A RAND NOTE

THE FEDERAL GOVERNMENT AND SOCIAL PLANNING FOR END-STAGE RENAL DISEASE: PAST, PRESENT, AND FUTURE

Richard A. Rettig, Ellen Marks

February 1983

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Prepared for

The National Center for Health Services Research
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The history of federal policy toward end-stage renal disease is considered in the years from 1960, when hemodialysis and kidney transplantation emerged as treatments for permanent kidney failure, through the Social Security Amendments of 1972 and the "kidney amendment" (Section 2991), to the imminent issuance of a final rule implementing changes in reimbursement policy required by legislation enacted in 1978 and 1981. This history is interpreted in light of the "tragic choice" dilemma of saving lives vs. conserving resources.

This Note represents part of a continuing research effort at Rand. An earlier Report, *Implementing the End-Stage Renal Disease Program of Medicare*, R-2505-HCFA/HEW, by Richard A. Rettig with the assistance of Ellen A. Marks, dealt with the period from the enactment of Public Law 95-292, which amended the amendment to provide greater incentives for hemodialysis and kidney transplantation. A Report, currently in progress, by Jerome Aroesty and Richard A. Rettig, considers the implications for kidney transplantation of a major advance in immunosuppression and thus the treatment of rejection of the transplanted kidney.
SUMMARY

Hemodialysis and kidney transplantation emerged more than twenty years ago as treatments for permanent kidney failure. During that time, the treatment of end-stage renal disease has posed a recurring dilemma for federal government policy makers: Should the government finance life-saving medical therapy at a very high resource cost? Or should it conserve scarce resources, and thus deny the fundamental societal value that life is beyond price? Although the Social Security Amendments of 1972 resolved the financing question in a definitive way, recent controversy over reimbursement regulations reveals that the basic dilemma remains, though the form of the policy issue has changed.

Conceptually, this policy dilemma—saving lives vs. conserving resources—can best be understood in light of the argument put forward by Guido Calabresi and Philip Bobbitt in their important and provocative essay, Tragic Choices. Societies define themselves, argue Calabresi and Bobbitt, by choosing the values they wish to preserve and those they are willing to forego. Tragic choices are societal choices among conflicting fundamental values or between fundamental values and scarcity. Because they involve fundamental social values, tragic choices are those "which the society finds intolerable."

The tragic choices that concern us here are those when the affirmation of fundamental societal values is jeopardized because of scarcity. Resource limits either prevent the affirmation of fundamental values or force the denial of such values. Scarcity in this type of choice may exist in an absolute (or physical) sense on the supply side, as is the case with interferon for cancer treatment or usable kidneys for organ transplantation. More frequently, it exists on the demand side in a relative sense: either the good in question is priced so high that it is beyond the financial means of all but very wealthy individuals, or society "is not prepared to forego other goods and benefits in a number sufficient to remove the scarcity." Tragic choices arise because scarcity cannot always be avoided in the provision of certain fundamental values; it must be confronted. In such situations,
a society is obliged "to make allocations in ways that preserve the moral foundations of social collaboration."

Four features characterize the tragic choice process:

- Societies must decide "which method of allotment to use"--the market, the political process, a lottery, or customary procedures, or some combination of these.
- Societies confront two types of decision: "How much of it [the valued good] will be produced;" and "who shall get what is made." Calabresi and Bobbitt designate these as first-order and second-order determinations, respectively.
- The tragic choice process is dynamic: "the detail of the pattern of tragic choices is movement;" "tragic choices show two kinds of moving progressions--the interplay between first-order and second-order determinations," and "the motion that is composed of the succession of decision, rationalization, and violence as quiet replaces anxiety and is replaced by it when society evades, confronts, and remakes the tragic choice."
- The success of the allocation method used in ameliorating the tragic situation depends upon how well it accommodates crucial values: equality and honesty are especially important; efficiency should be taken into account but will be found to be less helpful. The relationships among the methods of allocation, the types of decision, the underlying dynamics, and the crucial cultural values constitute the whole of the tragic choice process.

The nature of the tragic choice process is elaborated both for historical and contemporary federal government policy toward end-stage renal disease in the Note. Here, we note several points about the dynamic nature of the process. First, since tragic choices involve fundamental values, they are intolerable choices for societies to make. Consequently, there are strong incentives for society to avoid or evade such choices. The techniques of evasion are not dissimilar from those used to rationalize an allocation decision that only partially reconciles the values in conflict. Second, there are strong reasons,
stemming from societal inability to definitively resolve the conflict between fundamental values and scarcity, for societies to deny that a tragic choice is being made. Harsh results are made to seem necessary, inevitable, "a fatal misfortune," rather than the product of conscious choice. But these representations persuade only where the scarcity is a natural one; there is little escape from relative scarcity that is socially determined.

Third, when tragic choices are confronted, decisions are made that resolve the appearance of moral conflict, even though the tension among the values in conflict is unresolvable. In time, however, it will be revealed that such choices have merely postponed conflict, or displaced it to neighboring issues. As realization of this fact grows, action will again be called for. We quote Calabresi and Bobbitt:

In such conflicts, at such junctures, societies confront the tragic choice. They must all attempt to make allocations in ways that preserve the moral foundations of social collaboration. If this is successfully done, the tragic choice is transformed into an allocation which does not appear to implicate moral contradictions. Morally debasing outcomes are averted. But unless the values held in tension have changed, the illusion that denies their conflict gives way, and the transformation will have been a postponement. When emotions are again focused on the tragic choice, action will again be required.

Fourth, one of the two moving progressions alleged by Calabresi and Bobbitt consists of "the interplay between two different levels of allocation"--the decision about how much is to be produced and to whom it is to be distributed. First-order determinations, it will be remembered, "define the global setting," while the second-order determinations "allocate the available resources as defined by the first-order." All first-order decisions, the authors note, "contradict the postulate that a particular good is priceless," and all second-order determinations, unless supported by some dominant concept of distribution, "mar some distributional ideals of society." For tragic decisions, first- and second-order judgments are made separately; for nontragic goods, a single method allocates both of them. Where the first-order determination is that everyone or no one receives the good
in question, second-order determinations are relatively easy; where first-order determinations are intermediate, second-order decisions are much harder.

Fifth, it is the rationalization process in which the values-in-conflict problem is most clearly revealed. Consider the following quotes:

Thus the detail of the pattern of tragic choices is movement. In them society confronts the grave and constant in human suffering. Action in the context of necessary scarcity brings ultimate values, the values by which society defines itself, into conflict. We ask, 'What course without evils?' but we know that no true answer will give us comfort. As one critic has put it, 'Basic to the tragic form is its recognition of the inevitability of paradox, of unresolved tensions and ambiguities, of opposites in precarious balance. Like the arch, tragedy never rests.'

Scarcity in general remains a fact of life, but in the particular tragic choice situation, scarcity and suffering are not merely imposed: The society incurs them by its own decision or, at the least, society finally wills to accept them...It is then that we observe most dramatically the second movement we described, the progression from decision to rationalization to violence which in succeeding cycles characterizes the development of the tragic choice, the flight which evidences the attempt to transform a tragic dilemma into a situation in which the conflict of values is not exposed and which the society will not find tragic.

Evasion, disguise, temporizing, deception are all ways by which artfully chosen allocation methods can avoid the appearance of failing to reconcile values in conflict. Indeed, how could this not be so if society must confront suffering without being willing to discard its values every time it cannot uphold them? Averting the eyes enables us to save some lives even when we will not save all...

Given this framework, the analysis follows.

Before the 1972 legislation entitled victims of kidney failure to Medicare coverage for dialysis and transplantation, two periods in the evolution of federal government policy can be identified--from 1960 through 1965 and from 1965 through 1972. About the first of these periods, we draw the following conclusions:
1. New medical procedures like dialysis move along a continuum from an experimental status to that of an established therapy. In the experimental stage, efficacy constitutes the dominant value. When a procedure becomes an established therapy, however, that is, when efficacy becomes a settled issue, equity rises to the position of dominant value.

2. For dialysis, the movement along the experiment-therapy continuum varied over time, and among clinicians at any given time, and was perceived differently by different physicians. The emergence of dialysis generated great controversy because of deeply held, but widely disparate views, about whether the treatment was efficacious or not and, if so, whether it should or should not be made widely available.

3. Patient selection during this time was decentralized to the prominent centers of clinical research. Decentralized decisionmaking meant variation in both the criteria of patient selection and the mechanisms of choice. Resource scarcity, however, restricted access to life-saving treatment--explicitly in Seattle and implicitly elsewhere.

4. Various reactions to restricting access occurred during this initial period: the allocation of life-saving treatment on grounds of "social worth" offended deeply; the price of being explicit about such allocations appeared extremely high; the criteria of "medical suitability," consequently, were stretched to include clinical (renal failure, nonrenal complications), psychological (ability to understand and cooperate), psycho-social (stability of family unit), and social and economic considerations. Decision processes relying upon physicians to allocate life-saving treatment appeared preferable to those that formally included lay individuals.

5. Decentralized decisionmaking at the local (micro) level was driven by the absence of a first-order determination (how much of the valued good is to be produced) at the societal (macro) level. Second-order determinations (who receives the valued good) at the decentralized (micro) level were dramatized as a consequence.

6. The federal government's (macro) policy response to the first-order question was in turn, evasive, "logical," and inadequate. Congress, the White House, the Bureau of the Budget, and the bureaucracy
6. Since efficacy was no longer an issue, equity dominated considerations about patient selection. But scarcity precluded a fully satisfactory response on equity grounds. Physicians, having learned from the Seattle experience, however, avoided the "costs" of being highly visible in decisionmaking about who received treatment. Although selection criteria varied from center to center, processes of choice were regulated by physicians.

7. No penetrating literature emerged on the ethical implications of micro level decisionmaking about patient selection that was driven by resource-constrained macro level policies.

On July 1, 1973, Medicare coverage for kidney failure became effective for those under 65 years of age. The decade which has lapsed leads us the the following conclusions:

1. Practically all issues--whether clinical, institutional, or financial--have become matters of policy about the organization and operation of a government-made market. The 1973 screen worked as well as it did because policy officials in BHI recognized the simple fact that a universal Medicare entitlement eliminated the non-Medicare marketplace as a basis for reimbursement policy. The general point, however, deserves reiteration: the incentives and constraints governing the behavior of patients, physicians, and institutions are established within the framework of federal government policy. There is no escape from this institutional reality.

2. A constant demand for strong policy notwithstanding, the administration of the ESRD program has been adequate but hardly distinguished. Some observers regard the program as an administrative disaster, but it is far from clear that the program is less well-managed than any other federal government programs. The main point, however, is that second-best administration, whether disastrously weak or barely adequate, may be the best that one can expect--for structural reasons that go well beyond the ESRD program.

