

Chapter 1

INTRODUCTION AND SUMMARYOF THEKIDNEY DISEASE PROGRAM ANALYSIS

I. INTRODUCTION

A. Objectives and Goals of the Report

In the spring of 1967 the Surgeon General of the U. S. Public Health Service established, among others, a health program analysis group to undertake studies and analyses in the area of kidney disease. Members of the group were chosen from among senior staff of the National Institutes of Health and other bureaus of the Public Health Service, who were responsible for ongoing kidney disease-related programs or whose competence lay in the areas of program planning and analysis. In his charge to the group, the Surgeon General directed it to describe and discuss the nation's kidney disease problem, to outline the current state of knowledge and ongoing programs in the area of kidney diseases, to consider advanced states of knowledge and desirable programs, to develop goals and objectives for effective amelioration of the problem, and to explore alternative approaches to the attainment of these objectives.

An important part of the group's work was to be a logical analysis of programs leading to a solution or amelioration of the problem of kidney disease,

including:

- 1) A thorough discussion of goals and objectives and ways of measuring them;
- 2) A description of alternative approaches which could lead toward the same objectives;
- 3) An analysis of the cost of reaching various points on the continuum of objectives by means of alternative approaches; and
- 4) A discussion of the basic assumptions upon which conclusions depend, of uncertainties which affect the estimates used, and of the issues which cannot be resolved at this time.

The work of the kidney disease program analysis group is intended to guide the Office of the Surgeon General and, ultimately, the Office of the Secretary, Health, Education, and Welfare, in the development of future long range financial plans and budgets, and legislative proposals.

B. Background

During the last five years, diseases of the kidney have steadily gained in significance as an area of social importance for both Federal and non-Federal research and service efforts. Much of the impetus for this increasing interest in kidney diseases has come from the development of two dramatic but expensive therapeutic approaches to end-stage disease--chronic hemodialysis and kidney transplantation. The successes of both techniques--coupled with other research advances leading to a better understanding of kidney diseases--have led to a proliferation of activities directed toward reducing the morbidity and mortality these cause in the population.

There are a number of mechanisms, or program components, that are traditionally brought to bear on a disease problem such as this. These are:

- 1) Expanded use of existing preventive techniques.
- 2) Expanded use of existing diagnostic techniques.
- 3) Expanded use of existing treatments, including chronic dialysis, kidney transplantation and conservative management (drugs, diets, etc.).
- 4) Laboratory and clinical research to produce new preventive, diagnostic, therapeutic and rehabilitative methods.
- 5) Increased specialized scientific medical and paramedical training to provide the manpower needed for the research and treatment attack on the kidney disease problem. This also includes continued postgraduate education to train practicing physicians in the use of the latest diagnostic and treatment modalities.
- 6) Increased public education to alert potential victims of kidney disease to seek medical help at the earliest possible emergence of warning signs.
- 7) Provision of specialized facilities not currently in existence which are essential for the execution of any of the above programs.

It must be understood from the outset that these program components are interdependent in most cases. For example, preventive techniques exist that need further research to make them maximally effective for broad application. New treatment methods are useless if existing diagnostic techniques are not being applied in medical practice. Because of

the present inadequacies of existing treatments, be they dialysis, transplantation, or conservative management, a considerable research effort is called for to increase their efficacy and economy to make them more broadly useful.

C. Consideration of Program Approaches

It is unlikely that a single program component would lead to a major reduction in the national kidney disease problem; therefore, a mixture of approaches will have to be employed by the Federal Government to reduce the morbidity and mortality due to kidney disease. The total funding level and the respective proportions for each approach in the overall effort will determine, to a large extent, the benefits attainable in each successive year from this effort. Advances in the state of knowledge will affect the nature of this "mix" and will shift the emphasis from certain program components to others if we are to continue to derive maximum benefits from the total expenditure of funds in this area.

Another important consideration in making choices for the funding of specific program approaches is the effect of the expenditure of such Federal funds on the overall national expenditure of funds in this area including money spent by state and local governments, voluntary agencies, universities and foundations, and the large segment of private expenditures for medical diagnosis and treatment. Here, the precise choice of direction of the placement of Federal funds can determine to a large degree whether:

- 1) The resulting fruits of research or increased case findings at an early stage of the disease will stimulate an expanded use of nongovernmental money for earlier and more effective treatment--

with an overall beneficial effect on the state of kidney disease in the nation; or

- 2) Whether certain choices for the expenditure of Federal funds would serve to diminish the participation of the nongovernmental sector in efforts against kidney disease by making it financially more attractive to "let Sam do it."

