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Epidemiology of End Stage Renal Disease and Implications for Public Policy

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Synopsis

In 1972 the Congress extended Medicare coverage to all persons under age 65 suffering from end stage renal disease (ESRD). The intent of this law (PL 92-603, the Social Security Amendments of 1972) was to allow all

Americans access to an emerging and very expensive technology, regardless of their ability to pay.

The legislation had an immediate and dramatic impact on the population receiving dialysis. Prior to the passage of the legislation the dialysis population was white, educated, young, married, employed, and male. Within 4 years after implementation of the law, the dialysis population was more than one-third nonwhite, less well educated, significantly older, and about half female—making it more representative of the population as a whole.

During consideration of this legislation the dialysis population was expected to increase from 5,000 to 7,000 patients and cost \$135 million in the first year. Actually, in the first year of the program, there were 10,300 patients and the cost was \$241 million. Today, while patients with ESRD represent only 0.25 percent of Medicare beneficiaries, they consume approximately 10 percent of the Medicare Part B budget.

The humanitarian goals of the legislation have been met, but the costs of this program continue to rise as enrollment continues to grow. It is hoped that, through research and reimbursement policies, the per capita costs can be controlled and total costs can be reduced by shifts in treatment patterns and improvement in successful transplantation rates. There will, however, con-

tinue to be demands on our health care financing system to include reimbursement for new therapeutic modalities such as artificial hearts and heart and liver transplants. The lesson from the ESRD Program is that sound decisions require accurate epidemiologic data and cost projections. It is a challenge not easily met.

THIS REPORT ADDRESSES the epidemiologic issues of end stage renal disease and the implications for health resource allocations. The evolution of the End Stage Renal Disease (ESRD) Program illustrates the complex linkage between health care, financing, and resource distribution.

The 1972 decision to allow full access of the population to end stage renal disease treatment was based on humanitarian motives. Under this program Medicare coverage was extended to persons under age 65 suffering from end stage renal disease. The law extending benefits to the entire population was passed with little debate or analysis. Few cost estimates were made. Limited accurate epidemiologic data were provided. No total limits were placed on the reimbursements for the ESRD Program.

The intention of the legislation was clear—to allow all Americans access to an emerging and very expensive technology regardless of ability to pay. The arguments made in favor of the bill during the congressional debate in 1972 were dramatic.

Before the passage of the Social Security Amendments of 1972, Public Law 92-603, dialysis equipment and financing of this treatment were limited to a select few. Physicians and committees responsible for selecting patients did so on the basis of “social worth,” as it related positively to the outcome and impact of treatment (1). When the Medicare bill was under consideration in 1972, dialysis patients were expected to grow from 5,000 to 7,000 in the first year of the program, or an incidence of 38 cases per million population, for a cost of \$138 million (2). Shortly after the ESRD Program was implemented in 1974, there were actually 10,300 patients receiving care. The cost for the first year of the program was \$241 million (1).

As illustrated in table 1, the characteristics of the treatment population prior to the passage of the law were strikingly different from those who had access to care after passage of the law.

In general, the population receiving dialysis prior to the passage of Public Law 92-603 was a “select” group of white, educated, young, married, employed men. In 1967, for example, male patients outnumbered female

patients 3 to 1. In 1978, the distribution more closely resembled the general population. In 1967 almost all of the dialysis population was white; in 1978 nonwhites represented more than one-third. The proportion of patients with less than a high school education rose significantly from 1967 to 1978, while the proportion of those employed decreased significantly. Perhaps most striking, the proportion of patients over the age of 55 rose from 7 percent in 1967 to more than 45 percent in 1978 (1). What these statistics tell us is that when the financial constraints of treatment were removed, the population undergoing dialysis changed to much older, more financially disadvantaged, and sicker patients.

Table 1. Social and demographic characteristics of the hemodialysis patient population, 1967 and 1978 (percentages)

Characteristics	1967	1978
Sex:		
Male	75.0	49.2
Female	25.0	50.8
Race:		
White	91.0	63.7
Black	7.0	34.9
Other	2.0	1.4
Education:		
Junior high or less	10.0	28.7
Some high school	17.0	17.2
High school graduate	27.0	28.4
Some college	20.0	18.2
College graduate	12.0	5.7
Postgraduate school	13.0	1.8
Unknown	1.0	0.0
Age (years):		
Under 25	8.0	3.4
25-44	56.0	24.6
45-54	27.0	25.8
55 or older	7.0	45.7
Unknown	2.0	0.5
Employment status:		
Employed	41.7	18.4
Unemployed	38.3	17.7
Disabled		53.6
Student	13.2	NA
Retired		10.2
Unknown	6.8	0.0

SOURCE: Reference 1.