3. One of the more chronic and perennially disturbing features of the ESRD program's administration is its limited capacity to generate simple, good quality, timely data in a regular way. This deficiency has bedeviled the program from the outset and is likely to continue for a
long time to come. Again, structural features of the contemporary federal government combine with the complexities of the ESRD "system" to given the data problem its refractory character.

4. Regarding end-stage renal disease, a form of political stasis, if not advanced paralysis, appears to have developed. The legislative branch understandably retreats from directly confronting the central issue of whether a universal benefit has led to too much treatment. Unfortunately, the executive branch cannot act without clear political guidance from the Congress. The contending factions—the proponents of home dialysis, free-standing, largely proprietary dialysis, and hospital-based treatment—cannot secure their own objectives but are able to checkmate the actions of others. Patients, politically speaking, are not well represented. The result of this situation is that no political capacity exists to formulate policy.

5. It is reasonable to expect that whatever policy is adopted in 1983 will govern the program for the decade of the 1980s. Some may flinch at this assertion, preferring to believe that continued adaptation to new developments is better than submission to a long-standing regulatory regime with a tendency to ossify. But reflect for a moment that the interim regulations of June 29, 1973, still govern the ESRD program, modified by statutory changes for home dialysis and by administrative laxity and drift for the reimbursement of hospital-based treatment. Notwithstanding the expectation of BHI at the time that these interim regulations would be modified as experience was gained and data accumulated, reality turned out differently. No reason exists to think that the regulations of 1983, when finally established, will be changed any faster.

6. Finally, the present period reveals strenuous efforts to avoid the new manifestation of the "tragic choice" as it re-emerges in a period of relative abundance. Having made the first-order determination that all in medical need should have access to treatment, we now experience disquietude at the fact that though many lives are being extended in highly productive ways, scarce resources are also supporting a goodly number of patients who are at the margin of clinical acceptability and prognosis. These lives are being sustained at great cost, but dependency is often extended beyond the benefits of Medicare
to income support by the disability system. Are we technically or administratively required to treat these marginal patients because no defensible way exists to differentiate between them and the clinically better patients? Are we morally obligated to support such patients in order to affirm our societal commitment to preserving life? And are we morally obligated to spend for these renal patients without regard for other equally legitimate claimants on the public purse? The questions, of course, remain unanswerable, which leads us to our final section.

What lessons can we draw from the two-decade experience sketched in the preceding pages that might help us move with greater understanding into the future? The following stands out.

First, the conflict between scarcity and saving lives, whatever its complex manifestation, highlights the inadequacy of the languages of medicine, economics, and politics to address such issues. Medicine speaks of efficacy of a procedure and effectiveness of that procedure when applied to various purposes or patient populations. Clearly, effectiveness correlates directly with the strictness with which the criteria of medical suitability are defined and applied. But the strictness or liberalism of such criteria depend in large measure upon the scarcity or availability of resources, which is socially determined. Even though physicians may go beyond the observation of immediate treatment outcomes to the consideration of patient rehabilitation, they may proceed further only on the basis of sentiment or ideology or moral reasoning but not on the basis of clinical medicine.

The language of economics is equally impoverished. The major preoccupation of policymakers in the Medicare ESRD years has been cost control. Cost control, it is argued, has been hampered by the absence of good data and cost studies. This is partly true, but not entirely so. In fact, we know how to control costs: simply shift an increasing proportion of patients from higher cost to lower cost treatment settings. This probably involves a double movement from hospital-based to free-standing units, and from institutions to the home setting. What we do not know how to do, however, is to control costs without sacrificing other values: patient autonomy, freedom of physicians to prescribe the treatment setting, and the refusal to ration access. All cost control policies, therefore, require moral justification that
commands political consensus and supports authoritative public policy. Economics cannot provide such justification.

The language of politics is also bankrupt, but for more complex reasons. At one level, the most superficial, politics speaks to the relative advantage of one or another party of interest, but this constitutes no defensible moral basis for policy. At a deeper level, there is little understanding among contemporary politicians and policy makers that the central preoccupation of the political system is how society arranges and conducts its collective business. Few issues so illuminate the nature of the political system, as conceived in these terms, as do those surrounding end-stage renal disease. But the language of politics fails in the final analysis because tragic choices bring fundamental values into conflict in ways that suppress rather than encourage moral discourse. *Tragic choices are not amenable to political discourse.*

The second lesson we draw is that no "right" solutions exist. The tragic choice is ever-present. Scarcity issues, resolved at one point, predictably become politically salient at a later time. All policy trade-offs require the compromise of ultimate values. All institutional arrangements are second-best, there being no truly best arrangement. The quest in public policy, therefore, must be for socially acceptable value trade-offs and institutional arrangements, undergirded by a broad political consensus that acknowledges the painful choices required by the society. If a given arrangement lasts five years, that is all to the good; if ten, so much the better.

Third, we can expect political consensus to break down under the weight of various forces. One of the most powerful of these is the perception that we have reached the limits of our resources. That conclusion may not force changes in the ESRD program. But it may powerfully influence the next candidate program, like heart transplantation or the artificial heart or bone-marrow transplantation or other life-saving but expensive medical procedures. When the perception of having reached resource limits undermines the fragile consensus supporting existing policy, the search begins anew for a socially acceptable response.
Finally, we reflect on the nature of modern medicine and hope for scientific advance that obviates the need for cumbersome medical technology. The Salk and Sabin vaccines eliminated poliomyelitis and its iron lung treatment technology. The search for how to manage the immune response to transplanted kidneys and for knowledge of the etiology of kidney disease that permits preventive intervention must continue. In the meantime, we must struggle to do the best we can with our collective responsibility.
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I. INTRODUCTION

In 1980, Medicare spent $1.2 billion for beneficiaries with permanent kidney failure. There were 61,443 such beneficiaries at the end of calendar 1980 (HCFA, 1981). These individuals, entitled to benefits because they qualified on medical, disability, or age bases, were treated either by dialysis or kidney transplantation.

Not surprisingly, the End-State Renal Disease (ESRD) program of Medicare claimed the attention of policy officials in the Executive Branch and Representatives and Senators in Congress in 1981. Moreover, the unfinished policy business as 1981 drew to a close guaranteed that these officials would continue to be preoccupied with the ESRD program well into 1982.

A HIGHLY SELECTIVE HISTORICAL TOUR

In actuality, the policy issues related to the treatment of end-stage renal disease have proved vexatious to the federal government for an extremely long time. The year 1981 was not exceptional in that regard. Consider the following items:

- Item. 1962: In late October, the Deputy Surgeon General warned the Secretary of Health, Education, and Welfare that Life magazine would soon publish an illustrated story on the work of Dr. Belding H. Scribner, in Seattle, who was prolonging the lives of victims of chronic kidney failure by hemodialysis (Price, 1962). The story, which appeared on November 9, vividly described the process by which access to expensive, lifesaving treatment was rationed by a two-stage review process in which prospective patients were first evaluated for medical suitability by physicians and then for their potential "service to society" by an anonymous lay committee (Alexander, 1962). Although the federal government anticipated "strong pressures for some Federal action," no such public demand resulted and the government made no response to the immediate situation.
Item. 1963: In August, a Wall Street Journal story focused on the "tormenting question facing health officials, doctors, and legislators: 'How much is a human life worth?'" (Lawson, 1963). The excitement generated by Dr. Scribner's success was "now giving way to anxious soul-searching over costs." The outlook for a national program to treat patients was bleak and, consequently, "the shortage of machines is forcing doctors to make difficult life-and-death decisions." As a result of this story, White House staff asked HEW for background on the availability or scarcity of lifesaving artificial kidney machines. HEW responded that no funds were earmarked for renal disease, but did enumerate the possible sources of support (Jones, 1963). No further action occurred.

Item. 1966-1967: Early in 1966, the Bureau of the Budget convened a committee of experts under the chairmanship of Carl Gottschalk to advise it on the "problems posed by chronic kidney disease." The committee in 1967 recommended "a national treatment program aimed at providing chronic dialysis and/or transplantation for all of the American population for whom it is medically indicated" (U.S. Bureau of the Budget, 1967). The Bureau, however, never formally acknowledged receipt of the report and arranged for its release in a manner that drew the least amount of public attention to its far-reaching recommendation (Rettig, 1981).

Item. 1965-1972: During this period, over one hundred bills were submitted in Congress to provide for the treatment of end-stage renal disease. Although many of these bills were sponsored by very powerful Senators and Representatives, no hearings were held on any of them and, before late 1972, only one piece of legislation resulted: the Heart Disease, Cancer, and Stroke Amendments of 1965 were amended, in 1970, to add "kidney disease" wherever appropriate. Not until the inclusion of Section 2991 in the Social Security Amendments of 1972, when Congress extended Medicare health insurance coverage to end-stage renal disease, was this legislative log-jam broken (Rettig, 1976).
- 3 -

- Item. 1973: In January, a controversy erupted in the pages of the New York Times about the wisdom of the Congress in extending Medicare coverage to virtually everyone in the preceding October (Lyons, 1973; New York Times, 1973; Altman, 1973). It was rightly charged that the estimates used by Congress had seriously underestimated the expected costs of the new End-Stage Renal Disease program, but the reporter badly mangled the revised estimates that had been leaked to him by the Department of Health, Education, and Welfare. The estimated fourth-year cost used in the Senate debate was approximately $250 million, but the HEW estimates projected fourth-year costs twice that amount, rising to over $1 billion annually within a decade. Congress, it was charged, had been ignorant of the implications of its action at the time it passed this sweeping innovation in health financing policy. Confirming this interpretation, Representative Paul G. Rogers (D., Florida) said: "We in Congress had no idea that costs would be anywhere near that large."

- Item. 1975-1978: Congress, alarmed by the rapidly rising costs of the ESRD program and by the sharp decline in the proportion of dialysis patients treated at home, initiated oversight hearings in 1975 (U.S. House of Representatives, 1975) and then legislative hearings in 1977 that resulted in the passage of Public Law 95-292 on June 13, 1978 (U.S. House of Representatives, 1977). The primary purpose of this act was to remove existing disincentives and provide positive incentives to home dialysis and kidney transplantation. A careful reading of the legislative history, however, reveals a steady weakening of the "encouragement" to home dialysis and transplantation in the successive versions of legislation considered in 1977 and 1978. A key provision of the statute (section 1881.(b)(2)(B)) directed by the Secretary of HEW to prescribe regulations for reimbursement of providers (hospitals) and facilities (free-standing dialysis centers) treating patients for more efficient delivery of services, prospectively set rates, and cost-sharing.
arrangements. There exists virtually no legislative history to clarify the intent of Congress regarding this section.

