatment are covered under Medicare. More than 10 percent of the remaining transplants fail during the second year.

Patients who choose a transplant, the least expensive form of treatment, lose their Medicare coverage if their

transplant functions for 12 months. If it fails after that time, the patient is liable for costs associated with the failure and any dialysis treatment required during the waiting period before Medicare coverage resumes. The waiting period lasts until the third month after the patient begins dialysis. We believe this provision discourages transplants.

Patients who choose a transplant and have it last for more than 12 months save the Government millions of dollars that would otherwise be used to pay for their dialysis treatment. The requirement for another waiting period for medical coverage, however, discriminates against such patients.

Incentive for home dialysis could hold down costs

In 1972, the difference between center dialysis and home dialysis costs averaged about $15,200 in the first year of treatment and $23,100 in each succeeding year. (See p. 40.) On the basis of current cost information supplied by HEW in 1975, the annual cost difference between center and home dialysis averages about $9,400.

Because Medicare pays about 80 percent of the dialysis costs incurred after the waiting period, program costs obviously would be much less if more patients were treated at home. Although the consensus of 36 physicians associated with dialysis units is that about half the dialysis patients are suitable for home treatment, the trend is away from home and toward center dialysis.

Greater use of home dialysis would hold down treatment costs and, consequently, the Government's share of such costs. Some doctors have proposed paying a salary to those who elect home dialysis or paying for an assistant as incentives for home dialysis.

H.R. 12410, introduced on January 30, 1974, would amend title XVIII of the Social Security Act to authorize payment under the supplementary medical insurance program for home dialysis performed by a nurse or health aide.

Another alternative would be to pay all the home dialysis supply and appliance charges instead of 80 percent.[1]

Some people may still have difficulty paying for treatment

Although Medicare now pays a large percentage of each eligible patient's dialysis costs, the patient must still pay for

--treatment costs during the waiting period and

--the 20-percent co-insurance under Part B.

Even if the current temporary reimbursement limits of $150 per treatment and $190 per home training dialysis treatment became permanent, the average liability for a patient being treated at a center would be about $8,700 for the first year and about $4,900 for each succeeding year. These amounts were computed as follows.

	Annual cost (note a)	Waiting period	Part B co-insurance	Total waiting period and Part B co-insurance
First year	$23,600	$4,800	$3,700	$8,500
Succeeding year	23,600	-	4,700	4,700

[a]The patient would also pay about $200 a year for Part A and Part B deductibles and Part B premiums.

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[1]Section 245 of Public Law 92-603 authorized the Secretary of HEW to waive the 20-percent co-insurance for used durable medical equipment whenever the purchase price is at least 25 percent less than the reasonable charge for comparable new equipment.

The home patient's liability would be less than a center patent's, but it would still be significant. After the first year, a home patient's liability would amount to about $1,500, consisting of (1) the 20-percent co-insurance under Part B, (2) Part A and Part B deductibles, and (3) Part B premiums. The first-year liability would be much greater than $1,500 because the patient would also be liable for other expenses, such as the cost of treatment during the waiting period. The estimates for home or center dialysis do not include the cost of allowable physicians' services.

In 1975 HEW told us that, because current treatment costs for home dialysis are higher than they were at the time of our fieldwork, the home patient's liability has increased.

Since the average annual family income in the United States for 1969 was about $11,000, the patient's liability severely burdened most families without a third-party source of funds, such as private insurance, State programs, and other Federal programs.

During the 93d Congress, various modifications to the cost-sharing provisions of Medicare were considered in connection with national health insurance bills. These modifications would, in effect, have lessened the economic burden of kidney patients on dialysis under section 299I.

HEW said that the President's proposed revision of the current Medicare cost-sharing provisions--a part of a fiscal year 1976 budget proposal submitted to the Congress--provides annual liability limitations for beneficiaries of $750 under Part A and $750 under Part B.

CHAPTER 5

CONCLUSIONS, RECOMMENDATIONS, HEW COMMENTS AND OUR EVALUATION, AND MATTERS FOR CONSIDERATION BY THE CONGRES

CONCLUSIONS

The system of chronic kidney failure treatment has expanded rapidly since the first dialysis program in 1962. In July 1974, 664 dialysis centers and 167 hospitals which perform transplants were eligible for reimbursement under Medicare. This response to a serious national medical problem indicates that the medical profession, various State governments, and the Federal Government have been taking steps to treat those who need it.

Nevertheless, several problems require HEW's attention to insure that everyone needing treatment gets it.

During 1972, in the 12 States and 2 counties reviewed, an average of 36 new patients per million population were treated. Rates ranged from 68 in Los Angeles County to 14 in South Carolina. The wide variation in the number of new patients treated occurred because (1) patients were not being referred for treatment, (2) treatment criteria kept some patients from being treated, (3) treatment facilities were not dispersed in proportion to the population, and (4) a balance of treatment programs was not provided. These problems may have arisen because of the rapid growth of the system.

HEW could compare incidence and treatment rates for geographic areas as one means of determining the adequacy of available treatment. Differences between the incidence rates and the numbers actually treated could indicate problems requiring the attention of HEW and the medical profession.