The number of people receiving dialysis has grown significantly since the passage of the ESRD Program in 1972 and now includes patients with serious chronic illnesses such as heart disease and diabetes. In addition, better access to treatment has resulted in earlier diagnosis, prolonged lives, and increased costs. Although the original 5,000 patients under dialysis in 1972 were suffering from renal disease, they were probably much healthier than the patient population today, with far fewer secondary, complicating diseases (2). These factors have all contributed to the cost of a program that far exceeded the expectations of Congress in 1972. Today, persons with end stage renal disease represent only 0.25 percent of the Medicare beneficiaries but they consume almost 10 percent of the Medicare Part B budget.

Table 2. Percentage distribution of patients in the Medicare End Stage Renal Disease Program, by primary diagnosis, 1973-81

Primary diagnosis	1973 and prior	1976-77	1980-81
All causes	100	100	100
Glomerulonephritis	36	24	24
Primary hypertensive disease	13	18	19
Diabetic nephropathy	7	15	22
Polycystic kidney disease	9	7	6
Interstitial nephritis	14	10	7
Other ¹	3	5	9
Other, unspecified	9	10	5
Etiology unknown	9	11	8

¹ Includes collagen vascular disease, analgesic abuse nephropathy, obstructive uropathy, amyloidosis, multiple myeloma, and gouty nephropathy.

SOURCE: Eggers, P., Connerton, R., and McMullan, M.: The Medicare experience with end stage renal disease: trends in incidence, prevalence, and survival. HCFA Rev 5: 69-88, spring 1984.

Table 3. Demographic characteristics of patients in the Medicare End Stage Renal Disease Program, 1977-80

Demographic characteristic	Number per million				Percent change 1977-80
	1977	1978	1979	1980	
Age (years):					
0-24	13	15	15	15	15
25-44	60	66	69	74	23
45-64	132	145	163	169	28
65 or older	134	165	198	216	61
Sex:					
Male	71	82	91	96	35
Female	53	61	68	72	36
Race:					
White	52	58	63	68	31
All other	130	154	179	185	42
All persons	62	71	79	84	35

SOURCE: Eggers, P., Connerton, R., and McMullan, M.: The Medicare experience with end stage renal disease: trends in incidence, prevalence, and survival. HCFA Rev 5: 69-88, spring 1984.

The End Stage Renal Disease Population

Table 2 shows the distribution of end stage renal disease patients by diagnosis, prior to the passage of the ESRD Program and currently. Consistent with the earlier reference to a "sicker" population, the most noteworthy changes have been in the chronic categories, including diabetic nephropathy and "other," which includes collagen vascular disease. In comparison, some recent European data show striking differences. The proportion of end stage renal disease related to glomerulonephritis in Europe is 56 percent, compared with 24 percent in the United States; interstitial nephritis is 20.9 percent in Europe, compared with 7 percent in the United States; polycystic disease is 9.5 percent, compared with 6 percent; and diabetic nephropathy is 4.4 percent, compared with 22 percent (3). Some of the differences between European nations and the United States may be explained by differences in the composition of the populations, but a part is related to policies of European governments that restrict the patient population to younger, healthier individuals with a greater expectation of productivity. This is particularly notable in England, where total resources are limited.

Table 3 displays the incidence of end stage renal disease by age, sex, and race per million population within each grouping. This table again shows the shifts in patient population to an older group, with an increasing proportion of nonwhites. Note, as well, how far we have departed from the original estimate in 1972 of an incidence of 38 persons per million who would require dialysis.

Survival rates by age, sex, and race among Medicare ESRD patients, 1973-79, are as follows:

Population group	Percent surviving 5 years
All persons	48
Age group:	
0-14	77
15-24	76
25-34	66
35-44	59
45-54	50
55-64	43
65-74	25
75 and older	19
Sex:	
Male	46
Female	51
Race:	
White	48
Black	48
Other	49

¹ Sex and race survivals are age adjusted.
SOURCE: Eggers, P., Connerton, R., and McMullan, M.: The Medicare experience with end stage renal disease: trends in incidence, prevalence, and survival. HCFA Rev 5: 69-88, spring 1984.

Not surprisingly, there is a marked decrease in survival with increasing age. This must be weighed against the

knowledge that in the absence of financial constraints no Americans are denied treatment for any reason, including underlying health status and age. This trend is part of the dilemma of an unrestrained program created with the best intentions.