- Item. 1979-1982: Implementation of Sec. 1881.(b)(2)(B) remains unfinished at the end of 1981. Unpublished draft regulations in 1979 proposed a single rate to cover providers and facilities. A Notice of Proposed Rule Making (NPRM) in September 1980, reversing the previous year's draft, proposed separate rates for hospitals and free-standing facilities (Federal Register, 1980). The new Reagan Administration, in March 1981, announced its intention to publish an NPRM restoring the single rate concept. The House Ways and Means Committee accepted the single rate but extended it, by use of "composite rate" language, to home dialysis patients (1981). The Senate Finance Committee indicated preference for the dual rate proposal of the previous September.\(^1\) The conference committee retained the Senate's dual rate recommendation, but insisted that each rate apply on a "composite rate" basis to both institutional and home dialysis (1981). In late November, the Secretary of Health and Human Services announced the dual rate structure that would be embodied in forthcoming proposed regulations; the NPRM itself was not published in the Federal Register until February 12, 1982 (HHS News, 1981).

1981

Before the 1972 enactment of Public Law 92-603, the policy debate had addressed two questions: How can we as a nation afford the high cost of financing treatment for end-stage renal disease? How can we as a nation deny life-saving treatment to all who need it solely because of money (Rettig, 1976)? After the 1972 legislation, attention shifted to how near-universal treatment could be provided with the least expenditure of public funds, consistent with good quality medical care (Rettig, 1980). The point and counter-point of the policy debate, whether in the early period of scarcity or in the current period of virtually universal access, has remained the need to affirm the fundamental social value of saving lives while balancing that against other claims to the same scarce resources.

\(^1\) No legislative history exists for the Senate deliberations.
In 1981, however, for three reasons, the anxieties of the renal medical community about the ESRD program reached new heights. For one thing, the new Reagan Administration aggressively attacked the federal budget in order to slow its rate of growth and reduce the burden of government on the American citizen and taxpayer (U.S. House of Representatives, 1981). It succeeded beyond anyone's wildest expectations for the 1982 fiscal year, and the prospects for fiscal years 1983 and 1984 augured for sustained pressures to the same end. Would the ESRD program, many asked, become a target for this budget-cutting?

Technically no, since the ESRD program is an entitlement program, or part of the Medicare entitlement program, and thus immune from the budget-cutting applied to government programs financed through the annual budget-and-appropriations process. But the second source of anxiety was the Reagan Administration's openly avowed intention to shrink entitlement programs as part of its overall strategy for reducing federal government expenditures (U.S. House of Representatives, 1981).

Entitlement programs, of which Social Security, Medicare, disability, Aid to Families with Dependent Children, and food stamps are examples, have long been designated "uncontrollable" for budgetary purposes. Two reasons justify this designation. First, entitlement programs are open-ended: authorizing statutes stipulate benefits for individuals meeting certain eligibility criteria; if an individual meets these criteria, he or she is entitled to receive the benefits in question; the government lacks discretion and it must pay benefits to all those judged eligible. Second, since entitlements are not financed through the annual appropriations process, that avenue of control is closed to policy officials. Control, to be exercised, requires the hard political work by Congress of rewriting the basic statutory formulas.

Open-ended entitlements, according to Pechman, "have grown from about 27 percent of the budget in fiscal 1967 to an estimated 48 percent in fiscal 1982, or from 5.5 percent of the gross national product to 11.0 percent" (Pechman et al., 1981). Medicare grew from $3,172 million in benefit payments in fiscal 1967, its first full year, to $33,166 million in fiscal 1980, a ten-fold increase (Federal Hospital Insurance
Trust Fund, 1980). Medicare expenditures for end-stage renal disease beneficiaries increased from $229 million in calendar 1974, the first year of the ESRD program, to $1,208 million in 1980 (HCFA, 1981). The powerful growth in entitlements makes clear the rationale of the new administration's efforts to control the uncontrollables. The ESRD program, like a lighthouse, stands visible, if not vulnerable, in this setting.

The third source of anxiety about the future of the ESRD program stems from the slowly grinding wheels of the rule-making process as it moves to promulgate regulations for the reimbursement of provider- and facility-based outpatient dialysis. Policy officials are under great pressure to issue regulations that result in cost savings to the ESRD program. This process bids fair to occupy a number of months in 1983 before a final rule is published; it receives further comment below. Suffice it to say now that high financial stakes ride on the outcome of this regulatory process, thus intensifying the political tug-of-war among and between the parties-at-interest and the federal government.

How are we to understand the history of federal government policy toward end-stage renal disease? How are we to appraise the current situation? What do the above instances, cited from two decades of history, reveal about the nature, criteria, processes, and institutions of policy choice in this case? What basic values inhere in pertinent public policies, and what relationships exist among these values? What significance attaches to the outcome of the policy process and to how policies are actually developed? Finally, what does the end-stage renal disease experience suggest for other expensive, life-saving medical procedures?

This paper attempts to answer some of these questions. In the next section, we elaborate the nature of "tragic choices," as developed by Calabresi and Bobbitt, for conceptual assistance in addressing these questions. The following section interprets the period from the early 1960s to the enactment of the kidney failure provision of Medicare. Section IV examines the meaning of the ESRD program, including the current policy debate. Lessons about the renal program, and its pertinence to other medical procedures, are discussed in the final section.
II. TRAGIC CHOICES

Guido Calabresi and Philip Bobbitt, in *Tragic Choices*, have written an important and provocative essay that pertains directly to the issues confronting the federal government in its policy toward end-stage renal disease (Calabresi and Bobbitt, 1978). Indeed, they rely extensively upon the allocation of artificial kidneys to illustrate their argument, along with the cases of conscription and population control. The essay deserves to be widely read and reflected upon, but its complexity and somewhat convoluted style of writing limit its accessibility to a wide audience. We summarize it briefly here because of its value in interpreting the end-stage renal disease experience.

Societies define themselves, argue Calabresi and Bobbitt, by choosing the values they wish to preserve -- "at tremendous cost" -- and those they are willing to forego. Tragic choices are societal choices among conflicting fundamental values or between fundamental values and scarcity. Because they involve fundamental social values, tragic choices are those "which the society finds intolerable."

Tragic choices among competing values are not always driven by scarcity. Going to war to preserve a free society that is secure from foreign domination, but thereby consciously sacrificing the lives of young men, represents such a tragic choice. Liberty vs. lives constitutes a tragic choice, but scarcity is not the primary defining characteristic.

Tragic choices also occur when the affirmation of fundamental societal values is jeopardized because of scarcity. Resource limits either prevent the affirmation of fundamental values or force the denial of such values. Scarcity in this type of choice may exist in an absolute (or physical) sense on the supply-side, as is the case with interferon for cancer treatment or usable kidneys for organ transplantation. More frequently, it exists on the demand-side in a relative sense: either the good in question is priced so high that it is beyond the financial means of all but very wealthy individuals; or society "is not prepared to forgo other goods and benefits in a number sufficient to remove the scarcity" (Calabresi and Bobbitt, 1978).
Many societal choices are limited by scarcity but involve no fundamental values; for example, repairing potholes in city streets after a hard winter. Other choices involve preserving fundamental values that are not especially limited by scarcity; protecting freedom of speech is such a choice. Tragic choices arise because scarcity cannot always be avoided in the provision of certain fundamental values; it must be confronted. In such situations, a society is obliged "to make allocations in ways that preserve the moral foundations of social collaboration" (Calabresi and Bobbitt, 1978).

Four features characterize the tragic choice process (Calabresi and Bobbitt, 1978):

- Societies must decide about "which method of allotment to use" -- the market, the political process, a lottery, or customary procedures, or some combination of these.
- Societies confront two types of decision: "How much of it [the valued good] will be produced;" and "who shall get what is made." Calabresi and Bobbitt designate these as first-order and second-order determinations, respectively.
- The tragic choice process is dynamic: "the detail of the pattern of tragic choices is movement;" "tragic choices show two kinds of moving progressions" -- the interplay between first-order and second-order determinations, and "the motion that is composed of the succession of decision, rationalization, and violence as quiet replaces anxiety and is replaced by it when society evades, confronts, and remakes the tragic choice."
- The success of the allocation method used in ameliorating the tragic situation depends upon how well it accommodates crucial values: equality and honesty are especially important; efficiency should be taken into account but will be found to be less helpful.
The relationships among the methods of allocation, the types of decision, the underlying dynamics, and the crucial cultural values constitute the whole of the tragic choice process. We will elaborate this process more extensively in relation to both historical and contemporary federal policy toward end-stage renal disease in the sections that follow. Here we briefly amplify several of the above points.

In particular, the dynamic nature of the tragic choice process requires further comment along the following lines. First, since tragic choices involve fundamental values, they are intolerable choices for societies to make. Consequently, there are strong incentives for society to avoid or evade such choices. The techniques of evasion are not dissimilar from those used to rationalize an allocation decision that only partially reconciles the values in conflict. Second, there are strong reasons, stemming from societal inability to definitively resolve the conflict between fundamental values and scarcity, for societies to deny that a tragic choice is being made. Harsh results are made to seem necessary, inevitable, "a fatal misfortune," rather than the product of conscious choice. But these representations persuade only where the scarcity is a natural one; there is little escape from relative scarcity that is socially determined.

Third, when tragic choices are confronted, decisions are made that resolve the appearance of moral conflict, even though the tension among the values in conflict is unresolvable. In time, however, it will be revealed that such choices have merely postponed conflict, or displaced it to neighboring issues. As realization of this fact grows, action will again be called for. We quote Calabresi and Bobbitt (Calabresi and Bobbitt, 1978):

In such conflicts, at such junctures, societies confront the tragic choice. They must all attempt to make allocations in ways that preserve the moral foundations of social collaboration. If this is successfully done, the tragic choice is transformed into an allocation which does not appear to implicate moral contradictions. Morally debasing outcomes are averted. But unless the values held in tension have changed, the illusion that denies their conflict gives way, and the transformation will have been a postponement. When
emotions are again focused on the tragic choice, action will again be required.

Fourth, one of the two moving progressions alleged by Calabresi and Bobbitt consists of "the interplay between two different levels of allocation" -- the decision about how much is to be produced and to whom it is to be distributed (Calabresi and Bobbitt, 1978). First-order determinations, it will be remembered, "define the global setting," while the second-order determinations "allocate the available resources as defined by the first-order." All first-order decisions, the authors note, "contradict the postulate that a particular good is priceless," and all second-order determinations, unless supported by some dominant concept of distribution, "mar some distributional ideals of society." For tragic decisions, first- and second-order judgments are made separately; for nontragic goods, a single method allocates both of them. Where the first-order determination is that everyone or no one receives the good in question, second-order determinations are relatively easy; where first-order determinations are intermediate, second-order decisions are harder.

Fifth, it is the rationalization process in which the values-in-conflict problem is most clearly revealed. Consider the following quotes (Calabresi and Bobbitt, 1978):

Thus the detail of the pattern of tragic choices is movement. In them society confronts the grave and constant in human suffering. Action in the context of necessary scarcity brings ultimate values, the values by which a society defines itself, into conflict. We ask, "What course without evils?" but we know that no true answer will give us comfort. As one critic has put it, "Basic to the tragic form is its recognition of the inevitability of paradox, of unresolved tensions and ambiguities, of opposites in precarious balance. Like the arch, tragedy never rests.