Although the number of kidney transplants performed has increased greatly over recent years, the demand has not been satisfied because not enough cadaver kidneys are being donated.

Programs to obtain kidneys have not been effective in increasing the supply to meet the demand. Many kidney foundations believe that a public and medical education program is required to publicize the need for donated kidneys.

CHAPTER 5

CONCLUSIONS, RECOMMENDATIONS, HEW COMMENTS AND OUR EVALUATION, AND MATTERS FOR CONSIDERATION BY THE CONGRESS

Many factors affect transplant success. One is the type of donor. The functioning and death rates indicate the best transplants--in terms of the transplant lasting longer and the patient living longer--use kidneys from living related donors. Other factors include the number of transplants performed by a facility, the age of donors and recipients, the likelihood of patients not rejecting a transplant, and reaction-suppressant drugs.

Additional factors which may affect transplant success--but for which we did not obtain data--include the physical condition of patients, the proficiency of transplant teams, and the length of time the patients have been on dialysis. Identification and evaluation of the effect of these and other factors by HEW could improve the chance of transplant success.

The costs of treating chronic kidney failure depend on the type of treatment--dialysis or transplant--and type of dialysis program--home or center. In the long run, a transplant costs less than continued dialysis and home dialysis is less costly than center (hospital or nonhospital) dialysis.

On the basis of 1972 data, a patient whose transplant functions beyond the first year saves $29,700 or $6,600, depending on whether he was dialyzed in a center or at home. Current cost data supplied by HEW in 1975 also shows a significant savings when transplant costs are compared with dialysis costs.

Patients with kidney transplants from cadaver or living unrelated donors have a higher death rate than dialysis patients and patients with kidney transplants from living related donors. HEW should, however, encourage the donation and availability of cadaver kidneys for patients who want such a transplant and are medically suitable.

For every 1,000 dialysis patients treated at home rather than in a center, a significant annual savings would result. HEW should encourage those patients who wish to remain on dialysis to be treated at home rather than in a center if their medical and other conditions permit.

Although Medicare covers most people for chronic kidney disease, some changes should be considered because the program

--discriminates against those whose transplant fails after 12 months and

--does not provide specific incentives for home dialysis, the least expensive form of dialysis treatment.

RECOMMENDATIONS

By making the Government responsible for the costs of treating chronic kidney disease--estimated to be hundreds of millions of dollars annually--the Congress has shown an interest in the effectiveness of this program. We recommend, therefore, that the Secretary of HEW report annually to the Congress on the progress and problems of providing needed treatment. This information could be incorporated into the report required under section 1875 of the Social Security Act, which requires the Secretary to make a continuing study of the operations and administration of the insurance programs under Parts A and B of Medicare and report annually to the Congress on these programs. To be able to prepare this report on the kidney treatment program and to administer this program properly, we recommend that the Secretary provide for regular and systematic:

--Data-gathering on dialysis and transplant facilities, transplant donor and recipient characteristics, and survival and death rates.

--Data analysis to identify potential or actual problems, better or more cost-effective treatment, and geographic areas that may have special problems. Factors to consider in such analysis include

1. new-patient treatment rates;

2. the adequacy of available dialysis programs;

3. the effects of different treatment methods, considering both the best treatment for the patients and the costs;

4. the lack of donated kidneys, its effects, and how donations can be increased; and

5. factors affecting transplant success.

We recommend that the Secretary also:

--Set new-patient treatment goals by geographic area to determine whether persons considered treatable are being treated. Differences between the goals and actual treatment rates could indicate problems requiring the attention of HEW and the medical profession.

--Amend the Medicare regulations to require centers to provide training programs for home dialysis unless the Secretary determines on a case-by-case basis that such a requirement would not be warranted.

Because implementing the above recommendations may take time, the Secretary should act now to improve treatment for chronic kidney failure by providing for:

--Educating the public on the nature of kidney disease and how and where it can be treated and financed under Medicare.

--Encouraging cadaver kidney donations.

--Keeping the medical profession advised on improvements in patient care and treatment equipment.

--Encouraging liberalized treatment criteria at facilities not accepting patients because of age, suitability for home dialysis, and diabetes and other diseases by establishing guidelines for treatment under Medicare.

--Evaluating dialysis and transplant facility needs by geographic areas, especially those with low new-patient treatment rates.

--Seeking to encourage patients who wish to remain on dialysis to be treated at home rather than in a center if their medical and other conditions permit.

HEW COMMENTS AND OUR EVALUATION

HEW concurred (see app. I) with most of our recommendations and told us that, where administratively possible, it has begun to implement them. HEW also told us that regulations are being processed which directly address most of the issues contained in the report.

In commenting on our specific recommendations, HEW stated that:

--A report on chronic kidney disease was included in a report to the Congress as part of the annual report on Medicare, published on January 14, 1975, and such a practice would be continued in future years.

--Data will be regularly and systematically gathered and analyzed to evaluate the overall kidney disease treatment system. For example, a medical information system will be implemented by June 30, 1976, and will provide data on every facility and on every chronic kidney patient, including the rates of entry of new patients into the system and data concerning cost effectiveness as it relates to the quality of treatment provided by the system.

