ABSTRACT
This paper describes how society has responded to the issue of providing treatment for catastrophic illness. The end-stage renal disease (ESRD) program is discussed as a case study. An evaluation of the program, in terms of efficiency and equity, indicates that it has been fairly successful in providing permanent kidney failure patients with equal access to care. However, the program has not fared well in terms of efficiency or equity with respect to individuals needing other types of health care. Policy implications for the ESRD program and for treating other catastrophic illnesses are presented.

INTRODUCTION
In recent years health care costs have risen substantially. National health care expenditures rose from $76.4 billion in 1970 to $322.4 billion in 1988 [30]. Birnbaum [4] noted that total resources consumed by catastrophic illness alone accounted for more than 20 percent of national health care expenditures in the late 1970s. These expenditures reflect both general inflation in the economy and advances in medical technology for treating illness. The rising costs of health care in general and of medical technology specifically have lead to numerous discussions concerning the allocation of resources across health care programs, and to the rationing of treatments within programs. In response, there has been an increasing interest in health care program evaluation which addresses both economic and social costs, including lives saved [13].

The need for careful assessment of health care programs is particularly evident in the case of treatments resulting from technological advances "which place previously incurable and inevitably fatal conditions within the powers of medicine to retard, if not to control" [19, p. 8], but often at very high costs. Chronic conditions so treated are often referred to as catastrophic illnesses. For an individual with a catastrophic illness, the threat to life and economic burdens are more pronounced than with other illnesses. Katz and Capron [19] have defined a catastrophic illness as

...one for which some form of unusually expensive treatment must be available which can at least sustain life for a period of time. Moreover, the availability of insurance coverage or other financial support does not remove a condition from this category; the emphasis is on the great expense of the treatment, no matter who pays for it. [p. 8]

Major technological advances have been made for treating chronic diseases which often entail expensive long-term care. However, many of these interventions do not cure disease, and questions remain concerning the patient's ability to cope and to regain functioning. Since all persons with chronic diseases cannot be expected to benefit from medical technology, decisions to allocate resources to treat such conditions must be based upon careful analysis.

The purpose of this paper is to discuss how society has responded to the issue of providing treatment for catastrophic illness. The provision of treatments for individuals with end-stage renal disease (ESRD), chronic or permanent kidney failure, is examined as a case study. The discussion begins with an overview of the disease, treatments, related legislation and program growth. Second, the program is evaluated in terms of efficiency and equity. Cost-effectiveness analysis is used primarily to assess program efficiency. Policy implications for the ESRD program and for treating catastrophic illnesses, in general, are also presented.

THE END-STAGE RENAL DISEASE PROGRAM

Background
End-stage renal disease is a general designation for all diseases which lead to chronic kidney failure. Chronic kidney failure results when the kidneys permanently cease to perform their usual functions to such a degree that without treatment, death will soon occur. Primary treatment options available for individuals with ESRD are kidney transplantation, hemodialysis, and peritoneal dialysis. Kidney transplantation is a surgical procedure in which diseased kidneys are replaced with healthy ones obtained from living related donors or cadavers. Hemodialysis performs the kidney's purifying function by filtering the blood through an artificial kidney machine where wastes are removed before the blood is returned to the body. In peritoneal dialysis, the filtering of the blood takes place within the patient's abdominal cavity without the blood leaving the body. Dialysis can be performed in the individual's home or in a hospital or clinic.

With the passage Public Law 92-603 (Social Security Amendments of 1972) [22], ESRD patients became the first, and thus far only, victims of catastrophic illness in the United States whose

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treatment costs are paid primarily by the federal government. With this legislation, Medicare coverage was extended to individuals under age 65 with permanent kidney failure who were not already disability benefits recipients. These individuals qualify as Medicare recipients and are subject to the deductible, premium, and co-payment of the Social Security Act. To be eligible for ESRD program benefits, an individual is required to be insured or entitled to a monthly insurance benefit under the Social Security or Railroad Retirement Act, or to be the spouse or dependent of an individual who is so entitled. Under the original legislation, the federal government was to pay 80 percent of the patient's medical expenses and the other 20 percent was to be covered by the patient or a third party payer such as Blue Cross/Blue Shield, State kidney programs, or private non-profit organizations.

Prior to the passage of this legislation, major funding sources available for paying treatment costs included such federal programs as Medicare (for those over age 65), State programs, private hospital insurance programs, and patients' personal resources. Because resources for treatments were scarce, patients were selected to receive dialysis or transplants. Selection was often based on criteria such as age, medical stability, family involvement, criminal record, economic status (e.g., income, net worth), and employment [16]. The decision to provide treatment was often influenced by financial constraints, particularly in the case of dialysis. By largely removing the financial barriers to treatment, the federal government became the gatekeeper of dialysis and transplantation [19]. No longer was selection to be a matter of social worth and wealth, as was often the case before the legislation.