Scarcity in general remains a fact of life, but in the particular tragic choice situation, scarcity and suffering are not merely imposed: The society incurs them by its own decision or, at the least, society finally wills to accept them...It is then that we observe most dramatically the second movement we described, the progression from decision to rationalization to violence which in succeeding cycles characterizes the development of the tragic choice, the flight
which evidences the attempt to transform a tragic dilemma into a situation in which the conflict of values is not exposed and which the society will not find tragic.

Evasion, disguise, temporizing, deception are all ways by which artfully chosen allocation methods can avoid the appearance of failing to reconcile values in conflict. Indeed, how could this not be so if society must confront suffering without being willing to discard its values every time it cannot uphold them? Averting the eyes enables us to save some lives even when we will not save all...

Enough for now of Calabresi and Bobbitt. Let us proceed to illustrate the applicability of their analysis in the context of federal policy toward end-stage renal disease.
III. THE FORMATIVE YEARS OF FEDERAL POLICY TOWARD END-STAGE RENAL DISEASE

INTRODUCTION

Two general periods divide the time from 1960, when hemodialysis first emerged as a treatment for patients with chronic kidney failure, to 1972, when Medicare coverage was extended to include kidney failure (Rettig, 1976, 1978, 1979). The first period dates from 1960 to the years 1965 through 1967, during which hemodialysis moved from the status of an experimental procedure to that of an established treatment. The second period runs from the 1965-to-1967 years to the end of 1972, and the enactment of Section 299I, during which hemodialysis treatment capacity gradually increased and the number of patients being treated rose from approximately 1000 in 1968 to approximately 10,000 in 1972.

Kidney transplantation moved along the same experiment-therapy continuum during these years, having begun in Boston in 1951 with identical twins, then fraternal twins, and, in the 1960s, aided by the discovery of immunosuppressive drugs to prevent rejection of the transplanted organ, to transplantation using kidneys from an unrelated cadaver (Moore, 1972).

Analytically, Fox and Swazey have discussed the experiment-therapy continuum in medicine in detail (Fox and Swazey, 1978). They observe that the status of any new medical procedure along this continuum is always a matter of dispute. Controversy arises from two sources: first, semantically, there exists no objective metric by which the status of a new procedure is defined; and second, the perception of where a procedure lies along the continuum varies as a function of the role of the observer. Research-oriented physicians, for instance, tend to regard procedures as experimental longer than do treatment-oriented clinicians.

In this section, we examine developments in each of these two periods in light of the earlier discussion of tragic choices.
FROM EXPERIMENTAL PROCEDURE TO ESTABLISHED THERAPY

In 1960, at the University of Washington in Seattle, Dr. Belding H. Scribner developed a little device (a cannulae-and-shunt apparatus) that enabled victims of chronic kidney failure to be attached to an artificial kidney on a continuous, intermittent basis (Scribner et al., 1960). Repeated treatment cleansed the blood of toxic wastes and saved the lives of patients. Four patients were treated in 1960, and four the next year (Hegstrom et al., 1962). Scribner, convinced of the need to make treatment accessible to more patients, sought to expand the unit at the University of Washington. Stymied because funds were not available from the institution or from the National Institutes of Health, which was supporting Scribner's research, a community-based center—the Seattle Artificial Kidney Center (SAKC)—was established in Swedish Hospital and opened on January 1, 1962.

Patient selection at the University of Washington focused on criteria of medical suitability of patients for treatment and was administered by Scribner and his colleagues. In moving from the University to Swedish Hospital, however, the selection process was altered significantly in a way that earned Seattle substantial opprobrium. Persuaded that the treatment was efficacious, Scribner was nevertheless quite conscious of the limits that scarcity imposed on access to care.

Prospective candidates for treatment were screened by a Medical Advisory Committee of physicians. Criteria for evaluation of medical suitability included (Murray et al., 1962):

1. A stable emotionally mature adult under the age of 45 who is disabled by symptoms of uremia.
2. Absence of long-standing hypertension and permanent complications therefrom, particularly coronary artery disease and cerebrovascular or peripheral vascular disease.
3. Demonstrated willingness to cooperate in carrying out the prescribed medical treatment, especially the dietary restrictions.
4. Renal function should be stable or deteriorating slowly since any residual function simplifies the therapeutic program.

5. Children and young adults who are not potentially self-supporting have been excluded, so far.

Medically suitable candidates were then evaluated by a lay Admissions and Policy Committee responsible for allocating the few spaces in the treatment center to the greater number of prospective patients (Murray et al, 1962). Anonymous to press and public, this committee used economic and sociological criteria in the determination of who was to be admitted for treatment. In its first thirteen months, the SAKC considered 30 candidates, of whom 17 were judged medically suitable; the 13 "unsuitable" ones, all of whom died, included many who would have been "reasonably good candidates medically" according to one physician. Of the medically suitable, 10 were selected for treatment; the other 7 died.

Formal criteria for decision-making were not actually used by the lay committee. But in making its decisions, it considered the following: the ability of a housewife from eastern Washington to move to Seattle; the relative importance of saving a parent with two children compared to one with six; the prospect for rehabilitation and return to work; the potential of "service to society" based on education; the candidate's "character and moral strength" based on church membership and the probable opportunity of the surviving spouse to remarry (Alexander, 1962).

The lay committee survived in form until 1967; but it considered no cases for the final months of its life. In fact, its work began to diminish in 1964 when Scribner, in response to a dying teenage girl, a treatment center at capacity, and the demonstration by Boston physicians that patients could be treated at home, placed his first patient in the home. From that time onward, the Seattle Artificial Kidney Center (later the Northwest Kidney Center) led the country in placing dialysis patients at home and promoting the cause of home dialysis nationwide.
The experience of other centers differed from Seattle. Most importantly, there was substantial difficulty experienced by several centers in keeping dialysis patients alive. Dr. Willem Kolff, in 1963, reported on the Cleveland Clinic's experience from 1960 through early 1963 (Kolff, 1963). The Department of Artificial Organs had seen 137 patients with chronic kidney failure; 21 had been placed on chronic hemodialysis treatment; 16 had died; five were being maintained with twice weekly dialysis. Kolff summarized his criteria:

No attempt was made to select candidates for this program on the basis of age, type of disease, or the presence or absence of complications. Psychiatric factors were no deterrent initially; many of our patients were more or less psychotic until a series of dialysis had been given. When patients were unwilling or unable to cooperate after chemical balance had been restored, the program was discontinued. Failure of cooperation was rare, and occurred only early in our experience when hemodialyses were done at irregular intervals. Renal insufficiency severe enough to preclude life without chronic dialysis was the sole criterion for admission to the program when space was available.

Reliance upon essentially a first-come, first-served selection criterion has guided the Cleveland Clinic during the initial experimental period.

Dr. George Schreiner, of Georgetown University, reported in 1965 on that center's initial experience (Maher et al., 1965). Eleven patients had been treated in the five years from 1960 through 1964: the first seven survived 4, 2, 2, 2, 3, 5, and 9 months, respectively; two others were transplanted after 2-1/2 and 4 months on dialysis (though two voluntarily withdrew) and two were alive, for 8 and 5 months each, at the time of writing (October 1964). The acknowledged purpose of the Georgetown program was to conduct research on the "chemical and physiologic considerations" of hemodialysis and developing practical techniques for its use. But, in a lightly veiled criticism of Scribner, Schreiner and his colleagues charged:

The enthusiasm for dialysis has even promoted the concept that in this setting it is adequate therapy rather than an experimental procedure. We consider dialysis for chronic kidney failure a procedure that is still in the
investigational stage and from which much biochemical information may yet be obtained. Patients were selected on the basis of medical criteria: irreversible severe renal failure -- and their willingness to undergo extensive clinical investigation.

In Boston, at the Peter Bent Brigham Hospital, Dr. John Merrill and his colleagues had yet another experience. Merrill and Dr. Eugene Schupak, in 1965, wrote that early reports from Kolff, Schreiner, and themselves had indicated difficulty in replicating Schribner's ability to keep alive on hemodialysis (Schupak and Merrill, 1965). Their experience in 1961, for instance, included placing 12 shunts in 9 patients: one shunt survived 112 days, but the mean time of shunt survival in the others was only 10 days; clotting was the primary cause of shunt failure. Five patients treated in 1963 and 1964, however, experienced much greater success with shunt survival and management of clotting. Of these five, only one had died, two had been transplanted after 13 and 5 months, respectively, on dialysis, and the other two were alive after 5 months treatment each. The Brigham researchers concluded that there was "no doubt, at present, that this technique is no longer simply a research tool. It now occupies a place in the therapeutic armamentarium of the sophisticated nephrologist in the approach to chronic renal failure." (Schupak and Merrill, 1965)

Addressing the patient selection problem, which was "inherent" in a situation where "far more candidates exist than can be properly cared for with existing facilities," the Brigham physicians listed three factors to consider: (1) likelihood of a return to a useful role in society; (2) absence of disabling disease other than of renal origin; and (3) ability to adapt and cooperate" (Schupak and Merrill, 1965). Though they embraced social criteria, they did so in the context of physician decision-making, quite unlike the Seattle pattern. They also drew quite a different policy conclusion from the same clinical facts than did Schribner. "Hemodialysis," they wrote, "ought to be merely some phase of a larger program designed for the treatment of renal failure by an experienced team utilizing hemodialysis as a means to an end and not as a therapeutic end in itself" (Schupak and Merrill, 1965). The end, of course, was treatment by kidney transplantation.
How did the federal government respond to these early developments? Let us state the situation they confronted. First, the government understood that a dramatic new medical procedure had emerged which, though quite expensive, saved lives. Then, it was aware that medical opinion divided sharply on whether the procedure was still experimental or deserved to be regarded as established treatment. Scribner believed hemodialysis to be efficacious, was keeping alive a growing number of patients, and was strongly advocating a national program to respond to his perceived need for a treatment program; Merrill regarded dialysis as established, but believed it should be to support transplantation; Kolff and Schreiner viewed the procedure as still investigational. Third, the government knew that time favored Scribner: many younger physicians were trekking to Seattle to learn how to dialyze patients, thus circumventing the problems of some of their more prominent senior colleagues. Finally, the government recognized the moral dilemma for the nation inherent in the situation. The dramatic selection mechanism in Seattle constituted a microcosm of the problem writ large: scarcity limited access to live-saving treatment.

Less clearly understood was the appropriate policy response. But the government did respond, initially in 1963. Much to everyone's surprise, the Veterans Administration announced plans for establishing thirty dialysis units in VA hospitals around the country (AMA and National Kidney Disease Foundation, 1963). Treatment, however, would be limited to eligible veteran beneficiaries. This program, as it unfolded, later prompted a high-level review of federal policy by the Bureau of the Budget in 1966.