--NIH has made information available to the general public through members of the health profession, various medical societies, radio, television, and newspapers on the nature of kidney disease and how it can be treated. For people with chronic kidney failure, information will be prepared explaining the disease and the medical and health insurance options available, including Medicare coverage. In addition, HEW believes the publicity

given to Public Law 92-603 has increased the public's awareness of available financial assistance.

--The regulations in process for the kidney disease program will require the establishment of medical review boards and an integration of hospitals and other health facilities into organized "networks." Presently, attempts are being made to increase the number of donated kidneys by (1) requiring each network to meet certain standards concerning the number of patients receiving transplants and (2) requiring each transplant hospital to perform a minimum number of transplants each year. HEW expects such additional requirements will encourage physicians to increase efforts to obtain donated kidneys.

--A program aimed at increasing the medical profession's awareness of improvements in care and treatment equipment relating to chronic kidney failure has already been implemented.

--The purpose of Public Law 92-603 is to assure that patients will not be excluded from dialysis because of economic factors. HEW agreed in principle with the need for Medicare guidelines to assure that whole categories of patients--such as diabetics--are not excluded from receiving treatment.

--Through the implementation of the medical information system, HEW expects to be able to evaluate dialysis and transplant facility needs by geographic area.

--The regulations in process will require that each network make home dialysis training available to every patient. In addition, through the medical information system, norms and standards will be developed concerning the percentage of patients to be home trained. HEW told us that facilities will, therefore, be required to home train an acceptable number of patients.

Although HEW agreed with the need for guidelines to assure that whole categories of patients are not excluded

from receiving treatment, it stated that not all patients with chronic kidney disease should be dialyzed.

HEW did not elaborate on the reasons for this. In our opinion, HEW should provide guidance as to the conditions that render a patient unsuitable for treatment. We continue to believe such guidance is necessary to assure that all patients with similar conditions and medical histories are treated similarly. Otherwise, a patient could be refused treatment at one center and accepted at another. In our opinion, HEW has the responsibility under Medicare to assure consistent and equitable treatment by all centers.

HEW disagreed with our recommendation to establish new-patient treatment goals by geographic area for determining whether patients considered treatable are being treated. HEW stated that incidence and treatment rates should be the prevailing standards. It told us that rate variation will occur in response to predominant demographic conditions, and the response to this is rational development of service resources.

The intent of our recommendation for the establishment of treatment goals by HEW was to have HEW compare the incidence of kidney disease with the number of patients receiving treatment. With such a comparison, geographic areas could be identified that have a significant difference between the incidence rate and the treatment rate, indicating the need for HEW action to determine whether there are patients requiring treatment and not receiving it. Therefore, if HEW analyzes incidence and treatment rates, it will have complied with the intent of our recommendation.

HEW disagreed with our recommendation to require centers to provide home dialysis training programs unless the Secretary determines on a case-by-case basis that such a requirement is not warranted. HEW stated that such a requirement would (1) greatly enlarge demands for skilled personnel in short supply and (2) result in less-than-optimal home training programs at some facilities. In addition, HEW stated that our definition of a center disregarded the unique role played by some hospital and nonhospital sites in providing dialysis to patients who

do not require hospital resources but who cannot undertake home dialysis. HEW stated that the regulations in process will require each network to possess the capacity for performing a full scope of services, including training and education of patients and their families.

We recognized in this recommendation that it would not be desirable for each and every center to have a home dialysis training program. We intended that HEW take the necessary action to assure that all patients have access to a home training program. We believe that HEW's action to require each network to have home training programs is consistent with the intent of our recommendation, which would involve a case-by-case analysis of centers. Presumably, an analysis of the centers in each network will still have to be made to assure that (1) all patients have reasonable access to a home training program and (2) the centers selected for a home training program will result in the optimum use of available resources.

The actions HEW promised to take in response to our recommendations will, if properly implemented, correct many of the problems identified during our review.

MATTERS FOR CONSIDERATION BY THE CONGRESS

The Congress should consider legislation to (1) eliminate the waiting period for transplant patients who reject their transplant after 12 months and (2) encourage greater use of home dialysis treatment by providing an incentive for medically and psychologically suited patients to select home over center dialysis.

The waiting period for patients is derived from 42 U.S.C. 426(f) which states:

> "Medicare eligibility on the basis of chronic kidney failure shall begin with the third month after the month in which a course of renal dialysis is initiated and would end with the twelfth month after the month in which the person has a renal transplant or such course of dialysis is terminated."

We believe the waiting period problem could be alleviated by replacing the period at the end of this section with a semicolon and adding the following language after the semicolon:

> "except that Medicare eligibility will resume immediately for a person required to institute a course of renal dialysis due to renal transplant failure occurring subsequent to the twelve-month period following the month of the transplant."

Because there are a variety of ways to encourage greater use of home dialysis (see pp. 48 to 49), we have not developed specific legislative language to address this problem.