The ESRD program is administered by the Health Care Financing Administration (HCFA) in the U.S. Department of Health and Human Services. The primary goal of the program has been to assure ESRD patients equal access to high quality, cost-effective medical care.

Much progress has been made to provide equal access to medical care. According to Burton [6], ESRD would claim at least 45,000 lives if not treated with heroic means such as dialysis and transplantation. As of December 31, 1983, the latest date for which these data are available, 78,099 individuals were receiving ESRD treatments; 92 percent were dialyzing and 8 percent had received transplants in that year [31]. This is in contrast to the 16,000 beneficiaries covered in 1974, the first full year of the program [10]. In 1983, ESRD program beneficiaries represented approximately 93 percent of the ESRD population in the United States. Actual expenditures paid by the ESRD program for beneficiary services in 1983 were approximately $1.72 billion [31] compared to $250.5 million in 1974 [10]. It is estimated that more than 87,000 patients in the United States will be receiving program benefits by 1986 at a cost of almost $3 billion [29].

The original ESRD legislation stressed equal access to care; however, more recent legislation emphasizes intraprogram economy and cost-efficiency. The End-Stage Disease Program Amendment of 1978 [23] was designed to encourage home dialysis and transplantation as the most cost-effective treatments. Included among the provisions for home dialysis were full coverage for home dialysis supplies and 100 percent reimbursement of the reasonable costs for home dialysis equipment and maintenance. Provisions to encourage transplantation included an extension of post-transplant Medicare entitlement from 1 to 3 years and 100 percent reimbursement of kidney donor expenses. The Omnibus Budget Reconciliation Act (OBRA) of 1981 [24] included a further incentive to promote home dialysis through a differentiated prospective reimbursement method based on dialysis setting [11]. Another major provision of the OBRA made Medicare the secondary payor for services furnished to ESRD beneficiaries during a specified period of time up to 12 months if beneficiaries were also covered by employer group health plans. In addition, reimbursement for home dialysis equipment and maintenance was reduced from 100 percent to 80 percent.

Program Evaluation and Policy Implications

In this section, the ESRD program is examined in terms of efficiency and equity, two important criteria for evaluating health care programs. Efficiency refers to the allocation of resources to obtain maximum benefits for a given expenditure. Economic efficiency requires that resources are being put to their most valuable uses. Equity refers to the fairness of the resource distribution. Policy implications based on the evaluation are presented. Cost-effectiveness analysis is used to evaluate the cost-efficiency of the program.

Cost-effectiveness analysis is useful for this type of evaluation since alternative uses of resources to achieve a specified goal (an increase in the number of lives saved due to intervention) are being compared and only a single program outcome is envisaged (lives saved). With cost-effectiveness analysis the value of a life is imputed based on the dollars spent per year of life gained due to intervention, thus avoiding placing an explicit value on human life. The implicit value of a life year (IVLY), the cost-effectiveness criterion, may be expressed as follows:

\[
IVLY = \frac{\text{total present value of costs}}{\text{sum of discounted life years saved}}. \quad (1)
\]

Alternative treatments are ranked based on the IVLYs; the lowest value represents the most cost-effective strategy. The cutoff level of permissible cost per life year saved is based on the resources made available by society to achieve the goal [34].
Since the late 1960s, various studies have been conducted to access the intraprogram cost-effectiveness of alternative ESRD treatments in terms of the IVLY. A comparison of IVLYs based on the gross social costs of ESRD treatments is presented in Table 1. Gross social costs are the social opportunity costs of resources to provide treatments. Here they are represented by the various expenditures associated with each treatment. All values are presented in 1981 dollars. The results are not entirely comparable because of differences in the definition of treatments and costs; however, similar rankings for transplants, home dialysis, and in-center dialysis result.

The most cost-effective treatment modes are living related donor (LRD) transplant and home dialysis. Implicit life year values for a LRD transplant range from $12,319 [27] to $22,400 [18]. Values for home dialysis range from $15,944 [2] to $28,656 [28]. When LRD transplants and cadaveric donor (CAD) transplants are included in the analysis as separate treatments [27, 18], home dialysis is more cost-effective than is a CAD transplant. In all instances, in-center dialysis is the most cost-ineffective of the treatment modes with values ranging from a low of $18,600 [32] to a high of $44,142 [28].