A series of responses occurred within the Public Health Service during 1963, 1964, and 1965. First, in 1963, the PHS approved a grant to the Seattle Artificial Kidney Center from chronic disease funds, thus stepping in to fill a need that private philanthropy, community fund-raising, and fund-raising for specific patients could not meet. Then, in 1964, a Transplant Immunology program was established within the National Institute of Allergy and Infectious Diseases (U.S. Senate, 1966). In 1965, after substantial representations by Scribner and other advocates, and after extensive consultations, Congress created a second
NIH research program—the Artificial Kidney-Chronic Uremia program in the (then) National Institute of Arthritis and Metabolic Diseases. Simultaneously, it established a grant program to demonstrate the feasibility of delivering dialysis treatment and the PHS created the Kidney Disease Control Program to administer the effort (Freund, 1968). The interaction among the medical community, the Congress, and the executive branch resulted then in two NIH-based research programs, one directed to transplantation and the other to dialysis, and one demonstration grant program.

The other response of note, and that which demarcates the end of this initial period, was the convening by the Budget Bureau, in 1966, of a committee of experts to advise it on the national implications of dialysis and transplantation (Rettig, 1981). Triggered by a VA request for funds to construct dialysis units, the scope of the committee was expanded to include all federal efforts in response to advice from the Office of Science and Technology. The Committee on Chronic Kidney Disease (called the Gottschalk Committee, after its Chairman, Dr. Carl Gottschalk of the University of North Carolina) met on many occasions during 1966 and 1967. The committee concluded that dialysis and transplantation were no longer experimental procedures, thus "officially" bringing that debate to a close, and recommended in 1967 that a national treatment program (financed by Title XVIII -- Medicare) be established (U.S. Bureau of the Budget, 1967). The Budget Bureau, upon receipt of the report, sought to minimize its impact and its distribution and did nothing to implement its recommendations. "We just parked it, as I recall," said Charles Zwick, then assistant director of the budget (and director soon thereafter); "we had a little war going on in Southeast Asia."

How are we to interpret these events in light of our concern for tragic choices? Here are several conclusions on this initial period:

1. New medical procedures like dialysis move from experimental status to that of established therapy. Efficacy dominates equity as the primary value being sought in the experimental stage.
2. For the expensive, life-saving medical procedure dialysis, equity considerations arose immediately upon the establishment of efficacy, or as efficacy increased to a level of acceptability within the medical community. This movement along the experiment-therapy continuum, however, was uneven over time and among clinicians. So the transition from efficacy to equity as the dominant value was messy.

3. Patient selection during this time was decentralized to the prominent centers of clinical research in the given area of medicine. Decentralized decision-making varied in both the criteria of patient selection and the mechanisms of choice.

4. A variety of reactions occurred in this initial period: the allocation of life-saving treatment on grounds of "social worth" offended deeply; the price of being explicit about such allocations appeared extremely high; the criteria of "medical suitability" stretched to include clinical (renal failure, nonrenal complications), psychological (ability to understand and cooperate), psycho-social (stability of family unit), and social and economic considerations. Decision processes relying upon physicians to allocate life-saving treatment appeared preferable to those that formally included lay individuals.

5. Decentralized decision-making at the local (micro) level was driven by the absence of a first-order determination (how much of the valued good is to be produced) at the societal (macro) level.

6. The federal government's (macro) policy response to the first-order question was, in turn, evasive, "logical," and inadequate. Congress, the White House, the Bureau of the Budget, and the bureaucracy (HEW, PHS, NIH) all worked very hard to avoid confronting the first-order decision. The "logical" response by the Veterans Administration was to treat all eligible veteran beneficiaries; that by the PHS was to initiate research, development, and demonstration programs. In time, it was recognized that research, development, and demonstration programs were temporizing responses to the
central problem of financing patient care; they also produced inequities in access to treatment.

7. Scarcity imposed by a limited first-order (macro) determination provoked a search at the decentralized (micro) level for therapeutic alternatives, e.g., kidney transplantation and home dialysis.


EXTENDING THE POLICY COMMITMENT

From 1965 until late 1972, the federal government wrestled with the first-order determination of how much life-saving hemodialysis and kidney transplantation it should provide. It moved haltingly to establish, secure, and extend the policy commitment to provide such treatment to victims of chronic kidney failure. The direction of movement remained steady, but the pulling and hauling that characterized the development of federal policy and program revealed the tension between the moral obligation to save lives and the reality of scarce resources.

The primary plot line involved the Kidney Disease Control Program (KDCP) of the U.S. Public Health Service. A secondary theme concerned the Veterans Administration's treatment program. Consequential, but not primary, was the Artificial Kidney-Chronic Uremia research and development program of the National Institute of Arthritis and Metabolic Diseases. The latter supported clinical research related to dialysis treatment, provided an annual forum and special occasions for presenting research results, and helped raise a cadre of dialysis clinicians to positions of national leadership. But the KDCP represented the effort that, in the 1960s and early 1970s, sought to extend the nation's policy commitment and its capacity to treat patients.
The Demonstration of Dialysis

The KDCP, established in 1965, was called into existence by the fact that preliminary dialysis center grant proposals were being submitted to the Public Health Service in 1963 and 1964 (Rettig, forthcoming). The Seattle Artificial Kidney Center received the first grant award in 1963; a second grant was awarded to Downstate Medical Center in Brooklyn in mid-1964. As other proposals flowed in, a review process was set up, an ad hoc committee of expert reviewers was created, and, under Congressional direction, the KDCP itself was then established.

In 1965 and 1966, the KDCP made an additional 12 grant awards for dialysis demonstration centers, the final two being for the demonstration of home dialysis. Awards were for three years of level funding.

The explicit purposes of these grants were to demonstrate to local communities and to the medical profession the effectiveness of hemodialysis as a treatment of end-stage renal failure, and to learn about the ability of dialysis centers to generate local sources of financial support after the federal funds ceased. Implicitly the federal government was responding to strong pressures to provide lifesaving treatment, but in a limited way -- by avoiding direct patient-care financing, focusing on facility and manpower resources, and emphasizing the "demonstration" character of the grants.

The typical selection mechanism involved physicians and a representative of a behavioral discipline, although some relied exclusively upon physicians. Patient selection criteria consisted mainly of "medical suitability" sometimes modified by age, intellectual ability, emotional capability, social factors, rehabilitation potential and, in one case, ability to pay. Decision-making about patient selection, importantly, was decentralized to the local grantee institutions and the processes and criteria of choice left to physicians at the particular site.

In a paper published in February 1969, KDCP staff reported on 302 patients who were entered into hemodialysis treatment by the 14 PHS-grantee centers during the period from March 1960 to June 1967
(Lewis et al., 1969). The total represented an estimated one-third of the total dialysis patient population of the United States as of June 1967. Fifty-three patients, primarily from Seattle and Downstate, had been observed more than two years; the other 249 patients had been entered since June 1965. Forty-eight patients had died. Survival rates for the entire patient sample were: 87 percent after one year, 73 percent after two, and 64 percent after three. Sixty percent (182) of the patients were male, but no differences in survival between males and females were revealed. Patients ranged in age from less than 15 years to over 65 years, but the mean age was 35 years (with a standard deviation of 12 years) and the median age was 32. Mortality was consistently higher for those 46 years and over: differences were not statistically significant at one year or three years; a statistically significant difference existed for the two-year point, though the number of patients was small -- 25. The authors concluded: "Given the assumption that the patients under study could not be managed by more conservative measures, the study shows that chronic dialysis is effective in prolonging the life of the patient with uremia." One purpose of the demonstration, at least, was fulfilled.

Throughout most of 1966, the PHS and KDCP favored expanding the dialysis centers program. A variety of forces converged at that time, however, and forced the program along the pathway of home dialysis. Home treatment had been discussed as early as 1963 by Merrill and his Brigham colleagues, who actually treated the first home patient in the U.S. in 1964 (Merrill et al., 1964). Scribner and his Seattle colleagues aggressively began to treat patients in the home in 1964 and also to promote home dialysis as a national policy (Curtis et al., 1965). Scribner argued that home treatment permitted the escape from the capacity limits of facility dialysis, was less expensive, and resulted in equally good, if not better, patient survival. In November 1965, Representative John Fogarty (D., RI), chairman of the House subcommittee appropriating funds to the Department of Health, Education, and Welfare, visited Seattle, saw a patient being dialyzed at home, and pressed for a home dialysis policy upon his return to Washington, D.C.
Under President Lyndon B. Johnson's Great Society, domestic federal government programs underwent rapid expansion in 1964, 1965, and 1966. But though the President was still proclaiming in 1966 that the nation could afford both butter and guns, the war in Southeast Asia was claiming an increasing share of the federal government. The 1967 fiscal year budget, prepared by the administration in late 1966 and submitted to the Congress in January 1967, was destined to be lean. Kidney disease programs, like all domestic spending programs, were affected.

Late in calendar 1966, therefore, the emergence of home dialysis at the clinical level, the forceful advocacy on its behalf by Scribner, and the growing budget constraints forced the KDCP to switch emphasis from expanding center dialysis to supporting home dialysis. By mid-1967, 12 contracts had been awarded to demonstrate the effectiveness of training patients for home dialysis. Unlike the center dialysis grants, these contracts were five years in length and step-funded so the PHS share of total center resources would decline steadily over the life of the contract.

The KDCP home dialysis initiative occurred while the Gottschalk Committee was at work. The committee's report, finished in September 1967 and quietly released to the public that November, concluded that transplantation was preferred to dialysis and home dialysis to center dialysis (U.S. Bureau of the Budget, 1967). So clinical developments, budget realities, and program adaptations drove policy formulation.¹

The home dialysis training contracts were to demonstrate to individuals, communities, and the medical profession that patients could be trained to perform dialysis in their homes, usually with the help of a spouse or close relative. These contracts were also intended to learn about the ability of such programs to raise community financial support as federal funds declined and ceased. Finally, these contracts emphasized the government's commitment to the least costly means of

¹Subsequently, the Bureau of the Budget accepted the committee's recommendation and leaned on the Veterans Administration, as well as the PHS, to move its program toward home dialysis. The effect of the federal government's posture toward home dialysis, as it played out through the programs of the PHS and VA, was to increase the proportion of home dialysis patients to nearly forty percent of all dialysis patients by 1972 (Bryan, 1976).
dialysis treatment. The effect of scarcity on policy and program was clearer in 1967, then, than it had been in the 1963-1966 period.

The KDCP staff, in a March 1973 paper, presented data on 628 patients, of 736 trained, by the 12 home dialysis training programs (Gross et al., 1973). This constituted the first report of survival figures for a large home dialysis population. Survival for the first year was 86 percent, and 73 percent and 63 percent, respectively, for the second and third years. Again, as with center dialysis patients, no differences existed between male and female survival rates, though nearly 62 percent of the patients were male.