Treatment Modalities

During the 1972 congressional discussions preceding the passage of the ESRD law, it was estimated that hospital dialysis would cost \$35,000–\$40,000 per person per year, dialysis in an ambulatory care facility \$14,000–\$20,000, and home dialysis \$12,000–\$20,000 for the first year (for purchase of equipment, training, and so forth) and \$4,000–\$6,000 per year after that (4). The following table shows the average Medicare reimbursement per person by treatment category in 1979.

<i>Treatment category</i>	<i>Medicare reimbursement per person</i>
All persons	\$18,170
Hemodialysis:	
In-center	\$23,562
Home	\$18,629
Transplantation:	
1979	\$36,411
Before 1979 ¹	\$5,546
ESRD patients dying in 1979	\$29,769
Other, unknown	\$15,887

¹ Transplant never rejected.

SOURCE: Eggers, P.: The Medicare experience with end stage renal disease: trends in reimbursement. HCFA Rev. In press.

In constant dollars, the cost estimates in 1972 appear far more realistic than those made for the incidence of the disease. But the inflation of health care costs during the 1970s is well recognized.

Before passage of the ESRD law, 40 percent of the patients with end stage renal disease were undergoing dialysis at home (5). When the law was passed, it provided a higher reimbursement for treatment in centers than for treatment at home, and this bias produced a shift in treatment modalities with a substantial decline in the proportion of home dialysis patients.

By 1976, the level of home dialysis had dropped to 16 percent of the dialysis population. The level continued to drop to 14 percent in 1978. With this dramatic shift from less expensive home dialysis to more expensive center dialysis, Congress took steps to amend the ESRD law in 1978 to reduce the bias towards treatment in centers (1). The amendments were intended to provide incentives for self-dialysis, when medically appropriate, and to eliminate program disincentives to transplantation. The amendments extended coverage to all necessary home dialysis supplies and support services and included payment of donation-related medical expenses for transplan-

tation. The amendments also encouraged in-center self-dialysis.

Annual dialysis treatments as of June 30, 1982, were as follows:

<i>Type of treatment</i>	<i>Total number</i>	<i>Percent</i>
In-unit staff-assisted—		
Hemodialysis	49,671	79
Peritoneal dialysis	919	1
Self-hemodialysis	1,005	2
Self-peritoneal	11	...
Home:		
Hemodialysis	4,410	7
Peritoneal dialysis	782	1
Continuous ambulatory peritoneal dialysis	5,501	9
Self-dialysis training	683	1
Totals	62,982	100

SOURCE: "End-Stage Renal Disease Program Quarterly Statistical Summary," Health Care Financing Administration, Baltimore, Md., Feb. 2, 1983.

It is evident that the proportion of home dialysis is still much lower than center dialysis, although home dialysis appears to be on the increase since the amendment of the ESRD law in 1978. The number of kidney transplants is also increasing slowly, as shown by the following figures for both Medicare and non-Medicare patients:

<i>Year</i>	<i>Number of kidney transplants</i>
1973 ¹	1,600
1974	3,190
1975	3,730
1976	3,504
1977	3,973
1978	3,949
1979	4,271
1980	4,697
1981	4,885
1982	5,358

¹ July-December 1973.

SOURCE: "End-Stage Renal Disease Program Quarterly Statistical Summary," Health Care Financing Administration, Baltimore, Md., Feb. 2, 1983.

It is difficult to determine how much of the increase in kidney transplantation can be attributed to changes in reimbursement and how much to improved medicine. It should be noted that neither home dialysis nor transplantation is appropriate for everyone, particularly the very old and the very sick. Nevertheless, there is a portion of the population who potentially would benefit from these treatment methods.

Choice of therapy is a medical decision. It is not the role of government to advocate use of one treatment over another, although the Health Care Financing Administration has taken actions to encourage kidney transplants and home dialysis where medically appropriate. As part of this effort, the Department of Health and Human Services has taken several actions to increase public and professional awareness of the need for kidneys.