It is obvious therefore, that under a given set of conditions where unlimited Federal funds are not available for the solution of a single national disease problem, such as kidney disease, a rational balance must be struck between the various relevant program approaches--investigative, preventive, therapeutic and educational--so as to derive maximum benefits from any current or possibly extended future Federal efforts.

D. Program Analysis for Decision Making

The future of Federal programs in the field of kidney diseases, be it for research, disease prevention, improvement of treatment methods including hemodialysis and transplantation, or manpower training needs decisions based upon a thorough, dispassionate and logical analysis. With the aid of such analysis, public officials responsible for health programs who face the problem of allocation of limited financial resources in the struggle against kidney disease could make such decisions on the basis of logical priorities. These priorities would be based on the present state of knowledge and on needs based on present morbidities and mortalities, as well as on the basis of anticipated developments in the future state of the art and the pertinent changes which they are likely to introduce into the overall kidney disease picture. The fundamental intent of such an analysis and its *raison d'etre* is to provide maximum benefits in terms of prolonged, rewarding lives and reduced

morbidity for those afflicted with kidney disorders and for those in the population who will be stricken by it in the future, from the application of Federal funds to research, disease prevention, treatment, and manpower training, directed against kidney disease.

E. The Analysis

Faced with the fact that its study and explorations could perforce not be infinitely exhaustive it was decided that, for the sake of practicality and feasibility, the heterogenous field of kidney disease be divided into four major groups as follows:

- I. Infectious Diseases of the Urinary Tract,
- II. Hypersensitivity Diseases of the Kidney,
- III. Kidney Diseases Associated with Hypertension, and
- IV. End-Stage Kidney Disease.

The first three groups encompass in toto about 75 percent of kidney morbidity and mortality; the fourth group, end-stage kidney disease, exemplifies progressive and ultimately fatal kidney failure from all possible causes.

Each of these groups accounts for a major percentage of overall kidney morbidity and since each group of diseases was based on one major distinct causative principle it was felt that it is possible to discuss logically each group individually in terms of the common overall mechanisms involved and in terms of the application of the various possible program elements--research, prevention, treatment, professional training and lay education--to the solution of the problem which it represents.

In addition to the first groups, there remains a miscellaneous group of renal diseases of variable and distinct etiologies:

- a) Diseases of development (polycystic disease, hypoplastic kidneys, anomalies of position or structure, etc.);
- b) Renal involvement in metabolic diseases (diabetes, gout, amyloidosis, oxaluria, etc.);
- c) Kidney damage due to obstruction (benign prostatic hypertrophy of the aged, kidney stones, etc.);
- d) Cancer of the kidney, both of primary or secondary origin; and
- e) Mechanical injury.

2. Limitations

Programs and approaches for solution or amelioration of problems associated with this latter mixed group of renal diseases are discussed in the text of the report but were not subjected to individual cost-effectiveness or benefit-cost analyses. This decision was made to avoid an unwieldy, and in many cases, impractical fragmentation of the report. Moreover, each one of these disorders may be the end result of a primary disease for which there exist other, independent research and preventive and/or curative efforts which, hopefully, would affect beneficially the existing prevalence of the disease.

For example, research advances of the last seven years in the area of gout, once they are rigorously applied in the everyday practice of medicine, will decrease considerably the prevalence of kidney damage due to neglected or long standing chronic gout. Similar considerations were applied to other disorders belonging to the residual mixed group of miscellaneous diseases impinging on the functional integrity of the kidney.

It was also decided to exclude neoplasms of the kidney from the Program analysis. Inclusion of this category in the present analysis

was felt to be undesirable because other extensive research and public health programs affect the state of the art in cancer; moreover, in a large percentage of patients afflicted with primary or secondary cancer of the kidney, kidney function per se does not deteriorate until the extent of the lesion becomes overwhelming--at which point the life of the patient is usually threatened by the neoplasm and its metastases more than by the attendant renal failure.