CHAPTER 6

SCOPE OF REVIEW

This review covered chronic kidney failure treatment in Arizona, Arkansas, Georgia, Maine, Massachusetts, Minnesota, Missouri, New Hampshire, Oregon, South Carolina, Vermont, Washington, and Cook County, Illinois, and Los Angeles County, California. According to the 1970 census, the population in these areas is about 22 percent of the U.S. population. The demographic characteristics (race, sex, age, family income, urban, and rural) of this population were almost identical to the overall U.S. population.

Data was obtained from the 121 chronic dialysis centers and 48 transplant hospitals in these 12 States and 2 counties. Facilities, patients, treatment criteria, treatment methods available, treatment charges, and estimates of the number of treatable persons were analyzed. We also gathered information on dialysis patients and units from 10 additional States which had less than 3 units each.

ACS supplied data on transplants performed in the United States and Puerto Rico from 1951 through June 30, 1973. This data was summarized and analyzed. Information on kidney donor programs was requested from 48 local kidney foundations throughout the country and from 10 organ-sharing groups.

We reviewed legislation, the interim HEW regulations implementing section 299I of the Social Security Amendments of 1972, and pertinent reports, studies, legislative hearings, and professional papers on kidney disease detection, prevention, treatment, and research.

We also obtained information from components of HEW, the Department of Defense, and VA that are involved either directly or indirectly with kidney disease research, treatment, or prevention. This included reviewing research reports, appropriation hearings, reports or other professional papers prepared or sponsored by the agencies, and discussions with agency officials.

APPENDIX I

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
WASHINGTON, D.C. 20201

OFFICE OF THE SECRETARY

April 16, 1975

Mr. Gregory J. Ahart
Director, Manpower and
Welfare Division
U.S. General Accounting Office
Washington, D.C. 20548

Dear Mr. Ahart:

The Secretary asked that I respond to your request for comments on your draft report entitled, "Treatment of Chronic Kidney Failure: Dialysis, Transplantation, and Costs." We have enclosed our response to your recommendations, including some technical comments you may want to consider in preparing your final report.

We appreciate the opportunity to comment on this draft report before its publication.

Sincerely yours,

John D. Young
Assistant Secretary, Comptroller

Enclosure

APPENDIX I

COMMENTS ON GAO DRAFT REPORT, "TREATMENT OF CHRONIC KIDNEY FAILURE: DIALYSIS, TRANSPLANTATION, AND COSTS"

OVERVIEW

We concur in general with the recommendations to improve the end-stage renal disease (ESRD) program, and where administratively possible have begun to implement them. In this connection, PHS issued a statement (April 1974) which discussed policies to be embodied in the final ESRD regulations. Since that time an interim program has been implemented and final regulations have been written. These regulations, (in final clearance within the Department), will directly address issues cited in the report except as discussed in our detailed comments. Also, it should be noted that most of the descriptions contained in the report on renal treatment systems are based on statistics relating to care provided prior to July 1973 and do not show the effects of the extension of Medicare coverage to patients with kidney disease.

GAO RECOMMENDATION

That the Secretary report annually to the Congress on the progress and problems of providing treatment to those people who need it.

COMMENT

We concur and, in fact, have included a report on chronic renal disease as part of the "Seventh Annual Report on Medicare Covering Fiscal Year 1973," published January 14, 1975. We will continue this practice for subsequent years.

GAO RECOMMENDATION

That the Secretary regularly and systematically gather data and analyze it to evaluate the overall kidney disease treatment system.

COMMENT

We concur. The Health Services Administration through its Bureau of Quality Assurance (BQA) has developed specifications, forms and instruction manuals for the implementation of a National ESRD Medical Information System. This system will be pretested in various parts of the country and is expected to be fully implemented by June 30, 1976. Included in this system will be data

APPENDIX I

on every ESRD patient and facility. From this data it will be possible to answer all of the issues addressed under this recommendation. Specific outputs will include rates (for facilities, networks, regions and the nation) of the entry of new patients into the system, home training, transplantation, morbidity, mortality, etc. Data concerning cost effectiveness as it relates to the quality of treatment will also be provided by the system.

As an initial data development project, SSA's Bureau of Health Insurance (BHI) has developed formats for the Chronic Renal Disease Beneficiary History File and has accumulated base line data on demographic distribution of Medicare eligibles and some basic description of their treatment modality. BHI is working closely with SSA's Office of Research and Statistics and BQA on the continued role this information development system will play.

The Bureau of Health Insurance also accumulates claims payment data to assist in program management. One current project is to use the time-sharing computer system to compute costs per dialysis treatment for each renal facility and to relate them to the type of treatment (e.g., training, maintenance, or acute dialysis), and facility, size, location, patient census, etc. The results will be useful for cost control, program evaluation, and planning purposes.

GAO RECOMMENDATION

That the Secretary establish new-patient treatment goals by geographic area as one means of determining whether persons considered treatable are being treated.

COMMENT

We do not concur. ESRD incidence and treatment rates, not numbers of patients, should be the prevailing standard. It is generally conceded that rate variations will occur in response to predominant demographic conditions, and the appropriate response to this is rational development of service resources. The broad array of professional skills and facilities required for treating persons with ESRD requires a deliberate means of assuring cooperation, coordination and cost-constraint.