Table 4. Per capita expenditures for end stage renal disease as compared with other economic indicators

Year	ESRD benefits per capita		Health care expenditures per capita		Cost per patient day in community hospitals	
	Amount	Percent increase	Amount	Percent increase	Amount	Percent increase
1974.....	\$14,895	...	\$539.11	11.9	\$113.55	10.9
1975.....	16,667	11.9	607.53	12.7	133.81	17.8
1976.....	17,086	2.5	678.79	11.5	152.76	14.2
1977.....	18,463	8.0	768.30	13.2	173.98	13.9
1978.....	20,149	9.1	845.53	10.1	194.34	11.7
1979.....	19,482	-3.3	942.94	11.5	217.34	11.9
Average.....	...	5.6	...	11.8	...	13.4
5-year change 1974-79 (percent).....	...	30.8	...	74.9	...	91.4

SOURCE: Lowrie, E.G., and Hamers, C. L.: The success of Medicare's end stage renal-disease program. The case for profits and the private market place. *N Engl J Med*

305: 434-438, Aug. 20, 1981.

Table 5. Total Medicare reimbursements and end stage renal disease beneficiary population, 1974-81

Year	Total reimbursements (millions)	Reimbursements in 1974 dollars	Number of beneficiaries
1974.....	\$241	\$241	16,742
1977.....	649	529	37,079
1979.....	1,008	685	50,829
1980.....	1,245	745	57,818
1981 ¹	1,443	781	64,063

¹ Estimated.

SOURCE: Eggers, P.: The Medicare experience with end stage renal disease: trends in reimbursement. HCFA Rev. In press.

One such action is the formation of the American Council on Transplantation (ACT). This new group is an outgrowth of the recommendations of an earlier workshop that the Surgeon General of the Public Health Health Service, Dr. C. Everett Koop, convened in June 1983 at the request of President Reagan. The workshop members recommended the establishment of an umbrella organization of private groups and individuals concerned with organ donation. The workshop also recommended the formation of a group from the National Institutes of Health to address the problem of the maintenance of the body of a potential multiple organ donor and to provide necessary guidelines according to the best science available.

Cost

Table 4 illustrates the per capita costs of the ESRD Program. Compared with the total per capita health care expenditures and the cost per patient-day in community hospitals, the percentage increase from 1974 to 1979 in per capita ESRD benefits has risen more slowly. The average rate of increase from 1974 for ESRD was less than half the rate for per capita health care expenditures

and the cost per patient day in community hospitals. Total ESRD payments, therefore, have risen primarily because of increased population and the prolongation of life.

Table 5 summarizes the growth in beneficiaries and costs of the ESRD Program since 1974. Between 1974 and 1977, the cost of the program almost tripled while the number of beneficiaries more than doubled. From 1974 to 1981, the cost of the program increased almost sixfold while the population receiving treatment almost quadrupled. In constant dollars, however, the program cost increased slightly more than 200 percent.

International Review

While the United States was extending dialysis eligibility to everyone, countries in Europe and Israel and Japan were developing their own policies. As table 6 illustrates, these policies have resulted in a striking variation in both the rate of dialysis and the proportion of home dialysis around the world. In 1979, home dialysis rates ranged from a high of 64 percent in the United Kingdom to a low of 13 percent in the United States and even lower in Japan, Belgium, Israel, Italy, The Netherlands, Norway, the German Democratic Republic, and several other nations. Part of the variation may be explained by variations in the incidence of renal disease, but much is attributable to differences in national policy. While home dialysis is increasing in the United States, in the German Democratic Republic only two types of therapy are used—hospital dialysis and transplantation. Denmark, Sweden, Norway, and Finland rely heavily on transplantation (7).

Britain has had a national health insurance system since 1946. Since 1971, Britain has restricted the total level of expenditure for dialysis and has developed strict patient selection criteria. This policy has resulted in an emphasis on home dialysis and an unofficial age limit of

Table 6. Numbers of patients per million population on peritoneal dialysis, hemodialysis, and those alive with a functioning transplant, 1979

Country	Peritoneal dialysis	Hemodialysis	Percent on home dialysis	Functioning transplant	Total ¹
United States of America.....	5	205	13	66	277
Japan.....	² 2	235	<1	² 14	² 251
Switzerland.....	10	132	23	74	221
Belgium.....	6	134	7	60	206
Israel.....	14	150	12	31	201
Canada.....	29	92	35	² 72	² 193
France.....	8	150	17	23	188
Australia ³	14	80	45	91	185
Denmark.....	10	75	23	91	181
Luxembourg.....	0	122	0	2	164
Federal Republic of Germany.....	3	137	21	14	161
Italy.....	4	137	12	12	158
Sweden.....	8	64	22	71	149
Netherlands.....	1	95	9	47	148
New Zealand ³	6	62	52	67	135
Austria.....	<1	91	7	25	119
Finland.....	5	32	3	77	118
Norway.....	3	29	4	80	117
Spain.....	3	99	6	8	114
U.K.....	4	57	64	48	111
Greece.....	1	61	<1	8	77
Ireland.....	1	36	33	31	69
German Democratic Republic.....	1	37	0	16	56

¹ Includes patients known to be on treatment but whose mode of therapy was uncertain.