The present analysis was limited to kidney diseases which are predominantly chronic or to mechanisms which though they may precipitate acute kidney disease, play a major role in eventual or potential chronicity of the disorder. Thus, acute renal poisoning due to accidental causes or suicide attempts, and nephrotoxic drug reactions were not included in the analyses or program projections.

3. Appendices

In the course of discussing possible programs and their specific impacts, new ideas were developed which seemed of sufficient interest and potential benefit to be included in the report. Subsequently, the overall principles involved were fitted into the logical mainstream of the report. For the sake of brevity and continuity, however, the more detailed projections or applications of such future programs were included in appendices to the report, whenever they appeared of interest.

4. Recommendations

In projecting future programs and in analyzing their possible impact on the mortality and morbidity due to each major sub-group of kidney diseases, the committee attempted to avoid implied or overt recommendations.

It was felt that in each case the analysis and its logical extrapolations spoke for themselves.

II. SUMMARY

The following summary presents the committee's most significant generalized findings and a discussion thereof, and is not intended to include all observations made. These will be found in detail in the body of the report.

As a first step in its analysis in depth of kidney disease as a national health problem, the committee studied each of the many diseases of diverse etiologies which are encompassed in the general term 'kidney disease'. (Please see Chapter 2, Kidney Disease--Current Status) In each case the current state of scientific knowledge for each disease was determined including its underlying etiology, mechanisms of pathogenesis, symptomatology, prognosis, severity and duration, methods of diagnosis, and treatment. Where applicable, consideration was given to existing gaps in knowledge, additional research needs, possible prevention, diagnosis, and treatment under the conditions of present or future states of the art, and interrelationships with other diseases. Up-to-date statistical data were collected, such as prevalence in the population, mortality, morbidity in terms of days of restricted activity, average cost of treatment, and other relevant costs.

Since the subject matter embraces a vast number of diseases with highly divergent pathogenic mechanisms and nature, the committee made decisions-in-principle concerning which of these would serve best as a

basis for a rational analysis under the limitations of the present study (please see INTRODUCTION, E.,1., Organization of the Subject Matter). The three main groups of primary kidney diseases and end-stage kidney disease common to them were utilized in the statistical analyses in this report. This group encompasses the overwhelming majority of kidney mortality and morbidity. The remaining primary and secondary kidney diseases of statistically lesser import were discussed in the text of the report but were not included in the present program analysis.

Subsequently a thorough study was made (Chapter 3, Current Kidney Disease Control Programs) of the current governmental kidney disease programs and relevant public and private expenditures for the nationwide treatment of kidney disease. The latter includes cost of physician care, hospital care, nursing home care, and other professional services for diagnosis and therapy of kidney diseases, as well as the cost of drugs and net insurance costs. In addition, the cost was estimated for ongoing research efforts, for demonstration, screening and detection programs, for education and training efforts and for that portion of the cost of construction of hospital and medical facilities which can be prorated to the use of patients with kidney disease.

Program Analysis Models

Based on the substantive information obtained and statistical and economic data collected, the committee analysed the benefits to be gained by different approaches to the solution or amelioration of the overall national kidney disease problem at different expenditure levels of HEW funds. Models were devised after experimentation with various statistical mechanisms and indices.

They are based on a benefit-cost analysis for the four disease groups studied, i.e., infectious diseases of the urinary tract, kidney diseases related to hypersensitivity phenomena, kidney diseases related to hypertensive vascular diseases, and end-stage kidney disease. Four specific programs are considered for each disease group. These programs which are delineated by time, funding level, and state of the art comprise the following:

- 1) Hypothetical Program at the Current HEW Expenditure Level, Based on the Current State of the Art;
- 2) Hypothetical Program at an Intermediate HEW Expenditure Level, Based on the Current State of the Art;
- 3) Hypothetical Program at an Accelerated HEW Expenditure Level, Based on the Current State of the Art; and
- 4) Hypothetical Program for Fiscal Year 1975, at an Accelerated HEW Expenditure Level, Based on the Expected Advanced State of the Art in 1975.

Each program consisted of a hypothetical situation where a specific level of HEW program funding was divided among a rational mix of program components (screening, diagnosis and treatment, research, training, etc.) based on the particular characteristics of the specific disease group involved, and was applied to specifically involved or particularly vulnerable groups or, as the case may be, to the entire population. The benefits accruable from these programs were then estimated and stated in terms of overall reduction of mortality, prevalence, and morbidity due to kidney disease. Wherever the making of assumptions was unavoidable, the resulting estimates were based on the best scientific evidence and available data and were held within conservative limits.