With this in mind, the proposed final regulations for the ESRD program require the establishment of medical review boards and an integration of hospitals and other health facilities into organized "networks." This mechanism will allow local areas to be more responsive to local capabilities, with appropriate action to meet local needs.

GAO RECOMMENDATION

That the Secretary amend the Medicare regulations to require centers to provide training programs for home dialysis unless the Secretary determines on a case-by-case basis that such a requirement would not be warranted.

COMMENT

We do not concur. While we support the encouragement of home dialysis training, we do not feel this recommendation is realistic because home dialysis training is a complex undertaking, and the proposed requirement at this time would greatly enlarge demands for skilled personnel already in short supply. Such requirements would result in a less than optimum home training program at some facilities. GAO's definition of a "center" as any treatment site other than a patient's home appears to disregard the unique role played by some hospitals and nonhospital sites where community "dialysis" services are provided in meeting the needs, at lower cost, of those patients who do not require hospital resources, but who also cannot undertake self-dialysis for some reason. Incorporated in the "networks" concept delineated at this time in the proposed final ESRD regulations will be a requirement that each network possess the capacity for performance of the full scope of ESRD diagnostic and therapeutic services, including appropriate training and education of patients and their families. Every patient (no matter at what facility he is treated) will have available a home-training program within a reasonable distance.

GAO RECOMMENDATION

That the Secretary act now to improve the delivery of care for chronic kidney failure by educating the general public on the nature of kidney disease, how and where it can be treated and financed under the Medicare program.

COMMENT

We concur, and in fact, since 1973 the National Institutes of Health (NIH) has published and distributed instructional pamphlets which provide information of the type recommended by GAO. The information is made available to the public through several sources including distribution by members of the health profession and various medical societies as well as dissemination by radio, television, and nationally distributed newspapers.

For the population which is afflicted by chronic kidney failure, BQA is now in the process of publishing a booklet explaining the disease and those medical and health insurance options available to patients. Also, SSA will be releasing shortly a supplement to the Medicare Handbook relating specifically to Medicare coverage to patients with end-stage renal disease.

In addition to the programs financed by the Public Health Service, the publicity given to the enactment of the ESRD legislation has increased the public's awareness that financial assistance is now available to patients who require dialysis or kidney transplantation.

GAO RECOMMENDATION

That the Secretary act now to encourage the donation of cadaver kidneys to improve the delivery of care for chronic kidney failure.

COMMENTS

We concur. The PHS has already acted to implement this recommendation. Over the past 5 years, PHS through its Regional Medical Program has undertaken to estabish cadaver organ procurement systems across the nation. These systems will be a functioning part of the ESRD treatment networks being established under the provisions of the Social Security Act Amendment of 1972.

Additionally, BQA is presently attempting to increase the number of donated organs by (1) requiring each network to meet certain standards concerning the number of ESRD patients receiving transplanted organs and (2) requiring each transplant hospital to perform a minimum number of transplants each year. It is expected that such additional requirements will encourage ESRD physicians to increase efforts to obtain donated kidneys.

GAO RECOMMENDATION

That the Secretary act now to improve the delivery of care for chronic kidney failure by keeping the medical profession advised on improvements in patient care and treatment equipment.

COMMENT

We concur. PHS has already implemented an information program aimed at increasing the medical profession's awareness of improvements in care and treatment equipment.

relating to chronic kidney failure. This is being accomplished by the Artificial Kidney Chronic Uremia Program, a special activity of NIH in research and development for improving dialysis methods and other methods of treatment for ESRD. The results of their activities are printed and distributed to every member of the American Society of Nephrology (the definitive professional group involved in the treatment of chronic kidney disease) and to every member of the American Society for Artificial Internal Organs -- the transplanters.

Additionally, NIH conducts scientific meetings at which advances in methods of patient care in chronic kidney disease are discussed. Proceedings of these scientific meetings are published in full as special supplements to professional medical journals.

GAO RECOMMENDATION

That the Secretary act now to encourage the liberalization of existing criteria for treatment at facilities not accepting patients because of age suitability for home dialysis, diabetes and other diseases by establishing guidelines for treatment under the Medicare Program.

COMMENT

We concur in principle. However, we believe that this recommendation gives the impression that the criteria of the type listed should not be used to exclude patients from dialysis. While we agree that whole categories of patients should not be excluded because they have been labelled as being diabetic or are over a certain chronologic age, etc., we do not agree that every patient with end-stage kidney disease should be dialyzed. The purpose of Public Law 92-603 is to assure that patients will not be excluded from dialysis because of economic factors; it is not to require that every patient with kidney disease receive either dialysis or transplantation.

GAO RECOMMENDATION

That the Secretary act now to evaluate dialysis and transplantation facility needs by geographical areas especially those with low new-patient treated rates.

COMMENT

We concur. This is expected to be accomplished through the implementation of the National ESRD Medical Information System.

APPENDIX I

GAO RECOMMENDATION

That the Secretary seek means of encouraging patients that wish to remain on dialysis to be treated at home rather than in a center if their medical and other conditions permit this form of treatment.