² Provisional figure.

³ On April 30, 1980.

SOURCE: Wing, A. J., and Selwood, N. H.: Registry data, a collaborative exercise. In Proceedings of the 8th International Congress of Nephrology, Athens, 1981, pp. 571-576.

55 years for acceptance to dialysis (8). The large differences in the American and British rates of end stage renal disease treatment and the proportion of home dialysis (13 percent in the United States and 64 percent in Britain) reflect generous funding in the United States and limited funds and consequent cost consciousness in Britain.

Conclusions

There is little doubt that the humanitarian goals set forth by Congress when it created the ESRD Program in 1972 have been met. Today, no patient in the United States is denied treatment for end stage renal disease because of the cost. In this sense, the program is a success. But there are lessons to be learned, and these lessons must be applied to the ESRD Program as well as to other health care programs as they arise.

The total program enrollment for ESRD will continue to rise. Based on current incidence rates, mortality rates, and population projections, the Health Care Financing Administration estimates that the total enrollment in the ESRD Program may double by the year 2035 (9). Given no other changes, this will continue to increase total program costs. But per capita costs can be controlled, and total costs can be reduced by shifts in treatment

patterns and improvements in successful transplantation rates.

Government should not mandate treatment modalities. Its goal should be to ensure that information is given to all ESRD patients, their families, and the health professions regarding the various treatments and their advantages and disadvantages. Research on better and earlier diagnosis as well as prevention of end stage renal disease must be continued. Improved understanding of the causes of hypertension, for example, would have tremendous impact on the incidence of end stage renal disease as well as profound social and economic ramifications.

There will continue to be demands on our health care financing system to include reimbursement for treatment of more diseases as new therapeutic modalities become available, as shown by our experience over the last year with the artificial heart. The main lesson of the ESRD Program is that the best information should be used in determining public policy. Only with accurate epidemiologic data and cost projections can the Government and the public make sound decisions.

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Polychlorinated Biphenyls In Israel: a Risk Assessment

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Health, P.O.B. 1457, Jerusalem, Israel 91000. The article is based on Dr. Weisenberg's presentation at the Second Binational Symposium: United States-Israel, which was held in Bethesda, Md., October 17-19, 1983. It was given in Workshop 3, The Role of Epidemiology in Regulatory Programs.

THE HISTORY OF POLYCHLORINATED BIPHENYLS (PCBs) represents a unique example of a common industrial chemical which became a universal contaminant. During the years of widespread occurrence in the environment, the chemical and physical characteristics and chronic toxicity of PCBs have raised great concern about possible health hazards, especially in the industrialized countries (1).

PCBs, a mixture of synthetic aromatic halogenated biphenyl compounds, have been commercially available for more than 50 years. Beginning in the 1950s, because of their typical properties of an excellent dielectric constant, high electric resistance, thermal and chemical stability, and high lipophilicity, PCBs achieved practical importance which make them very useful in many industrial applications. The cumulative world production of PCBs through the years was estimated at around 1 million tons.

In 1966 PCBs were detected in dead fish in the Archipelago of Stockholm (2), and further evidence emerged each succeeding year of the presence of this industrial compound in the environment, in food, and in human beings. Many factors, such as areawide contamination by dumping or incineration of waste products containing PCBs, and serious accidental poisonings in man have

shown that these contaminants have become a controversial health hazard.

Starting in 1970, huge efforts have been made by regulatory agencies to introduce severe restrictions on or even ban production and use of PCBs. Parallel methods and techniques, followed by monitoring programs, have been developed for surveillance of PCBs' residues in the environment, in foods, and in humans in an attempt to elucidate the toxicological significance to man and provide the epidemiologic tools needed to correlate adverse health parameters to exposure and body burden (3).

PCBs in Israel

PCBs are not produced locally in Israel, but are imported as technical substances under their various trademarks, and no statistical information is available on the national consumption. Polychlorinated biphenyls found in Israel have the same versatile industrial applications as in other countries; however, following restrictions imposed on the international level, PCBs were replaced by alternative substances or limited to closed systems. The stringent scheme imposed on the uses, disposal, and distribution helps to assure that no further significant quantities of PCBs are introduced into the environment.