Although the various treatment modes may differ in terms of the effect they have on patient quality of life, none of the values presented were adjusted to reflect such differences. However, as noted by Ludbrook, "It is not certain that quality of life considerations would alter the allocation of resources [for ESRD treatments]; they may reinforce the order of selection as they reinforced the cost-effectiveness ranking of treatment" [21, p. 347].

A simple interprogram comparison of IVLYs indicates that ESRD treatments maybe somewhat less cost-effective than are other health care programs which have also been designed to increase life years saved. For example, Weinstein and Stason [35] estimated the cost per discounted quality adjusted life year (QALY) to manage hypertension (including costs due to medication side effects) to be in the range of $3,000 to $20,000, with $10,000 being common for mild hypertensives. Cole and Berlin [9] estimated that the undiscounted IVLY for an individual undergoing an elective hysterectomy to be $8,000. Discounting would likely quadruple this number however. The discounted present cost of mobile coronary care units to prevent heart attack deaths per QALY was estimated by Zeckhauser and Shepard [36] to be $1,985. A low cholesterol diet aimed at the same objective yielded a cost of $6,029 [36]. Although the values are not completely comparable due to differences such as time period and quality adjustment, it is evident that ESRD patients are competing with potentially large numbers of other individuals with major medical conditions for limited health care resources. As the competition for health care resources becomes more acute, rationing by design or by default might again be necessary for ESRD treatments, as was the case before the Social Security Amendments of 1972 [15].

### Table 1. Summary of Major End-Stage Renal Disease Studies: Implicit Life Year Values (1981 Dollars)

<table>
<thead>
<tr>
<th>Reference Study</th>
<th>Country</th>
<th>Discount Rate</th>
<th>Years</th>
<th>Home Dialysis</th>
<th>In-Center Dialysis</th>
<th>LRD Transplant</th>
<th>CAD Transplant</th>
<th>LRD/CAD Transplant</th>
</tr>
</thead>
<tbody>
<tr>
<td>GAO, 1977</td>
<td>U.S.</td>
<td>-</td>
<td>2nd</td>
<td>17,767</td>
<td>35,535</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Stange and Summer⁵, 1978</td>
<td>U.S.</td>
<td>5% - 7%</td>
<td>10</td>
<td>28,456</td>
<td>44,142</td>
<td>24,900</td>
<td>28,815</td>
<td></td>
</tr>
<tr>
<td>Roberts et. al., 1980</td>
<td>U.S.</td>
<td>-</td>
<td>Life</td>
<td>21,212</td>
<td>39,630</td>
<td>12,319</td>
<td>23,839</td>
<td></td>
</tr>
<tr>
<td>Ludbrook⁶, 1981</td>
<td>U.K.</td>
<td>7%</td>
<td>Life</td>
<td>15,944</td>
<td>30,790</td>
<td></td>
<td></td>
<td>12,783</td>
</tr>
<tr>
<td>DHHS⁷, 1982</td>
<td>U.S.</td>
<td>-</td>
<td>Annual</td>
<td>16,706</td>
<td>18,600-23,350</td>
<td>22,400</td>
<td>31,148</td>
<td></td>
</tr>
</tbody>
</table>

⁵Living related donor (LRD), cadaveric donor (CAD), and living related donor and cadaveric donor combined (LRD/CAD) transplants.
⁶Values based on low estimates of survival probabilities for cadaveric transplants. Home dialysis and in-center to home dialysis options yielded the same implicit life year values.
⁷Values based on high cost estimates and all ages.
⁸Values based on per treatment estimates for home, independent facility, and hospital-based facility dialysis; three treatments per week were assumed. Hospital-based facility dialysis was the most costly mode.
⁹Values based on low estimates of survival probabilities for all individuals undergoing treatment across all age and sex categories.
To assess efficiency within the ESRD program, it is necessary to examine where resources are actually being allocated. Although legislation exists to encourage the more cost-effective treatment modes, home dialysis and transplantation, the majority (75 percent) of all ESRD patients receiving treatment in 1983 were dialyzing in-center [31], the most cost-ineffective treatment. The dominance of in-center dialysis suggests that certain constraints and barriers exist which perhaps preclude the use of the more cost-effective treatments for all patients and which directly affect the efficiency of the program. For example, 50 percent of the dialysis population is over the age of 55; these individuals are probably not the best candidates for transplantation. Some of these patients may also have medical complications or other constraints which eliminate home dialysis as an option. Thus, in-center dialysis may not only be the most cost-effective treatment for these individuals, it may be the only viable alternative. Although only a minority of ESRD patients are true candidates for transplantation, the number of LRD transplants today is limited by the willingness and ability of living relatives to donate kidneys. Thus, this option is not currently a viable solution to the problem of rising costs associated with the ESRD program. In the case of a CAD transplant, improvements in patient survival and graft retention rates are necessary if it is to become a more cost-effective option. However, even with these improvements, the CAD transplant may also be a limited treatment option unless the supply of donor kidneys can be increased.