COMMENT

We concur. The impending ESRD regulations will require that each network make available to every patient the opportunity to be home trained. Additionally, through the use of data generated by the National ESRD Medical Information System; criteria, norms and standards concerning the desired ratio of percentage of patients to be home trained will be developed.

The performance of each facility in terms of its record for home training will also be analyzed. Thus facilities will be required to home train an acceptable number of patients.

(See GAO note)

APPENDIX I

GAO note: Deleted matter contained general and technical comments on our draft report which have been incorporated into the final report.

APPENDIX II

PERCENTAGE OF 1972 YEAREND DIALYSIS PATIENTS

AND 1972 NEW PATIENTS TREATED BY VA

	1972 yearend dialysis patients		1972 new-treatment rate (per million population)	Percent of rate attributable to VA
	Total	Percent treated by VA		
Arizona	68	29.4	31.1	29.1
Arkansas	61	63.9	20.8	57.5
Cook County, Ill.	528	25.8	42.8	20.0
Georgia	127	10.2	16.8	9.1
Los Angeles County, Calif.	681	12.2	67.5	6.5
Maine	22	4.5	23.2	13.0
Massachusetts	403	5.2	38.3	6.0
Minnesota	245	11.0	43.1	10.4
Missouri	252	19.0	26.5	30.6
New Hampshire (note a)	-	-	24.4	16.7
Oregon	76	46.1	25.3	20.8
South Carolina	40	30.0	13.5	34.3
Vermont	21	-	24.8	-
Washington	272	21.0	33.4	10.5
Total (note b)	2,796	17.6	36.3	14.2

[a]New Hampshire has no chronic dialysis facilities.

[b]HEW noted that as of September 1974--more than 1 year after kidney disease treatment legislation became effective--more than 2,600 Medicare eligibles were being treated in these 12 States, excluding Cook County, Illinois, and Los Angeles County, California.

1972 NEW-TREATMENT RATES AT VARIOUS DISTANCES

FROM URBAN AREAS IN THE STATES REVIEWED

Cities and States with major concentration of facilities	1972 new-treatment rate per million: Less than 20 miles from city	1972 new-treatment rate per million: 20 to 40 miles from city (note a)
Phoenix and Tucson, Ariz.	34.5	-
Little Rock, Ark.	21.9	-
Atlanta, Ga.	23.9	14.8
Portland, Me.	33.4	25.2
Boston, Mass.	51.5	31.7
Minneapolis-St. Paul and Duluth, Minn.	52.7	33.5
St. Louis and Kansas City, Mo.	34.0	15.3
N.H.-Mass. border (note b)	27.6	22.6
Portland, Oreg.	35.7	23.4
Charleston, S.C. (note c)	13.6	45.7
Burlington, Vt.	17.6	9.7
Seattle and Spokane, Wash.	42.7	18.8
Average	39.1	24.6

[a]Analysis in the Phoenix and Tucson area was not possible because towns are large in area and exact residence of patients was unknown.

[b]New Hampshire has no chronic treatment facilities and most patients are treated in Massachusetts. Therefore, Massachusetts was used as the base location.

[c]South Carolina was the only State that had a higher treatment rate in its 20- to 40-mile area than in its less-than 20-mile area.

FUNCTIONING RATES AFTER TRANSPLANT

BY RANGE OF TRANSPLANTS PERFORMED--1969

Range of transplants performed (note a)	Percentage of donor type (note b)		Percentage of transplants functioning after				
	Living related	Cadaver and living unrelated	3 months	6 months	12 months	24 months	36 months
1 to 5	39.8	60.2	74	68	60	48	39
6 to 10	33.3	65.8	70	64	55	50	44
11 to 15	38.2	61.8	69	62	54	47	39
16 to 20	66.1	33.9	78	75	71	64	61
21 to 25	33.0	66.1	74	68	57	45	37
26 to 30	51.9	48.1	59	52	44	41	37
31 to 40	-	-	-	-	-	-	-
41 to 50	44.7	55.3	75	73	65	53	49
51 to 75	55.9	44.1	77	66	62	55	51
76 to 100	-	-	-	-	-	-	-
100 plus	-	-	-	-	-	-	-
Total	44.3	55.5	73	67	59	51	45

APPENDIX IV

FUNCTIONING RATES AFTER TRANSPLANT

BY RANGE OF TRANSPLANTS PERFORMED--1970

Range of transplants performed (note a)	Percentage of donor type (note b)		Percentage of transplants functioning after			
	Living related	Cadaver and living unrelated	3 months	6 months	12 months	24 months (note c)
1 to 5	57.7	41.2	71	65	55	53
6 to 10	34.3	65.7	70	59	51	39
11 to 15	39.6	59.7	79	75	66	59
16 to 20	45.7	54.3	79	73	67	62
21 to 25	38.6	61.4	71	65	59	51
26 to 30	14.3	85.7	56	44	32	27
31 to 40	59.5	40.5	74	68	65	55
41 to 50	50.0	50.0	82	77	72	69
51 to 75	43.3	56.0	81	75	73	64
76 to 100	-	-	-	-	-	-
100 plus	-	-	-	-	-	-
Total	43.0	56.7	75	68	62	55