Patients were divided into three age groups: under 30 years, 30 to 49, and over 50. Survival for each group was as follows (Gross et al., 1973):

<table>
<thead>
<tr>
<th>Age Group</th>
<th>1st Year</th>
<th>2nd Year</th>
<th>3rd Year</th>
</tr>
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<tbody>
<tr>
<td>Under 30</td>
<td>87%</td>
<td>81%</td>
<td>70%</td>
</tr>
<tr>
<td>30-49</td>
<td>87</td>
<td>72</td>
<td>65</td>
</tr>
<tr>
<td>Over 50</td>
<td>83</td>
<td>68</td>
<td>42</td>
</tr>
</tbody>
</table>

The differences were statistically significant for the youngest and oldest age groups for the 2nd and 3rd years. "There was a tendency," as the KDCP authors wrote, "for survival to decrease as age at the start of dialysis increased."

The paper noted that survival data for home dialysis patients in the 1967 through 1971 period compared with survival for center dialysis patients in the 1960 through 1967 period. The failure of survival to improve for the latter, home dialysis group was discussed. "Although experience and expertise in managing uremic patients by means of dialysis has improved over the last decade, the expected improvement in survival rates may have been counterbalanced by a concomitant liberalization of selection criteria" (Gross et al., 1973). The noted widening of selection criteria had resulted in the inclusion of high risk groups such as patients with diabetes mellitus and other complicating illnesses.

Rehabilitation data for the 362 patients still alive and continuing
home treatment showed the following: 36 percent were employed full-time and 10 percent part-time; 4 percent were full-time students and 2 percent part-time; 22 percent were housewives engaged in normal activity, while 7 percent were restricted; 5 percent were retired; and 14 percent were employed.

Although marked variation in survival rates existed among the 12 participating centers, no persuasive explanations were provided. "Differences in patient populations, referral patterns, selection criteria, treatment schedules, staffing patterns within the units, and experience of dialysis personnel all probably played a role," the report impassively stated (Gross et al., 1973). Data on annual income, education, and race were not presented.

The report supported the view that home hemodialysis was an effective therapy for the uremia patients. Indeed, it noted that "home hemodialysis is becoming generally accepted as the preferred form of dialysis therapy for most patients." The demonstration, at the clinical level, was judged successful.

**Scarcity-Driven Policy**

The powerful force driving all policy toward hemodialysis and transplantation from 1965 through 1972 was the resource scarcity confronting the federal government. This explains why the KDCC shifted emphasis from center to home dialysis in 1966 and why the main recommendation of the Gottschalk Committee was ignored by the Bureau of the Budget in 1967. The Committee had recommended that a national treatment program be initiated and that patient care be financed by an amendment to Title XVIII (Medicare) of the Social Security Act. But the Bureau barely acknowledged the report, and gave no consideration to this recommendation. The war in Southeast Asia was simply too costly and new domestic initiatives were out of the question.

Scarcity also forced the federal government to reduce its actual commitments and withdraw from implied ones. In late 1967, the KDCC recognized a major problem looming before it in the coming year that pertained to the three-year dialysis center grants. Of the 14 grants, Seattle was ineligible for continued demonstration. But the 3 center grants were scheduled to end in fiscal 1968 (July 1, 1967 through June
30, 1968) and the other 10 at the end of fiscal 1969. The source of the problem was that these centers had experienced substantial difficulty in securing "community support" to finance patient treatment once federal dollars were gone (Prindle, 1967). The policy problem for the federal government was as follows: the PHS demonstration grants had been awarded, in part, to learn about the ability of centers to secure community support for their programs. The stark lesson was, as many expected, that community support was extremely difficult to secure. If, under the circumstances, the federal government continued support for such centers, contrary to the terms of the grants it would be acquiescing in this failure and assuming a heavy, continuing drain on resources. If it withdrew support, however, there was a good chance that centers would collapse and lives that potentially could be saved would be lost. The federal government would be "pulling the plug" on the life-saving treatment for some of its citizens and be vulnerable to public outrage.

In November 1967, therefore, the PHS surveyed dialysis centers receiving no federal support, of which 71 were identified that were treating 342 patients (Chadwick, 1967). Only eight were considered major, treating eight or more patients, and seven of these responded to the survey. Financing sources included: private insurance, 46 percent; ² private foundations and fund-raising, 19 percent; state and local funds (including Medicaid), 15 percent; personal resources of patients, 13 percent; hospital losses, 6 percent; and private donations to hospitals, 1 percent. But these centers reported that substantial month-to-month variation in support patterns occurred, insurance coverage was usually limited to a maximum amount, and state and local governments were not reliable funding sources.

For the PHS centers, VA support was not feasible. The KDCP, however, had encouraged each center to hire a fund raiser, to search all potential sources for support, and to seek state legislation and appropriations for kidney disease. Nevertheless, it was doubtful whether six of the grantee centers would succeed.

² The KDCP staff believed the insurance coverage to be atypically high.
The federal government's policy evolved through several stages in 1968. In April, the PHS communicated to each center the limited federal role under the terms of the grant and their obligation to seek all possible state and local support. Then, in July, Irving Lewis, who had moved from the Bureau of the Budget to be Deputy Director of the new Health Services and Mental Health Administration (the KDCP's new home), wrote the Assistant Secretary for Health: "We ought to decide whether and to what extent we should continue to support these centers, and take on new ones" (Lewis, July 1968). By September, Lewis had concluded that the original demonstration objectives had not been met; "little additional yield" would result from extending the centers; no further demonstrations of center dialysis were needed; each grant should be terminated after completing its three-year support period; and no further one-year extensions should be granted (Lewis, September 1968). Assistant Secretary Philip Lee concurred, but Secretary of HEW Wilbur Cohen, in mid-November, asked for more information on each center and on all possible sources of financial support. Lewis reported back that the situation was grim and that "cessation of grant support ... at the present time would precipitate severe difficulties for some centers, and might result in rather severe criticism of the Federal Government's role," especially in several of the financially weaker centers like the University of Mississippi and Louisville General hospital (Lewis, November 1968).

Two alternatives existed. First, fourth-year extension of the grants could be provided all centers. Second, the government could assume a continuing obligation for those patients "who can be identified by name as being supported by the Public Health Service grants." The Secretary approved a policy of allowing a one-year terminal extension to some centers "to convert from the demonstration grant to local funding." Consequently, 7 additional centers received such fourth-year extensions. But the Public Health Service was terminating its support for dialysis treatment centers.

The KDCP, from mid-1968 onward, was buffeted by a series of budgetary shocks that severely limited its ability to see any of its objectives through to successful completion. The program had received
$783,000 in fiscal year 1966; it received $3 million additional funds the following year to initiate the home dialysis training program; in fiscal 1968, KDCP received yet another $2,162,000 to expand the home training effort, for a total of $5,495,000 that year (Kidney Disease Program).

It was planned by the KDCP to increase the home dialysis training program until 900 patients had been trained by the 12 contract centers. This number of patients was deemed necessary to obtain statistically significant data on cost and medical outcomes and to assure that large patient loads could be handled.

The budgetary implications of this plan, which included other activities in addition to home dialysis, were: fiscal 1969, $12.9 million; fiscal 1970, $19.3 million; and fiscal 1971, $23.4 million. But "developments in international affairs" and "growing national inflation," in mid-1968 forced the following budget reductions on the program: fiscal 1969, $5,945,000; fiscal 1970, $7.5 million; and fiscal 1971, $7.5 million (KDCP, 1970). This shrinking of the planned budget for fiscal 1969 was later followed by a reduction of the fiscal 1970 budget by nearly 30 percent from the previous year, not upward by 25 percent as intended by the second revision, to a level of $4,210,000 (KDCP, 1970).

One strong effect these budgetary setbacks had was on the development of policy toward kidney transplantation. Policy toward transplantation had its roots in the Gottschalk Committee's report of 1967, which found it preferable to dialysis. But the KDCP, from 1965 through 1968, focused exclusively on dialysis. In November 1968, however, it convened a committee of experts to discuss the status of kidney transplantation and the prospect of expanding its use across the country. From this meeting, and internal discussions within KDCP staff, flowed several memoranda that articulated the rationale for a vigorous transplantation program.

Badly seared by the termination of the center dialysis grants, the KDCP staff argued that the policy alternatives were: "(1) to abandon further support for end-stage treatment programs with finality, or (2) to expand the capability of renal homotransplantation as a service-oriented procedure" (KDCP, 1969). The U.S. dialysis patient population
in April 1969 was approximately 2,200 individuals, and was growing at 600 to 700 patients each year. But fewer than 500 transplants were being done annually. Costs of the several treatments available differed substantially for keeping one patient alive ten years: "in-center dialysis -- $150,000; home hemodialysis -- $62,000; combined home hemodialysis and with two transplants, the second of which is successful -- $54,000; home or center dialysis for one year and one successful transplant -- $35,000." In addition, "significant cost reductions" from improved tissue typing, organ retrieval, and drug management were anticipated "within the next 3 to 5 years." Consequently, the staff judgment was that "between $5 and $15 million per annum for the next 5 years would be appropriate" for a transplantation program.

Lewis, by now Administrator of Health Services and Mental Health Administration, opted for an approach that recognized "the fiscal constraints which we are likely to be under for some time" (Lewis, 1969). He preferred to modify the existing home dialysis training center contracts to include transplantation. In fact, the transplantation program that emerged in mid-1969 included integrated home dialysis training and transplantation centers, seven cadaver organ procurement contracts,\(^3\) and a contract with UCLA to maintain a computerized donor-recipient matching program for the western United States.

It is highly unlikely that the $5 to $15 million figure cited above from a KDCP memorandum grew out of a detailed analysis of transplantation needs. But two things are clear and we may draw an inference about a third matter from this brief account. First, policy toward kidney transplantation was driven by the desire to escape the awesome costs of dialysis, even when the latter was delivered in the home. Second, the resource constraints under which the KDCP operated in 1968 and 1969 clearly influenced the size of its transplantation effort: the pattern was cut to fit the cloth. Finally, we infer, or at least conjecture, that organ procurement investment by the program, which ran

\(^3\) The institutions were: Emory University, Atlanta; Interhospital Organ Bank, Inc., Boston; Medical College of Virginia, Richmond; Transplantation Society of Northeastern Ohio, Inc., Cleveland; University of California, Los Angeles; University of California, San Francisco; and University of Utah, Salt Lake City.
for fiscal years 1970, 1971, and 1972, was under-capitalized relative to actual need. Scarcity shaped policy once again.

The budget cutbacks forced rethinking within the KDCP about the level of support for the home dialysis training contracts. Dr. Stanley Olson, director of Regional Medical Programs Service, first raised the issue with Irving Lewis in March 1969. Olson wrote about how to phase-in transplantation and create integrated home dialysis training and transplant centers (Olson, 1969). But continued funding of home dialysis was required in every case, and a serious problem was on the horizon. The existing funding arrangement called for reduced federal support on a 90-80-70-60-50 percent basis over the 5-year life of each contract. But some centers could be receiving as much as $250,000 in the fifth year, Olson noted, and thus face an abrupt jolt at the end of that year. Three termination options existed: terminate on schedule; provide a transitional 6th year for hardship cases; or extend the government's commitment to a 6th year at a 30 percent federal share and a 7th year at 10 percent. Lewis replied tersely: "At this time I am prepared to discuss the issue of extending federal money to these dialysis contracts beyond five years" (Lewis, 1969).