Benefit indices were quantified in terms of the reduction in annual mortality, the reduction in annual morbidity (number of sick days per year) and in terms of the disease prevalence in the total population due to the specific type of kidney disorder analyzed, which would accrue thanks to the impact of the various program components--such as research advances, disease prevention and improved treatment. It was felt that these specific benefit indices were more appropriate for the purposes of this study than other potential indices such as "loss of productivity," loss of gross national product due to the death of individuals, or loss to the Federal Government of tax revenue due to death or inactivity of individuals. Moreover, it was felt that it would be more desirable to quantify the benefits which could accrue from HEW-supported programs aimed at the kidney disease problem in terms related directly to the human beings who are to benefit from such expenditure, rather than in terms of a highly impersonal inert commodity--dollars. The fact that mortality and morbidity figures could be manipulated statistically just as well as dollars, but could be used without introducing too many estimates and assumptions ("What is the price of a human life?", "How much money is lost, and to whom, when a sick person does not report to work?") induced the committee to choose these indices for its benefit-cost analyses.

A detailed explanation of the various postulated programs and the analysis of their potential benefits will be found in Chapter 4, Research Methodology, and Chapter 5, Program Analysis. The nature of these programs, and the benefits and costs associated with each of the four programs in each disease group are summarized and discussed below.

Summary of Alternative Programs for Individual Disease Groups

1. Infectious Diseases of the Urinary Tract

a. Hypothetical Program at Current HEW Expenditure Level, Based on the Current State of the Art

A major component of this program is the screening of the following specific high-risk groups: patients in hospitals and nursing homes, non-hospitalized pregnant females, and non-hospitalized diabetic patients. This would be followed by the establishment of definitive diagnoses and vigorous treatment of any kidney infections discovered. A second major projected program component is laboratory and clinical research directly relevant to infections of the kidney. Other program components are concerned with the education of medical personnel and the specific training of additional manpower. The cost to HEW is estimated at \$9,203,000.

Short-term benefits of this program (discernible when the program reaches full operation), would be represented by an annual reduction in mortality of 70, a reduction in prevalence of 3,231,260 cases and a reduction of 15,962,420 morbid days in the involved vulnerable group. Long-term benefits (to be seen many years after the program becomes fully operational) are represented by the avoidance of irreversible, fatal uremia in 1,750 individuals per year.

b. Hypothetical Program at an Intermediate HEW Expenditure Level, Based on the Current State of the Art

At the intermediate program level, HEW expenditures are about two times greater than in the preceding program. Again a major component of this program is the screening, diagnosis and treatment

of urinary tract infections. An additional high-risk group has been added: females 6 to 9 years of age. The cost to HEW is estimated at \$20,179,000.

Short-term benefits attributable to this program are quantitatively greater (percentage reductions do not change), due to the addition of another high-risk group. A reduction in short-term mortality of 70 is again expected due to the very low mortality from infections of the urinary tract in the added vulnerable group. Prevalence is reduced by 3,243,860 and morbid days by 16,273,640. A yearly reduction of fatal end-stage kidney disease by 1,770 is expected.

Expansion of the proposed basic program (see previous model) to a level which is two times larger, in an effort to include an additional vulnerable group, did not result in a near-proportionate increase in benefits. Once a new potentially vulnerable group was included in which the percentage of individuals harboring urinary tract infections was much lower than in the previous hypothetical situation, the point of rapidly diminishing returns was reached. Thus an indication was received of the possible limits of effectiveness for a screening-diagnosis-treatment program for infectious diseases of the kidney in the general, non-morbid population under conditions of the current state of knowledge.

c. Hypothetical Program at an Accelerated HEW Expenditure Level, Based on the Current State of the Art

In this projected situation, the HEW expenditure level is about two and one-half times greater than the current level. Again, a major component of this program is the screening, diagnosis and

treatment of infections of the urinary tract. The high-risk group at which the program is aimed has been expanded to include all females under 21 years of age.

The short-term benefits attributable to this program include a similar percentage reduction in mortality and morbid days as before, but since a larger vulnerable population was involved, quantitative benefits are greater. The cost to HEW is \$27,394,000.