APPENDIX IV

FUNCTIONING RATES AFTER TRANSPLANT

BY RANGE OF TRANSPLANTS PERFORMED--1971

Range of transplants performed (note a)	Percentage of donor type (note b)		Percentage of transplants functioning after		
	Living related	Cadaver and living unrelated	3 months	6 months	12 months
1 to 5	37.2	62.8	52	45	39
6 to 10	46.9	53.1	70	63	56
11 to 15	45.4	54.6	75	67	58
16 to 20	28.6	71.4	61	56	45
21 to 25	34.6	64.9	71	64	61
26 to 30	58.3	41.7	72	69	62
31 to 40	44.4	55.6	76	71	67
41 to 50	41.3	58.7	65	59	54
51 to 75	62.3	37.7	84	79	73
76 to 100	55.8	44.2	80	77	71
100 plus	33.9	66.1	68	61	53
Total	43.5	56.4	71	65	58

[a]All hospitals are grouped by the number of transplants they performed.
[b]May not total 100 percent because donor types were not known for some transplants.
[c]The total percentage of transplants functioning after 24 months was 54.7 percent, which was rounded to 55 percent.

APPENDIX IV

DEATH RATES AFTER TRANSPLANT

BY RANGE OF TRANSPLANTS PERFORMED--1969

Range of transplants performed (note a)	Percentage of donor type (note b)		Cumulative percentage of transplant recipients dying after				
	Living related	Cadaver and living unrelated	3 months	6 months	12 months	24 months	36 months
1 to 5	39.8	60.2	15	20	29	43	53
6 to 10	33.3	65.8	18	23	34	40	45
11 to 15	38.2	61.8	19	25	33	41	48
16 to 20	66.1	33.9	10	14	18	25	27
21 to 25	33.0	66.1	13	20	30	40	49
26 to 30	51.9	48.1	31	35	39	42	46
31 to 40	-	-	-	-	-	-	-
41 to 50	44.7	55.3	15	18	24	34	38
51 to 75	55.9	44.1	7	17	23	32	37
76 to 100	-	-	-	-	-	-	-
100 plus	-	-	-	-	-	-	-
Total	44.3	55.5	15	20	28	37	43

APPENDIX V

DEATH RATES AFTER TRANSPLANT

BY RANGE OF TRANSPLANTS PERFORMED--1970

Range of transplants performed (note a)	Percentage of donor type (note b)		Cumulative percentage of transplant recipients dying after			
	Living related	Cadaver and living unrelated	3 months	6 months	12 months	24 months
1 to 5	57.7	41.2	10	15	24	30
6 to 10	34.3	65.7	13	20	28	44
11 to 15	39.6	59.7	8	10	21	28
16 to 20	45.7	54.3	10	14	19	23
21 to 25	38.6	61.4	14	19	22	32
26 to 30	14.3	85.7	22	29	48	50
31 to 40	59.5	40.5	10	16	20	24
41 to 50	50.0	50.0	9	12	16	19
51 to 75	43.3	56.0	5	12	15	25
76 to 100	-	-	-	-	-	-
100 plus	-	-	-	-	-	-
Total	43.0	56.7	11	15	21	29

APPENDIX V

DEATH RATES AFTER TRANSPLANT

BY RANGE OF TRANSPLANTS PERFORMED--1971

Range of transplants performed (note a)	Percentage of donor type (note b)		Cumulative percentage of transplant recipients dying after		
	Living related	Cadaver and living unrelated	3 months	6 months	12 months
1 to 5	37.2	62.8	15	19	28
6 to 10	46.9	53.1	18	25	28
11 to 15	45.4	54.6	13	20	27
16 to 20	28.6	71.4	19	22	33
21 to 25	34.6	64.9	15	19	23
26 to 30	58.3	41.7	12	15	23
31 to 40	44.4	55.6	9	14	17
41 to 50	41.3	58.7	13	18	21
51 to 75	62.3	37.7	4	8	12
76 to 100	55.8	44.2	9	13	18
100 plus	33.9	66.1	10	17	30
Total	43.5	56.4	13	17	23

[a]All hospitals are grouped by the number of transplants they performed.
[b]May not total 100 percent because donor types were not known for some transplants.

APPENDIX V

APPENDIX VI

AVERAGE ANNUAL CHARGE FOR CENTER DIALYSIS BY REVIEWED AREA

Area	All facilities	Hospital facilities	Nonhospital facilities
Georgia	$15,000	$15,800	$12,800
South Carolina	24,000	24,000	-
Oregon	21,900	22,200	21,200
Arizona	23,100	23,100	-
Cook County, Ill.	24,400	25,000	19,700
Washington	21,800	25,000	18,700
Los Angeles County, Calif.	38,700	39,600	35,500
Minnesota	28,300	29,300	18,700
Maine	39,200	39,200	-
Vermont	32,100	32,100	-
Arkansas	25,600	20,800	30,400
Massachusetts	29,700	30,100	25,000
Missouri	26,000	26,000	-
Overall	30,100	30,500	27,600

MEDICARE BENEFITS AND PAYMENT LIMITATIONS

HOSPITAL INSURANCE--PART A OF MEDICARE

Covered services

Hospital

Room and board
Ancillary services (e.g., laboratory, X-ray, etc.)
Drugs furnished by the hospital
Medical supplies

Extended care facility

Regular nursing services
Room and board
Drugs furnished by the facility
Medical supplies

Home health benefits (after a hospital stay)

Deductible and co-insurance

Hospital--Up to 90 hospital days for each benefit period.