Both the program staff, and the contractors, had anticipated initially that the KDCP would seek increased appropriations to permit expansion of home training programs. But when the KDCP budget was slashed to $4.2 million, in 1970, the staff chafed because the sheltered budgetary status of home dialysis restricted other program initiatives. Consequently, the contracts were lengthened to 6 years and the sliding scale of federal support modified to provide 90-80-70-50-35-20 percent over the contract life. The scarcity imposed from outside the program stimulated the complex bureaucratic search for new program opportunities and for the least painful way for the government to withdraw from its commitments.

Legacy

In 1972, the year in which the patient care financing question was resolved, the Public Health Service program for kidney disease bequeathed the following legacy to the new regime. The clinical efficacy of dialysis had been firmly established. The feasibility of
delivering dialysis treatment in both centers and homes had also been demonstrated. Government policy had basically conferred "preferred treatment" status on home dialysis. Further, a series of policy initiatives had emerged in direct response to scarcity and the resultant search for a less burdensome federal role: center dialysis had yielded to home dialysis; and dialysis, in turn, was being displaced by transplantation as the "preferred course of action."

Most significantly, scarcity placed the federal government in a highly vulnerable position. Dialysis therapy was expensive, beyond the means of practically everyone. "Community support" for saving lives developed slowly, unevenly, and inadequately for the same reason. But the PHS instruments of policy and program (grants and contracts) were of finite duration and limited scope -- not extending to patient care financing. On several occasions, the government was forced to drastically scale down the plans of the KDCP, restrict existing commitments, and withdraw from implied commitments -- all due to scarcity. In so doing, however, the government was exposed to the charge that it was pulling the plug on the lives of its citizens, a charge which went down much harder because of the cost of the Vietnam War.

There were some scarcity-offsetting developments. The KDCP was transferred into the Regional Medical Programs Service (RMPS), administratively in 1969 and by statute in 1970. This legislative enactment, strikingly, stands as the single kidney-disease related act of Congress in the period from 1965 to the enactment of the Social Security Amendments of 1972. Congress, in 1970, merely amended the Heart Disease, Cancer and Stroke Amendments of 1965 to include "kidney disease" at all appropriate places in the statute. Otherwise, the "legislative silence" of these years stands mute testimony to the reluctance of Congress to grapple publicly with the issue of scarcity versus saving lives.

The RMPS transfer gave the advocates of kidney disease treatment access to a larger amount of appropriated resources, though in competition with other disease claimants. Grant and contract awards no longer flowed directly from Washington. Instead, proposals were submitted to the 55 individual RMPS regions for initial review; if
recommended, they were then sent to Washington for final review and approval. According to KDCP records, 20 kidney disease projects were funded as RMPS grants in fiscal 1971 at about $1.8 million; in the following year, 29 RMP's funded renal programs with $6.2 million in grant funds (Summary History of Kidney Disease Program).

State action also occurred. Illinois, for example, created a program for direct payment of patient treatment costs. California and New York authorized the use of federal-state matching Medicaid funds to pay for kidney failure of the indigent. Minnesota made effective use of federal/state matching vocational rehabilitation funds, as did a number of other states. But, of course, many states did nothing or next to nothing.

Overall, there emerged a crazy-quilt pattern of financing, some funds flowing to patient care directly, some indirectly through facility, training, and research support. Funds came from the Public Health Service, through KDCP grants and contracts, from RMPS grants, and through NIH research awards; they came also from the Veterans Administration, from federal/state matching programs like Medicaid and vocational rehabilitation, and from states themselves. Still, the resources were inadequate by any dispassionate analysis to meet the need as judged by those who could benefit from treatment.

Similarly, an institutional patchwork arrangement emerged for providing treatment. The hospitals of major medical schools typically rejected any significant role in dialysis treatment (Rettig, forthcoming). From that rejection came such diverse institutional responses as the Northwest Kidney Center in Seattle, the Boston-based National Medical Care chain of proprietary dialysis centers, and the Nashville-based Dialysis Clinic, Inc., a chain of non-profit, free-standing dialysis centers. On transplantation, notable institutions that survive today include the Southeast Organ Procurement Foundation (SEOPF) and the UCLA-based, computerized transplant recipient and donor matching system. Two national registries also resulted from these years, both from NIH financing: the National Dialysis Registry, managed by Research Triangle, Inc.; and the Human Renal Transplant Registry, begun at Peter Bent Brigham Hospital in Boston and later managed by the American College of Surgeons in Chicago.
What of the patients? Evans, Blagg, and Bryan presented data in 1980 from two national surveys of patients, one in 1967 and the other in 1978 (Evans et al., 1981). These data revealed startling changes in dialysis patient composition: males accounted for 75 percent in 1967 but only 49 percent more recently; whites composed more than 90 percent of patients earlier, but only 64 percent in 1978, while blacks increased from 7 to 35 percent of the total; those over 55 years of age increased from 7 percent to nearly 46 percent; and those employed declined from nearly 42 percent to nearly 18 percent.

Everyone learned from the early Seattle experience not to court public opprobrium by a visible display of rationing access to life-saving treatment. But rationing perforce was occurring, derived from scarcity. Under the primary criterion of medical suitability, the location of treatment facilities, the age of prospective candidates, the access of candidates to various sources of financial support, were all factors entering into the patient selection process.

**SUMMARY**

How are we to understand the developments of 1965 through 1972?

1. The period was dominated by a constant search at the macro policy level for a satisfactory first-order determination -- how much life-saving treatment should be produced -- by the federal government.

2. A series of federal government policies, adopted and then quickly revised, attempted resolution of the first-order determination, only to be soon modified by a force of resource scarcity.

3. A Congress conspicuous by its "legislative silence" reflected the conscious avoidance of an extremely painful dilemma -- choosing between saving lives and scarce resources.

4. The progression of macro level policy, from research and demonstration through capacity-building, was clear and logical in retrospect, but in fact policy officials evaded the hard issues and policy was inadequate to need.
5. Decentralized decision-making at the micro level continued to be driven by the absence of a stable, satisfactory first-order determination at the macro policy level.

6. Since efficacy was no longer an issue, equity dominated considerations about patient selection. But scarcity precluded a fully satisfactory response on equity grounds. Physicians learned from Seattle, however, to avoid the "costs" of being highly visible in decision-making about who received treatment. Criteria varied from center to center but processes of choice were regulated by physicians.

7. No penetrating literature emerged on the ethical implications of micro level decision-making about patient selection that was driven by macro level policies that were resource-constrained.
IV. THE MEDICARE ESRD EXPERIENCE

DISCONTINUITY

In 1972, of course, the legislative silence of Congress was quietly broken, but with a thunderclap effect that would reverberate for a long while to come. Section 2991, included as a last-minute amendment to the Social Security Amendments of 1972, extended Medicare coverage to virtually all those under 65 years of age having permanent kidney failure and requiring dialysis or transplantation to live (Rettig, 1976). The financial guarantee of universal access to treatment lead to a steady, rapid increase of the patient population.

Discontinuity marked the transition to Medicare financing of end-stage renal disease patients (Rettig and Marks, 1980). The controlling legal regime was no longer the Public Health Service Act but now became Title XVIII (Medicare) of the Social Security Act. The responsible administrative agency changed from the KDCF within the Public Health Service to the Bureau of Health Insurance (BHI) within the Social Security Administration, and the responsible officials were no longer those who had grown up, so to speak, with dialysis and transplantation but a new set who were scrambling to understand their recently acquired obligations.

Institutional discontinuity was profound. The patchwork-quilt of financing patient care yielded suddenly to a single, dominant financing source. More importantly, no reason existed to assume that the jerry-built pattern of dialysis and transplantation providers would remain stable in the new era. The KDCF had articulated a model organizational pattern, in fact, while it was lodged within the Regional Medical Programs Services (National Kidney Foundation, 1972). But this institutional hierarchy of tertiary (major medical) centers, secondary (community hospital) centers, and primary (physician) centers, was largely rejected by BHI. Moreover, the model bore little relationship to the then-existing institutional order.
BHI focused on outpatient dialysis rather than on the RMPS hierarchy, finding no difference in service intensity between tertiary and secondary centers. In the interim regulations of June 29, 1973, the government promulgated a "screen" or de facto ceiling on the per treatment reimbursement of dialysis (Federal Register, 1973). This screen applied in the initial years to both hospital and non-hospital settings and constituted the financial incentives to the rapid growth of nonhospital, free-standing outpatient dialysis centers. These free-standing facilities were primarily proprietary, but included a number of non-profit centers as well. The shift from the higher cost hospital center to the lower cost free-standing facility brought about by the reimbursement scheme represents one of the major contributions of Medicare's ESRD program.

One other dynamic must be viewed in less sanguine terms. The de facto institutional policy of the KDCP at the time of transition favored home dialysis (Rettig and Marks, 1980). The legislative history of 1972, however, was so brief, so cursory, so superficial, that home dialysis was not even considered by the Congress. The absence of explicit statutory direction meant that BHI found its own actions governed by the most applicable portions of the Medicare statute and regulations. This body of law contained financial disincentives to home dialysis, some of which were administratively corrected. But not until 1978 and Public Law 95-292, were the main statutory disincentives to home treatment removed and positive incentives provided. More telling, however, neither BHI nor its successor, the Health Care Financing Administration (HCFA), ever articulated a clear policy towards home dialysis. Action follows the expression of intent, but the absence of intention guarantees inaction. The home dialysis posture stands as a policy discontinuity of large proportions.

What effects has the 1972 kidney entitlement had on patient selection processes and criteria and subsequently on the composition of the patient population? Briefly stated, scarcity has been eliminated as a consideration (if not criterion) in decisions about whom to treat. The selection processes are run by physicians, often with help from the associated health professionals. Selection criteria are basically restricted to considerations of medical suitability.
But it bears re-emphasizing that medical suitability is elastic over time and strongly influenced by scarcity. Age was already giving way as a selection criterion by 1972 because of successful dialysis experience with the elderly. Section 2991 only reinforced movement then occurring at the clinical level, and 20 percent of ESRD beneficiaries in 1980 were over 65 years of age (Rettig and Marks, 1980). Similarly, medical criteria before Medicare tended to exclude prospective patients with medical complications secondary to end-stage renal disease. Such complications no longer restrict access to care under the Medicare regime, and the proportion of "sicker" patients has grown over time. Today, diabetics with end-stage renal disease represent approximately 20 to 25 percent of all new patients admitted to dialysis treatment (Friedman, 1982).