Short-term benefits include an annual reduction of 70 deaths, 3,292,860 cases, and 17,483,880 morbid days.

Long-term benefits are represented by the elimination of irreversible, fatal uremia in 1,870 individuals per year.

The same comments made on the less-than proportionate increase in benefits in the intermediate program apply, even more strongly, to this hypothetical situation. It is obvious that under the conditions of the present state of the art the limits of effectiveness for this approach have been reached at the previous level of expenditure, in the intermediate program.

d. Hypothetical Program, for Fiscal Year 1975 at an Accelerated HEW Expenditure Level, Based on an Advanced State of the Art

In this projected situation, the HEW expenditure is about three and one-half times greater than the original program. Funds for research have been increased considerably. Screening, diagnosis and treatment still remain a major program component.

Under an advanced state of the art it is assumed that the extensive research efforts have made possible:

- 1) More effective antimicrobial therapy,
- 2) Better understanding of the pathophysiology of urinary tract infections, and

- 3) Better understanding of the natural history of pyelonephritis.

The cost to HEW is estimated at \$31,228,000.

Short-term benefits now include an annual reduction of 80 deaths, 5,630,780 cases, and 26,064,430 morbid days. Long-term benefits are represented by the elimination of irreversible, fatal uremia in 4,125 individuals per year.

2. Hypersensitivity Diseases of the Kidney

- a. Hypothetical Program at the Current HEW Expenditure Level, Based on the Current State of the Art

It was concluded that present knowledge of hypersensitivity diseases of the kidney is insufficient to justify a special program of case finding, diagnosis and treatment since it is doubtful whether it could make an effective impact on current morbidity and mortality figures due to these diseases. The most important projected program component is laboratory and clinical research relevant to immunology and hypersensitivity diseases of the kidney. An additional component is postgraduate physician education, research training, and expansion of research facilities. The cost to HEW is estimated at \$7,480,000.

Short-term benefits expected are a reduction of 610 in immediate mortality, primarily due to the postgraduate physician education and consequent improved medical practice. No immediate benefits are expected from the research effort undertaken.

A 1% reduction in mortality, a 50% reduction in prevalence and a 65% reduction in morbid days is anticipated over a future

ten-year period as a result of this program primarily due to anticipated research advances, and secondarily due to a higher quality of medical care (see anticipated benefits for 1975). This was one of the most uncertain estimates made; it was based on the research advances of the last 10 years and on the arbitrary assumption that the rate of new developments will remain the same.

b. Hypothetical Program at an Intermediate HEW Expenditure Level, Based on the Current State of the Art

In this situation, the program components have not changed essentially, but the HEW expenditure level has been increased. The most important program component is, again, research. The cost to HEW is estimated at \$20,000,000.

Short-term benefits would remain similar to those described at the previous, lower expenditure level (see above).

Long-term benefits will only be increased significantly over the previous program if the funds for research in the latter had been a limiting factor for productive research.

c. Hypothetical Program at an Accelerated HEW Expenditure Level, Based on the Current State of the Art

In this situation, the program components have not changed essentially, but the original HEW expenditure level has been tripled. The most important program component is, again, research. The cost to HEW is estimated at \$23,875,000.

Short-term benefits would remain similar to those described at a non-accelerated HEW level (see above).

Here again, long-term benefits will only be increased significantly over the previous program if the funds for research in the latter had been a limiting factor for productive research.

d. Hypothetical Program at an Accelerated HEW Expenditure Level, Based on an Advanced State of the Art (1975)

Under an advanced state of the art, it is assumed that the preceding research has resulted in the development of effective means of preventing hypersensitivity diseases of the kidney, or of treating them. Possible examples are:

- 1) An effective anti-streptococcal vaccine;
- 2) Failing that, discovery of a means for early detection of streptococcal infections and for the interruption of the immunological mechanisms that lead to acute glomerulonephritis and/or
- 3) Increased understanding of the meaning of proteinuria and means for identification and treatment of individuals in whom it heralds eventual chronic renal disease.

A program based on the use of an anti-streptococcal vaccine in a majority of the population and on early detection and treatment of persistent proteinuria would yield the following short-term benefits: an annual reduction in mortality of 770, a reduction in prevalence by 62,250 cases and a reduction of 2,610,000 morbid days in those affected.