First 60 days--Hospital insurance pays for all covered services except for the first $92.

61st through 90th day--Hospital insurance pays for all covered services, except for $23 a day.

After 90 days--Each beneficiary has 60 "lifetime reserve" days. For each lifetime reserve day used, hospital insurance pays for all covered services, except for $46 a day. Unless the beneficiary chooses not to use them, the extra days of hospital care will be automatically taken from a beneficiary's lifetime reserve.

Extended care facility--Up to 100 "extended care" days for each benefit period.

First 20 days--Hospital insurance pays for all covered services.

Next 80 days--Hospital insurance pays for all covered services, except for $11.50 a day.

Home health benefits--Up to 100 home health visits for each benefit period.

100 home health visits--Hospital insurance pays 100 percent of all covered services.

Benefit period

A benefit period is an amount of time used for measuring a beneficiary's use of hospital insurance benefits. A benefit period begins when a beneficiary enters the hospital for the first time. A benefit period ends as soon as a beneficiary has not been a bed patient in any hospital (or any facility that mainly provides skilled nursing care) for 60 days in a row. There is no limit to the number of benefit periods each beneficiary may have.

SUPPLEMENTARY MEDICAL INSURANCE--PART B OF MEDICARE

Covered services

Physicians' services
Outpatient hospital services (including dialysis treatments)
Home health benefits (without prior hospital stay)
Other medical services and supplies (including out-of-hospital dialysis)

Deductible

For each calendar year, the beneficiary must pay the first $60 of reasonable charges for covered medical expenses.

Co-insurance

Supplementary Medical Insurance will pay 80 percent of the reasonable charge for most of the covered services (including services received by chronic kidney disease patients) after the first $60.

Premium

$6.70 monthly

REIMBURSEMENT FOR CHRONIC KIDNEY FAILURE

SERVICES UNDER MEDICARE

CENTER DIALYSIS

Under interim instructions, charges for outpatient maintenance dialysis are limited to $150 per treatment and to $190 per home dialysis training session. If routine laboratory tests are billed separately, the limits are $145 and $185, respectively. Maintenance dialysis performed on inpatients will be reimbursed on a reasonable-cost basis. Exceptions to these limits may be granted if specifically justified. As of July 5, 1974, HEW had granted exceptions to 10 facilities.

HOME DIALYSIS SUPPLIES

Home dialysis equipment and supplies (coils, blood lines, heparin, etc.) are covered under Part B as durable medical equipment. Training of a dialysis aide is covered for the facility which does the training.

TRANSPLANT

For transplant the Medicare program will pay both hospital charges and physicians' fees on the basis of actual costs and reasonable charges, respectively.

PHYSICIANS' FEES

Center dialysis

Under interim instructions, physicians are not allowed to charge a fee-for-service for dialysis. They are allowed to charge for services rendered during emergencies because of complications during dialysis. For outpatients, physicians are allowed to charge, without documentation, for one office visit per month and for indepth evaluations twice a year. Physicians are reimbursed on a reasonable-charge basis for these services. Physicians can also be reimbursed by a facility for administrative duties and supervision of a dialysis treatment.

HEW regulations effective July 1, 1974, offer physicians an alternative reimbursement method under which they can bill monthly for services rendered to each beneficiary. The monthly payment will cover:

--Physicians' services during dialysis, including both supervisory services and personal services to the patient. Supervisory services do not include any administrative services, such as staff training and management of the dialysis facility. Such services should still be included as part of the facility cost.

--Office visits for the routine evaluation of patient progress.

--All services rendered during office visits, with minor exceptions.

The maximum reimbursable monthly fee for each physician choosing this method is $240.

Home dialysis

Under interim instructions, physicians can charge for emergency services, one office visit per month, and indepth evaluations twice a year. Effective July 1, 1974, the alternative reimbursement method was also offered to physicians serving home patients. The maximum reimbursable monthly fee is $168.

Physicians will receive a fixed $500 fee for training patients for home dialysis. If the training is not completed, the fee will be reduced in proportion to the time spent.

APPENDIX IX

PRINCIPAL HEW OFFICIALS

RESPONSIBLE FOR ADMINISTERING ACTIVITIES

DISCUSSED IN THIS REPORT

	Tenure of office	
	From	To
SECRETARY OF HEW:		
Caspar W. Weinberger	Feb. 1973	Present
ASSISTANT SECRETARY FOR HEALTH:		
Theodore Cooper (acting)	Feb. 1975	Present
Charles C. Edwards	Mar. 1973	Jan. 1975

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