Finally, contrary to almost pietistic optimism about patient rehabilitation voiced in the 1972 Senate floor debate, the patient population today consists of many who have not been restored to functioning. Gutman, Steed, and Robinson, for example, in analyzing data on 2,481 patients from 18 dialysis centers, found that "44 percent of the patients observed were probably too sick to work, irrespective of level of education and previous employment status. The most severe morbidity was found among older patients and patients with diabetes mellitus; in contrast, the observed degrees of morbidity and rehabilitation in younger and nondiabetic patients were similar to those reported earlier" (Gutman, 1981). These survey results the authors cautiously conclude, "suggest that a much larger number of American dialysis patients are severely debilitating than had previously been anticipated or reported."

The rehabilitation status of dialysis patients translates into an observable, but infrequently reported, additional cost burden to the government. In 1979, 35 percent of the average annual enrollment of all ESRD beneficiaries were categorized as "ESRD disabled" (Dowling, 1981). This meant that approximately 23,000 individuals were receiving, in addition to Medicare benefits for clinical treatment, monthly disability benefits (income support) from Titles II and XVI of the Social Security Act. These income benefits probably add another $100 million to $250
million annually to the cost to the government of sustaining the lives of the ESRD program beneficiaries.

1978 ET SEQ.

The decline in the relative proportion of dialysis patients treated at home, from nearly 40 percent of the total in 1972 to less than 13 percent by 1977, revoked Congressional efforts to reverse the trend. House Ways and Means Committee oversight hearings occurred in 1975 and 1976, followed by legislative hearings in both House and Senate in 1977 and 1978 (U.S. House of Representatives, 1975 and 1977; U.S. Senate 1977). Public Law 95-292, of June 13, 1978, resulted, the main purpose of which was to increase the incentives for home dialysis and transplantation (Public Law 95-292, 1962).

But another provision of that law, Section 1881.(b)(2)(B) directed the Secretary of Health, Education, and Welfare to "determine, on a cost-related basis or other economical and equitable basis ... the amount of payments to be made for part B services" and to issue regulations to include "to the extent deemed feasible by the Secretary, a system for classifying comparable providers and facilities, and prospectively set rates or target rates with arrangements for sharing such reductions in costs as may be attributable to more efficient and effective delivery of services." The provision, unfortunately, has practically no legislative history that clarifies the intent of Congress in enacting it.

The short history of attempts to publish implementing regulations for this provision grows longer every day. In 1979, draft regulations circulated on an informal basis that proposed a single rate for outpatient dialysis treatment to cover both hospitals and free-standing facilities. In 1980, reflecting the views of a new team, HCFA published a Notice of Proposed Rule Making (NPRM) that proposed a dual rate system -- one for hospitals and a lower one for free-standing facilities (Federal Register, 1980). (This NPRM ratified a dual rate structure that had come into existence largely because of administrative laxity in granting exceptions to the screen to hospital providers.)

Another reverse followed in early 1981, however, when the new Reagan administration indicated its intention to publish a single rate within the next few months. Driven by the incredibly tangled process of
actually writing and rewriting substantive legislation in the budget reconciliation process, the House Ways and Means Committee opted for a single composite rate, that is, a rate that applied uniformly to hospitals and free-standing facilities but also extended to patients dialyzed at home (U.S. House of Representatives, 1981). The Congress, through the joint House and Senate conference committee, "in its wisdom" as they like to say, married these two proposals (U.S. House of Representatives, 1981). The union resulted in a dual composite rate proposal, that is, one rate for hospitals and one for free-standing, with each rate to embrace patients treated in institutions and at home. Happily, escape-hatch language provided the Secretary with the authority to devise a better solution if he could.

The proposed regulation to sever the Gordian knot has bounced between the Health Care Financing Administration, the Office of the Secretary of Health and Human Services, and the Office of Management and Budget. The politics are heavy. National Medicare Care, a major owner of free-standing dialysis centers, in response to a publicly announced rate structure by Secretary Schweiker (HHS press release, 1981), issued a press release stating that it would be compelled to close nearly 60 of its dialysis centers (NMC news release, 1981). Several Congressional committees, the Senate Finance Committee's health subcommittee, the House Ways and Means Committee's subcommittee on intergovernmental and human relations, have held oversight hearings on the proposed regulations of February 12, 1982 (Federal Register, 1982).

The rule-making process may require as few as six and as many as twelve or more months beyond the NPRM to publish a final rule. Moreover, it would come as no surprise to astute observers if the final rule were immediately challenged in the U.S. courts. The immediate future is far from clear on this central issue of reimbursement.

ASSESSMENT

How are we to appraise the experience of the Medicare ESRD years? Several major conclusions emerge. First, practically all issues, whether clinical, institutional, or financial, have become matters of policy about the organization and operation of a government-made market. The 1973 screen worked as well as it did because policy officials in BHI
recognized the simple fact that a universal Medicare entitlement eliminated the non-Medicare marketplace as a basis for reimbursement policy. The general point, however, deserves reiteration: the incentives and constraints governing the behavior of patients, physicians, and institutions are established within the framework of federal government policy. There is no escape from this institutional reality.

Second, a constant demand for strong policy notwithstanding, the administration of the ESRD program has been adequate but hardly distinguished. Some observers regard the program as an administrative disaster (ECRI, 1982), but it is far from clear that the program is less well-managed than any other federal government program. The main point, however, is that second-best administration, whether disastrously weak or barely adequate, may be the best that one can expect, for structural reasons that go well beyond the ESRD program.

Third, one of the more chronic and perennially disturbing features of the ESRD program's administration is its limited capacity to generate simple, good quality, timely data in a regular way (Rettig, 1980). This deficiency has bedeviled the program from the outset and is likely to continue for a long time to come. Again, structural features of the contemporary federal government combine with the complexities of the ESRD "system" to give the data problem its refractory character.

Fourth, relative to end-stage renal disease, a form of political stasis, if not advanced paralysis, appears to have developed. The legislative branch understandably retreats from directly confronting the central issue of whether a universal benefit has led to too much treatment. Unfortunately, the executive branch cannot act without clear political guidance from the Congress. The contending factions -- the proponents of home dialysis, free-standing, largely proprietary dialysis, and hospital-based treatment -- cannot secure their own objectives but are able to checkmate the actions of others. Patients, politically speaking, are not well represented. The result of this situation is that no political capacity exists to formulate policy.

Fifth, it is reasonable to expect that whatever policy is adopted in 1983 will govern the program for the decade of the 1980s. Some may flinch at this assertion, preferring to believe that continued
adaptation to new developments is better than submission to a long-
standing regulatory regime with a tendency to ossify. But reflect for a
moment that the interim regulations of June 29, 1973, still govern the
ESRD program, modified by statutory changes for home dialysis and by
administrative laxity and drift for the reimbursement of hospital-based
treatment. Notwithstanding the expectation of BHI at the time that
these interim regulations would be modified as experience was gained and
data accumulated, reality turned out differently. No reason exists to
think that the regulations of 1983, when finally established, will be
changed any faster.

Finally, the present period reveals strenuous efforts to avoid the
new manifestation of the "tragic choice" as it reemerges in a period of
relative abundance. Having made the first-order determination that all
in medical need should have access to treatment, we now experience
disquietude at the fact that though many lives are being extended in
highly productive ways, scarce resources are also supporting a goodly
number of patients who are at the margin of clinical acceptability and
prognosis. These lives are being sustained at great cost, but
dependency is often extended beyond the benefits of Medicare to income
support by the disability system. Are we technically or
administratively required to treat these marginal patients because no
defensible way exists to differentiate between them and the clinically
better patients? Are we morally obligated to support such patients in
order to affirm our societal commitment to preserving life? And are we
morally obligated to spend for these renal patients without regard for
other equally legitimate claimants on the public purse? The questions,
of course, remain unanswerable, which leads us to our final section.

LESSONS

What lessons can we draw from the two-decade experience sketched in
the preceding pages that might help us more with greater understanding
into the future? The following stand out.

First, the conflict between scarcity and saving lives, whatever its
complex manifestation, highlights the inadequacy of the languages of
medicine, economics, and politics to address such issues. Medicine
speaks of efficacy of a procedure and effectiveness of that procedure
when applied to various purposes or patient populations. Clearly, effectiveness correlates directly with the strictness with which the criteria of medical suitability are defined and applied. But the strictness or liberalness of such criteria depend in large measure upon the scarcity or availability of resources, which is socially determined. Even though physicians may go beyond the observation of immediate treatment outcomes to the consideration of patient rehabilitation, they may proceed further only on the basis of sentiment or ideology or moral reasoning but not on the basis of clinical medicine.

The language of economics is equally impoverished. The major preoccupation of policymakers in the Medicare ESRD years has been cost control. Cost control, it is argued, has been hampered by the absence of good data and cost studies. This is partly true, but not entirely so. In fact, we know how to control costs: simply shift an increasing proportion of patients from higher cost to lower cost treatment settings. This probably involves a double movement from hospital-based to free-standing units, and from institutions to the home setting. What we do not know how to do, however, is to control costs without sacrificing other values: patient autonomy, freedom of physicians to prescribe the treatment setting, and the refusal to ration access. All cost control policies, therefore, require moral justification that commands political consensus and supports authoritative public policy. Economics cannot provide such justification.

The language of politics is also bankrupt, but for more complex reasons. At one level, the most superficial, politics speaks to the relative advantage of one or another party of interest, but this constitutes no defensible moral basis for policy. At a deeper level, there is little understanding among contemporary politicians and policy makers that the central preoccupation of the political system is how society arranges and conducts its collective business. Few issues so illuminate the nature of the political system, as conceived in these terms, as do those surrounding end-stage renal disease. But the language of politics fails in the final analysis because tragic choices bring fundamental values into conflict in ways that suppress rather than encourage moral discourse. Tragic choices are not amenable to political discourse.
The second lesson we draw is that no "right" solutions exist. The tragic choice is ever-present. Scarcity issues, resolved at one point, predictably become politically salient at a later time. All policy tradeoffs require the compromise of ultimate values. All institutional arrangements are second-best, there being no truly best arrangement. The quest in public policy, therefore, must be for socially acceptable value tradeoffs and institutional arrangements, undergirded by a broad political consensus that acknowledges the painful choices required by the society. If a given arrangement lasts five years that is all to the good; if ten, so much the better.

Third, we can expect political consensus to break down under the weight of various forces. One of the most powerful of these is the perception that we have reached the limits of our resources. That conclusion may not force changes in the ESRD program. But it may powerfully influence the next candidate program, like heart transplantation or the artificial heart or bone-marrow transplantation or other life-saving but expensive medical procedures. When the perception of having reached resource limits undermines the fragile consensus supporting existing policy, the search begins anew for a socially acceptable response.

Finally, we reflect on the nature of modern medicine and hope for scientific advance that obviates the need for cumbersome medical technology. The Salk and Sabin vaccines eliminated poliomyelitis and its iron lung treatment technology. The search for how to manage the immune response to transplanted kidneys and for knowledge of the etiology of kidney disease that permits preventive intervention must continue. In the meantime, we must struggle to do the best we can with our collective responsibility.
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