Long-term benefits would be represented by a decrease of 8,610 individuals per year who would otherwise reach end-stage kidney failure in the future. The cost to HEW has been estimated at \$77,320,000.

It is important to note that any of the program approaches involving the advances mentioned above would have a profound impact on the prevention and treatment of hypersensitivity diseases in general, such as rheumatic fever, rheumatic heart disease, and others.

8. Kidney Diseases Associated with Hypertension

a. Hypothetical Program at the Current HEW Expenditure Level, Based on the Current State of the Art

The projected program consists of three major components:

- 1) Screening, diagnosis and treatment of individuals 17 years of age and over with curable (non-essential) hypertension and non-curable hypertension;
- 2) Postgraduate education of practicing physicians and education of the population relevant to early recognition and treatment of the disease; and
- 3) Laboratory and clinical research.

A relatively minor component for research training of physicians and allied personnel is also included. HEW costs are estimated at \$9,180,000.

Estimated annual short-term benefits include a decrease in mortality by 7,830, a reduction in prevalence of 54,000 cases, and a reduction of 5,959,000 in morbid days due to hypertensive disease. It has been assumed that approximately 30% of the benefited individuals with hypertension have renal involvement. Thus the figures for benefits accruing to patients with renal disease associated with hypertension are 2,190, 27,000, and 1,802,000, respectively.

A reduction of 4,330 per year in the number of individuals dying from irreversible uremia is expected as a long-term benefit.

b. Hypothetical Program at an Intermediate HEW Expenditure Level, Based on the Current State of the Art

The projected program is similar to the preceding one except that under an increased funding level (about two and one-half times greater than before) an additional population group is subjected to screening, diagnosis and treatment. Reference is to persons 17 years of age and over who have had no care from a physician during the preceding year. The program affecting the additional group is expected to cover a six-year cycle. Estimated costs for HEW are \$21,207,000.

Estimated annual short-term benefits for patients with renal involvement are now increased to 2,270 avoided deaths, a reduction in prevalence of 34,880 cases and a reduction in morbid days of 2,056,820. Expected long-term benefits are estimated to include an annual reduction in fatal end-stage uremia of 4,820 cases.

c. Hypothetical Program at an Accelerated HEW Expenditure Level, Based on the Current State of the Art

This program is similar to the one postulated for an intermediate level of expenditure except that the program affecting the additional high-risk group of previously unscreened individuals has been accelerated to cover a three-year cycle rather than six years. The estimated cost to HEW is \$28,639,000 (about three times the original level of expenditure).

Estimated annual short-term benefits for patients with renal involvement now include 2,380 avoided deaths, a reduction in prevalence of 42,750 cases, and a reduction in morbid days of

2,311,340. Expected long-term benefits are estimated at an annual reduction in end-stage uremia of 4,820 cases.

In this case, further expansion of the program above the intermediate level did not appear warranted by the resulting increase in benefits, which was very far from proportional. Here again, an indication was received of the possible limits of effectiveness for a screening-diagnosis-treatment program for kidney diseases associated with hypertension in the non-symptomatic population ("individuals who have not seen a physician during the preceding year"), under conditions of the current state of knowledge.

d. Hypothetical Program at an Accelerated HEW Expenditure Level, Based on an Advanced State of the Art (1975)

Under an advanced state of the art it is assumed that the preceding extensive research efforts have resulted in the following:

- 1) Advances in understanding of the underlying cause(s) of hypertension;
- 2) Improved diagnostic tests for detecting hypertension;
- 3) Specific effective therapy(ies) directed toward the various underlying causes; and,
- 4) Advances in surgical methodology for the types of hypertension amenable to such treatment.

Screening, diagnosis and treatment still remain the major program components in this projected situation. The target population is the same as in the preceding programs. HEW costs are estimated at \$35,832,000.

Estimated annual short-term benefits for patients with renal involvement include a 9,300 decrease in mortality, a reduction of

289,700 in prevalence and a reduction in morbid days of 5,579,000.

Long-term benefits are expected to result in an estimated annual avoidance of fatal end-stage kidney disease in 9,480 individuals.