Barriers to the most cost-effective treatment modes also need to be identified and removed to promote efficiency. Barriers include a lack of public awareness of the need for donor organs, cost and resource constraints of the patient and patient’s family, treatment availability, and biases of medical teams associated with chronic kidney failure which reflect differences in treatment orientation and philosophy. With more specific information concerning constraints and barriers, the ESRD program can potentially become more efficient.

In addition to evaluating the ESRD program based on costs per year of life saved, other relevant variables, whether or not with monetary values, must also be examined. For example, patient outcomes (e.g., survival, rehabilitation, and quality of life) and quality of care are important factors in assessing program efficiency. These are important because it is conceivable that an individual could be placed on a treatment for which he is not well suited, or he may not received adequate care due to reductions in services. These could lead to increases in total ESRD program costs, and to patients settling for less in terms of care. Until recently, there has been little emphasis on the rehabilitation of patients. Several researchers [2, 18, 20] have identified potential deterrents to work for ESRD patients which include the receipt of government disability cash benefits, prejudices of employers, and general job availability. Coordination of the ESRD program with vocational and occupational rehabilitation programs to help patients become more active in caring for themselves and in becoming employable again has also been lacking [2, 18]. By focusing attention on the rehabilitation of individuals, improvements in patient quality of life could be expected since studies indicate that working is related to greater perceived quality of life [5, 7, 8, 18].

Based on the allocation of resources and patient outcomes, the ESRD program does not appear to be as efficient as it possibly could be. With the most recent ESRD legislation, it is obvious that federal government is attempting to reduce program cost. However, by focusing on cost-efficiency primarily, the least costly treatments could be promoted with little regard for which treatments are best for patients. Thus, as resource allocation and rationing decisions are brought into sharper focus, the need for adequate data concerning costs, patient outcomes and characteristics, program management, and quality of care become more critical [12, 17, 34].

When evaluated on the basis of equity, results of studies [10, 25] indicate that the ESRD program has made much progress in providing ESRD patients with equal access to care. Growth in the number of beneficiaries covered by the program, discussed earlier, is evidence of this. In addition, the program has been successful in protecting chronic kidney failure patients against the catastrophic cost of needed care [18].

However, by providing treatment to ESRD patients, individuals with other medical conditions in need of treatment are potential victims of discrimination. A few statistics can be used to highlight this issue. For example, in 1983, ESRD patients accounted for only 0.25 percent of all Medicare beneficiaries, but ESRD expenditures accounted for approximately 4 percent of Medicare expenditures [10]. Thus, the ESRD program is redistributing health care resources to individuals with permanent kidney failure and potentially away from other individuals needing care.

Currently the focus of the ESRD program is within program efficiency and equity. Yet, if resources for health care become more constrained than they are currently, the importance of efficiency and equity could extend from intraprogram to inter-program evaluation [14]. Thus, subsequent evaluations would need to address resource allocations for the treatment of other medical conditions, prevention activities, and research and development.

**DISCUSSION**

The ESRD program has opened the door to providing treatments for other catastrophic illnesses. However, due to unexpected growth in the ESRD program, policymakers are reexamining the issue of providing widespread coverage for expensive health care treatments, since other health care can be
just as costly. For example, it has been estimated that a heart transplant costs $125,000 on average and a liver transplant costs $140,000 [26]. Yet,

certain particular characteristics of catastrophic illnesses tend to distort the process of collective formulation of policy about allocation of resources for treatment. The immediacy and avoidability of death as a consequence of nontreatment, particularly when the lives of known individuals are at stake, put these decisions on a different level than many other medical ones. [19, p. 183]

Thus, when individuals and means of treatment are identifiable, policymakers are more likely to allocate resources for treatment. Birnbaum [4] suggested that given complex technologies which cost money and "save" lives, we use them. Yet, to determine if resources are being used efficiently and equitably, program evaluations should be conducted which include examinations of the short- and long-term consequences (e.g., medical, economic, ethical, legal) of resource allocation [1, 18].

The problem of severely constrained resources, and the realization that "not all persons with catastrophic or complicated medical conditions will be able to benefit from medical technology" [13] have lead to a reluctance to provide public support for other catastrophic illnesses. It seems evident that society may not be able to afford the best available medical technology to meet the health care needs of its population. However, the amount of resources available for catastrophic illnesses, and for health care in general, will depend upon the willingness of society to invest in health care as opposed to other needed and valued activities.

REFERENCES