4. End-Stage Kidney Disease

End-stage kidney disease as indicated earlier exemplifies progressive and ultimately fatal kidney failure from all causes. Because of the unique and costly treatment methods currently available this group was studied not only from the standpoint of the four program alternatives (used for the three primary disease groups) but also from the standpoint of a program which attempts to treat all patients with chronic kidney failure.

a. Hypothetical Program at Current HEW Expenditure Level Based on the Current State of the Art

The major component in this program consists of treatment of patients in end-stage renal failure by dialysis and/or kidney transplantation. A second program component is laboratory and clinical research relevant to both treatment modalities, developmental research for dialysis hardware improvement, and development of organ preservation technology and facilities. A third program component, considerably smaller, involves training of relevant manpower and provision of needed facilities. The estimated HEW cost is \$21,000,000.

The benefits in this program are measured in terms of mortality avoided in the total group of patients in irreversible renal failure whose lives are in jeopardy. Under the circumstances of this particular program, 600 patients will be maintained through

chronic dialysis and 90 lives yearly will be saved through successful transplantation.

This program of dialysis and transplantation, at current HEW expenditure levels, provides life-saving care for about 1.5% of the number of patients threatened by death during that particular year because of end-stage kidney disease.

b. Hypothetical Program at an Intermediate HEW Expenditure Level, Based on the Current State of the Art

In this projected situation the level of HEW funding has been increased appreciably to reflect the immediate urgency posed by the threatened lives of patients in irreversible renal failure. Treatment expenditures have been increased by a factor of 5 over the previous level, research expenditures by a factor of 1.5 and training and facilities by a factor of 5.

Under the circumstances of this particular program, about 1,150 patients would be maintained by chronic dialysis and about 420 individuals would be cured by transplantation.

This program which involves about \$56,000,000 of HEW funds will provide life sustaining treatment for about 3% of the annual number of persons who have end-stage kidney disease during the first year of the program. During the second year of such a program, however, because of the carry-over of about 80% of the patients dialyzed during the preceding year, the same sum of money will provide treatment for considerably less than 3% of the uremic patients threatened by death during the second year. Because of the increasing carryover load of dialysis patients

from previous years, this limiting effect will increase with each successive year of such a program. Unless the budget, manpower, and facilities are increased considerably during each succeeding year over the respective previous levels, only a small proportion of the total group threatened with death due to end-stage kidney disease each year will actually be saved in such a program. This problem is discussed in greater detail later in this summary chapter and particularly in Chapter 6, The Cost of Treating All Patients with Chronic Kidney Failure.

c. Hypothetical Program at an Accelerated HEW Expenditure Level, Based on the Current State of the Art

In this projected situation, the level of HEW funding has been increased tenfold to reflect the immediate urgency posed by the threatened lives of patients in irreversible renal failure. Although the overall funding is increased tenfold in an effort to extend treatment to as many patients as possible, research funds have only been doubled over the current level, since this was felt to be the limit of research and development which could possibly be productive at this point in time.

Training and facility expenditures have also increased tenfold because of the immensely increased patient load.

Under the circumstances of this particular hypothetic program 4,100 lives will be maintained through chronic dialysis and 3,575 lives will be saved yearly through successful transplantation.

This program, which utilizes \$210,000,000 of HEW money (about \$170,000,000 of which are expended for patient care), provides

treatment for about 15% of the overall number of patients threatened by death because of end-stage kidney disease and available during the first year of the program. The same problem of buildup of carry-over patients in future years exists under this program and interferes with the achievement of its goals unless the level of expenditure is raised appreciably during each succeeding year.

d. Hypothetical Program at an Accelerated HEW Expenditure Level, Based on an Advanced State of the Art in 1975

Under an advanced state of the art, it is assumed that the preceding extensive research efforts have resulted in the following advances:

- 1) Dialysis treatment can be carried out by the patient essentially independently of treatment facilities (except for periodic medical checkups), and the debilitating complications seen in patients on dialysis therapy have been eliminated;
- 2) A highly developed program for organ matching and preservation is in existence, immunosuppressive techniques are highly effective, transplantation survival is vastly increased, and the procedure can now be carried out in most of the general hospitals in the United States; and
- 3) In the case of both treatment modalities the cost has been reduced appreciably.

In this projected situation, the total HEW expenditure is smaller than the accelerated budget level assuming current state of the art (see above). The expenditures for research have been